

Submitter : Mr. Henry Westra
Organization : Pine Medical Group, P.C.
Category : Rural Health Clinic

Date: 11/22/2005

Issue Areas/Comments

GENERAL

GENERAL

It has been proposed that FQHCs receive supplemental payments for treating Medicare Advantage (Medicare Part C) patients each time a MA patient sees an FQHC 'core practitioner.' I would remind CMS and Congress that the payment mechanism to Rural Health Clinics (RHCs) is very similar to that for a FQHCs. At Pine Medical Group we have already turned patients away that have chosen the Part C option because there is no mechanism in place to assure RHCs payment to the maximum cost based reimbursements.

I would ask that any consideration given FQHCs be extended to RHCs as well so that RHCs can continue to serve its patient base that may choose the Medicare Part C option.

Thank you.

Submitter : Dr. Joel Goldwein
Organization : IMPAC Medical Systems, Inc
Category : Device Industry

Date: 11/29/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-FC-2-Attach-1.PDF



IMPAC

IMPAC Medical Systems, Inc.
www.impac.com

World Headquarters
100 W. Evelyn Avenue
Mountain View, CA 94041
T 650-623 8800

Peter Bach, MD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, MD 21244-8017
Attn: CMS-1502-FC

November 9, 2005

Dear Dr. Bach:

I am submitting this response to CMS-1502-FC specifically related to the Chemotherapy Demonstration Project - Reconfiguration of the Demonstration for CY 2006, and am commenting from the perspective of an Information System/EMR vendor in the oncology sector. As background, following the announcement of last year's Demonstration Project, my company, IMPAC Medical Systems, was able to incorporate support for the G-Codes and associated assessments within our product in a manner that fit seamlessly within the work flow supported by our product and consistent with how our customers practice. We did so by January 1, 2005 and were thus able to support our customer base in a timely manner albeit with an effort on our part that was out of the ordinary. In addition, to the credit of CMS, the G-codes themselves were well defined and sufficiently unambiguous as to not be subject to interpretation.

In contrast, we are concerned about the proposed G-codes in the 2006 Demonstration Project related to adherence to clinical guidelines. Our concern relates to the inherent vagaries of a clinical guideline, ill-defined guideline "adherence" definitions, and therefore the potential liabilities associated with the selection of G-code II, items #1-#5. These specific labels for the G-Codes have the potential for not strictly corresponding to the therapy delivered regardless of the intent of the treating physician. For example, will minor deviations from an intended guideline constitute, in the view of CMS, that the guideline was followed or not? While this may seem to be a somewhat minor concern, the manner in which an EMR vendor could programmatically monitor and report adherence ultimately depends on CMS' exact definition of "adherent". In the case of our product, guidelines are templated into our system, and it would thus be possible for us to "calculate" whether or not they are strictly followed. However, when it comes to guideline deviations where clinical judgment would be used to establish the level of adherence, software will clearly fall short unless very specific adherence definitions are provided. And, while it would be possible for EMR vendors to supply a check-off corresponding to the adherence level as judged by a clinician, the ideal and more elegant process would leverage the software to make that judgment automatically and consistently across the management of patients and against pre-established, well defined rules. We suggest that CMS either establish these rules (i.e. - strictly define adherence across all the guidelines at hand) or change the adherence G-Codes #1-#5 to begin with "Management intent" (i.e. - "Management intent adherent to guidelines").

Also, under the "primary focus of the visit" section, the proposed G-codes do not consider instances when a patient is seen in a single encounter for workup, staging, and evaluation in addition to treatment recommendations. Currently, the G-codes listed imply that these two processes (staging the patient and making treatment recommendations) are separate and do not consider cases where both processes occur within a single patient visit, which is often the case in new patient consultations in which the patient arrives fully evaluated by other caregivers. We urge CMS to consider the multitude of other "use cases" that could impact on the submissions. For example, how are facilities to respond for patients who originally fell into one of the 13 cancer categories, are being managed in follow-up in accordance with a guideline, but have developed another malignancy that is being managed and should be reported differently from their original cancer?

Additionally, we would request that CMS specify the exact ICD diagnosis codes qualifying for the program. For example, some specific Head and Neck cancer sites and some Colonic cancer sites often considered by oncologists to fall into these categories may or may not fit under the definitions presumed by CMS. Also, specification with regard

Office of the Vice President of Medical Affairs
417 Meadow Lane
Merion Station, PA 19066

Voice - (610) 664-5130
Fax - (413) 215-3528
email - jgoldwein@impac.com



IMPAC

IMPAC Medical Systems, Inc.

www.impact.com

World Headquarters
100 W. Evelyn Avenue
Mountain View, CA 94041
T 650-623 8800

to the CPT codes which correlate with the E & M visits (ex: Level 2 outpatient consult code is 99242, etc) and the type of visits (outpatient consults, follow-up visits, new patient visits?) qualifying for reimbursement would be useful.

Finally, and perhaps most importantly, we would respectfully request that CMS recognize the constraints under which Information System/EHR vendors produce their software. These systems are complex, demand high levels of quality control, and are being utilized in environments where patient safety is foremost. In an era where the use of such systems is being strongly encouraged, it would seem sensible to provide vendors with sufficient input on the front end and sufficient time on the back end not only to incorporate the changes necessary to support these important projects but also to implement them across an ever expanding and increasingly busy and taxed customer base.

Thank you for your consideration.

Sincerely,

Joel Goldwein, MD
Vice-President, Medical Affairs and Director, Decision Support
IMPAC Medical Systems, Inc.

cc: ASCO, NCCN

Office of the Vice President of Medical Affairs
417 Meadow Lane
Merion Station, PA 19066

Voice - (610) 664-5130
Fax - (413) 215-3528
email - jgoldwein@impact.com

Submitter :

Date: 11/29/2005

Organization : Meridian Health

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

We received word today that our hospitals' estimated revenue next year fell \$7 million short of expectations and overall we will be losing over \$35 million on Medicare costs next year. Add to that the proposed 4.4% decrease in physician reimbursement and it is abhorrent to me that in the most sophisticated country in the world we are losing professionals every day in the health care industry, not because they want to leave, but because reality has forced them out. Even just keeping the fee schedule neutral puts most everyone behind and this decrease will be the final straw for many dedicated professionals in our industry to have to make the dreadful decision that they can't afford to take care of their patients any more. Horrible, simply horrible.

Submitter : Mr. Duncan Ward Jr.

Date: 12/01/2005

Organization : Disabled Citizen

Category : Psychiatric Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please send your response to one of my children Ms. Mayatta Renee Harris-Dyer e-mail address is Dyer_R@DellSouth.net and she lives in McDonough, Georgia and is my oldest daughter who will share reading and understanding with my other children (3). Thank you and I am Mr. Duncan Johnson Ward Jr. (355-44-8279)

Interim Relative Value Units

Interim Relative Value Units

I was in a Hospital in Chicago, IL on 11/03/2004 thru 11/09/2004 and my question is, why did St. Mary Hospital send my first bill to a collection agency instead of making a payment plan with me. Back on 03/19/1998 I was in this same hospital for a heart attack related to food that didn't agree with my body and made me weak. I paid all of the money that they asked for on time. This recent visit to St. Mary has caused me problems with (3) credit agencies about who wants my money. I also filed a complaint with the CMS in Chicago IL about services I did not receive from the Hospital but I am being asked to pay the amount and all services that the Hospital and Doctors said that didn't perform. I haven't received a decision about my appeal yet and the last person I talked to was in Indiana (Mrs. Becky Nevel and she was confused as to why I had one story and the document she was reading didn't reveal the whole story or (complaint) I was like to know if and when I will get a final decision about my payment appeal.

Submitter : Dr. Jesse Butler

Date: 12/01/2005

Organization : Illinois Bone & Joint Institute

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am concerned that the rbrvs for kyphoplasty is too low. The procedural risk and time commitments make the procedure difficult to rationalize on an economic basis. This acts as a great disincentive for our elderly to receive the highest level of care for their spinal fractures. The results of the procedure continue to amaze me. The patients get such improvement I would be hard pressed emotionally to not offer kyphoplasty as an option. Unfortunately, the financial issues greatly limit the number of physicians willing to perform this procedure.

Submitter : Dr. Mary Mishefske

Date: 12/04/2005

Organization : Newborn Care Physicians of Southeastern Wisconsin

Category : Physician

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

I believe there's a typo in the Malpractice RVU for the new code 99300. It would be more appropriate to be about 0.16-0.18 not 2.4 to match 99299 which is similar.

Submitter : Dr. Mary Mishefske
Organization : Newborn Care Physicians of Southeastern Wisconsin
Category : Physician

Date: 12/04/2005

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

I believe there's a typo in the Malpractice RVU for the new code 99300. It would be more appropriate to be about 0.16-0.18 not 2.4 to match 99299 which is similar.

Submitter : Ms. debra steffen
Organization : lebanon plastic surgery associates
Category : Health Care Professional or Association

Date: 12/08/2005

Issue Areas/Comments

GENERAL

GENERAL

As a relatively new practice we seek your help in the reimbursements of insurance companies. Everyday we are torn between accepting insurances or having patients self pay at time of visit. I have worked in the medical field for over 20 years and every doctor that I have worked for has made the comment that if he knew then what he knows now he would have never went into the medical field. How sad is it for our great Nation to have physicians who are the most educated people in the world regret their career selection. Most physicians entered the field of medicine to help people. Unfortunately those days are gone. Not only do they have to learn medicine but they need to have a degree in finance and law. What has happened to our government that we have allowed this to happen. If the American people would only open their eyes to what is happening in medicine. They only realize how expensive their premiums are and usually have no clue as to what their coverage entails until something happens. Most people do not even know the name of their insurance carrier. How did we ever come up with the concept of negotiating prices for a service in the medical field? This is the only career that the provider of service does not get the price he is billing for. Pre-pricing? Who ever came up with such an idea? Has anyone ever stopped to think that the money that they are paying in salaries for people to pre-price is costing more than what the physician is charging? If someone would just step back and look at the big picture of medicine they would certainly see how stupid and wasteful it has become. When did the government go to medical school? The day has come that the physician has to ask "permission" to do a procedure. The liability of the outcome of that procedure of course lies with the physician. The malpractice insurance is more than most middle class people make in a year. Pennsylvania is third from the bottom of the barrel for reimbursement. But we are the second state in the country for the most elderly. Who is doing the math? What are the people going to do when there are no doctors left? Does anyone ever think about it? My physician is working two jobs to try and get this practice on its feet. His malpractice just went up 15% again this year after 18% last year. He is working to pay malpractice insurance. We are barely getting by. I am the only staff member. We are very cautious with spending. The American people think that physicians make lots of money. The money that they earn they are most certainly entitled too! They have loans to repay have taken years off their lives for lack of sleep and family time. Then they get out and try and start a practice to make a living and find they just keep getting kicked in the teeth.
Wake up somebody before we lose the physicians in Pa.

Submitter : Michelle Oxman
Organization : CCH, a Wolters Kluwer Business
Category : Media Industry

Date: 12/12/2005

Issue Areas/Comments

GENERAL

GENERAL

The citations to the authority for Parts 410 and 411 are inconsistent with recently published amendments.

Part 410: At page 70330, the citation 'continues to read' as sections 1102 and 1871 of the Social Security Act (SSA), 42 USC 1302 and 1395hh. On Aug. 26, however, at 70 FR 50946, the authority had been revised to include section 1834 of the SSA (42 USC 1395m).

Part 411: Also at page 70330, the citation 'continues to read' as SSA sections 1102 and 1871. On Sept. 30, 2005, however, at page 57165, the authority had been revised to include SSA sections 1860D-1 through 1860D-42 (42 USC 1395w-101 through 1395w-152).

Was the omission of the authorities added in August and September intentional?

Submitter : Mrs. Helen Osterkamp
Organization : Ingenix
Category : Health Plan or Association

Date: 12/12/2005

Issue Areas/Comments

GENERAL

GENERAL

Shouldn't these codes be changed to a bilateral indicator of either 1 or 3 so the claims system will accept these codes with the bilateral modifier attached?

Interim Relative Value Units

Interim Relative Value Units

Codes: 50387, 50592

Both are assigned a '0' indicator in the fee schedule but CPT states to use the 50 modifier on the codes.

Submitter : Michelle Oxman
Organization : CCH, a Wolters Kluwer Business
Category : Media Industry

Date: 12/13/2005

Issue Areas/Comments

GENERAL

GENERAL

At page 70332, the heading for sec. 414.904 reads: 'Basis for payment'.

On July 6, 2005, an interim final rule was published in which the heading for the regulation was amended to read: 'Average sales price as the basis for payment'.

See p. 70 FR 39021, at 39094.

Is the current amendment intended to reverse the change made in July?

Submitter : Dr. Jerome Richie
Organization : Brigham and Women's Hospital
Category : Physician

Date: 12/15/2005

Issue Areas/Comments

GENERAL

GENERAL

I am the Chairman of Urology at Brigham and Women's Hospital, running an academic group practice of 6 urologists. I am deeply concerned about CMS categorically rejecting the AUA practice expense data.

I appreciate that CMS accepted the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS use urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. Nonetheless, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to accept the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity.

The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process.

As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Submitter : Dr. Brian Scholbrock
Organization : Dr. Brian Scholbrock
Category : Physician

Date: 12/15/2005

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

To whom it may concern,

I am extremely concerned that the AUA's supplemental PE data was not used to calculate the PE RVU's for all Urology codes. In light of the increasing expenses to operate a Urology practice and our disproportionate % of Medicare patients, as compared to other specialties, this especially burdens our specialty. Actions such as these increasingly burden us and make more likely drastic actions such as limiting access to medicare patients in the future. Please reconsider your actions so that we may receive the reimbursements that we deserve. Thank you for your time and consideration in this matter.

Sincerely,

Brian Scholbrock, M.D.

Submitter : Dr. Thomas Shook
Organization : Urology Specialists of Coastal Georgia
Category : Physician
Issue Areas/Comments

Date: 12/15/2005

GENERAL

GENERAL
see attachment

CMS-1502-FC-13-Attach-1.DOC

I appreciate that CMS accepted the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA).

Despite this, CMS did not fully comply with the MMA since the MMA required that CMS use urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just drug administration.

CMS attributes this withdrawal of the entire PE methodology proposal to an error in its computer program that caused almost all the published RVU's to be incorrect. This error should have been handled through the use of a corrections notice rather than withdrawing the proposals, as currently physicians are paying for the error thought the loss of practice expense payments rightfully due them.

This decision to accept the data provided by the AUA but not to utilize it raises significant legal concerns and seriously impugns the agency's credibility and objectivity.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond. It is unfair and inequitable that implementation of the AUA survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used particularly since groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process.

As a practicing urologist servicing a burgeoning Medicare population, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVU's for all procedures performed by urologists.

Thomas E. Shook, M.D.

Submitter : Dr. Patrick Foley

Date: 12/15/2005

Organization : self

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS,

I am a solo practioner in Chattanooga, TN. I care for thousands of Medicare patients each year. It is my honor and privilege to do so. Despite the fact that the Medicare re-imbusement system is extremely flawed, I have chosen to abide by the governing rules and laws. The failure of CMS to do the same is disgraceful. Please reconsider your decision to not comply with the MMA requirement to use the AUA supplemental practice expense data when calculating the 2006 practice expense RVU's for all Urology procedures.

Sincerely,

Patrick H. Foley, M.D.

Submitter : Mrs. Helen Osterkamp
Organization : Ingenix
Category : Health Plan or Association

Date: 12/15/2005

Issue Areas/Comments

GENERAL

GENERAL

Query sent directly to Gaysha Brooks on 4/26/05, 8/9/05, and 9/7/05. If a change cannot be made to code 27165, please advise.

Interim Relative Value Units

Interim Relative Value Units

Should code 27165 (Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast) have the status changed to the bilateral indicator of 1 or 3? This code is currently listed on the co-surgeon eligible list indicating there is a potential for two surgeons to operate on the patient at the same time. Other codes immediately surrounding this code are also already on the bilateral eligible list.

Submitter : Dr. richard levin
Organization : Dr. richard levin
Category : Physician

Date: 12/15/2005

Issue Areas/Comments

GENERAL

GENERAL

12/15/05

Re: Talking Points: CMS Withdrawal of Proposed Practice Expense Increase

Dear CMS:

__ I appreciate that CMS accepted the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA).

__ However, CMS did not fully comply with the MMA, as the MMA required that CMS use urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

__ CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology.

__ However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

__ CMS's decision to accept the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity.

__ The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

__ CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process.

__ As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Submitter : Dr. Bruce Frantz

Date: 12/15/2005

Organization : Dr. Bruce Frantz

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am extremely displeased that CMS accepted the American Urological Associations supplemental practice expense data for 2006 and CMS did not do anything about it.

The fee increases should apply to all cpt codes and not just drug administration codes

CMS did not comply with the MMA requirements that expense data apply to all codes

Waiting for 2006 to apply any changes for 2007 will significantly impair the ability of physicians to care for medicare patients

All practice expenses are rising for 2006 -which includes malpractice insurance, salaries cost of equipment and supplies.

Please reconsider this vital issue

Thank you

Submitter : Dr. Daniel Curhan
Organization : Sansum Medical Clinic
Category : Physician

Date: 12/15/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-FC-18-Attach-1.DOC

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Daniel Curhan, M.D.
215 Pesetas Lane
Santa Barbara, CA
93105

December 15, 2005

Dear Doctor McClellan,

As a practicing urologist on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to *all* specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank you,

Daniel Curhan, M.D.
Sansum Medical Clinic

Submitter : Dr. Bhalchandra Parulkar
Organization : Tricounty Urology
Category : Physician

Date: 12/15/2005

Issue Areas/Comments

GENERAL

GENERAL

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

As a practicing urologists on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank you,

Interim Relative Value Units

Interim Relative Value Units

The cost and the restrictions on practicing medicine has made the quality care of patients very difficult. The cost of all entities including staffing, EMR and billing and disposables are all increasing and the CMS is unilaterally cancelling all guaranteed safeguards and protections to stabilize practices. I strongly request you to review the new revision rules of supplemental practice data and adopt them.

Submitter : Mrs. Helen Osterkamp
Organization : Ingenix
Category : Health Plan or Association

Date: 12/15/2005

Issue Areas/Comments

GENERAL

GENERAL

Temporary comment number 24808 was submitted on 9/29/05 but there were no changes to the January 2006 NPFS and no response. Please advise whether there will be a change to code 28285 or not. Thank you.

Interim Relative Value Units

Interim Relative Value Units

In the October 2005 NPFS, CMS changed the status indicator for code 28285 (Correction, hammertoe(eg, interphalangeal fusion, partial or total phalangectomy), to bilateral eligible. I understand that we have two feet, however, there are five toes on each foot. Why did CMS change this code to bilateral eligible when providers should really be using the toe modifiers (T1-9)? Is it likely that they would perform surgery on the two toes in the same position (eg T1 and T6) on each foot? I did not find any coding clarifications where it would instruct physicians to bill modifier 50 with the appropriate toe modifiers. The Coding with Modifiers book, published by the AMA has the following sample question: Which of the following would be the appropriate code(s) to report: A. 28285-50 B. 28285-LT & 28285-RT C. 28285-TA & 28285-T5 D. None of the above.

Submitter : Dr. David Wilhelm
Organization : Amarillo Urology Associates
Category : Physician

Date: 12/15/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-FC-21-Attach-1.DOC

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

As a practicing urologist on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to *all* specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank you,

David Wilhelm M.D.
1900 Medipark Dr
Amarillo, TX 79119
Dr.davidW@amarillourology.com

Submitter : Dr. John Franz
Organization : Stept and Arnhwim Urology Associates
Category : Physician

Date: 12/15/2005

Issue Areas/Comments

GENERAL

GENERAL

My wife thanks you for the decision of CMS to withdraw urology practice expense increases in the final rule of the physician fee schedule released November 2, 2005 on supplemental practice expense data submitted by the American Urological Association. You have already received the formal complaints of the appropriate officials of the American urological Association. let me tell you what will happen in the Southwest corner of Pennsylvania with the highest median age in the country, the testing ground for Medicare for the boomers.

My hourly income will become so low that I will be better off leaving the state and working for Kaiser Permanente or the VA. My wife wants to live near the ocean and has been promoting a move for some time. If I can not economically justify staying here, I will have to leave. But I am not alone. Our most recently recruited partner was dragged here from New York by his wife who wanted to raise her young children with the assistance and encouragement of her sisters and extensive local family. My son, a management consultant in San Francisco, about to marry his girlfriend, a native of the Phillipines, might just establish a lucrative business recruiting physicians and nurses from that country. My medical school roommate, a neurosurgeon at Georgetown and Fairfax hospitals, is supported by his realtor wife's far greater income. At some point his liability insurance will force him out of neurosurgery. He tells me all future neurosurgeons will come from overseas as Americans will not be able to amortize their educational expenses in that specialty. I would have a hard time justifying the current costs of a private American medical school education at this time on the same basis. I would not be surprised to see the demise of private medical schools. The hourly income doesn't justify the investment of time and money.

There has to be a better way of controlling the costs of American medicine other than driving competent health care workers out of the field with economic abuse. We need the moral leadership to address the issue of futile care of which I see so much. It is medically and ethically wrong, but I do not have the courage to fight too strongly with misguided families trying to absolve the normal guilt of the ambivalence of generational relationships. There are always lawyers lurking in the background with big billboards advertising for plaintiffs. We will need leadership from the clergy, ethicists and the government to resolve these ethical problems.

Submitter : Dr. Jonathan Block
Organization : Mohawk Valley Urology, PC
Category : Physician

Date: 12/15/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-FC-23-Attach-1.PDF

Jonathan D. Block, M.D., Ph.D., MBA, PFPM
Mohawk Valley Urology, PC
1703 Genesee Street
Utica, New York 13501

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: Failure to enact urology practice expense increases

Dear Dr. McClellan;

I am saddened to hear that CMS is not going to enact the urology practice expense increases as outlined by the American Urologic Association. It is imperative that practice expense increases be included in the 2006 CMS fee schedule set for January 1st to prevent a severe shortfall in urology practice's abilities to function in a tight and ever worsening economic environment. Failure to implement the practice expense increases will certainly place urology practice patterns at risk, and that means Medicare recipients may lose access to needed care or an inability to provide such care in a proper and quality fashion

Also, it is concerning that CMS decided to accept the AUA's survey assessments, yet not apply them to the appropriate fee schedules raises serious issues surrounding the legality of the CMS decision. In addition, the credibility of CMS is questioned when such decisions are made not to support a front line agencies assessment of current practice costs when done so in a good faith manner. Such a decision may create an irreparable rift between CMS and specialties that will extremely difficult to mend.

I cannot urge CMS strongly enough to implement the survey data and adjust the 2006 fee schedule for urology practices before it is too late.

Thank you.

Sincerely,

Jonathan D. Block, M.D., Ph.D., MBA, PFPM

Submitter : Dr. ganesh rao
Organization : metropolitan urology
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

The increasing cost of doing business is a matter of fact in this day and age for every business. The cost of living increases and the inflation mandate an increase in the pay structure every year and not a decrease as has been proposed. Is the salary of any member of congress, president or any CMS employee going down?? This case scenario spells disaster and would lead to a lot of physicians retiring early. Who is going to take care of the baby-boomers??? -- congress/CMS/President!!!!

Submitter : Dr. Casey O'Keefe
Organization : Cascade Urology Consultants
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

GENERAL

GENERAL

I appreciate that CMS accepted the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA).

However, CMS did not fully comply with the MMA, as the MMA required that CMS use urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology.

However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to accept the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity.

The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process.

As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Submitter : Dr. Erin Bird
Organization : Scott and White Urology
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

Is the goal of CMS to make it so no urologist wants to see Medicare patients? Your resent decision to disregard the Mandate of the MMA, puts at jepardy the care of millions of seniors. I fully understand cost containment, but this goes too far. ETB

Submitter : Dr. Mario Labardini
Organization : M. M. Labardini, M.D., P.A.
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

Today I received good news from Social Security. I was about to receive a raise due to an INCREASE in the "Cost of Living". But to offset that raise I have been saddened by the decrease in urology payments for all Medicare recipients by 4.84% Taking into consideration the increase in the cost of living and the decrease in payments. I believe that this has been a 10% decrease in my expected income for 2006. If this continues for the next four years, I will have taken a 50% reduction in income. I will formally decline to participate this year in order to offset this reduction and will make arrangements to retire as soon as possible from the practice of medicine. I hope many more of my colleagues do the same and the vast majority of future recipients find it impossible to find medical care. Only then will you actually take into consideration a fair reimbursement for services rendered or lose our beloved medical system altogether.

Submitter : Dr. Andre Gilbert
Organization : Dr. Andre Gilbert
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

As a practicing urologist on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank you,

Andre Gilbert, MD, FACS
Findlay, OH

Submitter : Dr. Robert Donato
Organization : Dr. Robert Donato
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

GENERAL

GENERAL

The CMS's call to submit practice expense data appeared as a step in the right direction for correcting this flawed reimbursement schema. However, despite adequate information, in particular from my specialty organization the American Urological Association, CMS has now done a complete 180 degree turn. While initially telling the AUA that its PE data would be used to calculate and adjust RVU's for 2006, the previously determined 4.4% decrease in reimbursement is now planned with NO adjustment to the formula or consideration of the actual cost of business in medicine.

This comes at a time when the government itself contemplates a Pay For Performance (P4P) initiative, whereby those physicians who comply with the program and demonstrate superior quality of care would be reimbursed at a higher rate. However, mandatory use of an Electronic Medical Record as dictated by the language of this proposed legislation would act only to further increase overhead.

Couple this with increasing malpractice premiums and you now have a precarious situation: Rising overhead with decreasing reimbursement in an already overworked population.

The proposed 4.4% decrease doesn't simply affect physician contracts with Medicare, whose numbers of participating physicians will likely decrease further with this current cut. It decreases physician payments from nearly ALL health insurance providers, who typically link their fee schedules to Medicare rates.

I strongly suggest that CMS revisit the PE data provided by the AUA and other medical organizations. While it is not the sole solution to correcting the flawed formula currently used, it is based in real numbers. And according to those numbers, physician reimbursement from CMS should be increasing, as it is with hospitals, home health and nursing homes. Without doctors willing to see Medicare patients, who would man these facilities?

Interim Relative Value Units

Interim Relative Value Units

The formula used to currently determine RVU's is flawed and has been deemed so for several years. Despite attempts by many physician groups, this erroneous calculation continues and leaves reimbursements in decline despite evidence that physician overhead and workloads are substantially increased.

Submitter : Dr. David Taub
Organization : University of Michigan Department of Urology
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

As a practicing urologist on the front lines of Medicare, I appreciate that CMS accepted the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS use urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to accept the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Submitter : Dr. frank albani
Organization : urology specialists
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS : We as urologists are experiencing cost increases yearly. We need the aua supported increases to occur to keep be able to take quality care of our medicare patients.

Submitter : Dr. Nejd Alsiakfi
Organization : Mount Sinai Medical Center
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

Interim Relative Value Units

Interim Relative Value Units

?X I appreciate that CMS !?accepted!? the AUA!|s supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA).

?X However, CMS did not fully comply with the MMA, as the MMA required that CMS !?use!? urology!|s supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

?X CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology.

?X However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency!|s error through the loss of practice expense payments rightfully due them.

?X CMS!|s decision to !?accept!? the data provided by the AUA!|s supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency!|s credibility and objectivity.

?X The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology!|s practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

?X CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA!|s survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar proces

As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA!|s supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Submitter : Dr. Barry Aron
Organization : Dr. Barry Aron
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

GENERAL

GENERAL

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

As a practicing urologist on the front lines of Medicare, I appreciate that CMS accepted the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS use urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to accept the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank you,

Submitter : Dr. michael ziegelbaum
Organization : lake success urologic associates
Category : Physician

Date: 12/16/2005

Issue Areas/Comments

GENERAL

GENERAL

It is my understanding that CMS has withdrawn urology's practice expense increases. This clearly does not comply with the Medicare Modernization Act that requires CMS to use urology's supplemental practice expense data to calculate the 2006 expense relative value units for ALL urologic procedures and not just for drug administration.

The withdrawal appears to be based on computational errors which now puts physicians in the role of paying for the agency's error. Additionally this raises substantial legal concerns and diminishes the agency's credibility.

As a practicing urologist, I strongly urge CMS to reestablish their original position and utilize the supplemental PE data as quickly as possible.

Submitter : william clark
Organization : Ak Urological Assoc
Category : Physician

Date: 12/17/2005

Issue Areas/Comments

GENERAL

GENERAL

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

As a practicing urologist on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible.

Submitter : Dr. H. Victor Braren

Date: 12/17/2005

Organization : NA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I was saddened to note the decision by the Centers for Medicare & Medicaid Services (CMS) to withdraw urology's practice expense increases. In the 2006 physician fee schedule final rule, released November 2, 2005, CMS withdrew its proposal to accept supplemental practice expense (PE) data submitted by the American Urological Association and six other groups. This seems to disregard the requirements of the 2006 Medicare Modernization Act (MMA) regarding use of supplemental PE survey data.

This is faxable and needs to be dealt with ASAP or patient services will be markedly limited. One in seven Medicare patients sees a urologist at least once a year. It would be tragic to have them lose that access. Patients cannot be taken care of at a loss.

Thank you,

H. Victor Braren, M.D.
Nashville, Tennessee

Submitter : Dr. Barry Rossman
Organization : Urology Group of Princeton
Category : Physician

Date: 12/17/2005

Issue Areas/Comments

GENERAL

GENERAL

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

As a practicing urologist on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to all specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank you,

Submitter : Dr. Kalpesh Patel
Organization : Old Pueblo Urology
Category : Physician

Date: 12/17/2005

Issue Areas/Comments

GENERAL

GENERAL

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

I practice urology in the state of Arizona, home of many Medicare recipients. As a physician, I know you have the best interests of our patients in mind. Continued assault on the Medicare reimbursement system will seriously and adversely affect our ability to deliver high quality care to our patients. As such, I must take exception to the news that CMS will not apply the previously accepted AUA's supplemental practice expense data used to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). This is a blatant disregard to the agency's commitment to the nations practicing urologists. CMS's decision to 'accept' the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. CMS attributes the withdrawal of its entire PE methodology proposal to a computer error. Rather than using common sense to fix the problem, CMS has decided to gut the whole issue. Lets not compound an error with another greater error. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for ALL procedures performed by urologists.

Thank you,

Kalpesh Patel, MD, FACS
445 N Silverbell Rd, #201
Tucson, AZ 85745

Submitter : Dr. albert katz
Organization : Dr. albert katz
Category : Physician

Date: 12/18/2005

Issue Areas/Comments

GENERAL

GENERAL

I strongly urge CMS to do whatever is necessary to assure the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Submitter : Dr. Paul Eckrich

Date: 12/19/2005

Organization : Eckrich Urology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

I find it distressing that Medicare only follows the rules that they feel are beneficial to themselves. I am specifically referring to the Medicare Modernization Act (MMA). CMS did not fully comply with the MMA; the MMA required that CMS use urologys supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

If I as an individual urologist decide to comply with only parts of the Medicare regulations, they then call me a felon and throw me in jail. I have been on the receiving end of Medicare fraud investigation (no violations were found)and understand following the Medicare regulations.

Why the double standard occurs is one that really does need an honest appraisal. To throw out the whole thing because of a 'computer error' is akin to throwing the baby out with the bath water. Accepting the AUA's data on supplemental surveys but not to utilize it is disingenuous at best; similar disregard for the regulations would result in a prison term for us non-government individuals.

Unfortunately, this is only what we physicians in the ranks have come to expect from CMS. I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Sincerely,

Paul Eckrich MD
Board Certified Urologist

CC Senator Tim Johnson
CC Senator John Thune
CC Rep. Stephanie Herseth
CC American Urological Association

Submitter : Dr. tobin grigsby
Organization : regional urology
Category : Physician

Date: 12/19/2005

Issue Areas/Comments

GENERAL

GENERAL

I think CMS should use the AUA's supplemental PE data for all urology codes.

Submitter : Dr. John Phillips
Organization : Dr. John Phillips
Category : Health Care Professional or Association

Date: 12/20/2005

Issue Areas/Comments

GENERAL

GENERAL

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

An elderly patient of mine had a growing tumor of the kidney and asked what options there were to treat it. As thousands of my fellow citizens depend on our hospital for care, I continue to provide state-of-the art technology regardless of cost. This tenet is becoming increasingly difficult to maintain especially with the continued downward trending of how physicians are being reimbursed to care for our city's elderly. State-of-the art technology like laparoscopic surgery affords quicker recovery, less pain, fewer days in the hospital; it also requires the best trained and skilled surgeons, an educational discipline that requires more than a decade of training and significant debt. This, combined with the shear costs of running a practice, are providing a dangerous disincentive for physicians to offer patients the labor-intensive care, sometimes expensive care, that they deserve. In many cases, care is often chosen not for what is most appropriate or clinically efficacious, but what may be a better business decision based on what the CMS schedule happens to be that year. I urge the CMS to reconsider the recommendations that the AUA proposed, and which the CMS accepted, but is unable to currently enact. I write on behalf of my patients, for whom I hold the highest regard and for whom I strongly desire to continue providing care.

Thank you,
John L. Phillips, MD
New York New York

Submitter : Dr. John Giella
Organization : Rockland Urology Associates
Category : Physician

Date: 12/21/2005

Issue Areas/Comments

GENERAL

GENERAL

I am shocked and dismayed to learn that CMS has completely disregarded carefully collected practice expense(PE) data from urology and other medical specialties, in blatant disregard of MMA regulations. CMS continues to discount our reimbursement, to unreasonably low levels, as our expenses continue to increase. The "computer error" that supposedly prompted CMS to disregard the PE data could have, and should have, been corrected properly. The actions of CMS have completely undermined their credibility and should be reversed immediately. As a practicing urologist who cares for a large portion of Medicare patients, I urge CMS to act now to reverse this egregious error.

John G. Giella, M.D.

Submitter : Dr. Lawrence Eskew
Organization : Piedmont Urological Associates
Category : Physician

Date: 12/21/2005

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1502-FC-44-Attach-1.DOC

Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

As a practicing urologist on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006 practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

CMS attributes the withdrawal of its entire PE methodology proposal to an error in its computer program that caused almost all of the PE RVUs published in the proposed rule to be incorrect. We understand that this error caused CMS to be concerned that interested parties were not provided notice of the actual effect of the proposed changes in the PE RVU methodology. However, this error should have been handled through the use of a correction notice rather than withdrawing the proposals, as now physicians are paying for the agency's error through the loss of practice expense payments rightfully due them.

CMS's decision to "accept" the data provided by the AUA's supplemental surveys but not to utilize it raises substantial legal concerns and seriously impugns the agency's credibility and objectivity. The AUA exercised the option that was given to *all* specialty societies to submit PE supplemental survey data under the good-faith assumption that if our survey met the criteria established by CMS, the data would then be used to adjust urology's practice expense cost data to more accurately reflect these costs in determining the PE RVUs for the services we provide in 2006. This assumption was reasonable, since CMS had previously accepted and implemented supplemental survey data from other medical societies.

CMS indicates that there is a possibility that survey data could still be used in 2007 and beyond, and that they hope to hold meetings on this topic early in 2006 to obtain maximum input from all interested parties. It is unfair and inequitable that implementation of the AUA's survey has been delayed and that the AUA should have to go through this process to determine whether supplemental urology data will be used, as groups who had supplemental survey data accepted prior to 2006 did not have to go through a similar process. As a practicing urologist, I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used as quickly as possible to calculate PE RVUs for all procedures performed by urologists.

Thank you,

Submitter : Dr. Michael Maves
Organization : American Medical Association
Category : Health Care Provider/Association

Date: 12/21/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1502-FC-45-Attach-1.PDF



Michael D. Maves, MD, MBA, Executive Vice President, CEO

December 21, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; *Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006*; Final Rule with Comment; 70 Fed. Reg. 70,116 (Nov. 21, 2005); File Code CMS-1502-FC

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates this opportunity to provide our views on the Centers for Medicare and Medicaid Services' (CMS) final rule with comment concerning *Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006*; 70 Fed. Reg. 70,116 (Nov. 21, 2005).

In the final physician fee schedule rule, CMS announced that it will extend the Stark physician self-referral ban to include diagnostic and therapeutic nuclear medicine and supplies, effective January 1, 2007. CMS bases its decision, in part, on the fact that nuclear medicine is a "subspecialty" of radiology. As support for this decision, CMS cites in the rule that the AMA "recognizes nuclear medicine as a subspecialty of radiology." CMS further states that the AMA CPT 2005 lists nuclear medicine codes as a subsection of the series of codes that applies to radiology procedures (in the 70000-79999 series).

The AMA would like to correct the record concerning our views on this matter, and we strongly express that we do not recognize diagnostic and therapeutic nuclear medicine services as a subspecialty of radiology. CMS is merely inferring this conclusion based on

American Medical Association 515 North State Street Chicago Illinois 60610
phone: 312 464 5000 fax: 312 464 4184 www.ama-assn.org

Mark B. McClellan, MD, PhD
December 21, 2005
Page 2

CPT coding. Yet, the AMA CPT coding categories are not intended to be a determination of subspecialties. Indeed, nuclear medicine has its own board certification and residency program. Thus, nuclear medicine should be recognized as its own specialty, separate from radiology.

We also reiterate our comments, as submitted to CMS on the proposed rule, about extending the physician self-referral ban to nuclear medicine. The AMA continues to question an underlying assumption for this proposal, *i.e.*, that because nuclear medicine and other imaging services have experienced rapid growth in the last several years, some of the growth must be due to physicians making inappropriate referrals to imaging facilities in which they have a financial interest. There may be a number of reasons for the growth in these services and thus it is not clear that this growth is inappropriate.

Further, this proposal may have serious repercussions with regard to continuity of patient care, as well as patient access to these services. Moreover, a mere one-year extension of the effective date of this provision, especially without a grandfather clause for existing arrangements, will not avert "fire sale" conditions wherein physicians will be forced to divest their investment interests in this expensive equipment without recovering the initial cost of their investment due to much greater supply than demand. Any resulting losses will only compound the impact of projected Medicare pay cuts, as well as skyrocketing medical liability premiums.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mike Maves".

Michael D. Maves, MD, MBA

Submitter : Dr. Joel Sherman
Organization : Consultants In Urology, PC
Category : Physician

Date: 12/22/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
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 : Mr. James Greenwood
Organization : Biotechnology Industry Organization (BIO)
Category : Health Care Professional or Association

Date: 12/23/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Interim Relative Value Units

Interim Relative Value Units

see attachment

CMS-1502-FC-47-Attach-1.DOC



December 23, 2005

BY ELECTRONIC DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1502-FC and CMS-1325-F (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B)

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) final rule with comment regarding revisions to payment policies under the Medicare physician fee schedule and certain provisions related to the Competitive Acquisition Program (CAP), published in the Federal Register on November 21,

2005 (the “Final Rule”).¹ BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

BIO is pleased that CMS has implemented several of the measures recommended by BIO to protect beneficiary access to drugs and biologicals. Through provisions such as setting reimbursement for all separately billable end-stage renal disease (ESRD) drugs at average sales price (ASP) plus 6 percent, providing an additional payment to physicians for locating and acquiring intravenous immune globulin (IVIG), and increasing the furnishing fee for clotting factor, the Final Rule will ensure that physicians and other providers are reimbursed appropriately for drugs and biologicals administered to Medicare beneficiaries.

BIO also thanks CMS for not implementing several provisions from the proposed rule. We support CMS’ decision not to reduce supplying fees for anti-cancer and immunosuppressive drugs, as initially proposed. Rather than cutting the supplying fee for additional prescriptions to \$8, the Final Rule sets the fee at a more appropriate \$16. We commend the agency for not implementing the proposed ASP calculation methodology that uses a weighted average of ASPs for direct and indirect sales that would not have had a significant impact on reported ASP and would have imposed great burdens on manufacturers. Finally, we appreciate CMS’ willingness to allow vendors offer additional national drug codes (NDCs) as well as the agency’s clarification regarding payment under the CAP for unused portions of single use vials.

We remain concerned that CMS has not implemented several significant recommendations. First, CMS did not correct its formula for calculating the payment amount for each drug or biological Health Care Common Procedural Coding System (HCPCS) code. As we explained in our comments on the proposed rule, CMS’ current formula fails to reflect the true weighted average of reported ASPs. Second, BIO is concerned that CMS’ regulatory text does not express the Secretary’s discretion in determining whether to substitute widely available market price (WAMP) or average manufacturer price (AMP) for ASP. BIO also believes it is imperative that CMS give the public notice and an opportunity to comment

¹ 70 Fed. Reg. 70116 (Nov. 21, 2005).

before any such substitution occurs. Finally, CMS decided to permit, but not require, CAP vendors to provide single indication orphan drugs and newly approved drugs. We urge CMS to reconsider these decisions and implement the changes in a revised rule.

I. ASP Issues

A. Price Concessions: Wholesaler Chargebacks; Weighted Average of Direct and Indirect Sales ASPs

BIO applauds CMS' decision not to implement its proposed requirement for manufacturers to calculate separate ASPs for direct sales and indirect sales and report a weighted average of the two numbers.² CMS correctly recognized that its proposed methodology would have little effect on the accuracy of reported ASP data and would substantially increase the complexity of manufacturers' calculations. CMS plans to continue working with manufacturers to "better understand the circumstances in which the proposed methodology may benefit the program and the potential for appropriate use of that methodology for certain or all [National Drug Codes]." ³ We appreciate CMS' ongoing efforts to work with manufacturers to refine its instructions for calculating and reporting ASP data. CMS' instructions must be clear and complete for the agency to receive the data it needs to calculate accurate ASPs. Because beneficiary access to critical drugs and biologicals depends on whether Medicare's reimbursement is adequate, BIO remains committed to ensuring that manufacturers have the information they need to file accurate ASP data and that payment rates are calculated accurately from these data.

B. Determining the Payment Amount Based on ASP Data

In our comments on the proposed rule, BIO explained why CMS' formula for calculating the payment amount for each billing code is incorrect.⁴ Under CMS' formula, the agency weights the ASP per billing unit by the total number of NDC units sold, not the total volume of the billing units sold. As a result, CMS does not determine a weighted average ASP for each billing code, but rather a weighted average ASP per NDC unit. Because this is not an appropriate number to

² Id. at 70217.

³ Id.

⁴ Letter from James C. Greenwood, President and CEO, BIO, to Mark McClellan, Administrator, CMS, Sept. 30, 2005.

use for CMS' rate-setting purposes for most therapies, we recommended that CMS revise its formula to calculate the average ASP per billing unit as follows:

1. Calculate the number of HCPCS units per NDC by dividing the volume of the NDC (e.g., 20 mg) by the volume of the HCPCS code (e.g., 10 mg).
2. Calculate the ASP per HCPCS unit for a NDC by dividing the reported ASP for a NDC by the number of HCPCS units in that NDC to determine the ASP per HCPCS unit for that NDC.
3. Calculate the number of HCPCS units sold for a NDC by multiplying the number of NDC units sold by the number of HCPCS units per NDC.
4. For the numerator:
 - a. Multiply the ASP per HCPCS unit by the number of HCPCS units sold for that NDC.
 - b. Repeat this calculation for each NDC in the HCPCS code.
 - c. Compute the total of all of these calculations.
5. For the denominator: Compute the total number of HCPCS units sold for all NDCs.
6. Divide the results of step 4 by the results of step 5.

The correct formula is:

ASP =

$$\frac{(\text{ASP/HCPCS unit}_A \times \# \text{ of HCPCS units sold}_A) + (\text{ASP/HCPCS unit}_B \times \# \text{ of HCPCS units sold}_B) + (\text{ASP/HCPCS unit}_C \times \# \text{ of HCPCS units sold}_C)}{\text{HCPCS units sold}_A + \text{HCPCS units sold}_B + \text{HCPCS units sold}_C}$$

In the Final Rule, CMS acknowledged that several stakeholders urged CMS to change its formula, but declined to implement this change.⁵ We reiterate our recommendation that CMS make this necessary change so that the agency will calculate more accurate ASPs for most therapies. For certain biologicals where the unit of measurement is determined by biological activity rather than by weight, there may be differences among therapies described by the same HCPCS code. Under those circumstances, weighting by the NDC packaging may reflect the distribution of sales more appropriately than weighting by HCPCS unit. Therefore, we recommend that CMS provide for weighting by NDC under an exceptions process to be applied when the units of biological activity vary among therapies in the same HCPCS code.

C. Limitations on WAMP

The Medicare statute allows the Secretary to substitute WAMP or AMP for ASP if ASP exceeds WAMP or AMP by a certain percentage.⁶ When Congress enacted this provision, it also intended that the Secretary provide “a number of procedural and substantive safeguards to ensure the reliability and validity of the data” in making determinations to use WAMP instead of ASP.⁷ In the Final Rule, CMS stated that the methodology used in the Office of Inspector General’s (OIG) review of drug prices will be available to the public upon completion of the study.⁸ In response to comments urging CMS to provide the public the opportunity to evaluate the validity of the processes used and the data obtained by OIG, CMS said that it does not believe rulemaking is appropriate at this time.⁹ The final regulation text states, “If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2006, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price.”¹⁰

BIO is concerned that the regulatory text does not express the Secretary’s discretion in determining whether to substitute WAMP or AMP for ASP. This language is inconsistent with section 1847A(d)(3)(A) of the Social Security Act that states, “The Secretary *may* disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage” (emphasis added). It also is inconsistent with Congress’ intent as expressed by the conference report both that the Secretary “make determinations” whether to substitute WAMP or AMP for ASP and that the Secretary use procedural and substantive safeguards in this process.

To the extent that there is a statutory tension between these provisions and another statutory provision that appears to require the Secretary to make such substitution when ASP exceeds the WAMP or AMP by the specified percentage,¹¹ the Secretary possesses the authority to resolve that tension. We urge the Secretary to do so in a manner that fulfills the policy goals of additional public input and

⁶ Social Security Act (SSA) § 1847A(d)(3)(A).

⁷ Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, H. R. Rep. No. 108-391, at 592 (noting that the safeguards include “notice and comment rulemaking, identification of the specific sources of information used to make [a determination to use WAMP instead of ASP], and explanations of the methodology and criteria for selecting such sources”).

⁸ 70 Fed. Reg. at 70222.

⁹ Id.

¹⁰ 42 CFR § 414.904(d)(3).

¹¹ SSA § 1847A(d)(3)(C).

ensuring beneficiary access to care. That is, we submit that the Secretary should clarify in the regulation text that he has discretion regarding substituting WAMP or AMP for ASP. We firmly believe that this is what Congress intended. Because OIG has broad authority in studying WAMP and many drugs and biologicals have unique market dynamics that could skew these studies depending on how they are conducted, it is essential that CMS obtain public input before deciding whether to substitute WAMP or AMP for ASP. Without this information, CMS could reduce payment rates inappropriately, potentially denying patient access to important drug and biological therapies.

BIO requests that CMS change its regulatory text accordingly. Specifically, CMS should modify 42 CFR § 414.904(d)(3) to read, "If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in calendar year 2006, the Secretary may, after notice and an opportunity for public comment, revise the payment limit in the quarter following the transmittal of this information to the Secretary to the lesser of the widely available market price or 103 percent of the average manufacturer price." In order to obtain meaningful public input, we urge CMS to provide a thorough description of the sources of information used in the OIG's study, the methodology and criteria for selecting these sources, a description of any surveys and how they were conducted, and the agency's plans to use the data. Again, we believe it is imperative that CMS give the public an opportunity to comment on any such substitution before the agency considers substituting WAMP or AMP for ASP.

II. Payment for IVIG

In the Final Rule, CMS announces its decision to provide an additional payment to physicians in 2006 to reflect the "substantial additional resources that are associated with locating and acquiring IVIG and preparing for an office infusion of IVIG."¹² The OIG also is studying the availability and pricing of IVIG as part of its monitoring of market prices under section 1847A(d)(2)(A) of the Social Security Act.¹³ BIO commends CMS for taking action to protect beneficiary access to IVIG during this time of market instability. We are concerned, however, that the additional payment will not be sufficient to protect beneficiary access to IVIG. We urge CMS to work with manufacturers and other

¹² 70 Fed. Reg. at 70220.

¹³ Id.

stakeholders to identify the costs associated with acquiring IVIG and preparing for its administration.

We also recommend that CMS create a unique HCPCS code for each brand name IVIG product. Currently, there are only two HCPCS codes for IVIG, even though the products are not interchangeable. As a result, the ASP calculation methodology reflects the prices of all brands of IVIG, not the specific brand that is best suited for a particular beneficiary. We believe that Medicare reimbursement for one brand of IVIG should not be based on another brand that is used for different indications and may be inappropriate for the patient. Creating unique HCPCS codes for each brand would help to protect beneficiary access by ensuring that Medicare's reimbursement is appropriate for each brand. This step also would help CMS better track the supply of each brand in the marketplace.

Finally, we recommend that CMS clarify that the new Current Procedural Terminology (CPT) code for chemotherapy administration by intravenous infusion, 96413, should be used to bill for administration of IVIG. The CPT coding guidelines instruct physicians to use the chemotherapy administration codes for non-radionuclide anti-neoplastic agents, substances such as monoclonal antibodies, and "other biologic response modifiers."¹⁴ IVIG is a biologic response modifier, and thus its administration should be billed using 96413, not 90765, the code for non-chemotherapy intravenous infusion for therapy or diagnosis.

III. Payment for ESRD Drugs

BIO supports CMS' decision to reimburse all end-stage renal disease (ESRD) drugs at ASP plus 6 percent when separately billed by freestanding or hospital-based ESRD facilities.¹⁵ This rate is "a more reliable indicator of the market transaction prices for these drugs" than updating the OIG's 2003 acquisition cost data to 2006 levels by the purchasing price index.¹⁶ BIO also supports the agency's decision to increase the drug add-on adjustment to the composite rate from 8.7 percent to 14.7 percent.¹⁷

IV. Furnishing Fee for Clotting Factor

¹⁴ CPT 2006 Current Procedural Terminology, Professional Edition, at 400.

¹⁵ 70 Fed. Reg. at 70162.

¹⁶ Id. at 70223.

¹⁷ Id. at 70167.

CMS implemented its proposal to increase the clotting factor furnishing fee by the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending June 2005.¹⁸ This increase is consistent with the statute¹⁹ and should help to protect beneficiary access to these life-saving treatments.

V. Supplying Fees for Oral Anticancer, Anti-Emetic, and Immunosuppressive Drugs

For 2006, CMS set the supplying fee for oral anticancer and anti-emetic drugs at \$24 for the first prescription and \$16 for each additional prescription within a 30-day period.²⁰ This is a decrease from the current rate of \$24 per prescription, but is more than the proposed rate of \$8 for each additional prescription. CMS kept the supplying fee for the first immunosuppressive prescription after a transplant at \$50, but reduced the fee for subsequent prescriptions to \$16. BIO thanks CMS for carefully considering the comments it received regarding the costs of supplying these therapies and the effect cuts in reimbursement would have on beneficiary access. We recommend that CMS monitor beneficiary access to these therapies and increase the supplying fee if it finds that access is impaired.

VI. Ensuring Appropriate Payment for Drug Administration Services

BIO continues to be concerned that the deep cut in the conversion factor will harm beneficiary access to care. This cut, on top of the expiration of the transitional adjustment payments, has reduced Medicare payment for most drug administration services by 25 to 70 percent from 2004 to 2006. We appreciate the agency's efforts to promote quality care in spite of these cuts, including its continuation of a modified oncology demonstration project, but we urge the agency to take whatever steps are necessary to ensure that physicians are adequately reimbursed for administering critical drug and biological therapies, as well as for office visits and other critical services.

VII. Clarifications Regarding the CAP

A. Process for Adding NDCs within a HCPCS Code in an Approved CAP Vendor's Drug List

¹⁸ Id. at 70225.

¹⁹ Social Security Act § 1842(o)(5)(C).

²⁰ 70 Fed. Reg. at 70234.

BIO is pleased that CMS amended the CAP regulations to allow vendors to request permission to expand their CAP drug lists by offering additional NDCs.²¹ This change will improve beneficiary and physician choice of treatment options so the treatment regimen ordered can be the most appropriate regimen for the patient and to minimize discard of excess supplies. We also agree with CMS' clarification that the addition of new NDCs to an approved drug list will not affect the CAP payment amount for that HCPCS that was set during the initial bidding process.

B. Process for Expediting the Addition of Newly Approved Drugs to the CAP

BIO appreciates CMS' recognition that "the earlier addition of newly approved or newly marketed drugs to the CAP is desirable."²² Instead of requiring CAP vendors to provide new drugs and biologicals as soon as they become available, however, CMS created a process, effective in 2007, for vendors to request permission to add the therapies to their lists. CMS also will consider new therapies for inclusion only if CMS is able to identify a single ASP payment amount for the drug.²³ We are concerned that this process will not ensure timely access to new therapies. Under this system, access to a new drug will be delayed by several months after it is approved for marketing, until the manufacturer reports an ASP, the CAP vendor requests permission to add the drug to its list, and CMS reviews and approves the request. Furthermore, because the process will not be implemented next year, any new therapy first marketed in 2006 or any existing drug for which an ASP had not yet been determined at the time the bidding began may not be available under the CAP until at least 2007. We urge CMS to reconsider this decision and mandate that vendors make available to CAP-participating physicians new drugs upon FDA approval. CMS should reimburse vendors at 106 percent of ASP or WAC plus 6 percent until ASP data are gathered and reported.

C. Inclusion of Single Indication Orphan Drugs in the CAP Category

We are disappointed that CMS decided not to include single indication orphan drugs in the CAP's single drug category.²⁴ Although CMS acknowledged comments explaining that including single indication orphan drugs in the CAP

²¹ 70 Fed. Reg. at 70239-40.

²² 70 Fed. Reg. at 70240.

²³ 70 Fed. Reg. at 70241.

²⁴ Id.

would minimize the burden on physicians who administer them and would improve beneficiary access to these therapies, CMS disagreed with requests to require CAP vendors to provide these drugs and biologicals. Instead, CMS created a process to allow vendors to request approval from CMS to supply single indication orphan drugs. We are concerned that this process will do little to improve beneficiary access to these therapies. By making inclusion of single indication orphans optional, CMS returns the burden to the physician to urge the vendor to provide these drugs and gives beneficiaries and physicians no assurance that they will be provided. We strongly recommend that CMS reconsider this decision and require CAP vendors to provide these drugs.

We recommend that one orphan therapy, alpha 1-proteinase inhibitor (J0256), continue to be excluded from the CAP. Alpha 1-proteinase inhibitor is a plasma-derived and recombinant analog therapy. Several brand name versions of this therapy are included in code J0256, but the brands are not therapeutically equivalent. Each brand has a unique effect on the patient, and response to each brand can vary from patient to patient, making it critical that each patient receives the specific brand that is best suited for his or her condition. As long as CAP vendors are required to offer only one NDC for this HCPCS code, it is highly unlikely that a CAP vendor would provide each patient's specific brand. We expect that physicians would have to use the "furnish as written" option frequently for patients who need alpha 1-proteinase inhibitor. It makes more sense, therefore, to exclude alpha 1-proteinase inhibitor from the CAP than to require physicians to routinely use the "furnish as written" option. Each patient's access to alpha 1-proteinase inhibitor would be protected best by excluding these products from the CAP.

D. Clarification Regarding Payment for Unused Drugs under the CAP

We thank CMS for clarifying its policy regarding payment under the CAP for unused portions of single-use vials of drugs and biologicals. CMS explains that it will consider the unused portion of a drug remaining in a single-use vial to have been administered for purposes of the CAP if the "participating CAP physician has made good faith efforts to minimize the unused portion of the CAP drug in how he or she scheduled patients, and how he or she ordered, accepted, stored, and used the drug."²⁵ In addition, the CAP vendor must make "good faith efforts to

²⁵ Id. at 70248.

minimize the unused portion of the drug in how it supplied the drug.”²⁶ This is consistent with CMS’ policy for drugs reimbursed under the ASP system and will help simplify administration of the CAP.

VIII. Conclusion

BIO appreciates the opportunity to comment on the important issues raised in the Final Rule, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Jayson Slotnik at (202) 312-9273 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

James C. Greenwood
President & CEO
Biotechnology Industry Organization

**CMS-1502-FC-48 Revisions to Payment Policies Under the Physician Fee Schedule for
Calendar Year 2006**

Submitter : Dr. Gary Dillehay

Date & Time: 12/27/2005

Organization : Society of Nuclear Medicine

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

Interim Relative Value Units

Interim Relative Value Units

See Attached

CMS-1502-FC-48-Attach-1.PDF

CMS-1502-FC-48-Attach-1.PDF