Submitter:

Organization:

Category:

Other Health Care Professional

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

See Attachment

CMS-1512-PN-1852-Attach-1.DOC

Date: 08/18/2006

ATTREHMENT TO 4/852

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (June 29, 2006); Comments re: Practice Expense

## 08/18/2006

Dear Dr. McClellan:

On behalf of Nebraska Heart Institute and our 33 individual practicing physicians, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

Nebraska Heart Institute has seven offices across the state, including four outpatient cath labs in Lincoln, Omaha, Hastings, and North Platte, Nebraska. Before Nebraska Heart Institute's cath labs in Hastings and North Platte were installed, patients had to travel hours to receive elective outpatient catheterizations, and our labs in those relatively rural areas have significantly improved patient care and access to proper diagnostic testing for suspected coronary artery disease. We perform 3,000 heart catheterizations in these four labs annually.

The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component ("TC") is a significant part of the overall procedure. Catheterization procedures are being used as an example of the impact of the proposed methodology on procedures with significant TC costs because they share the same problems that we will outline below. We also believe that the same solution should be applied to all of the procedures listed below.

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments for CPT 93510 TC. Similarly, payment for two related codes—93555 TC and 93556 TC would be reduced substantially. In fact, under the Medicare Physician Fee Schedule ("PFS"), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate for these three codes to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

CPT Code	Description	
93510 TC	Left Heart Catheterization	
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The stated purpose of the proposed change to a bottom up micro-costing approach is laudable and consistent with the statutory requirement that the Medicare program base payment on the use of necessary resources. However, the proposed methodology and inputs to the calculation do not comport with the statutory requirement that would match resources to payments. After reviewing the proposed methodology, including the 19 step calculation, we have identified several flaws that result in the PE RVU underestimating the resources needed to provide the technical component of cardiac catheterizations. We will address our concerns with the calculation of direct costs and indirect costs separately, as set forth below.

## **Direct Costs**

The estimate of direct costs is critical for the first step in calculating the PE RVU for each procedure code. The direct costs are based on inputs from the American Medical Association's RVS Update Committee ("RUC") and reflect the direct costs of clinical labor, medical supplies and medical equipment that are typically used to perform each procedure. The RUC-determined direct costs do not reflect estimates of additional labor, supply and equipment costs that were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 percent of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49 percent of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns. For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

Unless the RUC considers the actual costs of the clinical labor, supply and equipment used to perform a cardiac catheterization, the PE RVU that results at the end of the 19 step calculation will never reflect the actual resources needed to perform the procedure and will result in destabilizing practice expense payments to physicians. Therefore, CMS must evaluate the adequacy of the direct inputs and focus on developing a methodology that captures the average direct costs of performing a procedure, rather than the direct costs of performing a procedure that represents 51 percent of the patients.

A new methodology is needed based on the best data available so that the direct costs shown in the third column of the table below can be allocated in a manner similar to the allocation of indirect costs. This would result in a PE RVU that is a more accurate reflection of the direct and indirect costs for the resources that are critical to performing the procedure.

Categories of Cardiac Catheterization Direct Costs Included or Excluded From RUC-Determined Estimates

Direct Cost Category	Included In RUC- Determined Estimate	Excluded From RUC- Determined Estimate
Clinical Labor	Direct Patient Care For Activities Defined by RUC	Direct Patient Care For Activities Not Defined by RUC
	<ul> <li>Allocation of Staff         Defined by RUC         Protocol (1:4 Ratio of RN to Patients in Recovery)     </li> </ul>	Actual Staff Allocation     Based on Patient Needs
Medical Supplies	Supplies Used For More Than 51% of Patients	Supplies Used For Less Than 51% of Patients
Medical Equipment	• Equipment Used For More Than 51% of Patients	• Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	Approximately 55% of the direct costs are included in the RUC estimate	Approximately 45% of the direct costs are included in the RUC estimate

A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. There are additional improvements that can be made in the manner by which the indirect costs are estimated that are outlined below.

## **Indirect Costs**

The "bottom-up" methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities ("IDTFs"), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of cardiac catheterization facilities—that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 percent. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both (1) the direct costs at the procedure level, and (2) the indirect costs at the practice level.

## **Solutions**

We believe that the proposed "bottom up" methodology is flawed with respect to cardiac catheterization procedures and CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool ("NPWP") has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.

The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

We will be collaborating with our membership organization, the Cardiovascular Outpatient Center Alliance ("COCA") to develop improved estimates of direct and indirect costs that may be submitted to CMS to supplement these comments either separately or as part of our comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007. It is our understanding that CMS will accept additional data that helps CMS in evaluating the impact of the PE RVU methodology on our practices.

Because the cost data for catheterizations in particular do not reflect the actual cost of providing heart catheterizations, we may be forced to close our four Nebraska catheterization labs, as we would be losing money on every single procedure. This would move 3,000 elective catheterizations to other Nebraska hospitals, which would still be able to cover the cost of doing a catheterization. We believe this would cause a serious patient access problem for patients needing emergent catheterization in a hospital setting. Door-to-Balloon Time, an important measure of the survival of acute cardiac patients, would most certainly increase due to the large numbers of elective procedures in hospital labs. We believe that shifting elective catheterizations with low complication rates to hospital labs would create an inability to provide the high-quality care Nebraska's hospital patients currently receive.

Sincerely,

Patti Fierstein Business Office Nebraska Heart Institute

Submitter:

Dr. Fred Petty

Organization:

Dr. Fred Petty

Category:

Physician

Issue Areas/Comments

Practice Expense

Practice Expense

see attachment

CMS-1512-PN-1853-Attach-1.DOC

Date: 08/18/2006



Centers for Medicare and Medicaid Services

U.S. Department of Health and Human Services

(June 29, 2006); Comments re: Practice Expense

Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.
Joseph M. Cefalu, M.D., F.A.C.C.
Kevin L. Kilpatrick, M.D., F.A.C.C.
Terry L. Zellmer, M.D., F.A.C.C.
Daniel T. Fontenot, M.D., F.A.C.C.
Harold G. Clausen, Jr., M.D., F.A.C.C., F.S.C.A.I.
Fred H. Petty, M.D., F.A.C.C., F.S.C.A.I.
Henry C. Patrick, M.D., F.A.C.C.
Venkat R. Surakanti, M.D., F.A.C.C.
Evens Rodney, M.D., F.A.C.C.
Darrin M. Breaux, M.D., F.A.C.C.
Boyd M. Helm, M.D.
James R. Calvin, M.D., F.A.C.C., Emeritus

5231 Brittany Drive, Baton Rouge, Louisiana 70808, Phone: 225/769-0933, Fax: 225/769-6255

Mark McClellan, M.D., Ph.D.

Administrator

CMS-1512-PN

Mail Stop C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850

By Appointment

Practice Limited to Cardiology

A Professional Medical Corporation

6363

Cardiac Evaluation

Arrhythmia Management

Stress Testing

Nuclear Testing

Echocardiology

Transesophageal Echocardiography

Tilt Table Testing

Holter Monitors

Event Recorders

Diagnosiic Heart Catheterization

Post Heart Surgery Cardiac Management

Balloon & Laser Coronary Angioplasty

Coronary Atherectomy
& Stents

Cardiac Rehabilitation

Pacemaker Implantation & Follow-up

Lipid Management

syncope Evaluation

Electrophysiologic Studies

Radiofrequency Catheter Ablation

Detribullation Implantation 3 Follow-up Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the

Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology

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We have one cath lab, 1300 procedures per year with 11 physicians located in Baton Rouge, Louisiana.

The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component ("TC") is a significant part of the overall procedure. Catheterization procedures are being used as an example of the impact of the proposed methodology on procedures with significant TC costs because they share the same problems that we will outline below. We also believe that the same solution should be applied to all of the procedures listed below.

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Sincerely,

Fred Petty, M.D., F.A.C.C.

The ut

Submitter:

Dr. Henry Patrick

Organization:

Dr. Henry Patrick

Category:

Physician

Issue Areas/Comments

**Practice Expense** 

Practice Expense

see attachment

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Date: 08/18/2006



AMMZHMENT TO #1854 Boyd E. Helm Joseph Kevin I

Boyd E. Helm, M.D., FA.C.C., FS.C.A.I.
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5231 Brittany Drive, Baton Rouge, Louisiana 70808, Phone: 225/769-0933, Fax: 225/769-6255

By Appointment

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Arrhythmia

Management Stress Testing

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Lipid Management

Syncope Evaluation

Electrophysiologic Studies

Radiofrequency Catheter Ablation

Depdrillation Implantation 3 Follow-up Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services

Centers for Medicare and Medicaid Services U.S. Department of Health and Human Services

CMS-1512-PN Mail Stop C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850

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Submitter:

Dr. Venkat Surakanti

Organization:

Dr. Venkat Surakanti

Category:

Physician

Issue Areas/Comments

Practice Expense

Practice Expense

see attachment

CMS-1512-PN-1855-Attach-1.DOC

Date: 08/18/2006



Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.
Joseph M. Cefalu, M.D., F.A.C.C.
Kevin L. Kilpatrick, M.D., F.A.C.C.
Terry L. Zellmer, M.D., F.A.C.C.
Daniel T. Fontenot, M.D., F.A.C.C.
Harold G. Clausen, Jr., M.D., F.A.C.C., F.S.C.A.I.
Fred H. Petty, M.D., F.A.C.C., F.S.C.A.I.
Henry C. Patrick, M.D., F.A.C.C.
Venkat R. Surakanti, M.D., F.A.C.C.
Evens Rodney, M.D., F.A.C.C.
Darrin M. Breaux, M.D., F.A.C.C.
Boyd M. Helm, M.D.

James R. Calvin, M.D., F.A.C.C., Emeritus

5231 Brittany Drive, Baton Rouge, Louisiana 70808, Phone: 225/769-0933, Fax: 225/769-6255

By Appointment

Practice Limited to Cardiology

A Professional Medical Corporation

6363

Cardiac Evaluation & Counseling

Arrhythmaa Management

Stress Testing

Nuclear Testing

Echocardiology

Transesophageal Echocardiography

Tilt Table Testing

Holter Monitors

Event Recorders

Diagnostic Heart Catheterization

Post Heart Surgery Cardiac Management

Balloon & Laser Caronary Angioplasty

Coronary Atherectomy & Stents

Cardiac Rehabilitation

Pacemaker Implantation
& Follow-up

Lipid Management

Syncope Evaluation

Electrophysiologic Studies

Radiofrequency Catheter

Depilvrillation Implantation 3 Follow-up Mark McClellan, M.D., Ph.D.

Administrator

Centers for Medicare and Medicaid Services U.S. Department of Health and Human Services

CMS-1512-PN

Mail Stop C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850

Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (June 29, 2006); Comments re: Practice Expense

## Dear Dr. McClellan:

On behalf of Baton Rouge Cardiology Center and our 11 individual practicing cardiologists, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

We have one cath lab, 1300 procedures per year with 11 physicians located in Baton Rouge, Louisiana.

The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component ("TC") is a significant part of the overall procedure. Catheterization procedures are being used as an example of the impact of the proposed methodology on procedures with significant TC costs because they share the same problems that we will outline below. We also believe that the same solution should be applied to all of the procedures listed below.

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments for CPT 93510 TC. Similarly, payment for two related codes—93555 TC and 93556 TC would be reduced substantially. In fact, under the Medicare Physician Fee Schedule ("PFS"), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate for these three codes to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

CPT Code	Description
93510 TC	Left Heart Catheterization
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93526 TC	Rt & Lt Heart Catheters

The stated purpose of the proposed change to a bottom up micro-costing approach is laudable and consistent with the statutory requirement that the Medicare program base payment on the use of necessary resources. However, the proposed methodology and inputs to the calculation do not comport with the statutory requirement that would match resources to payments. After reviewing the proposed methodology, including the 19 step calculation, we have identified several flaws that result in the PE RVU underestimating the resources needed to provide the technical component of cardiac catheterizations. We will address our concerns with the calculation of direct costs and indirect costs separately, as set forth below.

## **Direct Costs**

The estimate of direct costs is critical for the first step in calculating the PE RVU for each procedure code. The direct costs are based on inputs from the American Medical Association's RVS Update Committee ("RUC") and reflect the direct costs of clinical labor, medical supplies and medical equipment that are typically used to perform each procedure. The RUC-determined direct costs do not reflect estimates of additional labor, supply and equipment costs that were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 percent of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49 percent of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns. For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

Unless the RUC considers the actual costs of the clinical labor, supply and equipment used to perform a cardiac catheterization, the PE RVU that results at the end of the 19 step calculation will never reflect the actual resources needed to perform the procedure and will result in destabilizing practice expense payments to physicians. Therefore, CMS must evaluate the adequacy of the direct inputs and focus on developing a methodology that captures the average direct costs of performing a procedure, rather than the direct costs of performing a procedure that represents 51 percent of the patients.

A new methodology is needed based on the best data available so that the direct costs shown in the third column of the table below can be allocated in a manner similar to the allocation of indirect costs. This would result in a PE RVU that is a more accurate reflection of the direct and indirect costs for the resources that are critical to performing the procedure.

# Categories of Cardiac Catheterization Direct Costs Included or Excluded From RUC-Determined Estimates

Direct Cost Category	Included In RUC- Determined Estimate	Excluded From RUC- Determined Estimate
Clinical Labor	<ul> <li>Direct Patient Care For Activities Defined by RUC</li> <li>Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery)</li> </ul>	<ul> <li>Direct Patient Care For Activities Not Defined by RUC</li> <li>Actual Staff Allocation Based on Patient Needs</li> </ul>
Medical Supplies	Supplies Used For More Than 51% of Patients	Supplies Used For Less Than 51% of Patients
Medical Equipment	Equipment Used For More Than 51% of Patients	• Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	Approximately 55% of the direct costs are included in the RUC estimate	Approximately 45% of the direct costs are included in the RUC estimate

A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. There are additional improvements that can be made in the manner by which the indirect costs are estimated that are outlined below.

## **Indirect Costs**

The "bottom-up" methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities ("IDTFs"), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of

cardiac catheterization facilities--that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 percent. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both (1) the direct costs at the procedure level, and (2) the indirect costs at the practice level.

## **Solutions**

We believe that the proposed "bottom up" methodology is flawed with respect to cardiac catheterization procedures and CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool ("NPWP") has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.

The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

We will be collaborating with our membership organization, the Cardiovascular Outpatient Center Alliance ("COCA") to develop improved estimates of direct and indirect costs that may be submitted to CMS to supplement these comments either separately or as part of our comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007. It is our understanding that CMS will accept additional data that helps CMS in evaluating the impact of the PE RVU methodology on our practices.

Sincerely,

Venkat Surakanti, M.D., F.A.C.C.

Submitter:

Ms. Jamie Shephard

Date: 08/18/2006

Organization:

Covenant Health Care

Category:

Health Care Professional or Association

**Issue Areas/Comments** 

#### **GENERAL**

#### **GENERAL**

I have recently been informed that the CMS has proposed changes in teh Medicare reimbursement of duel energy x ray absorptiometry (DXA). The plan is a large reduction in reimbursement to hospitals and physicians offices. This would cause a very large negative impace in the screening of osteoporosis patients. Many physicians offices and hospitals/clinics will not find it cost effective to provide the service for those who need it. Therefor, not only would it be inconvenient for those who need screening, many will just not be ordered and the disease missed. I have been an x-ray technologist for 16 yrs. many of which I have also done bone densitionetry. There are a large amount of people that have osteoporosis, ans or osteopenia, that if not for the DEXA test would go undetected, as it is the most accurate, of all bone density test available. These people need to be treated preventibly fefore they fall into a lower catagory and actually suffer form osteoporotic related fractures. Fractures in the elderly, especially hip and compression fractures, cost teh government many more millions of dollars than taking simple preventative measures i the first place. There are many drugs available and more in the future to help prevent bone loss. Please reconsider the changes that are being looked at for the reimbursement of bone density testing. Many lives and millions of dollars can be saved in the process. Thank you for your time. Any questions or concerns please contact me at the below address.

Sincerely, Jamie S. Shephard RT(R) bone density/x ray 5400 Machinaw saginaw, M1 486

Submitter:

Dr. Evens Rodney

Organization:

Dr. Evens Rodney

Category:

Physician

Issue Areas/Comments

**Practice Expense** 

Practice Expense

see attachment

CMS-1512-PN-1857-Attach-1.DOC

Date: 08/18/2006

BATON ROUGE CARDIOLOGY CENTER

AMACHMENT TO # 1857

Boyd E. Helm, M.D., F.A.C.C., F.S.C.A.I.

Joseph M. Cefalu, M.D., F.A.C.C.

Kevin L. Kilpatrick, M.D., F.A.C.C.

Terry L. Zellmer, M.D., F.A.C.C.

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By Appointment

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Cardiac Evaluation & Counseling

Arrhythmia Management

Stress Testing

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Echocardiology

Transesophageal Echocardiography

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Syncope Evaluation

Electrophysiologic Studies

Radiofrequency Catheter Ablation

Detribrillation Implantation 8 Follow-up Mark McClellan, M.D., Ph.D.

Administrator

Centers for Medicare and Medicaid Services U.S. Department of Health and Human Services

CMS-1512-PN

Mail Stop C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850

Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (June 29, 2006); Comments re: Practice Expense

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In whier

Submitter:

Dr. Darrin Breaux

Organization:

Dr. Darrin Breaux

Category:

Physician

Issue Areas/Comments

**Practice Expense** 

Practice Expense

see attachment

CMS-1512-PN-1858-Attach-1.DOC

Date: 08/18/2006



AMACHMENT TO # 1858

Boyd E. Helm, M.D., F.A.C.C., ES.C.A.I.

Joseph M. Cefalu, M.D., F.A.C.C.

Kevin L. Kilpatrick, M.D., F.A.C.C.

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By Appointment

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Cardiac Evaluation & Counseling

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Mark McClellan, M.D., Ph.D.

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A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. There are additional improvements that can be made in the manner by which the indirect costs are estimated that are outlined below.

## **Indirect Costs**

The "bottom-up" methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities ("IDTFs"), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of

cardiac catheterization facilities--that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 percent. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both (1) the direct costs at the procedure level, and (2) the indirect costs at the practice level.

## **Solutions**

We believe that the proposed "bottom up" methodology is flawed with respect to cardiac catheterization procedures and CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool ("NPWP") has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.

The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

We will be collaborating with our membership organization, the Cardiovascular Outpatient Center Alliance ("COCA") to develop improved estimates of direct and indirect costs that may be submitted to CMS to supplement these comments either separately or as part of our comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007. It is our understanding that CMS will accept additional data that helps CMS in evaluating the impact of the PE RVU methodology on our practices.

Sincerely,

Darrin Breaux, M.D., F.A.C.C.

Submitter:

Dr. Norman Fishman

Organization:

Diabetes & Endocrinology Specialists, Inc.

Category:

Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Page 1866 of 1934

August 19 2006 02:00 PM

Date: 08/18/2006

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

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

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

Submitter:

Susan Wedda

Date: 08/18/2006

Organization:

Susan Wedda

Category:

Social Worker

**Issue Areas/Comments** 

## **Practice Expense**

## Practice Expense

As a Clinical Social Worker for more than 35 years, I am very concerned about the proposed cuts in Medicare reimbursement rates. Not only are social workers providing over 40% of mental health treatment, perhaps higher for our elderly population, but the reimbursement is lower than for others providing the same services. The significant cuts proposed will make it far more difficult to continue treating Medicare enrollees as business expenses increase. This segment of our population is increasing and the need for service will also increase. Many studies have shown that adequate mental health treatment can help reduce other medical costs. Thus, a reduction in reimbursement, which will lead to a reduction in available services, would be extremely short-sighted and likely lead to increased medical costs overall.

I implore you to reconsider and withdraw the proposed reimbursement cuts to Clinical Social Workers. I would also encourage you to review the system that pays psychologists and social workers at different rates and look at equalizing the reimbursement.

Thank you for your consideration.

Submitter:

Dr. Norman Fishman

Date: 08/18/2006

Organization:

Diabetes & Endocrinology Specialists, Inc.

Category:

Physician

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

August 18, 2006

To Whom It May Concern:

According to the National Osteoporosis Foundation, 10 million individuals have osteoporosis and 34 million more have low bone mass. It is estimated that 1 in 2 women and 1 in 4 men over the age of 50 will have an osteoporosis-related fracture. In 2002 national direct care expenditures for osteoporotic fractures was \$18 billion per year. Moreover, osteoporotic fractures significantly lower a patient s quality of life. Specifically, osteoporosis-related hip fractures increase the need for long-term care and increase the risk of death.

People may not know they have osteoporosis until their bones break. Bone Mineral Density Tests can detect osteoporosis before a fracture occurs, predict the chance for fracture, and monitor effects of treatment. DXA (Dual Energy X-ray Absorptiometry) measures bone mineral density at the spine, hip, or total body. The International Society for Clinical Densitometry recommends DXA measurements of the spine and hip for diagnosis of osteoporosis or low bone mass, and the World Health Organization reference standard for osteoporosis diagnosis is based on DXA measurements. With the information obtained from a DXA, prevention or treatment options can be determined and implemented.

Decreasing reimbursement for DXA would limit patient access to its benefits. Without adequate payment for the use of a DXA machine, for trained personnel to operate the machine, and for educated physicians to interpret the findings, it will not be feasible to perform the test. Osteoporosis and low bone mass will be under diagnosed, and opportunities to prevent and treat disease will be missed. Finances that should be used to prevent and treat fracture will instead be required exponentially for hospitalization, nursing home care, and outpatient services related to the morbidity associated with osteoporotic fractures.

Sincerely,

Norman Fishman, M.D. Diabetes & Endocrinology Specialists, Inc.

Submitter:

Dr. Frederick Badke

Date: 08/18/2006

Organization:

Idaho Cardiology Associates, P.A.

Category:

Physician

# Issue Areas/Comments

# Practice Expense

Practice Expense

The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the TC is a significant part of the overall procedure. With regard to caths, the proposed change in PE RVUs would result in a 53% reduction of payments for CPT 93510 TC. Payment for two related codes 93555 TC and 93556 TC would be reduced substantially. Under the Medicare PFS, payment for these 3 codes would fall from 94% of the proposed 2007 APC rate for these 3 codes to 34% of the APC payment amount. The proposed methodology and inputs to the calculation do not comport with the statutory requirement that would match resources to payments. The direct costs are based on inputs from the AMA s RUC and reflect the direct costs of clinical labor, medical supplies and medical equipment that are typically used to perform each procedure. The RUC-determined direct costs do not reflect estimates of additional labor, supply and equipment costs that were submitted by American cardiology group practices. As a result, the RUC-determined cost estimate is about half of the estimate that would result if all data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24%. The estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC includes costs only if they are relevant to 51% of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49% of the patients that may not fit the average profile. CMS must evaluate the adequacy of the direct inputs and focus on developing a methodology that captures the average direct costs of performing a procedure, rather than the direct costs of performing a procedure that represents 51% of the patients. A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. The bottom-up methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24%, though that s still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both the direct costs at the procedure level and the indirect costs at the practice level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the NPWP has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care. The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures.

CMS-1512-PN-1862-Attach-1.DOC

AMACHMENT TO # 1862

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (June 29, 2006); Comments re: Practice Expense

Dear Dr. McClellan:

On behalf of Idaho Cardiology Associates, I appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

Idaho Cardiology Associates, P.A. is the largest cardiology group practice in Idaho consisting of sixteen (16) cardiologists providing board-certified and fellowship trained invasive, interventional and electrophysiological services. Since its development in 2002, the physicians have owned and operated ICA Cath Lab, LLC, an independent diagnostic testing facility (IDTF) in which over 800 high quality, low cost diagnostic cardiac catheterization procedures are performed annually. Our patients, many of whom are Medicare beneficiaries, universally and enthusiastically relate a very high degree of satisfaction with the services and care provided to them at ICA Cath Lab. On their behalf we are very concerned with the proposed changes to the practice expense methodology.

The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component ("TC") is a significant part of the overall procedure. Catheterization procedures are being used as an example of the impact of the proposed methodology on procedures with significant TC costs because they share the same problems that we will outline below. We also believe that the same solution should be applied to all of the procedures listed below.

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments for CPT 93510 TC. Similarly, payment for two related codes—93555 TC and 93556 TC would be reduced substantially. In fact, under the Medicare Physician Fee Schedule ("PFS"), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate for these three codes to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

CPT Code	Description			
93510 TC	Left Heart Catheterization	<u> </u>	<del></del>	· _
93555 TC	Imaging Cardiac Catheterization			
93556 TC	Imaging Cardiac Catheterization	<del></del> -	 	
93526 TC	Rt & Lt Heart Catheters	_	 	

The stated purpose of the proposed change to a bottom up micro-costing approach is laudable and consistent with the statutory requirement that the Medicare program base payment on the use of necessary resources. However, the proposed methodology and inputs to the calculation do not comport with the statutory requirement that would match resources to payments. After reviewing the proposed methodology, including the 19 step calculation, we have identified several flaws that result in the PE RVU underestimating the resources needed to provide the technical component of cardiac catheterizations. We will address our concerns with the calculation of direct costs and indirect costs separately, as set forth below.

#### **Direct Costs**

The estimate of direct costs is critical for the first step in calculating the PE RVU for each procedure code. The direct costs are based on inputs from the American Medical Association's RVS Update Committee ("RUC") and reflect the direct costs of clinical labor, medical supplies and medical equipment that are typically used to perform each procedure. The RUC-determined direct costs do not reflect estimates of additional labor, supply and equipment costs that were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 percent of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49 percent of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns. For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

Unless the RUC considers the actual costs of the clinical labor, supply and equipment used to perform a cardiac catheterization, the PE RVU that results at the end of the 19 step calculation will never reflect the actual resources needed to perform the procedure and will result in destabilizing practice expense payments to physicians. Therefore, CMS must evaluate the adequacy of the direct inputs and focus on developing a methodology that captures the average direct costs of performing a procedure, rather than the direct costs of performing a procedure that represents 51 percent of the patients.

A new methodology is needed based on the best data available so that the direct costs shown in the third column of the table below can be allocated in a manner similar to the allocation of indirect costs. This would result in a PE RVU that is a more accurate reflection of the direct and indirect costs for the resources that are critical to performing the procedure.

Categories of Cardiac Catheterization Direct Costs Included or Excluded
From RUC-Determined Estimates

Direct Cost Category	Included In RUC- Determined Estimate	Excluded From RUC- Determined Estimate
Clinical Labor	<ul> <li>Direct Patient Care For Activities Defined by RUC</li> <li>Allocation of Staff Defined by RUC         Protocol (1:4 Ratio of RN to Patients in Recovery)     </li> </ul>	<ul> <li>Direct Patient Care For Activities Not Defined by RUC</li> <li>Actual Staff Allocation Based on Patient Needs</li> </ul>
Medical Supplies	Supplies Used For More Than 51% of Patients	Supplies Used For Less Than 51% of Patients
Medical Equipment	Equipment Used For More Than 51% of Patients	• Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	Approximately 55% of the direct costs are included in the RUC estimate	Approximately 45% of the direct costs are included in the RUC estimate

A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. There are additional improvements that can be made in the manner by which the indirect costs are estimated that are outlined below.

#### **Indirect Costs**

The "bottom-up" methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities ("IDTFs"), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of cardiac catheterization facilities—that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 percent. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both (1) the direct costs at the procedure level, and (2) the indirect costs at the practice level.

#### **Solutions**

We believe that the proposed "bottom up" methodology is flawed with respect to cardiac catheterization procedures and CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool ("NPWP") has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.

The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

We will be collaborating with our membership organization, the Cardiovascular Outpatient Center Alliance ("COCA") to develop improved estimates of direct and indirect costs that may be submitted to CMS to supplement these comments either separately or as part of our comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007. It is our understanding that CMS will accept additional data that helps CMS in evaluating the impact of the PE RVU methodology on our practices.

Respectfully,

David A. Hinchman, MD, FACC

Submitter:

Dr. Rachel Fishman-Oiknine

Date: 08/18/2006

Organization:

Diabetes & Endocrinology Specialists, Inc.

Category:

Physician

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

August 18, 2006

To Whom It May Concern:

According to the National Osteoporosis Foundation, 10 million individuals have osteoporosis and 34 million more have low bone mass. It is estimated that 1 in 2 women and 1 in 4 men over the age of 50 will have an osteoporosis-related fracture. In 2002 national direct care expenditures for osteoporotic fractures was \$18 billion per year. Moreover, osteoporotic fractures significantly lower a patient s quality of life. Specifically, osteoporosis-related hip fractures increase the need for long-term care and increase the risk of death.

People may not know they have osteoporosis until their bones break. Bone Mineral Density Tests can detect osteoporosis before a fracture occurs, predict the chance for fracture, and monitor effects of treatment. DXA (Dual Energy X-ray Absorptiometry) measures bone mineral density at the spine, hip, or total body. The International Society for Clinical Densitometry recommends DXA measurements of the spine and hip for diagnosis of osteoporosis or low bone mass, and the World Health Organization reference standard for osteoporosis diagnosis is based on DXA measurements. With the information obtained from a DXA, prevention or treatment options can be determined and implemented.

Decreasing reimbursement for DXA would limit patient access to its benefits. Without adequate payment for the use of a DXA machine, for trained personnel to operate the machine, and for educated physicians to interpret the findings, it will not be feasible to perform the test. Osteoporosis and low bone mass will be under diagnosed, and opportunities to prevent and treat disease will be missed. Finances that should be used to prevent and treat fracture will instead be required exponentially for hospitalization, nursing home care, and outpatient services related to the morbidity associated with osteoporotic fractures.

Sincerely,

Rachel Fishman-Oiknine, M.D. Diabetes & Endocrinology Specialists, Inc.

Submitter:

Dr. Ralph Oiknine

Date: 08/18/2006

Organization:

Diabetes & Endocrinology Specialists, Inc.

Category:

Physician

Issue Areas/Comments

**GENERAL** 

**GENERAL** 

August 18, 2006

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Sincerely,

Ralph Oiknine, M.D. Diabetes & Endocrinology Specialists, Inc.

Submitter:

Dr. Murali Bathina

Organization:

Idaho Cardiology Associates

Category:

Physician

Issue Areas/Comments

**Practice Expense** 

Practice Expense

I wish to comment on the proposed changes to the PE methodology.

CMS-1512-PN-1865-Attach-1.DOC

Page 1872 of 1934

August 19 2006 02:00 PM

Date: 08/18/2006

AMACHMENT TO # 1865

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (June 29, 2006); Comments re: Practice Expense

Dear Dr. McClellan:

On behalf of Idaho Cardiology Associates, I appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

Idaho Cardiology Associates, P.A. is the largest cardiology group practice in Idaho consisting of sixteen (16) cardiologists providing board-certified and fellowship trained invasive, interventional and electrophysiological services. Since its development in 2002, the physicians have owned and operated ICA Cath Lab, LLC, an independent diagnostic testing facility (IDTF) in which over 800 high quality, low cost diagnostic cardiac catheterization procedures are performed annually. Our patients, many of whom are Medicare beneficiaries, universally and enthusiastically relate a very high degree of satisfaction with the services and care provided to them at ICA Cath Lab. On their behalf we are very concerned with the proposed changes to the practice expense methodology.

The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component ("TC") is a significant part of the overall procedure. Catheterization procedures are being used as an example of the impact of the proposed methodology on procedures with significant TC costs because they share the same problems that we will outline below. We also believe that the same solution should be applied to all of the procedures listed below.

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments for CPT 93510 TC. Similarly, payment for two related codes—93555 TC and 93556 TC would be reduced substantially. In fact, under the Medicare Physician Fee Schedule ("PFS"), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate for these three codes to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

CPT Code	Description		
93510 TC	Left Heart Catheterization		and the second of the second o
93555 TC	Imaging Cardiac Catheterization	n	<del></del>
93556 TC	Imaging Cardiac Catheterization	n	
93526 TC	Rt & Lt Heart Catheters		<del></del>

The stated purpose of the proposed change to a bottom up micro-costing approach is laudable and consistent with the statutory requirement that the Medicare program base payment on the use of necessary resources. However, the proposed methodology and inputs to the calculation do not comport with the statutory requirement that would match resources to payments. After reviewing the proposed methodology, including the 19 step calculation, we have identified several flaws that result in the PE RVU underestimating the resources needed to provide the technical component of cardiac catheterizations. We will address our concerns with the calculation of direct costs and indirect costs separately, as set forth below.

#### **Direct Costs**

The estimate of direct costs is critical for the first step in calculating the PE RVU for each procedure code. The direct costs are based on inputs from the American Medical Association's RVS Update Committee ("RUC") and reflect the direct costs of clinical labor, medical supplies and medical equipment that are typically used to perform each procedure. The RUC-determined direct costs do not reflect estimates of additional labor, supply and equipment costs that were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 percent of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49 percent of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns. For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

Unless the RUC considers the actual costs of the clinical labor, supply and equipment used to perform a cardiac catheterization, the PE RVU that results at the end of the 19 step calculation will never reflect the actual resources needed to perform the procedure and will result in destabilizing practice expense payments to physicians. Therefore, CMS must evaluate the adequacy of the direct inputs and focus on developing a methodology that captures the average direct costs of performing a procedure, rather than the direct costs of performing a procedure that represents 51 percent of the patients.

A new methodology is needed based on the best data available so that the direct costs shown in the third column of the table below can be allocated in a manner similar to the allocation of indirect costs. This would result in a PE RVU that is a more accurate reflection of the direct and indirect costs for the resources that are critical to performing the procedure.

Categories of Cardiac Catheterization Direct Costs Included or Excluded
From RUC-Determined Estimates

Direct Cost Category	Included In RUC- Determined Estimate	Excluded From RUC- Determined Estimate
Clinical Labor	Direct Patient Care For Activities Defined by RUC	Direct Patient Care For Activities Not Defined by RUC
	<ul> <li>Allocation of Staff         Defined by RUC         Protocol (1:4 Ratio of RN to Patients in Recovery)     </li> </ul>	Actual Staff Allocation     Based on Patient Needs
Medical Supplies	Supplies Used For More Than 51% of Patients	Supplies Used For Less Than 51% of Patients
Medical Equipment	• Equipment Used For More Than 51% of Patients	• Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	Approximately 55% of the direct costs are included in the RUC estimate	Approximately 45% of the direct costs are included in the RUC estimate

A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. There are additional improvements that can be made in the manner by which the indirect costs are estimated that are outlined below.

# **Indirect Costs**

The "bottom-up" methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities ("IDTFs"), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of cardiac catheterization facilities—that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 percent. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both (1) the direct costs at the procedure level, and (2) the indirect costs at the practice level.

#### **Solutions**

We believe that the proposed "bottom up" methodology is flawed with respect to cardiac catheterization procedures and CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool ("NPWP") has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.

The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

We will be collaborating with our membership organization, the Cardiovascular Outpatient Center Alliance ("COCA") to develop improved estimates of direct and indirect costs that may be submitted to CMS to supplement these comments either separately or as part of our comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007. It is our understanding that CMS will accept additional data that helps CMS in evaluating the impact of the PE RVU methodology on our practices.

Respectfully,

David A. Hinchman, MD, FACC

Submitter:
Organization:

Mr. Michael Uran

**Trinity Health** 

Category:

Other Health Care Professional

Issue Areas/Comments

Discussion of Comments-Radiology, Pathology, and Other Misc. Services

Discussion of Comments- Radiology, Pathology, and Other Misc. Services

Re: CMS-1512-PN I would urge that CMS withdraw the proposed payment reduction for codes 76082 and 76083 until a such time that a differentiation can be made between analog and digital CAD service costs can be differentiated. Analog CAD requires film digitization and that related equipment and staff time. The prop0osed rate does not nearly compensate for that. There have been no chaanges to substantiate this proposed reduction in payment for the analog services. Mike Uran

Date: 08/18/2006

Submitter :

Dr. Andy Chai

Organization:

**Idaho Cardiology Associates** 

Category:

Physician

Issue Areas/Comments

Practice Expense

Practice Expense

I wish to comment on the proposed changes to the PE methodology.

CMS-1512-PN-1867-Attach-1.DOC

Date: 08/18/2006

ATTACHMENT TO H 1867

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (June 29, 2006); Comments re: Practice Expense

Dear Dr. McClellan:

On behalf of Idaho Cardiology Associates, I appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

Idaho Cardiology Associates, P.A. is the largest cardiology group practice in Idaho consisting of sixteen (16) cardiologists providing board-certified and fellowship trained invasive, interventional and electrophysiological services. Since its development in 2002, the physicians have owned and operated ICA Cath Lab, LLC, an independent diagnostic testing facility (IDTF) in which over 800 high quality, low cost diagnostic cardiac catheterization procedures are performed annually. Our patients, many of whom are Medicare beneficiaries, universally and enthusiastically relate a very high degree of satisfaction with the services and care provided to them at ICA Cath Lab. On their behalf we are very concerned with the proposed changes to the practice expense methodology.

The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component ("TC") is a significant part of the overall procedure. Catheterization procedures are being used as an example of the impact of the proposed methodology on procedures with significant TC costs because they share the same problems that we will outline below. We also believe that the same solution should be applied to all of the procedures listed below.

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments for CPT 93510 TC. Similarly, payment for two related codes—93555 TC and 93556 TC would be reduced substantially. In fact, under the Medicare Physician Fee Schedule ("PFS"), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate for these three codes to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

CPT Code	Description	21
93510 TC	Left Heart Catheterization	
93555 TC	Imaging Cardiac Catheterization	
93556 TC	Imaging Cardiac Catheterization	
93526 TC	Rt & Lt Heart Catheters	

The stated purpose of the proposed change to a bottom up micro-costing approach is laudable and consistent with the statutory requirement that the Medicare program base payment on the use of necessary resources. However, the proposed methodology and inputs to the calculation do not comport with the statutory requirement that would match resources to payments. After reviewing the proposed methodology, including the 19 step calculation, we have identified several flaws that result in the PE RVU underestimating the resources needed to provide the technical component of cardiac catheterizations. We will address our concerns with the calculation of direct costs and indirect costs separately, as set forth below.

## **Direct Costs**

The estimate of direct costs is critical for the first step in calculating the PE RVU for each procedure code. The direct costs are based on inputs from the American Medical Association's RVS Update Committee ("RUC") and reflect the direct costs of clinical labor, medical supplies and medical equipment that are typically used to perform each procedure. The RUC-determined direct costs do not reflect estimates of additional labor, supply and equipment costs that were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 percent of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49 percent of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns. For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

Unless the RUC considers the actual costs of the clinical labor, supply and equipment used to perform a cardiac catheterization, the PE RVU that results at the end of the 19 step calculation will never reflect the actual resources needed to perform the procedure and will result in destabilizing practice expense payments to physicians. Therefore, CMS must evaluate the adequacy of the direct inputs and focus on developing a methodology that captures the average direct costs of performing a procedure, rather than the direct costs of performing a procedure that represents 51 percent of the patients.

A new methodology is needed based on the best data available so that the direct costs shown in the third column of the table below can be allocated in a manner similar to the allocation of indirect costs. This would result in a PE RVU that is a more accurate reflection of the direct and indirect costs for the resources that are critical to performing the procedure.

Categories of Cardiac Catheterization Direct Costs Included or Excluded From RUC-Determined Estimates

Direct Cost Category	Included In RUC- Determined Estimate	Excluded From RUC- Determined Estimate
Clinical Labor	Direct Patient Care For Activities Defined by RUC	Direct Patient Care For Activities Not Defined by RUC
	Allocation of Staff     Defined by RUC     Protocol (1:4 Ratio of     RN to Patients in     Recovery)	Actual Staff Allocation     Based on Patient Needs
Medical Supplies	Supplies Used For More Than 51% of Patients	Supplies Used For Less Than 51% of Patients
Medical Equipment	<ul> <li>Equipment Used For More Than 51% of Patients</li> </ul>	• Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	Approximately 55% of the direct costs are included in the RUC estimate	Approximately 45% of the direct costs are included in the RUC estimate

A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. There are additional improvements that can be made in the manner by which the indirect costs are estimated that are outlined below.

# **Indirect Costs**

The "bottom-up" methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities ("IDTFs"), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of cardiac catheterization facilities—that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 percent. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both (1) the direct costs at the procedure level, and (2) the indirect costs at the practice level.

#### **Solutions**

We believe that the proposed "bottom up" methodology is flawed with respect to cardiac catheterization procedures and CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool ("NPWP") has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.

The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

We will be collaborating with our membership organization, the Cardiovascular Outpatient Center Alliance ("COCA") to develop improved estimates of direct and indirect costs that may be submitted to CMS to supplement these comments either separately or as part of our comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007. It is our understanding that CMS will accept additional data that helps CMS in evaluating the impact of the PE RVU methodology on our practices.

Respectfully,

David A. Hinchman, MD, FACC

Submitter:

Dr. Robert Duerr

Organization:

**Idaho Cardiology Associates** 

Category:

Physician

Issue Areas/Comments

**Practice Expense** 

Practice Expense

I wish to comment on the proposed changes to the PE methodology.

CMS-1512-PN-1868-Attach-1.DOC

Date: 08/18/2006

ANTACHMENT TO # 1868

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (June 29, 2006); Comments re: Practice Expense

Dear Dr. McClellan:

On behalf of Idaho Cardiology Associates, I appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

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The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component ("TC") is a significant part of the overall procedure. Catheterization procedures are being used as an example of the impact of the proposed methodology on procedures with significant TC costs because they share the same problems that we will outline below. We also believe that the same solution should be applied to all of the procedures listed below.

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments for CPT 93510 TC. Similarly, payment for two related codes—93555 TC and 93556 TC would be reduced substantially. In fact, under the Medicare Physician Fee Schedule ("PFS"), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate for these three codes to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

<b>CPT Code</b>	Description	
93510 TC	Left Heart Catheterization	
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The stated purpose of the proposed change to a bottom up micro-costing approach is laudable and consistent with the statutory requirement that the Medicare program base payment on the use of necessary resources. However, the proposed methodology and inputs to the calculation do not comport with the statutory requirement that would match resources to payments. After reviewing the proposed methodology, including the 19 step calculation, we have identified several flaws that result in the PE RVU underestimating the resources needed to provide the technical component of cardiac catheterizations. We will address our concerns with the calculation of direct costs and indirect costs separately, as set forth below.

#### **Direct Costs**

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Respectfully,

David A. Hinchman, MD, FACC

Submitter:

Dr. Charles Eiriksson

Organization:

**Idaho Cardiology Associates** 

Category:

Physician

Issue Areas/Comments

# Practice Expense

Practice Expense

I wish to comment on the proposed changes to the PE methodology.

CMS-1512-PN-1869-Attach-1.DOC

Date: 08/18/2006

ATTACHMENT TO # 1869

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (June 29, 2006); Comments re: Practice Expense

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Respectfully,

David A. Hinchman, MD, FACC

Submitter:

Dr. Jim Field

Organization:

Idaho Cardiology Associates

Category:

Physician

Issue Areas/Comments

Practice Expense

Practice Expense

I wish to comment on the proposed changes to the PE methodology.

CMS-1512-PN-1870-Attach-1.DOC

Date: 08/18/2006

# ATTACHMENT to # 1870

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Proposed Notice re: Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology (June 29, 2006); Comments re: Practice Expense

Dear Dr. McClellan:

On behalf of Idaho Cardiology Associates, I appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Service ("CMS") regarding the June 29, 2006 Proposed Notice ("Notice") regarding Proposed Changes to the Practice Expense ("PE") Methodology and its impact on our practices.

Idaho Cardiology Associates, P.A. is the largest cardiology group practice in Idaho consisting of sixteen (16) cardiologists providing board-certified and fellowship trained invasive, interventional and electrophysiological services. Since its development in 2002, the physicians have owned and operated ICA Cath Lab, LLC, an independent diagnostic testing facility (IDTF) in which over 800 high quality, low cost diagnostic cardiac catheterization procedures are performed annually. Our patients, many of whom are Medicare beneficiaries, universally and enthusiastically relate a very high degree of satisfaction with the services and care provided to them at ICA Cath Lab. On their behalf we are very concerned with the proposed changes to the practice expense methodology.

The proposed approach is biased against procedures, such as outpatient cardiovascular catheterizations, for which the Technical Component ("TC") is a significant part of the overall procedure. Catheterization procedures are being used as an example of the impact of the proposed methodology on procedures with significant TC costs because they share the same problems that we will outline below. We also believe that the same solution should be applied to all of the procedures listed below.

With regard to catheterizations, the proposed change in PE RVUs would result in a 53.1 percent reduction of payments for CPT 93510 TC. Similarly, payment for two related codes—93555 TC and 93556 TC would be reduced substantially. In fact, under the Medicare Physician Fee Schedule ("PFS"), payment for these three codes would fall from 94 percent of the proposed 2007 APC rate for these three codes to 34 percent of the APC payment amount. These codes are representative of a range of procedures performed in cardiovascular outpatient centers.

CPT Code	Description	
93510 TC	Left Heart Catheterization	
93555 TC	Imaging Cardiac Catheterization	
93556 TC	Imaging Cardiac Catheterization	
93526 TC	Rt & Lt Heart Catheters	

The stated purpose of the proposed change to a bottom up micro-costing approach is laudable and consistent with the statutory requirement that the Medicare program base payment on the use of necessary resources. However, the proposed methodology and inputs to the calculation do not comport with the statutory requirement that would match resources to payments. After reviewing the proposed methodology, including the 19 step calculation, we have identified several flaws that result in the PE RVU underestimating the resources needed to provide the technical component of cardiac catheterizations. We will address our concerns with the calculation of direct costs and indirect costs separately, as set forth below.

#### **Direct Costs**

The estimate of direct costs is critical for the first step in calculating the PE RVU for each procedure code. The direct costs are based on inputs from the American Medical Association's RVS Update Committee ("RUC") and reflect the direct costs of clinical labor, medical supplies and medical equipment that are typically used to perform each procedure. The RUC-determined direct costs do not reflect estimates of additional labor, supply and equipment costs that were submitted by (The Society for Cardiovascular Angiography and Interventions ("SCAI") or an industry group). As a result, the RUC-determined cost estimate is about half of the estimate that would result if all of the data were included. The addition of these additional costs which are consistent with the RUC protocol would increase the proposed PE RVUs by 24 percent.

Even if the RUC estimates included the additional costs submitted by SCAI or an industry group, the estimate is not an accurate reflection of direct costs of the resources necessary to provide the procedure because the RUC takes a narrow view of direct costs. Specifically, the RUC includes costs only if they are relevant to 51 percent of the patients. This definition of direct costs does not count the costs of supplies and the clinical labor time that may be required for the other 49 percent of the patients that may not fit the average profile. This approach is particularly inconsistent with the realities of the clinical staff needed for a catheterization facility and does not reflect the differences in clinical practice patterns. For example, some catheterization labs may use wound closure devices that will increase supply costs while lowering clinical staff time. Other labs may not use closure devices to the same extent and may allocate more staff time to apply compression to the wound. These costs would not be counted in the RUC-determined direct cost estimate unless they apply to 51 percent of the patients. Based on the PEAC Direct Input data from the CMS website, it appears that the RUC inputs assume the time that may be required if wound closures were used, but it fails to include a wound closure device in the supply list of direct costs.

Unless the RUC considers the actual costs of the clinical labor, supply and equipment used to perform a cardiac catheterization, the PE RVU that results at the end of the 19 step calculation will never reflect the actual resources needed to perform the procedure and will result in destabilizing practice expense payments to physicians. Therefore, CMS must evaluate the adequacy of the direct inputs and focus on developing a methodology that captures the average direct costs of performing a procedure, rather than the direct costs of performing a procedure that represents 51 percent of the patients.

A new methodology is needed based on the best data available so that the direct costs shown in the third column of the table below can be allocated in a manner similar to the allocation of indirect costs. This would result in a PE RVU that is a more accurate reflection of the direct and indirect costs for the resources that are critical to performing the procedure.

Categories of Cardiac Catheterization Direct Costs Included or Excluded From RUC-Determined Estimates

Direct Cost Category	Included In RUC- Determined Estimate	Excluded From RUC- Determined Estimate
Clinical Labor	Direct Patient Care For Activities Defined by RUC	Direct Patient Care For Activities Not Defined by RUC
	Allocation of Staff     Defined by RUC     Protocol (1:4 Ratio of     RN to Patients in     Recovery)	Actual Staff Allocation     Based on Patient Needs
Medical Supplies	Supplies Used For More Than 51% of Patients	• Supplies Used For Less Than 51% of Patients
Medical Equipment	• Equipment Used For More Than 51% of Patients	• Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	Approximately 55% of the direct costs are included in the RUC estimate	Approximately 45% of the direct costs are included in the RUC estimate

A complete accounting of all of the direct costs associated with performing a cardiac catheterization procedure would result in a PE RVU that is almost two times the proposed amount, and would begin to approximate the actual costs of providing the service. There are additional improvements that can be made in the manner by which the indirect costs are estimated that are outlined below.

# **Indirect Costs**

The "bottom-up" methodology estimates indirect costs at the procedure code level using data from surveys of practice costs of various specialties. The methodology uses the ratio of direct to indirect costs at the practice level in conjunction with the direct cost estimate from the RUC to estimate the indirect costs for each procedure code. As a result, the indirect costs of cardiac catheterization procedure codes are understated because the direct costs do not reflect all of the actual costs. In addition, most of the PE RVUs reflect a weighted average of the practice costs of two specialties – Independent Diagnostic Treatment Facilities ("IDTFs"), which account for about two-thirds of the utilization estimate for 93510 TC, and cardiology. The IDTF survey includes a wide range of facilities, but do not reflect the cost profile of cardiac catheterization facilities—that may have a cost profile similar to cardiology in terms of the higher indirect costs that are associated with performing these services.

If CMS were to base the PE RVU for cardiac catheterization on the practice costs from cardiology surveys rather than a weighted average of cardiology and IDTFs, the PE RVU would increase about 24 percent. However, the payment would still fall far below the costs associated with the resources needed to provide the service efficiently. This finding supports the conclusion that the inputs to the calculations are flawed and need to be changed to ensure that they reflect accurately both (1) the direct costs at the procedure level, and (2) the indirect costs at the practice level.

#### **Solutions**

We believe that the proposed "bottom up" methodology is flawed with respect to cardiac catheterization procedures and CMS needs to develop a new approach that identifies the actual direct costs at the procedure level. The set of costs that are considered by the RUC are incomplete and need to be expanded now that the non-physician work pool ("NPWP") has been eliminated. The RUC-determined costs need to reflect all of the costs of clinical labor, not only the labor associated with the sub-set of patient care time that is currently considered. The supply and equipment costs also need to reflect current standards of care.

The problem created under the PE-RVU methodology set out in the Notice would result in a draconian cut in reimbursement for cardiac catheterization performed in practice or IDTF locations. The magnitude of the inequitable treatment caused by the resulting cuts is immediately apparent from a comparison with the APC payment rate for similar procedures. As a result, we request that CMS freeze payment for these cardiac catheterization-related procedure codes for one year to allow time for a complete assessment of the cost profile of the services listed in the chart provided above.

We will be collaborating with our membership organization, the Cardiovascular Outpatient Center Alliance ("COCA") to develop improved estimates of direct and indirect costs that may be submitted to CMS to supplement these comments either separately or as part of our comments in our response to the Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007. It is our understanding that CMS will accept additional data that helps CMS in evaluating the impact of the PE RVU methodology on our practices.

Respectfully,

David A. Hinchman, MD, FACC