

Submitter : Dr. Dorothy Danaher

Date: 08/18/2006

Organization : Psychsource

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

Reduction of payments for physician services is opposite of what is needed at this time. Many doctors are moving out of medicine to other fields. I am a psychologist who treats 32 patients in nursing home facilities. Without my intervention, many of my patients would isolate and suffer needlessly from depression, anxiety or psychosis. Please do not make any cuts, and instead increase payments in order to attract physicians, psychologists, and social workers back into treating the elderly and disabled.

Submitter : Dr. Stefanie Fry
Organization : Idaho Cardiology Associates
Category : Physician

Date: 08/18/2006

Issue Areas/Comments

Practice Expense

Practice Expense

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

CMS-1512-PN-1872-Attach-1.DOC

ATTACHMENT TO #1872

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***

<i>Direct Cost Category</i>	<i>Included In RUC-- Determined Estimate</i>	<i>Excluded From RUC-- Determined Estimate</i>
Clinical Labor	<ul style="list-style-type: none"> • Direct Patient Care For Activities Defined by RUC • Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery) 	<ul style="list-style-type: none"> • Direct Patient Care For Activities Not Defined by RUC • Actual Staff Allocation Based on Patient Needs
Medical Supplies	<ul style="list-style-type: none"> • Supplies Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Supplies Used For Less Than 51% of Patients
Medical Equipment	<ul style="list-style-type: none"> • Equipment Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	<ul style="list-style-type: none"> • Approximately 55% of the direct costs are included in the RUC estimate 	<ul style="list-style-type: none"> • 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. David Hinchman
Organization : Idaho Cardiology Associates
Category : Physician

Date: 08/18/2006

Issue Areas/Comments

Practice Expense

Practice Expense

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

CMS-1512-PN-1873-Attach-1.DOC

ATTACHMENT TO #1873

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
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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.

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David A. Hinchman, MD, FACC

Submitter : Dr. David Hinchman
Organization : Idaho Cardiology Associates
Category : Physician

Date: 08/18/2006

Issue Areas/Comments

Practice Expense

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

CMS-1512-PN-1874-Attach-1.DOC

ATTACHMENT TO # 1874

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-1512-PN
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Respectfully,

David A. Hinchman, MD, FACC

Submitter : Dr. Colin Lee
Organization : Idaho Cardiology Associates
Category : Physician

Date: 08/18/2006

Issue Areas/Comments

Practice Expense

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CMS-1512-PN-1875-Attach-1.DOC

ATTACHMENT TO #1875

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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.

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***

<i>Direct Cost Category</i>	<i>Included In RUC-Determined Estimate</i>	<i>Excluded From RUC-Determined Estimate</i>
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Medical Supplies	<ul style="list-style-type: none"> • Supplies Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Supplies Used For Less Than 51% of Patients
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All Direct Costs for Cardiac Catheterization	<ul style="list-style-type: none"> • Approximately 55% of the direct costs are included in the RUC estimate 	<ul style="list-style-type: none"> • 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. Mindy Marks
Organization : Idaho Cardiology Associates
Category : Physician

Date: 08/18/2006

Issue Areas/Comments

Practice Expense

Practice Expense

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

CMS-1512-PN-1876-Attach-1.DOC

ATTACHMENT TO # 1876

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. Mark Parent
Organization : Idaho Cardiology Associates
Category : Physician

Date: 08/18/2006

Issue Areas/Comments

Practice Expense

Practice Expense

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

CMS-1512-PN-1877-Attach-1.DOC

ATTACHMENT TO # 1877

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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Submitter : Dr. Walt Seale
Organization : Idaho Cardiology Associates
Category : Physician

Date: 08/18/2006

Issue Areas/Comments

Practice Expense

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

CMS-1512-PN-1878-Attach-1.DOC

ATTACHMENT TO #1878

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
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Mail Stop C4-26-05
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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***

<i>Direct Cost Category</i>	<i>Included In RUC-Determined Estimate</i>	<i>Excluded From RUC-Determined Estimate</i>
Clinical Labor	<ul style="list-style-type: none"> • Direct Patient Care For Activities Defined by RUC • Allocation of Staff Defined by RUC Protocol (1:4 Ratio of RN to Patients in Recovery) 	<ul style="list-style-type: none"> • Direct Patient Care For Activities Not Defined by RUC • Actual Staff Allocation Based on Patient Needs
Medical Supplies	<ul style="list-style-type: none"> • Supplies Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Supplies Used For Less Than 51% of Patients
Medical Equipment	<ul style="list-style-type: none"> • Equipment Used For More Than 51% of Patients 	<ul style="list-style-type: none"> • Equipment Used For Less Than 51% of Patients
All Direct Costs for Cardiac Catheterization	<ul style="list-style-type: none"> • Approximately 55% of the direct costs are included in the RUC estimate 	<ul style="list-style-type: none"> • 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. Karl Undesser
Organization : Idaho Cardiology Associates
Category : Physician

Date: 08/18/2006

Issue Areas/Comments

Practice Expense

Practice Expense

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

CMS-1512-PN-1879-Attach-1.DOC

ATTACHMENT TO # 1879

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.

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Solutions

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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 : Mr. Jack Cumming

Date: 08/18/2006

Organization : Hologic, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1512-PN-1880-Attach-1.DOC

HOLOGIC®

August 17, 2006

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1512-PN
P.O. Box 8014
Baltimore, MD 21244-8014

Re: CMS-1512-PN; Comments Regarding the Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology

Comments on CPT Codes 76075 (Dual energy X-ray Absorptiometry), 76077 (Vertebral Fracture Assessment), 76082 (Computer Aided Detection, Diagnostic), 76083 (Computer Aided Detection, Screening) and 76095 (Stereotactic Guidance)

Dear Dr. McClellan:

Summary

Osteoporosis and breast cancer are two of the nation's most prevalent diseases with risk factors associated with increasing age; however, the effects of both can be minimized through early detection and treatment. Enormous public efforts have gone into raising awareness of the availability of effective screening tools for these diseases, yet utilization remains substandard, especially for osteoporosis. In addition, the emergence of minimally invasive breast biopsy technologies offer women who need to undergo this procedure a safer and less traumatic alternative to open surgical biopsy (OSB); however, the number of unnecessary OSB procedures performed each year remains alarmingly high. The steep reimbursement cuts proposed for the above-listed procedures will have the effect of limiting access to high-quality preventive and diagnostic procedures, increasing morbidity and mortality for Medicare beneficiaries, and driving up healthcare costs associated with more costly treatments due to later diagnoses. In view of these factors, we request that CMS review the special resource considerations associated with the provision of these services and, at the least, make no changes to the current reimbursement rates for these procedures.

Introduction

Hologic, Inc. is pleased to submit comments on the Medicare Program Five Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology issued by the Centers for Medicare and Medicaid Services (CMS)¹. Hologic, Inc. is a leading developer and manufacturer of premium diagnostic and medical imaging systems dedicated to serving the healthcare needs of women. Our core business units are focused on osteoporosis assessment, mammography

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decreased from 31,656,490 to 26,354,871, at the same time, the number of 99213 office visits has increased from 83,527,221 to 112,649,520 and the number of 99214 office visits has increased from 30,561,026 to 55,837,512. These changes have cost the Medicare program more than \$3 billion. In total, there has been an 85 percent increase in allowed charges for 99213 alone between 1997 and 2004. In 2003, E/M services accounted for more than 30 percent of the growth in Medicare physician spending. This has been a concern expressed by the Agency in all of its reports, yet the Agency has ignored this in its decision to increase even further the work RVUs for these codes despite this clear and unprecedented shift to longer and more intense office visits

While we agree the demographics of Medicare patients are changing and the average beneficiary is older with more co-morbidities, this trend is not unique to E/M services. When these same patients have surgery, their increased co-morbidities and risk factors do not disappear. The characteristics that justify a 37 percent increase 99213 can be used to argue for a 37 percent increase to many procedural codes on the Medicare Fee Schedule. We do not believe the Medicare program can sustain such an increase, no matter how justified, and do not believe it is equitable to grant an increase to one code based on factors that apply to all specialties when that increase cannot be applied across the board. While it is correct that the E/M increases were applied to global surgical services, for many codes, the total work RVU was not calculated using the full value for E/M services, so adding only a differential means that these codes are still not "whole." Additionally, in many instances the actual pre-, intra-, and immediate post-services are also made more difficult by a patient's advanced age or co-morbidity, yet there was no consideration for the work in these time periods.

We are concerned that the true cost of the E/M increases will be much more than CMS' current \$4 billion estimate as more and more physicians bill code 99213 or 99214 instead of a lower level code. We note that the difference in these codes is often only the number of organ systems examined, something that is in the control of the physician, and which the physicians today are trained to pay attention to in correct coding. We already are concerned about the unexplainable increase in billing of code 99213 instead of lower level codes and fear this trend will increase exponentially with the 37 percent increase in this code.

Discussion of Comments – Cardiothoracic Surgery

We have concerns regarding the rejection of the RUC recommended work RVUs for the cardiothoracic codes. The RUC (which represents all of medicine) and the Society of Thoracic Surgeons (STS) worked diligently over several years of discussion to ensure these codes were placed in the correct relative rank order. The ASCRS joins all of medicine in being concerned that the recommendations put forward by CMS in the proposed rule destroy this work relativity and leave these codes in a state of disarray. For example, a three-vein CABG procedure is now valued higher than a four-vein CABG procedure. In addition, there are now many codes with higher values than a heart transplant, clearly the most difficult and work intensive of the cardiothoracic procedures.

We are also disappointed by CMS' comments regarding the STS Database. As we indicated in

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our General Comments above, we feel this information is invaluable, accurate, objective and should be considered the gold standard. While there will always be a certain amount of estimation and opinion, especially when attempting to determine intensity, we feel audited actual time measurements should be used whenever possible. We emphasize that many of the concerns raised by CMS in the proposed rule were vetted during the RUC Research Subcommittee meetings in February and April of 2005 and again at the Workgroup meeting in August 2005 and again at the RUC meetings in October 2005 and February 2006, with CMS in attendance at all of these meetings. Additionally, we do not understand CMS' concerns over representativeness of this data. The STS database includes over 3 million patient records, with more than 70 percent of hospitals reporting. How this can even be compared to a survey of 30 surgeons *willing* to complete a RUC survey instrument. Further, it is important to acknowledge that no data collection since the inception of the MFS, including the Harvard study, ever required that the geographic and practice distribution of data (by survey or database) match the geographic and practice distribution of procedures on a code-by-code basis. Clearly, the average (or median) of millions of cases will approach a national distribution better than the median of 30 survey volunteers.

We also agree with the RUC that the mean times are appropriate in this instance. While the RUC normally uses median times, this is because there is such little data to work with that the median is considered a statistically more reasonable "estimate" in those instances. This is not the case for data derived from the STS database, with millions of records. When a significant number of actual measurements are being used and not estimations, such as the case with the STS database, we believe mean times are appropriate, and we note that the RUC (and all of medicine) was in agreement with this. On the other hand, in determining which figures to use when analyzing NSQIP data, the RUC believed that the median times were more appropriate because the volume per code is much less than the STS database. Had NSQIP had the same percentage volume of cases, the mean data would have been more reflective of the true median. Statistically, this can be demonstrated. Statistically, this is why the RUC correctly uses the median for 30 surveys and Harvard used the geometric mean of 5-200 surveys. When the number of records approaches the level of the STS database, it was significantly clear to the RUC that the statistic that is most appropriate is the true mean (and not the median or the geometric mean). Also significantly, it should be noted that for procedures tracked by the STS database that have low volume, in particular several of the general thoracic codes, the median times were used for work RVU recommendations. While the RUC and STS attempted to review codes statistically (mean or median), CMS has chosen to not consider that statistics is a science with many variables that require unique consideration.

Regarding the Agency's discussion of intensity, we do not agree with the intensity values recommended by CMS for the cardiothoracic codes. The RUC spent considerable time over the past five years reviewing various methods for determining intraservice work per unit of time (IWPUT) and the methods used by STS were approved by the RUC after thorough vetting. First, STS utilized a magnitude estimation survey of more than 19 percent of practicing cardiothoracic surgeons. This method was approved by the RUC, with CMS in attendance; the surveys and instructions were reviewed by the RUC, with CMS in attendance; the reference codes utilized were RUC reviewed, with CMS in attendance; and CMS has accepted this methodology in the

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past as a reliable method for developing IWPUs (eg, neurosurgery and vascular surgery). In addition, a 32-member expert panel (with RUC oversight) was utilized to review the results code-by-code to ensure proper rank order of total work (ie, magnitude estimation) – and not work RVUs. Finally, the Rasch survey method was utilized to validate the survey results. This method has been used to validate work magnitude and intensity in the past. In its final recommendation, the RUC used the average of the IWPUs generated from a magnitude estimation survey and Rasch methods, recognizing that they were maintaining a relativity between procedures, as determined by the “experts” using two valid approaches.

In rejecting the RUC’s recommendations, CMS stated it believes the IWPUs created in the second five-year review are more accurate and should be used. We note that STS did use the IWPUs from the second five year review as anchors for the IWPuT magnitude estimation and Rasch surveys, and, we believe that CMS did not use the correct IWPuT numbers in the proposed rule because we cannot replicate CMS’ math.

Again, we urge CMS to review all of the information provided by STS and the RUC regarding the cardiothoracic codes and reconsider the RUC recommendations as most correct to set these codes relatively and accurately within the Medicare fee schedule.

Discussion Of Comments – General, Colorectal And Vascular Surgery

CPT Codes 44120 and 44130

For CPT codes 44120 and 44130, CMS expressed concerns with the RUC methodology to use the NSQIP data to increase the work RVUs above the median from the survey. In disagreeing, CMS is proposing to use the median survey values of 18.00 and 20.00 as the work RVUs for CPT codes 44120 and 44130, respectively.

First , we note that the abbreviated RUC rationale to CMS did not completely capture all of the discussion that occurred at the RUC for these two codes, which included comparison to the survey reference services and to other codes. We ask CMS to review all of the Agenda materials for these codes. Further, when the RUC does not believe that the survey median is the correct value (either too high or too low) for a code, a new value is facilitated – but only after considerable discussion. CMS has also used a facilitative approach in developing alternative proposed work RVUs.

Second, we note that the work RVUs cited by CMS as median survey work RVUs are incorrect because of a data transcription error from the official RUC Summary Forms to an Excel table. The RUC Summary of Recommendation forms presented the following correct survey work RVU statistics:

CPT	Min	25th	Median	75th	Max
44120	16.00	17.51	20.00	21.00	30.00
44130	16.00	18.00	19.00	21.00	35.00

Unfortunately, in facilitating new values, the RUC was using the data summary table that

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transposed the survey median work RVUs between 44120 and 44130 (the time and visit data on the summary table was correct for each code).

The table below presents the RUC facilitated time and visit data for 44120 and 44130, along with data for three references. We believe that 44120 is more total work than 44130. The 2006 work RVUs show this, our survey median data (above) shows this, and our recommendation to the RUC shows this. However, through the process of facilitation and a transcription error, the RUC recommendations and math inadvertently reversed this rank order. Further, CMS cited incorrect Excel table data instead of Summary Form data and also reversed the rank order for 44120 and 44130.

A CPT	B TOTAL TIME	C LOS	D PRE	E INTRA	F IM- POST	G VISITS 992-						H 2006 WORK RVU	I SPEC REC RVW	J RUC REC RVW	K CMS RVW
						33	32	31	38	13	12				
						44120	497	8	60	134	30				
44130	484	8	60	131	30	1	1	5	1	2	1	14.47	21.27	20.87	20.00
44140	462	7	60	150	30		1	5	1	2	1	20.97	REF	REF	20.97
43631	507	8	75	150	30		2	5	1	2	1	22.56	REF	REF	22.56
44626	524	8	60	150	30	2	3	2	1	1	1	25.32	REF	REF	25.32

In looking at columns B and K in the table above, and considering the data presented in columns C through G, it is clear that a rank order would be created by using the CMS proposed work RVUs for 44120 and 44130.

For codes 44120 Enterectomy, resection of small intestine; single resection and anastomosis and 44130 Enteroenterostomy, anastomosis of intestine, with or without cutaneous enterostomy (separate procedure), 44626 Closure of enterostomy, large or small intestine; with resection and colorectal anastomosis (eg, closure of Hartmann type procedure) (work RVU = 25.32) was cited as a key reference code. For all three operations, there are similarities in the actual conduct of surgery, such as an intestinal anastomosis. However, CPT 44626 is a complex and difficult pelvic operation with challenges that exceed 44120 and 44130. A second reference code discussed was 43631 Gastrectomy, partial, distal; with gastroduodenostomy. Codes 44120, 44130 and 43631 refer to patients who have urgent and emergent needs for surgery. Intra-operatively, the procedures focus on foregut and midgut surgery. Codes 44120 and 44130 typically involve extremely compromised bowel, reactive ascites and patients potentially suffering from bacterial translocation. This is a significant distinction of 44120 and 44130 compared with the gastrectomy. Pre-service and immediate post-service work is very similar for all patients. The LOS is the same for all three codes, however, 44120 and 44130 would require higher level of hospital visits because of issues related to the insult from the underlying intestinal conditions, fluid management, a higher risk of wound problems and the risk of fistula formation. The RUC also considered code 44140 (work RVU = 20.97) as a reference for rank order purposes only, because this code was also under review.

After discussion of all reference codes, the RUC agreed that the survey median work RVUs underestimated total work compared with several other reference codes that are significant anchors for other families of codes. The RUC agreed that the survey median work RVUs would

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create rank order anomalies. The RUC facilitated a recommendation for 44120 that was 1.11 work RVUs greater than the survey median to account for additional time and visit data compared to references. For 44130, the RUC facilitated a recommendation that was 0.87 work RVUs greater than the survey median to account for additional time and visit data compared to references. These facilitated additional work RVUs however were added to the incorrect work RVUs on the data summary table prior to submission to CMS. If added to the correct survey medians, the resulting facilitated work RVUs would be 21.11 for 44120 (20.00 + 1.11) and 19.87 for 44130 (19.00 + 0.87), as shown in column K below. The ranking between the codes is consistent with 2006 work RVUs and the ranking of the specialty recommended RVUs. Code 44120 is clearly more work than 44130 and 44140, similar to 43631, and less than 44626, as discussed above.

A CPT	B TOTAL TIME	C LOS	D PRE	E INTR A	F IM- POST	G VISITS 992-						H 2006 WOR K RVU	I SPEC REC RVW	J CMS RVW	K corrected RVW
						33	32	31	13	12					
						44130	484	8	60	131	30				
44120	497	8	60	134	30	2	2	3	18.00	1	1	16.97	23.43	18.00	21.11
43631	507	8	75	150	30		2	5	22.56	2	1	22.56	REF	REF	22.56
44626	524	8	60	150	30	2	3	2	25.32	1	1	25.32	REF	REF	25.32

We request that CMS accept the incremental adjustments facilitated by the RUC for each code – added to the correct survey medians - and recommend that CMS accept 21.11 for 44120 and 19.87 for 44130. These values result in an IWPUT of 0.074 for 44120 and 0.071 for 44130 which is also a correct ranking for these two procedures.

CPT Codes 45300-45327 and 46600-46615

For the proctoscopy-anoscopy families of codes 45300-45327 and 46600-46615, CMS is proposing to maintain the current work RVUs because the method used by the RUC to obtain work RVUs for these services was flawed. CMS indicates that the calculation of the recommended work RVUs depended solely on applying a workgroup-derived IWPUT to the surveyed physician time from surveys that were considered otherwise unusable and that the RUC has established rules that state that IWPUT cannot be the sole rationale for valuation. Further, as an example of a better methodology, CMS indicates that there were acceptable surveys that were used as anchors to create the correct rank order for dermatology codes without adequate surveys and if the specialty society wishes to resurvey these codes and the RUC submits work RVU recommendations to CMS, CMS would be willing to consider them.

We thank CMS for this opportunity to represent our survey data as requested and will submit a request to the RUC for reconsideration of survey data, on a code by code basis, using references and rationales to support recommendations based on a standard RUC survey and review methodology. We also will consider CMS' suggestion to use the data from the anchor codes that have a higher frequency to assist with development of recommendations for the less frequently performed endoscopies.

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OTHER ISSUES

Postoperative Visits Included in Global Surgical Packages

In the Proposed Rule, CMS indicated that it would apply the RUC-recommended new values for the E/M services to all surgical services with a 010- or 090-day global period. The intention of the RUC recommendation was that the full increase of the E/M would be incorporated into the surgical global periods for each CPT code with a global of 010 and 090. Further, the RUC indicated that E/M work is equivalent and a crosswalk of 100% of the E/M valuation should be bundled into the codes with global periods of 010 and 090 days, with appropriate documentation.

In the Proposed Rule, it appears that only the current incremental increases in proposed E/M services has been added to 010- and 090-day global services, and that the previous discounted incremental difference from the first 5-Year-Review, were not reinstated. We fully agree with the intention of the RUC and request that CMS add in the previously discounted work RVUs for all 010- and 090-day global services.

Budget Neutrality

We disagree with CMS's decision to utilize a separate work adjuster for the work RVUs. We believe that this additional calculation is cumbersome for billing purposes. We note that CMS has previously tried this methodology after the first five year review but abandoned it after two years because "...It added an extra element to the physician fee schedule payment calculation and created confusion and questions among the public who had difficulty using the RVUs to determine a payment amount that matched the amount actually paid by Medicare." Additionally, after the second five year review, CMS adjusted the conversion factor to adjust for changes in physician work. In the proposed rule, CMS states it is implementing the work adjuster as opposed to a conversion factor reduction because it believes it is more equitable to make the reduction to the portion of the physician payment formula that was directly involved in the five-year review. However, we note that the work RVUs are also used to determine the practice expense RVUs and it appears CMS has proposed to use the adjusted work RVUs to determine the indirect practice expenses. This in essence allows CMS to cut physicians twice – once by reducing the work RVUs and again when determining the indirect practice expenses. So this adjuster is NOT only applicable to the work RVUs.

Additionally, while we understand CMS' desire to protect the codes that do not contain work RVUs, the majority of these codes are technical radiology codes. Many of these codes will be reduced as a result of the Deficit Reduction Act of 2006. If the five-year review budget neutrality adjustment is made to the conversion factor, these codes will be reduced accordingly prior to their additional DRA-related cuts. The reductions relating to the budget neutrality cut will be kept in the Medicare physician payment system while the cuts relating to DRA will not. Either way, many of these codes will see drastic cuts on January 1, 2007. Given the current state of the Medicare physician payment system, we advocate maintaining as much money in the system as possible and believe this is the correct approach given that the five-year review is suppose to be a redistribution of money within the system and not a method for cutting total Part

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B. It appears the Agency is cutting payment to providers to add un-funded benefits. For this third five year review, we suggest that CMS apply budget neutrality adjustments to the conversion factor.

Use of Supplemental Survey Data

We have concerns regarding CMS' acceptance of supplemental survey data. We do not understand how surveys originally rejected and marked as unacceptable are now considered acceptable even though the surveys have not been redone or modified in anyway. We do not see how a survey deemed unacceptable can be used. For example, CMS originally expressed concerns regarding a survey conducted by the American Society for Therapeutic and Radiation Oncology (ASTRO) and stated the survey did not meet the agency's criteria. However, in the current proposed rule, CMS has accepted the survey data and proposes to blend it with a survey from another society. We do not believe blending a survey with another one corrects the initial concerns with the original survey, but instead just dilutes the questionable data. In addition, we have concerns about the survey submitted by the National Coalition of Quality Diagnostic Imaging Services (NSQDIS). We do not believe deleting records from the data set in order to obtain an acceptable precision range is an accepted statistical principle.

We also question the validity of all of the supplemental surveys given the fantastic increases many specialties claim have occurred in just a five year period. We do not believe values over \$200 per hour are credible. Either most or all specialties would have this same increase or these surveys are not comparable to the SMS survey data that was collected. (as CMS originally indicated).

First, we note that the accounting method for writing off capital equipment is key in calculating the "cost" of the equipment. CMS itself just changed the life expectancy for many pieces of equipment recently. It may be that specialties are now "accounting" for it differently. Second, we note that labor is the most significant component of practice expense and every practice has seen this same labor cost increase. We believe this data either seriously brings into question the validity of the original survey data, or brings into question the credibility of the supplemental surveys.

In either event, we do not believe it is plausible to use supplemental survey data for some specialties and use original data for others adjusted for inflation because we believe the numbers themselves show the two data surveys are not comparing apples to apples. If the supplemental surveys are correct, then costs have outpaced inflation and this would apply to all specialties, so adding only an inflation adjuster to some specialties is unfair.

There has been no investigation regarding the funding, validity, or reproducibility of these data, so we find it extremely interesting that CMS has chosen to use supplemental survey data that CMS itself has questioned for practice expense purposes, while in the same Rule CMS indicates that the NSQIP, STS, and CMS DRG databases are unacceptable, even though the former are society and possibly company financed and driven and the later are CMS and/or national audited databases. Again, how can the original data be almost 200 percent underestimated, unless this is

and breast biopsy. Hologic develops technologically superior imaging systems to facilitate the detection and diagnosis of breast cancer and osteoporosis. We consistently invest millions of dollars annually toward research and development of better technologies for earlier and more accurate detection of these diseases. We are proud of the work we do every day to preserve and extend the lives of countless women throughout the world.

As a technology company whose mission is to provide equipment to aid in the detection of disease, we monitor very closely any Medicare policy or payment changes for essential screening services under the Medicare Physician Fee Schedule (MPFS). Major decreases or year-to-year fluctuations in payments for screening services could negatively impact the availability of services for women who benefit from our products. This letter and its comments are directed toward major decreases occurring under the proposed relative value units in the CPT Codes listed above. We believe implementation of these dramatic cuts would impede access to critical screening and diagnostic services and would result in detrimental effects on the quality of life for Medicare beneficiaries, as well as impose significant and unnecessary additional costs on the nation's healthcare system.

Screening Trends and Issues

Osteoporosis and breast cancer are two of the nation's most prevalent diseases with risk factors associated with increasing age. Fortunately, advances in screening technologies and treatments now make it possible to mitigate the catastrophic effects of both when the diseases are detected early. Congress recognized the promise these screening technologies could bring to Medicare beneficiaries and created specific benefit categories to provide the services. However, this promise cannot be achieved unless access is assured. It is vitally important that government decision makers ensure that Medicare beneficiaries maintain access to potentially life-saving, high-quality screening services for these serious diseases.

Osteoporosis Assessment

Currently, 10 million Americans over the age of 50 have osteoporosis and an additional 34 million are at risk for developing the disease². Left unchecked, by the year 2020 more than 14 million individuals over the age of 50 will have osteoporosis and 47 million will have low bone mass². More than 1.5 million osteoporosis-related fractures require treatment each year, at a cost of \$12 - \$17 billion, measured in 2002 dollars². Sadly, more than 60,000 deaths/year are attributed to osteoporosis-related fractures, most occurring within the 12-month period following the injury. Until the last 10-15 years, osteoporosis was thought to be an inevitable process of aging; however, with the development of high-quality screening technologies to detect the disease, and effective drug therapies to stop or reverse the effects of bone loss, this is no longer true. Dual energy x-ray absorptiometry (DXA) is the only screening technology recognized by professional organizations for the diagnosis of osteoporosis. Vertebral fracture assessment (VFA) combined with DXA has the potential to identify future fracture risk and permit more effective and earlier pharmacological intervention.

Despite the known benefits, screening for bone density is vastly underutilized by patients and under-recognized by healthcare providers. Screening utilization rates remain under 25% of the eligible population, despite efforts to make screening equipment more widely available in primary care practices³. In addition, there are many studies documenting the failure to identify and treat individuals at high risk for fractures or other disorders of bone, even those who have already sustained a previous fracture (Andrade et al. 2003, Feldstein et al. 2003, Solomon et al. 2003, Kiebzak et al. 2002, Kamel et al. 2000). In a recent study of four well-established Midwestern health systems, only one-eighth to a quarter of patients who had a hip fracture were tested for their bone density, fewer than a quarter were given calcium and vitamin D supplements, and fewer than one-tenth were treated with effective antiresorptive drugs (Harrington et al. 2002).

Decreasing reimbursement of the technical component of DXA by 71% and VFA by 37% will make it financially infeasible for physicians to purchase the equipment and pay the personnel necessary to perform these tests. Utilization would decline from the already unacceptably low level of less than 25%, with resultant increases in patient morbidity and mortality and increased costs to the healthcare system for treatment of fragility fractures.

Breast Cancer Detection

The National Cancer Institute reports that one in eight women in the United States will develop breast cancer in her lifetime. In fact, breast cancer is the second-most common type of cancer among U.S. women. The risk of developing breast cancer increases with age and the risk is particularly high in women over the age of 60. However, when detected early, the chance for a successful cure is nearly 100%. Early detection also makes it feasible to use less aggressive and less traumatic forms of treatment and still achieve good clinical outcomes.

One of the newest and most successful technologies to enable earlier detection of breast cancers is computer aided detection (CAD). When used as an adjunct to screening and diagnostic mammography, CAD has been shown to increase the detection rate of breast cancers by 20% or more⁴. CAD is especially effective in lower volume sites, such as rural facilities, where the radiologists are less experienced because they read fewer mammograms on an annual basis. CAD has become the standard of care in most practices and is considered essential for the delivery of the highest quality service to patients.

The delivery of high quality mammography screening services is dependent on the availability of mammography clinics and qualified radiologists and technologists to operate them; however, according to the Institute of Medicine (IOM), there is a deepening shortage of both in the U.S⁵. More than one-third (36%) of women over 65 did not receive mammograms in 2002, and minority women and those who live in underserved areas have even lower screening rates⁵. In 1999, following enactment of the Mammography Quality Standards Act, there were 9,998 certified mammography facilities in the US. Today, only 8,881 such facilities are in existence⁶, although the number of women eligible for mammograms increased by 15% from 1998 to 2000, and is

projected to increase by approximately 1 million each year through 2050⁷. Reasons cited in the IOM report for the declining number of facilities include low payment rates from Medicare and a poor financial outlook that discourages new physicians from specializing in radiology.

The U.S. General Accounting Office (GAO) recently substantiated this claim, stating that despite an adequate nationwide capacity to provide screening mammography services, there is serious concern that the decrease in the numbers of radiologic technologists and radiologists entering the specialty will hinder access to screening services, particularly in traditionally underserved areas⁸. The GAO reports that in addition to a decreasing number of providers, “the loss or absence of mammography machines in certain locations may have resulted in access problems, consisting of lengthy travel distances of considerable wait times, including problems for women who are medically underserved⁸.” The projected reimbursement cut of 54% for the technical component for CAD will only exacerbate this disturbing trend.

Breast Biopsy

Breast biopsy remains the only definitive method for determining whether an area of abnormality detected during a screening exam is cancerous. In recent years technical advances have made it possible to perform breast biopsies on the majority of patients using minimally invasive techniques, such as stereotactically or ultrasound guided imaging. Despite these advances, more than 650,000 open surgical breast biopsies are still performed annually. Additional efforts are needed to reduce the number of unnecessary open surgical biopsies and ensure minimally invasive techniques are available to all women. A decrease of 81% in the technical component for stereotactic guidance would have the opposite effect, as many facilities will no longer be able to provide this service and women will be forced to undergo open surgical procedures, with resultant increases in morbidity to the patient and costs to the healthcare system.

Policy and Technical Comments on the CMS Notice

Hologic respects the importance and necessity of implementing sound fiscal healthcare policies. With healthcare budgets under continuous pressure, cost-effective treatment is paramount to payers, providers and patients. Indeed, we take pride in the fact that our products provide high-quality, cost-effective, and clinically-proven screening services to America’s women. Ultimately, the ability of health care providers to continue to deliver high quality screening and detection services relies greatly upon the payment received from the Medicare program.

It is imperative that reimbursement for these vital screening tests remain adequate to allow providers to render the services. When significant reimbursement cuts are made to bone mass measurement, mammography, and breast biopsy services, providers will be unable to purchase the necessary equipment or provide services that show little or no cost recovery. If the steep decreases noted earlier are implemented as proposed in the final MPFS rule, access to crucial screening services for women could be severely impacted,

ultimately driving up health care costs and endangering the lives of millions. In response to these proposed cuts, Hologic looked into different methodologies to help us better understand the severe cuts these services received and to explore alternatives for CMS to consider.

Budget Neutrality Adjustment (BN)

Hologic understands and respects the necessity for applying budget neutrality in an effort to control health care costs across all MPFS codes. However, applying budget neutrality to Medicare screening benefits contradicts the intent of Congress, whose goal it is to expand access to these services in an effort to capture 100 percent of the target population. Therefore, Hologic urges CMS to remove the budget neutrality adjuster from all MPFS screening codes. Indeed, the purpose of screening services is not therapeutic or diagnostic, but rather, is preventive -- and preventive services, when applied broadly, ultimately create cost savings. We agree that it is consistent with congressional intent for CMS to apply cost-reduction techniques for Medicare services where appropriate, *but* using a BN adjustment against screening codes is *not* the appropriate place to apply budget neutrality and is not within the bounds of congressional intent.

Allocation of Indirect Costs

Under the proposed methodology, the basis for allocating indirect costs to a procedure is surrounded by much speculation. Currently CMS's policy selects physician work (in addition to direct costs) as an allocator for indirect cost. After reviewing calculations using the CMS Public Use Data Files, we have found there may be alternative allocators for determining a sound formula to determine more appropriate indirect costs, particularly for services that have low or no physician work, such as screening services.

- CMS could utilize a percent of the direct cost as the proxy for indirect cost, which would result in a shift of relative value between these high clinical labor and low physician work types of procedures. We think this would introduce less distortion and excessive bias into values.
- Or, since differences are known in the direct and indirect cost structures among physician specialties, a separate approach could be to further multiply the "adjusted direct costs" by the percent of indirect costs for a procedure which would account for the variation in the split between these costs among specialties.
- The special resource considerations required for screening services could be factored into the MPFS, taking into account the need to promote services that fulfill the unique public policy objectives of early disease detection and treatment associated with statutorily mandated or other high impact screening benefits. Establishment of special resource considerations would help ensure the provision of preventive services across a large patient population to achieve the public policy goal of universal screening.

Hologic is also reviewing the broader proposed rule just published on the Medicare Physician Fee Schedule. We may have further suggestions to offer during that rule's comment period.

Conclusion

In the proposed rule, CMS has paid particular attention to the commendable goal of raising reimbursement rates for codes relevant to patient evaluation and management (E&M) services. Increasing payments for E&M services is intended to improve patient outcomes by rewarding physicians for their cognitive and medical judgment services and for spending time with patients helping them manage their health care. An integral part of helping patients manage their health care should be a focus on preventive medicine and the use of screening studies to enable earlier detection of diseases, when the chance of a successful outcome is greater. To arm physicians with the necessary time to interact with their patients, on one hand, while putting necessary screening tools beyond the reach of many Medicare beneficiaries, on the other hand, is counter-productive to what we believe CMS is trying to accomplish.

We believe it is in the public's best interest to ensure that access to screening services for bone mass measurement, high quality mammography, and minimally invasive breast biopsy technologies remain available and affordable. It is important to appreciate that increased utilization of vital screening tools and services is, indeed, sound public policy, as it has been shown to greatly improve the chances that many catastrophic diseases can be captured at an early and less-costly stage. Endorsing this philosophy not only saves valuable health care dollars, but, more importantly, saves lives and increases the quality of life for our most vulnerable of all patient populations. We encourage CMS to use all means available to ensure that, at the very least, no changes are made to current reimbursement levels for these crucial preventive services.

Hologic trusts that these comments will be useful to CMS as it considers revisions to the practice expense methodology of the MPFS. We look forward to further dialogue on this issue and encourage CMS to contact us promptly with any questions, comments, or requests for additional information.

Sincerely,



Jack Cumming
Chairman and CEO

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