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Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21224-8017

Comments on Kyphoplasty codes for Final Rule

Dear Dr. McClellan:

I wish to offer comments on the work values published in the current Final Rule for the new kyphoplasty codes (22523, 22524 & 22525). I worked with a group of surgeons with extensive experience with these procedures who felt that the work relative values recommended by the AMA RUC in April were undervalued. In September, we met with a team at CMS led by Ken Simon that reviewed those work RVUs and presented what we felt was compelling evidence to support our claim for refinement. Since that meeting, the Final Rule for 2006 has been published and CMS accepted the RUC work RVUs without change as interim values for 2006. I request that these values be reconsidered in light of some comparisons and information that may provide further support to our claim of misvaluation.

Although I do not represent a major specialty society in this appeal, I have had considerable experience in dealing with the valuation of physician services. I served as the Neurosurgery member of the AMA RUC until retirement from that position in 2002, and have subsequently represented a number of specialties and groups in both the CPT process as well as in issues regarding physician reimbursement and relative valuation of work.

An examination of the current work relative values for the kyphoplasty codes compared to those for the vertebroplasty codes, to which they are closely related, will serve to reveal the misvaluations that currently exist in both groups of these codes.

I realize that it is difficult for the agency to change work values assigned to new or revised codes forwarded from the RUC without the support of a major interest specialty group. In this case, some background analysis and examination of the actions by the RUC will offer some insights as to the methods used in reaching their recommended RVUs and provide an alternative justification for change. Since CMS has final responsibility for the fee schedule and it's valuation, I encourage the exercise of that authority to deal with problems of this nature during such comment periods and not wait another five years for possible corrective actions.

History and background of kyphoplasty codes

Problems with the kyphoplasty codes appeared early in the CPT process when those codes were developed and presented for approval. This came down to a debate over whether the kyphoplasty codes warranted a Category I or Category III classification in the CPT, with arguments about the

comparative efficacy of kyphoplasty vs vertebroplasty in treatment of vertebral compression fractures. It appeared that NASS and the Society for Interventional Radiology were opposed to accepting the kyphoplasty codes as Category I and argued that the differences from vertebroplasty were not supported by sufficient peer-reviewed literature. While there was agreement that both procedures were effective in pain control and stabilization, they claimed that reduction of the compression fracture of the vertebra had never been validated as a distinguishing feature from vertebroplasty. Nevertheless, the kyphoplasty codes were approved as Category I and went to the April RUC meeting for valuation.

What did not appear during those debates were some important data on complications from the kyphotic spinal deformity that results from a compression fracture of a thoracic vertebra. The key complication is a predictable loss of approximately 9% of the patient's vital capacity associated with each such kyphotic deformity, with additive effects from additional vertebral body fractures. When this is coupled with the statistic that the risk of another fracture either above or below an existing collapsed vertebral body is increased by about 50%, the additive effects of two or three such kyphotic angulations could easily result in a loss of one fourth of a persons vital capacity. This chain of complications is an important justification for the more extensive efforts applied in treatment of these fractures to fully expand the collapsed vertebral body and reduce the kyphotic deformity as much as the structures will allow. This most often includes insertion of the expansion balloons bilaterally in order to sculpt a central cavity that will respond to the balloon inflation by restoring the vertebral end plates to a more normal pre-fracture position. This reduction is then secured after removal of the balloons by filling the cavity bilaterally with methacrylate which maintains the reduction.

At the RUC, the kyphoplasty codes were referred to a facilitation panel for valuation. A RUC survey of these codes was done with 112 respondents from a variety of specialties interested in the procedure. It is informative to follow the adjustments to the survey data made by the facilitation panel in order to reach a relative value they deemed acceptable within the fee schedule.

RUC facilitation panel changes to kyphoplasty survey data

For thoracic kyphoplasty (22523), the panel noted that the most common code selected by the survey respondents as a key reference was thoracic vertebroplasty (22520), and that it was a good comparison code because of the similar work involved in both procedures. The panel agreed that the kyphoplasty code included slightly more work and was slightly more difficult than the comparable vertebroplasty code. They noted that the median survey work RVW of 13.00 was too high compared to the reference vertebroplasty code and reduced the work value to the 25th percentile value of 10.00. The panel agreed with the survey values for pre-, intra-, and post-service times as well as the single office visit (99213). However, they felt that since 40% of survey respondents reported only a discharge day visit for 22523, they removed 1.06 RVWs that the other 60% of the survey respondents did report for the one hospital visit (99232) from the 10.00 work value. This left 8.94 RVWs to represent the physician work for a thoracic kyphoplasty, and was the value accepted by the RUC and forwarded to CMS. These values provided an IWPUT of 0.084.

For lumbar kyphoplasty (22524), the panel reached similar conclusions as to the relationships for work and intensity to lumbar vertebroplasty (22521). However, they felt that the survey median for work at 12.00 and the 25th percentile of 9.50 were both too high. They agreed with the time and visit data from the survey with a discharge day visit (99238) and one office visit (99213). They then assigned an IWPUT of 0.081 to this code, ranking it at slightly lower than the 0.084 for the thoracic kyphoplasty. This combination produced an work RVW of 8.54.

For the additional level kyphoplasty (22525), the panel believed that the median RVW survey value of 6.00 was too high and reduced it to the 25th percentile survey value of 5.00. They noted the survey included 10 minutes of per-service time and 5 minutes of post-service time. The RVWs for these

times amounted to 0.33 RVWs which were then subtracted from the 5.00 to produce the recommended RVW of 4.67.

A table with calculation of the IWPUTs is appended in Appendix B.

Critique of RUC facilitation panel actions

These actions and changes can be viewed as an effort to support the claim that the work of kyphoplasty codes are almost the same as vertebroplasty codes, and that there are insufficient differences to warrant higher RVWs for the kyphoplasty procedures. When the differences are calculated (see below), it appears the effort was successful, notwithstanding the observation that some of the panel's actions appear misdirected and arbitrary.

For example, the removal of the single hospital visit (99232) from the thoracic kyphoplasty code appears to have been done to bring the IWPUT down from the unacceptably high value of 0.102 to the final IWPUT of 0.084. For the lumbar kyphoplasty (22524), the panel simply applied an estimated IWPUT of 0.081 to the intra-service work to reach a target total RVW of 8.54. Finally, for the add-on kyphoplasty code (22525), the recommended RVW of 4.67, which represents just the intra-service work, when divided by the RUC approved 40 minutes of intra-service time, produces an IWPUT of 0.117. This is clearly excessive and within the range of very complex surgical services.

Comparative Valuation of Work for Kyphoplasty vs. Vertebroplasty

What are the current differences in work RVUs?

The differences in relative values for work (RVW) between the kyphoplasty codes (22523. 22524 & 22525) and their key reference codes for vertebroplasty (22520, 22521 & 22522) do not fairly represent the actual differences in work. These differences are listed as follows:

CPT	Descriptor	Current total RVW	Diff. In RVWs
22523	**Thoracic kyphoplasty**	**8.94**	
22520	*Thoracic vertebroplasty*	*8.91*	**0.03**
22524	**Lumbar kyphoplasty**	**8.54**	
22521	*Lumbar vertebroplasty*	*8.34*	**0.20**
22525	**Each additional kyphoplasty**	**4.67**	
22522	*Ea. Addl vertebroplasty*	*4.31*	**0.36**

The differences expressed in RVWs are so small as to represent only a token amount of additional work for kyphoplasty compared to a vertebroplasty at the same spinal level. The differences do not fit with a number of facts that support a greater work value for kyphoplasty as compared to vertebroplasty.

Does Kyphoplasty involve more physician work than vertebroplasty?

Vertebroplasty work values are important to this argument because the three vertebroplasty codes, valued in 2000, were used as the key references in assigning relative values to the kyphoplasty code. Although both procedures share many of the same elements and steps, from the beginning there has been general agreement that the work of kyphoplasty procedures is greater at each level than the work for vertebroplasty at the same spinal level. The question is just how much is that difference.

- This position was supported at the RUC by an facilitation panel that reviewed the kyphoplasty codes in April, although they qualified their comparison by stating the kyphoplasty codes required only "slightly more work" than the comparable vertebroplasty codes. However, respondents to the RUC survey of the kyphoplasty codes (n=112) provided work estimates that rated all three kyphoplasty codes substantially higher than their reference vertebroplasty codes.

- A more compelling comparison of work for the two groups of vertebral augmentation codes is provided in a tabulation of the steps required for kyphoplasty vs. vertebroplasty. This shows that more time and work is required for a kyphoplasty due to the larger number of discrete steps involved in entering the vertebral body, developing a cavity within that structure, use of an expansion balloon to reduce the compression fracture, and injections of a larger volume of methacrylate to maintain the reduction. In addition, the majority of kyphoplasties are done bilaterally and include a bone biopsy from the vertebral body. Finally, general anesthesia is used in the majority of these patients who are then kept overnight in the hospital before discharge. This comparison is included in Appendix A.

- The time required to instruct physicians in the technique of kyphoplasty is approximately double the time needed for vertebroplasty training due to the larger number of steps to complete the procedure. Use of an expansion balloon inserted into the collapsed vertebral body requires additional time and work since the working channel must be enlarged to accommodate the expansion device and is generally done bilaterally. These steps require repeated insertions and removals of the various instruments and devices during the procedure on each side.

- Further validation of the difference in work is the fact that 51 % of 53 Medicare carriers are paying for kyphoplasty at a locally set rate of 1.5 to 2.0 times the current payment for a vertebroplasty at the same level. This is evidence that the work differential between the two procedures is not trivial.

Why are the current differences in RVW so small?

If the differences in work really are substantial, why are the current differences are so small? Either the kyphoplasty codes are too low, the vertebroplasty codes are too high, or possibly both.

Are vertebroplasty RVWs too high?

If the vertebroplasty codes are overvalued, examination of this possibility will provide a clearer insight to the real differences in time and work between these two groups of codes. The most obvious evidence of overvaluation are the intra-service times for vertebroplasty which exceed the kyphoplasty codes at each level from 25% for the add-on code to 38% for the thoracic kyphoplasty. This does not match the differences in work between the two procedures.

CPT code	Descriptor	RUC intra-svc time in min	Diff in min	Percent diff
22523	**Thoracic kyphoplasty**	**58**		
22520	*Thoracic vertebroplasty*	*80*	***22***	***+38%***
22524	**Lumbar kyphoplasty**	**55**		
22521	*Lumbar vertebroplasty*	*75*	***20***	***+36%***
22525	**Each additional level kyphoplasty**	**40**		
22522	*Each additional level vertebroplasty*	*50*	***10***	***+25%***

Examples of other reference codes and their intra-service times shows that the values for the vertebroplasty codes are also high relative to these other codes.

CPT	Descriptor	RVW	INTRA min
22520	Percutaneous vertebroplasty, one vertebral body, unilateral	8.91	80
22521	Percutaneous vertebroplasty, one vertebral body, unilateral	8.34	75
Reference Codes			
20206	Needle biopsy, muscle	0.99	18
20220	Bone biopsy, needle/trocar	1.27	22
20225	Biopsy, bone, trocar, or needle; deep (eg, vertebral body, femur)	1.87	60
20250	Biopsy, vertebral body, open; thoracic	5.02	100
22851	Replacement of intervertebral disk with synthetic/ substitute	6.70	90
62287	Percutaneous lumbar diskectomy	8.07	60
62290	Lumbar diskography	3.00	35

62287 (*Percutaneous lumbar diskectomy*) was a key reference when the vertebroplasty codes were surveyed in 2000. It has an intra-service time of 60 minutes which is 20 minutes less than the 80 minutes for thoracic vertebroplasty.

Possible explanations for the high times for vertebroplasty:

- In 2000, vertebroplasty was a new procedure and may have required 80 minutes to perform the injections. The experience gained in the subsequent five years probably has resulted in a decrease in the time for the procedure, although it has not been formally measured since 2000. There was a rumor that 22520, which was submitted by CMS for the 5 year review, had been surveyed with an intra-service time of 45 minutes, but that has not been confirmed since the recent RUC workgroup did not present survey data on 22520. Consequently, the original time and visit data for the vertebroplasty codes remain officially unchanged.

- Some parts of the vertebroplasty procedure have changed, with a shift away from target localization using CT imaging to use of biplane fluoroscopy, thereby shortening the time.

- Physicians who do vertebroplasties with some frequency have reported current times of 35-50 minutes for the intra-service part of the procedure. Our efforts to collect survey data on such times has failed, possibly due to burn-out by survey candidates who have just gone through the barrage of surveys associated with the current 5 year review.

What are reasonable estimates of intra-service time for vertebroplasties?

In the following model, we have assigned a new intra-service time for each vertebroplasty code based on the above estimates. This does not represent an effort to change the current time and work values of vertebroplasty. It is offered merely as a model for relative comparison of the time and work of the vertebroplasty codes to their matching level kyphoplasty codes using approximations of what we believe are more reasonable current intra-service times.

If we assume that the intra-service time of 22520 Thoracic Vertebroplasty is currently 45 minutes, we can extrapolate the times for 22521 Lumbar Vertebroplasty as 43 minutes and for the add-on vertebroplasty 22522 as 44 minutes. This maintains the rank order across these codes for time. Then, if we use these revised intra-service times, we can calculate each new RVW by using the new intra-service time and the existing IWPUT plus the pre/post RVWs. These new calculated RVWs from the new intra-service times produces RVWs that are substantially less than the current Medicare total RVWs for the vertebroplasty codes.

CPT code	Brief description	RUC intra-svc time	New est. intra- svc time	Calc. New RVW using New time
22523	**Thoracic kyphoplasty**	**58**		
22520	*Thoracic vertebroplasty*	*80*	*45*	*6.74*
22524	**Lumbar kyphoplasty**	**55**		
22521	*Lumbar vertebroplasty*	*75*	*43*	*6.46*
22525	**Each additional level kyphoplasty**	**40**		
22522	*Each additional level vertebroplasty*	*50*	*44*	*3.08*

If we assume that these new calculated RVWs for vertebroplasty more closely reflect current practice and Medicare pricing for vertebroplasty, then we can apply them in a comparison to the refined kyphoplasty codes. This comparison follows the discussion of our rationale for changing the kyphoplasty work values in the next section.

Valuation of Physician Work for Kyphoplasty

Methodology

We examined the kyphoplasty codes using a building block methodology (BBM) in order to compare the time, visit, and intensity values provided to the data for key reference and other related codes in each phase of physician work. This allowed a more detailed comparison of the relative amounts of time and intensity for each phase of the procedure to others with whom it shares components of the service. By making small adjustments to the time, intensity and visit data, rank order anomalies within each phase of a procedure can be identified and corrected.

Pre-service work

The pre-service times from the surveys for the thoracic and lumbar kyphoplasty codes were accepted by the RUC as reasonable and we agree with that assessment. The value for pre-service work for the thoracic and lumbar kyphoplasty codes is 1.17 RVW. There is no pre-service work attributed to the add-on code (22525) since it is only valued for the intra-service phase of service.

Intra-service work

This represents the work done during the skin-to-skin phase of the procedure and is measured as the product of the time X intensity during that period. Intensity is a variable that represents the rate of work provided during that time, and is expressed as the intra-service work per unit time (IWPUT). The units of measure are RVWs per minute.

The RUC survey for the kyphoplasty codes used responses from 112 physicians. The survey medians for all three codes were judged to be too high by the facilitation committee. These values were reduced to the 25th percentile, as has been the custom at the RUC when the survey medians appear to be poised to adversely affect the rank order compared to related codes in the fee schedule. The survey values are:

CPT	Descriptor	RUC svy median RVW	Survey 25th percentile
22523	**Thoracic kyphoplasty**	**13.00**	**10.00**
22524	**Lumbar kyphoplasty**	**12.00**	**9.50**
22525	**Each additional kyphoplasty**	**6.00**	**5.00**

Intra-service times

We agree with the RUC that the time of 58 minutes for a thoracic kyphoplasty and 55 minutes for a lumbar kyphoplasty are both reasonable. Both times are the RUC intra-service survey medians.

CPT code	Descriptor	RUC Rec. intra-svc min	New rec intra-svc min
22523	Thoracic kyphoplasty	58	58
22524	Lumbar kyphoplasty	55	55
22525	Each additional level kyphoplasty	40	**56**

However, the RUC survey estimate of time for the add-on kyphoplasty code at 40 minutes is too low. This time should be equivalent to the intra-service time required to do the initial kyphoplasty at either the thoracic or lumbar level. Since the intra-service time for the two primary codes is 58 and 55 minutes, **we believe that a time of 56 minutes for the add-on code represents a fair compromise between the times for the parent codes, and recommend this change.**

Intra-service intensity (IWPUT)

The RUC survey reported intra-service intensity for each phase of complexity and eight components of intensity for all three kyphoplasty codes. The same information was reported for each vertebroplasty code by the same respondents, since the vertebroplasty codes were used as key reference services in the RUC survey. This allows a direct comparison of the intensity of each component of intensity for kyphoplasty to the same respondents' estimates of the intensity for the vertebroplasty reference codes.

	Complexity			Intensity							
Kypho & Vertebr Codes	Pre service	Intra service	Post service	# of Dxs &/or # mgmt options	Amt & complxt y of clin data	Urgency of possible decisions	Tech skill	Physi cal effort	Risk of signf complicats, morbidity, mortality	Outcome depends on skill & judgment	Risk of suit w poor outcome
22523	3.04	3.72	2.08	3.04	3.15	2.51	3.87	3.02	3.45	3.77	3.64
22520	*2.83*	*3.02*	*2.00*	*2.91*	*3.00*	*2.43*	*3.23*	*2.64*	*3.21*	*3.47*	*3.57*
22524	3.08	3.5	2.06	3.06	3.26	2.6	3.76	3.00	3.32	3.88	3.64
22521	*2.92*	*2.98*	*2.00*	*2.98*	*3.16*	*2.56*	*3.26*	*2.72*	*3.18*	*3.58*	*3.58*
22525	2.83	3.56	2.13	2.95	2.87	2.45	3.78	2.89	3.47	3.72	3.46
22522	*2.69*	*3.04*	*2.17*	*2.89*	*2.84*	*2.45*	*3.24*	*2.6*	*3.33*	*3.46*	*3.37*

In each instance, the responses for the kyphoplasty codes are greater than those for the vertebroplasty codes. This is clear evidence that the IWPUT for each kyphoplasty code exceeds the IWPUT for a comparable vertebroplasty code.

What are the IWPUTs used for the current RUC recommended RVWs?

IWPUTs for each kyphoplasty code were calculated at the RUC based on the survey values that were adjusted by the facilitation panel. They are listed below. The survey intra-service times, which were not changed by the RUC, are included. Note the effect of using the new intra-service time recommended for the add-on kyphoplasty code of 56 minutes which corrects the excessively high IWPUT for 22525 of 0.117.

CPT code	Brief description	RUC Rec. work RVU 4/05	Intra -svc time	IWPUT from 4/05 RUC Rec RVW
22523	Thoracic kyphoplasty	8.94	58	**0.084**
22524	Lumbar kyphoplasty	8.54	55	**0.081**
22525	Each additional level	4.67	40	0.117
	Ea. Add'l using 56 min	4.65	56	0.083

(Source: April 2005 RUC Summary of Recommendations)

These IWPUTs represent the RVWs per minute of intra-service time used in calculation of the intra-service work of these procedures. These values are based on the RVW recommendations from the RUC for the two parent codes, while refining the intra-service time for the add-on kyphoplasty to better represent the work of that service. Since the total RVWs have been accepted at the RUC and now are published as interim values for the 2006 Medicare Fee Schedule, these IWPUTs have also been accepted by CMS.

The IWPUTs seem high when compared to those of the vertebroplasty codes, even after the reductions made to the survey work values by the RUC facilitation panel. These codes do represent a different level of complexity and intensity than vertebroplasty, even when compared to the open laminotomy/ laminectomy codes for spinal decompression. This is due to the "blind" nature of the method of reducing a vertebral compression fracture and the use of injections of a polymerizing plastic material in order to sustain the fracture reduction that results from the inflation of the kyphoplasty balloons inside the vertebral bodies. The risk to the spinal canal contents and adjacent vascular structures during such maneuvers is significant and requires careful monitoring and judicious incremental injections of the plastic material to achieve a lasting reduction of the fracture without compromise of the spinal canal and neural elements.

Intra-service RVWs from RUC recommendations

Calculation of the intra-serviceRVW for each of the kyphoplasty codes, using the refined time for 22525 and the above listed IWPUT values produces intra-service work values ranging from 4.65 to 4.87.

CPT code	Brief description	RUC Rec. work RVU 4/05	RUC Intra-svc work RVW	Intra-svc time	IWPUT from 4/05 RUC Rec RVW
	Thoracic kyphoplasty	8.94	**4.87**	58	**0.084**
22524	Lumbar kyphoplasty	8.54	**4.46**	55	**0.081**
22525	Each additional level	4.67	4.67	40	0.117
	Refined intra time	4.65	**4.65**	**56**	**0.083**

(Source: April 2005 RUC Summary of Recommendations)

Immediate same day post-service time

The survey times of 20 minutes for each of the three kyphoplasty codes were accepted without change by the RUC for time spent with the patient the same day as the procedure after the skin is closed and the patient is moved to the recovery room. We believe this time is too low when compared to the same time period for other related codes. For example, vertebroplasty (22520 & 22521) and percutaneous diskectomy (62287) both have same day post-service times of 30 minutes. An increase to 26 minutes for the two parent kyphoplasty codes would restore appropriate time to this phase of the procedure. **We recommend that the same day post-service time be increased to 26 minutes for 22523 and 22524.**

CPT	Descriptor	2006 RVW	glob	Time Source	INTRA min	Same day min
22523	Thoracic kyphoplasty	8.94	010	RUC 4/05	58	20
	Rec Refined values		010		58	26
22524	Lumbar kyphoplasty	8.54	010	RUC 4/05	55	20
	Rec Refined values		010		55	26
22520	Thoracic vertebroplasty	8.90	010	RUC 4/00	80	30
22521	Lumbar vertebroplasty	8.33	010	RUC 4/00	75	30
62287	Percutaneous diskectomy	8.07	90	RUC 8/95	60	30
63030	Laminotomy/ lumbar diskectomy	11.98	90	RUC 8/95 AANS94	90	30
63046	Decomp Laminectomy, thoracic	15.78	90	Hvd3	137	27

Post-service hospital visits

We noted the RUC survey for a thoracic kyphoplasty reported one hospital visit (99232) later the same day following the procedure and a discharge day service (99238) the following morning. This was supported by the Description of Services in the RUC Summary of Recommendations, which also indicated use of general anesthesia on the majority of these patients. When the facilitation committee at the RUC made their recommendations, they removed the one hospital visit (99292). In their rationale, the panel explained *that "40% of respondents reported only a discharge day (99238) for 22520"*. The panel failed to acknowledge that the other 60% of survey respondents reported a hospital visit (99232) in addition to a discharge day visit (99238). This change resulted in a reduction of 1.06 RVUs from the total work value which we believe was inappropriate. **We recommend restoring the 99232 visit and 1.06 RVUs for thoracic kyphoplasty.**

The lumbar kyphoplasty survey did not report a post-service hospital visit other than for a discharge visit even though the patient was described as staying in hospital overnight. By comparison, the key reference service, the survey for lumbar vertebroplasty 22521 did report a 99231 hospital visit as well as a 99238 discharge visit, but the 99231 was removed from that vertebroplasty by a facilitation committee.

Our experts, who have a large experience with kyphoplasty patients, have commented that in their practices, all patients that have a kyphoplasty (thoracic or lumbar) are seen later the day of the procedure while in hospital as well as the following morning at discharge. Since the surgical specialties perform the majority of these procedures in hospital, it would be appropriate to include a

hospital visit. **We recommend allowing a 99232 visit following surgery to cover this practice for patients with lumbar kyphoplasty.**

Justification of the need for closer monitoring of kyphoplasty patients following surgery as well as use of general anesthesia and an overnight stay in hospital include:

- The risks of post-procedure bleeding with hematoma formation, delayed neurological deficits, and injury to adjacent vascular structures.
- A predominantly older patient population with, on average, three medical co-morbidities under active medical management. This applies to both thoracic and lumbar kyphoplasty patients.
- The degree of pain generated during the inflation of the balloon within the vertebral body while reducing the compression of the end-plates warrants use of a general anesthetic and extends the time of in-hospital observation of the patient before discharge.
- The fact that the majority of patients have bilateral insertion of the expansion balloon in order to achieve maximum re-expansion of the collapsed vertebral body end plates increases the chances of complications compared to vertebroplasty.

Total Work

Total work represents the sum of the work of each phase of a service or procedure. To highlight the changes we are proposing, the following list will specify just what changes are required to each of the kyphoplasty codes in order to achieve a more appropriate rank order in terms of total work RVWs, intra-service time and work, and post-service time and visits.

The changes recommended for the kyphoplasty codes are as follows and in Appendix B:

22523 Thoracic Kyphoplasty

We recommend:

1. **Change the immediate post-service time from 20 to 26 minutes**
2. **Adding 1.06 RVUs for the post-procedure hospital visit (99232)**
3. **We recommend an IWPUT of 0.081 for this code**
4. **We recommend a refined new total work RVU of 10.00**

22524 Lumbar Kyphoplasty

We recommend:

1. **Change the immediate post-service time from 20 to 26 minutes**
2. **Adding 1.06 RVUs for the post-procedure hospital visit (99232)**
3. **We recommend an IWPUT of 0.077 for this code**
4. **We recommend a refined new total work RVU of 9.50**

22525 Each additional vertebral body

We recommend:

1. **Increase the intra-service time from 40 to 56 minutes**
2. **We recommend an IWPUT of 0.080 for this code**
3. **We recommend a total work RVU of 4.48 RVUs**

Do these changes correct the misvaluation alleged in the current RVWs?

When each of the changes are applied to the building blocks for each service, the total RVW recommended for the three kyphoplasty codes increases to a level above the current value proposed as interim RVWs in the Final Rule.

CPT	Descriptor	Current total RVW	Diff. In RVWs	New total RVW	New diff in RVWs
22523	**Thoracic kyphoplasty**	**8.94**		**10.00**	
22520	*Thoracic vertebroplasty*	*8.91*	**0.03**	*8.91*	**1.09**
22524	**Lumbar kyphoplasty**	**8.54**		**9.50**	
22521	*Lumbar vertebroplasty*	*8.34*	**0.20**	*8.34*	**1.16**
22525	**Each additional kyphoplasty**	**4.67**		**4.48**	
22522	*Ea. Addl vertebroplasty*	*4.31*	**0.36**	*4.31*	**0.17**

Use of adjusted intra-service times for the vertebroplasty codes

This is a good start but still does not meet the threshold of a significant increase that matches the differences in the amount of total work between procedures in the two families of codes. This appears to be due to the relatively high values still assigned to the vertebroplasty codes.

If we then use the adjusted intra-service times for the vertebroplasty codes, as discussed earlier, to recalculate a new total RVW for each of those codes, it should be possible to make a more useful comparison of the relative differences between the matched kyphoplasty and vertebroplasty codes at each level. The following tables illustrate the new total RVWs for the vertebroplasty codes using the adjusted intra-service times for each code:

	Thoracic Kyphoplasty			**INTRA**	
CPT	**Descriptor**	**RVW**	**IWPUT**	**Intra min**	**Intra RVW**
22520	Thoracic Vertebroplasty	**8.91**	**0.062**	**80**	**4.96**
22520	Same using 45 min intra time	**6.74**	**0.062**	**45**	**2.79**

	Lumbar Kyphoplastly			**INTRA**	
CPT	**Descriptor**	**RVW**	**IWPUT**	**Intra time**	**Intra RVW**
22521	Lumbar Vertebroplasty	**8.34**	**0.059**	**75**	**4.43**
22521	Same using 43 min intra time	**6.48**	**0.059**	**43**	**2.54**

	Each additional kyphoplasty			**INTRA**	
CPT	**Descriptor**	**RVW**	**IWPUT**	**Intra time**	**Intra RVW**
22522	Each addtl vertebroplasty	**4.31**	**0.086**	**50**	**4.30**
22522	Same using 44 min intra time	**3.08**	**0.070**	**44**	**3.08**

New comparative valuation of kyphoplasty to vertebroplasty codes

Although these adjusted time and new work values are not part of the current fee schedule, this model uses such assumptions in order to see if there has been both overvaluation of the vertebroplasty codes

as well as undervaluation of the current interim values for the kyphoplasty codes. This comparison is better visualized in the following table that compares these new/adjusted vertebroplasty RVWs to the new RVWs proposed for the kyphoplasty codes.

CPT	Descriptor	New total RVW for both codes	Diff. In RVWs
22523	**Thoracic kyphoplasty**	**10.00**	
22520	*Thoracic vertebroplasty*	*6.74*	**3.26**
22524	**Lumbar kyphoplasty**	**9.50**	
22521	*Lumbar vertebroplasty*	*6.48*	**3.02**
22525	**Each additional kyphoplasty**	**4.48**	
22522	*Ea. Addl vertebroplasty*	*3.08*	**1.40**

Use of Medicare carrier rates in validating appropriate work RVUs

How can we judge if the proposed changes in these values reflect the real differences in work between these two groups of codes? We already have an indicator of the difference as reflected in the local payment rates approved for kyphoplasty by the regional Carrier Medical Directors at 1.5 to 2 times the vertebroplasty RVW for the related kyphoplasty code. If we apply a 1.5 multiplier to the current RVWs for vertebroplasty, the resulting RVWs would create major rank order anomalies with other more common spinal procedures such as laminectomy or diskectomy. However, if we use the new/adjusted RVWs for each vertebroplasty code from the new intra-service times as above, we can then apply the 1.5x multiplier to the new RVW to see if that provides a better baseline for comparison of the relativity of vertebroplasty to kyphoplasty. This comparison is provided in the following table.

CPT code	Descriptor	New total RVW from new Intra time for vertebroplasty	New vertebro plasty total RVW X 1.5 multiplier	New total RVW for kyphoplasty
	Thoracic -plasty	6.74	10.10	**10.00**
22524	Lumbar -plasty	6.48	9.72	**9.50**
22525	Each additional level	3.08	4.62	**4.48**

What is the significance of using the carrier adjusted rates for comparison?

Using the lower adjusted intra-service times for vertebroplasty produces RVWs that are probably close to their current relative values, considering the changes in the procedure and providers over the past 5 years.

The significance of applying the Medicare CMD factor of a 1.5 x multiplier to the base vertebroplasty code to reach a fair payment amount for the kyphoplasty code is that it reflects a Medicare based market pricing of the kyphoplasty procedures. Applying this same 1.5 x multiplier to the adjusted vertebroplasty codes as above results in CMD kyphoplasty rates virtually identical to those calculated for the same codes by the BBM. This conjunction of work values supports our claim that the current kyphoplasty codes are undervalued, and provides guidance as to the amount of correction appropriate for each code.

This also illustrates that the reductions imposed by the RUC beyond use of the 25th percentile of the survey for total RVWs were inappropriate and depressed the work values to levels that do not represent reasonable relative valuation within the fee schedule.

Final Recommendations

We offer these recommendations for changes in the present interim values assigned to the kyphoplasty codes based on the foregoing discussions and rationales. We request your attention to this problem and are hopeful that our arguments will be compelling in considering such changes.

22523 Thoracic Kyphoplasty

We recommend:

1. **Increase the immediate post-service time from 20 to 26 minutes**
2. **Adding 1.06 RVUs for the post-procedure hospital visit (99232)**
3. **We recommend an IWPUT of 0.081 for this code**
4. **We recommend a refined new total work RVU of 10.00**

22524 Lumbar Kyphoplasty

We recommend:

1. **Increase the immediate post-service time from 20 to 26 minutes**
2. **Adding 1.06 RVUs for the post-procedure hospital visit (99232)**
3. **We recommend an IWPUT of 0.077 for this code**
4. **We recommend a refined new total work RVU of 9.50**

22525 Each additional vertebral body

We recommend:

1. **Increase the intra-service time from 40 to 56 minutes**
2. **We recommend an IWPUT of 0.080 for this code**
3. **We recommend a total work RVU of 4.48 RVUs**

Vertebroplasty codes 22520, 22521 and 22522

We suggest that these three codes be considered for revaluation based on a new RUC survey in order to correct what we believe are significant misvaluations based on time data that no longer represents the current practice of these procedures. We believe that new survey data would confirm our model RVWs for the intra-service times for the vertebroplasty codes and provide more realistic total RVWs.

Sincerely,

Robert E. Florin, M.D.
Past Member, AMA RUC Representative for Neurosurgery

Appendix A

Comparison of steps required for kyphoplasty vs. vertebroplasty

Kyphoplasty	Vertebroplasty
Patient Positioning (pre-service)	**Patient Positioning (pre-service)**
• The patient is brought to the operating room and general anesthesia is administered	• The patient is brought to the radiology suite and local anesthesia is administered.
• The patient is positioned prone on the physician's choice of radiolucent spinal frame	• The patient is placed in the prone position
• The back is prepped and draped	• The image intensifier is brought into position and the target pedicles are identified
Vertebral Body Access (intra-service)	**Vertebral Body Access (intra-service)**
• A spinal needle is used to localize the location for the skin incision based upon fluoroscopic visualization of the pertinent anatomy	• An 11-gauge needle is introduced through the pedicle into the vertebral body at the target level. Positioning is confirmed in the AP and lateral plane
• A skin incision is made	• Following satisfactory placement of the needle, the stylet is removed
• An 11-gauge entry needle is placed overt the facet joint and pedicle of the vertebrae and advanced into the vertebral body. The trajectory is adjusted to achieve access to the center of the vertebral body. Position is confirmed on the AP and lateral plane fluoroscopy	• Often, a venogram is performed to identify the potential pathway for bone cement extravasation
• The stylet is removed from the entry needle	
• A guide pin is passed through the needle 2 mm past the distal end	
• The 11-gauge needle is removed leaving the guide pin in place.	
• A blunt dissector with an outer sleeve cannula is placed over the guide pin and advanced into the posterior part of the vertebral body. Position is verified in the AP and lateral plane. The guide pin and the blunt dissector are removed leaving the working cannula in place	
• A drill is advanced through the working cannula, into the vertebral body under fluoroscopic guidance toward the anterior cortex to create a tunnel for the expandable bone tamp	
• A bone-filling device is passed though the working channel to smooth out the channel	
• A biopsy is obtained from the vertebral centrum	
• The expandable bone tamp is inserted through the cannula and advanced under fluoroscopic guidance into the vertebral body. The position of the bone tamp is verified using AP and lateral fluoroscopic images	
• **The entire procedure is repeated on the contralateral side, which is the case for a majority of the patients**	
Vertebral Body Fracture Reduction	**Vertebroplasty is done bilaterally only in patients in whom thecement does not adequately fill the side of the vertebra contralateral to the injection, which are less than 50% of patients**
• The expandable bone tamps are sequentially inflated in an attempt to elevate the compressed/fractured end plates and thereby restore vertebral body height	

- During tamp expansion, careful attention is paid to the pressure exerted, the volume of dye as well as tamp position. Tamp inflation and fracture reduction is monitored with AP and lateral imaging
- Tamp expansion is stopped once the vertebral body is restored back to its native height
- Tamp expansion will create a cavity surrounded by compacted cancellous bone in the vertebral body
- The inflatable bone tamps are removed.

Body Cavity Fill/ Augmentation/ Internal Stabilization

- With fluoroscopic guidance the cavity is filled using a controlled, low-pressure injection of a thick, viscous bone void filler into the cavity created by the bone tamp
- Frequent fluoroscopic monitoring of the filling is done in both AP and lateral planes to identify spread into the adjacent structures or spinal canal
- Filling progresses with 1.5 cc incremental injections until the void is filled bilaterally
- Once the defect is filled the working cannulae are removed
- The incisions are closed with a single stitch. Sterile surgical dressings are applied

Reversal of Anesthesia and Patient Transport to Recovery (post-service)

- Dressings are applied and the patient is turned supine
- Anesthesia is concluded
- Patient is transferred to recovery room

Fracture Stabilization

- Under fluoroscopic imaging, internal fixation is achieved through high pressure injection of bone cement into the vertebral body
- Extravasation of the bone cement is monitored.
- The needles are removed

Completion of Procedure (post-service)

- Dressings are applied and the patient is turned supine\
- Patient is moved to recovery room

APPENDIX B

Calculations of IWPUT and New RVWs for Kyphoplasty Codes; Comparison of RUC Facilitation Panel calculations to New Recommended Values

	Thoracic Kyphoplasty 1st panel adjustment			Thoracic Kyphoplasty 2nd panel adjustment			Thoracic Kyphoplasty Rec. new values		
			RVW			RVW			RVW
		Calc. RVW =	10.00		Calc. RVW =	8.94		Calc. RVW =	10.00
	Survey data	RUC values	RVW	Survey data	RUC values	RVW	Survey data	RUC values	RVW
Pre-service	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**
Pre-service evalutaion	53	0.0224	1.19	53	0.0224	1.19	53	0.0224	1.19
Positioning time	18	0.0224	0.40	18	0.0224	0.40	18	0.0224	0.40
Scrub, prep, wait time	15	0.0081	0.12	15	0.0081	0.12	15	0.0081	0.12
Pre-service total			**1.71**			**1.71**			**1.71**
Post-service	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**
Immediate post	20	0.0224	**0.45**	20	0.0224	**0.45**	**26**	0.0224	**0.58**
Subsequent visits:	**Visit n**	**E/M RVW**	(=n x RVU)	**Visit n**	**E/M RVW**	(=n x RVU)	**Visit n**	**E/M RVW**	(=n x RVU)
99232	0.0	1.06	0.00	0.0	1.06	0.00	**1.0**	1.06	1.06
Discharge 99238	1.0	1.28	1.28	1.0	1.28	1.28	1.0	1.28	1.28
Office 99213	1.0	0.65	0.65	1.0	0.65	0.65	1.0	0.65	0.65
Post-service total			**2.38**			**2.38**			**3.57**
	Time	**IWPUT**		**Time**	**IWPUT**		**Time**	**IWPUT**	
Intra-service	58	**0.102**	**5.91**	58	**0.084**	**4.85**	58	**0.081**	**4.72**
	Note IWPUT of 0.102			Note assigned IWPUT of 0.084			Added 6 min Immed post Restore 99232 hv		

APPENDIX B

	Lumbar Kyphoplasty 1st panel adjustment			Lumbar Kyphoplasty 2nd panel adjustment			Lumbar Kyphoplasty Rec. new values		
			RVW			RVW			RVW
	Calc. RVW =		9.50	Calc. RVW =		8.54	Calc. RVW =		9.50
	Survey data	RUC values	RVW	Survey data	RUC values	RVW	Survey data	RUC values	RVW
Pre-service	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**
Pre-service evalutaion	53	0.0224	1.19	53	0.0224	1.19	53	0.0224	1.19
Positioning time	18	0.0224	0.40	18	0.0224	0.40	18	0.0224	0.40
Scrub, prep, wait time	15	0.0081	0.12	15	0.0081	0.12	15	0.0081	0.12
Pre-service total			**1.71**			**1.71**			**1.71**
Post-service	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**
Immediate post	20	0.0224	**0.45**	20	0.0224	**0.45**	26	0.0224	**0.58**
Subsequent visits:	**Visit n**	**E/M RVW**	(=n x RVU)	**Visit n**	**E/M RVW**	(=n x RVU)	**Visit n**	**E/M RVW**	(=n x RVU)
99232	0.0	1.06	0.00	0.0	1.06	0.00	1.0	1.06	1.06
Discharge 99238	1.0	1.28	1.28	1.0	1.28	1.28	1.0	1.28	1.28
Office 99213	1.0	0.65	0.65	1.0	0.65	0.65	1.0	0.65	0.65
Post-service total			**2.38**			**2.38**			**3.57**
	Time	**IWPUT**		**Time**	**IWPUT**		**Time**	**IWPUT**	
Intra-service	55	**0.098**	**5.41**	55	**0.081**	**4.45**	55	**0.077**	**4.22**
	Note high IWPUT of 0.098			Note assigned IWPUT of 0.081			Add 6 min Immed post time & 99232 hv		

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APPENDIX B

Kyphoplasty	Each additional level 1st panel adjustment			Each additional level 2nd panel adjustment			Each additional level Rec. new values		
		Calc. RVW =	RVW 5.00		Calc. RVW =	RVW 4.67		Calc. RVW =	RVW 4.48
	Survey data	RUC values	RVW	Survey data	RUC values	RVW	Survey data	RUC values	RVW
Pre-service	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**
Pre-service evalutaion	10	0.0224	0.22	0	0.0224	0.00	0	0.0224	0.00
Positioning time	0	0.0224	0.00	0	0.0224	0.00	0	0.0224	0.00
Scrub, prep, wait time	0	0.0081	0.00	0	0.0081	0.00	0	0.0081	0.00
Pre-service total			**0.22**			**0.00**			**0.00**
Post-service	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**	**Time**	**Intensity**	**(time x intensity)**
Immediate post	5	0.0224	**0.11**	0	0.0224	**0.00**	0	0.0224	**0.00**
Subsequent visits:	**Visit n**	**E/M RVW**	(=n x RVU)	**Visit n**	**E/M RVW**	(=n x RVU)	**Visit n**	**E/M RVW**	(=n x RVU)
99232	0.0	1.06	0.00	0.0	1.06	0.00	0.0	1.06	0.00
Discharge 99238	0.0	1.28	0.00	0.0	1.28	0.00	0.0	1.28	0.00
Office 99213	0.0	0.65	0.00	0.0	0.65	0.00	0.0	0.65	0.00
Post-service total			**0.11**			**0.00**			**0.00**
	Time	**IWPUT**		**Time**	**IWPUT**		**Time**	**IWPUT**	
Intra-service	40	**0.117**	**4.67**	40	**0.117**	**4.67**	**56**	**0.080**	**4.48**

Panel selects 25th percentile for RVW | Panel deletes pre- and post-svc time | New intra-time and total RVW

2

DEC 16 2005

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December 9, 2005

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

To Whom It May Concern:

I am writing in regard to the changes in the Medical Physician Fee Schedule (MPFS) for 2006. As you are aware, on November 21, 2005 CMS published in the Federal Register its proposed Final Rule for the 2006 MPFS. According to the fee schedule the reimbursement for 2006 for thoracic kyphoplasty, diagnosis code 860.33 and lumbar kyphoplasty, diagnosis code 809.31, plus an additional level 458.86, has dropped. The difference is $271.01 less in 2006 than in 2005. This is just a few dollars above the reimbursement for vertebroplasty, which is much simpler and less complicated procedure. The relative value units are nowhere near equivalent, yet the fee seems to have equilibrated. I am writing in protest of the current fee reductions. I think it is unfair and unjustified total hip arthroplasty there is more than a 31% drop in reimbursement for the thoracic and lumbar kyphoplasty procedures.

The physician's time at the hospital is approximately one and a half hours plus 3 months of follow up in the global period and does not justify this 31% reduction.

In addition, the vertebroplasty, which requires less follow up and less technical skill and time, has almost equal reimbursement. This is not consistent with the relative value of the two procedures.

According to Medicare guidelines, the relative value units for thoracic kyphoplasties, CPT code 22523, is 16.29. For a lumbar kyphoplasty, CPT

code 22524, it is 15.61. Each additional level, CPT code 22525, is 7.47 relative value units. In contradiction, the vertebroplasty, CPT code 76012, and each additional level, 70613, have 1.88 and 1.93 relative value units respectively. Again, I don't see how Medicare justifies nearly comparable reimbursement for the two procedures.

Please make every effort to reconsider your proposed reductions.

Sincerely,

Vito Loguidice, MD
VL/lmh

Dictated, not read.

3

DEC 16 2005

American Optometric Association
1505 Prince Street • Alexandria, VA 22314 • (703) 739-9200
FAX: (703) 739-9497

December 13, 2005

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

To Whom It May Concern:

The American Optometric Association (AOA) is pleased to submit comments related to the November 21, 2005 *Federal Register* publication of the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006.

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Please let us know if you need additional information.

Sincerely,

Kelly Hipp

Kelly Hipp
Director, Professional Relations

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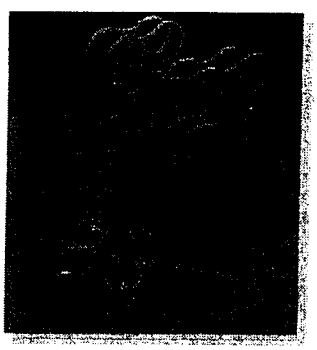

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RETURN MERCHANDISE AUTHORIZATION (RMA): All returns must be authorized by WILSON OPHTHALMIC CORPORATION. Please complete the reverse side of this sheet and FAX it to 800-329-9133. Your request will be reviewed and faxed back to you. If we have any questions concerning your request, we will contact you. ***Unauthorized returns will be refused.*** RMA numbers are valid for thirty (30) days after issue. Due to the costs of processing returns, ***no authorization will be issued for merchandise valued at less than $20, unless it is due to our error, defective product, or replacement product is being ordered.***

DAMAGED MERCHANDISE: Inspect shipments upon receipt. Any visible damage should be noted on the freight bill at the time of delivery. Check and sort through all packing materials before discarding to locate small items you may have ordered. Report merchandise damaged during shipment immediately to the carrier, requesting inspection of damage, and advise WILSON OPHTHALMIC CORPORATION. The original shipping container is required to process your claim, so please check your merchandise carefully upon receipt.

DEFECTIVE MERCHANDISE: Following Return Merchandise Authorization by WILSON OPHTHALMIC CORPORATION, defective items must be returned for replacement or credit within 30 days.

MERCHANDISE SHIPPED IN ERROR: Call WILSON OPHTHALMIC CORPORATION for instructions. Full credit will be issued upon our receipt of the merchandise in original packaging and in resalable condition.

MERCHANDISE ORDERED IN ERROR: To receive credit, merchandise must be returned in original packaging and in resalable condition within 30 days, freight prepaid. When selecting method of return, keep in mind that proof of delivery may be needed later. Return Merchandise Authorization must be issued, and restocking fees may apply. Original shipping charges remain due. Restocking fees may be waived on non-special order items, if replacement products are ordered.

SPECIAL ORDER ITEMS: Special order items may be non-returnable or subject to higher restocking fees. You will be notified prior to shipment of any Special Order Status, and indication will also appear on the invoice.

WARRANTIES: All products distributed by WILSON OPHTHALMIC CORP. and contained in this catalog accurately reflect the representations made to WILSON by the manufacturers of those products. There are no warranties which extend beyond those of the manufacturers. In addition, manufacturers' warranties may vary, or be null and void, for exported items.

WILSON PHARMACEUTICALS: Our no-minimum order policy gives our customers the opportunity to order in very small quantities suited to their needs. No pharmaceutical may be returned after six (6) months from date of purchase except for short-dated product (less than 9 months dating at time of shipment). No opened bottles or partial boxes may be returned for credit. The amount of eligible credit will decrease at a rate of 10% per month from date of shipment. Impact of returns on quantity discounts and free goods received at time of purchase will be considered in determining credit due. Prior Return Merchandise Authorization is required on all returns. We encourage you to purchase no more than a six (6) month supply of any pharmaceutical due to the FDA's recent trend toward shorter dating approval.

MAILING LISTS: WILSON OPHTHALMIC guarantees your satisfaction and respects your privacy. We do not sell or rent the names of our customers to anyone -- you'll never receive any unwanted mailings because somebody misused our mailing list.

Ordering Items Not Shown in this Catalog

Due to space limitations, it is impossible for us to show all of the products we can provide. Whatever your product needs, please ask. If we don't have the item in stock, we can likely get it at a very competitive price. If not, we may save you time by advising you where to look.

Gentak 0.3% 3.5gm Oint	Akorn	003-0245461-00	21.15	6+	20.41
Gentamicin Sulfate 0.3% 15ml Soln	B & L	006-0366498-00	12.05	12+	11.63
GenTeal Lubricant Eye Drop 15ml	Novartis	007-0878815-00	8.84	12+	8.53
GenTeal Lubricant Eye Gel 10ml	Novartis	007-0879036-00	9.30	12+	8.97
Glutose 15 gel 40% 3x15gm		030-2200830-03	10.53	12+	10.16
Gonak 2.5% 15ml Soln	Akorn	003-0001230-00	11.75	12+	11.34
GPS	See page 1				

H

Hypotears PF 30x0.02oz Soln	Novartis	007-0650978-00	11.08	12+	10.69
Hypotears 3.5gm Oint.	Novartis	007-0271322-00	11.08	12+	10.69
Puralube	See page 2				
Hypotears 1% 30ml Soln	Novartis	007-0021474-00	14.69	12+	14.17
Hypotears 1% 15ml Soln	Novartis	007-0021466-00	10.12	12+	9.77

I

Ibuprofen 200mg 100ct Tabs		030-0634468-00	5.47	12+	5.28
Ibuprofen 400mg 100ct Tabs		030-0509140-00	13.70	12+	13.22
Ibuprofen 400mg 500ct Tabs		030-0537233-00	25.49	6+	24.60
Ibuprofen 600mg 100ct Tabs		030-0446777-00	9.27	12+	8.95
Ibuprofen 800mg 100ct Tabs		030-1680131-00	12.18	12+	11.76
IC-Green 25mg 6x25ml SDV (Non-Returnable)		020-0962112-06	517.88		
Inflamase Forte 1% 5ml Soln	Novartis	007-0021504-00	21.01	12+	20.28
Prednisolone Sodium Phosphate 1%	See page 4				
Inflamase Forte 1% 10ml Soln	Novartis	007-0021512-00	30.89	6+	29.81
Insta-Glucose Tri-Pak Gel 3x31gm		030-1758689-00	10.99	12+	10.61
Iopidine 0.5% 5ml Soln.	Alcon	004-0867829-00	83.85	3+	80.92
Iopidine 1% 12x2x0.1ml Soln	Alcon	004-0594539-12	334.05	3+	322.36
Isopto Atropine 1% 5ml Soln	Alcon	004-0003549-00	22.80	12+	22.00
Atropine Sulfate 1%	See page 1				
Isopto Carbachol 3% 30 ml Soln	Alcon	004-0003638-00	59.57	6+	57.49
Isopto Carpine 1% 15ml Soln	Alcon	004-0003670-00	26.29	6+	25.37
Piloptic Pilocarpine 1%	See page 5				
Isopto Carpine 2% 15ml Soln	Alcon	004-0003700-00	28.94	6+	27.92
Piloptic Pilocarpine 2%	See page 5				
Isopto Homatropine 2% 5ml Soln	Alcon	004-0003883-00	24.93	6+	24.06
Isopto Homatropine 5% 5ml Soln	Alcon	004-0003905-00	28.64	6+	27.64
Isopto Homatropine 5% 15ml Soln	Alcon	004-0003913-00	37.94	6+	36.61
Isopto Hyoscine 0.25% 15ml Soln	Alcon	004-0234478-00	34.50	6+	33.29
Isopto Hyoscine 0.25% 5ml Soln	Alcon	004-0003921-00	25.00	6+	24.13

K

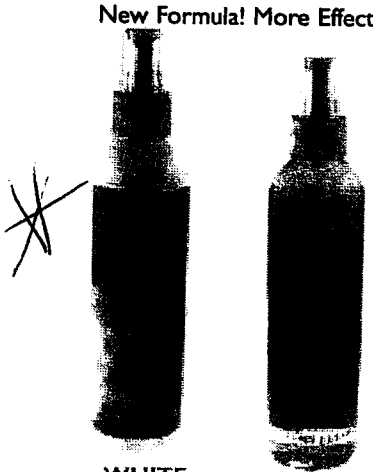
Keflex 250mg Pulvule		030-0024023-00	196.06	3+	189.20
Kenalog-10 10mg 5ml Vial.	Bristol-Meyers	030-0242357-00	10.32	12+	9.95
Kenalog-40 40mg 10ml Vial.	Bristol-Meyers	030-0274631-00	60.53	6+	58.42
Kenalog-40 40mg 5ml MDV	Bristol-Meyers	030-0082961-00	40.53	6+	39.11
Kenalog-40 40mg SDV 1ml.	Bristol-Meyers	030-0179817-00	7.99	6+	7.71

L

Lacrilube 7gm Oint	Allergan	005-0005118-00	18.59	12+	17.94
Lacrilube NP 24x0.7gm UD Oint.	Allergan	005-0484881-00	55.47	6+	53.53
Lacrilube SOP 3.5gm Oint	Allergan	005-0234583-00	10.75	12+	10.38
Dry Eyes	See page 2				
Lactated Ringers Inj Plastic IV Bag 12x1000ml.		030-1617638-12	23.49	6+	22.67
Lanoxin 0.125mg 100ct Tabs		030-0018570-00	28.29	6+	27.30
Lens Plus 12oz Aerosol	Allergan	005-0309885-00	6.27	12+	6.05
Lens Plus Daily Cleaner 15ml.	Allergan	005-0484954-00	6.30	12+	6.08
Lidocaine 2% 25x30ml MDV.	Wyeth	014-0026530-25	23.46	6+	22.64
Lidocaine 2% Viscous 100ml Topical Oral Soln.		030-0103489-00	6.44	12+	6.21
Lidocaine 4% 40mg/ml 25x5ml		030-0377295-25	68.09	3+	65.71
Lidocaine Topical 4% 50ml Soln		030-0386529-00	10.25	12+	9.89
Lidocaine w/Epi 1% MDV 1:100M 25x20ml		030-0624772-25	39.72	6+	38.33

Shield Lens Cleaner

New Formula! More Effective Cleaning! Non-aerosol pump spray lens cleaner is great for glass, plastic and even AR coated lenses.



WHITE BOTTLE

CLEAR BOTTLE

	1 oz.		2 oz.		4 oz.		8 oz.	
CLEAR	34/191/0000		34/192/0000		34/194/0000		34/198/0000	
	48 (min), ea	.69	48 (min), ea	.94	24 (min), ea	1.05	Less Than 24, ea	1.52
	1-3 gross, ea	.65	1-3 gross, ea	.85	1-3 gross, ea	.95	24 (case), ea	1.38
	4+ gross, ea	.62	4+ gross, ea	.81				
WHITE	34/130/0000		34/132/0000		34/134/0000		34/138/0000	
	48 (min), ea	.68	48 (min), ea	.77	24 (min), ea	.86	Less Than 24, ea	1.40
	1-3 gross, ea	.62	1-3 gross, ea	.70	1-3 gross, ea	.78	24 (case), ea	1.27
	4+ gross, ea	.59	4+ gross, ea	.66	4+ gross, ea	.74	1-3 gross, ea	1.21
	34/131/0000 SQUEEZE							
	144 (min), ea	.35						
	4-6 gross, ea	.31						
	7+ gross, ea	.30						

ONE Great Product! Four Convenient Sizes! And Best of All . . .FREE* Personalization!

- ONE Great Product
- Two Attractive Styles
- Four Convenient Sizes

and Best of All . . . FREE* Personalization!

*Add $4.50 one-time-set-up-charge for each product and each bottle size for new or changed imprints.
Maximum imprint size:
- 1 oz Pump spray bottles: 3 lines of type. First line 20 characters, other lines 22 characters.
- 2 oz; 4 oz; and 8 oz. Pump spray bottles: 5 lines of type. First Line 20 characters, other lines 25 characters.

Positioning and layout of imprints at Shield's discretion.

When ordering product without imprint, replace "00" at end of product number with "99."

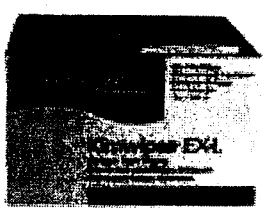
Pre-Moistened Lens Cleaner Towelettes

Hilco's new formula lens cleaner in convenient, individually packaged towelettes.

Box of 18 towelettes
11/121/0000 **3.25**

4 Boxes of 18 (72)
11/122/0000 **11.70**

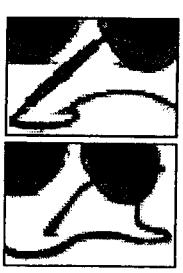
Kimwipes EX-L



Low-lint, absorbent material is ideal for cleaning most types of lenses.

4.5" x 8.5" (Box of 280)
135-0034155-00 **2.65 per box**
Case (60 boxes) **2.35 per box**

Dualies™ Sports Band or Standard Holder



- Attaches to eyeglass temples
- Cord Stays behind ear and out of the way
- Tighten by cinching cord to desired fit
- "Slip Knot" Adjustable
- Holds tight to eyeglass temple in front of ear
- Keeps eyewear within easy reach

Each style features a sliding cinch.

Dualies™ Thin Line
3 Black, 3 Brown 13.49 08/713/0000
6 Assorted Colors 13.49 08/715/0000

Dualies™ Sports Line (Active Wear)
6 Assorted Colors 13.49 08/718/0000

Dualies™ Rugged Line
6 Assorted Colors 13.49 08/721/0000

Dynaband® Eyewear Retainers

Sleek elastic band with rubberized ends. One size fits all — great for infants, children and adults.

Black **1.50** **045-0MN6942-00**

Fashion Holders

Small Curb Chain
Gold 1.79 each 08/008/0100
Silver 1.79 each 08/008/0200

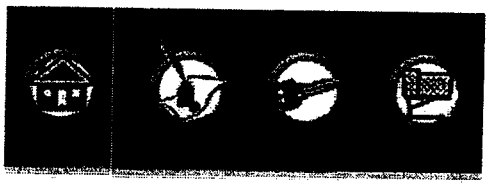
Small Rope Chain
Gold 1.79 each 08/009/0100
Silver 1.79 each 08/009/0200

Anchor Chain
Gold 1.79 each 08/003/0100
Silver 1.79 each 08/003/0200

Double Cobra
Gold 5.59 each 08/164/0100

OptiSource™ International

The Optical Supply Resource



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Lens Polish	All Surfacing Supplies	Lens Cleaners & Anti-Fog	Microfiber Cleaning Cloths	Optical Tools & Frame Parts	Nose Pads & Screws	Eyeglass Cases	Sunglass Clips	Other Accessories	Exam S & E

1-800-OptiSource (678-4768)
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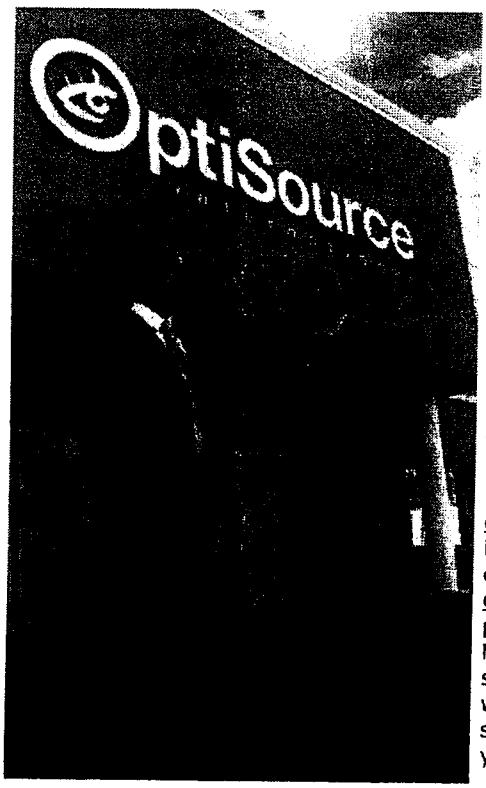
Fast Easy Order Form



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Track Orders	trackorders@1-800-optisource.com
Vendors	vendors@1-800-optisource.com
Web Wizard	ken@1-800-optisource.com
Vice-President	daryl@1-800-optisource.com

And remember, you may always reach us from 8am-6pm Monday-Friday New Yor to remember, 1-800-OPTISOURCE (678-4768). International Customers may cal FAX US at 631-924-8375.

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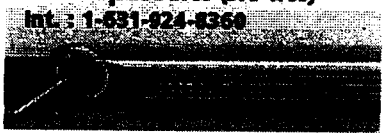

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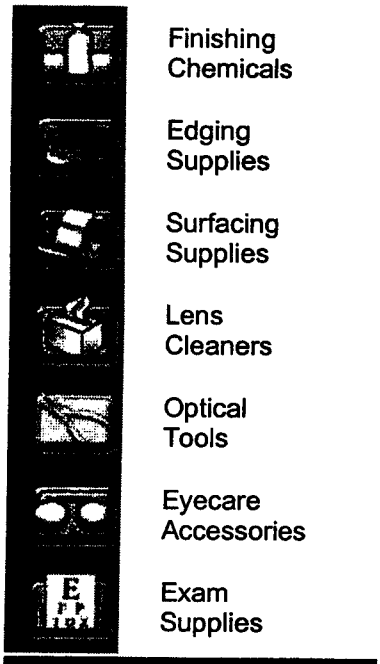

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Surfacing Supplies

Lens Cleaners

Optical Tools

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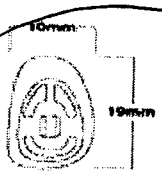


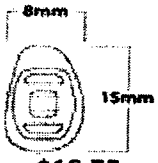
$19.75

Add to Cart

19mm Silicone Symmetrical Snap Nose Pad

More Info

- These symmetrical snap on nosepads have a Special Ultra - Soft Silicone composite and a special oval shape which eliminates the need for left and right pads
- These 19 mm snap on nosepads are the softest for maximum comfort
- They are exceptionally clear and flexible and match virtually any frame



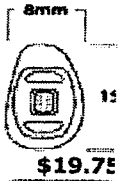
$19.75

Add to Cart

15mm Silicone "D" Shape Screw Nose Pad

More Info

- These Classic "D" screw on nosepads have a Special Ultra - Soft Silicone composite and each pair consists of a left and right nosepad
- These 15 mm screw on nosepads are the softest for maximum comfort
- They are exceptionally clear and flexible and match virtually any frame



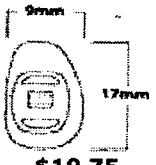
$19.75

Add to Cart

15mm Silicone "D" Sh Pad

More Inf

- These Classic "[nosepads have a S Soft Silicone compc pair consists of a le nosepad
- These 15 mm si nosepads are the s maximum comfort
- They are except and flexible and ma any frame



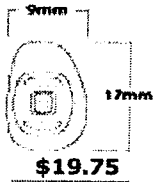
$19.75

Add to Cart

17mm Silicone "D" Shape Screw Nose Pad

More Info

- These Classic "D" screw on nosepads have a Special Ultra - Soft Silicone composite and each pair consists of a left and right nosepad
- These 17 mm screw on nosepads are the softest for maximum comfort
- They are exceptionally clear and flexible and match virtually any frame



$19.75

Add to Cart

17mm Silicone "D" Shape Snap Nose Pad

More Info

- These Classic "D" snap on nosepads have a Special Ultra - Soft Silicone composite and each pair consists of a left and right nosepad
- These 17 mm snap on nosepads are the softest for maximum comfort
- They are exceptionally clear and flexible and match virtually any frame

$19.75

Add to Cart

19mm Silicone "D" S Nose Pac

More Inf

- These Classic "[nosepads have a S Soft Silicone compc pair consists of a le nosepad
- These 19 mm si nosepads are the s maximum comfort
- They are except and flexible and ma any frame

THE LEADER IN VISION DIAGNOSTICS™

December 9, 2005

Ms. Kelly Hipp

Kelly:

Thank you for your phone call concerning the Marco Radiusgauge.

This particular product sells for approximately $1595.00 and is available through our network of Authorized Marco Distributors.

If you have any further questions, or need the contact information of a Marco Distributor near you, please contact me directly at 800-874-5274.

Thanks again for your interest.

Sincerely,

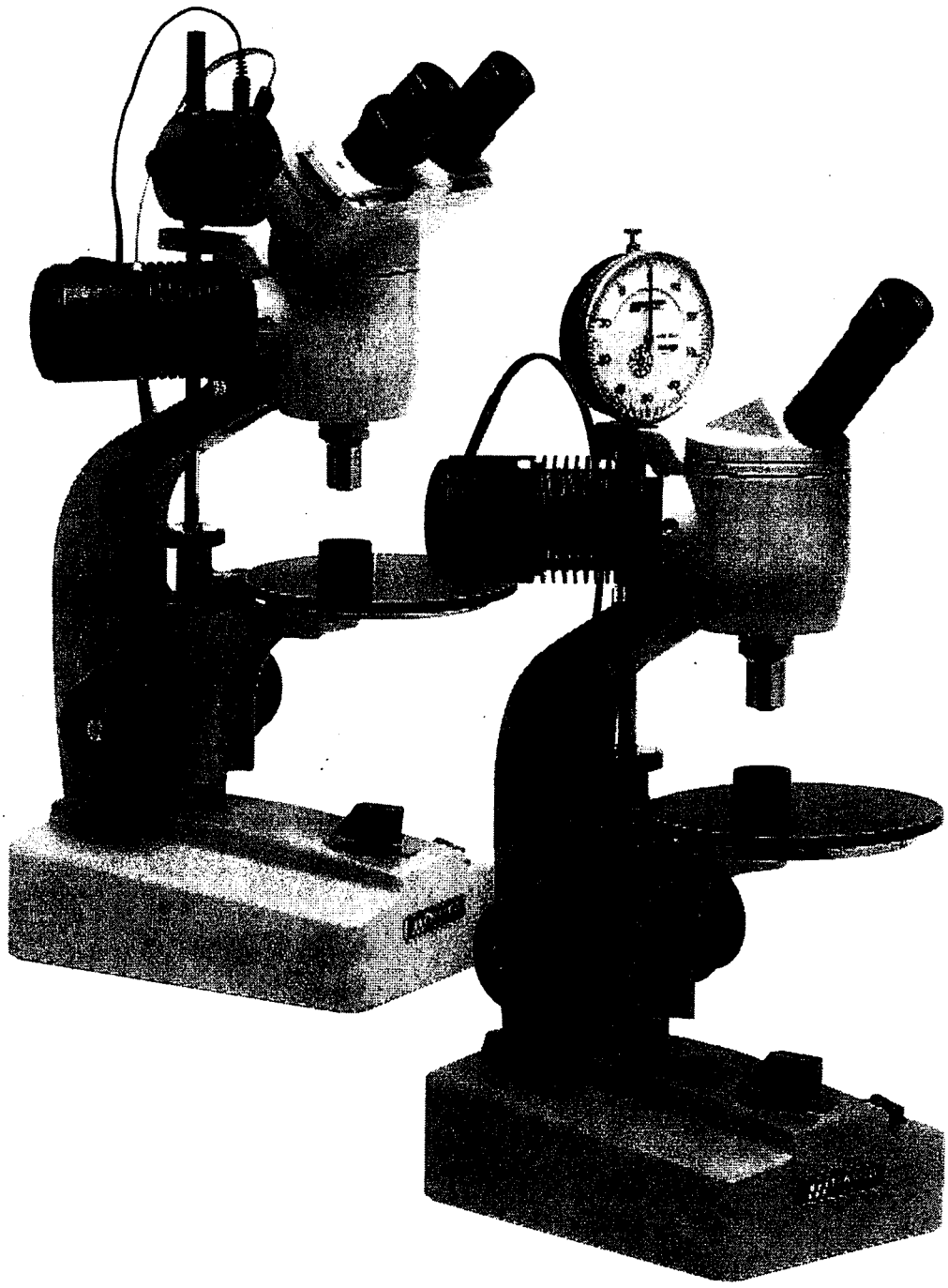
J. Brad Santora
Director of Sales – Classical Products

11825 Central Parkway | Jacksonville, FL 32224 | 800-874-5274 | 904-642-9330 | Fax 904-642-9338 | www.marco.com

MARCO

THE LEADER IN VISION DIAGNOSTICS™

STANDARD RADIUSGAUGES



MARCO RADIUSGAUGES are available with either a standard or digital gauge as well as in either monocular or binocular form. All offer the functions of two instruments in one, measuring both the curvature and thickness of contact lenses on a single instrument.

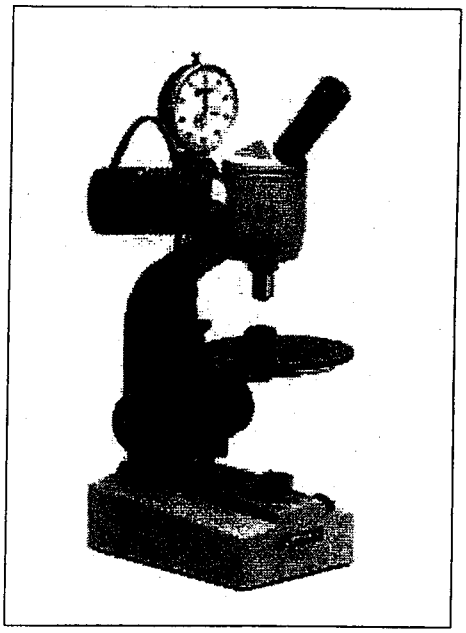
The accuracy of both measurements is increased through the 100x magnification and a coaxial coarse and fine focusing knob.

SPECIFICATIONS & FEATURES

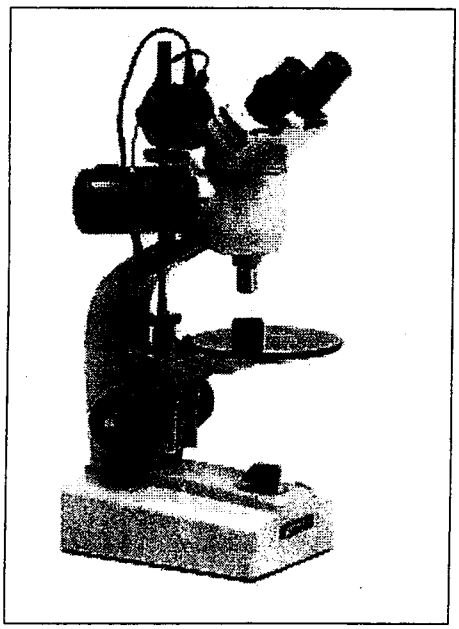
- Measurement of contact lens curvature and thickness.
- Standard 100x magnification with 10x objective and 10x eyepiece.
- Large external dial gauge.
- Coaxial coarse and fine focusing.
- Large or small aperture.
- Variable voltage transformer incorporated into base of unit.
- Monocular or binocular.
- Standard or digital gauge
- Compact, modern design, simple to use.

$1595.

Dimensions:	Height:	19"
	Depth:	10"
	Width:	8"
	Weight:	Approximately 13 pounds.
	Color/Finish:	Grey.



Monocular Radiusgauge



Digital Binocular Radiusgauge

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Marco-Certified Quality assures you of the very finest vision products, offering advanced technology, industry-leading durability and enhanced productivity for your practice. Marco-Certified Quality is your mark of confidence.

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December 6, 2005

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Post Office Box 8017
Baltimore, MD 21244-8017

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

Dear Dr. McClellan:

ZLB Behring is a leading researcher and manufacturer of life-saving biotherapeutics such as intravenous immune globulin (IVIG), which is used in treating conditions such as immune deficiencies; blood clotting factors to treat bleeding disorders, including hemophilia and von Willebrand disease; and alpha$_1$-proteinase inhibitor, used to treat alpha$_1$-antitrypsin deficiency, which is commonly referred to as genetic emphysema. These therapies are created by pooling and manufacturing donated human blood plasma into lifesaving therapies or through the development of recombinant DNA technology.

ZLB Behring applauds the special recognition that CMS has provided IVIG through the creation of a pre-administration code (G0332). However, the preadministration code does not address the primary cause of the ongoing access problem: physicians and infusion suites reporting that they cannot purchase IVIG at the existing reimbursement rates. We believe that three measures need to be implemented by the agency quickly to resolve patient access to this critical therapy.

- An additional payment/service fee for IVIG, similar to the precedent enacted for another blood plasma therapy, hemophilia clotting factor, under Medicare Part B;
- NDC based (brand-specific) reimbursement through the creation of HCPCS codes for individual brands of IVIG
- Classification of IVIG as a Biologic Response Modifier

With regard to the Competitive Acquisition Program (CAP), we believe CMS has been very sensitive to the need of plasma and recombinant therapies and support the agency decision not to list these therapies as CAP eligible. Congress recognized the uniqueness of IVIG and the difficulties that would be posed for patient access under CAP and statutorily excluded the therapy from CAP consideration. Moreover, in the conference report that accompanied the Medicare Modernization Act, specific reference was made to blood clotting factors not being suited for CAP. ZLB Behring also supports CMS' rationale not to include the single indication orphan therapies under the list of CAP eligible products. While CMS has decided to allow CAP vendors to request incorporating certain single indication therapies, we urge that alpha$_1$-proteinase inhibitor therapy be excluded. The concern that CMS raised about access difficulties under CAP for single indication orphan therapies is correct and especially relevant for alpha$_1$-proteinase inhibitor.

Payment for Covered Outpatient Drugs and Biologicals

The rule was clear in stating CMS' belief that the current listed reimbursement rates are reflective of acquisition costs. This is contrary to reports that existing IVIG reimbursement under Medicare Part B is not adequate to assure patient access to care. Patients, patient organizations such as the Immune Deficiency Foundation and Jeffrey Modell Foundation, medical providers and manufacturers, have communicated this concern. Reports and surveys have been presented that demonstrate patients are having treatment delayed, dosage regimes changed and are being turned away or steered into the hospital. Even national publications such as The New York Times, Washington Post and Associated Press have reported on access difficulties. This is because the payment rates put forward by CMS, which are based on volume-weighted averages from ASPs submitted 2 quarters ago, are not reflective of acquisition pricing.

Regretfully, the pre-administration fee established by CMS under code G 0332 does not address the actual acquisition costs of IVIG and as such does not address the underlying cause of the continued patient access difficulties.

An IVIG summit group comprised of the plasma therapeutics industry, patient organizations, distributors, group purchasing organizations and the American Academy of Allergy, Asthma and Immunology continue to reiterate the following remedies to solve the ongoing IVIG access problems.

Add-on Payment

An add-on payment for storage, handling and pharmacy costs associated with administering IVIG would help reimbursement reflect the true cost of IVIG for providers and help maintain patient access, just as the furnishing fee for blood clotting factors has assisted in maintaining access to that therapy. The $0.14 furnishing fee for blood clotting factor under Medicare Part B equates to a 16-29% add-on for the individual classes of blood clotting factors. IVIG also has costs for overhead, distribution and other indirect costs that are not adequately reflected in the ASP plus 6% methodology.

The Plasma Protein Therapeutics Association (PPTA), a trade association of which ZLB Behring is a member, has commissioned the Lewin Group to perform a study to clarify supply and handling costs associated with IVIG. PPTA will submit the findings from the Lewin Group with their comments to this final rule. We hope that CMS will consider these findings and determine an add-on payment that will assist patient access to IVIG, through the issuance of a program memorandum or modification of the final rule.

NDC Based (brand specific) Reimbursement

Implementing brand-specific reimbursement for IVIG would also contribute to solving the IVIG access issues related to its reimbursement, in combination with the other suggested remedies. There are multiple brands of plasma therapeutics within a HCPCS code, although each brand has unique features that match up with different patient profiles. Access to all brands is essential so that individual patients may be treated properly. Under the present reimbursement methodology for Part B, the volume-weighted average calculation within the HCPCS code has resulted in the reimbursement level being lower than providers can purchase some of the individual brands, thus creating access difficulty. A remedy would be to create HCPCS codes for each individual brand of IVIG based on the current ASP plus 6% methodology.

CMS stated in the final rule that they did not find a compelling reason to override the existing standard for only having HCPCS codes for classes of therapy. ZLB Behring strongly disagrees with this CMS position, as the ongoing patient access issues are indeed quite compelling. The ongoing access concerns compelled over 50 members of the United States Congress to urge CMS to address the present situation. Patient access to IVIG for Medicare beneficiaries is not a limited problem and it is indeed a compelling reason to consider remedies that are different than reported normal procedure. There are very few biologics that have multiple therapies in a single HCPCS code. Besides, by definition, the change to brand-specific reimbursement for IVIG would be revenue neutral when compared to a volume-weighted average calculation.

IVIG as a Biologic Response Modifier

The CMS creation of a pre-administration code provides some assistance in paying for administration of this therapy. However, this code is only in place for 2006 and is designed strictly to cover time involved in procuring IVIG. The pre-administration code does not recognize the complexity of administering IVIG. That is why in lieu of G0332; ZLB Behring recommends the reclassification of IVIG as a Biologic Response Modifier.

For 2005, CMS, in coordination with the American Medical Association (AMA), created new temporary Current Procedural Terminology (CPT) codes that are used to bill for drug administration services and assigned payment rates to these codes. While we understand that IVIG is billed using codes for intravenous therapeutic or diagnostic infusions (G0347), the agency can specify that IVIG be declared a biologic response modifier (BRM) in terms of billing for administration. Under these new codes, chemotherapy administration codes apply to parenteral administration of biologic response modifiers. As a result, any product, such as IVIG, that is a "biologic response modifier" should be billed under such codes. According to the National Library of Medicine, biologic response modifier therapy is referenced as "immunotherapy," which is defined as "treatment to stimulate or restore the ability of the immune system to fight cancer, infections, and other diseases." IVIG is precisely a treatment that restores the ability of the immune system to stave off such infections and diseases. Thus, IVIG should be considered a biologic response modifier, and CMS should state clearly that hospitals bill for administering the product using the CPT codes applicable to biologic response modifiers.

Further, IVIG is a therapy of high complexity to administer. In addition to physicians, there are requirements for infusion nurses to monitor treatment, including checking for vital signs frequently and being vigilant for adverse events. At the September 23rd HHS/CMS meeting held in Secretary Leavitt's office with the IVIG Summit Group, a leading physician, representing the American Academy of Allergy, Asthma and Immunology, and an experienced infusion nurse, described in detail the complexity of administering IVIG and stated that it was more complex than some chemotherapy and other BRMs they administer, which are reimbursed a higher BRM rate. The payment rate associated with a BRM is the minimum that they reported needing, but it is possible that the IVIG community will seek to come back for further refinement in 2007.

The determination of IVIG as a biologic response modifier is consistent with the CMS definition and the Medicare Modernization Act. Such a classification will serve to help ease patient access to this life-saving therapy by allowing physicians greater reimbursement for its administration. We support CMS and the AMA addressing the administration costs associated

with highly complex biological therapies with new CPT codes, and request that this authority be exercised for IVIG.

Conclusion

IVIG patient access difficulty due to reimbursement has been widely reported, as CMS is undoubtedly aware. ZLB Behring seeks to partner with the communities that rely upon our therapies and with the government to craft reasonable and creative solutions for this situation. We believe that the proposals we have put forward meet that goal and are within CMS' administrative authority, and we urge the agency to reconsider and incorporate these remedies through a program memorandum. ZLB Behring is not advocating for the abandonment of ASP-based reimbursement. On the contrary, we are suggesting refinements so the methodology can work for unique plasma protein therapies, such as IVIG, and the challenges that are presented in their administration. It also is worth noting that HHS' own Advisory Committee on Blood Safety and Availability on September 19, 2005 again raised concern regarding access to IVIG caused by reimbursement and endorsed the types of approaches that we have outlined in this letter. We request that CMS consider the three solutions proposed (1. add-on payment; 2. brand-specific reimbursement and 3. classifying IVIG as a BRM) and implement them in combination in the final rule or in a program memorandum.

ZLB Behring applauds CMS for its actions regarding the Competitive Acquisition Program within the final rule and agrees with the sentiment put forward by the agency. We simply ask that for alpha$_1$-proteinase inhibitor, the agency reject any requests from CAP providers to supply the therapy. The CMS rationale for excluding single indication orphan therapies is valid with regard to patient access and is especially appropriate for alpha$_1$-proteinase inhibitor.

Thank you for the opportunity to comment on the final rule. Should there be any questions or if we may be of assistance, please feel free to contact either myself or Patrick Collins (610-878-4311). Your consideration of these comments in the formulation of the final rule is greatly appreciated.

Sincerely,

Dennis Jackman
Senior Vice President, Public Affairs

5

JCAAI

DEC 16 2005

Joint Council
of Allergy,
Asthma and
Immunology

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December 12, 2005

Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Re: Physician Fee Schedule for CY 2006; Final Rule with Comment; CMS 1502-FC

Dear Dr. McClellan:

We appreciate the opportunity to submit comments on the Medicare Physician Fee Schedule CY 2006 final rule with comment period as published in the November 21, 2005 Federal Register. The Joint Council of Allergy, Asthma and Immunology is an organization sponsored by the American Academy of Allergy, Asthma and Immunology (JCAAI) and the American College of Allergy, Asthma and Immunology. It represents the interests of over 4,500 physicians who are board-certified in allergy and immunology.

Education and Training for Patient Self-Management

We disagree with CMS' decision that the new education and training for patient self-management codes (CPT codes 98960-98962) are not covered by Medicare. CMS does not support this determination with any rationale; nor are we aware of any. The new codes describe educational and training services prescribed by a physician and provided by a qualified nonphysician health professional using a standardized curriculum. They clearly come within the definition of a

service "furnished as an incident to a physician's professional service" as defined in Section 1861(s)(2)(A) of the Act and consequently are covered under Medicare Part B. Further, there is nothing in section 1862 of the Act which would exclude them from coverage.

Coverage of these codes is critical to the delivery of optimal and cost-effective asthma care. Asthma affected an estimated 14.9 million persons in the United States in 1995 and was responsible for over 1.5 million emergency department visits, about 500,000 hospitalizations and over 5,500 deaths in that year. Estimated direct and indirect monetary costs for the disease were $11.3 billion in 1998 with hospitalizations accounting for the single largest portion of total costs. [1]

An essential component of an effective asthma treatment plan is instructing the patient in self-management, including medication management, exercise, and environmental controls. The National Asthma Education and Prevention Program coordinated by the National Heart Lung and Blood Institute (NHLBI) of the National Institutes of Health, in its Expert Panel Report 2, *Guidelines for the Diagnosis and Management of Asthma,* includes patient education as one of its four disease-management strategies necessary to keep asthma under control and improve the quality of life for people with the disease. See http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf. Further the efficacy of patient education in controlling and preventing asthma is well documented in the medical literature. [2]

In addition, timely and appropriate asthma education has been shown to prevent hospital admissions, reduce the number of outpatient visits, and reduce overall health care costs. [3] In one study, participation in an education program reduced hospitalizations by 60% and

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[1] Data Fact Sheet, Asthma Statistics. National Institutes of Health, National Heart, Lung and Blood Institute, http://www.nhlbi.nih.gov/health/prof/lung/asthma/asthstat.pdf.

[2] See, for example, Cote J, Cartier A, et.al., Influence of asthma education on asthma severity, quality of life and environmental control. Canadian Respiratory Journal 2000 7:5; 395-400; Clark N, Partridge M. Strengthening Asthma Education to Enhance Disease Control. Chest 2002; 121; 161-1669.

[3] Castro M, Zimmermann NA, Crocker S, Bradley J, Leven C, Schechtman KB. Asthma intervention program prevents readmissions in high healthcare users. Am J Respir Crit Care Med 2003 November; 168: 1095-99; George MR., O'Dowd LC, Martin I, Lindell KO, Whitney F, Jones M, Ramondo T, Walsh, L, Grissinger J, Hansen-Flaschen J, Panettieri RA Jr. A comprehensive educational program improves clinical outcome measures in inner-city patients with asthma. Arch Intern Med 1999 Aug 9 23; 159(15): 1710-6. Gibson PG, Coughlan J, Wilson AJ, Abramson M, Bauman A, Hensley MJ, Walters EH. Self-management education and regular practitioner review for adults with asthma. Cochrane Database Sys Rev 2000; (2): CD001117; Mayo PH, Richman J, Harris HW. Results of a program to reduce admissions for adult asthma. *Ann Intern Med* 1990 Jun 1; 112(11): 864-71.

saved $6,462 per patient. [4] In another study involving children, education to improve asthma management reduced hospitalizations saved $11.22 for every $1.00 spent. [5]

Given the current focus on quality and the practice of cost-effective medicine, it makes no sense for CMS to deny coverage for asthma education.

In summary, we believe patient education and training for self-management is a service covered by Medicare Part B and, therefore, should be paid under the physician fee schedule. Further, coverage of these services will, as demonstrated above, improve care for Medicare beneficiaries and reduce costs to the Medicare program. Therefore, we urge that the agency reconsider its decision that these services are not covered by Medicare.

Failure to implement practice expense supplemental survey data

JCAAI is very disappointed that CMS has decided not to implement the supplemental survey data it submitted. The survey was submitted by the deadline set forth in section 414.22 of the regulations and met CMS precision criteria. CMS proposed to accept and use the data in the CY 2006 proposed rule published in August of 2005. That data demonstrated that the practice expense per hour for the specialty of allergy and immunology is $233.70/hour – a rate that is 30% higher than the data CMS is currently using. Further, the new survey represents data from 154 physicians – approximately five times the number in the existing SMS survey data currently used by CMS.

JCAAI undertook the survey because it believed the SMS data currently used to determine PE-RVUs was based on too small a sample size and was not accurate. In addition, the scaling factors which are derived from the SMS data resulted in many allergy services (e.g., the allergy immunotherapy and venom immunotherapy services) being substantially discounted, to the point where Medicare reimbursement did not even equal *direct costs* of providing the service – not to mention indirect costs. When JCAAI met with CMS staff in 2003 to discuss this problem, CMS staff suggested that problems related to the scaling factors could best be addressed by undertaking a practice expense survey. Now, having followed the agency's suggestion, and having spent significant time and resources in conducting a survey, CMS refuses to use it even though it meets the published criteria. Consequently, allergy services continue to be under-compensated as a result of incorrect scaling factors attributable to the faulty SMS data. What is particularly disturbing is that CMS has made no commitment to ever using the new survey data.

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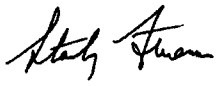
4 Zimmermann, note 3.

5 Clark, note 2.

JCAAI believes CMS has a legal obligation to use data that meet its criteria and that it must use the data as soon as possible. In enacting section 212 of the BBRA, Congress specifically intended that survey data that met CMS criteria be "used." Further, CMS' own regulations at 42 CFR § 414.22 state that data submitted by March 1 of 2005 would be considered for the FY 2006 PFS. Having concluded that the survey met CMS' published criteria, we do not believe the agency has the discretion to simply ignore it.

CMS' rationale for not implementing the survey data submitted by JCAAI, as well as several other specialties that also submitted surveys, is that the PE-RVUs published in the proposed rule were incorrect and consequently parties did not have an opportunity to comment. We understand the need to comply with APA rulemaking requirements of the Administrative Procedure Act; however, we believe CMS should simply correct the error, publish a new proposed rule for comment and implement a new final fee schedule sometime in the first quarter of 2006 which incorporates the new data. At the very least, we believe CMS must use the data in the CY 2007 physician fee schedule.

Sincerely,



Stanley M. Fineman, MD
President

AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.

December 15, 2005

DEC 16 2005

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

RE: CMS-1502-FC
Comments on Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule (70 Fed. Reg. 70116, November 21, 2005)

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 podiatric physicians and surgeons, is pleased to provide comments on the final rule that addresses Medicare Part B payment policy, including the physician fee schedule that is applicable for calendar year 2006. The APMA offers the following comments:

Practice Expense (70 Fed. Reg. 70134)

We support the decision by the Centers for Medicare & Medicaid Services (CMS) to withdraw its proposal to utilize a new bottom-up methodology for the calculation of direct practice expense (PE) for all services. We look forward to working with CMS in addressing practice expense issues for the future and are supportive of efforts by CMS to schedule a meeting with specialty societies so that the relevant issues can be more thoroughly explored and discussed. We look forward to participating in those discussions.

We realize that consideration is being given to surveying all specialties for current practice expense information. In recent years, several specialties have submitted supplemental surveys, which have been used to update PE data. While we understand that performing a survey of all specialties would be a significant undertaking, we believe there is value to obtaining new and updated information. We know that some discussions have occurred with the American Medical Association (AMA) regarding this project. The APMA is not a specialty society of the AMA and we urge CMS to take the steps necessary to ensure that non-MD/DO specialties are included in the process in a fair and equitable manner.

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Tel 301-581-9200 Fax 301-530-2752 http://www.apma.org

Payment for Splint and Cast Supplies (70 Fed. Reg. 70137)

We appreciate that CMS has decided to work with affected specialty societies and the RUC in clarifying issues related to Medicare payment policy and establish more appropriate amounts of casting/strapping materials for the relevant services of fracture management codes and casts and strapping application codes. The APMA is working cooperatively with other specialty societies through the RUC process in developing the requested recommendations. We thank CMS for providing the opportunity to develop recommendations using the traditional process.

Payment for Extracorporeal Shock Wave for Plantar Fasciitis (28890)

In February 2005, new CPT code 28890 *(Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia)* underwent RUC review. The APMA appreciates and supports CMS's decision to assign practice expense relative value units (RVUs) for the procedure when performed in the non-facility, as well as the facility settings. Since the procedure does not require the administration of general anesthesia and may safely be performed using a regional block, we believe it may appropriately be performed in the office setting. While we recognize that a differential exists between practice expense relative value units for the non-facility vs. the facility settings, we believe the PE relative value units are not sufficient to cover the actual costs associated with the performance of the procedure in the office setting.

While we acknowledge that a single payment scheme for the purchase or rental of the ESW equipment used in the procedure does not exist, we believe that expense to be higher than what has been calculated by CMS. According to data we have received, our member physicians pay a technical fee ranging from $700-$1500 each time the procedure is performed in the office setting. From what we have been told, some physicians pay the fee to the company owning the equipment while other physicians use a company that then bills the insurer directly for the technical portion of the procedure. If the office procedure will be reimbursed at approximately $342, the Medicare payment, which is expected to cover the physician work, practice expense and malpractice expense associated with the procedure, is insufficient. As a result, many physicians will decide against providing the service in the office setting and will instead select a more costly facility setting.

We contacted one of the companies delivering a high-energy, FDA approved Dornier Epos Ultra ESWT Lithotripter in an attempt to better understand the costs associated with the delivery of the rental equipment to a physician office so that we could better

understand why the technical fee is required. In response to our inquiry, the company identified the following costs associated with its technical fees:

EPOS Ultra High-Energy Lithotripter with ultrasound: $437,000
Specialized transport truck: $63,000
Service contract with manufacturer for Lithotripter: $39,000
Salary plus benefits for technologist/operator: $92,000
Salary plus benefits for transport driver: $50,000
Medical director's fee / part time: $36,000
Regional ankle block anesthesia: $250
Procedure supplies and physician training materials: $125
Malpractice and liability insurance: $10,000/year
Fuel cost/day: $67

While we are unable to verify these costs, we think they help demonstrate why a technical fee is required. At current levels, payment for the procedure does not cover the reported technical fee. We urge CMS to reconsider payments for 28890.

Pay-for-Performance

We continue to carefully monitor CMS activities related to pay-for-performance. We have reviewed the recently released G-codes and look forward to working with CMS in the development of performance measures that may appropriately be reported by podiatric physicians and surgeons. We realize that PFP is a work in progress and we are committed to working cooperatively with the agency in ensuring that podiatric physicians and surgeons are included in PFP activities.

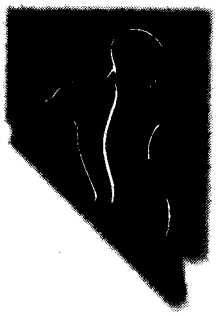
Conclusion

The APMA appreciates the opportunity to offer these comments. If you require additional information, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

Harold B. Glickman DPM

Harold B. Glickman, DPM
President



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DEC 19 2005

December 8, 2005

Centers for Medicare and Medicaid Svcs.
Department of Health and Human Svcs.
Attention: CMD-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

RE: Physician Reimbursement for Kyphoplasty/New CPT Codes

To Whom It May Concern:

I am a Fellowship Trained Spinal Surgeon. My private practice is based in a multidisciplinary spine center. I also maintain academic affiliations with two university centers. I have had the opportunity over the last four years to perform nearly 300 kyphoplasty procedures. My own personal experience echoes that reported in the literature. Specifically, kyphoplasty is the most consistently successful spinal surgical procedure being performed world wide. The benefit to our patients has been great. Nearly all of them have received significant reduction in pain and have attained higher functional levels. This has allowed them to shorten their hospital stays or eliminate hospital stays completely. Unfortunately with the new CPT Code and reimbursement rates it will no longer be economically feasible for me to perform this procedure for my patients. I fear that if it was the intention of Medicare and Medicaid Services to save money by reducing the reimbursement rate; that in fact this strategy will backfire and costs will increase. Costs will increase because kyphoplasty, which is proven to be cost effective in reducing the length of hospital stay, medication usage and rehabilitation time will no longer be performed. Instead patients will be treated on the old medical model which provided for prolonged bed rest, analgesics and the concomitant complications which accompanied that treatment.

It is also important to note that the new reimbursement rates virtually equate kyphoplasty reimbursement to that of a vertebroplasty. The procedures are dramatically different in what they can accomplish, as well as in the degree of technical difficulty and time involved in performing the procedure. Kyphoplasty not only stabilizes the fracture, as does vertebroplasty, but kyphoplasty may also reduce the fracture, restore vertebral height and decreased kyphosis. These are all important considerations in decreasing pain levels, returning function, and decreasing the incidence of additional fractures.

The proposed reimbursement rates simply do not provide for adequate reimbursement for the time and risks involved in taking care of these generally fragile patients and

SURGERY

James R. Rappaport, M.D.
Spinal Surgeon
Board Certified
Fellowship Trained
Specializing – Micro Surgery of the Spine
Asst. Clinical Professor – University of CA San Francisco
U.S. Ski Team Physician

Phelps C. Kip, M.D.
Spinal Surgeon
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Specializing – Micro Surgery of the Spine
Orthopaedic Surgery
U.S. Ski Team Physician

James H. Olson, M.D.
Fellowship Trained Spine Surgeon
Orhopaedic Surgeon
Board Eligible

PHYSICAL MEDICINE AND REHABILITATION

Robert G. Berry, M.D.
Board Certified
Physical Medicine & Rehabilitation
Electrodiagnostic Medicine
Pain Management
Specializing in Non-operative disorders

Christopher D. Twombly, M.D.
Board Certified
Physical Medicine
Physical Rehabilitation
Electrodiagnostic Medicine

Dallin L. DeMordaunt, M.D.
Board Eligible
Physical Medicine
Physical Rehabilitation
Electrodiagnostic Medicine

performing the kyphoplasty. Since performing a kyphoplasty will now represent an economic loss to the physician performing that procedure, I would expect the number of kyphoplasty procedures to drop dramatically. This is a shame as the kyphoplasty procedure has demonstrated its benefit to thousands of patients, as well as its excellent safety profile. I am afraid that this new policy will simply result in a return to a higher incidence of pain and suffering and higher cost of providing care for these patients with osteoporosis and compression fractures.

Kyphoplasty represents a paradigm shift in the way fractures in the spine have been managed and in the way fractures in other areas of the body can be managed. It is unfortunate that this excellent technique will see much less usage as the result of a short-sighted, penny-pinching administrative decision.

Sincerely,

James R. Rappaport, M.D.
6630 S. McCarran Blvd. #A4
Reno, NV 89509
JRR:cj

L O T U S
UROLOGIC GROUP

KAREEM A. ZAKI, M.D.

8

DEC 19 2005

December 15, 2005
To whom it may concern:

I am writing to you today to plead with the CMS to reconsider its decision to withdraw the recent Urology Practice Expense increase.

You will undoubtedly receive many of these letters. I am sure that you have also considered many angles for this debate and I respect your decisions and the responsibility you have to bare. However, I urge you to see how vital this is for many urology practices in the country. There is a real and grave crisis in medicine today. Many urologists are fighting to keep their clinic doors opened. We are constantly losing income while overhead and malpractice insurance rise. As reimbursement continues to drop and expenses sore, the point when these two lines intersect will inevitably mean that we have to close our doors. Many have tried to see more patients and do more surgeries to make up for lost revenue and simply maintain the status quo. But as you know, that can only go so far without jeopardizing the quality of care. Unfortunately, a few physicians have even resorted to choosing to perform lesser procedures because they are more lucrative.

As a physician, I am fighting for my survival and my patients well being. I detest having to make choices between what is good business as opposed to what is best for my patient.

Please, I implore you to reconsider your decision. Please help us maintain the standard of care in our country.

Thank you for your time and consideration.

Sincerely,

Kareem Zaki, M.D.
Lotus Urologic Group

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SANTA BARBARA • SANTA CRUZ

DEC 19 2005

DEPARTMENT OF UROLOGY

Please Reply to: RALPH V. CLAYMAN, M.D.
PROFESSOR AND CHAIR
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Mark McClellan, M.D., Ph.D.,
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Doctor McClellan,

To be sure, you will be receiving multiple letters with the following text objecting to the rescinding of the long overdue increases in reimbursements to Urologists for their efforts in behalf of their patients. The continued erosion of appropriate reimbursement for services is having several negative effects on health care in the country, especially with regard to Urology. Firstly, on the back end, it is encouraging more urologists to retire either from the surgical suite or from Urology entirely at an earlier age, while on the front end, it is discouraging bright, energetic medical students from seeking a career in Urology. Secondly, the miserly reimbursement for major Urological surgery complemented by the exorbitant reimbursement for office procedures is pushing more and more urologists to shun the operating room in preference for the office suite. As a result, we are beginning to see the evolution of a two-tiered system of office urologists and operating urologists. The latter, bear the stress of the operating room and the significantly more complex patient care with a reimbursement schedule that is truly unfair. How CMS can justify paying a urologist a professional fee of $1800 to deliver an in office microwave therapy to the prostate which requires all of 30-45 minutes in an office setting and no stress on the part of the physician and no postoperative care of which to speak and then pay that same amount to a surgeon performing a complex laparoscopic radical nephrectomy in a high risk individual with kidney cancer is beyond my ken. Indeed, the latter requires upwards of 3-4 hours of operating time, tremendous skill on the part of the surgeon, and a minimum of 2-3 days of postoperative care along with the subsequent office visits (all of which are "covered" by the $1800 professional fee). Truly, this is a travesty and one that will "come home to roost" as operating surgeons are going to become fewer and patient waiting time for important cancer surgery by truly competent urologists is already growing. Somehow this glaring inequity needs to be corrected. Already, operating Urologists are beginning to reject all insurance and Medicare in preference for a "cash" only policy; this is not a healthy trend for the nation. Now is not the time to be reducing reimbursement to our overworked and under rewarded surgeon population.

As a practicing urologist on the front lines of Medicare, I appreciate that CMS "accepted" the AUA's supplemental practice expense data and used the data to calculate the 2006

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DEPARTMENT OF UROLOGY

Please Reply to: RALPH V. CLAYMAN, M.D.
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practice expense relative value units for the urology drug administration CPT codes, as required by the Medicare Modernization Act (MMA). However, CMS did not fully comply with the MMA, as the MMA required that CMS "use" urology's supplemental practice expense data to calculate the 2006 practice expense relative value units for ALL urology procedures, not just for urology drug administration.

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

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

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

Sincerely,

Ralph V. Clayman, M.D.
Professor and Chair
Department of Urology

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Oregon Urology
SPECIALISTS

DEC 19 05

Robert B. Litin, M.D.
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Peter W. Bergreen, M.D.
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December 15, 2005

Centers for Medicare &
Medicaid Svcs
Dept of Health & Human Svcs
ATTN: CMS-1502-FC
P O BOX 8017
Baltimore MD 21244-8017

RE: CMS withdrawal of proposed urology practice expense increases

To Whom It May Concern:

You are making it increasingly difficult to provide service to the Medicare population. With the cost of our providing services constantly increasing, you are creating a situation where Medicare patients will not be given access to the medical system.

Sincerely yours,

PETER W. BERGREEN, M.D.

PWB:bjm

AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.

December 16, 2005

DEC 21 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-FC
P.O. Box 8016
Baltimore, MD 21244-8018

RE: CMS-1501-FC
Comments on Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Final Rule (70 Fed. Reg. 68516, November 10, 2005)

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 podiatric physicians and surgeons, is pleased to provide comments on the final rule that revises the Medicare hospital outpatient prospective payment system. The APMA offers the following comments:

Payment for Extracorporeal Shock Wave for Plantar Fasciitis (28890)

The Centers for Medicare & Medicaid Services (CMS) has assigned new CPT code 28890 *(Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia)* to Ambulatory Payment Classification (APC) 1547, which has a payment rate of $850. The APMA is concerned that this APC does not adequately reimburse for the costs associated with the performance of the procedure.

Specifically, our concerns relate to payments for the "technical fee" commonly charged for the rental of the ESW equipment. According to information we have received, our member physicians are aware of technical fees ranging from $700-$1500 each time the procedure is performed. In the office setting, the physician either pays the fee directly or the company bills the insurer. It is our understanding that a technical fee is also charged when the procedure is performed in the facility setting. We are concerned that if the APC payment rate is $850, it may be insufficient to appropriately reimburse for the costs associated with the performance of the procedure, including technical fees, in the outpatient setting.

We do not have actual cost data for supplies and equipment used in the outpatient setting and we acknowledge that there is variability in the technical fees. We realize that the

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assignment of an APC to any procedure is an involved process and that CMS does not rely solely on any single source of information in determining an appropriate APC. We are concerned, however, that the current payment levels may be insufficient for the procedure and urge CMS to reconsider the APC for 28890 in the outpatient setting.

Conclusion

The APMA appreciates the opportunity to offer these comments. If you require additional information, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

Harold B. Glickman DPM

Harold B. Glickman, DPM
President

DEC 2 1 2005

J. D. Williams, M.D.

2463 Legends Way
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Phone: (859) 331-7213
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Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Att: CMS -1502-FC
P.O. Box 8017
Baltimore, MD 21244-8017

Dear Dr. McClellan,

I am a practicing urologist. I certainly have compassion for the arduous task that faces all who manage health care expense. However, I am equally upset with the recent decision to accept the data by the AUA's supplemental surveys relative to an update on practice expenses but not utilize the information to calculate the 2006 practice expense relative value units for ALL urological procedures. I understand that the Medicare Modernization Act (MMA) mandated such data be utilized. This appears to me to be in violation.

You see, physicians have been carrying the burden of giving to the needs of our patients while suffering unfairly the financial shortfalls of a budgetary driven medical delivery system. Congress recognized some of the unfairness and has reacted with MMA. I appeal to you to reconsider the survey data for adjustments in 2007 and beyond.

Sincerely yours,

James D Williams, MD

James D. Williams, M.D.
The Urology Group
20 Medical Village Dr.
Edgewood, KY 41017

DEC 2 1 2005

Dr. T. K. Slabaugh
2132 Island Drive
Lexington, KY 40502

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

Dear Doctor McClellan,

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

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

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

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

Thank you,

Thom K Slabaugh

DEC 2 1 2005

JOHN S. F. DALY, M.D.

Grace Urological Inc.

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December 16, 2005

Mark McClellan, M.D., PhD
Administrator
Center for Medicare Medical Service
Dept. Health & Human Services
ATTN: CMS-1502-FC
PO Box 8017
Baltimore, MD 21244-8017

Dear Mark,

I practice urology in Brattleboro, Vermont and am the busiest urologist in the southeastern part of the state. As you know, we get paid very poorly, compared to the national standard and my income, as low as it has been in the past, has been cut by 1/3 to ½. I have been in practice 30 years and would like to continue for another 10 years. However, it is beginning to not make any sense. Your recent cuts for practice expense and inability to implement payment for the huge increases in the costs of medical care are making it attractive for me to simply quit. This would indeed be a great loss, not only to me, but the people of southern Vermont. There are no urologists who want to come to this state. I have been looking for one for ten years.

It is interesting that the government now wants us to use the electronic medical record. Forget it. Who is going to pay for it? Just this past year, I have acquired a series of computers that allow me to view CT scans, done at our local hospital, minutes later here in my office. For that ability, I have paid $15,000, which clearly will never be reimbursed to me. Our system continues to be broken and gets worse every day. I strongly urge CMS to do whatever is necessary to assure that the AUA's supplemental PE data will be used quickly, so that I might be encouraged to continue practicing medicine.

Thank you for your consideration of these matters.

Sincerely,

John S. F. Daly, M.D.

AMERICAN SOCIETY OF PLASTIC SURGEONS

PLASTIC SURGERY EDUCATIONAL FOUNDATION

DEC 23 2005

15

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December 27, 2005

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

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Final Rule

Dear Dr. McClellan:

The American Society of Plastic Surgeons (ASPS) is the largest association of plastic surgeons in the world, representing surgeons certified by the American Board of Plastic Surgery. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, and cancer. ASPS promotes the highest quality patient care, professional, and ethical standards and supports the education, research and public service activities of plastic surgeons.

ASPS offers the following comments on the Centers for Medicare and Medicaid Services (CMS) Final Rule with comment period for "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006" (CMS-1502-FC) that was published in the November 21, 2005 *Federal Register*. As requested in the Final Rule, the relevant "issue identifier" is used as a sub-heading throughout this letter to assist the Agency in reviewing these comments.

Work Relative Values

The American Society of Plastic Surgeons (ASPS) would like to thank the Centers for Medicare and Medicaid Services (CMS) for recognizing the physician work involved with CPT codes, 97605 (*Negative pressure wound therapy (for example, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 sq cm)* and CPT 97606 (*Negative pressure wound therapy (for example, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 sq cm.* The Society greatly appreciates that CMS approved coverage of NWPT and also accepted the RUC's recommendation of 0.55 work RVUs for CPT 97605 and 0.60 work RVUs for CPT 97606.

In addition, ASPS would like to thank CMS for accepting 100% of the RUC recommendations for Work RVUs for the 41 new and revised CPT free skin graft codes submitted by the American Society of Plastic

Surgeons and the American Burn Association this year. These new and revised codes will describe the various application techniques that are available today for the treatment and healing of extensive burn and skin wounds.

Miscellaneous PE Issues

ASPS appreciates the Agency's consideration in accepting the PEAC's recommendation to include the cost of a moulage kit as part of its practice expense payment for CPT code 19396 (*Preparation of moulage for custom breast implant*) (Table 14:SA090).

Professional Liability Insurance (PLI) Relative Values – Dominant Specialty for Low Volume Codes

Finally, the ASPS would like to comment on its recommendation to CMS regarding dominant specialty for low volume codes. After an exhaustive review of 1,844 codes with utilization less than 100 Medicare claims per year, the RUC forwarded a suggested dominant specialty for each of these low volume codes to CMS and suggested the use of this list as a substitution for claims data. CMS has indicated that in most cases, the dominant specialty suggested by the RUC is reflected as the specialty with the highest utilization in the most recent dataset. This may be true, however, these errors in claims will impact low volume codes differently each year. We respectfully request that CMS should not rely on claims data to determine the appropriate PLI specialty risk factor for these very low volume codes, but instead use the list as developed by the RUC.

As always, we appreciate the opportunity to offer these comments to CMS. We look forward to the work ahead in 2006 to further improve the RBRVS.

Sincerely,

Deborah S. Bash, MD
Chair, ASPS Payment Policy Committee

CC: Bruce L. Cunningham, MD, President

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DEC 27 2005

The Coalition for the Advancement of Prosthetic Urology
1301 K Street, N.W., Suite 1100
Washington, DC. 20005
202-414-9241

December 22, 2005

VIA EXPRESS MAIL

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1502-FC: Changes to the Physician Fee Schedule for CY 2006
Prosthetic Urology – Practice Expense RVUs and Malpractice RVUs

Dear Administrator McClellan:

The Coalition for the Advancement of Prosthetic Urology (CAPU[1]) is submitting comments on the Centers for Medicare & Medicaid Services (CMS) final rule on "Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule for CY 2006," as published in the November 21, 2005 *Federal Register*. CAPU supports the efforts of the CMS to provide the best health care to Medicare beneficiaries in a cost-effective manner vis-à-vis prospective payment systems such as the physician fee schedule. Prospective payment systems are an appropriate means of controlling costs, encouraging efficiency and predictability for physician services. However, payment under the physician fee schedule must be reasonable and fair and must not limit access or discourage the provision of appropriate high-quality care for particular types of services.

We are concerned that the Centers for Medicare and Medicaid Services did not use the supplemental survey data provided to it by the American Urological Association (AUA) to calculate the 2006 practice expense relative value units for all urology procedures. The Coalition's comments and recommendations are briefly summarized as follows:

RE: Practice Expense

Accordingly, CAPU recommends that CMS:

- **Adopt urology's supplemental survey data to calculate the practice expense relative values units (RVUs) for all urology procedures, not just the drug administration services and to issue these re-calculated RVUs via a correction notice in the Federal Register, as soon as possible. The supplemental practice expense survey conducted by the AUA better represents the costs associated with operating a urology practice than the American Medical Association SMS data that CMS has used to establish current RVUs.**

[1] CAPU is an organization responsible for establishing unified prosthetic urology policy on matters affecting th prosthetic urology industry. CAPU's members include leading urologists and manufacturers.

The Coalition for the Advancement of Prosthetic Urology
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- **Hold meetings on this topic in January 2006 and ensure that all interested parties, such as CAPU, are included in these deliberations regarding the use of supplemental survey data to calculate practice expense RVUs. A survey conducted by CAPU also demonstrates that non-scaled CPEP/PEAC clinical staff time are more representative of the actual more typical time spent by clinical staff in a typical prosthetic urology practice.**

Background – Practice Expense:

Prosthetic urology procedures encompass the surgical inventions that utilize implantable devices to treat patients with urinary incontinence and erectile dysfunction. These surgical interventions are often the last and only option for effective treatment of these disorders for approximately 10,000 Medicare patients each year. Prosthetic urology procedures have a 90-day global period. As such, Medicare considers payment for the procedure to include the surgical procedure and all services that are provided within the global (90-day) period.

Practice Expense RVUs

The results of the CAPU survey demonstrate that there is a significant difference between the clinical staff time reported and the scaled clinical staff time that CMS has used from 1999 – 2005 in their calculations for the direct costs. The CAPU survey demonstrated that the total number of post-operative clinical staff time minutes is at least 30-40% higher than the inputs listed in the CMS PE database.[2]

Post-op visits for urinary sphincters and penile prosthesis involve activating the device and teaching the patient how to operate the device, especially the pump component. These visits involve considerable physician and nursing staff time. In addition, in spite of the training provided in the office, it is common that such patients frequently call with additional questions or need reassurance. Finally, we also wish to emphasize that although there may be a few exceptions, other surgical procedures do not involve post-op components similar to this type of device activation or this level of post-op teaching.

Consequently, to provide fair and reasonable reimbursement for prosthetic urology procedures, CAPU supports the AUA in its request to CMS that it use urology's supplemental practice expense data to calculate the 2006 practice expense RVUs for all urology procedures.

CAPU has been concerned for the last **six years** that many of the urologists specializing in prosthetic urology procedures would not be able to continue to offer these procedures due to the heavy financial burden and lack of appropriate payment rates. The AUA exercised the option on behalf of itself and all the urology sub-specialty organizations to submit PE supplemental survey data under the good-faith assumption that if its survey met the criteria established by CMS, the data would be used to adjust urology's practice expense cost data to better reflect the costs used to determine PE RVUs. The fact that CMS had an error in its computer program causing all the PE RVUs in the proposed rule to be incorrect should not inhibit CMS was still using the AUA data and then issuing a correction notice in the Federal Register.

---

[2] CAPU survey results for a comparative group of three prostate surgical procedures were consistent with CMS PE database and basically appropriate and reflective of actual practice.

The Coalition for the Advancement of Prosthetic Urology
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Therefore, CAPU urges CMS to incorporate urology's supplemental survey data into the practice expense relative values units (RVUs) for all urology procedures, not just the drug administration services and to issue these re-calculated RVUs via a correction notice in the Federal Register, as soon as possible. The supplemental practice expense survey conducted by the AUA better represents the costs associated with operating a urology practice than the American Medical Association SMS data that CMS has used to establish current RVUs.

As always, we look forward to working with CMS to address these important issues. If CAPU can provide CMS with additional information, please do not hesitate to contact Jill Rathbun, at 703-486-4200 or Gail Daubert at 202-414-9241.

Sincerely,

John J. Mulcahy, MD
Chair

cc: Dr. Jim Regan, Chairman of Health Policy Council, AUA
CAPU Board Members (via email only)

AMS
Solutions for Life

DEC 27 2005

10700 Bren Road West
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December 22, 2005

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26.05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS -1502-FC**; Final Changes to the Physician Fee Schedule for Calendar Year 2006

Dear Dr. McClellan:

American Medical Systems ("AMS") appreciates the opportunity to comment on the Final Rule with comment for the 2006 Medicare Physician Fee Schedule (MPFS), CMS-1502-FC.

AMS is a leader in medical devices and procedures to treat urological and gynecological disorders such as erectile dysfunction ("ED"), urinary incontinence, and menorrhagia. Although not life-threatening, these disorders can greatly affect one's quality of life and social relationships. As such, AMS is very concerned that the Centers for Medicare and Medicaid Services did not use the supplemental survey data provided to it by the American Urological Association (AUA) to calculate the 2006 practice expense relative value units for all urology procedures. Our comments are intended to ensure that MPFS payments for urology services supports high quality care for Medicare patients.

AMS is also a member of the Coalition for the Advancement of Prosthetic Urology ("CAPU"). CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology. AMS supports CAPU's comments on the proposed final rule with comment for 2006 and wishes to emphasize the following points.

Our recommendations are summarized briefly below:

- **We urge CMS to use urology's supplemental survey data to calculate the practice expense relative values units (RVUs) for all urology procedures, not just the drug administration services and to issue these re-calculated RVUs via a correction notice in the Federal Register, as soon as possible.**

- **AMS encourages CMS to hold meetings on this topic in January 2006 and to ensure that all interested parties, such as CAPU, are included in these deliberations regarding the use of supplemental survey data to calculate practice expense RVUs.**

RE: Practice Expense

AMS Joins with CAPU and in the AUA in urging CMS to move forward in good faith to incorporate the supplemental practice expense survey data collected by the AUA and validated by CMS. We are concerned that an error CMS' computer program causing almost all of the practice expense RVUs in the proposed rule to be incorrect is the reason that CMS is now not incorporating urology's supplemental survey data. We believe that CMS issuing a correction notice would have been a more appropriate way to handle this versus what is now occurring in that physicians seem to be losing payments that are rightfully due them.

We feel that the urology community followed CMS' instructions and exercised its option, an option given to all specialties, and submitted practice expense data under the good-faith assumption that it the survey instrument and data met the criteria established by CMS, that the data would be used to adjust urology practice expense cost data to more accurately reflect the costs to conduct each type of urologic procedure and thus the practice expense RVUs would be more accurate.

Use of the AUA submitted data will ensure that the time and practice expense costs involved in providing the actual service and post-service care are captured and reimbursed. AMS has been concerned for the last six years that many of the urologists specializing in prosthetic urology procedures may not be able to continue to offer these procedures due to a lack of financial viable under current payment rates. Furthermore, the continued viability of the sub-specialty of prosthetic urology definitely appears to be in jeopardy. The use of scaling factors in the "Top-Down" practice expense methodology, coupled with incomplete cost data has caused prosthetic urology procedures to be dramatically "under valued and under paid." Specifically, the current scheme, inappropriately reduces by half the clinical staff practice expense costs that are used to provide care during the post-operative visits.

Post-op visits for urinary sphincters and penile prosthesis involve activating the device and teaching the patient how to operate the device, especially the pump component. These visits involve considerable physician and nursing staff time, yet much of this activity is not captured in CMS' existing practice expense data. In addition, in spite of the training provided in the office, it is common that such patients frequently call with additional questions or need reassurance.

Therefore, we strongly recommend that CMS incorporate the supplemental AUA data and thereby correct the negative "under payment" situation which in turn may facilitate Medicare beneficiary access to these services.

***

Again, AMS thanks CMS for the opportunity to provide comments on the Final Rule with comment on Medicare Physician Fee Schedule Changed for 2006. If you have any questions regarding these comments, or if you would like additional information, please contact Gary Goetzke at 952-930-6155 or Jill Rathbun at 703-486-4200.

Sincerely,

John Nealon
Senior Vice President
Business Development

Gary Goetzke
Senior Director
Health Care Affairs

cc: Dr. John Mulcahy, Chairman, CAPU
Dr. Jim Regan, Chairman, Health Policy Council, AUA

18

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DEC 27 2005

December 22, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1502-FC - Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8017

Dear Dr. McClellan:

The American College of Cardiology (ACC) is a 30,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC is pleased to offer comments on the notice of proposed rulemaking entitled **Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B; Final Rule [CMS-1502-FC]** published in the *Federal Register* on November 21, 2005. Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal.

Supplemental practice expense data

The ACC is disappointed that CMS did not implement the proposal to use the supplemental survey data submitted by seven specialties.

We believe that CMS should make use of the best available data in determining the practice expense RVUs. The data have met higher standards for precision and are more representative of these specialties than the SMS data being used now. A good faith effort to use the data as soon as possible is important to maintaining the public-private partnership that has been so effective in improving the RBRVS. Moreover, we believe that CMS's failure to use these data is inconsistent with the intent of section 212 of the BBRA, which directs to CMS to establish a process for accepting and using "to the maximum extent practicable and consistent with sound data practices" supplemental practice expense data. Congress clearly intended that CMS use such data.

Staff of the ACC, along with representatives of several other organizations that have submitted supplemental practice expense surveys, met with CMS staff in late November to discuss options for the supplemental surveys. We are grateful for the time and thoughtful discussion about how to proceed. The ACC would like to offer additional comments on several of the issues discussed in that meeting.

Timeline for using supplemental data

The ACC was somewhat reassured to learn from CMS staff that no decision has been made to never use the supplemental data. Nevertheless, we remain troubled by CMS's unwillingness to commit to or even discuss a specific timeline for implementing the supplemental data. The ACC urges CMS to develop specific plans for incorporating the supplemental data independent of any proposal for changes to the underlying resource based practice expense methodology.

Impact of error in proposed rule

CMS has stated, both in the Final Rule and in the November meeting, that because of an error in calculations for the RVUs published in the August 1 Proposed Rule many interested parties had no meaningful opportunity to analyze and comment upon the proposed methodology and RVUs. We urge CMS to publish the corrected RVUs and impact analyses as soon as possible. In addition to publishing correct RVUs for the August 1 proposal, CMS should also publish RVUs for other options such as using the supplemental survey data under the current methodology. Impact analyses should allow each specialty to analyze the impact of each component of propose changes separately. That is, CMS should construct tables that show, by specialty, the impact of: switching to a bottom-up methodology; eliminating the non-physician work pool, using the supplemental data, and any other options under consideration. We recommend that CMS provide this information prior to its planned Town Hall meeting on the practice expense methodology.

Multi-specialty survey

CMS has also expressed concern about the distributional and equity effects of using current practice expense data for some, but not all specialties. The Final Rule discusses briefly the possibility of conducting a multi-specialty practice expense at some point in the future. A multi-specialty survey equal in rigor and quality to the supplemental surveys already submitted to and accepted by CMS may well be a worthwhile endeavor. Such a survey would require a significant investment of time and funding. It would be fundamentally unfair and in conflict with Congressional intent to delay indefinitely implementation of the existing supplemental surveys until a multi-specialty survey can be fielded and implemented. The ACC will work with CMS and the physician community to develop plans for updating the practice expense per hour data for all specialties. We could not, however, support a proposal that would require either a significant delay in use of our data or investment of substantial additional resources from cardiology.

Non physician work pool

The non-physician work pool (NPWP) poses special issues for using cardiology's supplemental data. The ACC previously requested that CMS not use the cardiology supplemental data until the NPWP issues could be resolved. We must emphasize that any resolution to the NPWP issue or any change to the overall practice expense methodology that does not include use of the cardiology supplemental data is unacceptable to the ACC.

Multiple Procedure Payment Reduction for Diagnostic Imaging

The ACC continues to believe that CMS has overestimated the savings in practice expenses resulting from performing multiple diagnostic imaging services during the same patient care session. CMS has decided to proceed with the payment reduction, though it will be phased in over two years. We strongly encourage CMS to provide more detailed guidance to physicians concerning how claims for the affected procedures should be submitted. The guidance should provide specific instructions for using appropriate modifiers and determining correct allowed charges.

Thank you for the opportunity to comment upon this final rule. The ACC appreciates CMS' continued willingness to work cooperatively with the physician community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Rebecca Kelly, ACC's Director of Regulatory Affairs at 301-498-2398 or rkelly@acc.org with any questions.

Sincerely,

Pamela S Douglas

Pamela Douglas, MD, FACC
President