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# KIDNEY CARE COUNCIL

*Providers of Quality Care for the Nation's Dialysis Patients*

October 10, 2006

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

Re: **CMS 1321-P:** Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Administrator McClellan,

I am writing on behalf of the Kidney Care Council (Council), formerly known as the Renal Leadership Council, to provide you with our members' comments regarding the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year (CY) 2007 (Proposed Rule). As you may know, the Council is a coalition representing the nation's dialysis providers who collectively provide life-saving care to more than 70 percent of the dialysis population.[1] We welcome the opportunity to comment on the Proposed Rule. We also appreciate the collaborative relationship that has developed over the years with Centers for Medicare and Medicaid Services (CMS), and we look forward to working with the CMS staff to ensure access to quality dialysis services for Medicare beneficiaries.

Overall, the Council is generally supportive of the ESRD-related provisions included in the Proposed Rule. It is apparent from the Proposed Rule provisions and the accompanying preamble explanation that CMS has taken into consideration many of the issues the kidney care community has encountered in years past. We appreciate the Agency's willingness to work with the community to ensure that its policies result in efficient and high quality care for patients with kidney failure.

Although generally pleased, we do have some concerns about the transparency of the methodology underlying the Proposed Rule. Specifically, we encourage the Agency to:

- Clarify the methodology it used in updating the drug add-on adjustment and ensure that the price and utilization estimates are based on accurate data or are indexed appropriately;

[1]See Attachment A for a list of the members of the Council.

- Clarify that separately billed drugs for CY 2007 will be reimbursed at Average Sales Price (ASP)+6 percent;

- Outline the methods used to develop the budget neutrality calculation for the geographic wage index; and

- Implement the MedPAC recommendation to equalize the payments between hospital-based and independent dialysis facilities.

## I. ESRD PROVISIONS: The Council agrees that the drug add-on adjustment should be updated using a standard index, but is concerned about the methodology used to determine price and utilization.

The Council is pleased that CMS proposes using an index to update the drug add-on adjustment, consistent with the requirements of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The use of an index will provide a stable estimate of the increases that influence the update of the drug add-on adjustment. However, based upon the limited amount of information provided in the Proposed Rule, we are concerned that the proposed methodology is not based upon a reliable data series and may, in particular, result in an inaccurate assessment of the utilization of drugs that will affect the calculation of the update. Therefore, we urge the Agency to work closely with the kidney care community to develop an appropriate proxy that can be used until CMS has accurate price and utilization data. In addition, we strongly urge CMS to perform an adjustment to account for any forecasting error until CMS has stable data as it does with other reimbursement programs, such as the managed care program, to ensure that if estimates are not consistent with the actual price or utilization changes, there is a process to account for the differences and to ensure that facilities receive the appropriate reimbursement payments.

### A. CMS Should Clarify How It Arrived at the Proposed Producer Price Index of 4.9 Percent for Drug Prices

As a threshold matter, the Council is concerned about how the growth in drug prices is estimated in the calculation of the update to the drug add-on adjustment. We agree that the Producer Price Index (PPI) could potentially provide a stable and accurate estimate of price changes. However, the Proposed Rule states that CMS estimates the PPI to be 4.9 percent. We understand that CMS uses an outside consultant to forecast the PPI. Even so, we are concerned that the forecast of 4.9 percent does not appear to be consistent with other data. For example, the reported PPI 2006 through September is 6.3 percent. Looking at the 2004/2005 PPI would result in 5.1 percent. If these figures were used, there would be significant differences in the update to the drug add-on adjustment. We encourage CMS to work with the Council to evaluate the differences between the figures in the Proposed Rule and independent data sources to ensure that the appropriate price forecasting method is used in calculating the update to the drug add-on adjustment.

### B. CMS Should Clarify the Utilization Estimate

A second important factor in calculating the drug add-on adjustment is estimating the utilization changes. In this regard, the Council also has questions about the data and methodology CMS proposes to use to determine this estimate. We appreciate the Agency's need to estimate utilization because its current volume data based on Medicare claims is unstable and not suitable for purposes of calculating the update to the drug add-on adjustment. However, the methodology CMS uses to determine this estimate is not transparent. Given the importance of the utilization to the calculation of the update for the drug add-on adjustment, we encourage CMS to review the analysis provided by The Moran Company, which concludes that utilization rose modestly in 2005 over 2004.

The Moran Company, using the most recent data available from CMS, has reviewed the Proposed Rule and determined there is a minor discrepancy between the two analyses. However, even small differences have a significant impact on provider payments ultimately for the kidney care community. For example, when member companies of the Council estimated the change in price and utilization using their own internal data, they found a decrease in price of 13.2 percent and an increase in utilization of 1.8 percent. With these slightly different figures, the resulting drug add-on adjustment would be approximately 15.46 percent. A different data set would lead to different results as well.

Additionally, we are concerned about the Agency's conclusion that the new EPO Monitoring Policy (EMP) will decrease utilization of that biologic. As we have discussed with CMS previously, dialysis facilities do not prescribe EPO and, therefore, cannot control its utilization. However, our concern in this instance is that CMS is assuming the decrease in utilization without having actual data to support the conclusion. We urge CMS to examine the impact of the policy closely and to avoid basing payment policies on assumptions about how it may or may not change behavior.

If the pricing change is consistent with the assessment of The Moran Company, then the utilization is not flat and should result in a slightly higher update to the drug add-on adjustment. As these examples demonstrate, small changes result in important differences in the ultimate update to the drug add-on adjustment. Therefore, as described below, the Council urges CMS to adopt a more stable estimate by using a proxy for CY 2007. However, if CMS follows this approach it should, at a minimum, use the most recent data set available.

### C. CMS Should Work with the Council To Develop a Stable Utilization Estimate for CY 2007 and Establish a Mechanism to Allow for Forecasting Error Adjustments

Because of the difficulties associated with the estimates in the Proposed Rule, The Moran Company suggests that in the Final Rule CMS should (1) adopt an appropriate proxy of both price and utilization and (2) establish a mechanism to adjust for forecasting error in prior estimates before calculating subsequent years' updates.

For CY 2007, the Council seeks to work with CMS to develop an appropriate proxy to establish a utilization estimate until volume trends stabilize. As described in The Moran Company report, we suggest using the Agency's own NHE projection for prescription drugs to ensure an accurate update to the drug add-on adjustment. The NHE is superior to the PPI because it includes both price and utilization. As The Moran Company indicates, although there are concerns about the NHE aggregate trend projection being prejudiced by Part D drug utilization, it is possible for the CMS Actuary to separate the Part B and Part D forecasts and use the Part B utilization as an index for the growth in ESRD drugs. Historically, ESRD and part B annual drug utilization changes have tracked closely. This proxy would be useful until CMS has credible ESRD trend data for both price and utilization. We encourage the Agency to work with The Moran Company and the Council to assess the possibility of using this index or another proxy that would ensure stable and reliable data *until* CMS's volume data is more stable and reliable and the Agency has addressed the data concerns related to the methodology of the Proposed Rule.

Regardless of the estimate or proxy CMS ultimately adopts, the Final Rule should contain a mechanism that would adjust for forecasting error adjustments of prior year estimates until the Agency has stable data. If either the price or utilization forecasts are incorrect, then CMS can take the correct numbers and use them to recalculate the volume or price before projecting for 2008. This mechanism should only need to be employed for one or two years until CMS has accurate utilization data.

As The Moran Company report notes and the discussion of the price and utilization estimates demonstrates, there are significant data difficulties that make forecasting price and utilization for ESRD drugs problematic. Because of these data problems, there is not a clear methodology that would allow CMS to construct accurate estimates for at least the next few years. Until the data regarding ESRD drugs stabilizes, it is important that CMS ensures that price and utilization are corrected on a prospective basis. As you know and as MedPAC has repeatedly recognized, Medicare margins for dialysis payment, including separately billable drugs, remain negative. Small changes in reimbursement rates have significant implications for the community. This fact coupled with the Agency's conservative indexing practices could lead to inappropriate long-term implications for the payment system if adjustments are not made. Again, we envision that this mechanism should be focused on correcting errors on a prospective basis and would be needed only until CMS has accurate volume data, most likely one or two years. For example, if the NHE estimate were not representative of the actual trend, CMS could fix it in the base. We strongly urge CMS to allow for forecasting error adjustment for this limited period, as it has done for managed care payments to health plans and other programs. Therefore, it seems appropriate for CMS to adopt a mechanism that would allow it to adjust for forecasting errors in prior price and utilization estimates before calculating the next year's update to assure that any incorrect estimating problems do not accumulate.

### D. CMS Should Incorporate Hospital Utilization Data in Its Calculation of the Drug Add-on Adjustment

Finally, the Council encourages CMS to collect cost data from hospital-based providers to enable accurate estimates of the costs of separately billable drugs in that setting. The Agency

acknowledged the importance of collecting this data in the Final Rule published last November. "We agree that the ideal approach would be to collect data from hospital-based facilities... We intend to pursue options for obtaining additional data to more accurately compute and update the drug add-on adjustment."[2] This approach is also consistent with MedPAC's recommendations.[3] This data will allow CMS to estimate the true drug add-on adjustment amount and the appropriate updates by incorporating the hospital-based provider data into the analysis as well. Therefore, we urge CMS to describe its data collection activities and how the data affect the calculation of the update to the drug add-on adjustment.

## II. ESRD PROVISIONS: CMS Should Provide More Transparency on the Calculation of the Budget Neutrality Factor for the Geographic Wage Index.

The Council continues to support the revisions to the geographic wage index. Yet once again, we are concerned with the lack of transparency in terms of the data and methodology used. Without this information, it is impossible to assess the accuracy of the budget neutrality calculation for the wage index calculation. Calculation of budget neutrality for the geographic wage index methodology proposal is a process that is subject to a number of possible variables. However, it is difficult to understand the methodology CMS has employed because the Proposed Rule does not explain the Agency's approach. Therefore, the Council encourages CMS to provide the data and methodology it used to calculate the budget neutrality factor in the Final Rule.

## III. ASP ISSUES: The Final Rule Should Explicitly State that CMS Will Reimburse Separately Billed Drugs at ASP+6 Percent.

In describing the reimbursement for separately billed drugs, the Proposed Rule states that drugs will be reimbursed "based on section 1847A of the Act." 71 *Fed. Reg.* at 49004. The text is clearer and states the reimbursement will be at 106 percent of ASP. We encourage the Agency to provide a clear, concise statement of the reimbursement rate in the preamble as well to ensure that there is no confusion because of the different wording.

## IV. ESRD PROVISIONS: CMS Should Implement the Medicare Payment Advisory Commission's Recommendation that the Composite Rate Be Equalized between Hospital-Based and Independent Dialysis Facilities.

The Proposed Rule notes the continued application of an approximate $4.00 differential in composite rate payments that favor hospital-based providers.[4] Consistent with our previous comments, the Council strongly urges CMS to follow the MedPAC recommendation to equalize payments between hospital-based providers and independent dialysis facilities. As MedPAC notes, the difference is the result of the Omnibus Budget Reconciliation Act of 1981, which "mandated

[2] 70 *Fed. Reg.* 70116, 70163 (Nov. 21, 2005).
[3] MedPAC, "Report to the Congress: Issues in a Modernized Medicare Program" 96 (June 2005).
[4] 71 *Fed. Reg.* at 49005.

separate rates for the two types of facilities."[5] Initially, "the Secretary attributed this $4 difference to overhead, not to patient complexity or case mix."[6] MedPAC concludes:

> The current payment method is not consistent with the Commission's principle of paying the costs incurred by efficient providers who furnish appropriate care, regardless of the care setting. Consequently, we reiterate our recommendation that the Congress eliminate differences in payment for composite rate services between freestanding and hospital-based facilities.[7]

As MedPAC recognizes, there is no longer a legitimate reason to pay hospital-based providers more than independent dialysis facilities. We appreciate that CMS would prefer to have Congress explicitly indicate that it supports this change as well. However, we continue to believe the existing statutory language provides sufficient authority to allow CMS to implement this change in the Final Rule. Specifically, Section 1395rr(b)(7) states that the Secretary must develop a composite rate payment system that, among other things:

> *differentiate*[s] between hospital-based facilities and other renal dialysis facilities and which the Secretary determines, after detailed analysis, *will more effectively encourage the more efficient delivery of dialysis services.*

(emphasis added). The language does not mandate that CMS provide a higher composite rate to hospital-based providers. Instead, it instructs the Secretary to engage in a "detailed analysis" that will ensure that the payment methodology encourages the more efficient use of dialysis services. As MedPAC has noted, the $4 differential payment does not appear to meet the efficiency requirement of the statute.

Without this change, CMS is sending mixed signals to providers by rewarding less efficient hospital-based providers, while simultaneously trying to develop programs that reward efficiency and the delivery of high quality care. The Council again strongly encourages CMS to follow MedPAC's recommendation and establish reimbursement parity among hospital-based providers and independent facilities.

## V. Conclusion

The Council appreciates the on-going collaborative relationship between CMS and the Council and we look forward to the opportunity to work with you and your staff to ensure the appropriate implementation of ESRD reimbursement policies. On behalf of the Council, I would like to thank you for your willingness to consider our perspective on these reimbursement changes that significantly affect the clinical settings in which dialysis care is rendered and for the opportunity

[5]MedPAC, "Report to the Congress: Medicare Payment Policy" 121 (March 2006).
[6]*Id.*
[7]*Id.*

to comment on the Proposed Rule. We hope to continue working with the Agency staff to ensure that effective and high-quality dialysis services are accessible for Medicare beneficiaries. Please do not hesitate to contact Rob Foreman (202) 756-3578 if you have comments or questions.

Sincerely,

Rob Foreman
President

**Appendix A**

# THE KIDNEY CARE COUNCIL

American Renal Associates, Inc.

Centers for Dialysis Care

DaVita, Inc.

Fresenius Medical Care North America

Northwest Kidney Centers

Renal Advantage, Inc.

Satellite Healthcare, Inc.

U.S. Renal Care, Inc.



Options for Improved

# The Proposed End Stage Renal Disease Prospective Payment System Update for 2007:

## Evaluating Technical Options for Improved Payment Accuracy

As part of the Medicare Professional Fee Schedule rulemaking on August 22, 2006, the Centers for Medicare & Medicaid Services (CMS) proposed updates to the End Stage Renal Disease Prospective Payment System, which it has administered, since 2005, under the requirements of the Medicare Modernization Act of 2003[1] (MMA). Under that system, dialysis providers are paid for their services in two ways: they receive a prospective payment for each treatment, and they are separately reimbursed for drugs that are not explicitly "packaged" in the per treatment payment rate.

The prospective payment rate is itself composed of two components. The largest component, called the "composite rate," is fixed by statute, and provides for a $4 positive differential in payment for treatment in a hospital. A second component, which was implemented in 2005, is called the "drug spend add-on." This component, which is valued at $18.88 per treatment in 2006, is designed to hold dialysis providers harmless for reductions in pharmaceutical reimbursements mandated by the MMA.

In 2005 and 2006, CMS established the amount for these payments by projecting the expected volume of separately-reimbursable drugs likely to be used in the program year, and the reimbursement rates for each drug under both prior and current law. The aggregate drug spending "spread" between prior and current reimbursement policies was then divided by the projected number of dialysis treatments to establish a per treatment payment amount.

Citing the growing complexity of maintaining this estimation method in an environment of changing payment methodologies, CMS has proposed, for 2007, to simplify this calculation by indexing the 2006 drug spread add-on value to a two-part index.

The first part of the index would be a proxy for rising drug reimbursement rates under the current payment methodology. CMS is proposing to use a projection of the increase in the Producer Price Index (PPI) for pharmaceutical manufacturing as a proxy for this value. The projected PPI value they published for calendar year 2007 is 4.90%

The second part of the index would be a projection of the likely increase in drug volume consumed per dialysis beneficiary. In its proposed rule, CMS used data on reimbursement changes from 2004 to 2005 to estimate the year-over-year change in volume, which they then imputed to the 2006-2007 period. In the NPRM, the projected value of this component is proposed to be zero, i.e., the update would be limited to 4.9% of the 2006 drug spend add-on amount.

[1] *Federal Register*, Vol. 71, No. 162, p. 49004ff.

The Moran Company was engaged by the Renal Leadership Council, a trade group of companies providing dialysis services, to evaluate the data CMS used and the methodology it employed to make this estimate, and to evaluate technical alternatives that could improve the accuracy of the projected payment update for 2007[2]. The highlights of our findings are as follows:

- Several aspects of the methodology CMS has proposed are not fully transparent based on the description of the methodology in the preamble.

- The volume growth projection is based on estimated values for "enrollment growth," the volume-weighted change in drug pricing, and the year-over-year change in drug reimbursements from 2004 to 2005.

- They estimate 3% "enrollment growth," but do not indicate what "enrollment" concept this value relates to. The actual growth in Part B enrollment, for example, was 1.7% from 2004 to 2005.

- They estimate a 12% decline in volume-weighted drug reimbursement rates from 2004 to 2005, based in part on a prior estimate of a 13% reduction from AWP-based reimbursement to reimbursement based on Average Acquisition Price.

- They estimate a 9% decline in total reimbursements for separately billable drugs between 2004 and 2005. We checked this estimate using data from the 2004 Outpatient Standard Analytical File, and from a new 2005 ESRD Limited Data Set (LDS) file. After working with CMS staff to resolve discrepancies between the documentation of the LDS and the data actually placed in the file, we obtain a slightly higher value for this ratio, which would increase CMS's volume projection by about 1%.

- Under the CMS methodology, however, the real issue is what the projected update would be once their formula is run through the values observed in the later claims data they will use for the final rule.

- The closer that value gets to the present projection of zero volume growth, the less likely it would be to serve as a valid proxy for volume growth *in 2007.*

- We believe that using the National Health Expenditures projection published by CMS each February, adjusted to restrict the projection to Part B drugs, would prove a better interim measure for 2007 than the index proposed.

- However this index is generated, it should be retrospectively rebased each year to prevent a permanent accumulation of conservative underestimates of ESRD drug spending growth.

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[2] During the course of this engagement, the RLC formally changed its name to the Kidney Care Council.

## The CMS Volume Estimating Methodology

The methodology CMS chose to employ was, we believe, motivated by concerns about coding accuracy in ESRD claims data, particularly for erythropoietin (EPO), which comprises 70% of the drug volume billed by dialysis providers. The table below summarizes reported drug claims volumes, as measured by discrete claims lines, billed by dialysis providers over the 2001-2005 period[3].

**Claims Lines Billed for Separately-Reimbursed Drugs**

| | 2001 | 2002 | 2003 | 2004 | 2005 |
|---|---|---|---|---|---|
| Epogen & Aranesp | 2,496,480 | 2,697,620 | 2,820,000 | 5,183,120 | 6,319,323 |
| Other Drugs | 4,193,240 | 4,543,760 | 4,927,000 | 6,368,880 | 6,176,360 |
| Total | 6,689,720 | 7,241,380 | 7,747,000 | 11,552,000 | 12,495,683 |

As these data indicate, there was a sharp jump in reported claims lines in 2004, particularly for Epogen®. It is our understanding that this increase is due to a change in coding guidance. Prior to 2004, Medicare intermediaries apparently paid separately reimbursed drug claims for dialysis treatments without requiring accurate HCPCS coding, particularly for Epogen, as long as the claims had proper revenue codes. The claims counts in the table above for Epogen and Aranesp® were, in fact, generated by identifying claims by revenue code[4]. Since the claims line count more than doubled after the requirement for HCPCS coding was implemented, it is likely that many prior claims bundled billings for multiple days of EPO that are now being billed separately.

Given this trend, CMS reasonably concluded that it could not infer a volume trend directly from historical volume data. Instead, it elected to estimate volume by looking at the percentage change in reimbursement between 2004 and 2005, and then adjust for known changes in reimbursement rates between periods to back into the implied volume change. Their decision to impute the 2004-2005 experience to 2006-2007 implicitly suggests that they believe that the experience of the period prior to 2004 was likely to be atypical of trends going forward.

They based their calculation on three key data points:

- The increase in "enrollment" between 2004 and 2005.
- The change in drug reimbursements from 2004 (when they were based on prior payment policy) to 2005 (when they were based on Average Acquisition Price (AAP); and

[3] Throughout our analysis, the data for 2001-2004 are Moran Company estimates developed using the Outpatient 5% Standard Analytical Files for each of these years. The data for 2005 were extracted from the 2005 ESRD PPS Ratesetting Limited Data Set, which CMS released in the last week of September.

[4] Under the Uniform Bill revenue coding structure, EPO claims are billed with revenue codes 634(EPO < 10,000 units) or 635 (EPO > 10,000 units). Fewer than 10% of these claims had accurate HCPCS codes for EPO in 2001-2003.

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- The volume-weighted change in reimbursement rates from prior policy to AAP.

In the calculations presented on p. 49007 of the August 22, 2006 *Federal Register,* they show the following values:

"(.91 / (1.03 * .88) = 1.00)"

Presumptively:

- The .91 factor is the assumed change in drug reimbursements between 2004 and 2005.
- The 1.03 factor is "enrollment growth"; and
- The .88 factor is the volume-weighted change in reimbursement rates.

This calculation is presented as the support for their conclusion that the adjustment for drug volume growth should be zero in 2007.

Discussing these values in reverse order:

Volume-Weighted Drug Reimbursement Rate Changes

The volume-weighted change in payment rates, applied to both EPO and non-EPO drugs, reflects the result of the calculation of this ratio in prior rules. CMS updated the 2004 reimbursement rates for non-EPO drugs to 2005 by applying the PPI (which they did not disclose, but which was 5.17% in 2005). They then applied the ratio of AAP to prior policy payment rates calculated in the Final Rule for 2005. This resulted in a determination that the ratio of AAP to prior payment rates was .88, which is then used in the denominator of the CMS formula to deflate the magnitude of the year-over-year declines in payment rates.

Refining this estimate would require more complete payment data for 2005, since the CMS factor of .88 is sensitive to assumptions about market share by product. As we indicate below, the best way to resolve uncertainties about this estimate would be to retrospectively rebase their calculated 2007 price and volume forecast using later data prior to developing their forecast of the 2008 index.

"Enrollment Growth"

The derivation of the enrollment growth factor used in the CMS methodology is unclear, since the term "enrollment" is undefined. If this is an attempt to estimate an increase in the prevalence of dialysis use, the source of the 3% factor is unclear. If it is intended as a measure of Part B enrollment growth, it is substantially too high, since the 2006 Trustees Report shows Part B enrollment growth of 1.7% in 2005 over 2004.

Because this factor appears in the denominator of the CMS volume estimating equation, lowering the enrollment factor would increase the estimated volume growth. Applying

actual Part B enrollment growth of 1.7% in lieu of the assumed 3% factor would increase the estimate from 1.0040 to 1.0168

Change in Drug Reimbursement

In the preamble, CMS did not directly present their estimate of year-over-year change in reimbursements for separately reimbursed dialysis drugs. They indicated that they started with twelve months of paid claims for services incurred in 2005, and adjusted upward by 13% to reflect the lack of claims run out[5]. In their formula, the value they enter is .91, implying that their adjusted reimbursement totals in 2005 were 9% below 2004.

We attempted to replicate this estimate. We used the data furnished in the new ESRD PPS Ratesetting Limited Data Set released at the end of September to tabulate 2005 values for drug reimbursements, compared to estimates of 2004 drug reimbursements generated using the 2004 Outpatient 5% Standard Analytical File.

Our initial attempt at replication was unsuccessful. In comparison to the CMS estimate of a -9.0% change from 2004 to 2005, we were computing a modest 1-2% increase in total drug payments between years. Since this is a substantial disparity, we shared our data with CMS staff. Upon analysis, it was determined that the disparity was the result of a mismatch between the data concepts used to create the file, and the description of the data concepts presented in the data dictionary accompanying the file. While the payment field was described in the documentation as comprising payments from intermediaries to providers excluding beneficiary cost sharing[6], the payment values actually contained in the file did contain the cost sharing amounts. When we corrected the data concept employed to tabulate the 2004 values using the same data concept, most of the disparity went away.

Here is the payment comparison prior to adjustment for differences in the duration of paid claims experience:

## Reimbursements for Separately Billable Drugs

| | 2004 | 2005 | 2005/2004 |
|---|---|---|---|
| EPO | $ 2,126,524,032 | $ 1,915,636,264 | 0.9008 |
| Other | $ 1,061,015,152 | $ 679,171,618 | 0.6401 |
| Total | $ 3,187,539,184 | $ 2,594,807,883 | 0.8140 |

2004 Data from Outpatient 5% Standard Analytical File, as Paid through 6/30/05
2005 Data from ESRD PPS Ratesetting Limited Data Set as Paid Through 12/31/05

[5] For 2004, CMS had claims data for reflecting all payment adjustments made to these claims throughout 2005. For 2005 claims, by contrast, their data don't reflect payments or adjustments after December 31, 2005.

[6] It is our understanding that the CMS program staff had intended that the data concept described in the documentation would be used in creating the file.

which is the data concept actually required to implement the proposed CMS methodology.

The closer the value CMS estimates comes to the zero growth forecast presented in the proposed rule, the more difficult it will be to conclude that the 2005 experience represents a valid proxy for drug volume growth in 2007. Growth in the volume of drugs used to treat ESRD patients has been consistent for many years, as new drugs are added to the arsenal of treatments available to nephrologists to better manage care. While there are valid reasons for CMS to conclude that volume trends may be turbulent between 2004, when the previously-described coding changes were implemented, and 2006, when efforts to modify EPO dosing are being implemented, there is no reason to assume continued turbulence going forward from 2006 into 2007 and later years.

Until volume trends stabilize, therefore, CMS may find it useful to consider alternative proxies for price and volume change in ESRD drugs. Historically, the growth in drug pricing and volume in the ESRD program has been comparable to that observed for drug reimbursements under Part B generally. Since the CMS Office of the Actuary has traditionally forecast the Medicare share of growth in prescription drug expenditures as part of the annual National Health Expenditures (NHE) projection, CMS could easily link the update of the drug spend add-on to that forecast.

In the preamble to the proposed rule, CMS indicated that it considered this option, but rejected it due to the fact that, for 2006 and 2007, the NHE forecast of Medicare drug spending is heavily dominated by assumptions about the early trend under the new Medicare Part D drug program. While we are sympathetic to that concern about using the aggregate NHE trend projection, it would be possible for the Actuary to decompose that forecast into Part B and Part D forecasts, respectively, and use the former to index growth of the drug spend add-on until such time that it has credible trend data for price and volume growth under the ESRD program itself.

## Retrospective Rebasing

Given the state of the data, we see no clearly superior methodology for improving this estimate. Accepting that reality, it strikes us as prudent to suggest that it would be in the interest of both the agency and the industry to adopt an update mechanism that makes provision for retrospective rebasing of prior estimates before calculating the subsequent year's update. Such rebasing should be for both pricing and volume effects. Whatever 2007 value CMS calculates under it final rule methodology for both price and volume, their methodology should provide for adjusting that value (up or down) to reflect known variations from the forecast trend (PPI + Volume or NHE) before projecting forward from that base to calculate the 2008 update.

In saying this, we are not endorsing a permanent policy of basing the drug spend add-on for a year on the assumption that volume growth in a year will be equal to the volume growth rate observed two years prior. Clearly, what CMS is doing now is a stopgap measure designed to bridge to a period when time series data on actual drug volumes can

be used to make this projection. Until that time, however, we believe it's important to have some ability to retrospectively adjust toward reality. Given CMS's fiduciary responsibility to be inherently conservative in indexing future program growth, failure to do so could accumulate a substantial payment deficit relative to the stated policy intent of making providers whole for the impact of changes in drug reimbursement policy.

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October 10, 2006

OCT 10 2006

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Baltimore, MD 21244-1850

Re: **CMS-1321-P:** Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Dr. McClellan,

I am writing on behalf of Biosphere Medical, Inc., to provide you with comments on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year (CY) 2007 Proposed Rule (Proposed Rule).[1] Biosphere Medical is a medical device manufacturer specializing in the development of embolotherapy technology, including the use of microsphere embolization for the treatment of uterine fibroid tumors. BioSphere Medical works with physicians, patients, and patient advocates to raise awareness about uterine fibroid embolization (UFE) as a safe and effective alternative to surgical options, such as myometomies and hysterectomies. We appreciate the opportunity to comment on the Proposed Rule and look forward to working with the Centers for Medicare and Medicaid Services (CMS) staff to ensure access to effective and efficient services for women with fibroid tumors.

As we discussed with your staff earlier this year, BioSphere Medical is concerned that CMS may adopt a new CPT code for UFE procedures that the RVS Update Committee (RUC) of the American Medical Association (AMA) has inappropriately valued. If this were to occur, many women who need UFE and want to avoid surgery may not be able to access it because under the new code radiologists will not be able to cover the cost of providing the treatment. Therefore, BioSphere Medical strongly urges CMS not to adopt the new UFE CPT code and to provide the RUC more time to learn about UFE and the costs associated with performing the procedure.

[1] 71 *Fed. Reg.* 48982.

## I. UFE is a safe, effective, and less expensive treatment option for women with uterine fibroids.

UFE is a promising new treatment for uterine fibroid tumors, one of the most prevalent women's health problems in the United States today. Uterine fibroids (benign tumors) grow on the muscle tissue of the uterus. These tumors cause pelvic pressure, abdominal bloating, heavy menstrual bleeding, anemia, urinary pressure or incontinence, and possible infertility. More than 20 percent of women of childbearing age experience fibroids. African-American women are three times as likely to be affected by the condition.

Traditionally, women suffering from fibroids have had to have hysterectomies (removal of the entire uterus) or myomectomies (removal of the affected portion of the uterus). Researchers estimate that more than one-third of the 600,000 hysterectomies performed in the United States each year is undertaken to treat uterine fibroids. Both of these surgical procedures are invasive, painful, and require a lengthy recovery period. In addition, they can result in complete infertility and health complications during and after surgery.

UFE provides women with a non-surgical alternative treatment for uterine fibroid tumors. Clinical studies demonstrate that UFE is minimally invasive, clinically effective, and cost-efficient. In addition, it allows women to retain their uterus and studies show maintain her fertility. UFE is performed using the insertion of two small catheters to inject tiny particles into the uterine blood stream that block the blood supply to the tumor. Clinical data demonstrate that at five years after the procedure, there is relief of symptoms among 73 percent of patients. The cost associated with UFE is generally lower than surgical treatment. A recent study found that 96 percent of women who undergo UFE are satisfied with the treatment 12 months following the procedure.

Many women prefer UFE. First, it shortens the hospitalization period. The procedure generally includes an overnight hospital stay, rather than the three-to-four day hospitalization associated with surgical treatments. Second, it provides for a quicker recovery. Patients can usually return to work in 7-10 days, as opposed to the several weeks of recovery following surgical treatment. Third, it preserves fertility. Because the uterus is not removed, patients typically can still have children.

In addition to its clinical benefits and patient-friendly attributes, UFE has also been shown to be more cost-effective than traditional surgical treatments for fibroid tumors. The procedure generally allows a patient to go home the next morning rather than requiring a three-to-four day hospital stay like hysterectomy significantly reduces the costs of treating fibroid tumors. Furthermore, because a patient is typically able to return to work and normal activity within 10 days instead of waiting the four-to-six weeks required for recovery after a hysterectomy, there is also less expense associated with recovery costs of the procedure. Given the significant population of women who experience fibroid tumors and the number of procedures undertaken each year to treat this condition, the development of UFE as a clinically effective and cost efficient treatment method holds tremendous promise for savings.

## II. The Process to Establish the Values for the New UFE CPT Code Is So Flawed that It Is Highly Unlikely the Values Will Reflect the Cost of Providing the Services

Access to UFE is threatened because CMS is poised to adopt a new CPT code for the procedure that is based on flawed survey data and that will undervalue this procedure. If the code is adopted, physicians may not be able to cover the cost of providing UFE. Women suffering from uterine fibroid tumors may be forced to rely solely on surgical options.

Biosphere Medical understands the importance of establishing codes that properly capture the cost of providing medical services and CMS's role as a responsible fiduciary for the federal government. As part of this responsibility, it is especially important that CMS exercise all of its possible resources to ensure that the value inputs assigned to individual service codes reflects the true costs of furnishing the service. We also appreciate the difficulty in developing the appropriate values and CMS's reliance upon the RUC.

However, BioSphere Medical is extremely concerned by the process that has unfolded this year with regard to a single CPT code to bill UFE services. Currently, interventional radiologists bill for the service using a combination of existing office visit, radiology, and transcatheter placement CPT codes to capture all of the components of the UFE procedure. Given the difficulties multiple codes create in the billing and auditing process, we appreciate the need to establish a single code. Yet, when undertaking this process the RUC and the Society for Interventional Radiology (SIR) have failed to base their evaluation of the practice expense and work values on solid data. As you are aware, the RUC met over the weekend to finalize the values for this and other codes. In doing so, we understand that they failed to consider the full scope of the procedure. As described below, we have serious concerns about the process used to develop these values and worry that if they are adopted they will result in fewer UFEs being performed. This will not only cost the health care system more in terms of treatment dollars, but also result in fewer women being able to access a less-invasive treatment option.

First and foremost, we are concerned that the RUC lacks comprehensive and correct data on the costs and physician time associated with of performing UFE. Although an early attempt to collect survey information from practitioners performing the service was conducted by the SIR, the RUC dismissed the results because of flaws in the data collection process. It is our understanding that SIR conducted another survey and that the results of this survey are currently being tabulated for submission to the RUC. We are concerned that this survey may repeat one of the most glaring errors of the initial survey, which is the estimated number of global days that CMS should assign to the procedure.

As Dr. James Spies (Professor of Radiology, Chairman and Chief of Service, Department of Radiology at Georgetown University Hospital) has discussed with CMS staff, the clinical literature focuses on only a small piece of the actual UFE procedure. These studies describe the process from the time the catheter is inserted in the patient to the time it is removed. As an author of many of these studies, Dr. Spies stresses that they do not account for the preparation time or the follow-up

care. Clinicians who actually perform these services (and many of who were not survey during the SIR process) suggests that while the procedure is performed on an outpatient basis, most UFE patients spend the night following the procedure at an inpatient facility for pain management and observation purposes. In fact, in one of the leading peer-reviewed clinical studies on the UFE procedure involving more than 3000 patients. Ninety-four percent of the patients were kept in the hospital overnight and discharged the next day.[2] They also typically receive several follow-up calls with their physician during the week following the procedure and a follow-up office visit. Thus, while some patients may go home the day of the procedure, the vast majority of patients have one night of inpatient care as standard practice. When these factors are taken into account, it is most appropriate to assign 10-day global to the new code. SIR, however, has not recognized this fact because it has not consulted with the key experts in the community.

We understand that SIR has attempted to resolve this problem, but it appears to be too little too late. Dr. Spies attended the RUC meeting, but only after the survey was conducted. Because the RUC bases its values on the surveys, we are concerned that the SIR's decision to involve experts at the eleventh hour is not sufficient to ensure that the RUC assigns the appropriate values for the new code. The RUC may still be tempted to move forward with a decision based upon this unreliable data because of a single member of the panel. It would be unfortunate indeed if a biased physician who does not perform UFE procedures could establish a value for UFE that does not reflect the true cost of providing the service. If the code is undervalued, those interventional radiologists will not be able to cover their costs when providing the service and are likely to stop performing it. This will result in fewer women being able to access the procedure.

## III. To Ensure Access to UFE for All Women, CMS Should Delay Adoption of the UFE CPT Code.

To ensure that all women have access to UFE, any new code must appropriately account for the time, skill, and intensity it takes to provide UFE. The proposed code likely to be adopted is based upon an incorrect number of global days and, thus, will undervalue the work involved. Therefore, BioSphere Medical urges CMS to refrain from adopting a new CPT code for UFE until appropriate survey data that is based on an accurate understanding of the procedure can be gathered. Until that time, CMS should allow physicians to use the set of codes that are currently used to process claims.

CMS has the authority not to adopt all of the CPT codes proposed by the AMA. BioSphere Medical understands that the code will remain in the AMA CPT code book even if CMS does not adopt the code. However, under the HIPAA transactions and code set regulations, all health insurers must use codes that have been adopted by the agency for electronic claims transactions.[3] If CMS does not adopt this particular code, it will not become part of the HIPAA code set and,

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[2]Robert Worthington Kirsch, *et al.*, "The Fibroid Registry for Outcomes Data for Uterine Embolization," 106 Obstetrics & Gynecology (July 2005).

[3]45 C.F.R. 162.925.

therefore, cannot be used to process claims transactions. We understand that applying this rule in this manner should be a rare occurrence. However, given the potential harm that the new CPT code would likely create, we believe this extreme measure should be exercised.

If CMS does not adopt the code, the SIR, RUC, and the specialists who perform this procedure will have the additional time they need to resolve the outstanding questions and concerns questions. To assist with the appropriate valuation of the codes, we encourage CMS to acknowledge that it agrees that a 10-day global period would be appropriate to assign to the code. In addition, CMS should encourage the interested parties to resolve the issue in a thoughtful and deliberative manner that demonstrates a comprehensive understanding of the procedure and the needs of patients. Although Medicare beneficiaries do not frequently suffer from fibroid tumors, it is nonetheless important that the procedure is properly valued given the impact of Medicare values on reimbursement in other sectors, including Medicaid and the private insurance market.

## IV. Conclusion

BioSphere Medical appreciates the opportunity to comment on this important issue for women. It is imperative that CMS provide appropriate guidance to the RUC and SIR to ensure that its coding decisions do not threaten access to UFE and thwart the desire of many Members of Congress who are working to educate more women, especially those in the African-American community, about this important and effective alternative to surgery. We understand the role of the RUC in assisting CMS with the valuation of codes; however, there are times when it is appropriate for the Agency to address problems that the RUC process creates. Thus, to remain consistent with Agency's overall objective to assign appropriate values to codes and to ensure patient access to promising, new technologies, CMS should not adopt the UFE CPT code in the Final Rule. We would welcome the opportunity work with CMS to ensure the code is appropriately value and available for adoption next year. Please do not hesitate to contact me at 202-457-6562.

Sincerely,

Kathleen J. Lester
Partner

KIDNEY CARE
PARTNERS

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OCT 10 2006

October 10, 2006

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

Re: **CMS 1321-P:** Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B

Dear Administrator McClellan,

Kidney Care Partners (KCP) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year (CY) 2007 (Proposed Rule).[1] KCP is an alliance of members of the kidney care community that works with renal patient advocates, dialysis care professionals, providers, and suppliers to improve the quality of care of individuals with irreversible kidney failure, known as End Stage Renal Disease (ESRD).[2] Specifically, KCP urges CMS to:

- Establish price and utilization estimates for purposes of calculating the update to the drug add-on adjustment that are tied to an existing index or based on accurate data;
- State clearly that for CY 2007, CMS will reimburse separately billable drugs at Average Sales Price (ASP)+6 percent; and
- Clarify the budget neutrality calculation for the geographic wage index by explaining the methodology CMS uses.

[1] 71 *Fed Reg* 48982 (August 22, 2006).

[2] A list of Kidney Care Partner coalition members is included in Attachment A.

costs may have the effect of reducing various Medicare payment obligations. If the government created disincentives for pass throughs to occur in connection with these non-possession takers, the government would experience negative fiscal effects.

As a final point, to date, CMS' bona fide service fee guidance has only been issued in the ASP reporting context. There has been no discussion of how the guidance may or may not apply to Medicaid or other price reporting contexts. Since the guidance has not been expanded to include other contexts, we will assume the guidance does not apply in any other context other than ASP reporting.

B. Bundled Price Concessions

Bundled price concessions are commonly described as arrangements in which a purchaser's price for one or more drugs is contingent upon the purchase of other drugs or items. In the Proposed Rule, CMS acknowledged that it has not provided prior guidance in the ASP context regarding the proper method to apportion price concessions across drugs that are sold under bundling arrangements, and that manufacturers may make reasonable assumptions in their ASP calculations.

We agree with the suggestion contained in the Proposed Rule that the price reporting treatment of bundles must be consistent with the treatment of bundles for fraud and abuse purposes under the AKS. Significantly, the Discount Safe Harbor to the AKS only protects bundled arrangements under circumstances where the same reimbursement methodology applies to the products subject to the bundle under the applicable federal program.[5] To constitute a bundle under the Safe Harbor, however, the arrangement must "induce" a purchase.[6]

Some arrangements that involve multiple products do not induce purchases of one product based on the offer relating to another product on a formulary and are not, therefore, a bundle under the AKS, and should not, in order to ensure consistency in federal policy, constitute a bundle for price reporting purposes.

It may be, for instance, that Product A and Product B, if placed individually, these arrangements will each be subject to a 5 percent discount, but if both are placed on formulary, will offer a 7 percent discount. Since formulary placement does not require that any purchases actually occur and since the extra 2 percent discount will be earned whether or not both products are ordered or whether any particular volume of purchases are made, the additional discount does not induce purchases and does not create a bundle. In an arrangement like this, purchasers making orders will place those orders only if they want the specific product that they ordered.

Similarly, there are situations where a volume or other rebate arrangement may be triggered based on a target that may be satisfied by purchases of two or more

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[5] The OIG proposed to change the "same methodology" standard to require the same payment under the same payment code in a 2000 Proposed Rule, but that Rule was never finalized and is of no force or effect. Medicare and State Health Care Programs: Fraud and Abuse; Revisions and Technical Corrections, 65 Fed. Reg. 63035, 63041 (Oct. 20, 2000).

[6] 42 CFR § 10001.952(h)(5)(ii).

products, without requiring that any combination of product be ordered. For instance, a 2 percent rebate may be earned where 100 units of any combination of Products A and B are ordered. Because the rebate may be earned solely on purchases of A or B, the arrangement does not require any bundled or combined purchases and should not, therefore, be considered a bundle for price reporting purposes.

At one point, the Proposed Rule might be read to suggest that a request to place two or more products on formulary creates a bundle. For the reasons stated above, we disagree with this possible interpretation of the ambiguous language from the Proposed Rule. Such a policy position would be fundamentally inconsistent with the term "bundling" as it is used under the AKS.

## II. Conclusion

Thank you again for your consideration of our comments on the Proposed Rule. We appreciate your thorough review of our concerns regarding the treatment of bona fide service fees and bundled price concessions. Novo looks forward to continuing to work with you to improve the health of Medicare beneficiaries.

Sincerely,

Thom Schoenwaelder
Senior Director - Pricing, Contract Operations & Reimbursements

Additionally, KCP supports the Agency's decision to reimburse for medical nutritional therapy, diabetes self-management training, and blood flow monitoring. These are important preventive treatment options that can have a positive impact on the ability of physicians, facilities, and patients to slow the progression of and better manage kidney disease.

## I. ESRD PROVISIONS: CMS should consider adopting a proxy to estimate the update to the drug add-on adjustment for CY 2007 and allow for forecast error adjustments to ensure that the estimates are correct.

KCP supports the use of an index to establish the update to the drug add-on adjustment. However, we are concerned that the Proposed Rule's methodology does not provide an accurate estimate of 2007 prices and utilization of ESRD separately billable drugs. We agree with the recommendations outlined in The Moran Company's report "The Proposed ESRD Prospective Payment System Update for CY 2007: Evaluating Technical Options for Improved Payment Accuracy" that CMS should (1) use a proxy for CY 2007 to calculate the update and (2) establish a mechanism that would allow for forecast error adjustments if the estimates are incorrect.

### A. KCP encourages CMS to clarify how it developed its estimates for price and utilization.

KCP encourages CMS to re-examine its estimates of price and utilization for purposes of calculating the update to the drug add-on adjustment. Given the data and methodological concerns about the price and utilization estimates used to calculate the update to the drug add-on adjustment in the Propose Rule, KCP encourages CMS to clarify how it developed its estimates. As described below, KCP urges CMS to recognize that because of the data and methodological problems associated with the proposal, the Agency should use a more stable and predictable proxy to estimate price and utilization for purposes of calculating the update to the drug add-on adjustment for CY 2007. Given that the payment to cost ratio for dialysis payment, including separately billable drugs, remain negative,[3] as reported by MedPAC, it is important that the method used to calculate the update results is an accurate assessment of the price and utilization changes to ensure economic stability for kidney care providers.

In terms of the price estimate, KCP understands the value of using the Producer Price Index (PPI). However, we are concerned that the forecast outlined in the Proposed Rule is significantly lower that what other sources suggest it should be. The Proposed Rule states that CMS estimates the PPI to be 4.9 percent. The current reported PPI 2006 is 6.3 percent. Looking at the 2004/2005 PPI would result in 5.1 percent. If CMS determines it is appropriate to continue to use the PPI to estimate price changes, we suggest that the Agency review the 2006 PPI and other data to ensure that in the Final Rule the PPI estimate reflects the most current data available.

[3]MedPAC "Report to the Congress" (2006).

KCP is also concerned about the data and methodology CMS uses in the Proposed Rule to estimate utilization changes. We agree that CMS's current volume data is not stable and, as such, cannot be used to accurately estimate changes in volume. Without accurate data, CMS proposes a methodology that relies on incomplete data and results in a conclusion that utilization is flat. KCP is concerned that this analysis does not accurately reflect the true trends in drug utilization.

Although we acknowledge that it is unlikely there has been double-digit growth in utilization for separately billable drugs, our data as well as an analysis conducted by The Moran Company on behalf of the Kidney Care Council suggest that utilization is not flat, but slightly higher. Additionally, we are also concerned that CMS has assumed, without having data to confirm its conclusion, that the new EPO Monitoring Policy will result in a significant decrease in the utilization of EPO. While we may disagree about the accuracy of this statement, CMS should not incorporate potentially premature assumptions into a calculation as complex as estimating utilization. Moreover, the data upon which the estimate is based is not the most recent data available about separately billable drugs. Because of these problems and based upon its review of the Proposed Rule and CMS data, The Moran Company concludes that the use of the proposed methodology is flawed. These flaws make it difficult to ensure that any utilization estimate accurately reflects reality.

Given the questions about the price and utilization estimates, KCP believes that CMS should adopt a proxy index for both price and utilization that will avoid the pitfalls outlined above.

**B. Given the difficulties associated with the proposed methodology to calculate the update to the drug add-on adjustment, KCP encourages CMS to adopt a stable proxy index for both price and utilization and to establish a mechanism to permit forecast error adjustments.**

As noted, KCP is concerned that the proposed methodology does not accurately reflect the changes in price and utilization for separately billed drugs. Given the lack of data (especially for purposes of estimating utilization changes), we encourage CMS to (1) adopt an appropriate proxy index that accounts for both price and utilization changes and (2) establish a mechanism for making adjustments to account for forecasting errors in prior estimates before calculating subsequent years' updates.

KCP agrees with The Moran Company's suggestion to use the National Health Expenditure (NHE) index for purposes of determining the update to the drug add-on adjustment. The benefit of the NHE index is that, unlike the PPI, it includes both price and utilization changes. We are sympathetic to the concerns about Part D data distorting the NHE. However, as The Moran Company explains, CMS can easily separate the Part D and Part B data so that the update would be determined looking only at trends in Part B drugs. Therefore, KCP urges CMS to use the NHE as a proxy for price and utilization changes until CMS has credible data that will allow it to estimate price and utilization more accurately.

Regardless of how CMS addresses the proxy issue in the short-term, CMS should also establish a mechanism that will allow it to "check its work" on a prospective basis until it has stable

data with which to estimate the utilization change. We also agree with the suggestion outlined in The Moran Company report that in the short-term CMS should adopt a mechanism that would allow it to forecast error adjustments of prior price and utilization estimates before calculating the next year's update to assure that any incorrect estimating problems do not accumulate. This approach is consistent with CMS policies in other parts of the Medicare program, most notably in the Medicare Advantage program payments to health plans. For example, if the estimates were incorrect for 2007, CMS could use the correct numbers to adjust the 2007 update before calculating the 2008 update. This mechanism would be necessary only until CMS has accurate volume data for ESRD drugs. KCP encourages CMS to adopt such a mechanism for a limited time (most likely one to two years) in addition to using an adjusted NHE as a proxy to ensure that updating the drug add-on adjustment is done in as accurate a manner as possible. These recommendations would only be necessary until CMS has accurate, stable volume data for ESRD drugs.

## II. ASP ISSUES: The Final Rule should expressly state that CMS will reimburse separately billed drugs at ASP+6 percent for CY 2007.

Given the importance of separately billable drugs to the kidney care community, it is important to ensure that reimbursement rates are stable and predictable. We understand that the Agency intends to reimburse separately billable drugs at ASP+6 percent for the foreseeable future. However, we wanted to raise a discrepancy between the preamble and the text of the regulation. The preamble states that separately billable drugs will be reimbursed "based on section 1847A of the Act." 71 *Fed. Reg.* at 49004. However, the regulation text more clearly states that these drugs will be reimbursed at "106 percent of the average sales price." To avoid potential confusion, we suggest that CMS state clearly in the preamble to the Final Rule that it will reimburse separately billed drugs at ASP+6 percent. This statement would be consistent with the regulatory text and provide needed clarity for the community.

## III. ESRD PROVISIONS: KCP urges CMS to clarify the budget neutrality calculation for the geographic wage index by explaining the methodology it used.

As CMS continues to implement the geographic wage index, KCP encourages CMS to examine the effect of the changes on facilities. Similar to last year, we are concerned that the calculation of the budget neutrality factor for the geographic wage index is not transparent in the Proposed Rule. The modifications to the geographic wage index have an enormous impact on small providers. They need to understand that the budget neutrality factor is being calculated correctly. Small differences have a large impact on the payments to these facilities. Thus, KCP urges CMS to provide the data and methodology it used to calculate the budget neutrality factor in the Final Rule to enable the community to assess the impact of the proposed changes.

## IV. CMS should encourage patient services, such as self-management for diabetics, as well as blood flow monitoring and medical nutritional therapy through appropriate reimbursement.

KCP is pleased that CMS recognizes three important services that can help improve care for patients and allow them to learn how to better manage their disease. We encourage CMS to continue its efforts to provide coverage for these and other services that can help slow the progression of kidney disease and help patients who have kidney failure achieve a higher quality of life.

One precursor to chronic kidney disease (CKD) is diabetes. Patients who manage their diabetes effectively can slow the progression or even prevent the onset of kidney disease. The more opportunities patients have to learn how to manage their disease, the less likely they will need dialysis services. For these reasons, KCP supports the proposal regarding diabetes self-management services. Patient education and training is a critical tool in the prevention of conditions related to diabetes, including kidney failure; KCP encourages CMS to continue to explore additional services that help slow the progression of CKD.

Once patients are diagnosed with progressive kidney failure, they must have surgery to create an access for dialysis. For hemodialysis patients, an AV fistula is the best type of access. Monitoring a patient's access, whether it is a fistula, graft, or catheter, is extremely important to assuring that the patient can receive the appropriate dialysis treatments. As indicated in the Kidney Care Quality and Improvement Act, KCP strongly supports further support for blood flow monitoring services. These services allow dialysis professionals to assess a patient's access and determine whether additional maintenance services are required before a problem occurs. These services allow a provider to accurately assess a patient's blood flow rate and the status of the vascular access. By enhancing the quality of the dialysis treatment being provided, blood flow monitors not only enhance the quality of care the patient receives but also lower overall costs by reducing patient morbidity and the need for numerous other tests and procedures, all of which add costs to the Medicare program and inconvenience for a dialysis patient. This preventive care is critically important in maintaining the patient's well-being. CMS should recognize the importance of providing dialysis patients with blood monitoring services and ensure appropriate coverage and reimbursement of these services for physicians and facilities.

Finally, KCP also supports increased coverage for medical nutritional therapy. The limited access to nutritional therapists is problematic for many patients with Stages 3 and 4 kidney disease. Patients will be best served by a system that encourages the multidisciplinary approach to CKD care, including dietitians. Medical nutritional therapy and counseling are important tools to assist patients to optimize nutritional status by controlling the levels of several critical elements in their bodies. Dietary counseling is important for certain electrolytes in Stages 3 and 4 patients such as sodium (which is important in blood pressure regulation), potassium (which can lead to fatal arrhythmias) and phosphorous (which has a long term effect on bones and cardiovascular disease). Nutritional therapy is also important to ensure protein intake is optimal to avoid malnutrition at inadequate levels of intake and rapid loss of kidney function at excessive levels of intake. Since diabetes is the

most common cause of CKD in the United States, patients with CKD and diabetes have the additional consideration of carbohydrate intake regulation, emphasizing the complexity of nutritional management in CKD. The availability of nutritional therapy will help patients understand how to better manage their disease.

KCP is pleased that CMS continues to recognize the importance of providing preventive care, such as blood flow monitoring, medical nutritional therapy, and self-management for diabetics. These programs not only help to slow the progression of CKD, but also help dialysis professionals manage their patients better. We encourage CMS to continue to provide incentives for educational and preventive services.

## V. Conclusion

On behalf of KCP, I would like to thank you for your willingness to consider our comments about the Proposed Rule. As in the past, we hope to work with you to resolve these issues and ensure appropriate implementation of the Final Rule. Please do not hesitate to contact Kathy Lester at (202) 457-6562 if you have comments or questions.

Sincerely,

Kent Thiry
Chairman
Kidney Care Partners

KIDNEY CARE
PARTNERS

Abbott Laboratories
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
DaVita Patient Citizens
Fresenius Medical Care North America
Genzyme
Medical Education Institute
Nabi Biopharmaceuticals
National Kidney Foundation
National Renal Administrators Association
Northwest Kidney Centers
Renal Advantage Inc.
Renal Physician's Association
Renal Support Network
Roche
Satellite Healthcare
Sigma Tau
U.S. Renal Care
Watson Pharma, Inc.

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Providence Health & Services

October 10, 2006

Honorable Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

**RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule CMS-1321-P**

Dear Ms. Norwalk:

On behalf of Providence Health & Services, I want to thank you for the opportunity to provide our comments on the changes proposed by the Centers for Medicare and Medicaid Services (CMS) to payment policies under the Medicare Physician Fee Schedule for Calendar Year 2007. CMS published these changes as part of its Notice of Proposed Rule Making in the Federal Register on August 22, 2006. Providence Health & Services is a faith-based, non-profit health system that operates acute care hospitals, physician groups, skilled nursing facilities, home health agencies, assisted living, senior housing, PACE programs, and a health plan in Washington State, Oregon, California and Montana.

As a Catholic health care system striving to meet the health needs of people as they journey through life, Providence is committed to strong partnerships with physicians in the communities we serve; both specialists affiliated with our hospitals and other facilities and employed primary care physicians. We also operate medical residency programs at several of our institutions to train primary care physicians and specialist physicians.

Before commenting on specific issues, Providence would like to again strongly urge CMS to advocate on Capitol Hill for a revamping of the Sustainable Growth Rate (SGR) methodology to ensure greater stability in physician payment under Medicare and to improve payment for primary care physicians, who are increasingly closing their practices to new Medicare beneficiaries. Many of our physicians are very concerned

about the scheduled -5.1% CY 2007 update, particularly as medical practice costs continue to rise and new benefits drive increased demand on the part of beneficiaries. While it is likely that Congress will pass legislation to at least hold physicians harmless from the negative update for CY 2007, it is important that CMS strongly advocate for more structural reforms to the payment system to improve the accuracy of physician reimbursement and to align physician payment with broad Medicare reform principles.

## GPCI

As required by the Medicare Modernization Act, a 1.0 floor for the work Geographic Practice Cost Index (GPCI), is set to expire beginning on January 1, 2007. CMS notes in the Aug. 22 proposed rule that while the Geographic Adjustment Factors (GAFs) for most payment areas will not see a negative effect, the floor removal will adversely affect the GAFs for a number of payment localities. Of those negatively affected localities, nearly all are rural or semi-rural areas and 23 of the 32 payment localities cited in Table 3 of the proposed rule as projecting a negative impact of more than one percent are in states in the bottom half of the country for Medicare spending per capita[1]. Using per capita spending as a proxy for utilization, it appears that those areas with lower utilization and larger access concerns would be disproportionately affected by removing the 1.0 Work GPCI floor. Among those areas are localities in which Providence Health & Services provides care to Medicare beneficiaries: Rest of Oregon, Rest of Washington and Montana.

While we acknowledge that the statute intends that the floor be temporary through Jan. 1, 2007, we are concerned that, in the context of the 5.1 percent reduction in payment derived from the Sustainable Growth Rate (SGR), removing the floor will mean an even larger payment reduction for physicians in those rural areas that are most acutely facing access problems. This is particularly a concern for primary care physicians, who have seen their inflation-adjusted income fall by more than 10 percent over the last decade.[2]

**Recommendation:**

In the proposed rule, CMS notes its interest in further studying alternative ways to reconfigure the payment localities and intends to work with MedPAC and the Government Accountability Office (GAO) to study the current methodology and develop alternative options. We support this effort to reconsider how payment localities are determined. For example, the "Rest of Washington" payment locality, which would experience a .77% decrease in its GAF, includes Everett, Washington, a community that is contiguous with Seattle-King County, Washington. Everett is a community of more than 100,000 people and Snohomish County, Washington has a population of more than 600,000 residents. This population compares more closely with Tacoma-Pierce County than other, rural communities in the Rest of Washington payment locality. Accordingly, because of its proximity to an urban area, wages for nonphysician labor are higher and more closely aligned with those of Seattle-King County. Consequently, removing the floor would create a disproportionate negative impact to physicians in Everett-Snohomish County.

Further, we recommend that CMS forego implementing the floor expiration or hold harmless those payment localities facing a larger than one percent decrease, until such time as an alternative methodology is developed and proposed via rulemaking, such as incorporation of the American Community Survey (ACS) under development by the U.S. Census Bureau.

**Deficit Reduction Act (DRA) Related Proposals: Imaging Services**

In the Aug. 22 proposed rule, CMS proposes to implement Section 5102 of the Deficit Reduction Act (DRA), which modifies payment for certain imaging procedures performed in the physician office or at Independent Diagnostic Testing Facilities (IDTFs).

The two provisions would: 1) for 11 families of imaging procedures, continue the 25 percent reduction in payment for each additional imaging procedure performed, rather than move to 50 percent as called for in the CY 2006 Final rule; 2) implement the budget neutrality exemption for this policy, which would transfer savings from these discounted payments to the CY 2007 Practice Expense RVUs; and 3) Implement a cap on payment for the Technical Component (TC) of imaging services performed in the physician office or IDTF at the Hospital Outpatient Department fee schedule amount.

Providence Health & Services shares CMS' and others' concerns about the explosive growth in imaging services in recent years. Moreover, we support Medicare policy that would reduce payment for specific imaging procedures performed on contiguous body parts in the same session.

However, we are concerned that while the ACR analysis conducted of 25 code combinations may support a reduction of between 21 and 44 percent, some of the 11 families of imaging procedures included in the CY 2006 Final Rule do not provide the to warrant a 25 percent reduction in payment. For example, Families 5 and 8 (Magnetic Resonance Imaging (MRI) and Magnetic Resonance Angiography (MRA) of the chest/abdomen/pelvis; MRI and MRA of the lower extremities) and Family 10 (MRI and MRA of the upper extremities and joints) require that a specific coil be used for the body part (e.g., a neck coil for neck imaging, head coil for head imaging). As such coils must be removed and switched for contiguous party parts for these families and there are little to no economies of scale.

**Recommendation:**

Section 5102 of the DRA does not mandate which imaging procedures should be subject to the multiple imaging discount policy under the Medicare Physician Fee Schedule, giving CMS the latitude to determine which imaging procedures are included for this policy. Therefore, we urge CMS to remove those procedures with code combinations that do not meet or exceed a threshold 25 percent reduction in cost from the first procedure to subsequent procedures performed in the same session.

**IDTF Issues: Proposed Performance Standards for IDTFs**

CMS proposes to establish 14 performance standards for Independent Diagnostic Testing Facilities in order to be certified for enrollment in the Medicare program. Providence Health & Services strongly supports the creation of these standards to help ensure patient safety and program integrity for the services provided in IDTFs.

However, **we ask CMS to provide clarification on standard #7: the IDTF shall agree not to directly solicit patients.** While we recognize the intent of this standard and support that intent, it is unclear as to whether this standard is, in effect, a prohibition or limit on diagnostic screenings such as mammograms, which are often performed without a physician order and are considered preventive in nature. The standard states: "The IDTF would accept only those patients referred for diagnostic testing by an attending physician, who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem.

## CONCLUDING REMARKS

As previously mentioned, we recognize that CMS does not have the authority to hold physicians harmless from the 5.1 percent across-the-board reduction scheduled for Jan. 1, 2007. We, like you, are deeply concerned about the potential impact of this cut on beneficiary access to physicians in our communities and the cascading effect that reduced access has on our hospitals and others in those communities. We strongly urge CMS to actively advocate on Capitol Hill for legislative changes to the SGR system, as well as the RVU structure to bring about greater stability to physician payments – at the same time addressing the factors that are driving volume and costs in the Medicare program. We are particularly concerned about the impact of this cut on the dwindling supply of primary care physicians both across our region and the country.

Thank you again for the opportunity to comment on this proposal and for your thoughtful consideration of our remarks. If you have any questions, please contact Steve Brennan, System Director, Government Affairs, at (206) 464-4717 or via e-mail at steve.brennan@providence.org.

Sincerely,

John Koster MD

John Koster, M.D.
President/CEO
Providence Health & Services

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[1] "Medicare State Profiles: State and Regional Data on Medicare and the Population it Serves," Kaiser Family Foundation, 1999.

[2] "Losing Ground: Physician Income 1995-2003," Center for Studying Health System Change, Tracking Report, June 2006.

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October 10, 2006

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**Re: CMS-1321-P; Comments re Reassignment and Physician Self-Referral**

Dear Ladies and Gentlemen:

We are filing these comments on behalf of AmeriPath, Inc. ("AmeriPath"), headquartered in Palm Beach Gardens, Florida. AmeriPath appreciates the opportunity to submit the following comments to the Centers for Medicare and Medicaid Services' ("CMS") "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule" published at 71 Fed. Reg. 48981 (August 22, 2006) ("2007 Proposed Physician Fee Schedule"). These comments are directed toward revisions to the reassignment and physician self-referral rules and changes to the rules governing how anatomic pathology services are billed.

AmeriPath is appreciative of and supports the efforts of CMS to curb abusive practices in the anatomic pathology industry. So called pod labs or condo labs and other models marketed to certain physician specialists carefully skirt prohibitions in the federal anti-kickback statute, 42 U.S.C. § 1320a-7b ("Anti-kickback Statute"), and the federal patient referral law, 42 U.S.C. § 1395nn ("Stark II"). In reaction to recently issued guidance from the government, management companies have continued to modify their pod lab models. As CMS notes, many pod arrangements or other contractual joint ventures are established either in contravention of existing requirements or by taking advantage of ambiguities that exist. While the proposed rules would go a long way to impede abusive arrangements and AmeriPath is in full support of the efforts of CMS in this regard, AmeriPath strongly urges CMS to make certain additional revisions to the proposed reassignment and physician self-referral rules in order to protect further

against program or patient abuse that occurs in anatomic pathology models currently being marketed to physicians.

## I. BACKGROUND

In the 2007 Proposed Physician Fee Schedule, CMS proposes several amendments to its regulations on reassignment and physician self-referral to address the suspect laboratory arrangements.

### A. Reassignment Rule

CMS recommends several amendments to 42 C.F.R. § 424.80 where a physician or medical group bills for a diagnostic test "following a reassignment involving a contractual arrangement with the physician or other supplier who performed the technical component" ("TC"). The first two proposals are set forth in a new proposed regulation text. The third proposal is being considered by CMS and regulation text is not yet proposed.

#### 1. Proposal One

CMS would clarify the application of the anti-markup rule for the TC of diagnostic tests billed under a reassignment involving a contractual arrangement by imposing the same billing limitations that currently apply to the purchase of diagnostic tests by physicians from independent physicians or entities.[1] In order for the anti-markup rule to apply, there must be a reassignment of the TC in a contractual arrangement and the TC must be performed by the physician or other supplier who reassigns the right to bill for the test. If those conditions are met, billing for the TC would be limited to the lowest of:

(i) the physician or other supplier's net charge to the billing physician or medical group;

(ii) the billing physician's or medical group's actual charge; or

(iii) the fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.[2]

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[1] Section 30.2.9 of the Medicare Claims Processing Manual provides that a physician or medical group may submit a claim and receive payment for the technical component ("TC") of diagnostic tests which the physician or group purchases from an independent physician, medical group, or other supplier, but must accept the lowest of the fee schedule amount if the supplier had billed directly, the physician's actual charge, or the supplier's net charge to the purchasing physician or group as full payment for the test.

[2] 71 Fed. Reg. at 49056 and 49084.

### 2. Proposal Two

Under the second CMS proposal, in order for a physician or medical group to bill for the TC "following a reassignment involving a contractual arrangement with the physician or other supplier who performed" the TC, the physician or medical group "must directly perform" the professional component ("PC").[3]

It is not clear what is meant by "following a reassignment" and "directly perform."

### 3. Proposal Three

A third proposal being considered by CMS would amend § 424.80(d) to impose conditions on when a physician or medical group may bill for a reassigned PC of a diagnostic test. The conditions being considered are: (i) "the test must be ordered by a physician that is financially independent of the person or entity performing the test and also of the physician or medical group performing the interpretation;" (ii) "the physician or medical group performing the interpretation does not see the patient;" and (iii) "the physician or medical group billing for the interpretation must have performed the TC of the test."[4]

It is not clear from the preamble whether this proposal would apply only where there is a contractual arrangement for the provision of the TC or in all circumstances where a PC is reassigned.

As an alternative to this proposal, CMS is considering applying anti-markup principles to reassigned PCs.

### 4. Applicability Beyond Pathology

CMS also seeks comments as to whether the changes in reassignment rules should apply to the provision of all diagnostic tests.

## B. Stark Provisions

### 1. Size of Space

CMS proposes to amend the Stark definition of "centralized building" in § 411.351 for purposes of the in-office ancillary services exception and the physician services exception. These proposed changes would mandate a minimum square footage requirement for a centralized building of 350 square feet. The square footage requirement would not apply to

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[3] *Id.*

[4] *Id.*

"space owned or rented in a building in which no more than three group practices own or lease space in the 'same building,' as defined in § 411.353."[5]

**2. Equipment**

CMS also would require that the equipment necessary (or a significant percentage (90%) of the necessary equipment) to perform substantially all of the designated health services that are performed in the space be located in the space.[6]

**3. Lab Distance from Office Practice**

Further, CMS is seeking comments on whether there should be a limit on the distance between the centralized building and the physician practice's office if a group practice performs a designated health service in a "centralized building" in a state that is different than the state in which its office practice is located.

**4. Non-physician Personnel**

CMS also seeks comments on whether at least one non-physician employee or independent contractor must provide services at least 35 hours per week.

**C. Current Pod Lab Arrangements**

Management companies have been marketing a slightly different and more sophisticated pod lab model to physicians and group practices than the former pod lab models that were discussed in the proposed rule. The physician or physician practice still has little to no economic investment in the lab or its medical and non-medical personnel and, therefore, is at little or no economic risk. Under most of the newer models, the physician or group practice leases space and equipment from a management company in a building that qualifies as a "centralized building" for purposes of the in-office ancillary services exception. The space and equipment leases, however, often are either short-term or terminable without cause by either party on little notice. The physician or group practice employs, possibly on a leased-basis from the management company, the histologists or other technicians necessary for the lab to perform the TC of the diagnostic tests ordered by the physician or group practice. The physician or group practice either enters into an independent contractor agreement with, or employs (generally on a part-time basis; rarely, if ever, is the pathologist a full-time employee), a pathologist, who is referred to the group practice by the management company, to supervise the lab and provide the PC. The management company typically retains control over the work of the histologists and technicians, rendering them employees of the physician or group practice in name only. Further, the group practice does not provide any continuing education or quality control. To the extent these services are provided, they are provided by the management company, far from the

[5] 71 Fed. Reg. at 49056-49057.

[6] 71 Fed. Reg. at 49057.

oversight or control of the physician or group practice. In sum, the group practice, made up of physicians who do not have the professional credentials to supervise the lab or prepare or interpret slides under CLIA, and have little economic investment or risk, collect a portion of the reimbursement.

Nonetheless, for technical Stark purposes, the lab is the physician's or group practice's lab and, assuming the pathologist and histologist perform their tasks in the appropriate lab space, the pod labs fall within the Stark in-office ancillary services exception. As an in-office ancillary service, it is the physician or group practice which is considered to provide the TC, not the pathologist. Moreover, while the contracted pathologist will supervise the lab, the pathologist does not perform the TC. The TC is performed by the histologist. Thus, for most pod labs there is no reassignment of the TC and the proposed changes to reassignment in Proposal One and Proposal Two would not be triggered. The practice could still bill for the TC alone or the TC and the PC.

Moreover, if a group practice employs a pathologist on a part-time basis rather than engaging the pathologist as an independent contractor, the group practice would escape application of all of the revised reassignment rules because there would not be a reassignment of the TC or the PC under a contractual arrangement. A sufficiently large physician practice could employ a pathologist part-time and still satisfy the Stark requirements for a "group practice" as its full-time employed physicians could average out the part-time pathologist to meet Stark's 75% test. In such an arrangement, the increased 350 square foot requirement for lab space could be met and still make the arrangement economical.

We applaud CMS' significant strides in its goal to "prevent abusive arrangements such as pod labs, while not disqualifying legitimate, stand-alone physician offices that are unusually small."[7] However, to achieve its goals, further refinements are necessary.

## II. AMERIPATH SUGGESTED REVISIONS

### A. Reassignment

#### 1. Proposals One and Two

It appears that these two proposals only apply to tests that involve a contractual arrangement (and not an employment arrangement) to perform the TC. Because these newer pod lab models do not always involve a contractual arrangement for the TC, to bring them within the ambit of the proposals, § 424(d)(3) should be expanded to apply to situations where there is a contractual arrangement for a pathologist to supervise the TC, not just perform the TC.

Thus, § 424.80(d)(3) should read as follows (additional language is double underlined):

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[7] 71 Fed. Reg. at 49057.

> (3) *Contractual arrangements for provision of diagnostic tests services.* If a physician or medical group bills for the technical component of a [diagnostic] test covered under section 1861(s)(3) of the Act and paid for under part 414 of this chapter (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act), following a reassignment involving a contractual arrangement with the physician or other supplier who performed or supervised the technical component (or supervised the laboratory in which the technical component was performed), each of the following conditions must be met: ...

**2. Proposal Three**

CMS is also considering imposing certain conditions on when a physician or medical group may bill for a reassigned PC of a diagnostic test. The conditions would subject a reassigned PC to the same restrictions that apply to a purchased interpretation. AmeriPath supports this effort with the following qualifications:

Among the conditions CMS proposes is a requirement that the test must be ordered by a physician that is financially independent of the person or entity performing the test and also of the physician or medical group performing the interpretation. Currently, Medicare permits a pathologist to order additional tests which are medically necessary to render a complete and accurate diagnosis.[8] Pathology is unique in this regard. In most circumstances, the pathologist who requests the additional tests would not be financially independent of the person or entity performing the additional test or performing the interpretation.

In addition, the physical presence of a pathologist is sometimes required at the collection of a specimen in order to ensure that sufficient or proper tissue is obtained. In such a case, we believe the pathologist would be considered to "see the patient."

In order to maintain traditional quality patient care, AmeriPath urges CMS to preserve a pathologist's current ability to order additional tests and be present at the collection of the specimen, where necessary. Pathologists should continue to be specifically excluded from the condition that the test must be ordered by a physician that is financially independent of the person or entity performing the test or interpretation and from the requirement that the physician or medical group not see the patient. AmeriPath also believes certain other clarifications should be made. The new conditions should provide as follows (additional language is double underlined):

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[8] *See* 69 Fed. Reg. 66234, 66292 (Nov. 15, 2004).

(i) the test must be ordered by a physician that is financially independent of the person or entity performing or supervising the test and also of the physician or medical group performing the interpretation, except, that, additional tests requested by a pathologist would not be deemed to be ordered by that pathologist; (ii) the physician or medical group performing or billing for the interpretation does not see the patient, except for a pathologist whose presence is necessary when collecting the specimen, (iii) the physician or medical group billing for the interpretation must have performed the technical component of the test, and (iv) the physician or medical group billing for the interpretation must keep on file the name, national provider identifier, and address of the interpreting physician. A medical group performs an interpretation or sees a patient if any physician employee or independent contractor of the medical group performs the interpretation or sees the patient. The provisions of this subsection [**insert number**] do not apply to hospital-based multi-specialty physician groups that include all specialties based at the hospital.

### 3. Anti-Mark Up of PC

AmeriPath does not support prohibition on mark ups of the PC. Limitation on mark up of the PC would be counter-productive as it could jeopardize legitimate test purchases that occur between legitimate pathology practices and pathologists who wish to remain as independent contractors, between subsidiaries of commercial laboratory companies, and between laboratory companies and their professional corporations in states where the corporate practice of medicine is enforced. Such situations do not raise fraud and abuse concerns because neither the laboratory nor the pathologists triggered the referral; the referral will have always come from an outside physician. Instead of introducing a new prohibition on mark ups of the PC which may have unknown and unintended consequences, it is believed that the current restrictions on the purchase of professional interpretations, which are already found in the Claims Processing Manual, are likely to be most effective in curbing abuse. As these requirements are already in place, they should be easier to enforce and should be void of unforeseen consequences that may hamper legitimate practices.

### 4. Application to Services Other Than Pathology

In almost all cases, the physicians who seek to establish pod labs do not have professional credentials to supervise an anatomic pathology lab, prepare the slides, or provide the PC. Indeed, virtually none could satisfy CLIA requirements to perform these services. At the same time, there have been demonstrated abuses of ordering medically unnecessary anatomic pathology tests that have prompted CMS to impose restrictions. This is in contrast to other ancillary services such as certain radiology imaging services where the physicians who order the

tests are also capable of supervising the TC and performing the PC, and often use the scan in their examination and diagnosis. AmeriPath supports restrictions on pathology laboratories, but absent evidence of abuse in other specialties, it does not support extension beyond pathology.

## B. Stark

### 1. 350 Square Feet Rule

AmeriPath appreciates CMS' efforts to tighten the Stark centralized building requirements. While the additional requirement of lab space of at least 350 square feet may deter some group practices, unfortunately others will be undaunted. And, while AmeriPath appreciates the need to protect smaller group practices, the carve out for buildings where no more than three practices own or lease space in the building may create a loophole for pod labs. Pod labs could be located in office parks where the histologist and pathologist could easily move from one building to another. Thus, additional safeguards are necessary.

### 2. Lease of Space and Equipment

In addition to the new requirement of at least 350 square feet of space, the definition of a centralized building should be expanded to include these additional requirements:

- The group practice must either own the centralized building or occupy it subject to a fair market value lease with a term of at least one year that is not terminable except under traditional commercial lease termination provisions.
- Equipment essential for the performance of the clinical laboratory services must be owned by the group practice, leased by the group practice under a commercially reasonable capital lease, or leased under a long term lease with a term of at least three years.
- All histologists and other technicians must be *bona fide* W-2 employees and the group practice must have full control over, and responsibility for, the employees' work.
- The employees who provide services in the centralized building for clinical laboratory services must be covered by the group practice's professional liability insurance.

### 3. Location of the Centralized Building

CMS should require that a centralized building must be located not more than fifteen miles from a group practice office that meets the Stark "same building" requirement. There appears to us to be no reason for a group practice to maintain a laboratory at any significant distance from its offices. This restriction would not penalize any physician practice from establishing a legitimate clinical laboratory to perform diagnostic tests. Rather, a limitation on distance would serve as an additional check on the quality of the lab, as the group practice would be in closer proximity to at least minimally observe the lab conditions and the

pathologist's work. As an example, certain pod labs that are located in Florida and Texas serve group practices located hundreds of miles away within the state borders or as far away as the midwestern or northeastern states.

**4. Full time Histologist or Other Technician**

AmeriPath is not taking a position on this issue. It does occur to us, however, that if our other recommendations are accepted, a requirement for a full-time histologist or other technician may not be necessary and it may create unintended consequences.

**5. Employment of the Pathologist**

With changes in reassignment rules, group practices may opt to employ the pathologist on a part-time basis. As noted above, a practice where all other member physicians are full-time practitioners may still meet the 75% test under Stark even if the pathologist provides services on a very limited part-time basis. Accordingly, AmeriPath recommends that CMS modify the Stark group practice definition to require that for a medical practice with one or more members who are pathologists but which does not consist exclusively of pathologists, each member must provide at least 50% of his or her patient services through the group. In the alternative, CMS should provide in the group practice definition that no pathologist who is a member of the group may be a member of more than two group practices.

AmeriPath commends CMS on its efforts to curb abuses in the pathology industry. To strengthen these efforts, AmeriPath strongly urges CMS to adopt the comments in this letter.

## III. INDEPENDENT LAB BILLING

The Proposed Rule would also significantly change the rules governing how anatomic pathology services are billed to the Medicare program when an independent clinical laboratory performs those services on behalf of a hospital. 71 Fed. Reg. at 49062. In 1999, CMS announced a change in the requirements applicable to billing for the TC of anatomic pathology services furnished to hospital inpatients and outpatients by independent laboratories. That change would have required laboratories to bill hospitals for the TC of those services. However, the Benefits Improvement and Protection Act ("BIPA") enacted a special grandfather provision that exempted certain hospitals from this provision. The provision was extended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), but is now scheduled to expire at the end of 2006. As a result, beginning in 2007, independent laboratories will be required to bill hospitals for the TC of anatomic pathology services furnished to inpatients and outpatients.

In the Proposed Rule, CMS states, "We continue to believe, however, that hospital prospective payment amounts already compensate hospitals for the TC of physician

pathology tests and that additional payment under the PFS is inappropriate." *Id.* Therefore, CMS is proposing to amend § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

AmeriPath strongly disagrees with CMS' assertion that hospital prospective payment amounts already compensate hospitals for the TC of these tests. We are not aware of any documentation available to the public to support this assertion. Therefore, we do not support the implementation of these changes, which would prohibit independent laboratories from billing the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

In addition, AmeriPath is very concerned about the impact of the expiration of the grandfather because it will require a significant change in the way that hospitals and clinical laboratories have historically done business. Hospitals will have to establish new contractual relationships with clinical laboratories to provide these services to hospital inpatients and outpatients, which may lead to a disruption in patient care. Furthermore, it is our experience that many hospitals still are not aware of this impending change and therefore are not taking any steps to address these new requirements. Given this major change to these historical billing rules, we strongly urge CMS to help hospitals understand their new obligations and move forward to address them to ensure that Medicare beneficiaries have full access to necessary clinical laboratory testing services.

AmeriPath again thanks CMS for the opportunity to file these comments. Please do not hesitate to contact me if you need any further information or explanation.

Sincerely,

Marion Kristal Goldberg

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October 10, 2006

**VIA HAND DELIVERY**

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**Re: CMS-1321-P; Comments re Reassignment and Physician Self-Referral**

Dear Ladies and Gentlemen:

We represent numerous clients in the healthcare industry, including several clients involved in providing radiology and other imaging services as in-office ancillary services. On behalf of our clients, we appreciate the opportunity to provide the following comments on the Centers for Medicare and Medicaid Services' ("CMS") "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule" published at 71 Fed. Reg. 48981 (August 22, 2006) ("2007 Proposed Rule"). These comments concentrate on the application of any proposed revisions to the reassignment and physician self-referral rules.

## Background

The 2007 Proposed Rule discusses concerns regarding new potential fraud and abuse vulnerabilities resulting from recent changes to the Medicare reassignment rules. Specifically, CMS recognizes concerns over the recent growth of "pod" or "condo" laboratories involving pathology services. The proposed amendments to the federal physician self-referral statute, 42 U.S.C. § 1395nn ("Stark II"), and the reassignment rules are designed to curb these abusive arrangements. In addition to seeking comments regarding the phrasing and structure of the proposed amendments, CMS is also seeking comments as to whether the amendments should apply only to pathology services and, if not, whether diagnostic tests in the designated health services ("DHS") category of radiology and certain other imaging services should be excepted from any of the proposed amendments.

**Discussion**

We recognize that changes to Stark II and the reassignment rules are needed to curb recognized abuses in the provision and reimbursement of pathology services. However, similar abuses have not been identified in the provision of other diagnostic testing including, radiology and other imaging services, as in-office ancillary services. It is not appropriate or advisable to apply new rules to a segment of healthcare that has operated appropriately within Stark requirements.

In the 2007 Proposed Rule, CMS has identified abuses in the anatomic pathology industry that result from recent changes to Medicare reassignment rules made pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") and loopholes in the Stark regulations, resulting in the recent growth of pod laboratories. 71 Fed. Reg. at 49054-49055. These include ordering of unnecessary biopsies, kickbacks, fee splitting and referrals that would otherwise be prohibited under Stark. These concerns are limited to the anatomic pathology industry and similar problems have not been identified in other healthcare services, including radiology and other imaging services. Absent similar evidence of abuse in other specialties, it would be unfair and would jeopardize patient care if the proposed limitations were extended beyond anatomic pathology.

It is also important to note that the radiology and other imaging industry is unlike the pathology industry in several ways that are directly linked to the potential for abuse. First, in contrast to a pod laboratory for anatomic pathology, the financial investment involved in establishing in-office radiology or imaging service is much greater than the investment needed to establish an in-office anatomic pathology laboratory.

Second, unlike pod laboratories seen in the anatomic pathology industry, imaging equipment is not moved from cubicle to cubicle in a building hundreds of miles from a physician or group practice's office practice. Unlike anatomic pathology where a tissue sample can be sent to another state for analysis, imaging requires the patient's presence and, thus, the location of the equipment must be close to, if not in, the group practice's office. Further, mobile vehicles, vans, and trailers do not qualify under Stark II's "same building" requirement and only qualify under the "centralized building" requirement if they are leased or owned on a full-time basis by a group practice. 42 C.F.R. § 411.351. These limitations inherent in the radiology and imaging industry distinguish it from the anatomic pathology pod laboratories. Radiology in a physician practice is truly an in-office ancillary service as that term is envisioned under Stark.

Additionally, the pathology industry is unique in that, in almost all circumstances, the physicians who seek to establish pod laboratories do not have the requisite professional qualifications or abilities to supervise the laboratory they are establishing, prepare the slides, or provide the professional component of the pathology services. The Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and its implementing regulations as 42 C.F.R.

§ 493.1, *et. seq.* specify the stringent qualifications required of laboratory directors or supervisors and of laboratory testing personnel. Most group practices seeking to establish pod laboratories will not meet these requirements and do not have the requisite scientific background necessary to provide the CLIA-mandated supervision of an anatomic pathology laboratory for the provision of the technical component ("TC"). Nor do they have the requisite training to provide the professional component ("PC") to interpret the anatomic pathology slides. Thus, without added clinical value to the patient, the arrangement sets up the wrong incentives.

The same does not hold true with group practices providing radiology and other imaging services as in-office ancillary services. The Stark statute recognizes that certain services traditionally furnished in a physician's office. That is the purpose of the in-office ancillary services exception. When Stark II was enacted, x-rays and ultrasound were standard in-office procedures. MRIs and CT scans have, for certain specialties, taken the place of x-rays.

In general, a physician ordering these services is trained to supervise the provision of the services and to interpret the results of the tests. While only rudimentary interpretation of slides is taught in medical school and residency, medical students and residents are taught to read MRI and CT scans. These physicians use their reading of imaging tests in the course of examination, diagnosis, and treatment of patients.

In the radiology arrangement, the patient receives the benefit and convenience of an in-office radiology test. There is no benefit to the patient when a group practice establishes a pod laboratory. While there is always risk in any profession that someone will over-order, in the eleven years that Stark II has been in effect, other than with anatomic pathology, abuses have not been identified among physicians who operate within Stark II limitations. With that record, it does not make sense, and it would be demonstrably unfair to impose further limitations on any services beyond anatomic pathology.

Sincerely,

Marion Kristal Goldberg

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October 10, 2006

Mark McClellan, MD, PhD
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Re: Exclusion of Bona Fide Services Fees from the Calculation of the Average Sales Price in CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule

Dear Dr. McClellan:

We, the undersigned organizations, write to support the Centers for Medicare and Medicaid Services' (CMS) proposal in the proposed physician fee schedule to exclude bona fide service fees from the calculation of the Average Sales Price (ASP) under Medicare Part B. We urge you to finalize this proposed rulemaking in November and to ensure that the Agency does not create an exclusive list of services that may be excluded from ASP. Our organizations will be better able to maintain the safety and effectiveness of Part B drugs if we retain the ability to provide and contract for a broad array of value-added services. This will further ensure stable, predictable and transparent ASP reimbursement rates protecting beneficiary access to innovative therapies. It is also critically important that the bona fide fees earned while providing those services do not artificially and inappropriately reduce physician and provider reimbursement.

Each of the undersigned is submitting separate comments to CMS regarding the physician fee schedule rulemaking, but we are united on the critical issue of excluding fees for bona fide services from the calculation of ASP. It seems clear to us that, so long as a bona fide service (as reflected in a market contract between two parties) is provided to a customer at fair market value, no prescriptive regulatory requirements should have to be met in order to determine whether the value of the fee should be excluded from the calculation of the ASP.

The reason for our common approach to this issue is straightforward and consistent with previous interpretations of Medicare and Medicaid law. Historically, if a service is bona fide and reimbursed at fair market value, then it is not considered a price concession. When a service is provided between entities within the pharmaceutical supply chain, CMS need only look to determine whether the fee provided for that service affects the "price actually realized by the manufacturer." If the service being provided is not serving as an overt or a disguised price concession, then there is no reason to include it within the calculation of ASP.

As part of the final rulemaking, we note that so long as a service is performed by an entity on behalf of a manufacturer and provides value to the manufacturer, then it should be considered bona fide. We also note that CMS discusses the requirement that the bona fide service be "itemized." We recognize the value in requiring service fee contracts to specify the services to be performed, but we advocate that no separate itemized payment for each service be required. In the marketplace, bona fide services are frequently offered together and the fees aggregated. It should always be appropriate to exclude aggregated, non-itemized services from the calculation of ASP so long as the services are being performed at fair market value. Manufacturers should be permitted to pay a service fee that covers an array of services provided and still be compliant with the bona fide service fee definition. Moreover, manufacturers should be permitted to obtain a fair market value analysis of the array of services offered rather than for each service individually.

Within the pharmaceutical supply chain, the types of services being provided to entities is rapidly evolving. Accordingly, any effort to "freeze in place" some specific list of services now will reduce innovation and make it more difficult for distributors, pharmacies and physicians to meet the increasingly difficult compliance challenges involved in distributing and administering complex new biotech products. If the marketplace deems the service appropriate and the service is not functioning as a price concession, then it should be definitively excluded from the calculation of ASP.

With respect to the issue of fair market value, we request that CMS clarify that manufacturers may establish fair market value through any generally accepted methodology. The Agency should state that any reasonable and supportable method for determining fair market value is appropriate. Further, the Agency should clarify that any reasonable payment system, including fees earned on a percentage basis, is appropriate.

On behalf of our many members, we commend CMS for its efforts to promulgate a rule that excludes bona fide service fees from the calculation of ASP. We would be pleased to provide the Agency with any information or assistance necessary to ensure that appropriate language is included in the Physician Fee Schedule for CY 2007 Final Rule.

Respectfully Submitted,

Steven M. Coplon
Executive Director
Community Oncology Alliance

John M. Gray
President & Chief Executive Officer
Healthcare Distribution Management Association

John F. Akscin
President
Specialty and Biotech Distributors Association

biogen idec

October 9, 2006

*BY HAND DELIVERY*

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

Re: CMS-1321-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B) – Impact

Dear Administrator McClellan:

Biogen Idec is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the physician fee schedule for calendar year 2007, published in the Federal Register on August 22, 2006 (the "Proposed Rule").[1] Biogen Idec is an international biotechnology company that creates new standards of care in oncology, neurology, and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, we transform scientific discoveries into advances in human healthcare. Biogen Idec also is a member of the Biotechnology Industry Organization (BIO), and we support these comments as well.

Biogen Idec is greatly concerned that the proposed 5.1 percent reduction in payments for all physician fee schedule services will prevent beneficiaries from receiving appropriate care. In particular, this reduction to the conversion factor, when added to the proposed changes in the practice expense relative value units (RVUs), will drastically reduce payment for administration of radioimmunotherapies such as Zevalin® (ibritumomab tiuxetan). Zevalin® is a unique one-week therapy for certain forms of non-Hodgkin's lymphomas. It offers beneficiaries new hope in fighting these diseases, but access to Zevalin® will be assured only if physicians are reimbursed adequately for the costs of preparing and administering the therapy.

[1] 71 Fed. Reg. 48982 (August 22, 2006).

The Zevalin therapeutic regimen is indicated for the treatment of patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphomas (NHL), including patients with rituximab-refractory follicular NHL. Unlike other treatments that require months of chemotherapy, the Zevalin® therapeutic regimen is administered over seven to nine days in two separate steps:

(1) On day 1, a predose of rituximab 250 mg/m$^2$ is followed by an imaging dose of In-111 ibritumomab tiuxetan 5 mCi. At 48 to 72 hours after administration of the imaging dose, whole-body gamma images are performed to evaluate the biodistribution of In-111. Additional imaging studies may be performed at other time points if ambiguities arise.

(2) On day 7, 8 or 9, a therapeutic dose of Y-90 ibritumomab tiuxetan 0.3 or 0.4 mCi/kg (maximum total dose of 32 mCi) is administered. A predose of rituximab 250 mg/m$^2$ is also given 4 hours before the therapeutic dose to improve the biodistribution of the radioimmunconjugate.

Each therapeutic dose administration is reimbursed under a single Current Procedural Terminology (CPT) code, 79403 (radiopharmaceutical therapy, radiolabeled monoclonal antibody, by intravenous infusion). If the proposed 5.1 percent reduction in the conversion factor is implemented, payment for this service will decline by 12 percent under the 2007 transitional RVUs and 34 percent under the fully implemented RVUs. We are deeply concerned that the proposed drastic cuts in reimbursement for preparing and administering Zevalin® will prevent physicians from being able to offer this service in their offices. We urge CMS to take care in implementing the proposed revisions to the physician fee schedule to ensure that reimbursement remains adequate to protect access to critical services, such as administration of radiopharmaceuticals like Zevalin®, in appropriate physician office settings.

* * *

Biogen Idec appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact me at (202) 383-1440 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

Kathleen Weldon

Kathleen Weldon
Vice President, Government Strategy
Biogen Idec

detrimental effect on beneficiaries needing rehabilitation services and could lead to complications, ultimately resulting in greater costs to the Medicare program. We recognize that it will take Congressional action to provide additional statutory authority and prevent the implementation of the therapy caps, and we continue to strongly urge Congress to take timely action to pass legislation that would repeal the therapy cap or extend the exceptions process if repeal is not feasible.

APTA commends you on the significant amount of work that CMS has conducted over the past few years in an effort to identify an alternative to the therapy cap. We strongly believe that therapy care should be based on the needs of the patient, not governed by an arbitrary financial limit. We urge CMS to place a high priority in resources and funding on continuing to conduct research that could be used to identify alternatives to the cap that would ensure that patients receive medically necessary therapy services. This research is a key factor in identifying more clinically appropriate ways to control the growth in Medicare spending.

In its June 2006 report to Congress, the Medicare Payment Advisory Commission (MedPAC) made specific recommendations regarding the direction CMS should take to reform the payment system. We encourage CMS to pursue MedPAC's recommendations with regard to research. Specifically, MedPAC states CMS should consider ways to reform the payment system and comments that before CMS considers changing Medicare's method of paying for therapy services, it needs more information about therapy users and their outcomes. MedPAC states that this would require CMS to design patient assessment tools that gather risk factor information and outcomes measures. CMS also would need to develop valid risk adjusters to account for differences in patients so that CMS can make valid comparisons of patient's outcomes.

One way for CMS to test its selection of patient assessment tools recommended by MedPAC would be to conduct pilot studies. These pilots would test the feasibility of assessment instruments for patients in various outpatient settings. At the completion of these studies CMS would be able to evaluate which tools work for which types of patients and settings. When more compete information about therapy users is available through these tools, CMS can consider how to appropriately reform the payment system.

In addition to MedPAC, the Government Accountability Office (GAO) published a report in November 2005 (GA0-06-59) in which they recommended that DHHS "expedite development of a process for ensuring that these services were considered in its efforts to standardize existing patient assessment instruments."

While we recognize that you face many important priorities in allocating limited funds for research and pilot projects, we believe that few would have as direct and immediate impact on beneficiaries as finding an appropriate alternative to the therapy cap. **APTA strongly urges CMS to conduct these pilot studies so that the arbitrary cap can be removed and a new payment system can be developed that ensures the needs of the patients are met through the delivery of high quality care.** We look forward to providing input and assistance as you proceed with these studies and the development of alternatives to the therapy cap.

## Medicare Payment Rate for 2007: SGR methodology

APTA is also alarmed at the potential impact of the 5.1% reduction in payment that CMS is predicting for 2007. As CMS is aware, the "sustainable growth rate" (SGR) is a seriously flawed formula that will continue to result in significant, unsustainable payment cuts in the future. These cuts are forecasted to continue, totaling about 37 percent or more by 2015, while the practice costs faced by physical therapists and other providers continue to rise.

The potential impact of SGR cuts are magnified this year when combined with the proposed budget neutrality adjustment in the 5 year review rule. The combination of these adjustments would result in a cut in payments of around 10% for physical therapists and even more significant cuts for many other health care professionals in 2007. APTA is deeply troubled that these cuts will significantly hinder the ability of physicians to care for their patients and of physical therapists to care for Medicare beneficiaries needing rehabilitation services.

These proposed cuts undermine the goal of Congress and CMS to create a Medicare payment system that preserves patient access and achieves greater quality of care. If health care professionals experience significant and compounding cuts in payment at a time of rising practice costs, access to care for millions of elderly and disabled will be jeopardized.

Clearly, a new formula that bases updates on the increases in the cost of delivering health care services is needed. We recognize that it will be necessary for Congress to act to change the formula. However, until a new formula is adopted CMS should assist Congress in resolving the SGR problem by taking administrative actions that would reduce the size of the projected cuts.

**To reduce the cost of an SGR solution, CMS should remove spending on physician-administered drugs from calculations of the SGR, retroactive to 1996. Drugs should not be considered physician services and therefore should not be included in the physician SGR pool. In addition, when establishing the SGR spending target, we urge CMS to take into account regulatory changes, such as national coverage decisions, that result in increases in spending.** When the impact of the regulatory changes are not taken into account, the cost of the new benefits and program changes are financed by cuts in payments to physicians, physical therapists, and other health care professionals.

## Payment for Splint and Cast Supplies

CMS proposes to allow separate payment using HCPCS Q-codes for certain medically necessary splint and cast supplies. This would allow payment for medically necessary splint and case supplies used for serial casing, wound care, or other interventions. CMS clarifies that practitioners would continue to bill the HCPCS Q-codes, in addition to the cast/strapping application procedure codes, to be paid for these materials. In the rule CMS specifies the supplies that would be paid separately and identifies the CPT codes that do not include splint and cast supplies in the practice expenses.

**APTA commends CMS's decision to allow separate payment for the splint and cast supplies identified in the rule. It is important to allow payment for these and other medically necessary supplies.**

**Proposed Changes to Physician Self-Referral Rules Relating to Diagnostic tests**

In the rule, CMS proposes changes related to the Stark II self-referral rules for diagnostic tests. CMS expresses concern about the existence of certain arrangements that are not within the intended purpose of the self-referral rules that allow physician group practices to bill for services furnished by a contractor physician in a "centralized building." They are also concerned that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization. We are pleased that CMS is revising its regulations to prevent arrangements that result in abusive practices.

Although CMS is addressing self-referral in the context of diagnostic tests in this rule, we would also like to highlight another physician ownership issue that CMS and the federal government should address. In the past few years, there has been significant increase in physician ownership in entities that provide physical therapy services. The physicians with a financial interest refer their patients to these entities for physical therapy services, creating an incentive for potentially abusive practices. APTA has seen a number of advertisements urging physicians to add a physical therapy clinic to their practice to make huge profits.

Situations in which physicians receive compensation as a result of referring for, prescribing, or recommending physical therapy services create serious potential for abuse. The purpose of the Stark II law was to discourage financial incentives from influencing the delivery of care. **Therefore, APTA strongly urges CMS to create and implement regulatory measures to discourage physician self-referral of physical therapy services. We believe that this can be achieved by strengthening the physician self-referral (Stark) laws, specifically, by making revisions to the "in-office ancillary" exception.** Physician self-referral creates a potential conflict of interest and must be avoided to protect patients and the overall healthcare system.

The APTA appreciates the opportunity to offer these comments to CMS. We look forward to working with you on these issues in the future.

Sincerely,

Dave Mason

G. David Mason
Vice President, Government Affairs

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10 October 2006

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1321-P: Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Dr. McClellan:

Novo Nordisk ("Novo") appreciates the opportunity to submit these comments regarding the proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (the "Proposed Rule").[1] Novo Nordisk is a focused healthcare company and world leader in diabetes care and other pharmaceutical products. The company has the broadest diabetes product portfolio in the industry and also manufacturers and markets products for haemostasis management, growth hormone therapy and hormone replacement therapy. Our pharmaceutical products make a significant difference to our society – patients, the medical profession, and importantly, to Medicare beneficiaries.

In summary, Novo presents the following comments for consideration regarding the Average Sales Price ("ASP") related provisions of the Proposed Rule:

- Treatment of Bona Fide Service Fees: We have concerns about CMS' proposal to expand its prior bona fide service fee guidance to include non-possession taking entities. Novo believes this guidance should only apply to wholesalers and distributors.

- Bundled Price Concessions: We believe CMS' proposal to provide additional guidance on how to apportion price concessions across bundled drugs will be helpful, but we believe the Proposed Rule is ambiguous on the issue of what constitutes a bundle.

We thank you in advance for consideration of our comments on these issues, which are discussed in detail below.

[1] 71 Fed. Reg. 48982 (Aug. 22, 2006).

**Novo Nordisk Inc.** 100 College Road West Princeton, New Jersey 08540 USA Telephone: +1 609-987-5800 Internet: www.novonordisk-us.com

## I. Fees Not Considered Price Concessions

### A. Application of the Bona Fide Service Fee Guidance to GPOs and PBMs

We note the discussion in the Proposed Rule of the modified bona fide service fee guidance and the circumstances under which those bona fide service fees shall not constitute price concessions for ASP reporting purposes. We are concerned about the guidance and the likely unintended consequences of the proposed guidance. We believe this proposal is unnecessary and will impair beneficiary access to drugs, as will be further discussed below.

The Proposed Rule provides the following definition of bona fide service fees:

> "fees paid by a manufacturer to an entity, that (1) represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer (2) that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and (3) that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug."[2]

Of major concern is the provision that states the guidance would apply prospectively "whether or not the entity takes title to the drug." This would substantially broaden the scope of prior guidance, which was directed only to wholesalers and distributors. The prior guidance's focus on wholesalers and distributors is evidenced by the fact that the guidance was announced in the context of a guidance letter specifically addressed to and designed for a wholesaler and a distributor trade association. Despite the limited nature of the prior guidance, CMS is now proposing that it also would prospectively apply to entities that do not take title to product, such as Pharmacy Benefit Managers ("PBMs") and Group Purchasing Organizations ("GPOs").

Novo fears that this expansion of the guidance to include fees paid to PBMs and GPOs will completely erode the ASPs for many products, leading to significant threats to access for Medicare beneficiaries. We urge CMS to continue to apply the guidance to wholesalers and distributors, as per the established industry practice. In Novo's experience, most GPOs and PBMs will not represent and warrant that they will not, under any circumstances, pass on any portion of the fees we pay them to their clients or customers. Thus, the effect of applying this guidance to GPO and PBM administrative fees would be to reduce the reimbursement rate that Congress intended of 106 percent of ASP to 106 percent of ASP, less the GPO and PBM administrative fees.

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[2] *Id.* at 49082.

Since the GPO Safe Harbor to the Antikickback Statute ("AKS") explicitly permits GPO administrative fees of up to 3 percent of the purchase price and even more than that amount, if certain steps are taken, [3] and because the Office of the Inspector General for the Department of Health and Human Services ("OIG") has encouraged manufacturers to base their PBM relationships on the GPO safe harbor,[4] by analogy, the effect of the proposed rule would be to reduce reimbursement to an effective rate of 103 percent of ASP, or even less. Because ASP is merely an average of all acquisition prices and because a significant portion of purchasers are acquiring product at prices above ASP now, CMS' proposed policy will necessarily mean that a significant portion of customers will be asked to acquire product at a price that is below the effective rate of reimbursement.

This problem will become even more acute as manufacturers are forced to take some price increases to, at a minimum, keep pace with the rate of inflation and for increased costs. Because of the two quarter lag, those price increases will further erode the effective reimbursement rate. Novo is concerned that as high as half of all purchasers could be asked to pay more for a product than they are reimbursed. Under these circumstances, we believe that an effect on beneficiary access is inevitable.

Further, we do not believe that this proposed expansion of the bona fide service fee definition is necessary because GPOs and PBMs have been subject to AKS guidance since the GPO Safe Harbor was promulgated fifteen years ago. As discussed above, at least from that time, manufacturers have used the AKS Safe Harbor to inform the scope of permissible activity in the price reporting arena. For example, many manufacturers treat an administrative fee of 3 percent of the purchase price as a bona fide service fee and any administrative fees in excess of that amount, if any, as price concessions. This yields a price reporting rule that is consistent with the AKS Safe Harbor, and we believe that CMS should formally adopt this position as a price reporting rule. One danger of the Proposed Rule is that it would create a disconnect between the AKS Safe Harbor and the price reporting rules, where, in one case, FMV is presumed under certain circumstances (and, with fewer requirements, where the administrative fee does not exceed 3 percent) and where, in the other, a manufacturer must collect some as yet undefined "proof" of fair market value.

We also note that the government has an interest in both GPOs and PBMs being able to pass along fees because it sponsors some PBMs and because pass through fees reported by the customers of GPOs, such as hospitals, that report their

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[3] The Safe Harbor provides that payments by a vendor of goods or services to a GPO do not constitute prohibited remuneration under the AKS if (1) the GPO has a written agreement with each entity; (2) the fee paid to the GPO is 3% or less of the purchase price of the goods or services; (3) if the fee paid to the GPO is not fixed at 3% or less of the purchase price, the agreement specifies the maximum amount that will be paid; and (4) the GPO discloses to its members at least once a year the fees its receives. 42 CFR § 1001.952(j).

[4] Specifically, the OIG stated "Any rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBMs customers' purchases *potentially* implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952(j)." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736 (May 5, 2003).