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Talecris BIOTHERAPEUTICS

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October 10, 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:

Thank you for the opportunity to provide the following comments in response to 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] We are committed to working openly with the Centers for Medicare and Medicaid Services ("CMS"). Your work will have a critical effect on health care access for Medicare beneficiaries.

Talecris Biotherapeutics is a new company proud to inherit a legacy of more than 60 years of providing lifesaving and life-enhancing plasma-derived therapeutic proteins. Through the assets of Bayer Biological Products' plasma business, Talecris' heritage of patient care innovations in therapeutic proteins dates back to the early 1940s. We aim to be the recognized global leader in developing and delivering Gamunex®, our Intravenous Immune Globulin (IVIG) and other premium protein therapies. We are committed to ensuring access to this life-saving therapy. Accordingly, we continue to take reports of IVIG access issues seriously, and we are glad to assist by providing the following comments.

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

- ASP Based Reimbursement for IVIG: We are deeply concerned about the problem of beneficiary access to IVIG. We believe this problem stems from coding related reimbursement issues, and we

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

appreciate the opportunity to propose some solutions that are entirely consistent with the existing ASP reporting methodology.

- Treatment of Bona Fide Service Fees: We have concerns about CMS' proposal to expand its prior bona fide service fee guidance beyond wholesalers and distributors. Talecris encourages the Agency to reconsider this unnecessary expansion and to look to the Anti-kickback Statute ("AKS") Safe Harbors to inform its development of price reporting rules.

- Distinction Between Types of Services: In the Proposed Rule, we are unsure if CMS is suggesting that some types of services wholesalers and distributors provide to manufacturers will qualify for bona fide service fee treatment while others will not qualify. If this is what CMS is suggesting, then we respectfully disagree with this proposal, because we believe that bona fide services of all types must reduce ASP if they are, in fact, bona fide services.

- Determination of Fair Market Value: Talecris believes that CMS should set a standard for fair market value that is consistent with the AKS and then permit manufacturers to comply with that standard in any appropriate and reasonable manner.

- Bundled Price Concessions: We appreciate CMS' proposal to provide additional guidance on how to apportion price concessions across bundled drugs, but we do not believe the Proposed Rule contains enough information about the proposal to provide us a reasonable opportunity to provide meaningful comments.

- Price Reporting Rules vs. Accounting Rules: Talecris strongly urges CMS to recognize the differences between accounting rules and price reporting rules when developing the Final Rule.

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

I. ASP Based Reimbursement for IVIG

A. Problem of Beneficiary Access to IVIG

Talecris manufacturers Gamunex®, an IVIG product that is a vitally important therapy for many patients with immune deficiency disorders and others. Since Talecris is one of only a small number of manufacturers of IVIG, we have a strong commitment to ensuring Medicare beneficiaries have access to our products. We look forward to working cooperatively with CMS on this beneficiary access issue.

Based on reports from patient advocacy groups and our own experience, we believe that beneficiary access to IVIG can be substantially improved by making IVIG ASPs consistent with ASPs for other products. To be clear, we support ASP. However, Talecris has identified two coding related reimbursement issues that are contributing to instances where providers are forced to infuse IVIG products at a reimbursement rate below the provider's acquisition cost. CMS has the authority to remedy this situation that is, often, negatively affecting beneficiary access to this life saving treatment. We urge CMS to partner with us and the rest of the IVIG community to develop a workable long term solution to the access problem.

Talecris first became aware of problems with beneficiary access to IVIG in the physician office setting in 2005. Reports of access problems were, significantly, and largely localized on Medicare patients and in non-HOPD sites of service. This is significant because beginning in January of that year, the ASP methodology became the basis of Medicare reimbursement for non-HOPD sites of service. When Medicare hospital outpatient reimbursement transitioned to the ASP payment system one year later, Talecris began receiving reports from patient groups that Medicare beneficiaries were then experiencing difficulty accessing IVIG in this setting also. We do not believe it is a coincidence that these access issues arose only after IVIG became subject to reimbursement under ASP methodology. We are aware that some in the government believe that this access problem is caused by a product shortage and not a reimbursement issue. We respectfully disagree.

Over the past five years, Talecris has increased the amount of IVIG we make available to patients in the United States by 75 percent. Additionally, to increase our capability to meet the growing demand for IVIG, we have dedicated substantial resources to meet the needs of patients who depend upon our products for their health and well-being. For example, we invested more than $250 million to build a state-of-the-art IVIG manufacturing facility. In addition to these efforts, we also established the Gamunex® Emergency Supply Program for physicians whose patient(s) face an urgent need for IVIG therapy. Talecris reserves approximately 2 percent of its inventory for this program, which provides product on a first come, first served basis to patients in emergency situations. To date, we have not exhausted our emergency supply. This suggests to us that the beneficiary access problem stems from reimbursement issues, not supply issues.

B. Proposed Solutions to Beneficiary Access Problem

Talecris offers two solutions to ameliorate the problems discussed above, both of which are entirely consistent with the ASP methodology which Talecris supports so strongly: (1) CMS should issue separate Healthcare Common Procedure Coding System ("HCPCS") codes to each, single source IVIG product and (2) CMS should increase the payment for administration services to reflect adequately the full cost of providing the service. We note, again, that these recommendations are completely consistent with ASP methodology and with the letter and spirit of the Medicare Modernization Act ("MMA"). These proposed solutions are discussed in greater detail below.

1. Issuing Separate HCPCS Codes to Different IVIG Products

Where there is only one product in a HCPCS code, which is true for the vast majority of drugs subject to ASP, ASP is equal the price of that product's manufacturer reported ASP. This system typically results in stable reimbursement that is consistent with acquisition prices. We believe this is what Congress intended when it mandated ASP as a payment methodology. However, all IVIG products are currently treated as multiple source products, even though they are not bioequivalent. Ordinarily, CMS only groups products into one HCPCS code when the products are rated by the FDA as being therapeutically equivalent, pharmaceutically equivalent and bioequivalent. However, IVIG products do not meet any of these three tests for a number of reasons, including the fact that they differ in product formulation and clinical usefulness.

Due to this designation as a multiple source product, IVIG ASP reimbursement is based on the weighted average of the ASPs for multiple IVIG products. Thus, some IVIG products will be reimbursed based on a class ASP that is below the product's actual ASP. As mentioned earlier, this leads to the unfortunate consequence of some Medicare providers having to provide IVIG at a reimbursement rate below his or her acquisition cost. Fortunately, CMS has the authority to code and reimburse all IVIG products separately. Talecris urges CMS to take this important first step toward solving the IVIG access issue, which we believe is entirely consistent with ASP methodology.

2. Increasing Payment for Administration Services

In addition to the coding problem discussed above, we believe that IVIG access is also compromised due to inadequate reimbursement for administration services. The MMA contemplated that administration service reimbursement could and should be altered where additional reimbursement was proven necessary. We ask that CMS undertake a review of the extraordinary costs inherent in the administration of IVIG, and make appropriate adjustments based on the evidence presented.

Because it is a unique product, the safe and effective administration of IVIG is extremely complex. We understand that the infusion times for IVIG range from 2 to 8 hours. There is a 1:1 nurse to patient ratio, and a physician must be immediately available to assess potential complications. In addition to a physician's evaluation of a patient, the administration service includes the complete evaluation of vital signs and neurological status by a highly trained infusion nurse, pre-medication by an infusion nurse, if needed, a complete assessment of vital signs and neurological status every 15 minutes. To ensure adequate reimbursement for all these services, Talecris strongly supports an increase in the payment for administration services

C. Commitment to a Long Term Solution

We understand that CMS may be considering a National Coverage Determination ("NCD") restricting coverage of IVIG. Talecris believes that a significant number of Medicare beneficiaries would be negatively impacted by an NCD. Since it would take a year or more for an NCD to evaluate the various uses of IVIG, the inevitable consequence of IVIG would be to interject tremendous uncertainty into the

IVIG marketplace. This uncertainty may prevent Talecris and other manufacturers from making necessary additional investments in production capacity. We urge CMS to proceed cautiously when developing policies that may restrict access to this life saving therapy. The Local Coverage Determination process is more than adequate to ensure prompt review of any concerns that CMS may have about the appropriate use of IVIG therapy.

II. Fees Not Considered Price Concessions

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

Talecris took note of the Agency's discussion of the modified bona fide service fee guidance and the circumstances under which those bona fide service fees will not be considered price concessions for ASP reporting purposes. We are quite concerned about the guidance and the likely unintended consequences of the proposed guidance. This proposal is unnecessary, and we fear it will significantly erode the ASPs of many products, thus negatively impacting beneficiary access.

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]

We are particularly concerned about 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").

Talecris believes that this expansion of the guidance to include fees paid to PBMs and GPOs will substantially erode the ASPs for many products, resulting in significant threats to access, or in the case of IVIG, exacerbating existing access problems. We urge CMS to continue to apply the guidance only to wholesalers and distributors. In our experience, most GPOs and PBMs will not represent and warrant that, under no circumstances, will they make any fee we pay them available, at least in part, to their clients or customers. The effect, then, of applying this guidance to GPO and PBM administrative fees would be to reduce the reimbursement rate that Congress

[2] *Id.* at 49082.

intended (106 percent of ASP) to 106 percent of ASP, less the GPO and PBM administrative fees.

Since the GPO Safe Harbor to the 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] the effect of the proposed rule would be to reduce reimbursement to an effective rate of 103 percent of ASP, or perhaps 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.

The situation will grow even more dire as price increases must be taken to 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. It is possible that, even in the case of a single source drug, as high as half of all purchasers could be put into a position where they are asked to pay more for a product than they are reimbursed. In the case of single source products that are treated as multiple source products, such as IVIG, an even higher percentage of customers will find themselves unable to cover their costs when they supply this often life saving therapy. In such circumstances, we believe that an effect on Medicare access is inevitable.

Additionally, we believe that this proposed expansion of the bona fide service fee definition is unnecessary because GPOs and PBMs have been subject to AKS guidance since the GPO Safe Harbor was promulgated in 1991. As indicated 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. Many manufacturers, for instance, 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 of the dangers of the Proposed Rule is that it would create a disconnect between the AKS Safe Harbor and the price reporting rules, where, in the case of the

[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).

Safe Harbor, FMV is presumed where certain requirements apply, and where, in the other case, some as yet undefined "proof" of fair market value must be established.

We should also note that the government has an interest in both GPOs and PBMs being able to pass along fees because the government sponsors some PBMs and because pass through fees reported by the customers of GPOs, such as hospitals, that report their costs may have the effect of reducing various Medicare payment obligations. If the government creates disincentives for pass throughs to occur in connection with these non-possession takers, the government will experience negative fiscal effects.

Lastly, 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. Distinction Between Types of Services

CMS received comments in response to the ASP reporting Interim Final Rule stating that bona fide services include handling, storage, inventory reporting, shipping, receiving, patient education, disease management and data. This is no surprise, as these services and these fees are widely recognized in the pharmaceutical industry. According to CMS, the commenters reportedly did not explain the process for determining whether these activities are bona fide services actually performed on behalf of the manufacturer or otherwise.

Talecris is confused by this portion of the Proposed Rule. It appears that CMS may be trying to draw a distinction between the types of services wholesalers and distributors provide to manufacturers, with some types of services perhaps qualifying for bona fide service fee treatment and others perhaps categorically not permitted to have such status. Thus, CMS has sought comments on the "specific types of services entities perform on behalf of manufacturers that a manufacturer would otherwise perform (or contract for) and the necessity of those services in the efficient distribution of drugs."[5]

We are troubled if CMS is, in fact, suggesting that some services provided to manufacturers cannot be treated as bona fide service fees because there was no suggestion of this in the prior guidance and because we see no principled distinctions to be made based on the type of services wholesalers and distributors provide to manufacturers. Talecris believes that the requirement that all services must be performed "on behalf of" manufacturers for purposes of ASP reporting clearly can apply with respect to all of the types of services that CMS listed in its Proposed Rule.

To be sure, manufacturers should be required to ensure that the services they contract for and treat as bona fide services offer a benefit to the manufacturer. This means that they involve services that the manufacturer would provide itself or through others to customers of the manufacturer or that the manufacturer would seek from

[5] 71 Fed. Reg. at 49001.

others to support its operations as a manufacturer. Given the fact specific nature of the inquiry and the likely evolution in services over time, categorical conclusions offered by regulation are unwarranted and unhelpful.

C. Determination of Fair Market Value

CMS is also soliciting comments on the determination of fair market value. The prior guidance has been widely criticized because of its ambiguous reference to payments that are consistent with what would be made to "third parties" for the applicable services. If, as we believe to be the case, this guidance merely indicates that FMV must be determined without regard to the fact that a wholesaler or distributor is a customer, and that FMV cannot involve any "extra" payment, beyond fair market value, then we believe that the current guidance on the determination of fair market value is largely correct and appropriate as it currently stands.

A minority of analysts, however, have suggested that this standard may mean that there can be no FMV determination where the service is of a kind that only a wholesaler or distributor can provide, because of their unique role in the pharmaceutical sector, even though the manufacturer is only paying an appropriate amount to the service provider, as determined in arms length negotiations. If this is the intent of the current guidance, it is unrealistic, unworkable, and inconsistent with the long-standing guidance issued under the AKS addressing the very same issue.

In a Special Fraud Alert, the OIG has stated that "'fair market value' must reflect an arms length transaction which has not be adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them."[6] Talecris believes that this well-settled understanding of what constitutes FMV is the standard that CMS should adopt in connection with wholesaler and distributor arrangements.

On the issue as to whether CMS should issue more specific guidance as to the manner in which particular services should be analyzed for FMV purposes, we do not believe that this exercise would prove fruitful. FMV is, of necessity, always a reflection of changing circumstances, and we do not think it would be possible for CMS to anticipate all of the relevant variables or to anticipate the range of relationships that exist or will come to develop in the marketplace. If CMS did issue detailed guidance on how to determine FMV for ASP reporting purposes, it would be an anomalous because in other contexts the government, particularly the OIG, has refused to give detailed guidance on FMV.

In fact, the OIG will not opine on FMV issues in advisory opinions. Virtually every OIG Advisory Opinion that discusses the concept of FMV includes a footnote that reads in part, "We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property."[7] The statutory authority for this statement is found in the Social Security Act.[8]

[6] Issued October 1994.
[7] *See, e.g.*, Adv. Op. No. 03-15 (Dec. 11, 2003).
[8] § 1128D(b)(3)(A).

approach that will ensure accuracy and fairness to all interested parties—the government, providers, patients, and others.

Additionally, Talecris respectfully suggests that CMS should eliminate the "no pass through" requirement even for wholesalers and distributors. We believe that the only inquiry should be whether the manufacturer paid FMV for the itemized services. If this is the case, we believe it is unimportant what the wholesaler or distributor ultimately does with its FMV payment, so long as the manufacturer did not direct that payments be passed through to end customers.

Further, Talecris does not know how to determine whether or not fees are passed through because only the wholesalers and distributors know what they will or may do with the fees. If CMS is determined to maintain the no pass through requirement, it should explicitly state that, if a manufacturer receives a no pass through representation from a wholesaler or distributor, this is sufficient to meet the requirement.

III. Conclusion

On behalf of IVIG patients and all patients undergoing other premium protein therapies, we thank you for your ongoing work. Please let us know how we might be of further assistance to you in developing the final rule.

Sincerely,

Bruce Bunyan

Bruce Bunyan
Vice President
Corporate Communications and Public Policy

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October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 8010
Baltimore, MD 21244-8010

Delivered via http://www.cms.hhs.gov/eRulemaking/01_Overview.asp

RE: CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment, Specifically **Provisions Regarding Standard Supplies & Equipment for Procedures with a 90 day Global Period and Resource-Based Practice Expense (PE) RVU Proposals for CY 2007**

Dear Dr. McClellan:

On behalf of the Coalition for the Advancement of Prosthetic Urology (CAPU), we are pleased to submit comments in response to Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for CY 2007 and other Changes to Payment under Part B. CAPU is a national organization that includes leading clinical experts and researchers in prosthetic urology and the nation's leading manufacturers and developers of innovative prosthetic urology devices. As the leading representative of the prosthetic urology community, CAPU's mission is to ensure that the issues affecting this community are given appropriate consideration in the formation of federal health care and reimbursement policy.

Over the past few years, CAPU has been concerned regarding the Relative Value Units (RVUs) assigned to prosthetic urology procedures. We are encouraged by CMS' actions regarding some of the elements of the proposed practice expense methodology; however, there is still more that can be done to ensure future access for Medicare beneficiaries to prosthetic urology procedures. Therefore, as explained in greater detail below, CAPU has the following recommendations:

I. Summary

- Standard Supplies and Equipment for CPT Codes with 90 day Global Periods:
    - Many of the prosthetic urology procedures have been negatively impacted by the use of standard packages for various practice expense inputs, partly because of the assertion by CMS that most 90 day global period codes only contain three post-operative (post-op) visits. This is not the case with prosthetic urology procedures where the average number of post-op visits is five. Thus we recommend that CMS re-evaluate the number of post-op visits packaged into each 90 day global period code.
    - We appreciate CMS soliciting comments regarding standard packages of supplies and equipment for post-operative visits associated with a 90 day global period procedure. With regard to standard supply inputs, CAPU would recommend to CMS that for each post-op visit standard supplies should include the following:
        - Office visit supply package
        - Post-surgical incision care kit

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- Two sets of gloves
- Exam table paper
- Drape, non-sterile sheet
- Additional items recommended by the RUC/PERC.

o With regard to standard equipment inputs, CAPU would recommend to CMS that for each post-op visits that standard equipment should include the following:

- Exam Table
- Exam Light
- Additional equipment recommended by the RUC/PERC.

- Proposed Changes to Practice Expense Methodology:

o CAPU strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it meets CMS's stated goals of using the most appropriate data, simplifying the practice expense methodology and increasing the stability of the practice expense payments.

o In general, CAPU is concerned that compared to last year's "bottom-up" methodology for calculating PE RVUs, this year's method proposes to use budget neutrality adjustors in three separate steps. Physicians cannot continue to absorb these under-valuations, especially as they face 37% in Medicare payment cuts over the next nine years, as projected by the Medicare Trustees. There are steps that the CMS and the Administration could take, even without legislative action, to improve this dire financial picture. CAPU urges CMS to investigate these steps.

o CAPU appreciates CMS using the American Urological Association's supplemental survey data as part of the process of creating a more accurate, intuitive and stable Practice Expense (PE) methodology.

II. Detailed Discussion

A. Provisions - Standard Supplies and Equipment for CPT Codes with 90 Day Global Periods

1. Number of Post-Operative Visits Packaged in Codes with 90 Day Global Periods

The results of the CAPU Survey of Post-Operative Office Visits and Clinical Staff Time demonstrate that the number of post-operative visits in the Centers for Medicare and Medicaid Services (CMS) Practice Expense (PE) Inputs Database are not representative of a typical prosthetic urology practice.

In general, the total number of visits in the CMS PE database for prosthetic urology procedures is three (3). The results of the CAPU survey demonstrate an average of four (4) to five (5) and, in some cases, six (6) post-operative visits depending on the CPT code.

Created Pre- 1990 - Prosthetic Urology CPT Codes 53445, 53447, & 54405:

The CAPU survey results for three CPT codes (53445, 53447, & 54405) created before 1990 reflect that the use of the 90-day global period standardized package of three (3) post-operative visits for most surgical CPT codes as the PE input is not representative of actual prosthetic urology practice.

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In conjunction with the 2003 PEAC review, the PEAC recommended a standardized package of three (3) post-operative visits for "all" surgical procedures with a 90-day global period. However, the results of this survey show that three (3) post-operative visits is not representative of actual prosthetic urology practice.

The CAPU survey results demonstrate that for all three of these CPT codes the mean number of post-operative visits is five (5). The median is also at least five (5) visits, with one exception. For CPT code 53445, the median is six (6) office visits.

Created in 2002 - Prosthetic Urology CPT Codes 53444, 54410, 54411, 54416, & 54417:

While the differences between the CAPU aggregate results for this group of CPT codes and the clinical staff inputs in the CMS PE database are not as wide as the group of CPT codes discussed above, the survey results of prosthetic urology codes created in 2002 also confirm that using standard packages for 90 global period codes is not representative of typical prosthetic urology practice.

The CAPU survey results for the CPT codes in this group, with the exception of CPT code 54417, demonstrate that mean and median number of post-operative visits in a typical practice is four (4) – five (5). This is one -two visits more than the standard of 3 post- operative visits for a 90-day global CPT code.

2. Standard Supplies and Equipment for 90 day Global Period Codes:

A review of the CPEP data used to calculate the proposed 2007 PE RVUs for PU codes revealed that most of the CPT codes have an office visit package and a post-surgical incision care kit assigned to them. However, the number of visit packages and the number of incision care kits in the CPEP data base is three versus the typical number of post-operative visits which is five. CMS needs to update the number of packages and kits based on the results of the CAPU survey, stated above.

Also, CMS needs to include as "standard" supplies that are used to prevent any risk of infection or for patient comfort, such as gloves for the physician and clinical staff, exam table paper, gowns, and drapes.

With regard to equipment, all of these CPT codes were assigned an exam table under the CPEP data for equipment. This is appropriate; however, we would also recommend that an exam light be included as this is standard equipment in an exam room and can be used to illuminate the wound site for greater inspection by the physician.

B. Practice Expense (PE)

1. Bottom-Up Methodology

CAPU strongly supports switching to a bottom-up methodology for calculating PE RVUs and believes that it meets CMS's stated goals of using the most appropriate data, simplifying the practice expense methodology and increasing the stability of the practice expense payments. CAPU is pleased that CMS is seeking ways to provide more stability to the practice expense RVUs now that the AMA and the specialty societies have completed refinement of the original CPEP-collected data. For calculating the direct cost portion of PE RVUs, relying on the direct cost inputs (clinical labor, supplies and equipment) for urology procedures, as refined by the AUA, is an improvement over the previous methodology, which scaled direct cost inputs to a pool of money that was developed based on AMA SMS survey data. The scaling factors in the previous methodology led to inaccurate distribution of PE RVUs among urology's codes, and CAPU strongly supports the change in methodology that does away with the need for scaling factors.

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2. Budget Neutrality

In the newly-proposed PE methodology discussed in the proposal, CMS applies a budget neutrality adjustment three times – to the direct inputs, to the indirect allocators and also as a final step. It is unclear why CMS does not apply budget neutrality just once as a final step in the methodology, and we seek clarification on the impacts of applying three separate budget neutrality adjustments in the new methodology. We are concerned that physicians are being forced to "pay" CMS a 30% discount on all of their direct costs because those direct costs are being subjected to a greater than 30% budget neutrality adjustment.

3. Use of Supplemental Survey Data

CAPU applauds CMS for proposing to use the urology supplemental survey data that AUA submitted originally for use in calculating PE RVUs for the 2006 fee schedule. We were disappointed that although CMS accepted AUA's data last year based on Lewin's recommendation that the data met all of the necessary criteria; an error in the proposed rule's list of 2006 PE RVUs caused CMS to withdraw its proposal to actually use the data in calculating the PE RVUs for 2006. Nevertheless, CAPU strongly support the use of AUA's supplemental data in 2007 and beyond (until a new multi-specialty survey is conducted) for calculating the indirect portion of urology PE RVUs.

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As always, we look forward to working with CMS to address these important issues. If CAPU can provide CMS with additional information, please do not hesitate to contact Jill Rathbun, at 703-486-4200 or Gail Daubert at 202.414.9241.

Sincerely,

John J. Mulcahy, MD

John J. Mulcahy, M.D., Ph.D., F.A.C.S.
Chair

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

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Medical Imaging Contrast Agent Association

October 10, 2006

Via Hand Delivery and Email

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-1321-P**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Revisions to Payment Policies Under the Physician Fee Schedule for 2007 and Other Changes to Payment Under Part B (CMS-1321-P): Medical Imaging Drugs (Contrast Agents)

Dear Dr. McClellan:

The Medical Imaging Contrast Agent Association (MICAA) is pleased to submit comments on the Centers for Medicare & Medicaid Services' ("CMS") proposed rule on Revisions to Payment Policies Under the Physician Fee Schedule for 2007 and Other Changes to Payment Under Part B (the "Proposed Rule").

MICAA is a national non-profit association comprised of developers, suppliers, and manufacturers of medical imaging contrast agent drugs, all of which are administered in the hospital outpatient setting. Medical imaging contrast drugs are increasingly important to accurately diagnose and effectively manage Medicare patients with serious conditions. They enable health care providers to have better information and make more informed treatment decisions.

In brief, our comments are as follows:

- MICAA supports separate payment for High Osmolar Contrast Media ("HOCM"), and we urge CMS to issue guidance to carriers regarding the policy.

- MICAA requests that CMS clarify that separate payment is available for magnetic resonance ("MR") medical imaging drugs.

MICAA notes that adequate reimbursement for the full range of medical imaging contrast agents is particularly important in 2007, when CMS estimates that Medicare reimbursement for medical imaging procedures will be reduced by 16 percent as a result of the Deficit Reduction Act and other payment changes.

MICAA also supports the recommendations of the American College of Radiology regarding Medicare reimbursement for medical imaging procedures furnished by physicians.

A. MICAA supports CMS's proposal to establish separate payment for HOCM, and urges education about the policy.

In the proposed calendar year 2006 Medicare physician fee schedule rule, CMS had advocated paying for HOCM separately from payment for the procedure. MICAA strongly supported this recommendation. Unfortunately, as a result of CMS's delay in implementing a proposed new practice expense ("PE") methodology for 2006, however, CMS also delayed implementing separate payment for HOCM and instead re-bundled the costs of HOCM into the procedures.

For 2007, CMS again is proposing to establish separate payment for HOCM, and to delete HOCM (along with Low Osmolar Contrast Media) from the PE database. We commend CMS for again proposing separate payment for HOCM, and we are confident that CMS can finally institute this policy in 2007 since it is proceeding with its five-year review of Medicare physician work relative value units. We urge CMS to adopt this policy in the final rule.

Moreover, to avoid confusion among carriers about the new policy and to facilitate payment to providers, CMS should educate carriers and physicians regarding the availability of separate payments for HOCM through issuance of a program transmittal.

B. CMS should clarify that separate payment is available for MR agents.

Likewise, MICAA requests that CMS clarify its payment policy for magnetic resonance ("MR") imaging contrast drugs (i.e., codes Q9952-Q9954) and reiterate that these drugs are eligible for separate reimbursement. This would be consistent with CMS policy regarding HOCM and LOCM, and ensure continued beneficiary access to the most clinically-appropriate medical imaging contrast agents.

Note that we have confirmed vis-à-vis review of the supply inputs for the MR procedures that the costs of MR drugs have not been included in the payment for the procedure. Therefore, we believe that CMS should clarify that the physician fee schedule payment for the MR procedure does not include payment for the MR drugs. Again, it is important for CMS to instruct carriers that separate payment is available for MR drugs through the billing of the appropriate Q code, and that the carriers in turn educate physicians regarding billing for MR agents.

* * * *

We would be pleased to discuss any of these issues with CMS in greater detail and will contact the agency to follow-up on these recommendations.

Sincerely,

Jane Majcher
Jane Majcher
Co-Chair
MICAA Health Care Committee

Jay Schafer
Jay Schafer
Co-Chair
MICAA Health Care Committee

cc: Carol Bazell, M.D., Acting Director, Division of Outpatient Care
MICAA members (via email)
Pamela Kassing, ACR
Diane Millman, ASE

Attachment
1. Coding and Billing for MR, LCD Companion Article

RAD024_billing.pdf

FINAL

Companion Article

Article Type
LCD Companion Article

Article Title
Coding and Billing Guidelines for Magnetic Resonance Imaging (RAD-024)

Effective Date
07/01/2005

National Coverage
Title XVIII of the Social Security Act section 1862(a) (1) (A). This section allows coverage and payment of those services that are considered medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862(a) (7). This section excludes routine physical examinations and services.

Title XVIII of the Social Security Act section 1833(e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42CRF410.32 Diagnostic tests may only be ordered by the treating physician (or other treating practitioners acting within the scope of their licenses and Medicare requirements) and diagnostic tests payable under the Physicians Fee Schedule must be furnished under the appropriate level of supervision by the physician.

CMS Pub.100-3, Ch. 1, Part 4, §220.2, CMS Pub.100-4 Ch.13 §40; *CMS Pub.100-4 Rev.502;

Coding Information

1. V67.00, V67.09 V67.1, V67.2, and V71.1 are non-specific ICD-9 codes that require an additional ICD-9-CM code to specify the disease entity treated. *When a metastasis of the primary neoplasm is suspected report V71.1 with a secondary neoplasm ICD-9 code (196.0-198.89) or personal history of neoplasm ICD-9 code (V10.00-V10.9).
2. List the appropriate CPT/HCPCS procedure code that most clearly describes the service(s) performed; include any necessary modifiers (e.g. 26, TC).
3. *Effective for services performed on or after 04/01/2005 HCPCS code Q9952 replaces HCPCS code A4643.
4. *When reporting MRI procedure codes (70549, 70553, 70559, 71552, 72197, 73220, 73223, 73720, 73723, and 74183), these procedures should be reported only once per day. The first and second code in each series of the above listed codes will deny according to the Correct Coding Initiative (CCI) when reported with the above listed codes
5. List the appropriate ICD-9 code that most clearly describes the condition/diagnosis of the patient that is the reason for performance of the MRI. ICD-9 code(s) must be present on all Physicians' Service claims and must be coded to the highest level of accuracy and digit level completeness.
6. Consult the CCI for services that may be considered bundled into the MRI.
7. When billing for a screening test, requested by the beneficiary for denial, report a screening ICD-9 code and the GY modifier. (Item or service statutorily excluded or does not meet the definition of any Medicare benefit.)
8. When billing services, requested by the beneficiary for denial, for individuals that do not meet the medical necessity criteria listed in section "Indications and Limitations of Coverage or Medical Necessity," section of the MRI LCD, report an ICD-9 code that best described the patient's

condition and the GA modifier if an ABN signed by the beneficiary is on file or the GZ modifier (item or service expected to be denied as not medically necessary) when there is no ABN for the service on file.

Q9952 Instructions and Information

On April 1, 2005 CMS **replaced** HCPCS code A4643 (*supply of **additional high dose** contrast material(s) during magnetic resonance imaging, e.g., gadoteridol injection)* **with** Q9952 (*injection gadolinium-based magnetic resonance contrast agent, per ml)*. Previous to 4/1/2005 WPS paid A4643 per invoice rather than based on a fee schedule per dose. Q9952, on the other hand, is paid per fee schedule at ASP + 6 %, **per ml**.

Per IOM (Internet Only Manual, Pub 100-4, Ch 13,§40), the technical component (TC) Relative Value Units (RVUs) for MRI procedures that specify "with contrast" include payment for paramagnetic contrast media (A4647). Therefore, A4647 (*supply of paramagnetic contrast material [e.g., gadolinium])* is an inactive (status I) code, and Medicare does not make separate payment for code A4647.

A4643, and therefore Q9952, is only payable by Medicare when billed with one of four specific CPT codes (70553, 72156, 72157, & 72158), which are all central nervous system (brain & spinal canal) MRI studies. All four CPT codes are defined as *".....without contrast material, followed by contrast material(s), and further sequences"*. These MRI exams can be performed with a normal dose of contrast agent or with an additional/high dose of contrast agent, often referred to as a "double or triple dose study"

The commonly used gadolinium based contrast agents have a concentration of 0.5mmol/ml. The **normal dose** is 0.1mmol/kg, or 12 – 20 ml. The **additional dose** (Q9952) utilized in the "double or triple dose study" is an additional 0.1 – 0.2mmol/kg, or 12 – 40 ml.

Clinical opinions indicate that we should expect additional, high dose contrast (Q9952) to be used in <3% of MRI studies designated by CPT codes 70553, 72156, 72157, & 72158.

Q9952 Summary:

Q9952 should only be billed in conjunction with, and **on the same claim as** CPT codes 70553, 72156, 72157, or 72158, and represents **only** additional, high dose (*in addition to* the normal dose) of gadolinium based contrast agent which was utilized for that patient. **Documentation** for Q9952 should indicate, in the patient's medical record, the **total dose**, and the **normal dose, in ml,** for that patient, of contrast agent utilized. The billed units of Q9952, should represent the **difference between** the total dose and the normal dose, in ml used for the "double or triple dose study".

Denial Summary

Possible Contraindications: MRI may not be covered when the following patient-specific contraindications are present unless acceptable clinical judgment and current literature dictates otherwise:

1. For patients with cardiac pacemakers
2. For patients whom have metallic clips placed on vascular aneurysm, vena cava filters and other metallic implants.
3. For acutely ill patients requiring life support systems and monitoring devices which employ ferromagnetic materials.
4. For patients who have ferrous ocular foreign bodies imbedded shrapnel fragments, or Cochlear implants.
5. For patients who have claustrophobia or who can't lie still, unless these can be controlled by use of conscious sedation or appropriate imaging equipment is available.
6. During a viable pregnancy.

Reasons for Denial

1. Services that do not meet the medical necessity criteria will be denied as not medically necessary.
2. Services performed in other than approved setting will be denied as non-covered.
3. Services performed on other than FDA approved equipment will be denied as non-covered.
4. Services performed for screening purposes will be denied as non-covered.
5. Physicians' Services submitted without an ICD-9 code to support medical necessity or not coded to the greatest level of accuracy and digit completeness will be denied as unprocessable

Notes

Italicized font – represents CMS national policy language/wording copied directly from CMS Manuals or CMS Transmittals. Carriers are prohibited from changing national policy language/wording. Providers, through their associations/societies, should contact CMS to request changes to national policy through the Medicare Coverage Policy Process at www.cms.hhs.gov/coverage

Article Published Dates

*10/01/2005; 07/01/2005

Revision History/Explanation

WI, IL, MI, MN	*10/01/2005, Q9952 clarification (two); 07/01/2005, CMS citations, documentation requirements and denial explanations separated from policy and placed in this companion document due to LCD reformatting, in accordance with CMS instructions.

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October 9, 2006

Via Hand Delivery and Electronic Submission

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1321-P
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1321-P -- Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 -- **Request to Remove CPT 77421 Stereoscopic X-Ray Guidance from List Subject to DRA / Hospital Outpatient Cap**

Dear Dr. McClellan:

BrainLAB appreciates this opportunity to submit comments on the proposed rule setting payment policies under the Physician Fee Schedule ("PFS") for Calendar Year 2007 and Other Changes to Payment Under Part B, 71 Fed. Reg. 48981 (August 22, 2006). BrainLAB develops, manufactures, and markets software-driven medical equipment to provide advanced radiotherapy, radiosurgery, and neurosurgery services, among other things. Accordingly, the company is keenly interested in the impact CMS's proposed changes to PFS payments for 2007 would have on patient access to physician services performed using its technologies.

Specifically, our recommendations are as follows:

- BrainLAB wishes to encourage CMS to refine the list of radiology imaging procedures subject to the cap imposed by the Deficient Reduction Act of 2005 ("DRA"); and

- We respectfully request that CMS remove CPT Code 77421 stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy from the list of "imaging" procedures subject to the DRA / hospital outpatient payment cap.

As you know, in the DRA, Congress mandated that the PFS payment for certain imaging services not exceed the payment rate under the Hospital Outpatient Prospective Payment System ("HOPPS"). We believe that the DRA was not intended to include imaging guidance that is integral to and inseparable from the performance of an interventional radiology treatment during the same outpatient encounter. The DRA, section 5102 (B) describes imaging as follows:

> (B) Imaging Services Described. For purposes of subparagraph (A), imaging services described in this subparagraph are imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography.

In the proposed rule, CMS defines imaging as services that provide visual information regarding areas of the body that are not normally visible, thereby assisting in the diagnosis or treatment of

illness or injury. CMS considered the "7XXXX series" of CPT codes for radiology services plus some additional CPT / HCPCS codes that describe imaging services.

However, listing all the 7XXXX codes by virtue of their position in CPT is a very broad approach that may not be consistent with the intent of Congress. On this BrainLAB agrees with the American College of Radiology ("ACR") and other specialty societies that the list of procedures affected by the DRA should not include the 7XXXX codes that describe imaging guidance for interventional procedures. While supervision and interpretation codes for diagnostic angiography may meet the definition of an imaging procedure, we agree with ACR that imaging guidance for biopsy and certain radiation treatments (such as CPT 77421 stereoscopic x-ray guidance for localization of target volume for radiation therapy) do not.

As you may know, imaging guidance has been incorporated into several new CPT codes for surgical / therapeutic procedures such as cryoablation of the prostate, endovascular stent placement, and bone ablation, and these CPT codes are not affected by the DRA cap. Unfortunately, a few interventional and therapeutic radiology codes, those in the 7XXXX series, remain subject to the DRA provision, including CPT 77421. These codes are similar to those excluded from the DRA cap in that they are integral to a therapeutic treatment. Thus, in the interest of consistency, BrainLAB believes that, when imaging guidance is used to facilitate a surgical procedure or radiation treatment, those codes should not be defined as diagnostic imaging nor included on the list of codes subject to the DRA provisions.

Moreover, recent cost data for the technical component was recently reviewed by CMS and used to establish the non-facility relative value units for CPT 77421 stereoscopic x-ray guidance, effective January 1, 2006.

The ACR and other specialty societies have recommended that CMS further refine the DRA list to exclude "interventional and therapeutic" radiology codes such as 77421. If action is not taken, doctors will not be adequately reimbursed for the significant expenses associated with providing these services in the physician office setting. As a result, they may not be able to afford to provide these valuable services to patients. BrainLAB supports the ACR's recommendations and respectfully requests that CMS act now to preserve patient access to interventional/ therapeutic radiology procedures by excluding CPT 77421 stereoscopic x-ray guidance from the DRA list.

We appreciate your attention to this important matter. Please contact me at 440.213.3951 or Gail Daubert at 202.414.9241 for any further information you may need.

Sincerely,

Jason Chandler

Jason Chandler
Director of Business Development, BrainLAB

cc: Carolyn Mullen, CMS, Deputy Director, Practitioner Services (via email)
Pam Kassing, Senior Director, Economics and Health Policy, American College of Radiology
Trish Crishock, ASTRO

Josh Ofman, MD, MSHS
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October 10, 2006

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

Re: 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 Administrator McClellan:

Amgen is writing to comment on the proposed rule regarding revisions to payment policies under the Medicare Physician Fee Schedule for calendar year 2007 and other changes to payment under Part B (the "Proposed Rule"), which the Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* on August 22, 2006.[1] As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals (collectively referred to in this letter as "drugs," following the agency's convention) for Medicare beneficiaries. For this reason, our comments address the following issues:

- the agency's proposals related to the calculation of the average sales price (ASP) of drugs;
- the use of the ASP methodology as the basis for Medicare payment to dialysis facilities for certain separately billed drugs; and
- other issues impacting access to drugs in the physician office setting.

Amgen recognizes the importance of ensuring adequate payment for Part B covered drugs so that Medicare beneficiaries have access to critical treatments. The success of the ASP system in achieving Congressional objectives and reducing Medicare

[1] 71 *Fed. Reg.* 48,982 (Aug. 22, 2006).

expenditures has been well documented.[2] Given the success of the ASP-based payment system in lowering the costs of drugs for both Medicare and beneficiaries, we are concerned about certain suggested changes to the ASP calculation.

Specifically, as there is no readily apparent compelling policy reason to change the ASP methodology with respect to "bundled price concessions," we strongly urge CMS to:

- consider carefully the potential increased costs to Medicare and its beneficiaries and other unintended consequences of requiring reallocation of bundled price concessions;
- require demonstrable and conclusive evidence that existing ASP reporting, or the existing market-based methodology itself, is significantly flawed before proposing any such reallocation requirements; and
- ensure that all stakeholders have the opportunity to comment on the specifics of any proposed change through rulemaking before it is effective.

Amgen also requests that CMS:

- revise the Proposed Rule to clarify that fees paid to non-purchasers, such as group purchasing organizations (GPOs), need not be considered in the ASP calculation;
- specify that fair market value, for purposes of the *bona fide* service fee standard, may be established by any generally recognized and accepted methodology;
- specifically identify services such as, but not limited to, chargeback administration, inventory management, data services, and guaranteeing the timely delivery of products as the types of services that can qualify as a *bona fide* service;
- permit manufacturers to utilize a sales-dollars based ratio for estimating lagged exempt sales; and
- provide further explanations and details regarding its proposal related to estimating lagged price concessions where a national drug code (NDC) has been redesignated.

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2 *See e.g.*, statements of Robert A. Vito, Regional Inspector General for Evaluations and Inspections, U.S. Department of Health and Human Services (HHS), before the House Ways and Means Subcommittee on Health, July 13, 2006 ("recent data on Medicare reimbursement and expenditures provide evidence confirming that the ASP-based reimbursement system has substantially lowered reimbursement amounts for numerous drugs.") and of Mark Miller, Executive Director, Medicare Payment Advisory Commission (MedPAC), before the House Ways and Means Subcommittee on Health, July 13, 2006 (the change to ASP-based payment "lowered the payment rate for most drugs and decreased Medicare spending for Part B drugs.").

Additionally, we support the following:

- the clarification in the Proposed Rule that Medicare payment in 2006 and subsequent years for separately billed drugs furnished by freestanding and hospital-based renal dialysis facilities will be based on the 106 percent of ASP methodology;

- the agency's guidance on the distinction between Medicare coverage for drugs under Parts B and D of the program; and

- the proposal to exempt colorectal cancer screening services from the Part B deductible.

Finally, we urge CMS to continue the oncology demonstration project into 2007. Below, we discuss each of these issues in greater detail.

ASP ISSUES

I. CMS Should Not Undermine the ASP System by Requiring Reallocation of "Bundled Price Concessions," and There is No Compelling Policy Rationale for Such Regulation.

In the preamble to the Proposed Rule, CMS invited comment on the need for future guidance concerning the methodology for calculating the ASP of drugs sold under market-based pricing arrangements, including "bundling arrangements", described by CMS as "for example, when a purchaser's price for one or more drugs is contingent upon the purchase of other drugs or items".[3] Indicating a desire to better understand these arrangements, CMS solicited comments on a number of issues, including the types of arrangements, how common they are in the marketplace, and their potential effects on the ASP calculation, beneficiary access to care, and costs to Medicare and its beneficiaries.

Amgen's comments in response to this request have been developed with several policies and principles in mind:

- First, the Congressionally mandated Medicare Part B drug payment system is predicated on the use of market-based pricing (denominated as ASP). CMS should not change this effective, fair, and transparent price reporting system, which has resulted in substantial savings to the Medicare program and beneficiaries, without a full discussion of the potential consequences. Any possible changes to the ASP system that may be proposed by CMS after the agency's review of comments in response to the request for information in the Proposed Rule should be made through notice-and-comment rulemaking, giving

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71 *Fed. Reg.* at 49,003.

all stakeholders a meaningful opportunity to respond to an actual proposal before it is adopted.

- Second, changing the current methodology would risk distorting the ASP so that it no longer reflects market prices. Because ASP has resulted in substantial Medicare savings and changes to the ASP methodology could have unpredictable effects on Medicare expenditures, CMS should not change the ASP system unless it can demonstrate conclusively that the existing methodology is significantly flawed.

- Finally, CMS should not make decisions based on unproven allegations or make judgments about the merits of litigation pending in federal court. The CMS mission is to implement Medicare and Medicaid laws. Other agencies and the courts can enforce other laws and resolve commercial disputes.

Amgen's comments make the following points, which are discussed in more detail below:

- Multiproduct contracts are common, pro-competitive mechanisms for price competition;

- An accurate ASP reflects a drug's price in the marketplace, and reallocation of discounts from one product to another could result in inaccurate ASPs, with the potential for unintended consequences, including impaired beneficiary access and inappropriate financial incentives;

- Use of the existing ASP methodology has resulted in lower Medicare and beneficiary payments, and a reallocation requirement could result in higher Medicare and beneficiary costs; and

- CMS should not publish guidance on this issue without giving all affected parties a meaningful opportunity to comment on the specifics of a proposed rule before it becomes final and effective.

Multiproduct contracts are common, pro-competitive mechanisms for price competition.

It is our understanding that so-called "bundled discounts," which provide buyers the opportunity to obtain larger discounts when purchasing multiple products that remain separately available, are common and provide recognized benefits to producers and consumers.[4] Bundled discounts, which are distinct from tying arrangements because

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[4] *See* John Thorne, Discounted Bundling by Dominant Firms, 13 Geo. Mason L. Rev. 339 (2005)("Bundled discounts are in many ways akin to ordinary volume discounts, because in both cases the purchase of additional units leads to a lower overall price."); Michael A. Salinger, A Graphical Analysis of Bundling, 68 J. Bus. 85 (1995) ("Bundling can . . . increase consumer surplus when it results in lower prices.").

they do not require a consumer to purchase one product in order to purchase a second product in the bundle, often promote price competition and efficiency. The Supreme Court recognized that the discounting of a package of multiple products or services can benefit consumers and the market when it said, "[t]here is nothing inherently anticompetitive about packaged sales."[5] Specifically addressing this form of discount for items and services paid for by Medicare or Medicaid, the Office of Inspector General (OIG) said, "in certain circumstances, discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale. Such circumstances exist where the goods and services are reimbursed by the same Federal health care program in the same manner, such as under a DRG payment."[6]

CMS did not identify any specific concerns about such sales in the preamble to the Proposed Rule or point to any harm resulting from manufacturers' current treatment of bundled discounts. The agency merely asked for help in understanding whether bundled price concessions that are legal under applicable laws and regulations, might nonetheless cause inaccurate ASPs or inappropriate financial incentives.[7] Amgen believes that such is not likely the case, for several reasons, as discussed in more detail below.

An accurate ASP reflects the prices available in the market for a specific product. Reallocation of discounts from one product to another is unnecessary and could result in inaccurate ASPs, impaired beneficiary access, and inappropriate financial incentives.

It should not be necessary to allocate price concessions among the products in a multiproduct contract in order to calculate an accurate ASP. In fact, where all products in a multiproduct contract are paid for by Medicare based on ASP (as Amgen's are), the discounts are appropriately disclosed in the quarterly ASP submissions discussed below (as is the case with Amgen's discounts), and all price concessions benefit Medicare and its beneficiaries (as Amgen's do). That would not be the case with respect to a contract that "bundled" discounts on Part B covered

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5 Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 25 (1984); *see also*, Daniel Crane, Multiproduct Discounting: A Myth of Nonprice Predation, 72 U. Chi. L. Rev 27, 48 (2005) ("Packaged discounting is a common phenomenon among firms that have no predatory ambition. It is a business strategy that often makes perfectly good sense without any need for injury to a rival. In the short run it cannot harm competitors any more than an equivalent discount on a single product and, in the long run, it increases consumer welfare by lowering the price of goods and services even if no competitor exits the market.")

6 *See* 64 *Fed. Reg.* 63518, 63530 (Nov. 19, 1999).

7 *See* 71 *Fed. Reg.* at 49003-4. ("We note that we expect manufacturers of drugs reimbursed by Medicare Part B to comply with all applicable laws, regulations, and legal decisions including, but not limited to the Stark law, other relevant anti-kickback laws, antitrust laws, and laws governing fair trade practices...[O]ur goal is to ensure that the ASP is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives.")

drugs with devices, supplies, or other items for which Medicare does not pay or pays based on a different methodology. For example, when a manufacturer offers rebates on medical devices or supplies as an incentive to purchase Part B covered drugs (as we understand is done in our competitor's, Johnson & Johnson's (J&J's), hospital contracts), the price concessions on the devices and supplies are not reflected in ASP and may not benefit Medicare Part B and its beneficiaries at all.[8]

Despite there being no compelling policy reason to change the ASP methodology, we anticipate that CMS will receive comments from J&J that claim that all bundled price concessions on drugs, particularly those alleged not to have clinical alternatives, should be reallocated. This is because J&J is attempting to avoid true price competition in the marketplace. In fact, J&J senior executives have stated publicly this intent, as evidenced in the following statements to investors:

- Third Quarter 2005 Earnings Webcast (October 18, 2005), Statement by Bob Darretta Vice Chairman and Chief Financial Officer, J&J

  "We're pleased about the [Procrit®] price stability....The latest competitive tactic, though is very difficult to handicap should we be unsuccessful in getting the injunction to which we believe we are entitled, because it will reinject tremendous price pressure...."

- Fourth Quarter 2005 Earnings Webcast (January 24, 2005), Statement by Christine Poon, Vice Chairman and World Chair, Medicines and Nutritionals, J&J

  "On Procrit I think you know that in a third of the marketplace at the oncology clinics that we are in litigation now with Amgen regarding what we believe is an illegal bundling of Neulasta and Aranesp...for that piece of the business its going to be tough going; a lot of pressure on pricing."

While there is no reason for CMS to enter into this legal and commercial dispute, Amgen feels compelled to set the record straight on several issues in response to the misinformation disseminated about Amgen's multiproduct contracts. Here are the facts:

- The J&J proposal is based on allegations in a lawsuit pending in federal court. Amgen vigorously denies the allegations in that lawsuit, including the allegation that its contracts give discounts on drugs for which there is no clinical alternative in lieu of discounts on a drug (Aranesp®, darbepoetin alfa) with which J&J's product

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[8] Our understanding is that price concessions in such contracts would not qualify for the OIG discount safe harbor provisions of the anti-kickback rules. *See* 42 C.F.R. §1001.952(h)(5)(ii) ("The term *discount* does not include—(ii)Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected, where appropriate, and as appropriate, to the reimbursement methodology.")

Procrit® (Epoetin alfa) competes. The federal court will determine whether Amgen's portfolio contract is good for competition and for consumers.

- The other drugs in the contract at issue are NEUPOGEN® (filgrastim) and Neulasta® (pegfilgrastim), both of which are available for sale individually. J&J has alleged that there are no clinical alternatives to Neulasta®. This statement is simply not true. Both NEUPOGEN®, which Amgen markets, and Leukine® (sargramostim), which is marketed by another company, Berlex, Inc., represent clinical alternatives across many indications, when used appropriately. Importantly, numerous Medicare Part B carriers acknowledge this fact in their Local Coverage Determinations (LCDs). These policies specifically demonstrate the availability of Medicare coverage for these three products across many of the same International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes.[9]

- J&J has alleged that such multiproduct discounts that include a product without a clinical alternative are intended to be an incentive to induce sales of other drugs and so should be reallocated. The agency may be told that Medicare should **infer** that discounts on drugs with no clinical alternatives were intended solely to benefit other drugs in the bundle. There is no such intent with respect to Amgen's multiproduct contracts, and this intent should **not** be inferred because there are many reasons for discounting across a family of products, including (1) brand loyalty considerations, (2) the practice of giving the best discounts to the best customers, (3) the clinical attributes and practice patterns related to such products, and (4) other appropriate marketing considerations.

- J&J has told Congress and may be telling CMS that it should reallocate discounts because customers who do not choose to access additional discounts in a multiproduct contract could receive a discounted price on one product that is below the ASP-based reimbursement that CMS sets for a drug, creating an access barrier. This alleged access barrier is rhetorical rather than real. While there is no reason for CMS to insert itself into this legal dispute, we think it appropriate to clarify that all Procrit® users have access to white blood cell growth factor (WBCGF) drugs, as we outline below:

    - ***Oncology clinics are making choices.*** Specifically, there are many reasons why oncology clinic customers might choose not to access Amgen

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9 *See, e.g.*, CMS Medicare Coverage Database: Noridian Administrative Services, Local Coverage Determination (LCD) for Filgrastim (NEUPOGEN), Sargramostim (Leukine), and Pegfilgrastim (Neulasta) [L14920]; AdminaStar Federal, LCD for Granulocyte Colony-Stimulating Factors [L15352]; TrailBlazer Health, LCD for Colony Stimulating Factors [L18411]; Wisconsin Physicians Service Insurance Corporation, LCD for Human Granulocyte/Macrophage Colony Stimulating Factors [L19956]; Palmetto GBA, LCD for White Cell Colony Stimulating Factors [L6332]. Amgen continues to believe that these products all have clinical differences and that physicians should be able to choose which products to use for their patients. The CMS Medicare Coverage Database is available at http://www.cms.hhs.gov/mcd/search.asp.

portfolio incentives that could enable them to purchase Neulasta® at a lower price and obtain a price below the Medicare reimbursement level. Chief amongst those reasons is the J&J clinic contract, under which clinics can choose to meet certain performance tiers that allow them to obtain Procrit® at a price that is much lower than the relatively high ASP of Procrit®. The ASP for Procrit® is high (higher than Aranesp®) because it is pulled upward by J&J's success in selling Procrit® at a higher price in the retail segment of the market. This market reality may lead customers to take advantage of the best J&J discounts rather than to take advantage of the best Amgen discounts. For CMS, the relevant issue is that, under a market-based ASP system with competitive products, customers are making choices. Both companies offer their best discounts to their best customers, and each clinic chooses which discount program is most advantageous to it. Some clinic customers may voice displeasure to CMS or others at not having the ability to access the very best discounts from both companies concurrently, but that situation is the result of competition that is benefiting Medicare and its beneficiaries.

- ***NEUPOGEN® and Leukine® are options for oncology clinics.*** Those customers who do not participate in Amgen's best contract offerings can still acquire NEUPOGEN® at a net price that is below the Medicare reimbursement rate. Physicians may also choose to purchase Leukine®. Importantly, it should be noted that these two products hold a 24 percent market share of the WBCGF market, showing again that there are economically feasible clinical alternatives to Neulasta®.

- ***Amgen provides some discounts on its WBCGF products independent of Aranesp® sales.*** Amgen's multiproduct contract offers price concessions, including a discount and a rebate, to Neulasta® and NEUPOGEN® customers without regard to the amount of Aranesp® they purchase, including if they purchase no Aranesp® at all. That fact that Procrit® users also have access to Neulasta® is evident just from looking at how much Neulasta® is purchased by customers who choose to purchase more Procrit® than Aranesp®. Of the Procrit® prescribers who also use either of Amgen's WBCGF drugs, the vast majority of them purchase Neulasta®. A critical point is that clinics evaluate their ability to prescribe drugs in an economically feasible manner (*e.g.*, without losing money) across their entire payer mix. The high utilization of Neulasta® by Procrit® users demonstrates this point and dispels the myth that clinics consider Medicare reimbursement alone in deciding whether to provide our products to their patients. Furthermore, the Medicare Payment Advisory Commission (MedPAC) issued a report earlier this year examining whether the change to ASP-based reimbursement for oncology services has caused access issues. Though MedPAC did note that "[e]very practice reported that they could not buy some drugs at the [Medicare] payment rate," the

Commission concluded that "the payment changes did not affect beneficiary access to chemotherapy services."[10]

- ***The Competitive Acquisition Program (CAP) is another option for oncology clinics.*** Finally, Congress anticipated that, with the implementation of ASP, some providers may not participate in contracts that enable them to purchase below the ASP of some drugs. While J&J asserts that CMS should act on this issue by regulating bundled price concessions in a way that is different from how the market allocates discounts, Congress has provided another alternative in CAP. This program is an important alternative source of supply for physicians who administer Part B covered drugs to Medicare beneficiaries. Under CAP, any physician clinic can order, at absolutely no cost, most Part B covered drugs that the clinic would need for its Medicare beneficiaries, with the CAP vendor assuming the reimbursement risk. For example, Aranesp®, Procrit®, Neulasta®, and NEUPOGEN® are all available under CAP. Since oncology clinics generally evaluate their economics by taking into account the reimbursement they receive from all payers and the reimbursement they receive for all services related to patient care, the vast majority are still finding it economically preferable to acquire on the open market the drugs needed to treat their Medicare beneficiaries and to forego the CAP alternative.

Requiring the reallocation methodology for multiproduct contracts would also inject an intolerable additional burden of complexity and risk to an already complicated and risky reporting requirement.[11] As we understand the suggested reallocation method, a determination would have to be made that one or more drugs (say "Product A") in a bundled sale have no "clinical alternatives." If so, then a determination would have to be made that some price concessions on Product A were conditioned on the purchase of one or more drugs with "clinical alternatives" (say "Product B"). If so, then a determination would have to be made regarding how much of the price concession on Product A was the result of the condition relating to Product B and how much was the result of other factors (*e.g.,* volume of purchases of Product A; historical market share; prompt payment; or a myriad of other legal price concessions).

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[10] *See* MedPAC Report to the Congress: Effects of Medicare Payment Changes on Oncology Services (Jan. 2006). In the report, MedPAC also noted, "We saw no indication that quality of care was affected, and patients continue to be satisfied with the care they are receiving."

[11] Under the statute and existing regulations, manufacturers calculate the ASP for each unit of each drug at the end of each quarter, by determining the sales to all non-exempt purchasers, deducting price concessions and dividing by the number of units. The manufacturer has to carefully account for all transactions and follow the quite complicated methodologies for dealing with lagged price concessions, exempt sales, and other factors, a number of which are discussed elsewhere in this comment letter. Importantly, manufacturers are required to certify the accuracy of each quarterly ASP report, there are significant penalties for misrepresentations, and CMS has not established a procedure for correcting inadvertent errors. *See* SSA §§ 1847A(d)(4), 1927(b)(3)(C); 42 C.F.R. §414.804(a)(6).

As discussed in more detail below, these reallocations could create access issues for beneficiaries whose physicians purchase only or primarily Product B, because the ASP on which the Medicare payment rate was based would include a "phantom discount" moved from Product A. That discount would not actually be available to purchasers of Product B. This reallocation would also result in inappropriate financial incentives to purchase Product A, since its ASP would not include price concessions actually given in the marketplace.

Use of the existing ASP methodology has resulted in lower Medicare and beneficiary payments, and a reallocation requirement could result in higher Medicare and beneficiary costs.

It is widely accepted that the use of ASP-based payment rates for Part B covered drugs has generally reduced payment rates and rates of increase in Medicare spending.[12] Making a fundamental change to the current methodology could put continuation of these positive trends in jeopardy.

There are several risks that CMS should take into consideration in deciding whether or not to propose a reallocation requirement for ASP calculations. First, reallocation of price concessions to a product with "clinical alternatives" could result in the market shifting to a higher-cost drug. For example, this would be the result of applying the reallocation methodology supported by J&J to certain Amgen products. Reallocation would result in higher Medicare spending, in part because the ASP of Procrit® is generally higher than that of Aranesp®, even without any reallocations. The drugs are comparably priced in the physician and hospital market segments, but a higher proportion of Procrit® sales are in the retail pharmacy sector, where acquisition costs tend to be higher. As mentioned above, these higher priced retail sales raise the ASP of Procrit®. Since the reallocation supported by J&J would likely succeed in shifting market share to the more expensive product (*i.e.,* Procrit®), it could substantially increase Medicare expenditures. Most assuredly, the reallocation would **not** lower costs as J&J has erroneously stated to Congress, to the media, and possibly to CMS.[13]

To be clear, this issue represents the crux of the difference between the widely disparate cost estimates. In our estimate of the costs associated with reallocating all NEUPOGEN® and Neulasta® discounts to Aranesp®, we took into account the fact

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12 *See, e.g.,* aforementioned statements by Robert A. Vito (HHS) and Mark Miller (MedPAC).

13 Amgen has estimated the potential financial impact to Medicare of adopting the J&J proposal to reallocate bundled price concessions. Any appropriate analysis of the financial impact of reallocating NEUPOGEN® and Neulasta® discounts to Aranesp® under the J&J proposal must minimally include assumptions regarding (1) the utilization shift from Aranesp® to Procrit® that could result from a lower Aranesp® ASP and (2) the potential increase in the ASPs for NEUPOGEN® and Neulasta®. Our analysis includes both of these assumptions, and we estimate that if 50 percent or more patients are switched from Aranesp® to Procrit® that it could result in more than half a billion dollar increase in Medicare expenditures. Furthermore, the Amgen estimate is conservative because it does not include any assumptions regarding the potential increase in utilization of NEUPOGEN® and Neulasta® that could result from receiving a higher payment rates as a result of the reallocation of discounts.

that the reallocation would result in an artificial ASP for Aranesp® that could be below the price available to any purchaser. Since there is an alternative product (Procrit®) with an ASP that is above acquisition cost, many buyers likely would shift their purchases to that product. In other words, in this situation, any reduction in the ASP for Aranesp® as a result of reallocation of discounts is likely not to result in Medicare savings (even though ASP for Aranesp® would be even lower than it is now, compared to the ASP for Procrit®) because sales of Aranesp® would not continue at the pre-allocation level.

A related risk is that the complexity and market-distorting effects discussed above could lead manufacturers to discontinue use of multiproduct contracts. If price competition is reduced, costs to Medicare and its beneficiaries could rise.[14] In addition, there almost surely would be additional Medicare spending on products whose ASPs are increased artificially by the allocation to other products of discounts actually given on them. If these are products without clinical alternatives, the costs would be difficult to avoid. [15]

Finally, CMS should not publish guidance on this issue without giving all affected parties a meaningful opportunity to comment on the specifics of a proposed rule before it becomes final and effective.

CMS signaled in the preamble to the Proposed Rule that it might use its authority to provide guidance in this area through program instruction or other guidance. CMS should not use this authority to give guidance which is predicated on facts that are in dispute. It would be especially inappropriate to do so where issues in such a dispute are before a court. As discussed in detail above, this is a complicated issue with significant potential for unintended adverse effects. All stakeholders must have an opportunity to comment on the specifics of any possible proposal (in the form of a proposed rule), before it is effective.

II. CMS Should Not "Clarify" that Service Fees Paid to Non-Purchasers Need To Be Considered When Calculating ASP.

The Proposed Rule seeks to amend the agency's existing guidance, found in Q&A #3318, regarding administrative and service fees.[16] Specifically, CMS proposes to "clarify" that fees paid by manufacturers to an entity, whether or not that entity takes

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14 As noted earlier, it is clear that the reason J&J brought a lawsuit seeking an injunction against Amgen's use of a particular multi-product contract is to relieve price pressure on its competing product. *See, e.g.,* aforementioned statements by Bob Darretta, Vice Chairman and Chief Financial Officer, J&J, and Christine Poon, Vice Chairman and World Chair, Medicines and Nutritionals, J&J.

15 Importantly, none of the products in the Amgen contracts at issue in the pending litigation could be classified by CMS as "without clinical alternatives". Procrit® and Aranesp® were declared by CMS to be "functionally equivalent" several years ago. Further, as noted earlier, Medicare Part B carriers often issue combined LCDs for NEUPOGEN®, Neulasta®, and Leukine®. In these policies Medicare carriers show that coverage is available for these products across many of the same indications.

16 *See* CMS Q&A #3318, located at http://questions.cms.hhs.gov.

title to the product, must be included in the calculation of ASP where those fees do not satisfy the Proposed Rule's definition of a *bona fide* service fee.[17] The preamble's discussion of this issue specifically notes that this standard would apply to fees paid to GPOs as well as pharmaceutical benefit managers (PBMs).[18]

The expansion of the agency's existing guidance to apply to entities that do not take title to product is inappropriate, because ASP is defined by statute as including only "the manufacturer's sales to all purchasers...."[19] This definition limits ASP to purchaser transactions because ASP is meant to measure an average sales price, so that reimbursement rates can approximate average acquisition cost. Inclusion of fees paid to non-purchasers will distort the ASP calculation so that it understates rather than approximates acquisition cost, which in turn will have significant provider and patient access implications.

Amgen believes that fees paid to GPOs should not be considered price concessions, because GPOs are not purchasers. GPOs are entities that negotiate contracts with manufacturers on behalf of health care providers—such as hospitals, nursing homes and physician clinics. GPOs generally do not purchase or buy any products. Instead, they negotiate discounted pricing on behalf of their members, who are purchasers. Inclusion of GPO fees in the calculation of ASP likely would lower ASP figures and, thus, reimbursement rates.[20] If CMS nevertheless decides that GPO administrative fees are to be considered for inclusion in the ASP calculation, Amgen urges CMS to adopt the safe harbor to the federal anti-kickback statute as the test for evaluating whether or not those fees need to be included in the ASP calculation.[21] Through the existing safe harbor for GPO administrative fees, the OIG has identified conditions which, if satisfied, represent an acceptable and non-abusive arrangement that fosters business competition and economy.[22] No additional criteria should need to be met in order to exclude GPO fees from the ASP calculation.

CMS also proposes to require that fees paid to PBMs be considered price concessions for ASP purposes unless they meet the *bona fide* service fee definition. Amgen requests that CMS clarify whether the basis for the Proposed Rule is that CMS considers PBMs to be purchasers. If that is the case, Amgen requests further

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17 71 *Fed. Reg.* at 49,001.

18 *Id.* The Proposed Rule itself is overbroad, in that it would appear to apply to any entities providing services for a fee to a manufacturer, whether or not they take title to a drug, although the agency's discussion does not appear to anticipate the rule's application to other types of non-possession-taking entities that also provide services to manufacturers

19 *See* SSA § 1847A(c)(1) (emphasis added).

20 GPOs perform various services in exchange for the administrative fees paid by manufacturers. Those services include notifying their members of the manufacturer's product offerings and the discounted pricing available on those products, monitoring member compliance with the terms of the GPO contract (*e.g.*, own-use requirements), distributing prescribing information in response to product inquiries from members, and facilitating product recalls and investigations of diversion or counterfeit product.

21 *See* 42 C.F.R. § 1001.952(j).

22 54 *Fed. Reg.* 3088 (Jan. 23, 1989).

that CMS clarify the basis for that position in relation to fees paid to PBMs that do not relate to product purchased by the PBM.[23]

III. Amgen Asks that CMS Clarify the Methodologies for Determining Fair Market Value When Evaluating *Bona Fide* Services and Specify That Certain Types of Services Can Qualify as *Bona Fide* Services.

The Proposed Rule also states that CMS is considering providing guidance on the approach or methodology manufacturers must use to determine the fair market value of *bona fide* services performed on their behalf. Amgen requests CMS to clarify that manufacturers may rely on any generally recognized and accepted methodology in determining the fair market value of such services.

In the Proposed Rule, CMS also stated that it is considering providing guidance on the types of services that may qualify as *bona fide* services for purposes of the *bona fide* service fee standard. Wholesalers and distributors perform many services on behalf of Amgen that are a great value to our company. These include, but are not limited to, chargeback administration, inventory management (*i.e.*, consistent purchasing patterns that result in stable inventory levels), data services, and guaranteeing delivery of our products to the end-user in a timely fashion. A wholesaler or distributor that performs these services need not do so in order to resell our products. These services are critical to Amgen's business model, and, accordingly, Amgen has contracted with these entities to perform these services on our behalf. Therefore, CMS should specifically identify these types of services as the types of services that can qualify as *bona fide* services.

As CMS works to finalize its definition of *bona fide* service fees, Amgen also strongly urges CMS to ensure that any such definition be flexible enough in its criteria to accommodate new business models. Manufacturer arrangements with service providers are likely to continue to evolve, both in terms of the types of entities that perform services as well as the types and structures of fee payments. Amgen encourages CMS to carefully parse the terms of any definition to ensure it is not unduly rigid.

Amgen notes that this section of the Proposed Rule seeks comments from stakeholders on a wide variety of industry practices that relate to the application of the *bona fide* service definition to service fee arrangements. All interested stakeholders should have an opportunity to review and comment on any proposed guidance generated by the current information request before those proposals become final.

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[23] Certain PBMs do purchase product to the extent that they own a mail order pharmacy and purchase product for dispensing through the mail channel. Product dispensed through the non-mail/retail channel, however, typically is not purchased by the PBM, but rather by a provider or supplier, typically a retail pharmacy.

IV. CMS Should Permit Manufacturers to Utilize a Sales-Dollar-Based Ratio for Estimating Lagged Exempt Sales.

As recognized by CMS, certain sales that are to be excluded from the ASP calculation, such as sales to state pharmacy assistance programs or to prescription drug plans under Medicare Part D, are typically identified through chargeback and rebate data that are not available in time to include in the ASP calculation on an actual basis.[24] Amgen is pleased that CMS has proposed to require the use of a rolling average ratio methodology to estimate such exempt sales. Amgen recognizes the importance of establishing a uniform approach for such an estimation methodology, but requests that CMS permit manufacturers to utilize either a sales-based ratio or the Proposed Rule's units-based ratio in the estimation methodology included in the Proposed Rule.

Due to the importance of the ASP calculation, significant rigor must be followed in making any changes to the software or data flow process. To modify the ASP system to move from sales to units would require review and modification to both the averaging code as well as the source of that data. Significant time will be required in making the modifications as well as in validating and testing the results. Amgen believes that either type of ratio will lead to similarly accurate results, and permitting manufacturers to choose between a sales-based or units-based based ratio will provide manufacturers with the flexibility needed to accommodate their individual information technology and methodology systems. In the event CMS requires manufacturers to utilize a units-based approach, Amgen asks that CMS provide manufacturers with a minimum of two quarters to implement the new methodology for estimating lagged exempt sales.

V. CMS Should Provide Further Guidance on its Proposal Related to Estimating Lagged Price Concessions Where an NDC Has Been Redesignated.

The Proposed Rule also addresses the circumstance in which a manufacturer changes the NDC assigned to a specific product and package size while "continuing or offering price concessions that span across sales of the product under its prior and redesignated NDCs."[25] This NDC change may occur when there is a change in the labeler code or where the manufacturer modifies the package design or other non-drug feature of the NDC and assigns a new NDC to reflect the revised packaging.[26] CMS has proposed that when an NDC is modified in this manner, and the lagged price concessions offered by the manufacturer for the prior NDC continue to be offered on the new NDC, the manufacturer be required to use 12 months of sales data from the prior and redesignated NDCs to estimate the lagged price concessions applicable to the redesignated NDC. Amgen recognizes the value in specifying uniform calculation rules and, in this case, preventing manufacturers from restarting

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24 71 *Fed. Reg.* at 49,001.
25 *Id.* at 49,003.
26 *See id.*

the 12 month period when no product change has occurred. Amgen requests, however, that the Proposed Rule clarify significant aspects of the rule to ensure consistent and fair application of its requirements.

When a product is given a new NDC, such as where the packaging is redesigned, it is often the case that product labeled with the existing NDC continues to be sold and/or remain in the sales channel until the shelf life of the last lot sold expires, such that both the existing and the new NDCs are in the sales channel at the same time. This means that the manufacturer will continue to report ASP for the old NDC and will also report ASP for the new NDC. The Proposed Rule does not specifically address the proper way in which to estimate lagged price concessions in this circumstance. Amgen requests that CMS clarify whether manufacturers are to combine the lagged price concession data for the two products to create a single ratio, and if so, whether that ratio is to be applied to both the old and the new NDCs. This approach would be the most straightforward and also the most consistent with the agency's desired goal of treating both NDCs as the same product for ASP-reporting purposes. Amgen also requests that CMS clarify that the time period during which such a combined ratio must be calculated ends with the expiration of the shelf life for the existing NDC. While the lagged price concession data for the existing NDC may continue to come in to the manufacturer after the expiration of the shelf life for the existing NDC, the manufacturer need not report an ASP for the existing NDC beyond that time. Accordingly, Amgen believes it is appropriate, and consistent with a manufacturer's existing reporting requirements, to cease calculation of a combined ratio when the shelf life for the existing NDC expires.

Amgen also asks for further clarification regarding the types of situations to which this rule will apply. The Proposed Rule refers to situations where the labeler code is changed, or where the manufacturer modifies its package design or other "non-drug feature" of the NDC and assigns a new NDC to reflect the revised packaging.[27] Amgen requests that CMS clarify that this new requirement does not apply to the creation of a new package size of a product. Amgen also seeks clarification that the Proposed Rule does not apply where there is a change to the product itself, such that the resulting product receives a new product code portion of the NDC. The Proposed Rule suggests that product changes would not be covered by the Proposed Rule by defining the rule's scope as applying only where a "non-drug feature" is changed. Amgen asks that CMS clarify in its final rule that this regulation would be inapplicable to a situation where a product obtains a new product code.

ESRD PROVISIONS

I. Payment for Separately Billable Drugs Furnished in Connection with Renal Dialysis Services Should Continue To Be 106 Percent of ASP.

In its Medicare Physician Fee Schedule final rule for 2006, CMS stated that payment for a separately billable dialysis-related drug furnished during 2006 by hospital-based

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[27] *See id.*

and freestanding dialysis facilities would be based on 106 percent of ASP.[28] CMS now clarifies in the Proposed Rule that it intended this payment methodology to apply to 2006 and subsequent years (until it specifies otherwise). Amgen supports this approach.

There has been some confusion about the use of terminology in these rulemakings. For example, in the preamble to the Proposed Rule, CMS refers to "section 1847A of the Act" as the basis for the dialysis drug payment rates in calendar 2006 and subsequent years.[29] In the regulation itself, CMS refers to the rates being "106 percent of average sales price."[30] We recommend that CMS state explicitly in the final rule for 2007 that the two terms are generally synonymous in this context.[31]

OTHER PROVISIONS AFFECTING ACCESS TO DRUGS

I. Continuation of the Oncology Demonstration Project

We appreciate the agency's efforts to promote quality care for Medicare beneficiaries and believe that adequate reimbursement is a critical and important part of this process. Along this line, we ask that CMS continue the oncology demonstration project, with improvement deemed necessary, because it serves not only to gather data regarding quality, but also to provide necessary additional reimbursement to physicians for the care of cancer patients.

II. Guidance on Coverage for Drugs under Parts B and D

In the Proposed Rule, CMS states, "The Medicare Part D program does not change Medicare Part B coverage." Amgen supports and agrees with this statement. The Part B benefit design is substantially different from Part D, and patients and providers need to understand the continued availability of coverage for certain provider-administered drugs and biologicals under Part B. We appreciate this and previous CMS statements regarding continuing Part B coverage that help ensure that patients and providers clearly understand that benefits for provider-administered drugs and biologicals remain available.

III. Proposal to Exempt Colorectal Cancer Screening from the Part B Deductible Requirement

Colorectal cancer is a particularly grave disease that often exhibits no symptoms until it reaches an advanced stage. It is for this reason that timely screening for colorectal cancer is imperative in order to fight it. Under the provisions of the Deficit Reduction Act of 2005 (DRA), colorectal cancer screening services are no longer subject to the

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28 70 *Fed. Reg.* 70,116, 70,162, 70,224, and 70,332 (Nov. 21, 2005).

29 71 *Fed. Reg.* at 49,004.

30 *Id.* at 49,083.

31 We recognize that there are some circumstances under which the ASP methodology calls for use of a payment rate other than 106 percent of ASP (*e.g.*, new single source drugs before an ASP is available).

Part B deductible beginning January 1, 2007.[32] In the Proposed Rule, CMS states its intention to conform its regulations to this statutory change, and, accordingly, its regulations now also will except from the Part B deductible colorectal cancer screening services.[33] We strongly support this proposal as it will increase patient access to this important screening service and will help in the fight against this deadly disease.

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32 DRA, § 5113, Pub. L. No. 109-171 (2005).

33 71 *Fed. Reg.* at 48,999.

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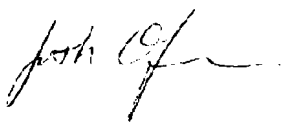
Amgen appreciates this opportunity to comment on the important issues raised in the Proposed Rule and we look forward to working with you to ensure that Medicare beneficiaries continue to have access to new and important drug and biological therapies. Please contact Sarah Wells Kocsis at (202) 585-9713 to arrange a meeting or if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Regards,



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THE AMERICAN SOCIETY OF HEMATOLOGY

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October 10, 2006

Mark McClellan, MD, PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

The American Society of Hematology (ASH) appreciates the opportunity to comment on the proposed physician fee schedule changes for 2007. ASH represents approximately 10,000 hematologists in the United States who are committed to the treatment of blood and blood-related diseases. ASH members include hematologists and hematologist/oncologists who frequently render services to Medicare beneficiaries utilizing under the physician fee schedule. We would like to offer two general comments for your consideration.

First, the combination of this rule and the proposed Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology rule (CMS-1512-PN) published on June 29 will lead to significant changes in Medicare payment for 2007. We appreciate the fact that some of these changes are quite controversial, particularly the revision to the practice expense methodology. If in the final rule CMS decides to significantly revise the policies that were previously proposed, this could dramatically change payment to individual specialties from what was previously announced. We would ask, therefore, that in this event, CMS provided another opportunity for comment before the rule is finalized. Since the standard 60-day comment period might not be feasible, we would suggest that an abbreviated comment period be considered.

Second, while we all hope that Congress will act to "fix" the conversion factor problem for 2007, it is unclear when these changes will be enacted into law. Obviously this might occur very late in the year or possibly even after January 1, 2007 which could greatly complicate the payment of claims for services rendered early in 2007. We urge CMS, in concert with physician groups, to consider ways to avoid increasing the administrative burden on physicians in this period of confusion. We are particularly concerned about the potential requirement for physicians to resubmit adjustment claims and the need for multiple participating physician enrollment processes.

Thank you for the opportunity to offer these comments. If you have questions, please contact Pamela Ferraro, ASH Practice Advocacy Manager, at pferraro@hematology.org or 202-776-0544.

Sincerely,

Kanti R Rai

Kanti R. Rai, MD

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Oct. 6, 2006

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

Dear Administrator McClellan,

Novartis Pharmaceuticals Corporation appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed physician fee schedule rule: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B. Novartis is a leading global pharmaceutical manufacturer that is dedicated to the discovery, development, and marketing of innovative products to cure diseases, to ease suffering, and to enhance the quality of life. Novartis manufacturers both traditional pharmaceuticals and physician administered drugs and biologics, many of which are utilized under the Medicare Part B benefit.

ASP Issues – Bona Fide Service Fees

We generally support CMS's proposal to give further guidance on the types of "bona fide service fees" that would be exempt from the Average Sales Price (ASP) calculation. We are very concerned, however, that an attempt to define exhaustively such services, or even to set forth definitive criteria, will (a) inappropriately limit the types of arrangements that should be permissibly exempt and (b) conflict with criteria for services, which various manufacturers may look to for guidance in other contexts. For example, CMS's suggestion that one such criterion should be whether or not the manufacturer would otherwise perform or contract for the service or would have done itself is too restrictive, and this standard is not common across other sets of definitions. On the other hand, "fair market value," "actually performed," and "having an itemized service or written agreements" are more general standards that are either common across many definitions of services (accounting, personal services safe harbor to the antikickback statute, etc.) and/or reasonable based upon common sense.

Accordingly, rather than issuing a new set of itemized guidelines "for purposes of ASP," we recommend that CMS limit itself to the concept of legitimate, lawful, and bona fide services for fair market value. It would be up to the manufacturer to demonstrate that bona fide nature of

the services, and in doing so the manufacturer could point to industry practice and other standards to support its position. At the most, CMS could list a set of example services that it believes are widely recognized as legitimate, so long as it also makes clear that the list is not exhaustive and that additional permissibly exempt services do not need to be the same as or similar to the services set forth in the list. This would not limit the ability of manufacturers to develop contracts that may not be presumed of today.

ASP Issues – Lagged Sales

In this proposed rule, CMS offers several recommended corrections to the ASP calculation. We strongly support CMS' attempt to update the definition of and process for excluding nominal sales as that which is defined under the Deficit Reduction Act (DRA). We further support any attempt to synchronize the definition of nominal sales with that which is used in conjunction with the calculation of the AMP. We also support CMS' recommendation of utilizing 12 month rolling averages to calculate lagged sales which should be exempted from the ASP calculation. However, we would ask for some additional clarification on the how to model this, as this may be more difficult to accomplish than is the case with non-exempt sales.

Operational Issues Surrounding the comparison of ASP with either the Widely Available Market Price (WAMP) or Average Manufacturer Price (AMP)

The Medicare Modernization Act mandates that the Office of the Inspector General conducts studies to compare the ASP of drugs and biologicals to both the WAMP and AMP.[1] In cases where the ASP exceeds either the WAMP or AMP by an applicable threshold (set at 5% by CMS), the Secretary may disregard the ASP and reimburse the drug or biological at the lesser of: 1) WAMP or 2) 103% of AMP[2]. In the proposed rule, CMS notes there are numerous operational issues surrounding such a comparison and asks for comments on how to carry forward this statutorily mandated comparison. Given that the methodology for calculating the WAMP has not yet been defined, our comments center on the comparison of ASP to AMP.

We recognize that this is an obligation mandated by statute, and we agree that it is important to have a metric against which the appropriateness of a drug's ASP is measured. However, there are potential pitfalls surrounding the comparison of ASP to AMP that CMS should take into consideration. First, it is important to note that ASP and AMP are not directly comparable in large part because they measure different prices: AMP is designed for the Medicaid system to measure the retail class of trade (or what a pharmacy would pay for a drug). ASP, on the other hand, is a much broader price reporting measure that takes into account a range of price concessions that occur along the distribution chain. In addition, the 2005 DRA has removed prompt pay from the AMP calculation while it remains in the ASP calculation.

It is also important to note that AMP is potentially subject to greater fluctuations than is ASP. CMS realized the fluctuations that can occur in price reporting as a result of lagged price concessions and incorporated a mechanism to help smooth this in the ASP calculation methodology. No such mechanism exists for AMP. Indeed, manufacturers have 36-months from the time of initial AMP submission to re-report a quarter's AMP as a result of lagged concessions not recorded at the time of initial calculation. As CMS has stated on numerous occasions (including in responses to the various 2006 OIG reports on ASP methodology and ASP: AMP comparison) maintaining consistency of ASP is important. This marketplace consistency could be severely compromised if CMS begins to compare ASP to AMP without

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[1] Section 1847A(d)(2) Social Security Act
[2] Section 1847A(d)(3)(B)(i) Social Security Act

taking into account the above mentioned issues of lagged price concessions in AMP, removal of prompt pay from AMP but not ASP, or the fact that AMP was established to measure costs in the retail class of trade whereas ASP was established to determine prices passed onto the end user.

ASP Issues – Bundled Price Concessions

For purposes of allocating discounts in any bundling arrangements, for purposes of the ASP calculation, we suggest that CMS adopt the methodology set forth in the Manufacturer Rebate Agreements under the Medicaid Rebate program. Again, as is true in connection with any attempt to define bona fide services, it is important to create some level of consistency among applicable standards governing manufacturer conduct and calculations.

ASP Issues – Prompt Pay Discount

We understand that CMS is mandated legislatively to require manufacturers to include prompt pay discounts given to wholesalers and/or distributors in their ASP calculations. However, we feel strongly that, since this discount is not passed on to the end user of the product, the prompt pay discount should not be part of the ASP calculation for purposes of setting reimbursement rates to the end users, in this case physicians and hospitals. We would welcome the opportunity to work with CMS in seeking a legislative fix for this error.

Part D Vaccine Administration Payments under Part B

In the Part D final rule, CMS stated that costs related to the administration of Part D vaccines could be paid to physicians as part of the Part B benefit.[3] In that rule, CMS discussed the importance of covering vaccine administration in a manner that ensures that Part B and Part D provide a seamless benefit. CMS further stated that their regulations should reflect Congressional intent that Part D provides beneficiaries with access to vaccines not covered under Part B. However, in its May 8, 2006, and July 11, 2006, guidance documents to Part D plans, CMS implies that Part B coverage of administration services are only applicable to Part B covered drugs.

We think that this new CMS policy, while not being consistent with prior guidance, is also potentially disruptive in terms of patient access to vaccines, which have proven to be able to prevent disease and the costs associated therein. Therefore, we would strongly support any rule that CMS would publish, which would specify that physician administration services for Part D vaccines are eligible to be billed under the Part B benefit.

Oncology Demonstration Project

Novartis strongly supports the 2006 Quality of Cancer Care demonstration project and encourages CMS to continue this program into 2007. The 2006 demonstration project provided the first systematic data collection of the adherence to nationally recognized clinical treatment guidelines for Medicare patients. This type of data will be very useful in understanding the level of care Medicare patients with cancer are receiving as well as moving in the direction of improving their care. Such data is most useful if collected over a period of more than one year. Indeed, it would be useful to see if the level of adherence to treatment guidelines improves with time and only a longitudinal data collection will be able to determine this.

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[3] 70 Fed. Reg. 4,194, 4,328, 4,231 (Jan. 28, 2005).

We realize that CMS was criticized for its 2005 "Chemotherapy Demonstration Project." This project did not collect the same data as the current project nor was that program's method of data collection as rigorous as the current demonstration project. CMS realized this when revising the program for 2006. It would be a disservice to Medicare beneficiaries and oncologists alike for the current program, and the useful insights it will yield, to be a victim of the flaws of an earlier, different program.

Thank you for the opportunity to comment on the 2007 Proposed Fee Schedule Rule. We hope that these comments are helpful to CMS as they prepare the final rule.

Sincerely,

Bonnie Washington
Vice President, Health Policy
Novartis Pharmaceuticals

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bio scrip

Dr. Mark B. 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, DC 20201

Re: CMS-1321-P; Comments Regarding the Proposed Physician Fee Schedule Rule for Calendar Year 2007

Dear Dr. McClellan:

BioScrip was formed from the 2005 strategic merger of Chronimed Inc. and MIM Corporation -- two companies with a shared vision of balancing health care cost containment with better patient outcomes. Our goal - to recognize, understand and exceed our partner's expectations and provide pharmaceutical healthcare solutions that are effective and affordable -- appeared to mesh with the primary purposes of the Competitive Acquisition Program (CAP) for Part B drugs and biologicals under the Medicare, Modernization, Improvement and Prescription Drug Act of 2003 (MMA). Given the limits on alternative means for presenting public comments to CAP, BioScrip submits its comments to the above-referenced proposed rule. We also submit limited comments to the proposed rule concerning the hospital outpatient prospective payment system. As the sole CAP vendor, BioScrip is uniquely positioned to present comments with first-hand knowledge of the program and its obstacles to date, as well as sufficient investment in ensuring program success.

BACKGROUND

Section 303(d) of the MMA required that CMS implement a Competitive Acquisition Program (CAP) through which physicians administering certain drugs and biologicals would have an alternative to assuming the costs and risks associated with purchasing products for reimbursement under the Average Sales Price (ASP) methodology ("buy and bill"). Although CMS accepted bids from five (5) potential CAP vendors, BioScrip was the sole vendor willing to enter into a three-year contract with the Agency to invest in this novel program. BioScrip expended approximately $9 million to incorporate the infrastructure necessary for compliance with the CAP vendor contract and physician outreach and education activities. It has acted in good faith, providing exceptional service to its participating physicians.

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Unfortunately, physician uncertainty with the risks and costs of CAP participation significantly impeded enrollment in 2006. Relatively unprecedented claims submission complexities, claims processing delays, and other programmatic obstacles encountered to date will discourage continued and new CAP election and, BioScrip fears, eliminate the potential for CAP viability in 2007 and beyond.

BioScrip has yet to receive a final payment that would, under CMS' subregulatory interpretation of the coinsurance collection protocols, enable collection of these funds from secondary insurers and/or beneficiaries. Within days, it will face the almost certain denial of a significant portion of its valid claims for supplied drugs and biologicals, and the accompanying, expense of attempting to resolving an issue that CMS and its contractors could not untangle over the past three (3) months, i.e., what went wrong with the claims processing systems for CAP. With each recent CMS communication, BioScrip's hope of a pragmatic, streamlined, and workable CAP diminishes, and it finds itself pushed closer to the classic conundrum of evaluating the risks and benefits of "throwing good money after bad."

We have subdivided our comments into three (3) general areas as follows:

1) **Burdensome and Confusing Claims Submission and Processing Mechanisms**

2) **Requirement to Ship to Location of Administration**

3) **Implementation of the Emergency Re-Supply Provision**

BioScrip contends that CMS had and continues to have broad discretion in implementing the CAP in a manner that facilitates vendor/physician satisfaction with the Program and enables the Medicare program, physicians, and beneficiaries to capture the significant benefits of increased participation. These comments are a further step in BioScrip's efforts to partner with CMS during this very limited window of time available to address the issues and obstacles identified below, and to establish a track record of CAP success.

1) Burdensome and Confusing Claims Processing Mechanisms

The single most significant impediment to the CAP's success is the complex claims submission and drug administration verification procedure. This procedure places the burden of verifying drug administration on the CAP Designated Contractor through a prepayment "matching" of BioScrip's drug claim with a physician administration claim in the Common Working File (CWF). To facilitate this matching process, CMS requires CAP physicians to submit claims for drug administration services that contain the information required under the buy and bill system, plus: (1) a unique prescription number; (2) the NDC number for the administered drug; and (3) appropriate modifier(s). Physicians have asserted that the additional information required under CAP is significant enough to constitute an unreimbursed office expense that deters interest in CAP participation. The process, to date, has not resulted in receipt of a single final payment based upon a match of a drug administration claim to BioScrip's claim for supplied drugs.

The most comprehensive descriptions of the current claims processing methodology were provided through a series of Program Transmittals modifying the Medicare "manual" instructions to providers and claims processing contractors. A fairly broad outline of the CAP claims processing system was also announced in the Preamble to the proposed rule implementing CAP. 70 Fed. Reg. 10,754 *et seq.* (March 4, 2005). That system was designed to verify drug administration to the beneficiary "by means of a prescription number that would be placed on the physician claim for drug administration and the drug vendor claim for the drug." *Id.* The "claims processing system would use the prescription number to match the two claims and authorize payment to the vendor." *Id.*

Comments to the proposed rule reflected much concern about the technical aspects of prescription identification numbers and matching. 70 Fed. Reg. 39,022 *et seq.* (July 6, 2005). In fact, 104 of the 211 physicians commenting to the proposed CAP rule focused their statements on the burden of simply including a prescription drug number on each claim (the addition of modifiers and the NDC was not announced until subsequent subregulatory guidance was released just prior to CAP implementation). The American Medical Association anticipated difficulties with the entire matching system, stating:

> [h]owever, CMS is going beyond this statutory requirement by proposing that payment to the vendor also would be dependent upon the filing of the drug administration claim by the physician and approval of the physician's claim by the CMS claims processing system.

The American College of Gastroenterology echoed the AMA's concerns:

> CMS interprets the Medicare statute to require verification of physician administration of a drug before final payment can be made. . . . These drug order and verification provisions are not only burdensome but do not accurately reflect the realities of patient care and could potentially increase costs to the Medicare system. . . . ACG recommends that CMS revise the rule to incorporate more flexibility to accommodate these clinical circumstances.

.In response, CMS noted in the Preamble to the proposed rule that this system's success depends on specific information technologies and data management practices:

> The electronic version of the Medicare carrier claim form has space for a series of prescription numbers, which CMS has not utilized previously for Part B drugs. As part of implementing the CAP program, we would require that vendors and physicians who elect to participate in CAP have the capability of submitting these prescription numbers to us in their claims processing systems. If physicians and potential vendors are not already billing

> other payors using prescription numbers, they would need to work with their internal information systems staff or practice management software vendors to make the necessary changes to submit these data elements to Medicare in a manner consistent with HIPAA transaction guidelines for capturing prescription numbers.

Id. at 10,754-55. The prescription number requirement was the only available detail for physicians and potential vendors considering CAP participation, and CMS informed stakeholders that the specifics of the CAP process would be articulated outside the notice and comment process: "[a]fter publication of the interim final rule, we will issue billing instructions with guidance about the appropriate fields on our electronic and paper claim form to use in billing." *Id.* at 39,043.

The Michigan Society of Hematology and Oncology did not view the potential changes to internal information systems as the simple matter envisioned in CMS' preamble:

> The requirement is that the physician is to place the unique ID number for that patient's drug on the claim form for that date of service. This may appear to be an easy requirement, but there are complications. . . Each practice has a software system that would have to be adjusted and tested in order for the claim form to be submitted in the proper fashion. . . .

In fact, subsequent to the July 6, 2005 publication of the CAP Interim Final Rule in which CMS assured physicians and potential vendors that the Medicare carrier claim forms were fully equipped to accommodate the prescription number field, the Agency permitted those contractors a period of time until October 2, 2006 to install essential modifications to accommodate physician claims submitted pursuant to CMS CAP instructions. Neither participating physicians nor the CAP vendor were specifically informed that the carrier claims processing systems were likely inadequate to process correctly-submitted claims. Stakeholders were not informed that these deficiencies could impede physician claims for payment or that they would (until corrected) virtually guarantee the inability to achieve a "match" between physician and vendor claims. See, "*Transmittal of Change Request 4306, MCS Screen Expansion for the Prescription Order Number for the Competitive Acquisition Program (CAP) for Part B Drugs to be Developed Over the July 2006 and October 2006 Release, With Final Implementation on October 2, 2006.*"[1] This CMS instruction demonstrates that the Agency underestimated the intricacies inherent in its proposed CAP system when it considered stakeholder comments objecting to that system. Moreover, the additional time afforded to its claims processing contractors illustrates CMS' ability to modify its requirements when it chooses to do so.

The complex claims submission and matching processes are not mandated by the MMA. The law clearly commands that "the payment under this section (and related amounts of any applicable deductible and coinsurance) for such drugs and biologicals -- (I) shall be

[1] http://www.cms.hhs.gov/Transmittals /2006Trans/ itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder= ascending& itemID=CMS060580 (last visited September 7, 2006).

made only to such contractor; and (II) shall be conditioned upon the administration of such drugs and biologicals." 42 U.S.C. §1395w-3b(a)(3)(A)(iii).

Congress was unambiguous: the only requirements for payment to the CAP vendor are that the drug is medically necessary and actually administered to the patient. Payment is *not* conditioned on compliance with the artificial prepayment matching requirement crafted by CMS. There are several less onerous -- but equally valid and accurate -- options to matching a 30-digit prescription number and NDC number on two claim forms. Implementing any one of these would ensure CMS' compliance with the law. Moreover, the MMA contains an "adjustments" provision to recover funds from vendors for erroneously paid drug claims, i.e., claims for drugs not actually administered to the patient:

> PROCESS FOR ADJUSTMENTS. --- The Secretary shall provide a process for adjustments to payments in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

42 U.S.C. §1395w-3b(a)(3)(B). If Congress had anticipated a prepayment matching system through which the verification of drug administration could be accomplished only through the prepayment "matching" process, this provision would be mere surplusage. The Agency's regulation implementing this provision does not shed any light on the required process:

> *Adjustments*. There is an established process for adjustments to payments to account for drugs that were billed, but which were not administered.

42 CFR 414.906(d).

It is well established that "all words in a statute are to be assigned meaning, and . . . nothing therein is to be construed as surplusage." *Qi-Zhou v. Meissner*, 70 F.3d 136, 139 (D.C. Cir. 1995). CMS relies exclusively on a prepayment verification process and gives short-shrift to the post-payment determination of actual drug administration contemplated by Congress. CMS' interpretation renders the adjustments provision meaningless and violates one of the central rules of statutory construction. The MMA's statutory provisions, therefore, clearly enable CMS to revise its CAP claims submission methodology. The Agency's early experience in implementing CAP through pre-payment matching has failed of the essential MMA purpose of enabling payment for vendor drugs that are medically necessary and actually administered to the beneficiary.

Similarly, BioScrip asserts that the complex claims submission and processing protocols, including the matching process and inclusion of a prescription number, NDC number, and various modifiers are not required under the Agency's relevant regulations. The regulations implementing 42 U.S.C. §1395w-3b(a)(3)(A)(iii) read, in relevant part:

> Competitive acquisition program as the basis for payment.
>
> (a) *Program payment.* Beginning in 2006, as an alternative to payment under §414.904, payment for a CAP drug may be made through the CAP if the following occurs:
>
> (1) The CAP drug is supplied under the CAP by an approved CAP vendor as specified in §414.908(b).
>
> (2) The claim for the prescribed drug is submitted by the approved CAP vendor that supplied the drug, and payment is made only to that vendor.
>
> (3) The approved CAP vendor collects applicable deductible and coinsurance with respect to the drug furnished under the CAP only after the drug is administered to the beneficiary.
>
> (4) The approved CAP vendor delivers CAP drugs directly to the participating CAP physician in unopened vials or other original containers as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer and includes language with the shipping material stating that the drug was acquired in a manner consistent with all statutory requirements. If the approved CAP vendor opts to split shipments, the participating CAP physician must be notified in writing which can be included with the initial shipment, and each incremental shipment must arrive at least 2 business days before the anticipated date of administration.
>
> (5) The approved CAP vendor bills Medicare only for the amount of the drug administered to the patient, and the beneficiary's coinsurance will be calculated from the quantity of drug that is administered.

42 CFR 414.906, and:

> (1) Subsequent to receipt of final payment by Medicare, or the verification of drug administration by the participating

CAP physician, the approved CAP vendor must bill any applicable supplemental insurance policies.

(2) If a balance remains, after the supplemental insurer pays their share of the bill, or if there is no supplemental insurance, the approved CAP vendor may bill the beneficiary.

(3) At the time of billing the beneficiary, or the participating CAP physician's presentation of the bill on behalf of the approved CAP vendor, the approved CAP vendor must inform the beneficiary of any types of cost-sharing assistance that may be available consistent with the requirements of section 1128A(a)(5) of the Act and §414.914(g).

(4) If the beneficiary demonstrates a financial need, the approved CAP vendor must follow the conditions outlined in paragraph (g) of this section.

42 CFR 414.914(h).

This regulatory language does not preclude CMS from modifying its claims submission and processing approaches as BioScrip suggests below. In fact, vendor verification of physician administration would be more consistent with the regulatory identification of two alternative triggers for vendor collection of payments from supplemental insurers and beneficiaries. The vendor must bill supplemental insurers when either (a) it receives payment from Medicare; or (b) the physician verifies drug administration. It is not logically consistent that CMS would require matching of drug and administration claims in order to make payment, yet require vendors to bill supplemental insurers, and permit them to bill beneficiaries, upon physician notification that the drug is administered. As with the statutory language, the regulatory language regarding payment for CAP vendor claims does not require:

(1) prepayment matching of vendor claims to physician administration claims;

(2) inclusion of a prescription number on both vendor and physician claims;

(3) inclusion of the J1 and J2 modifiers indicating that the physician has administered a CAP drug;

(4) inclusion of the NDC number for the administered product;

(5) delay of vendor collection for applicable deductible and coinsurance beyond the point in time at which the condition precedent of physician administration has been met; or

(6) that the Contractor processing CAP vendor claims bear the burden of ensuring that the drug has been administered prior to paying a vendor drug claim.

As noted above, CMS has acknowledged the fact that its own contractors are not (or were not) capable of processing claims that comply with the process it dictates, and has afforded claims processing carriers a transition period for implementing the system modifications necessary to accommodate inclusion of a prescription number for CAP drug administration claims. Accommodating the specific realities of existing claims submission and processing systems is consistent with the general theoretical design announced in the CAP rule's Preamble and does not harm CAP stakeholders.

BioScrip believes that CMS devised a CAP claims submission and processing system that it may have thought and may have hoped would enable payment for CAP drugs and their administration. It has furnished guidance to CAP vendors, CAP physicians, and its claims processing contractors. All parties, including CMS and its contractors, have made good-faith efforts to operationalize those instructions. Unfortunately, these systems have impeded both CAP participation and claims payment. There is no legally cognizable basis for CMS to adhere to complex subregulatory processes that have failed to accomplish the essential purpose of the CAP, i.e., to provide a convenient, cost-effective alternative to physician purchase of Part B drugs.

For the reasons stated above, and supported by comments received by CMS in connection with its Proposed CAP rule, BioScrip urges CMS to realign CAP claims submission and processing systems in a manner more consistent with the requirements for other providers and suppliers. We strongly suggest that the Medicare trust fund focus its resources on providing beneficiary care through program efficiencies rather than in dissecting a cumbersome, failed system to identify the source of clear disconnects between claim submission and provider/vendor payment. BioScrip suggests the following alternative to balance Medicare's program integrity concerns with the interests of vendors and providers in receiving payment for supplies and services.

Eliminate the requirement that the physician include the prescription number, NDC, and J1 and/or J2 modifier, as well as a dollar value for the administered product on the claim for drug administration services:

- Carriers processing physician administration claims maintain records of CAP-electing physicians in their jurisdictions, and institute edits ensuring carrier nonpayment for drugs within CAP unless the claim includes the "furnish as written" modifier signaling the carrier to reimburse for physician-purchased product under the ASP system -- the J1 modifier is a duplicative process;
- Physician inclusion of the J-code describing the product is a sufficient program integrity tool for ensuring that the vendor and physician claims are consistent. If claims subject to post-payment review include "bare" physician drug administration claims (i.e., the physicians does not include a line describing the product and containing the appropriate J-code), Noridian and/or the physician's carrier would request further documentation from the administering physician;

- Inserting a dollar value on the line containing the J-code describing the administered therapy leads to accounting difficulties within physician billing systems. Instructing physicians to place a "0" in that field would ensure that no payment is made for the product, and would also alleviate the accounting difficulties encountered to date with CAP physicians;
- If CMS requires tracking of the prescription number, it should be sufficient for the provider and vendor to maintain a record of the number in the patient's medical record;
- Simplification of claims submission for administration of CAP products will reduce claims submission and processing errors (e.g., inadvertent use of improper modifier combinations, rejections due to use of NDCs not yet entered as applying to CAP products, etc.), enable timely payment to physicians, facilitate accurate and efficient post-payment (or PSC) review, and reduce Medicare's cost of operating the CAP;
- It is difficult to believe that physician offices can easily adjust to CAP system requirements given the amount of time it is taking for CMS' claims processing carriers to modify their systems. If physicians continue to face the paperwork burden associated with the current system, and the payment delays that have resulted from the claim submission and processing complexity, they will decline to re-enroll in CAP.

Utilize the post-payment review systems applicable to other suppliers in paying CAP vendor claims, at least in the initial phase of CAP implementation. BioScrip would submit claims after confirming physician administration of the product, and Noridian would pay the claim without the administrative costs associated with the "matching" process:

- The prepayment matching system has proven unworkable for physicians and most claims processing carriers;
- Permit the CAP vendor to verify drug administration with the physician. BioScrip (or other vendors) would then wait until administration verification has occurred to submit a drug claim and include a modifier on the claim signifying that this verification has been accomplished by fax (or other written form) or by phone (with name of contact person and date of verification). This is similar to the system in place for certain durable medical equipment (DME) supplies for which CMS has identified a risk for overutilization (and would appear to suffice in the case of CAP products for which the Agency has identified no such risk);
- BioScrip or any other vendor would maintain a record of its confirmation of physician administration for review by Noridian or any Program Safeguard Contractor (PSC) examining the propriety of CAP drug claims;
- PSCs do not require inclusion of a unique prescription number or NDC number to confirm that a CAP vendor claim is appropriately paid -- a date of administration, physician and beneficiary identification numbers, and J code sufficiently identifies the product, beneficiary, and date of service.

In fact, as noted above, it is not clear that the prescription number would be helpful to these contractors without costly changes to their IT systems;

- CMS claims processing carriers currently have the ability to identify physicians that have elected to participate in CAP and many, if not most, have implemented "edits" to ensure that these physicians do not receive payment for CAP products unless the "furnish as written" J3 modifier is included on the claim. The J1 modifier is not necessary;
- As more fully detailed in discussion of the re-supply provision, inclusion of the J2 modifier to identify drugs that have been administered from the physician's inventory and re-supplied by the CAP vendor is confusing to physicians and does not further any program integrity interest that is likely to effect Medicare expenditures for Part B drugs;
- In the event that the administration claim is denied by the Carrier for medical necessity reasons, Noridian could easily inform BioScrip or any other vendor, and collect any overpayment;
- The process CMS has established need not be discarded completely. Noridian (or any PSC) could conduct random postpayment reviews utilizing the Common Working File to quantify the potential benefits of reinstituting prepayment matching of claims, as well as inclusion of a prescription number, NDC, and/or modifiers identifying CAP physicians and/or the means through which the physician acquired the product (re-supply or advance order).

2) Requirement to Ship to Location of Administration

The MMA requires CAP vendors to ship CAP products directly to the physician. In its regulations, CMS interpreted this statutory language to direct shipment to the location at which the physician would administer the particular product. Unfortunately, many practices have satellite offices in rural or remote areas. These offices have limited hours of operation so that the expense of coordinating resources for CAP drug delivery to satellite locations may prevent these practices from participating in a program that would otherwise represent a very attractive option to buy and bill.

Moreover, several practices were not aware of the requirement to include each satellite office location of the CAP election form, or of the requirement that the drug be delivered to that location in advance of the date of administration. BioScrip is aware of instances in which physician offices were granted an exception from CMS and permitted to opt out of CAP before the end of the 2006 election period. In other cases, CAP electing physician offices are faced with the alternatives of: 1) absorbing the additional cost of accommodating drug delivery outside ordinary office hours; 2) decline to administer therapies to beneficiaries treated at satellite offices; or 3) require patients in remote or rural areas to travel to the location at which office staff is generally available to accept CAP deliveries. None of these options are attractive to physicians or the patients they serve.

Medicare does not dictate the place of delivery for drugs supplied under the buy and bill system. Physicians and distributors are capable of complying with safety requirements and state laws in determining the most efficient means for drug delivery. BioScrip, therefore, urges CMS to modify its regulatory language to either a) mirror the MMA language so that the vendor and physician can contract for drug delivery options that suit the particular physician practice; or b) explicitly state that CAP drugs will be delivered to the physician at the location designated by the physician.

3. **Implementation of the Emergency Re-Supply Provision**

CMS heard from many physicians and specialty societies (both through the comment process and in the various open door forums) regarding the complexities associated with incorporating the advance ordering requirements of CAP into the intricacies of patient care within their specific practices. For example, oncologists often adjust treatment decisions on the date of administration due to shifting disease states, or to accommodate unanticipated therapeutic needs. Other specialties communicated that as much as 90-95% of their injections and infusions are performed without the physician's advance notice that the patient will require a specific therapy.

BioScrip agrees that CMS must work with the statutory language contained in the MMA, and believes that the policy decision to place the determination of an emergent situation in the physician's judgment is consistent with Congressional intent. Unfortunately, physicians and specialty societies sense mixed messages between the deference to physician judgment and the caveat of carrier review over whether or not an emergent situation actually existed. For specialties in which a majority of therapies are administered on an emergent basis, physicians have expressed fear that their ordinary standard of care would trigger CMS scrutiny and the accompanying paperwork burden of submitting medical documentation for each CAP related claim.

The MMA provides for CAP products to resupply products administered on an emergent basis, and affords CMS considerable discretion in determining what, if any, program integrity safeguards are appropriate. BioScrip contends that contractor monitoring and review of physician use of the re-supply provision would expend Medicare program funds without any potential for collection of overpayments or other balancing financial interest. CMS regulations place determination of an emergent situation in the treating physician's judgment. Medicare coverage rules would not permit claim denial of a medically necessary treatment on post-payment review based on second-guessing the physician's judgment regarding the timing of medical need. It is, therefore, unlikely that any postpayment denial would survive the initial appeals processes. CMS has the discretion to determine the fraud and abuse protections needed to implement the emergency provision, and can remove the J2 modifier requirement and potential for scrutiny over the treatment timing decision by acknowledging that there is no compelling Medicare interest to justify the additional complexity in claims submission. This simple "fix" would eliminate one of the major obstacles to CAP participation.

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CONCLUSION

BioScrip is interested in further discussing the issues contained in these comments. We continue to believe that the CAP can provide a convenient, cost-effective means for supplying Medicare Part B drugs and biologicals. As you know, BioScrip has encountered significant financial and programmatic difficulties that have the potential to continue into 2007. We urge CMS to leverage the lessons learned during the initial CAP implementation by adopting a streamlined claims submission and processing system that will maximize the potential benefits of CAP to physicians, beneficiaries, and the Medicare program.

If you have any questions or require further information, please contact me at 614-850-6903.

Very truly yours,

Russ Corvese

Russ Corvese
Vice President, Operations

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October 10, 2006

VIA HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1321-P
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"—COMMENTS ON "*REASSIGNMENT AND PHYSICIAN SELF-REFERRAL*" AND "*IDTF ISSUES*"

Dear Administrator McClellan:

On behalf of our client, Alliance Imaging, Inc. ("Alliance" or the "Company"), we submit these comments on certain proposed revisions to policies under the Medicare physician fee schedule ("MPFS") for 2007.[1] Specifically, the Centers for Medicare and Medicaid Services ("CMS") has proposed to amend its reassignment regulations to clarify how the purchased diagnostic test and purchased test interpretation policies should apply to contractual arrangements. In conjunction with this clarification, CMS also intends to amend the regulatory definition of "centralized building" under the agency's regulations implementing the Physician Self-Referral Law ("Stark Regulations").[2] In addition, the agency has proposed a set of performance standards for independent diagnostic testing facilities ("IDTFs"). Alliance is concerned about a number of aspects of the agency's proposals and appreciates the opportunity to offer its comments and recommendations.

Alliance is the leading national provider of diagnostic imaging services, based on the number of diagnostic imaging systems deployed. The Company's services include magnetic resonance imaging ("MRI"), positron emission tomography and positron emission tomography/computed tomography ("PET/CT"). The Company contracts with hospitals and other healthcare providers to furnish imaging and therapeutic services to their patients. These

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1 *See* 71 Fed. Reg. 48982 (Aug. 22, 2006) (proposed reassignment and physician self-referral provisions to be codified at 42 C.F.R. pts. 411 and 414).

2 *See generally* 42 C.F.R. § 411.350, *et seq.* (2006) (implementing 42 U.S.C. § 1395nn).

services normally include the use of the Company's imaging systems, technologists to operate the systems, equipment maintenance and upgrades and management of day-to-day shared-service and fixed-site diagnostic imaging operations. Alliance also provides services to its own patients as an IDTF. Alliance has approximately 500 diagnostic imaging systems, including 335 MRI systems and 74 PET or PET/CT in 43 states.

Alliance offers the following comments and recommendations for CMS's consideration:

(1) **CMS should not incorporate its current manual provisions regarding purchased diagnostic tests into the contractual arrangements exception.** The agency's proposal would unnecessarily combine two separate reassignment exceptions, contrary to Congress's intent. Although we agree that the terms of the purchased diagnostic test do control, the proposed codification would blur rules rather than offer clarity to the exceptions under the reassignment rules.

(2) **CMS should not apply an anti-markup requirement to the reassignment of interpretations of diagnostic tests.** It would be inconsistent with the reassignment rules to extend the anti-markup requirement in this way. The Company believes that because Congress has not mandated an anti-markup provision here, it would be inappropriate to treat this area differently than other areas for which reassignment exceptions exist.

(3) **CMS should not implement the proposed amendments to the Stark Regulations.** Specifically, the proposed changes to the definition of "centralized building" would place unfair restrictions on mobile IDTFs by excluding them from the in-office ancillary services exception. In addition, mobile IDTFs do not pose the fraud and abuse risks posed by pod labs; therefore, the agency should either not implement the proposed amendments or should provide a carve-out for mobile IDTFs.

(4) **CMS should delay the effective date of its performance standards for currently enrolled IDTFs.** CMS should permit currently-enrolled facilities that have already demonstrated a commitment to providing high quality services an additional 90-day period to incorporate new standards. This will ultimately help ensure continued beneficiary access to high quality imaging services.

(5) **CMS should ensure its performance standards recognize both fixed and mobile IDTFs.** Alliance believes that CMS should take into account certain practical differences in fixed and mobile IDTFs in promulgating any new standards. The Company also urges CMS not to amend its current reporting deadlines for changes to information contained on the enrollment application. In addition, Alliance urges the agency to recognize that an IDTF would be afforded an opportunity to respond to, or otherwise cure, findings of a possible failure to comply with these standards.

(6) **The agency should revise its proposed regulations regarding supervising physicians to account for certain implications of the IDTF industry.** The current regulations require that a supervising physician be proficient in the tests being performed. Alliance is concerned that this provision is being interpreted by Medicare contractors in an unduly restrictive way by requiring that imaging services may only be supervised by radiologists. CMS should take this opportunity to make clear that an IDTF's supervising physician may be proficient in the tests conducted at the facility without being a specialist in a particular area. This would mean that a supervising physician for certain imaging services need not always be a radiologist. In addition, CMS should not implement its proposal that a supervising physician can only oversee 3 IDTF sites.

Below are more detailed explanations of each of the Company's comments.

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

I. CMS SHOULD NOT INCORPORATE THE PURCHASED DIAGNOSTIC TEST RULES INTO THE REGULATION ON CONTRACTUAL ARRANGEMENTS AND SHOULD NOT APPLY AN ANTI-MARKUP RULE TO THE PROFESSIONAL COMPONENT OF DIAGNOSTIC TESTS.

Alliance does not disagree with CMS's conclusions that the Medicare purchased diagnostic test rules should be applicable to contractual arrangements. However, the revised regulatory language is misplaced in 42 C.F.R. § 424.80 and instead should be included, if at all, in 42 C.F.R. § 414.50 –where it more appropriately further defines the parameters of the anti-markup rule. In addition, the reassignment regulations currently found at § 424.80 adequately recognize that "[n]othing in this section alters a party's obligations under . . . the rules regarding physician billing for purchased diagnostic tests (§ 414.50 of this chapter)."[3]

A. Proposals

CMS proposes to clarify its reassignment regulations to indicate how the purchased test and purchased interpretation rules apply to the contractual arrangement exception set forth at 42 C.F.R. § 424.80(d)(2). Specifically, CMS intends to amend 42 C.F.R. § 424.80 to clarify that reassignments pursuant to the contractual arrangement exception are subject to reduced payment amounts for diagnostic tests.[4] CMS's proposal is two-fold.

First, the agency would apply the anti-markup rule, as currently codified at 42 C.F.R. § 414.50, to reassignment of the technical component ("TC") of a diagnostic test under a contractual arrangement. Specifically, if the TC of a diagnostic test is billed by a physician or medical group (the "billing entity") under reassignment, the amount billed to Medicare by the

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3 42 C.F.R. § 424.80.

4 *See* 71 Fed Reg. at 49054.

billing entity (less applicable deductibles and coinsurance) cannot exceed the lowest of the following:

- The physician or other supplier's net charge to the billing physician or medical group;
- The billing physician's or medical group's actual charge; or
- The fee schedule amount for the service that would be allowed if the physician or other supplier billed directly.[5]

These very provisions are longstanding requirements under the Medicare program and are found in both the Medicare statute and in existing Medicare regulations on the anti-markup rule.[6] The agency would also require that, in order to bill for the TC, the billing entity must perform the interpretation.[7]

Second, CMS would impose certain conditions on when a physician or medical group can bill for the professional component ("PC") under a contractual arrangement. The agency is considering the following conditions:

- The physician ordering the test must be financially independent of the person or entity performing the test and the physician or group performing the interpretation;
- The physician or group performing the interpretation cannot see the patient; and
- The physician or group billing for the interpretation must have performed the technical component of the test.[8]

These provisions currently appear in the Medicare Claims Processing Manual and apply to physicians or suppliers who bill for PC for a purchased diagnostic test.[9]

Finally, the agency also indicates that it is soliciting comments on whether an anti-markup provision should apply to the reassignment of the PC of diagnostic tests performed under a contractual arrangement.[10]

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5 *See id.* at 49056.

6 *See* 42 U.S.C. § 1395u(n); 42 C.F.R. § 414.50; *see also* Medicare Claims Processing Manual (Pub. No. 100-4), Chapt. 1, § 30.2.9 (manual provisions regarding the purchased diagnostic test rules).

7 *See* 71 Fed. Reg. at 49056.

8 *See id.*

9 *See* Medicare Claims Processing Manual (Pub. No. 100-4), Chapt. 1, § 30.2.9.1.

10 *See* 71 Fed. Reg. at 49056.

B. Comments

Alliance urges CMS not to incorporate its current and longstanding policies regarding the purchased diagnostic tests into the rules regarding contractual arrangements. The Company believes that incorporating current manual provisions and the anti-markup rule into the contractual arrangements regulations will only further confuse suppliers and physicians and will not provide clear parameters regarding reassignment, as CMS intends. If the agency does move forward with the proposal, it should instead revise the regulatory text of 42 C.F.R. § 414.50. It is this regulatory provision that squarely addresses appropriate billing requirements. In addition, the agency should not adopt the proposed anti-markup approach for the professional component because such a result would be inconsistent with the way all other reassignments are paid.

As CMS notes in the preamble to the proposed rulemaking, to clarify that the anti-markup rule applies to the contractual arrangement exceptions to the reassignment rules, the agency already revised § 424.80(a) to make clear that the "rules regarding physician billing for purchased diagnostic tests (§ 414.50 of this chapter)," are applicable.[11] Alliance concurs with CMS that the provisions of § 414.50 do and should apply under any contractual arrangement for the technical component of diagnostic tests. Longstanding policies regarding purchased diagnostic tests—previously found in the Medicare Carriers Manual—are found in the Medicare Claims Processing Manual.[12] It is unnecessary, therefore, to offer the additional clarifications of only one other reassignment exception in the contractual arrangement exception. By folding in other exceptions in this manner, the agency would effectively blur separate and distinguishable exceptions to the prohibition on reassignment (contractual arrangements and purchased diagnostic tests).

The contractual arrangement exception was intended, as CMS notes in the preamble to the proposal, to allow hospital emergency staffing companies that employ physicians to bill for their services. Joint and several liability was one of the program safeguards imposed for these arrangements.[13] It would not be appropriate to now take this new exception and define it in a way that would appear to supplant established policies to address abuse or potential abuse in a circumscribed area.

In addition, Alliance strongly urges the agency to consider the implications of its proposed changes in the radiology area, where an interpreting physician—usually a radiologist—does not need to be the physician who is performing or ordering the test for his or her patient. The rules that require the purchasing physician to be the physician who personally interprets the test would not seem to be the same as in the area of pathology. If CMS does go forward with the proposed language in the regulations, therefore, the Company would urge the agency to recognize those tests for which the performance of the technical and professional components may be accomplished by different specialties.

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11 *See id.* at 49055.

12 *See* Medicare Claims Processing Manual (Pub. No. 100-4), Chapt. 1, § 30.2.9.

13 71 Fed. Reg. at 49054.

Finally, Alliance urges CMS not to implement its suggestion to apply the anti-markup rule to the reassignment of PC of diagnostic tests performed under a contractual arrangement. Such treatment would be inconsistent with other exceptions to the reassignment rule—for which no anti-markup limitation is imposed on physician professional services. Most importantly, Congress did not choose to apply the anti-markup provision to billing for the professional component; Section 1842(n) of the Social Security Act, which contains the anti-markup rule, only applies to billing for the technical component.[14] Further, a uniform approach to the treatment of billing for the professional components of tests should be adopted, whether under the existing longstanding exception (*i.e.*, the "purchased interpretation" exception currently found in the Medicare Claims Processing Manual) or under the relatively new contractual arrangement exception. As such, the agency should not implement its suggestion for an anti-markup rule for interpretations.

II. CMS SHOULD NOT IMPLEMENT THE PROPOSED STARK LAW AMENDMENTS.

A. Proposal

In the proposed 2007 MPFS, the agency has indicated its intent to modify certain definitions contained in the Stark Law and Regulations. CMS notes that the purpose of the proposed revisions is to obstruct the operation of so-called "pod laboratory" arrangements. CMS notes the concern that pod labs allow for physician practices to purchase diagnostic tests and then turn a profit by billing Medicare—a situation that could result in abuse and over-utilization.

CMS proposes to slightly modify the definition of "physician in the group practice" under the Stark Regulations by adding that an independent contractor's contract must comply with both the reassignment rules at 42 C.F.R. § 424.80(d)(3), as well as section 30.2.9.1 of chapter 1 of the CMS Claims Processing Manual.

CMS also proposes to change the definition of "centralized building" in the Stark Regulations as follows:

- The definition would include a 350 minimum square footage requirement; however, the proposed minimum square footage requirement would not apply to space owned or rented in a building where three group practices or fewer own or lease space in the building and share the same "physician in the group practice." CMS notes that the purpose of the square footage requirement is to prevent abusive arrangements, such as pod labs, which tend to cover less than 350 square feet, but not to disqualify legitimate, stand-alone physician offices that are unusually small;

- The definition would require the space in a "centralized building" to permanently contain the equipment required to perform substantially all of the designated

[14] *See* 42 U.S.C. § 1395u(b)(6).

health services performed in the space. CMS notes that its goal is to prevent a situation in which an entity can frequently and easily move equipment as needed from one group's cubicle to another group's cubicle, as is the case in a traditional pod lab;

- The definition would preclude a group practice from maintaining a "centralized building" in a different state from the group practice's primary location; and

- The agency is considering, but has not yet proposed, that the definition require a group practice to employ, in the space in a "centralized building," a nonphysician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week.

B. Comments

Although Alliance understands the agency's desire to curb the abuse of pod labs in the context of pathology services, the Company is concerned that the proposed changes to the Stark Law would have unintended negative consequences for common diagnostic imaging arrangements, such as the provision of mobile diagnostic imaging services to medical group practices.

For example, the proposed minimum square footage requirement may unintentionally exclude certain mobile diagnostic imaging vehicles, vans or trailers from the definition of a centralized building requirement, even when they are owned or leased on a full-time basis and used exclusively by a medical group practice. Alliance also asks the agency to withdraw from consideration the requirement that the medical group practice staff the space with a nonphysician employee or independent contractor who performs services exclusively for the group practice in that space no less than 35 hours per week. This requirement also would effectively limit use of the centralized building equipment to those medical group practices that have a significant volume of diagnostic testing or other ancillary services to support the existence of a centralized testing site.

As technological advances increase the portability of diagnostic imaging equipment and decrease the space requirements for operation of such equipment, mobile service units and mobile equipment will enable medical group practices of all sizes to offer their patients higher quality services in a cost-effective manner. As such, the agency should not implement the proposed Stark Law amendments or, at a minimum, should exclude diagnostic imaging services from such amendments.

IDTF ISSUES

III. THE AGENCY SHOULD TRANSITION THE EFFECTIVE DATE OF ITS PROPOSED PERFORMANCE STANDARDS FOR CERTIFIED IDTFs.

CMS proposes to promulgate 14 supplier standards for IDTFs, to be included at 42 C.F.R. § 410.33.[15] An IDTF would be required to meet these standards by January 1, 2007 in order to obtain or retain enrollment in the Medicare program.[16] The agency has proposed that if an IDTF fails to meet one or more of the proposed standards at the time of enrollment or at the time of re-enrollment, then its application would be denied or the agency would revoke an IDTF's billing privileges.[17]

Alliance applauds the agency for its proposal to implement performance standards. But, the Company suggests that a transition period be provided for IDTFs currently enrolled in the program. CMS notes that its goal of implementing the performance standards is to "improve the quality of services provided to Medicare beneficiaries by IDTFs" and that "legitimate businesses would not oppose [the agency's] changes."[18] Alliance agrees that these standards would help to ensure only quality services are provided to beneficiaries. Implementation by the agency's contractors, however, might take additional time, and IDTFs already enrolled should have sufficient notice for any changes that might need to be undertaken for continued enrollment. Allowing IDTFs sufficient time to ensure full compliance with these standards would best serve the needs of beneficiaries by improving their access to high quality services. This may easily be accomplished with a 90-day transition period, once the standards become effective.

IV. CMS SHOULD MODIFY THE PROPOSED PERFORMANCE STANDARDS TO ACCOUNT FOR CERTAIN PRACTICAL IMPLICATIONS ON THE DIAGNOSTIC IMAGING INDUSTRY.

Although Alliance supports the agency's efforts to ensure that Medicare beneficiaries receive high quality diagnostic testing services, the Company would urge CMS to revise its proposed performance standards to account for certain practical considerations of the IDTF industry. Specifically, the Company recommends that CMS acknowledge certain important distinctions between fixed and mobile IDTFs. The agency should also retain its current reporting deadlines for changes to information included on a program enrollment application. Finally, CMS should provide a grace period in which an IDTF can cure any failure to comply with the proposed standards. Alliance firmly believes that such adjustments would ensure continued compliance with the standards without undermining in any way the agency's goals relating to quality services to beneficiaries.

The Company also holds serious concerns about the agency's proposed standard that

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15 *See* 71 Fed. Reg. at 49061-62.

16 *See id.* at 49061.

17 *See id.*

18 *Id.* at 49061.

supervising physicians cannot supervise more than 3 IDTF sites. This issue—along with more details about the standards for supervising physicians—is addressed in Section V below.

A. CMS should account for distinctions between mobile and fixed IDTFs.

Alliance believes that CMS should revise its proposal in a way that acknowledges certain differences between fixed and mobile IDTFs. Importantly, based on their physical limitations and method of operation, the Company recommends that CMS revise the proposed performance standards to account for the following differences for mobile unit operations: (1) the mobile IDTF may maintain hand washing, patient privacy and document storage at the "physical site" at which the unit is parked during its operations rather than within the mobile unit itself; (2) all equipment for mobile units, as well as a catalog of all current inventory, may be maintained at a centralized location and not within the mobile unit itself; (3) the primary business phone should be that which is at a centralized location rather than the mobile unit itself, for which business hours vary; (4) the mobile IDTF documentation of all patient contacts may be maintained at a centralized location rather than at the mobile unit; (5) the mobile IDTF should be given additional time to provide medical records, to the extent they are stored at fixed locations; and (6) the mobile IDTF may not be able to post regular business hours because its hours of operation are variable.

Alliance urges CMS to account for mobile IDTFs by taking an approach similar to that contained in the Medicare supplier enrollment application, Form 855-B. Form 855-B specifically distinguishes between an IDTF's "base of operations" and its "mobile facilities."[19] A "base of operations is the location from where personnel are dispatched, where mobile/portable equipment is stored, and when applicable, where vehicles are parked when not in use."[20] A "mobile facility" is "a mobile home, trailer, or other large vehicle that has been converted, equipped, and licensed to render health care services."[21] Through this distinction, CMS recognizes that a base of operations performs the administrative functions of the imaging services company, whereas the mobile units are "dispatched" to perform the actual testing services. Similarly, the Company believes that it is most logical to have a central facility monitor patient contacts, store documents and keep track of each mobile unit's location and schedule. This central facility could be a regional office, base of operations or other centralized location, depending upon the particular mobile facility.

Because many of the Company's comments turn on this point, Alliance urges CMS to incorporate the following changes into its proposed regulations (recommended revisions to

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19 *See* Centers for Medicare & Medicaid Services, *Medicare Enrollment Application for Clinics/Group Practices and Certain Other Suppliers* (Form 855-B), at 13, 18, *available at* http://www.cms.hhs.gov/CMSforms/downloads/cms855b.pdf.

20 *Id.* at 18.

21 *Id.* at 13.

proposed 42 C.F.R. § 410.33(i) are underlined and italicized):[22]

> (i) Definitions. For purposes of this section, the following definition applies: *Point of actual delivery of service. . . .*
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> * * *
>
> *Centralized location. This term means any fixed location from which the activities of a mobile IDTF are managed or dispatched, where business and medical records are stored, and where primary contact information for the mobile IDTF is maintained.*
>
> *Mobile facility or mobile IDTF. These terms refer to a mobile home, trailer, or other large vehicle that has been converted, equipped, and licensed to render diagnostic imaging services inside the vehicle.*[23]

Alliance also submits the following comments with respect to the agency's specific proposed performance standards.

1. *Proposed Requirement to Maintain a Physical Facility.*

The agency has proposed that an IDTF maintain a physical facility on an appropriate site. A physical facility would be required to have space for equipment, facilities for hand washing, adequate patient privacy accommodations and storage of business records and medical records.[24]

While mobile IDTFs do keep appropriate equipment on site, it is a common practice for mobile IDTFs to rely on a staging area on the premises of the client where tests are being performed for hand washing and patient privacy accommodations. Simply put, mobile units may not have hand washing and patient change rooms in the unit itself. However, the facility at which the unit is parked offers such accommodations. Accordingly, CMS should revise its proposal to account for mobile units' usage of other sites for these functions.

With respect to the storage of business records and medical records, this type of documentation could more appropriately be kept at a centralized location. The Company believes that storing business records at a centralized location permits ready access to files and facilitates potential responses to beneficiary questions or agency requests for such documentation. In addition, CMS should recognize in its regulations that a mobile IDTF may store patient records and films at the premises of the IDTF's clients, which are health care providers located where the mobile IDTF parks in order to perform the diagnostic services.

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22 In Sections IV and V of this letter, the Company makes several suggested changes to regulatory language. In each suggestion, proposed language is in italics and underlined and proposed deleted language is scored.

23 *See* 71 Fed. Reg. at 49080 (proposed 42 C.F.R. § 410.33(i)).

24 *See id.* at 49061.

Alliance would also note that there is a security risk if a mobile unit drives around with patient files and other records. As currently drafted, because there is no exception for mobile IDTFs, these types of facilities could start to pare down patient records to the barest of documents. Accordingly, Alliance urges CMS to adjust its proposal to permit such centralized storage of documents and storage at the physical site where the tests were performed.

Based on the above proposals, Alliance suggests the following revisions to proposed § 410.33(g)(3):

> (g)(3) Maintain a physical facility on an appropriate site. *A mobile facility is considered a physical facility.* For the purposes of this standard, a post office box or commercial mail box is not considered a physical facility. The physical facility must contain space for equipment appropriate to the services designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records. *A mobile facility is considered to meet this standard if facilities for hand washing and adequate patient privacy accommodations are located on the premises where the mobile facility is parked and tests are performed and if it stores its business and current medical records either at a centralized location or at the premises where the mobile facility is parked and tests are performed.*[25]

2. *Proposed Requirement to Have All Equipment at the Physical Site.*

The agency has proposed that an IDTF have all applicable testing equipment available at the physical site. CMS would also require that a catalog of portable equipment, including serial numbers, be maintained at the physical site. In addition, portable equipment would be made available for inspection within 2 business days of an inspection request by CMS. The IDTF would also be required to maintain a current inventory of the equipment (including serial and registration numbers), provide this information to the CMS contractor and notify the CMS contractor of any changes in equipment.[26]

With respect to the requirement that all applicable equipment must be stored at the physical facility, the Company believes that CMS must incorporate a definition of physical facility that includes mobile units in addition to fixed facilities. In addition, the definition should distinguish between the actual mobile IDTF and an IDTF's centralized location.

The Company also urges CMS to recognize that a mobile IDTF may maintain a catalog of current inventory of equipment (including serial and registration numbers) at its centralized location. Just as mobile IDTFs store patient information at central locations or at the premises of

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25 *See id.* at 49080 (proposed 42 C.F.R. § 410.33(g)(3)).

26 *See id.*

the IDTF's client where the tests were performed, a mobile IDTF also stores records of units and equipment types, serial numbers and trailer registrations, among other information, at central locations. The Company asks that CMS recognize this storage method by acknowledging that a mobile IDTF may store their inventory records at a central location.

Accordingly, based on the above proposals, Alliance suggests the following revisions to proposed § 410.33(g)(4):

> (g)(4) Have all applicable testing equipment available at the physical site excluding portable equipment. A catalog of portable equipment, including equipment serial numbers, must be maintained at the physical site *or at a centralized location in the case of a mobile IDTF*. In addition, portable equipment must be available for inspection within two business days of a CMS inspection request. The IDTF must maintain a current inventory of the equipment including serial and registration numbers, provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days. *An IDTF must maintain the current inventory at the physical site or at its centralized location.*[27]

3. *Proposed Requirement to Maintain a Primary Business Phone.*

CMS would require that an IDTF maintain a primary business phone at the designated site of the business.[28] Here as well, exceptions should be recognized for mobile units. It is common practice for mobile IDTFs to adopt temporarily lines from the clients on whose premises the mobile units are performing tests. These lines belong to the client and only function when the mobile unit is parked on the client's premises. Alliance urges CMS to revise this proposal to permit mobile IDTFs to maintain a primary business phone through its centralized location. These centralized locations can better keep track of patient contacts and better stay in touch with the actual mobile units. Therefore, Alliance suggests the following revision to proposed § 410.33(g)(5):

> (g)(5) Maintain a primary business phone under the name of the designated business. The business phone must be located at the designated site of the business. The telephone number or toll free numbers must be available in a local directory and through directory assistance. *A mobile IDTF will be considered to meet this standard if its centralized location maintains a primary business phone.*[29]

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27 *See id.* at 49080 (proposed 42 C.F.R. § 410.33(g)(4)).

28 *See id.* at 49061.

29 *See id.* at 49080 (proposed 42 C.F.R. § 410.33(g)(5)).

4. *Proposed Requirement to Maintain Documentation of Patient Contacts.*

CMS also proposes to require that IDTFs answer beneficiaries' questions and respond to their complaints, maintaining documentation of such contacts at the physical site.[30] The agency should revise this proposal to account for the fact that such documentation can be maintained at a mobile IDTF's centralized location rather than on the actual mobile unit itself. As is the case with business records documentation and medical records documentation described above, it is more practical for patient contact documentation to be maintained at a central facility. Therefore, Alliance suggests the following revision to proposed § 410.33(g)(8):

> (g)(8) Answer beneficiaries' questions and respond to their complaints. Documentation of those contacts must be maintained at the physical site, *which includes a centralized location in the case of a mobile IDTF*.[31]

5. *Proposed Requirement to Provide Medical Records to CMS.*

CMS has also proposed that an IDTF must be able to retrieve medical records upon request from CMS within 2 business days.[32] The Company would urge CMS to extend its proposed requirement that IDTFs provide requested medical record documentation to Medicare contractors within 2 days of the agency's inspection request.[33] Although the Company agrees to provide contractors with all information requested, the time line is extremely tight, particularly if multiple requests are made simultaneously. Allowing 5 business days to respond would enable an IDTF to confirm the accuracy of its responses both at its centralized location and at the site where a mobile unit parks, in the event of a mobile IDTF that stores patient documents there. Additional time to respond would avoid the submission of documentation in installments or through supplements.

6. *Proposed Requirement to Permit CMS to Conduct Unannounced Inspections.*

The agency has proposed that IDTFs must permit CMS to conduct unannounced, on-site inspections to confirm compliance with performance standards during regular business hours. In addition, CMS would require that IDTFs post visible sign posting the normal business hours of the IDTF.[34]

Because mobile units only operate when patients need services and move from location to location, it may not always be practicable for CMS to perform unannounced on-site

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30 *See id.*

31 *See id.* at 49080 (proposed 42 C.F.R. § 410.33(g)(8)).

32 *See id.* at 49062.

33 *See id.*

34 *See id.*

inspections of such units. CMS would have to know the location and schedule of the mobile unit in advance in order to conduct such an inspection. Consequently, Alliance recommends that CMS consider revising its proposal to account for mobile IDTFs by indicating that CMS will contact the mobile unit's centralized location in advance for location and schedule information.

In addition, Alliance urges the agency to acknowledge in its proposed standards that many mobile IDTFs do not have regular business hours. Instead, these units are open while there are patients on the schedule; when there are no more patients on the schedule, the unit departs for the next service location. As such, mobile IDTFs cannot fully comply with the requirement to maintain a visible sign posting the IDTF's normal business hours.

Based on these suggestions, Alliance urges that the agency make the following revisions to proposed § 410.33(g)(14):

> (g)(14) Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. *For mobile IDTFs, CMS will obtain the mobile IDTF's schedule and location from the centralized location in order to conduct an on-site inspection.* The IDTF must be accessible during regular business hours to CMS and beneficiaries, *or, in the case of a mobile IDTF, the mobile IDTF must be accessible during the hours reported to CMS and beneficiaries by the centralized location. The IDTF* ~~and~~ must maintain a visible sign posting the normal business hours of the IDTF *or, in the case of a mobile IDTF, contact information where the mobile IDTF's schedule can be obtained.*[35]

B. CMS should retain current reporting timeframes.

Alliance believes that the agency should amend its proposal that an IDTF must report any change in information contained on its enrollment application within 30 calendar days.[36] The current 90-day requirement for reporting changes to such information has been in place for a number of years and amply allows CMS and its contractors to receive and review up-to-date information.[37] Alliance believes that the administrative burden of a 30-day reporting requirement should be carefully weighed, particularly since some changes, such as the changes in technician personnel, would not significantly impact the day-to-day operations of an IDTF's business.

Alliance, which has over 100 sites, takes its relationship with the Medicare program very seriously. The Company is concerned that a requirement for all *de minimus* changes to be made

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[35] *See id.* at 49080 (proposed 42 C.F.R. § 410.33(g)(14)).

[5] *See id.*

See Centers for Medicare & Medicaid Services, *Medicare Enrollment Application for Clinics/Group ·actices and Certain Other Suppliers* (Form 855-B), at 1.

within 30 days would result in an almost constant stream of reporting. Because Alliance operates both fixed and mobile facilities, in order to monitor and report the changes, the Company must (1) coordinate with human resources to determine who has been hired and terminated, (2) collect and confirm each new staff-person's credentials, (3) monitor updates to imaging equipment, and (4) confirm, on a continuous basis, the contractual relationship of each site's supervising physician. Although constant tracking is done, the current 90-day requirement for reporting changes to information on the application form—which also may require supporting documentation—allows suppliers to compile all the changed information that takes place for each site as it occurs and to submit one update every 90 days. It would also appear that the time line is more efficient not only for the IDTF, but for the agency and its contractors, which must ultimately review and process this information. It would also not unfairly jeopardize an IDTF's relationship when a *de minimus* update is not reported within 30 days. To ensure 30-day reporting of new and existing technicians, imaging equipment, and physicians who join or leave the group, among other items of information, the Company would need to hire new staff dedicated to collecting and reporting this information.

In addition, it should not be overlooked that CMS already has certain regulatory provisions in place regarding timelines for reporting changes in ownership and controlling interests.[38] A 35-day timeline remains in place for this type of reporting.

C. CMS should provide a period to cure discrepancies and should include appeal rights in the event of a non-compliance determination.

Alliance strongly urges the agency to revise its proposed regulations regarding the revocation of billing privileges after a determination of non-compliance with these performance standards. Notably, the agency proposes that "if an IDTF fails to meet one or more of the proposed standards at the time of enrollment or at the time of reenrollment, then its enrollment application would be denied."[39] Furthermore, the agency notes that if at any time it determines that "an enrolled IDTF no longer meets the proposed supplier standards, its billing privileges would be revoked." Alliance is particularly concerned that the regulation does not address notice and ability to address erroneous finding or appeal rights.

The Company believes that the agency should modify its proposed regulation to acknowledge that the IDTF must be given sufficient notice of any finding that it does not meet the supplier standards contained in the agency's regulations, particularly if such findings lead to a determination that the supplier's billing privileges will be revoked.[40] In addition, as is the case with all other billing privileges, IDTFs should be given an opportunity to explain and/or cure a noted discrepancy before any determination is made regarding billing privileges. A period of time—at minimum, 30 days—should be afforded during which the IDTF to explain or otherwise cure a finding of a discrepancy that may lead to a determination of noncompliance. This would

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38 *See* 42 C.F.R. § 420.206(b)(3).

39 *See* 71 Fed. Reg. at 49061, 49080 (proposed 42 C.F.R. § 410.33(h)).

40 *Cf.* 42 C.F.R. § 424.57(d) (providing for a 15-day notice prior to revocation of DMEPOS supplier billing privileges).

be in line with how Medicare contractors address discrepancies prior to making any revocation determinations. Alliance is particularly concerned that a minor discrepancy or erroneous finding of non-compliance could otherwise have a devastating consequence.

Finally, Alliance submits that formal appeal rights should be incorporated into any regulation addressing revocation of billing privileges. Again, this would be in line with regulatory standards for other providers and suppliers.[41]

V. THE AGENCY SHOULD ADJUST ITS PROPOSED LANGUAGE REGARDING SUPERVISING PHYSICIANS TO ACCOUNT FOR CERTAIN IMPLICATIONS OF THE IDTF INDUSTRY.

A. CMS should clarify the qualifications of supervising physicians in its proposed performance standards for IDTFs.

The agency's current regulations require each IDTF to have a supervising physician, who "must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF."[42] The agency notes that this proficiency "may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located."[43] In the case of a procedure requiring direct or personal supervision, the regulation continues, "the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location."[44]

Although Alliance believes that the language of the regulatory provision is clear, some Medicare contractors are not evaluating a supervising physician's proficiency but instead restricting the supervisory physician role to radiologists for all imaging services. Consequently, the Company urges CMS to provide clarifying language in its final rule to ensure that only

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41 *See, e.g.*, 42 C.F.R. § 405.874 (addressing appeal rights for DMEPOS suppliers).

42 42 C.F.R. § 410.33(b)(2).

43 *Id.*

44 *Id.* The supervision requirement uses the terms "general," "direct" and "personal" supervision. The agency defines these terms as follows:

> "General supervision" means that a procedure is furnished under the "physician's overall direction and control, but the physician's presence is not required during the performance of the procedure . . . . [T]he training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.
>
> "Direct supervision" means the physician "must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed."
>
> "Personal supervision" means a physician "must be in attendance in the room during the performance of the procedure."

Id. at § 410.32(b)(3)(i)-(iii).

proficient physicians are acting within this role. Alliance believes that this interpretation of the regulation is reasonable and practical: supervision of a test, as the regulation notes, requires proficiency with the test, not specialization in an entire field of medicine such as radiology.

In its contracts with supervising physicians, the Company currently distinguishes between general and direct or personal supervision. In Alliance's typical model, a radiologist provides general supervision, which includes ongoing oversight of the quality of testing performed, the proper operation and calibration of the equipment used to perform tests, maintenance of equipment and supplies and the qualifications of non-physician personnel who use the equipment. Generally, a non-radiologist physician provides direct or personal supervision of tests involving injection of contrast material. In fact, a non-radiologist physician is well-qualified to perform contrast material injections and to monitor patients for negative reactions, among other duties.

Despite the clear regulatory language, certain carriers have been declining to authorize IDTF testing unless a radiologist provides all supervision, including the direct supervision of the administration of contrast materials. Alliance believes that the requirement imposed is unreasonable. If a non-radiologist is *proficient* in performing contrast administration, as is required by the regulations, that non-radiologist's direct supervision of the contrast administration should be acknowledged as appropriate.

For example, at a fixed imaging center located next to a family practice, an IDTF might have a radiologist provide the IDTF's general supervision, while a family practice physician provides the direct supervision of the testing. Alternatively, there could be a mobile IDTF dispatched to a physician group where it parks in the medical group's parking lot. A radiologist, again, provides the general supervision of the testing and a neurologist from the group provides any required direct supervision, which consists of supervision of the contrast administration. As the agency is aware, administering contrast material involves an injection. In each example, the supervising doctors, based on their experience, are more than proficient in the use and administration of contrast material, including proper dosages and quantities needed for the particular tests. The non-radiologist is capable of explaining the testing process to the patient and to non-physician technicians and can address any concerns about the contrast medium or the use of the equipment. These licensed and qualified physicians are capable of ensuring that the contrast is safely and properly administered. The risk presented by the use of contrast medium is allergic reaction, which is a medical issue that does not require a radiologist's supervision.

As these examples show, an IDTF typically divides supervision responsibilities among more than one physician. If such a division of duties exists, the direct or personal supervising physician does not need to be proficient in the performance or interpretation of every type of diagnostic procedure performed by the IDTF so long as he or she is proficient in the actual function being supervised (e.g., the administration of contrast materials). In such a situation, the physician providing the general supervision of the facility should be proficient in the performance and interpretation of each type of diagnostic procedure performed by the IDTF (e.g., a physician with a specialty in radiology).

As such, Alliance urges the agency to clarify that being a radiologist should not be a criterion for a licensed physician to be able to directly or personally supervise the administration of contrast materials to ensure safety of the patients. Alliance believes that the agency should clarify that radiologists are not required to provide direct or personal supervision for such services, so long as a proficient physician is available to directly or personally supervise the procedure.

B. CMS should not implement the proposal that supervising physicians can supervise only 3 IDTF sites.

As noted in Section IV above, Alliance also urges the agency not to adopt the proposed requirement that supervising physicians are limited to providing supervision for three IDTF sites.[45] The Company notes that physicians who supervise imaging facilities typically have an administrative role and are not responsible for performing every test. They are responsible for ensuring clinical integrity and the quality of tests. The current regulation's language accurately captures this fact in noting that the appropriate level of supervision is that described in 42 C.F.R. § 410.32(b) as "general supervision."[46] As such, supervising physicians should be permitted to oversee more than three sites. The Company therefore recommends that the agency adjust its proposal accordingly by removing the restriction that supervising physicians are limited to three sites.

In addition, the agency's proposed requirement that supervising physicians are responsible for "overall operation and administration" and for ensuring compliance with "applicable regulations" should be amended. Instead, the Company suggests that the agency retain current policies that require supervising physicians to take responsibility for the clinical integrity of the testing. Moreover, the term "applicable regulations" is vague and does not clearly indicate the responsibilities of a supervising physician.

C. CMS should not remove the express requirement that an IDTF have a supervising physician.

Finally, Alliance seeks clarification of the proposed language at 42 C.F.R. § 410.33(b)(1). In the preamble to the proposed rule, the agency notes that it is "proposing to revise § 410.33(b)(1) to read that physicians will be limited to providing supervision to 'no more than three (3) IDTF sites.'"[47] The text of the revised regulation, however, no longer articulates an explicit requirement for a supervising physician. Whereas the previous language recognized that the "IDTF must have one or more supervising physicians," the proposal, as drafted, removed this express requirement altogether. Alliance recommends that CMS add back this language.

Based on all of the recommendations described in this Section V, Alliance proposes the following revisions *to the current language of* 42 C.F.R. § 410.33(b)(1) & (2):

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45 *See id.* at 49080 (proposed 42 C.F.R. § 410.33(b)(1)).

46 *See* 42 C.F.R. § 410.33(b)(1).

47 *See* 71 Fed. Reg. at 49062.

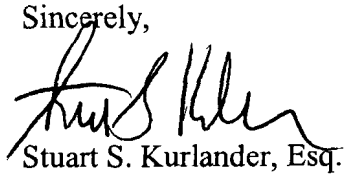
(1) An IDTF must have one or more supervising physicians who are responsible for ~~the direct and ongoing oversight of the quality of the testing performed, the proper operation and calibration of the equipment used to perform tests, and the qualification of nonphysician personnel who use the equipment~~ *the overall operation and administration of the testing performed at the IDTFs, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently.* This level of supervision is that required for general supervision set forth in §410.32(b)(3)(i).

(2) *In the event that an IDTF has more than one supervising physician, (i) t*~~T~~he ~~supervising~~ physician *who provides direct or personal supervision of any aspect of a particular diagnostic procedure* must evidence proficiency in the performance ~~and interpretation~~ of *that aspect of the* ~~each type of diagnostic~~ procedure *(e.g., administration of contrast material), but is not required to be proficient in the performance of all aspects of diagnostic procedures performed by the IDTF* ~~performed by the IDTF~~, *and (ii) any supervising physician who provides general supervision of the IDTF must be proficient in the performance and interpretation of all diagnostic procedures performed by the IDTF. Neither the direct or personal supervising physician nor the general supervising physician is required to be certified or otherwise credentialed in any particular specialty (e.g., a physician supervising imaging services need not be a radiologist).* ~~The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located.~~ In the case of a procedure requiring the direct or personal supervision of a physician as set forth in §410.32(b)(3)(ii) or (b)(3)(iii), the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services, at the remote location. The IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished. In the case of procedures requiring direct supervision, the supervising physician may oversee concurrent procedures.

We believe that if these changes are incorporated, CMS's goal of clarifying its regulations regarding IDTFs will be accomplished.

Thank you for considering Alliance's comments regarding the agency's proposed revisions to the policies under the MPFS. Should you have any questions or comments, we can be reached at (202) 637-2200.

Sincerely,



Stuart S. Kurlander, Esq.
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Cc: Alliance Imaging, Inc.
Matthew E. Wetzel, Latham & Watkins LLP

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October 10, 2006

Mark McClellan, MD, PhD
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 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Notice**

Dear Dr. McClellan:

The American College of Obstetricians and Gynecologists (ACOG), representing more than 49,000 physicians and partners dedicated to improving women's health, appreciates the opportunity to comment on the "Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule" published in the August 22, 2006 **Federal Register**. Our primary concern in reviewing any proposal for new reimbursement policies is the potential impact these policies may have on access to and quality of health care for women.

Practice Expense

CMS asked medical specialty societies to review direct practice expense (PE) inputs. ACOG identified a problem with SA075, the kit used for hysteroscopic tubal implant for sterilization, used for CPT 58565, hysteroscopy, sterilization. The cost for this kit has increased from the original $980 to $1245, plus tax.

A4562: Medicare payment for pessaries, HCPC code A4562, is consistently less than the cost incurred by the practice, and there are large disparities in the amount that Medicare fiscal intermediaries pay for pessaries across the country. We have included an invoice from a practice in Washington state for $50.00 plus $10.69 shipping, plus $4.40 sales tax, for a total of $65.09. Medicare reimbursement for this pessary was $18.63. We ask that CMS address this problem to ensure that all providers are adequately reimbursed for the cost of pessaries.

Please contact ACOG staff person Kim Longworth at 202-863-2456 if you need additional documentation or information.

Sustainable Growth Rate

ACOG has commented in previous years and will do so once again, that ACOG believes Medicare's formula for updating physician payments is flawed and will result in payment levels that are inadequate to assure access to physician services for Medicare beneficiaries. The projected -5.1% physician payment update for 2007 underscores the need for comprehensive, fundamental change to the Sustainable Growth

Rate (SGR) system for annual changes to Medicare's physician payments. Although the framework of the update system is defined in statute, we believe that CMS has authority to make some adjustments that will lessen the potential negative impact on the physician community. We join the American Medical Association and other physician organizations in urging CMS to exercise that authority to address the following issues. We urge CMS to work cooperatively with Congress and the physician community to create an update process that will ensure continued access to care for Medicare beneficiaries and fair compensation for the physicians who care for them.

The Medicare Fee Schedule and Resource Based Relative Value System are used not only by CMS, but are also used as benchmarks by many insurers. Declining reimbursement in the face of rising costs, especially the cost of professional liability insurance, is already forcing some physicians to stop accepting new Medicare and Medicaid patients, and will soon have serious adverse effects on women's access to care. We are hopeful that CMS will act to prevent the projected reductions in payments to physicians.

ACOG appreciates CMS's continued willingness to work cooperatively with the physician community to assure implementation of sound policies for governing Medicare payment policy. We are eager to work with CMS to resolve the issues identified in these comments.

Sincerely,

Ralph W. Hale, MD

Ralph W. Hale, MD, FACOG
Executive Vice President

enclosure

REMIT TO:
P.O. BOX 712280
CINCINNATI, OH 45271-2280 USA
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CooperSurgical

95 CORPORATE DRIVE TRUMBULL, CT 06611
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INVOICE

INVOICE NO.: 1171911 Page 1
INVOICE DATE: 07-06-05
CUSTOMER NO.: 024427

BILL TO
024427
[redacted]
FEDERAL WAY, WA 98003-6700
USA

SHIP TO
[redacted]
FEDERAL WAY, WA 98003-6700
USA

SOLD TO
[redacted]
FEDERAL WAY, WA 98003-6700
USA

993539	KAY	SHIP POINT	
07-05-05	UPS GROUND	0.00/000/030	07-06-05

			Contact: KAY 253-838-3695					
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PLEASE PAY FROM INVOICE

HCPC
A4562
Pessary
Medicare Payment: $18.63

INVOICE SUB TOTAL	DISCOUNT	VAT	SALES TAX	SHIPPING & HANDLING	PLEASE PAY THIS AMOUNT
50.00	0.00		4.40	10.49	

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American
Clinical Laboratory
Association

October 10, 2006

VIA HAND DELIVERY

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

RE: Comments on the Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 – File Code CMS–1321–P

Dear Sir or Madam:

Enclosed please find the comments of the American Clinical Laboratory Association on the Centers for Medicare and Medicaid Services' proposed revisions to payment policies under the physician fee schedule for calendar year 2007. 71 Fed. Reg. 48982 (Aug. 22, 2006).

If you have any questions or comments, please feel free to contact me.

Sincerely yours,

Alan Mertz /ED

Alan Mertz
President

1250 H Street, N.W. • Suite 880 • Washington, DC 20005 • (202) 637-9466 Fax: (202) 637-2050

American
Clinical Laboratory
Association

Comments of the American Clinical Laboratory Association on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

[CMS–1321–P]

The American Clinical Laboratory Association ("ACLA") is pleased to submit these comments on the proposed revisions to payment policies under the physician fee schedule for calendar year 2007 (the "Proposed Rule"). 71 Fed. Reg. 48982 (Aug. 22, 2006). ACLA is an association representing clinical laboratories throughout the United States, including local, regional and national laboratories. ACLA members perform a variety of services that are reimbursed under the physician fee schedule. Thus, ACLA members will be significantly affected by the changes in the Proposed Rule. ACLA's comments on the Proposed Rule focus on the revisions to the practice expense for flow cytometry services, the reassignment and physician self-referral rules, changes to the rules governing how anatomic pathology services are billed, the process for developing payment levels for new tests, development of quality measures for physician services, and changes to the date of service rules for laboratory tests on stored specimens.

PROVISIONS

Resource-Based Practice Expense RVU Proposal for Flow Cytometry

The Centers for Medicare and Medicaid Services ("CMS") is proposing to revise the direct Practice Expense ("PE") inputs for the flow cytometry CPT codes 88184 and 88185, based on additional data provided by the laboratory community regarding the time and equipment required for this testing. *Id.* at 48988. ACLA supports CMS' decision to make these revisions to the technical component of flow cytometry services in order to more accurately pay for these services. This action will ensure that patients have access to life-saving technology used to diagnose, treat, and monitor serious health conditions.

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

ACLA is very pleased that CMS is taking action designed to curb the growth of so-called "pod" or condo laboratories. *Id.* at 49054. As ACLA has pointed out in the past, these arrangements give referring physicians the opportunity to earn revenues based on their own referrals for services performed by other physicians. The Medicare program has always expressed concern about such arrangements and has numerous provisions in place to curb such abuses. CMS is taking an important step in its revision to the reassignment rules and the Stark self-referral laws as a way of curbing these abusive arrangements. However, ACLA believes that in order to be effective in addressing the pod issue, CMS must implement not only the independent contractor reassignment revisions that pertain to the technical and professional components of anatomic pathology, but also measures that would limit the use of part-time employee pathologists in such arrangements.

As CMS recognizes, there are two different, but related, means of curbing these practices: first, clarify the provisions of the prohibition on reassignment, which is designed specifically to prevent Medicare from paying physicians for work performed by others, except in limited situations and second, modify the Stark self-referral law, which is designed to prevent physicians from profiting by referring business to entities with which they have a financial relationship. As CMS notes, many pod arrangements are established either in contravention of these requirements or by taking advantage of ambiguities that exist. Generally, ACLA is supportive of the changes that CMS is making, but we do have some proposals to clarify or more closely define the requirements set out by CMS, as well as to address the issue of part-time employees. In addition, in these comments, we respond to specific suggestions that CMS has made.

Changes to the Reassignment Rule

In the area of the changes to the prohibition on reassignment, CMS makes the following proposals:

- Clarify that physicians acting pursuant to the contractual arrangement exception must still meet the requirements applicable to the purchase of diagnostic testing, with regard to the professional component.

- CMS requests comments on what additional limitations should be put on the purchase of the professional component.

- CMS asks whether all diagnostic testing in the designated health services ("DHS") category should be covered or whether it should apply specifically to pathology; and whether any of the provisions should apply to services performed on the premises of the billing entity, and if so, how to define the premises appropriately.

ACLA responds to each of these proposals below.

Reassignment of the technical component. ACLA strongly supports CMS' proposal to require that physicians acting pursuant to the contractual arrangement provision comply with limitations, including the anti-markup provision, that currently exist on the purchase of diagnostic testing with regard to the technical component ("TC"). Under those requirements, a physician or billing group acting under the contractual arrangement exception must still meet the following conditions:

- The amount billed to Medicare cannot exceed the lowest of the net charge to the billing physician or medical group; the billing physician or medical group's actual charge; or the fee schedule amount for the service.

- In order to bill for the TC, the billing entity would be required to perform the interpretation.

ACLA strongly supports this change or clarification to ensure that the current rules applicable to the TC continue to be applicable even in situations where physicians are taking

advantage of the contractual arrangement provision.[1] Thus, these should apply to the purchase or reassignment of a TC involving a contractual arrangement with the physician or the supplier who performed or supervised the TC.

Reassignment of the professional component. CMS stated that it is also considering further amendments to the contractor reassignment rule that would incorporate existing requirements concerning the purchase of the professional interpretation or PC. ACLA agrees with CMS' view that there is no practical difference between the reassignment of either the technical or professional component from an independent contractor pathologist and a purchase of the same component from that pathologist. Thus, just as CMS is doing with regard to the technical component of a diagnostic test, CMS should clarify that existing limits on the purchase of the *interpretation* of a diagnostic test apply equally to reassignment situations.

Further, the proposed rule changes under § 424.80 address only the reassignment of the technical component. While these are necessary, they are insufficient to effectively deter those pod arrangements that rely on the use of contracted pathologists. We agree with CMS that adopting the conditions on billing for a reassigned PC in order to guard against patient and program abuse is within its authority. Thus, we strongly urge, as CMS has said it is considering, that the purchased interpretation safeguards be incorporated into the independent contractor reassignment rule.

CMS has suggested the following conditions be adopted for a purchased PC, which is also subject to the contractual arrangement provision:

- In order to bill for a purchased PC, 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;

- The physician or medical group performing the interpretation may not see the patient; and

- The physician or medical group billing for the interpretation must have performed the TC of the test.

ACLA supports these general changes, with some minor modifications discussed below, which more closely track the current Claims Processing Manual. These provisions are similar to those requirements currently found in the Medicare Claims Processing Manual, Chapter 1, § 30.2.9.1, and which have long been Medicare requirements,[2] although as discussed below, the

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[1] The one suggestion that ACLA would make is in the regulatory text in § 424.80, which states that the payment to the billing physician or medical group less the applicable deductibles and coinsurance cannot exceed the lowest of the net charge to the billing physician or medical group, billing physician's or medical group's actual charge, or the fee schedule amount. This appears to suggest that the deductibles and coinsurance should be *subtracted* from the payment. It would be clearer to revise this language as follows: "the payment to the billing physician or medical group, *including applicable deductibles and coinsurance*, may not exceed the lowest of the following amounts."

[2] Although the origin of these specific requirements is unclear, it appears they were drafted in this way to recognize that in many instances corporate practice of medicine requirements prevent laboratories from directly employing pathologists. As a result, these pathologists are often set up in separate, controlled, corporations that are supported

formulation seems clearer than, and preferable to, the interpretation included in the Preamble. In the proposed regulatory text that is attached, we have followed this approach, although we have stated that the person or entity "billing for the service" cannot also have initiated the testing. We believe this language is clearer than the current Manual formulation that refers to the person or entity "providing" the service. The original formulation of this provision that appeared in § 3060.5 of the Medicare Carriers Manual, which has now been replaced by the Claims Processing Manual, permitted the physician or group that furnished the interpretation "to add tests or otherwise modify the original order for the tests in accordance with usual professional practice." We would support including that language in the provision, as it is not infrequent that pathologists must add tests to the order; as they did not initiate the testing, that should be permissible.

In the proposed rulemaking, CMS solicited suggested regulatory text for incorporating the purchased interpretation rules into the contractor reassignment provision. At Exhibit I hereto, ACLA is submitting a regulatory proposal that would accomplish this purpose by adding a new § 424.80(d)(4), and follow the current language of the Manual, although we believe it is clearer to use "billing for the service." This proposal is consistent with the format and wording used by CMS in the Proposed Rule on contractual arrangements for provision of diagnostic test services under § 424.80(d)(3).

Professional component anti-markup limitation. ACLA does not support the implementation of an anti-markup provision on the PC. CMS' view, while not clear in this area, seems to be that the anti-markup requirement, rather than the current Claims Processing Manual requirements, will be most effective in curbing the abuse of pods. In fact, the opposite seems true: the current limitations on purchased interpretations – if enforced – are the most effective way of dealing with these arrangements. The anti-markup limitation on the PC will be counterproductive and likely ineffective to prevent the abuse of pods.

The anti-markup limitation on purchased PCs will be counterproductive because there are specific situations where a laboratory entity may need to purchase the professional component or where doing so is otherwise an appropriate business structure that permits pathologists that do not want to be employed to remain independent. In particular, many states still have corporate practice of medicine requirements, under which a laboratory is not permitted to directly employ pathologists. As a result, other arrangements are made necessary, including one in which the pathologists are employed under a separate professional corporation with substantial technical, clerical and administrative support from the laboratory. The laboratory, which performs the TC, purchases the PC from those physicians. Such situations do not raise fraud and abuse concerns because neither the laboratory nor the pathologists triggered the referral; the referral will always have come from an outside physician. As noted above, it seems likely that the current restrictions on the purchase of the PC, which currently appear in the Claims Processing Manual, were written to take into account just these situations. Given the fact that Medicare has apparently recognized the need for laboratories and other entities to purchase the PC from physicians, it seems inappropriate now to implement an anti-mark-up provision that basically ignores that necessity.

Further, even if enforced, it is not clear that the anti-mark up limitation on the purchase of PCs would be effective. Unlike the limitation on the purchased TC, CMS has no experience with

a mark up limitation on the PC. In our view, it would be unwise to introduce a new anti-mark up provision with unknown and unintended consequences when a tested approach is already available. Finally, there might be ways for groups to circumvent the limitations on the mark-up. For example, even though they could not mark up the price from the pathologist, they might require the pathologist to pay rent for the space used to perform the services. Further, we note there is a specific statutory authority for the anti-markup provision as related to the TC, which is found in § 1842(n) of the Social Security Act. However, that provision applies specifically to the TC and does not apply to the PC. Therefore, the anti-markup requirement on the PC is neither required nor appropriate.

Finally, if they were enforced against these arrangements, then the current restrictions on the purchase of interpretations, which are already found in the Claims Processing Manual, are likely to be the most effective in curbing abuse. This is because they would prevent a physician who triggered a referral from also purchasing the PC, a situation in which he directly profits from his or her own referral. Even if a group sets up its own laboratory to do the TC, it should not be able to simply contract with a pathologist who performs the PC. In that case, there is no compelling or legitimate reason for the Medicare Program to change its usual practice and pay someone other than the physician who actually performed the test. Finally, the requirements of the Claims Processing Manual should be easy to enforce, as they are requirements that are already in place. It should be simple to ensure that the UPIN of the referring physician is: (1) not the same as the entity that is billing for the PC, or (2) not part of the group practice that is billing for it.

Should other services be included? ACLA has no position on whether these sorts of restrictions should apply to other physicians and specialties. We are primarily familiar with the abuses that have occurred in connection with pathology.

Limitation to specific premises. CMS also requests comments on whether these limitations should be applied to services performed on the premises of the billing entity. ACLA sees no reason to restrict the applicability of these provisions based on where they occur. Previously, prior to the implementation of the contractual arrangement provision, there were restrictions that limited when a service could be purchased based on what premises they were performed on. However, those restrictions were eliminated by the contractual arrangement provisions.

ACLA sees no reason to go back and reinsert those limitations under the contractual arrangement provision. Indeed, Congress specifically wished to eliminate those restrictions when it implemented the new contractual arrangement provision. We are concerned that if a limitation on the premises of the billing entity is used, it will simply cause many of these relationships to restructure so that an independent contractor physician continues to perform the services simply on the site of the group, or that the group will instead open a small satellite office at the site of the pod laboratory just to take advantage of this provision. As a result, ACLA does not support a limitation on the particular premises where the services are being performed.

Stark Self Referral Provisions

As CMS recognizes, in order to limit these types of practices in all areas, it is also necessary to further clarify certain specific provisions or exceptions in the Stark self-referral law. ACLA agrees that this is imperative. We are especially concerned that in response to changes in the reassignment rules, discussed above, many pod arrangements will simply restructure and hire pathologists as part-time employees, which could circumvent the purpose of many of these changes. ACLA believes that the Stark law may provide the most direct way of curbing these new abuses. Therefore, before discussing the other changes proposed by CMS to the Stark provisions, we wish to make one additional proposal designed to limit part-time pathologists.

Part-Time Employment of Pathologists

ACLA is concerned that in response to the provisions in the Proposed Rule, existing and new arrangements may be restructured so that pathologists will be retained as part-time employees rather than independent contractors. For example, a pathologist could become a part-time employee of several different groups under arrangements that potentially satisfy both the reassignment rules and the physician service or in-office ancillary services exceptions to the Stark self-referral provisions. From the standpoint of the group practice and the retained pathologist, the arrangement need not differ significantly from an independent contractor relationship. Thus, ACLA considers it to be essential that CMS address both structures in its rulemaking.

ACLA recognizes that some groups may decide to hire their own pathologist, but they should be required to make the same investment in salaries and capital that any other business would have to make in that endeavor and undertake the same type of business risk. They should not be able to avoid that requirement by re-characterizing an "independent contractor" pathologist as a "part-time employee" pathologist, without incurring the additional costs and risk attendant to hiring that person. Without some limitation on this practice, groups will simply restructure without any risk and continue to profit from their own referrals. ACLA believes that the part-time employee concern could be addressed through modifications in the "group practice" requirements under the Stark self-referral rules or, potentially, through changes in the employee reassignment provision.

Attached as Exhibit II are two alternative regulatory proposals that would address this issue through the "substantially all" requirements for group practices under Stark. In essence, they require that, in addition to the group practice as a whole having to perform at least 75% of its patient care services through the group, each individual member would need to perform at least one-half of its patient care services through the group. Such a provision could be limited to pathology services. Alternatively, CMS could, in the same provision of Stark establish a maximum number of group practices to which any one pathologist could belong. ACLA would strongly support this approach. Both options are presented in this Exhibit.

CMS has proposed a version of this in its amendments to the centralized building requirements, which specifically limits the number of group practices that could share the same physician in the group. ACLA believes this would be included as an independent requirement, which would apply to all group practices with regard to their arrangements with pathologists.

For example, in Alternative 2 of our proposal, in no instance could a pathologist be shared by more than two practices. If a pathologist arrangement did not meet this requirement, then the group practice would not be able to bill for pathology services that it refers to the pathologist. We believe that such a provision would limit restructuring that might be anticipated in response to the proposed changes in the contractor reassignment rules.

Other Changes to Stark

We turn now to the other changes that CMS has proposed in the Stark law. As part of its actions, CMS proposes to implement the following new restrictions with regard to the self-referral law:

- Redefine "centralized building" to include a minimum square footage requirement of 350 square feet where certain other conditions also apply.
- Require that substantially all of the equipment be located in the centralized building space.
- Require that a non-physician employee or independent contractor perform services exclusively for the group at least 35 hours per week.
- Limit the centralized building to states in which the group has an office or require that it be within a certain number of miles from the office of the group.

ACLA responds to each of these areas below.

Centralized building square footage and equipment requirements. ACLA is supportive of efforts to ensure that the "centralized building" constitutes a true entity that serves a bona fide laboratory rather than simply a cubicle through which pathologists pass while performing services. ACLA fears that limiting the square footage to 350 square feet is unlikely to have much impact on pods, which are inherently self-profitable entities that can easily afford to rent more than the necessary number of feet. Moreover, the additional limitation that CMS is proposing – that the minimum square footage requirement would not apply to space owned or rented in a building in which three or fewer practices lease space or where three or fewer group practices share the same physician in the group – would permit several groups to share two physicians and still qualify for protection, regardless of the amount of square footage. Thus, while ACLA is supportive of limitations on the centralized building, this provision seems unlikely to have a significant impact on stemming the proliferation of pod laboratories.

In addition, ACLA generally agrees that all of the equipment should be in place in the centralized building space. Thus, ACLA agrees that in most situations, groups should not be able to move equipment from one space to another or from one cubicle to another. However, in the case of most pathology laboratories, this provision is unlikely to be a significant deterrent because there is simply not that much equipment that is required nor is the equipment that is required very expensive.

Requiring a full-time employee on-site. It would be advantageous to require that the group have a full-time employee or independent contractor, such as a non-physician, who is on-

site some minimum amount of time per week in order for that site to qualify as a centralized building. This criterion will increase the likelihood that the laboratory will be a bona fide entity rather than one that is simply used intermittently for servicing an individual group's patients. Therefore, ACLA supports the proposal that: (1) a group be required to have a non-physician employee or independent contractor on-site in a "centralized facility," and (2) that that person be required to perform services exclusively for the group at least 35 hours per week.

Mileage requirements. ACLA does not support limitations on the state in which the centralized building is located, nor the requirements that the group or laboratory be a certain distance from where the group practices. Such limitations can easily be circumvented and it is impossible to come up with a distance that embraces only bona fide arrangements and excludes those that are inappropriate.

Application to the physician services exception. Whatever limitations are placed on the "centralized building" requirements, they should apply both to groups taking advantage of the "in-office ancillary services" exception, as well as to those using the "physician services" exception. CMS notes in the Preamble that it expects to apply limitations to both types of entities. ACLA supports this view, but it is not clear how CMS intends to implement that limitation. The "centralized building" requirement appears only in the "in-office ancillary services" exception, and thus, there is no current requirement that physicians operating under the "physician services" exception meet those requirements. It appears, and ACLA supports this view, that CMS intends that a "physician in the group" must also be operating in a centralized building, if he or she is not practicing in the space where the group provides other services to patients. This is inherent in the current requirements, which state that a "physician in the group" includes an independent contractor physician who is providing services to the group's patients "*in the group's facilities*." CMS appears to be proposing, although it is not spelled out, that where a "physician in the group" is providing services at a location where the group does not otherwise supply patient care services, then that facility must meet the centralized building requirements. ACLA would support this application of the centralized building requirements.

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 technical component ("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 Modernization Act ("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.

The Proposed Rule misstates the intention of the proposal to discontinue the grandfather provision, where it states "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital

...dd a new § 414.408 to indicate when cross walking or gap
...ross walking would be used if a new test is determined
...ing test codes, or a portion of an existing test
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urge CMS to correct this language in the Final Rule.

In addition, the Proposed Rule CMS states, "We continue to believ
hospital prospective payment amounts already compensate hospitals for the
pathology tests and that additional payment under the PFS is inappropriate."
CMS is proposing to amend § 415.130 to provide that, for services furnished after
2006, an independent laboratory may not bill the carrier for physician patho
furnished to a hospital inpatient or outpatient.

ACLA strongly disagrees with CMS' assertion that hospital prospectiv
amounts already compensate hospitals for the TC of these tests. We are not aw
documentation available to the public to support this assertion. Therefore, we do not s
implementation of these changes, which would prohibit independent laboratories from l
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Moreover, ACLA is very concerned about the impact of the expiration of the grar
because it will require a significant change in the way that hospitals and clinical labor
have historically done business. Hospitals will have to establish new contractual relatio
with clinical laboratories to provide these services to hospital inpatients and outpatients, v
may lead to a disruption in patient care. Furthermore, it is our experience that many hosp
still are not aware of this impending change and therefore are not taking any steps to ado
these new requirements. Given this major change to these historical billing rules, we stron
urge CMS to help hospitals understand their new obligations and move forward to address th
to ensure that Medicare beneficiaries have full access to necessary clinical laboratory testi
services.

CLINICAL DIAGNOSTIC LAB TESTS

Public Consultation for Payment for a New Clinical Diagnostic Laboratory Tests

In the Proposed Rule, CMS is taking steps to implement § 942(b) of the MMA, which
required that CMS develop specified regulatory procedures for consulting with the public on
how to establish payment for new lab tests. 71 Fed. Reg. at 49063. ACLA supports these new
procedures for consulting with stakeholders to develop appropriate payment amounts for new
tests. We believe that the public must be provided (1) sufficient information on new
payment levels that are being proposed by CMS, (2) an adequate opportunity
feedback on such proposals, and (3) a full explanation of the ultimate
CMS. Thus, we support the new procedures being proposed
as required by the MMA.

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CMS will also need to address existing regulatory restrictions on the release of laboratory results (*e.g., see* 42 C.F.R. § 493.1291(f)).

Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens

In the Proposed Rule, CMS proposes to add a new regulatory section, § 414.410, to address concerns that have been raised regarding the date of service ("DOS") for some clinical diagnostic laboratory tests. *Id.* at 49065. We have reviewed the CMS proposal carefully and believe that it should be modified slightly to be effective. ACLA is pleased that CMS is addressing this issue and appreciates the time and effort that CMS has put into helping to resolve it.

Background on the 30-Day Rule

In order to understand the issues created, ACLA believes it is helpful to trace the history of this particular issue. As part of the November 23, 2001 Final Rule on Coverage and Administrative Policies for Diagnostic Lab Services, CMS established for the first time a DOS for clinical diagnostic laboratory services. CMS determined that the DOS for a clinical laboratory service would be the date the specimen was collected. 66 Fed. Reg. 58792 (Nov. 23, 2001). At the same time, CMS acknowledged that there was nothing particularly significant about the date of collection and that there were several different dates that could be utilized as the DOS. CMS recognized that it could use as the DOS: (1) the date that the specimen was received by a laboratory; (2) the date the test was actually performed; or (3) the date of collection. CMS stated it chose the date of collection so it could eventually link the claim for the testing back to the date of the physician's visit from which the test order originally arose. According to CMS, the agency decided to establish the date of collection as the DOS over other possible options because that date "most closely relates to the date the test was ordered and ... the use of only one date of service is consistent with the goal of promoting program integrity and national uniformity." 66 Fed. Reg. at 59791.

At the same time, CMS recognized there would need to be certain exceptions to this requirement. If the laboratory test required a specimen from stored collections, for example, the DOS would be defined as the date the specimen was removed from archives, rather than the date of collection. Initially, CMS left it to carriers to determine how long the specimen had to be stored before it could be considered "archived." However, in February 2005, CMS issued a Notice that refined this requirement and stated that to be considered archived, the specimen had to be stored for more than 30 calendar days. If the specimen were stored for more than 30 days, then the DOS would be the date the specimen was removed from storage; otherwise, the DOS would be the date of collection. 70 Fed. Reg. 9355, 9357 (Feb. 25, 2005). (Prior to this change, however, few, if any carriers, had required that the specimens be stored as long as 30 days in order to be considered "archived.") At the same time, CMS established other exceptions including those that would apply when the testing took place over more than a single day. Subsequently, CMS issued a Program Memorandum that implemented these DOS requirements. Transmittal 800, Change Request 4156 (Dec. 30, 2005).

not even know the oncologist who has ordered the test; and may be unaware of the medical necessity of the testing. Further, because the test results do not relate directly to the hospital stay, the hospital may be unwilling to be financially responsible for billing and collection. Finally, the bundling requirement will mean that labs must have a contract with all hospitals that could potentially send specimens – a tremendous and expensive burden.

CMS Proposal

As noted, to alleviate these issues, CMS has proposed a special exception to the DOS rule. CMS has proposed that the testing would not be subject to the bundling requirements if the following criteria were met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital.
- The test could not reasonably have been ordered while the patient was hospitalized.
- The procedure performed while the beneficiary is a patient of the hospital is for purposes other than collection of the specimen needed for the test.
- The test is reasonable and medically necessary.

ACLA has two concerns about this proposal. First, if the proposed regulation is meant to govern live tissue, which is not technically "stored," but maintained for possible future testing, the proposed regulation does not account for unique circumstances that arise in the preservation of fresh versus fixed tissue. Second, the 14-day requirement will not alleviate the concerns raised above. We discuss each of these concerns separately below.

The requirement that the test could not reasonably have been ordered while the patient was hospitalized will not fully address the concerns where live tissue must be used. In these situations, where live tissue is needed for the testing, the physician doing the surgery may elect to send certain specimens to an outside laboratory for certain cases. The specimen may be accompanied by a "provisional" or "conditional" order, which requires the lab to hold or culture the tissue while additional routine testing is completed at the hospital. When this routine testing is completed, and the results known, the physician can determine whether the additional testing is necessary. This process is necessary because live tissue cannot be stored in the same way that paraffin-embedded specimens can be stored. This type of testing has been done for some time, and CMS has always paid for it separately. To our knowledge, CMS has never required that the testing be bundled.[3]

Second, the 14-day requirement is also not fully workable. As noted for live tissue, the test is sent to an outside laboratory while the patient is still in the hospital. Even where stored tissue is used, the 14-day standard is not helpful. While most testing is ordered 14 days after the patient's discharge, some small percentage of testing will still be ordered within the 14-day window. As a result, laboratories will still be required to enter into contracts with hospitals to cover those periods.

[3] In many instances, the live tissue must be "cultured" or further processed during the initial period. In a sense, this is comparable to the "storage" period envisioned by the 30-day rule. The actual testing does not occur until later in the process.

inpatient or outpatient." *Id.* We believe the intent was to state that "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the technical component of physician pathology services furnished to a hospital inpatient or outpatient." We urge CMS to correct this language in the Final Rule.

In addition, 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.

ACLA 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.

Moreover, ACLA 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.

CLINICAL DIAGNOSTIC LAB TESTS

Public Consultation for Payment for a New Clinical Diagnostic Laboratory Tests

In the Proposed Rule, CMS is taking steps to implement § 942(b) of the MMA, which required that CMS develop specified regulatory procedures for consulting with the public on how to establish payment for new lab tests. 71 Fed. Reg. at 49063. ACLA supports these new procedures for consulting with stakeholders to develop appropriate payment amounts for new lab tests. We believe that the public must be provided (1) sufficient information on new test payment levels that are being proposed by CMS, (2) an adequate opportunity to provide feedback on such proposals, and (3) a full explanation of the ultimate determinations made by CMS. Thus, we support the new procedures being proposed by CMS to accomplish these goals, as required by the MMA.

Payment for a New Clinical Diagnostic Laboratory Test – Crosswalking and Gapfilling

In addition, CMS is proposing new requirements for determining payment amounts for clinical laboratory tests assigned a new or substantially revised code on or after January 1, 2005.

Id. Specifically, CMS intends to add a new § 414.408 to indicate when cross walking or gap filling may be used. Under the proposal, cross walking would be used if a new test is determined to be comparable to an existing test, multiple existing test codes, or a portion of an existing test code. In such situations, a new test code would be assigned the related existing local fee schedule amounts and national limitation amount, and payment for the new test code would be made at the lesser of the two amounts. Gap filling would be used when no comparable, existing test is available. Each Medicare carrier will determine a payment amount for its geographic area(s) for use in the first year, and the carrier-specific amounts will be used to establish a national limitation amount for following years. Carriers may rely on these sources of information to determine gap fill amounts, if available: charges for the test and routine discounts; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other comparable or relevant tests.

ACLA supports CMS' desire to more clearly define when each methodology should be used to determine payment amounts for new tests. In addition, we support the proposal to use the national limitation amount in the second and subsequent years because, as CMS recognizes, this will result in more consistent payment across all areas. Finally, we look forward to continuing to work with CMS to ensure that new and innovative approaches to testing, which are not reflected on the current fee schedule, are reimbursed fairly and appropriately.

Quality

In the Proposed Rule, CMS highlights the role of lab results in physician decisions about patient care, and expresses its commitment to working with the lab community (and others) to promote quality care while avoiding unnecessary costs. 71 Fed. Reg. at 49064. CMS states that it "could require those who perform laboratory tests to submit laboratory values using common vocabulary standards," such as LOINC. CMS also discusses the proposed rule on HIPAA claims attachments, which identified LOINC as the appropriate standard for reporting lab results. However, CMS notes that there are significant challenges that must be addressed before Medicare could collect lab values appropriately.

ACLA welcomes CMS' commitment to work collaboratively with the clinical lab community on these efforts. ACLA members share CMS' vision to improve access and quality of care for Medicare beneficiaries by initiating value-based purchasing. Diagnostic tests comprise only five percent of total hospital costs and only 1.6 percent of Medicare costs, but they influence a much larger portion (over 70 percent) of clinical decision-making that improves care and decreases cost. Today's laboratory tests inform treatment decisions, allow physicians to prescribe targeted therapies, and monitor disease progression – all significant value added services, and independent labs have been in the business of providing these for many years.

Clinical laboratory tests are critical to measuring performance in quality programs. ACLA looks forward to collaborating with CMS in designing such a program; however, it is paramount that CMS recognize that the clinical laboratory fee schedule has not been fully updated for inflation in 13 of the past 15 years and is frozen until 2009. As CMS moves toward a pay for performance approach, the additional administrative cost to collect, submit and analyze performance and access measure data needs to be accounted for in the reimbursement schedule.

not even know the oncologist who has ordered the test; and may be unaware of the medical necessity of the testing. Further, because the test results do not relate directly to the hospital stay, the hospital may be unwilling to be financially responsible for billing and collection. Finally, the bundling requirement will mean that labs must have a contract with all hospitals that could potentially send specimens – a tremendous and expensive burden.

CMS Proposal

As noted, to alleviate these issues, CMS has proposed a special exception to the DOS rule. CMS has proposed that the testing would not be subject to the bundling requirements if the following criteria were met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital.
- The test could not reasonably have been ordered while the patient was hospitalized.
- The procedure performed while the beneficiary is a patient of the hospital is for purposes other than collection of the specimen needed for the test.
- The test is reasonable and medically necessary.

ACLA has two concerns about this proposal. First, if the proposed regulation is meant to govern live tissue, which is not technically "stored," but maintained for possible future testing, the proposed regulation does not account for unique circumstances that arise in the preservation of fresh versus fixed tissue. Second, the 14-day requirement will not alleviate the concerns raised above. We discuss each of these concerns separately below.

The requirement that the test could not reasonably have been ordered while the patient was hospitalized will not fully address the concerns where live tissue must be used. In these situations, where live tissue is needed for the testing, the physician doing the surgery may elect to send certain specimens to an outside laboratory for certain cases. The specimen may be accompanied by a "provisional" or "conditional" order, which requires the lab to hold or culture the tissue while additional routine testing is completed at the hospital. When this routine testing is completed, and the results known, the physician can determine whether the additional testing is necessary. This process is necessary because live tissue cannot be stored in the same way that paraffin-embedded specimens can be stored. This type of testing has been done for some time, and CMS has always paid for it separately. To our knowledge, CMS has never required that the testing be bundled.[3]

Second, the 14-day requirement is also not fully workable. As noted for live tissue, the test is sent to an outside laboratory while the patient is still in the hospital. Even where stored tissue is used, the 14-day standard is not helpful. While most testing is ordered 14 days after the patient's discharge, some small percentage of testing will still be ordered within the 14-day window. As a result, laboratories will still be required to enter into contracts with hospitals to cover those periods.

[3] In many instances, the live tissue must be "cultured" or further processed during the initial period. In a sense, this is comparable to the "storage" period envisioned by the 30-day rule. The actual testing does not occur until later in the process.

A Proposed Solution

ACLA has discussed this issue with the affected laboratories. We recognize the need for CMS to impose some program integrity limits so that the Medicare Trust Fund is protected and testing is not "unbundled" inappropriately. However, there are good reasons for establishing an exception to the bundling requirement in this case. First, as noted, it is a very narrow type of testing that is at issue here. It is almost always cancer tissue that is being used for the specimens. Where blood or other specimen types are used, they can almost always be drawn in the physician's office later in the process. Second, this type of testing is unrelated to the reason for which the patient was admitted to the hospital. Third, this is not the type of testing that is routinely done in hospitals, or which would usually have been part of the DRG or PPS payment.

Finally, and perhaps most importantly, there is no policy reason for the testing to be bundled with the hospital stay. The testing performed is unrelated to the underlying hospital visit. The only reason that the bundling issue arises is because CMS chose to make the date of collection the DOS for a lab service. That decision was wholly unrelated to the issue here, and CMS acknowledged that there were other possible choices for the DOS, none of which would have created the same bundling questions. Thus, the bundling issue comes up, not because of underlying policy rationale, but simply because CMS made a wholly unrelated and separate decision that the date of collection would be the DOS. And, as discussed, CMS has already revised its DOS criteria in other situations.

As a result, we believe a unique exception to the DOS criteria should be added and the following requirements should be considered. Laboratory testing would not be "bundled" into the hospital stay in the following circumstances:

- The testing is performed on either fixed or live tissue taken during a hospital stay;
- The testing performed is related to the future course of care and treatment (*i.e.*, the likely progress of the condition, or what types of therapies, such as chemotherapy, may or may not be effective);
- The testing performed is not the type commonly or routinely performed in hospital laboratories.

The third and fourth bullets already proposed by CMS would continue – *i.e.*, the testing could not be the original purpose for the hospital stay and the testing itself must be reasonable and necessary.

We believe this exception, which is narrowly crafted to these specific situations, should alleviate the issue. In these situations, we would propose to use either the date the specimen came from archives or the date the testing was actually performed, without regard to the date of collection. In those instances, the bundling requirements would not occur.

CONCLUSION

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed changes to the physician fee schedule. Please

do not hesitate to contact us should you have any questions about this information or need any further information.

PROPOSED NEW REGULATORY LANGUAGE
EXHIBIT I
PROPOSED REGULATORY TEST TO IMPLEMENT
LIMITATION ON PURCHASED INTERPRETATIONS

Sec. 424.80 Prohibition of reassignment of claims by suppliers.

* * *

(d) *Reassignment to an entity under an employer-employee relationship or under a contractual arrangement:* ***[after new section (3) proposed by the rule, insert the following]***

(4) *Contractual arrangements for the provision of the interpretation or professional component of diagnostic test services.* If a physician or medical group bills for the professional interpretation of a diagnostic test paid for under Part B (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special rules set out in section 1833(h)(5)(A) of the Act), following a reassignment involving a contractual arrangement with the physician or other supplier who performed the professional component, each of the following conditions must be met:

(i) the professional component must have been ordered by a physician who is financially independent of the person or entity billing for the test and also of the physician or medical group billing for the interpretation;

(ii) the physician or medical group billing for the interpretation may not see the patient;

(iii) the physician or medical group billing for the interpretation must have performed the TC of the test; and

(iv) the physician or medical group billing for the interpretation must keep on file the name, provider identification number, and address of the interpreting physician.

PROPOSED NEW REGULATORY LANGUAGE
EXHIBIT II
PROPOSED REGULATORY TEST TO IMPLEMENT
LIMITATION ON "PART TIME EMPLOYED" PATHOLOGISTS

Sec. 424.80 Prohibition of reassignment of claims by suppliers.

* * *

(b) Exceptions to the basic rule. * * *

(1) Payment to employer. Medicare may pay the supplier's employer if the supplier is required, as a condition of employment, to turn over to the employer the fees for his or her services; provided, however, that if the supplier is a member of a group practice as defined in 42 CFR § 411.352, Medicare may only pay the supplier's employer if it qualifies as a group practice under 42 CFR § 411.352.

Sec. 411.352 Group Practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

* * * * * * * * * *

ALTERNATIVE 1

(d) *Services furnished by group practice members.* (1) Except as otherwise provided in paragraphs (d)(3), (d)(4), (d)(5), and (d)(6) of this section, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75% of the total patient care services of the all group practice members and at least 50% of the total patient care services of each group practice member)* must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group.

ALTERNATIVE 2

(b) *Physicians.*[Add, at the end of the current regulatory text, the following:]

The group practice cannot employ any pathologist who is a member of more than two group practices.

* This could also be limited just to pathologists, if preferable.

LEGAL02/30100727v1

RPA
Renal Physicians Association

October 6, 2006

Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Dr. McClellan:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease. We are writing to provide comments on selected portions of the 2007 Medicare Fee Schedule Proposed Rule.

RPA's comments will focus on the following issues:

- **Work Relative Value Units (WRVUs) for Inpatient Dialysis Services**
- **Payment changes for multiple imaging services affecting vascular access care commonly provided to kidney patients;**
- **The composite rate payment formula for dialysis facilities; and**
- **Continued use of the Sustainable Growth Rate (SGR) formula in the physician fee schedule.**

BACKGROUND

Work RVUs/Most Recent Changes to the Fee Schedule

In the Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology, CMS' promulgated its decision to adopt the recommendations from the American Medical Association's Relative Value Update Committee (RUC) regarding the work RVUs for E&M services. In our comments on this

regulation, we concurred with the RUC that there was compelling evidence to review the E&M services due to the use of incorrect assumptions in the previous valuation of these services, and noted that RPA believes that values proposed in the Five-Year Review notice will more closely reflect the physician work involved in providing these services. RPA's comments on that regulation addressed the applicability of the E&M work RVU increases to outpatient and inpatient dialysis services. This comment is intended to provide greater specificity regarding the inpatient dialysis services.

In our comments on the previous rule, we noted that CMS indicates in the notice that the agency agreed with the RUC's recommendation to incorporate the full increase for the E&M codes into the surgical global periods for each CPT code with a global period of 010 and 090. RPA proceeded to state our belief that the outpatient and inpatient dialysis services that use E&M codes as "building blocks" or components of their valuation should have the full increases for the E&M codes incorporated into their values as well. This passage of the comment concluded by noting that the inpatient service codes (CPT Codes 90935-90947) are reported to describe both hemodialysis and dialysis procedures other than hemodialysis with the common daily E&M services related to the patient's renal disease on the day of the procedure.

In the Medicare Physician Fee Schedule Proposed Rule for CY 1995 published on December 8, 1994, and Transmittal 1776, Change Request 2321 of the Medicare Claims Manual, HCFA/CMS states in both documents that "we will bundle payment for subsequent hospital visits (CPT code 99231 through 99233) and follow-up inpatient consultations (CPT codes 99261 through 99263) into the fee schedule amounts for inpatient dialysis (CPT codes 90935 through 90457)." While follow-up inpatient consultations (CPT codes 99261 through 99263) have been deleted from the fee schedule for payment purposes, the subsequent hospital visit codes are of course still part of the fee schedule, and RPA urges CMS to add the increase for the mid-level subsequent hospital visit, CPT code 99232, to the work RVUs for the four inpatient dialysis codes. The increase in work RVUs for CPT code 99232 was 0.33 RVUs. Following is a chart providing the impact of the increases on the inpatient dialysis codes, and the impact of the increase on CPT code 99232, in order to allow for comparison on a relativity basis:

CPT Code	2005 Work RVU	Our Proposed 2006 Work RVU	% Increase
99232	1.06	1.39	31%
90935	1.22	1.55	27%
90937	2.11	2.44	15%
90945	1.28	1.61	25%
90947	2.16	2.49	15%

As the chart indicates, all of the increases for the inpatient dialysis codes would be proportionately less than the increase for the mid-level subsequent hospital visit code. Further, these changes would help maintain relativity between the subsequent hospital visit code family and the inpatient dialysis code family (although it would not maintain this relativity at current levels). As RPA noted in its comments on the Five-Year Review pertaining to relativity, "as an example it is illustrative that in 2004 the reimbursement for CPT code 90935 was roughly equivalent to a level three subsequent hospital visit (CPT code 99233), and if left unchanged the proposed 2007 values will result in a reimbursement level that would be roughly equivalent to a

level two subsequent hospital visit (CPT code 99232). Such a change in relativity does not have face-value validity."

For these reasons, RPA strongly urges CMS to upwardly adjust the work RVUs for each inpatient dialysis code by 0.33 to maintain both equity and relativity with the E&M code family as noted above. These recommended changes are separate from, and intended to complement, similar recommendations for change affecting outpatient dialysis services that were addressed in our comments on the Five-Year Review.

DRA PROPOSALS

As noted in RPA's comments to the Agency on the Five-Year Review and the Revised Practice Expense Methodology, we recognize the policymaking constraints placed upon CMS by legislative mandates such as the Deficit Reduction Act (DRA), and we support efforts to exercise more comprehensive oversight of the provision of imaging services due to the tremendous growth in utilization of those services. However, RPA continues to feel obligated to point out the disconnect between implementation of changes for multiple imaging services affecting vascular access care and broader policy goals in this area.

It is our understanding that the reduced technical component payment for multiple imaging procedures, when combined with other planned fee schedule reductions, will have the immediate effect of reducing payments for outpatient office-based (i.e. "access center") vascular access services by approximately 6-7% starting in January, 2007. These reductions run counter to several salient points regarding vascular access services, including:

(1) The existence of CMS' own Fistula First program, which is intended to "ensure that kidney patients receive the most optimal form of vascular access and to seek to avoid vascular access complications through appropriate monitoring and intervention" as noted on the Fistula First website;

(2) The increased expense to the Medicare program of providing these services associated with the likely shift back to the hospital-based setting for this care in some areas; and

(3) The fact that Medicare beneficiary satisfaction and convenience is optimized when vascular access services of this nature are provided in the outpatient setting.

For these reasons, we continue to urge the Agency to develop a more nuanced methodology of implementing the DRA changes that does target the areas of inappropriate growth in utilization of imaging services, but does not have the unintended consequence of negatively impacting the appropriate provision of vascular access services to kidney patients.

ESRD PROVISIONS

In general, RPA supports CMS' proposals with regard to the composite rate payment methodology for dialysis facilities. While RPA concurs with the Agency's proposals in the areas of the drug add-on adjustment and the reimbursement for separately billable drugs, we would urge CMS provide greater clarity in both areas.

Regarding the drug add-on adjustment, RPA recommends that CMS, rather than use the producer price index (PPI) and develop a utilization estimate of its own as described in the proposed rule,

should instead use a more established and comprehensive index like the National Health Expenditure to determine the drug add-on adjustment. Such a change will promote consistency and predictability for this component of the composite rate payment. For separately billable drugs, we urge the Agency to specifically state that the rate will be the average sales price (ASP) +6 percent, and that this rate will be locked in for at least calendar year 2007. It is our opinion that making both of these changes will provide greater stability in reimbursement for 2007 and provide CMS with the opportunity over the next year to make any necessary changes.

OTHER ISSUES

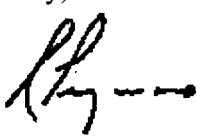
Use of the SGR Formula in the Medicare Physician Fee Schedule

RPA recognizes that similar to other issues affecting Medicare physician payment, the use of the Sustainable Growth Rate (SGR) formula has its basis in authorizing legislation, and thus addressing potential changes outside of Congressional action is complex. Nonetheless, it is the opinion of the RPA and the balance of organized medicine that there are administrative steps that the Agency could take to correct the flaws in the SGR. Further, we strongly believe that Congress would welcome such an effort. RPA therefore calls on CMS to openly and creatively seek revisions to the existing SGR formula.

As noted in RPA's comments in previous years, the structural flaws in the SGR formula are well documented. These shortcomings include: (1) the inappropriate link between the performance of the overall economy and the actual cost of providing physician services; (2) the continued inclusion of the cost of physician-administered drugs in its formula calculation (despite the fact that physicians have no control over the price of drugs); and (3) the fact that the full cost of new Medicare benefits and coverage decisions are not accounted for in the SGR target. In the NPRM CMS includes a section entitled *Promoting Effective Use of Health Information Technology (HIT)* that discusses the Administration's recognition of the potential of HIT to facilitate improvements in the quality and efficiency of health care services. Accordingly, many physician practices are evaluating investment in the HIT necessary to achieve these improvements. However, the continued use of an outmoded reimbursement methodology that results in projected negative updates in the Medicare physician fee schedule for the next five years or more will limit such improvements, and is simply unacceptable. RPA believes that the SGR must be replaced with a reimbursement mechanism linked to increases in the actual costs of medical practice to not only facilitate investment in HIT and other improvements, but also to allow the practice of medicine to remain viable.

As always, we welcome the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's ESRD patients, and we stand ready as a resource to CMS in its future endeavors. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,



Robert Provenzano, M.D.
President