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September 27, 2006

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

SEP 28 2006

ATTN: FILE CODE CMS-1321-P

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; ASP Issues

Dear Administrator McClellan:

Thank you for this opportunity to comment on the proposed revisions to the physician fee schedule for calendar year (CY) 2007. This comment addresses manufacturers' reporting requirements under the average sales price (ASP) system. Since finalizing the ASP rule, CMS has provided guidance on its website in the form of "Questions and Answers." This letter requests that CMS clarify in the final rule that drug manufacturers are required to report ASP data for *all* sales of a given Part B drug. Such a clarification is consistent with the Medicare statute and regulations, and would help to ensure that ASP accurately reflects the market prices of Part B drugs.

Summary

There has been some confusion among manufacturers regarding whether sales of Part B drugs for non-Medicare-covered uses must be reported for purposes of calculating ASP. In creating the ASP system, Congress intended to enable CMS to capture more accurately the market prices of drug products. Pursuant to the Section 1847A of the Social Security Act (SSA), if a drug is covered under Part B, manufacturers are required to report sales data for all of their sales of that drug. CMS should clarify in the final rule that drug manufacturers are required to report ASP data for *all* of the NDCs assigned to a given Part B drug, and that they are prohibited from selectively omitting sales data for certain non-covered uses of the product.

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I. The ASP Reporting System was Designed to Capture the Market Price of Drug Products

When Congress created the ASP system through the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), its basic goal was to better align Medicare payment rates for Part B drugs with their actual price in the marketplace. The purpose of the ASP system is thus to ensure that Medicare payment rates are consistent with the widely available market price (WAMP) of Part B drugs. Congress defines WAMP as "the price that a prudent physician or supplier would pay for the drug or biological," net discounts and rebates.[1]

To this end, Congress created a statutory mechanism under which WAMP acts as an explicit check on manufacturer-reported ASP. Specifically, the MMA requires the DHHS Office of Inspector General (OIG) to compare ASP data for sales of Part B drugs with both WAMP and average manufacturer's price (AMP).[2] The fact that the MMA authorizes the DHHS Secretary to *substitute* WAMP for the manufacturer-reported ASP indicates that Congress considers WAMP the best measure of what Medicare *should* be paying for a drug. That is, Congress views the statutory ASP methodology as a proxy for the actual price that prudent physicians and suppliers would pay for Part B drugs in the marketplace. As the proposed rule itself states in a related context, CMS's goal in administering the ASP system "is to ensure that ASP is an accurate reflection of market prices for Part B drugs."[3]

II. The MMA Requires Manufacturers to Report Sales Data for All Sales of a Part B Drug

The MMA and CMS regulations require manufacturers to report *all* sales of a given Part B drug. Some Part B drugs are sold for both covered and non-covered uses. When Congress established the ASP reporting requirements, it did not distinguish between covered and non-covered sales of a Part B drug. The statute states that ASP is based on "*the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological . . . .*" The only sales exempted from the ASP calculation are sales calculated for "best price" under section 1927(c)(1)(C)(i), and sales at a nominal charge.

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[1] SSA § 1847A(d)(5)(A).

[2] SSA § 1847A(d)(2). AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." SSA § 1927(k)(1).

[3] 71 Fed. Reg. at 49004.

Omitting sales data for indications not covered by Medicare would distort the market price. In some cases, a vast majority of the sales of a Part B drug may be for non-covered indications. In cases where a drug product is priced lower for non-covered sales than for covered sales, the exclusion of the former has the potential to understate the true market price, thus artificially inflating the drug's ASP and, with it, the Medicare payment rate. CMS should therefore make explicit that Section 1847A of the SSA and its implementing regulations prohibit manufacturers from insulating a significant portion of a Part B drug's sales from the ASP reporting requirement.

III. Non-Covered NDCs are not Exempt from ASP Reporting Requirements

There is no exemption from ASP reporting requirements of sales data for non-covered NDCs.[4] To the contrary, the statutory language itself requires manufacturers to report sales data for ***all*** of the NDCs assigned to a Part B drug product. The provision setting forth manufacturers' reporting requirements for single source drugs is illustrative, specifying that ASP is to be calculated for "***all National Drug Codes assigned to such drug or biological product.***"[5]

Although the statute and regulations setting forth the ASP framework require drug manufacturers to report ASP data for each drug product by its NDC(s), this legal framework does not exempt manufacturers' sales of non-covered NDCs from ASP reporting requirements. The SSA provides that "the manufacturer's 'average sales price' means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—(A) the manufacturer's sales to all purchasers . . . in the United States for such drug or biological . . . ."[6] The regulation implementing the ASP system similarly states that "[t]he manufacturer's average sales price for a quarter for a drug or biological represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code."[7]

The fact that drug manufacturers report ASP data for each drug product by its NDC(s), however, does not alter that drug products, and not NDCs, are the subjects of the ASP system. Section 1847A(b)(2)(B) defines the basic ASP unit as the lowest

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[4] *See* FDA, National Drug Code Directory (available at http://www.fda.gov/cder/ndc/). National Drug Codes, which are administered by the U.S. Food and Drug Administration (FDA), are unique ten-digit, three-segment numbers that identify the labeler, product, and trade package size of drug products that are manufactured, prepared, propagated, compounded, or processed by registered establishments for commercial distribution in the United States.

[5] SSA § 1847A(b)(4)(A).

[6] SSA § 1847A(c)(1)(A).

[7] 42 C.F.R. § 414.804.

identifiable quantity of the drug—such as a single tablet, or a milligram of molecules.[8] Further, CMS classifies drugs for reimbursement purposes according to standardized procedural codes, called Healthcare Common Procedure Coding System (HCPCS) codes. HCPCS codes identify the drug and dosage, but do not identify the manufacturer(s) or packaging size(s). Multiple brand name products and NDCs are often included within a single HCPCS code.[9] The quantity of a given drug described in an NDC frequently differs both from the quantity of the same drug described in another NDC, and from the corresponding HCPCS code.

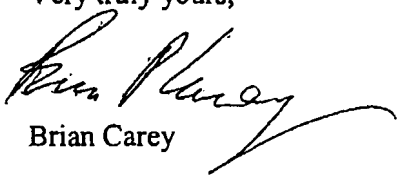
Request for Clarification

We respectfully request that the final rule include the following clarification:

The statutory requirement that manufacturers report ASP data by 11-digit NDCs applies to all sales of a given Part B drug. Manufacturers must submit ASP data for each NDC assigned to a Part B drug, including those NDCs that describe non-covered sales of the that drug. When at least one of the NDCs assigned to a given drug product is eligible for coverage under Part B, the manufacturer of that drug product is required to submit sales data for all of the NDCs assigned to that drug product.

Thank you for your consideration of this issue.

Very truly yours,



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[8] Acting under the DHHS Secretary's statutory discretion to adopt an alternative unit for ASP reporting, CMS directed manufacturers to report drug sales by the quantity of the drug represented by each NDC.

[9] When an HCPCS code is comprised of more than one NDC, the ASP must be volume-weighted to account for the relative volume of each component NDC sold during that quarter.

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September 28, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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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 Under Part B

Dear Dr. McClellan:

On behalf of Ortho Biotech Products, L.P. ("Ortho Biotech"), a Johnson & Johnson company, I am pleased to submit comments on the proposed rule: "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B," published in the *Federal Register* on August 22, 2006 (Volume 71, No. 162, p.48982). Ortho Biotech markets Procrit (epoetin alfa), a manufactured form of a naturally occurring hormone (erythropoietin) that is given by injection to stimulate the bone marrow's production of red blood cells.

In this letter, we respond to the agency's request for comments on the methodology manufacturers should use for apportioning price concessions across Part B drugs sold under bundling arrangements for purposes of calculating average sales price (ASP). At the outset, we wish to express our strong support for the stated CMS goal "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".

We also support the CMS statement that manufacturers of drugs reimbursed by Medicare Part B are expected 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". However, CMS should not rely on the application of these laws to address the issue of drug pricing under the ASP payment

methodology for Part B drugs that was established by the Medicare Modernization Act of 2003 (MMA).

In the sections that follow, we respond to the specific CMS requests for comments on the effect bundling arrangements may have on the ASP calculation, on beneficiary access to high quality, appropriate care (including access to drugs that may not have clinical alternatives), and on costs to the Medicare program and its beneficiaries. In addition, we recommend a specific methodology for apportioning price concessions across Part B drugs sold under bundling arrangements.

Need for Guidance on Apportioning Price Concessions across Part B Drugs Sold under Bundling Arrangements

For the purposes of calculating ASPs, clear guidance for the apportionment of bundled incentives across Part B drugs is essential. The enforcement community has repeatedly made plain its expectation that manufacturers appropriately identify and allocate bundled discounts. In its Final Guidance to the Pharmaceutical Industry, the OIG advised that "any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues.)" 69 Fed. Reg. 23,832 (May 5, 2003). In the next breath, the OIG warned manufacturers to "pay particular attention to ensuring they are calculating [AMP and Best Price] accurately and that they are paying appropriate rebate amounts for their drugs," implying that the fair apportionment is expected in connection with government pricing calculations. Elsewhere, the OIG has explained that they expect bundled drug discounts to be properly and fairly allocated down to the individual line item. See Corporate Integrity Agreement between the HHS OIG and Abbott Laboratories, Page 7, Paragraph (c), dated July 22, 2003.

While perhaps clear in purpose, the agency and OIG guidance has lacked the level of specificity needed to ensure consistent practices among manufacturers. Absent explicit guidelines, pharmaceutical companies are thus at risk that their apportionment methodologies will be construed to contravene CMS's caution that they must comply with relevant laws, legal decisions and regulations, including "the Stark law, other relevant anti-kickback laws, antitrust laws, and laws governing fair trade practices." An explicit uniform methodology, moreover, best serves CMS's stated objective of ensuring ASPs incorporate the incentives derived from full and fair price competition. Explicit guidance is, therefore, essential and should be issued as soon as possible.

Definition of a "Bundle"

CMS has solicited comments concerning the appropriate methodology to apportion incentives among drugs in bundled sales arrangements, including bundles that include drugs that have no clinical alternatives. As CMS recognizes, a threshold question in determining how to allocate bundled incentives is to define what constitutes a "bundled sale". While there are myriad contractual arrangements for the sale of multiple drugs, not all should qualify as "bundled sales" for ASP reimbursement purposes. It is our view that

arrangement for the sale of multiple drugs should be deemed a "bundled sale" if it involves the payment of incentives on (at least) one drug that are expressly contingent or calculated in whole or in part based on the actual purchases of (at least one) other drug.

This definition of a bundle is clear, relatively easy to implement, and captures the bundled incentives that may and should be subject to apportionment to individual drugs. It provides consistency with what qualifies as a bundle under the Medicaid Rebate program, the Anti-Kickback Discount Safe Harbor and arrangements on which the OIG has provided guidance through the Advisory Opinion process.

By adopting this clear and concise definition of a "bundle", CMS need not, and should not, itemize specific business arrangements that are bundles for which the discount must be apportioned. It is not possible to itemize all such arrangements or to foresee all types of bundled arrangements that may exist in the future. A listing of arrangements deemed "bundles" may be construed as an implicit pronouncement that the omitted arrangements are not subject to the apportionment rules.

Bundles Containing Drugs with No Clinical Alternatives

CMS also has recognized that any proposed apportionment rule must account for bundles that include "drugs that may not have clinical alternatives," which we term "dominant drugs" for ease of reference. Bundles with dominant drugs have the potential to result in unfair competitive advantage to the detriment and cost to the public health system and Medicare. These adverse consequences result where large incentives are paid on the dominant drug (or drugs) to drive sales of a competitive drug (or drugs) in the bundle.

In such circumstances, the general Medicaid apportionment rule will not achieve the requisite reallocation of incentives to the drugs that benefit from the incentives paid. If that rule were to be applied, incentives paid solely to drive sales of the competitive drugs wrongly would be allocated to the dominant drug. The apportionment, therefore, would decrease the ASP for the dominant drug (which does not face competition) and increase the ASPs for the competitive drugs, thereby exacerbating the perverse incentives of such bundles by affording the competitive drugs an artificial competitive advantage. Absent an appropriate alternative apportionment rule to allocate the bundled incentives to the drugs that benefit from the incentives, the drugs' published ASPs will not reflect - and will be insulated from - competitive market forces. We appreciate the agency's recognition of the problems associated with this particular class of drugs and agree an alternative rule is required to ensure the Federal reimbursement system is not manipulated to the detriment of competition or at a cost to the Medicare program.

i. the approved indications and risk profile relative to other approved drugs and therapies;

ii. whether the drug is a single source product;

iii. whether the drug is patent protected;

iv. the drug's market share;

v. the incentives provided on the drug after, relative to before, it was introduced into a bundle; (a dominant drug historically has a minimal discount; if/when a dominant drug is bundled with a drug that has competition and a significant discount is placed on the dominant drug, there is a strong inference that such incentive is used to drive sales of another product in the bundle);

vi. the effect of the introduction of the drug into the bundle on the sales volume of the other bundled products; (a significant increase in the sales of the competitive drugs following the introduction of the dominant drug into the bundle is indicative of the power of, and lack of alternatives for, the dominant drug); and

vii. the relative Medicare expenditures on the drug (e.g., large Medicare expenditures for the dominant drug relative to any purported alternatives is evidence the dominant drug is the only viable alternative).

It will be fairly self-evident in virtually every instance that a dominant drug exists and the manufacturer would be expected to report the incentive discounts based on its good faith interpretation of whether these guidelines apply. We recognize, however, that certain manufacturers may object to the imposition of an apportionment rule addressing bundles with dominant drugs unless afforded an opportunity to present their views as to whether there are viable clinical alternatives to such drugs. As discussed further below, we propose the adoption of a notice and response period to provide manufacturers with that opportunity to be heard with respect to the determination of dominant drugs. There should be minimal incremental administrative demands on the agency as a consequence of this protocol because, once the rule is adopted, there likely will be few instances that a dominant drug is bundled to drive the sales of competitive drugs.

Guiding Principles for Bundle Apportionment

With bundles and dominant drugs defined, CMS can promulgate apportionment rules to allocate the bundled incentives to individual drugs in such a way to ensure ASP-based reimbursement reflects (rather than distorts) the drugs' market prices and, in turn, that bundles are used to further the efficient (rather than coercive) sale of drugs.

As noted previously, CMS explicitly stated that the goal of its contemplated guidance is to ensure 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." Moreover, while CMS has given no specific guidance to date, the existing precedent provides two guiding precepts that should be respected in fashioning the appropriate apportionment rules. First, CMS has indicated that manufacturers' apportionment practices must be consistent with the general

requirements and intent of the Social Security Act and applicable Federal regulations, which would include, most notably, the Medicaid Drug Rebate Program. As a practical matter, this means that, as a general rule, manufacturers offering bundled arrangements should allocate incentives proportionally among the products, as suggested by the Medicaid rebate agreement. Second, through the discount safe harbor, various Advisory Opinions addressing bundled arrangements, and its Final Compliance Program Guidance for pharmaceutical manufacturers, the HHS OIG has consistently stated that discounts associated with bundled arrangements must be appropriately and accurately reflected in reported discounts. See e.g., 42 C.F.R Section 1001.952(h)(5)(ii); OIG Advisory Opinion 99-3; 69 Fed. Reg. 23832 (May 5, 2003).

The clear purpose of this requirement is to assure that the Federal pricing programs, including the ASP-based regimen under Medicare Part B, receive the proper benefit from any such discount arrangements and to assure there is no inappropriate inducement to purchase certain products so as to increase the cost to the Federal program. To comply with these directives as applied to the ASP reimbursement regimen –which is premised on a fair and accurate reporting by the manufacturer of its drugs acquisition costs— bundled incentives must be allocated to the drugs whose sales are driven by such incentives.

In most instances, the Medicaid bundle rule, which allocates incentives on the basis of sales, achieves that end. In the limited instances where bundles include dominant drugs, however, an alternative rule is required to ensure the Federal reimbursement system is not manipulated to the detriment of competition or at the cost to the Medicare program.

Proposed Apportionment Methods

Two apportionment rules are required to achieve the legal and regulatory requirement that bundled incentives be allocated to the drugs that derive the benefit of the incentives for the ASP calculation: (i) a general rule encompassing most bundled sales; and (ii) an exception for bundled sales that involve discounts/rebates on dominant drugs.

First, for bundled sales that do not contain dominant drugs, the bundled incentives should be allocated proportionally to the dollar value of the units of each drug sold under the bundled arrangement. This approach aligns the incentives with the sales generated thereby. This general rule is consistent with the Medicaid bundling principles.

Second, for bundles that contain dominant drugs, incentives granted on such drugs that are conditioned in whole or in part on purchases of a drug (or drugs) with clinical alternatives ("competitive drugs") should be allocated to the competitive drug (or drugs, based on the relative sales of the competitive drugs). For dominant drugs there is no clear economic incentive to offer large incentives, and thus, there is a strong inference the payment of such incentives actually are intended to be an incentive on other competitive drugs within the bundle. This proposed apportionment approach for bundles that include dominant drugs therefore appropriately reflects the price concessions or incentives created by such bundles.

By requiring the allocation of bundled incentives to drugs that derive the benefit of the incentives, the two proposed apportionment rules achieve CMS's stated goals that the guidance ensure 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."

Amgen's Bundle

This propriety of the proposed apportionment rule for incentives on bundled dominant drugs is illustrated through the use of an existing example from the field of medical oncology and the bundling arrangements of Amgen Inc. The products involved are red blood cell growth factors (RBCGFs) and white blood cell growth factors (WBCGFs).

The RBCGFs are epoetin alfa sold by Ortho Biotech under the brand name Procrit and darbepoetin alfa sold by Amgen Inc. under the brand name Aranesp. RBCGFs are used to treat severe anemia that is commonly seen in patients undergoing chemotherapy. Chemotherapy can destroy red bloods and depress the production of erythropoietin, the human hormone that stimulates red blood cell creation. Ortho Biotech and Amgen are the only two competitors for the sale of RBCGF drugs to treat chemotherapy-induced anemia in the United States. Ortho Biotech's drug Procrit is an exact replicate of the naturally produced erythropoietin molecule; Amgen's drug Aranesp is a modified version of erythropoietin molecule.

The WBCGFs are filgrastim and pegfilgrastim sold by Amgen under the brand names Neupogen and Neulasta, respectively, and sargramostim sold by Berlex Laboratories Inc. under the brand name Leukine. The WBCGFs are used to treat neutropenia, a severe white blood cell deficiency that is potentially life threatening. WBCGF drugs stimulate the production of infection-fighting white blood cells known as granulocytes. These cells are reduced or destroyed during many kinds of cancer chemotherapy. White blood cell counts become dangerously low in some cancer patients, leaving them vulnerable to life-threatening infections. WBCGF drugs lessen patients' chances of infection and reduce their need for antibiotics and hospitalization, resulting in a significant improvement in their quality of life. Neupogen was Amgen's initial WBCGF product. In 2002, Amgen introduced Neulasta, a drug modified version of Neupogen that, according to Amgen, may be administered less frequently than Neupogen.

Amgen dominates the sales of WBCGF products, which have become the recognized standard of care for the treatment of neutropenia. Although Berlex's product has been on the market for many years, unlike Amgen's drugs, it (i) not indicated for the treatment of neutropenia, (ii) has a significantly higher risk profile than Amgen's drugs, and (iii) must be administered intravenously, which is a longer and more costly process than the subcutaneous injection process employed with Amgen's drugs. As a consequence, Berlex's drug has a *de minimis* share of WBCGF sales and Amgen's WBCGF products are undisputedly the dominant drugs.

Virtually all oncology clinics administer both RBCGFs and WBCGFs to patients. These clinics must buy their WBCGF drugs from Amgen and, therefore, Amgen need not offer large competitive incentives on its WBCGF drugs to make those sales. But Amgen nevertheless offers large discounts and/or rebates to oncology clinics on the condition that these facilities reach certain volume purchase requirements for Amgen's RBCGF and WBCGF drugs (individually and in aggregate). That is, Amgen's bundle conditions the grant of rebates for its WBCGF drugs on the purchase of large volumes of its competitive drug Aranesp (darbepoetin alfa).[1] As a consequence, oncologists and oncology clinics must buy less Procrit (arguably a superior alternative) and more Aranesp in order to get access to both the WBCGF and RBCGF rebates.

Oncologists who accede to Amgen's demands to purchase Aranesp in lieu of the competition (Ortho Biotech's Procrit) earn significant incremental back-end rebates on Amgen's WBCGF drugs. Oncologists who fail to purchase the large volumes of Aranesp, however, are denied the rebates on Amgen's WBCGF drugs required to break even on the WBCGF drugs administered to Medicare patients (i.e., because of the back-end rebates that are awarded, the WBCGF drugs' ASP reimbursement is lower than their acquisition prices, net of any available discounts).

Thus, the rebates Amgen provides on its WBCGF drugs are intended to drive Aranesp purchases. But Amgen allocates the rebates to its WBCGF drugs for its ASP calculations to keep the WBCGF drugs ASPs low and the Aranesp ASP high, thereby creating an artificially high ASP that overpays Aranesp and is a net cost to Medicare. As a consequence, the Amgen drugs' ASPs (i) do not reflect their market prices and (ii) are used wrongly by Amgen to induce oncologists to purchase Aranesp in circumstances where they otherwise might purchase Procrit.

Our proposed ASP calculation methodology corrects this inequity and achieves CMS's stated goals. By requiring bundled incentives offered on dominant drugs to be allocated to the competitive drugs, the new apportionment rule would require Amgen to report pricing on Aranesp that reflects the economic reality of its offering by stating its ASP at an amount that reflects the incentives that drive its sales, thereby forcing it to compete on a level playing field with Procrit. And the methodology would remove Amgen's ability to force oncologists to incur losses on its WBCGF drugs administered to Medicare patients by increasing their ASPs to an amount that reflects the actual incentives attributable to the drugs.

The proposed policy also would mitigate opportunities to distort Medicare reimbursement rates and any resulting inducement to purchase Medicare Part B covered products with overstated reimbursement rates. In turn, this would foster meaningful competition and lead to reduced drug acquisition costs and ASPs. Thus, the proposed apportionment rule ensures the drugs' ASPs do in fact represent the drugs' market prices and would allow the competitive marketplace to operate, which would benefit patients and Medicare.

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[1] This condition is effectuated through the imposition of minimum Aranesp purchase requirements, and the structure of contract's rebate schedule, which requires large Aranesp purchases to earn higher incentives on Neulasta.

Proposed Policy Generates Savings for Medicare and its Beneficiaries

The proposed policy will generate immediate savings for the patients and Medicare. The allocation of incentives from Amgen's WBCGF drugs to Aranesp decreases the Aranesp ASP and increases the WBCGF drugs' ASPs. However, ASP is a per unit reimbursement amount and a much larger percentage of the total Aranesp sales volume is reimbursed by Medicare than Amgen's WBCGF drugs. That is, Medicare reimburses more units of Amgen's Aranesp than Amgen's WBCGF drugs. Consequently, even though the proposed policy would result in increased ASPs for Amgen's WBCGF drugs, the lower Aranesp ASP generates immediate cost savings to Medicare. We estimate those savings to approximate $50 million.

Currently, Medicare pays a "dose premium" for Aranesp compared to Procrit. A dose premium is the difference in reimbursement costs for comparable doses of two different drugs used for the same clinical indications. In the case of Aranesp and Procrit, the existing Amgen bundle forces oncologists to purchase Aranesp, which is by far the more costly drug to private payors and Medicare due to the high doses of Aranesp administered relative to Procrit.[2]

We estimated the dose premium on Aranesp cost Medicare an excess $177 million in 2005 alone. At the 20% coinsurance rate, the excess costs to the Medicare beneficiaries was $35 million.

These cost estimates were derived from two studies of the comparable doses of Procrit and Aranesp administered in oncology clinics. The first is an independent study conducted by Oncology Therapeutics Network (OTN) of its proprietary database, which provides the relative average weekly doses of Aranesp and Procrit administered in oncology clinics.[3] The second is an analysis of the average cumulative dose data from the Medicare Standard Analytic Files.[4] Both sets of data – the first from the providers and the second from the payor – yielded the same ratio of Procrit to Aranesp doses administered on average to oncology patients in 2005: 266:1. That is, on average 266 International Units of Procrit were administered for every microgram of Aranesp administered. (The two drugs are packaged by Amgen in different units.)

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[2] Private payers (e.g., Blue Cross Blue Shield of Georgia and Virginia) have recognized this dose premium and begun to take the extraordinary step of paying much greater per unit reimbursement amounts for Procrit relative to Aranesp to offset the Aranesp dose premium.

[3] OTN is a leading specialty distributor of drugs and supplies to more than 2,400 office-based oncology practices. OTN provides practices integrated point-of-care drug dispensing and tracking systems. These systems also can provide summary data on the amount of a particular drug provided to patients across all practice locations.

[4] These Medicare data files contain claims for a 5% random sample of Medicare beneficiaries and are commonly used to study diseases in elderly patients.

At the published reimbursement rates for 2005, this dose ratio translates to a 22.4% dose premium for Medicare (and a 37.2% dose premium for private payors).[5] Applying the dose premium percentage to the total Medicare allowed charges for Aranesp – derived from the National Procedure Summary Data File as of August 17, 2006 produces an excess Aranesp dose premium to Medicare of $177 million based on the August 2006 report.

Absent action by the agency, Medicare will continue to incur an Aranesp dose premium as oncology clinics are coerced to purchase Aranesp in lieu of Procrit. Indeed, our studies show that the Aranesp dose premium has increased dramatically in 2006, corresponding with the approval of Amgen's new dosing regimen.[6] The proposed apportionment rule would alleviate the coercive nature of the bundle, allowing oncologists to purchase Procrit and thereby generating savings to patients and Medicare.

Moreover, by leveling the competitive playing field for Aranesp and Procrit, the proposed apportionment rule would foster price competition, which in turn will reduce the drugs' acquisition costs and ASPs. Thus, our proposed bundle apportionment policy ensures the drugs' ASPs do in fact represent the drugs' market prices and would allow the competitive marketplace to operate, which would benefit patients and Medicare.

Implementation of Bundle Apportionment Policy

Guidance should be issued immediately through program instruction or other guidance (consistent with the authority under section 1847A(c)(5)(C) of the Act) on the methodology manufacturers must use for apportioning price concessions across Part B drugs sold under bundling arrangements.

For bundled sales that do not contain dominant drugs, the bundled incentives should be allocated proportionally to the dollar value of the units of each drug sold under the bundled arrangement. Because this general rule is consistent with the Medicaid bundling principles, we view its implementation as straightforward.

For bundles that contain dominant drugs, we believe it will be self-evident to the manufacturer in virtually every instance that such a drug exists and compliance with the apportionment policy could be done voluntarily. However, before any manufacturer is required to modify their ASP reporting for bundles with dominant drugs, we believe it should be provided the opportunity to respond to a finding by the Secretary that the apportionment policy for dominant drugs applies to their bundle.

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[5] The Medicare premium percentage was derived using the average of the published ASPs for Procrit and Aranesp in 2005. The private payor premium percentage was derived using the average published list prices for 2005, the assumption being that payors reimbursed Aranesp and Procrit at the same discount off of AWP (which in turn was set at for the two drugs at the same fixed markup over WAC).

[6] In March 2006, Amgen secured approval for its new regimen that allows dosing of up to 500 micrograms every three weeks.

We recommend that the 2007 final rule for the physician fee schedule include a finding by the Secretary that Amgen's bundle of Neupogen/Neulasta with Aranesp is subject to the apportionment policy for bundles with dominant drugs. Such a finding should be apparent based on the information provided in this comment letter and the fact that Amgen readily concedes in its public filings that its white blood cell growth factor drugs Neupogen and Neulasta are monopoly products without viable competitive alternatives. However, Amgen should be provided 30 days to provide evidence to rebut the finding that its bundle includes a dominant drug before they are required to comply with the ASP reporting requirements.

As other bundles with dominant drugs are identified, the Secretary would be required to make an initial determination followed by an opportunity for the manufacturer to rebut the finding during a 30-day comment period.

Harm Will Increase if the Bundle Apportionment Policy is Not Adopted

Amgen has exploited the absence of clear guidance to pursue its anticompetitive bundle to the detriment of oncologists, patients, and the healthcare system. The rule is required to prevent Amgen's approach from becoming the norm in each instance that a dominant drug may be bundled with drugs for which there are clinical alternatives ("competitive drugs").

CMS may be aware of an antitrust lawsuit that has been filed by Ortho Biotech over Amgen's bundling practices. We urge CMS not to accept arguments that that this lawsuit obviates the need for any action by the agency. It is not sufficient to rely on the judiciary to prevent or alleviate the costs and harm from bundles containing unique therapies. A judicial determination that a bundle does or does not violate the antitrust laws involves a different standard and analysis than involved in assessing the appropriate allocation methodology for reimbursement purposes. The proposed bundle apportionment rule for dominant drugs is required to achieve CMS's stated goal of ensuring that drugs' ASPs reflect market prices and do not create inappropriate financial incentives.

Conclusion

We support the CMS goal of ensuring 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. We believe specific guidance is needed and we recommend the following:

1) For bundled sales that do not contain dominant drugs, the bundled incentives should be allocated proportionally to the dollar value of the units of each drug sold under the bundled arrangement. This general rule is consistent with the Medicaid bundling principles.
2) For bundles that contain dominant drugs, incentives granted on such drugs that are conditioned in whole or in part on purchases of a drug (or drugs) with clinical alternatives ("competitive drugs") should be allocated to the competitive drug (or

drugs, based on the relative sales of the competitive drugs). The methodology for applying discounts/rebates is as follows:

a) Determine the total incentives paid on the dominant drug;
b) Determine the amount of incentives paid on the dominant drug that are conditioned in whole or part on the purchase of another bundled product;
c) Allocate the incentives determined in step (b) to the other competitive products in the bundle;
d) Allocate the difference between the amounts determined in step (a) and (b), if any, to the dominant drug; and
e) Apportion the incentives on the competitive products, including those amounts allocated in step (c), based on the dollar value of the units of each drug sold. .

Guidance should be issued immediately through program instruction or other guidance (consistent with the authority under section 1847A(c)(5)(C) of the Act) on the methodology manufacturers must use for apportioning price concessions across Part B drugs sold under bundling arrangements. Amgen's WBCGFs should be identified as dominant drugs in a bundle and Amgen should be given 30 days to rebut this finding before the new ASP reporting requirements are implemented for the drugs in their bundle.

In addition to eliminating inappropriate financial incentives, the guidance we have recommended would generate savings for the Medicare program and its beneficiaries and it would foster price competition, which in turn would reduce the drugs' acquisition costs and ASPs.

Thank you for your consideration of our comments and recommendations. If you have any questions, please contact Cathleen Dooley, Executive Director, Federal Affairs at 202-589-1008 or by e-mail at cdooley@obius.jnj.com.

Sincerely,

Cathleen M. Dooley
Executive Director, Federal Affairs
Johnson & Johnson

Neuton S. Stern, M.D. (1890-1969)
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David H. Holloway, Jr., M.D., FACC
William L. Russo, M.D., FACC
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James E. Klemis, M.D.
Holger P. Salazar, M.D., FACC

The Stern Cardiovascular Center
EXCELLENCE IN CARDIOVASCULAR MEDICINE, RESEARCH AND PATIENT CARE

October 5, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and 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: Proposed Rule; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (Federal Register, August 22, 2006)

Dear Dr. McClellan:

On behalf of The Stern Cardiovascular Center, we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services ("CMS") regarding the above proposed Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; Proposed Rule ("Proposed Rule"). We are concerned about several provisions that will impact Medicare beneficiaries' access to services in outpatient cardiac centers, particularly those related to cardiac catheterizations. Specifically, we are concerned about the payment method proposed for cardiac catheterization related procedures. The Cardiovascular Outpatient Center Alliance ("COCA"), of which we are a member, will address the CMS proposal to require standards for Independent Diagnostic Testing Facilities ("IDTFs"). Our concerns related to the payment method are outlined below.

<u>Payment Method</u>

Under the proposed rule CMS states that the payment for cardiac catheterization related procedures (e.g. CPT code 93510 TC, 93553 TC and 93555 TC) will be established by the Medicare carriers. The change in the payment method appears only in Addendum B, and CMS provides no explanation or justification in the body of the proposed rule for this change.

We object to this approach because it is inconsistent with the overall policy of basing Medicare payment rates for physician services on a national fee schedule methodology. We are also concerned that if carrier pricing were to be implemented, the carriers would look to the values in the June 29, 2006 Notice that addressed the changes to the methodology for the development of practice expense (PE) relative value units (RVUs). Therefore, we request that CMS give serious consideration to addressing the flaws in the proposed changes to the bottom up "PE" methodology for procedures where the technical component (TC) can be billed separately. We know that developing an adequate solution will take time and, therefore, request that CMS set the 2007 relative value units for the three codes listed based on the 2006 values.

We urge CMS to use the current relative value units as the basis for determining reimbursement for these procedures rather than relying on the Medicare carriers to price these services. By doing so, CMS will be able to set a reimbursement rate that fairly reflects the costs of performing these procedures. This recommendation is supported by actual data from outpatient centers. COCA sponsored a study to estimate the costs of performing a cardiac catheterization (CPT Code 93510 TC) in an outpatient center. The study results demonstrated that the 2006 Part B physician fee schedule payment approximates the average cost of providing these services. As a result, we do not believe that a new pricing methodology is necessary.

The current relative value units result in a payment rate that is in relative parity with the payment amount hospitals receive under the hospital outpatient prospective payment system. In fact, the 2006 physician fee schedule payments for the three CPT codes included in the Ambulatory Procedure Classification ("APC") for cardiac catheterizations are 93 percent of the relevant APC rate.

In our response to CMS' Proposed Changes to the Practice Expense Methodology (Federal Register, June 29, 2006) we outlined our concerns with the proposed changes to the PE Methodology, i.e., use of a bottom-up methodology and the elimination of the non-physician work pool. The proposed payment rates resulting from the use of the practice expense RVUs for the left heart catheterization procedure alone (CPT code 93510 TC) reduce payment levels in 2007 by 16 percent, and by 2010 make overall reductions of 53 percent. The flaws in the methodology, particularly as they relate to the cardiac catheterization procedure codes were described in general in the August 22, 2006 comment letter submitted by COCA.

Cardiac catheterizations that are billed through the Medicare physician fee schedule are performed primarily in cardiology groups and freestanding centers which are grouped into a diverse group of diagnostic testing facilities

known as IDTFs.

We believe that the development of unique standards for each type of diagnostic testing facilities will facilitate the development of a consistent Medicare policy for outpatient cardiac catheterization services. The standards will provide a solution to the issue that cardiac catheterization labs faced when the national coverage determination for outpatient catheterizations was rescinded because of the change of scope in the CMS contracts with the Peer Review Organizations in January 2006.

The need to develop unique standards for each type of diagnostic testing facility provider is consistent with the observation that CMS made in the Proposed Rule regarding the practice expense for different types of remote cardiac monitoring and anticoagulation monitoring. Similar to CMS's observation that these types of IDTFs are different, we believe that cardiac catheterization centers are unique and that their cost structure and quality standards are similar regardless of whether they are performed in a cardiology practice or an independent outpatient center. The COCA cost study shows that the cost profile of outpatient cardiac centers is quite different from the average profile of all IDTFs. We believe the COCA cost analysis will be helpful to CMS as it begins to develop standards, specifically for cardiac outpatient centers because the data can be used to estimate the impact that each standard has on practice expenses. The cost study will also be helpful as CMS works to develop a practice expense RVU for cardiac catheterization procedures that reflect the resources needed to perform the service.

In summary, we have grave concerns about the use of carrier-based pricing for procedures that are offered nationwide and historically have been paid according to the physician fee schedule methodology. The carrier based pricing approach is more often used for new services where there is insufficient data on which to determine a national rate. We have previously described our concerns with the proposed 2007 PE RVUs for the cardiac catheterization-related procedures, and, therefore, request that the 2006 rates be frozen so that payments reflect the costs of performing the procedure in the outpatient setting and are on par with the APC rate for a comparable family of cardiac catheterization-related procedures. In addition, we also note that carrier-based pricing has the potential to create disparities in beneficiary co-payment liability.

We thank you for the opportunity to describe our concerns about the proposed rule, specifically as it relates to payment for cardiac catheterization-

related procedures and the development of standards for centers that perform these procedures on an outpatient basis.

Sincerely,

Debbie Eddlestone
Chief Operating Officer
On Behalf of The Stern Cardiovascular Center

The 60 Plus Association

70

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Phone 703.807.2070 • Fax 703.807.2073 • www.60Plus.org

James L. Martin
President

Rep. Roger Zion (R-IN, 1967-75)
Honorary Chairman

Pat Boone
National Spokesman

October 4, 2006

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

Dear Mark,

I have been sent a copy of a letter mailed to you dated September 26, 2006, signed by the entire Louisiana delegation, calling your attention to a matter that has come to be called the "Rita penalty."

Upon review, and on behalf of senior citizens in those six Louisiana parishes still reeling from the devastation of Hurricane Rita, I wanted you to know I agree with the points spelled-out in that letter.

I add my support on behalf of the 60 Plus Association and our members nationwide, but especially in Louisiana, acknowledging that helping senior citizens from those six affected parishes by waiving the penalty for late enrollment for the extension of the Medicare prescription drug program would be, in my opinion, both cost effective and compassionate.

Yours sincerely,

Jim Martin

James L. Martin

The 60 Plus Association is a 15-year-old nonpartisan organization taking on important issues such as death tax repeal, saving Social Security, working to lower energy costs, affordable prescription drugs and other senior-friendly issues featuring a less government, less taxes approach. 60 Plus calls on support from nearly 4.5 million citizen activists. 60 Plus publishes a quarterly magazine, SENIOR VOICE, and a Scorecard, bestowing a Guardian of Seniors' Rights award on lawmakers of both parties who vote "pro-senior." 60 Plus has been called "an increasingly influential senior citizen's group" and "the conservative alternative to the AARP." 60 Plus has established a membership benefit program. To join 60 Plus or for further information, please go to our website at www.60plus.org or call 888-560-PLUS (7587).

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CENTER

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71

In light of our track record of clinical success, I am writing today to express my grave concern with CMS 2007 Update to the PE RVUs for Interventional Radiology CPT codes.

Impact – Work and PE RVU Changes for Interventional Radiology

I urge CMS to reconsider the drastic 2007 cuts to the PE RVUs for interventional radiology stemming from the changes to the PE calculation methodology.

My practice and I fully understand CMS need to make difficult budgetary decisions to maintain the solvency of the Medicare trust funds. However, we have serious concerns with the proposed practice expense reductions for interventional radiology. Per Table 7 of the CMS-1321-P, the combined 2007 impact of Work and PE RVU Changes for Interventional Radiology is estimated to be -14%, the third hardest hit specialty.

A significant portion of our center's vascular access procedures involve imaging, and as such, these reductions will have a dramatic impact on our ability to treat patients. We would not want to see CMS inadvertently limit patients' access to convenient, efficient and clinically successful vascular access care. Their only alternative is to go back to the hospital for these services. This result is truly unfortunate since we can provide these services in their entirety for on average 30% - 40% of hospital rates.

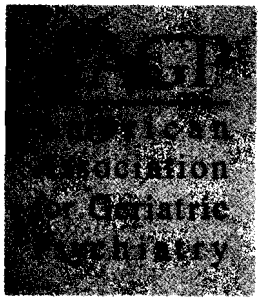
In addition, we are concerned that the reductions did not adequately take into account the costs of providing imaging services. For example, a significant driver of costs is tied to the equipment. The current system does not have a specific mechanism for capturing those costs thus they may have been overlooked.

In closing, I thank you in advance for your thoughtful consideration of these comments. If I can further assist your understanding of the benefits of outpatient vascular access patient care, I would be delighted to do so.

Respectfully submitted,

Nicolas Lorero, M.D.
Interventional Nephrologist

September 28, 2006



Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P. O. Box 8015
Baltimore, MD 21244-8015

Dear Sir/Madam:

We are pleased to submit these comments on the proposed rule for Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 on behalf of the American Association for Geriatric Psychiatry (AAGP). The AAGP is a professional membership organization dedicated to promoting the mental health and well-being of older people and improving the care of those with late-life mental disorders. Our membership consists of more than 2,000 geriatric psychiatrists as well as other health care professionals who focus on the mental health problems faced by senior citizens.

SGR

We continue to be deeply concerned about the impact of the sustainable growth rate (SGR) formula on payments for physician services under the fee schedule. We again urge you to use your discretion to revise the calculation of physician expenditures and to support efforts in Congress to replace the SGR policy. The preamble to this proposed rule estimates the update for calendar year 2007 to the conversion factor will be a minus 5.1 percent. We believe if a reduction of this magnitude is put into place, the quality of care and beneficiary access to physicians' services will be adversely affected. We strongly recommend that you consider changes in the way you estimate spending increases for purposes of applying the SGR policy under the Medicare fee schedule.

Specifically, we do not think physician expenditures should include the cost of prescription drugs furnished incident to a physician's service. As you know, drugs administered in a physician's office are not paid for under the physician fee schedule; including them in the estimates of spending under the fee schedule holds physicians accountable for an expense that is largely outside their control, and one that is rising very rapidly. In addition, we believe that the estimate of physician expenditures should be adjusted to

account for increased outlays related to new national coverage decisions. Coverage decisions that expand beneficiary access to advancements in medical diagnosis and treatment should be treated in a manner similar to changes in law and regulation that are expected to affect outlays for physicians' services. In our view, there is no difference between a change in law that extends Medicare coverage and a change in national coverage policy initiated by CMS.

For psychiatry, a negative update to the fee schedule and other changes in work and practice expense relative value units (RVUs) results in a 7 percent reduction in total Medicare payments for the specialty in 2007. This cut comes in the face of forecasted increases in practice costs including malpractice premiums of 3.8 percent and increases in the cost of clinical labor of 3.7 percent, as reflected in the estimated Medicare Economic Index (MEI) for 2007.[1] It's important to underscore that this proposed negative update to the fee schedule is not merely a slowing in the rate of increase in fees – it's a reduction in the payment amount and, taking into account the estimated MEI for 2007, the total impact is a 10.7 percent decline in the value of Medicare physician payments. In other words, if Medicare payments were adjusted to be consistent with the forecasted MEI, then payments should be 3.7 percent higher in 2007 than in 2006. Instead, payments for psychiatrists will be 7 percent lower in 2007, which amounts to a net loss of 10.7 percent (- 3.7 percent + -7 percent).

The Congressional Budget Office has recently estimated that under current law, payment rates for physician services could decline by a total of 25 to 35 percent. CBO further estimates that total Medicare spending for physicians' services will increase on average about 2 percent annually through 2012.[2] Clearly, this cannot continue without significant adverse effects on beneficiary access to care. For our members who care for a significant number of patients over age 65, these payment policies are likely to threaten the financial viability of many of their practices. Current payment rates already fail to recognize adequately the added costs of caring for a frail population with multiple chronic conditions and the additional time that must be given to family members and care givers.

While we do not have evidence of a significant increase in the number of psychiatric practices that have placed limits on new Medicare patients, our members are especially vulnerable to these limitations. We do know that a number of geriatric psychiatry practices are near bankruptcy or have been forced to close. Many other geriatric psychiatrists are actively re-evaluating the financial feasibility of maintaining their geriatric practice. At a time when there is growing evidence of undiagnosed and untreated mental illness in the senior population, these policies are likely to erode access to mental health care for growing numbers of elderly and disabled beneficiaries.

Changes in the Medicare Economic Index (MEI)

We also want to express our strong opposition to the recently announced 0.5 percent reduction in the estimated Medicare Economic Index (MEI). The reduction was not discussed in the

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[1] Medicare Payment Advisory Commission (MedPAC). "Report to the Congress: Medicare Payment Policy." p. 97. March 2006.

[2] Congressional Budget Office (CBO). "The Sustainable Growth Rate Formula for Setting Medicare's Physician Payment Rates." Economic and Budget Brief, September 6, 2006, p. 2.

evidence that these practices are struggling to remain financially viable. We believe that CMS should take every opportunity to exercise its discretion to expand access to psychiatric services for Medicare beneficiaries. We hope you will reconsider your options for updating the fee schedule and will join with us in asking Congress to replace the current SGR policy.

Thank you for this opportunity to comment on the proposed rule.

Sincerely,

Christine M. deVries
Executive Director

The Center for Pain Relief *Michael S. Gorback, M.D.*

17099 Texas Avenue
Webster, TX 77598

Telephone: *281-554-3400*
Facsimile: *281-554-3404*

September 25, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
P.O. Box 801
Baltimore, MD 21244-8015

RE: Proposed Rule on the Medicare Physician Fee Schedule for Calendar Year 2007

Physicans' real income has decreased over the past 10 years, as fees have not risen in step with inflation. A major contributor to this has been the devastating effect of the SGR formula, which promises to inflict a further 5% fee cut in 2007. To make matters worse, CMS has issued the Proposed Rule on the Medicare Physician Fee Schedule for Calendar Year 2007. In my specialty of interventional pain management (designation –09) the Proposed Rule would decimate my practice, with cuts estimated as high as 40-50% for my procedures.

This is not survivable. If these changes go into effect I will be providing services below cost and I will be forced to close my practice. Please place a moratorium on these changes for at least one year so that the impact of the changes in the physician fee schedule can be properly assessed.

Thank you for your consideration.

Sincerely,

Michael S. Gorback, M.D.
Diplomate, American Board of Anesthesiology with Subspecialty Certification in Pain Management
Diplomate, American Board of Pain Medicine

The Center for Pain Relief *Michael S. Gorback, M.D.*

17099 Texas Avenue
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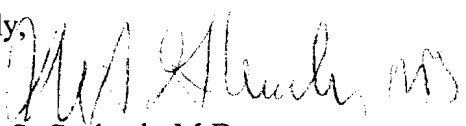

Michael S. Gorback, M.D.
Diplomate, American Board of Anesthesiology with Subspecialty Certification in Pain Management
Diplomate, American Board of Pain Medicine

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September 25, 2006

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Department of Health and Human Services
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Thank you for your consideration.

Sincerely,

Michael S. Gorback, M.D.
Diplomate, American Board of Anesthesiology with Subspecialty Certification in Pain Management
Diplomate, American Board of Pain Medicine

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301 Penobscot Drive
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COMMENTS FOR GENOMIC HEALTH ON THE PROPOSED PHYSICIAN FEE SCHEDULE REGULATIONS

September 21, 2006

Genomic Health is pleased to have the opportunity to submit comments on the proposed fee schedule regulations, which was issued on August 22, 2006 (71 Fed. Reg. at 48982). Genomic Health is an independent clinical laboratory that has developed an important new test, Oncotype Dx™, that is used to determine whether a woman diagnosed with breast cancer is likely to have a distant recurrence. For a number of reasons, explained below, Genomic Health's Oncotype Dx™, test was directly affected by changes in the "archived specimen" or date of service ("DOS") rule, published by CMS in February 2005. We have spoken with CMS officials on various occasions about this concern, and we are pleased that CMS is focusing on the issue in the proposed regulations, and wish to express our appreciation to CMS for doing so.

We have some concerns about certain parts of the CMS proposal which are discussed below. In our comments, we wish to explain how the problem occurs and the impact of the archived specimen rule. Then we will discuss the proposed changes by CMS.

Factual Background

Genomic Health has developed a clinical laboratory test that is performed on fixed, paraffin-embedded breast cancer tissue, which is used to assess the likelihood of recurrence in women with Stage I or Stage II, breast cancer who are node negative, estrogen receptor positive. The Oncotype Dx™ test is ordered by an oncologist after an

office visit with a patient, who has been recently diagnosed with breast cancer. In most cases, the tumor tissue that is used for the test was previously removed when the woman underwent surgery for suspected cancer, such as a lumpectomy or mastectomy. After the surgery, the tissue is stored at the hospital, as is the usual surgical and hospital practice.

The "Archived Specimen" Rule

In order to understand the current problem, it is necessary to provide some background. As part of the November 23, 2001 Final Rule on coverage and administrative policies for diagnostic lab services, CMS clarified that the date of service ("DOS") for clinical diagnostic laboratory services should be the date the specimen was collected. *See* 66 Fed. Reg. 58797 (Nov. 23, 2001). At the same time, there were several exceptions instituted to this requirement. One such exception was intended to deal with tests conducted on patient specimens that were collected at an earlier date and then stored (or "archived"). For laboratory tests requiring a specimen from stored collections, the date of service was defined as the date the specimen was obtained from the archives. The final rule did not further define how long a specimen must be stored before it was considered "archived," but a subsequent Program Memorandum clarified the contractors had discretion in making this determination. PM 02-134 (Oct. 4, 2002).

Subsequently, CMS issued a national standard that established that a specimen must be stored for more than 30 calendar days to be considered "archived." The DOS for these archived specimens would be the date the specimen was obtained from storage. Testing performed on specimens stored 30 days or less would have a date of service of the date the specimen was collected (70 Fed. Reg. at 9355).

This relatively small change in the DOS rules has created significant problems for Genomic Health and other laboratories providing innovative life-saving testing for patients. In most instances, the DOS for the Genomic Health test will be the date the specimen was collected. This is because the specimen is usually stored for fewer than 30 days when the test is ordered. As a result, Genomic Health must use the date the specimen was collected when billing for this service, which is when the patient was a hospital patient. Edits in the Common Working File ("CWF") may cause the claim to be rejected because it will appear that the claims should have been bundled as part of the hospital stay. This is inappropriate because the patient has usually been discharged from the hospital long before the service was ordered.

As CMS is aware, carriers have had difficulty in applying the 30-day rule to the Genomic Health situation. For example, National Heritage Insurance Company ("NHIC"), the Medicare carrier for California and Massachusetts, has issued coding guidelines that use the 30-day rule as a basis for establishing different rules for laboratory tests, depending on whether the specimen was taken during a Part A inpatient hospital stay, an outpatient hospital stay, an ambulatory surgery center visit, or an office visit.

The difficulty with these standards is that they would require the laboratory to bill the hospital for the test in certain situations, which is virtually impossible for the laboratory to do. First, such an interpretation would require the hospital and the laboratory to have a contract, which would mean the laboratory, would be forced to have a contract with thousands of hospitals across the country from which the specimens might originate. Further, hospitals are unwilling to enter into such contracts for good reasons. Because the test is often performed after the patient has been discharged, the hospital will

no longer have any relationship with the delivery of care to the patient, and the hospital is unwilling to be responsible for such after-discharge services. The hospital has no basis for determining the medical necessity of the test for that particular patient, because the testing is not used in conjunction with any services provided during the in-patient encounter, but is only used for determining the future course of treatment for the patient, after the patient's discharge. It is also possible that the hospital may receive a request to forward a specimen for this purpose from a physician that has no relationship with the hospital that is storing such tissue. The likely effect of these rules is that hospitals, unwilling to accept financial responsibility for these tests, will make it exceedingly difficult for physicians to utilize them for appropriate patients. This will result in greatly restricted access for those Medicare beneficiaries who had their surgeries performed on an in-patient basis.

The Proposed Rule

Genomic Health is pleased that CMS has recognized the archived specimen rule may have "created some unintended consequences, especially in situations in which a specimen is taken in a hospital setting, but then later used for a test after the patient has left the hospital." *Id.* at 49065. As a result, CMS has proposed to change its policy so that the date of service for a test will be the date the specimen for a test was obtained from storage, even if the specimen is obtained less than 31 days from the date it was collected, without violating the unbundling rules. CMS proposes the following additional conditions, however, which must be 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 the collection of the specimen needed for the test and the test is reasonable and necessary.

Id.

Genomic Health greatly appreciates the action that CMS is taking in this area. Genomic Health has several concerns, however, with the CMS proposal.

As noted above, CMS proposes to permit the laboratory to use the date the specimen is obtained from archives so long as the test is ordered at least 14 days following the date of the patient's discharge. Thus, if the patient has surgery on January 1 and is discharged on January 3, if the test is ordered on the 17th or later, the date the specimen is taken from archives will be the date of service. However, if it is ordered between the 3rd and the 16th, it will be billed to the hospital. (Of course, if it were billed later than 31 days from the date of surgery, the date would always be the date that it was removed from archives.)

Unfortunately, this change, while useful, will not eliminate the issues created. First, in most instances, patients do not see their oncologist or the oncologist does not order the test, for more than 14 days following the date of patient's discharge. However, there are situations in which this is not the case. As a result, if the test is ordered, the laboratory would be required to bill the hospital. In order to account for these situations,

laboratories would still be required to have contracts with hospitals to deal with those situations, rare though they may be, where the test is ordered within the new 14-day window. For all of the reasons noted above, however, hospitals are likely to be unwilling to pay for the test.

The likely impact of this change will simply be that physicians will learn they should wait at least 14 days following the date of discharge before ordering the test. Genomic Health will have no control over this eventuality, but it does seem likely that physicians will learn that by waiting 14 days, they can avoid the unnecessary patient hassles that will otherwise result. In those instances, physicians may decide to wait a couple of extra days before ordering the test. Given that the patient is dealing with a potentially life-threatening diagnosis of breast cancer, it seems unreasonable to establish a situation that will force patients to wait even an extra day to obtain results that could relieve them of the concerns associated with their condition. As a result, we do not believe the "14-day window" is practical.

We recognize that CMS has instituted this 14-day window because it wants to ensure that hospitals and laboratories do not abuse or circumvent the bundling rules. That is, it appears that CMS is concerned that hospitals or physicians will simply discharge a patient and then wait a day or two to order the test in order to ensure that it is not bundled into the DRG or PPS payment. We recognize CMS' concern and understand the need for some limitation to deal with these program integrity concerns. We believe there are more targeted, and less blunt, approaches than the 14-day window.

For example, this issue arises for the most part in situations where tissue is being used for the test. If blood or other specimen is used, those are almost always simply

drawn in the physician's office and this concern does not arise. Thus, one limiting fact is that the testing is done either on paraffin-embedded or live tissue. Second, the tests at issue, such as the Genomic Health test, involve analysis of tumor tissue that is used to assess or predict the future course of the disease or future treatment options, such as whether the cancer will recur or if chemotherapy is the best choice for this patient. These types of tests have never been, nor can they currently be, routinely performed in hospitals, nor have their costs been considered as part of the DRG or outpatient PPS systems as they are not related to, or associated with, the hospital procedure/stay or occurrence. Thus, the Genomic Health assay is easily identified as a test that has no relation to the inpatient hospitalization, in that it gives a result that has no ramifications for that admission and cannot be performed by a hospital laboratory.

Given the narrow types of tests involved, Genomic Health believes that these program integrity issues can be addressed more directly. We propose that the limitation be limited to tests which 1)have no impact on the current hospital stay and cannot have any impact (such as the eventual prognosis of the cancer or a predictive test suggesting whether future chemotherapy is necessary) and 2)cannot be performed by the hospital laboratory.

In those situations, carriers would have discretion to utilize a date of service other than the date of collection, such as the date the specimen was removed from archives, or if the specimen was never archived, as in the case of live tissue, the date the surgery was performed. Given the small number of circumstances where this concern arises, we believe this is an appropriate course and will both protect CMS' program integrity concerns and avoid the current logistical issues created by CMS' proposed solutions.

We appreciate the opportunity to comment. If there are any further questions or comments, please do not hesitate to contact us.

Steven Shak, M.D.
Chief Medical Officer
Genomic Health, Inc.

cc: Terry Kay
Liz Richter

GORE
Creative Technologies Worldwide

W. L. GORE & ASSOCIATES, INC.

3750 WEST KILTIE LANE • P.O. BOX 2400 • FLAGSTAFF, ARIZONA 86003-2400
PHONE: 928/779-2771 • MAIN FAX: 928/779-1456 • MARKETING FAX: 928/774-3525

MEDICAL PRODUCTS DIVISION

October 5, 2006

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

Reference: PROVISIONS

The Resource-Based Practice Expense (PE) RVU Proposals for CY 2007 invites comments no later than October 10, 2006. W.L. Gore & Associates would like to take this opportunity to offer comments in regards to the payment for splint and cast supplies.

We agree with the recommendation to keep payment for casting and splinting supplies separate from the PE component of the PFS. We also support the continued use of HCPCS Q Codes for the billing of casting and splinting supplies. The continued use of Q Codes will reduce confusion and help standardize local practice regarding the separately billable status for such supplies. Our experience has been that many healthcare providers are not aware that casting supplies can be billed separately; therefore, we would also like to suggest that CMS re-educate providers through *MedLearn Matters* articles and local Carriers.

The Proposed Rule includes a list of casting and splinting supplies that will continue to be paid separately using Q Codes and that will not be included in the PE database upon adoption of the Proposed Rule. There are many different supplies utilized in the treatment of fractures and dislocation. The list in the Proposed Rule includes many of them, such as "Kerlix" (KERLIX® Lite Gauze Bandages and "Webril" (WEBRIL II® Cotton Under Cast Padding). As previously noted in the Final Rule published in the Federal Register November 1, 2000 (65 FR 65396), we would like to suggest that GORE PROCEL® Cast Liner cast padding be added to the list. This will further help reduce billing/reimbursement questions when using this type of cast padding material. Adding GORE PROCEL® Cast Liner to the list will clarify that the item is not in the PE expense database, as well as prevent incorrect interpretation about products that are not specifically included in the list and their *continued* ability to be billed with a Q Code.

I am available by telephone or e-mail to answer any questions or provide further information.

Sincerely,

Trish Martinell

Trish Martinell
W.L. Gore & Associates, Inc.
tmartine@wlgore.com
928.864.2066

HEMMO A. BOSSCHER, M.D., P.A.

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October 2, 2006

Mark B McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8017

Re: CMS 1321-P

Dear Dr. McClellan,

I would like to make a few comments with respect to the proposed rule on the Medicare Physician Fee Schedule for the Calendar Year 2007. With the aging population, treatment of moderate to severe chronic pain will put significant demands on our resources (Medicare).

Methods of treatment consist of medication, interventional pain management or observation. Treatment with medications will consist of prescribing time contingent narcotics. Even though this is of great interest to the Pharmaceutical industry (through Medicare D), it has significant ethical, financial and medical problems associated to it.

Appropriate interventional pain management targets the pain problem directly. It is more effective and provides better patient satisfaction. It is also a cheaper solution. However, it comes with certain expenses in the office. In addition, Interventional pain management involves treatment of neural elements with all its associated risks. Inadequate reimbursements for the physician may lead to the third solution which is observation, since pharmaceutical therapy alone is not a viable alternative in many pain management clinics.

Sincerely,

Hemmo A. Bosscher, M.D., P.A.

Pain Management
3505 22nd Place • Lubbock, TX 79410
phone (806) 785-5700 • fax (806) 785-6768

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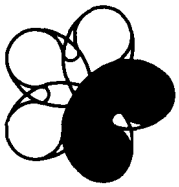

National Kidney Foundation™

October 4, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS - 1321 – P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Sir or Madam:

The National Kidney Foundation (NKF) is America's oldest and largest voluntary health organization serving the needs of kidney patients. In addition to kidney patients, our 50,000 members include health care professionals who deliver kidney care services, loved ones of kidney patients, and concerned members of the lay public, from every walk of life, and every part of the country. I am responding to the Proposed Rule: "Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B" (***Federal Register***, August 22, 2006, CMS – 1321- P) on behalf of this diverse constituency, in general, and, in particular, representing the 1,450 dietitians who are members of the National Kidney Foundation (NKF) Council on Renal Nutrition (CRN).

Malnutrition is a major cause of morbidity in dialysis patients and nutritional counseling for patients with chronic kidney disease, before they need dialysis, can have a positive impact on outcomes after dialysis is initiated. In addition, protein and mineral controlled diets, designed and monitored by dietitians, can help to delay progression from chronic kidney disease to end stage renal disease and prevent related complications.

For these reasons, NKF supported the provision in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106-554) that authorizes Medical Nutrition Therapy (MNT) for Medicare beneficiaries with chronic kidney disease. (This benefit does not include Medicare beneficiaries receiving dialysis since they are entitled to MNT services pursuant to the composite rate for dialysis treatments.) MNT is defined as the assessment of nutritional status and the provision of nutritional counseling by a registered dietitian or nutrition professional. Medical Nutrition Therapy provides chronic kidney disease patients with the tools they need for self management.

However, since the Medical Nutrition Therapy benefit became effective on January 1, 2002, NKF has been disappointed with its utilization. It is estimated that less than $1 million was expended for individual and group MNT services

during the first year of coverage. Analysis of CMS data by the American Dietetic Association indicates Medicare Part B MNT costs of approximately $3.3 million over 2003-2004. Conversely, the Congressional Budget Office projected $60 million annual outlays for this program.

Access to MNT has been circumscribed by the limited number of dietitians willing to participate in this program. Another problem has been the paucity of institutional settings where MNT services can be delivered. Therefore the National Kidney Foundation supports those aspects of the Proposed Rule that address these problems.

First of all, CMS proposes to establish, for the first time, work relative values for the MNT procedure codes that registered dietitians use in providing these services to Medicare beneficiaries with chronic kidney disease. This should provide an incentive for dietitians to continue to provide MNT services, as well as attract more dietitians to MNT practice, and, thereby, improve access to this benefit for Medicare beneficiaries with chronic kidney disease. NKF encourages CMS to carefully review the work values established for the MNT and the MNT G HCPCS codes. The work values should reflect the detailed and complex cognitive and behavioral therapy components inherent in MNT services.

NKF also endorses the proposal to amend section 405.2446 (b) to expand the scope of Federally Qualified Community Health Center (FQHC) services to include certified providers of MNT services, to expand the definition of an FQHC visit to include MNT Services, and to permit a separate additional FQHC visit for MNT services on the same date of service when the beneficiary received care from their FQHC physician or non-physician practitioner, when reasonable and necessary. Since the burden of chronic kidney disease is disproportionately higher among African Americans and Hispanic Americans, and since both of these groups are served by FQHCs, once finalized this proposal should also serve to expand access to MNT for Medicare beneficiaries with chronic kidney disease.

Sincerely,

David G. Warnock, MD
President, National Kidney Foundation
Professor and Director
Division of Nephrology
Department of Medicine
University of Alabama at Birmingham

National Kidney Foundation

October 3, 2006

Centers for Medicare and Medicaid Services
HIPAA TCS Enforcement Activities
P.O. Box 8030
Baltimore, MD 21244-8030
HIPAAComplaint@cms.hhs.gov

Questions: Michael Phillips
(410) 786-6713

Dear CMS;

In September 2006, the National Council for Prescription Drug Programs (NCPDP) received a notice of a complaint filed against it (Reference Number: 06-TCS-01197). The complaint alleges that

> "The NCPDP Telecommunications Standard, Version 5.1, for retail pharmacy prescription drug claims contains standards for reporting and transacting pharmacy professional services using NCPDP-derived PPS codes. The HIPAA Transaction and Code Set Rules designated X12N, Version 4010, Health Care Claim Professional (837), Volumes 1 and 2, and Addenda, Version 4010A1, for all professional health care services claims using HCPCS codes and the CPT-4 codes for health services. The NCPDP is also supporting and distributing an Implementation Guide specifically for the implementation of pharmacy professional services using the NCPDP PPS codes. This appears to be a HIPAA violation.."

Per the letter, NCPDP is responding with the demonstrations cited by the OESS letter.

NCPDP is not a covered entity.
NCPDP is a standards development organization. NCPDP is not a covered entity as defined in Section 160.103 Definitions of 45 CFR Parts 160 and 162 Health Insurance Reform: Standards for Electronic Transactions.

A History of Industry Stakeholder Activities Related to Professional Pharmacy Services.

Health Claims and Equivalent Encounter Information – Professional Pharmacy Claims

> **9/2000 Update** - The Standards for Electronic Transactions final rule incorrectly stated that NCPDP Telecommunication Standard Version 5.1 could not support the billing of professional pharmacy services since it did not support HCPCS J-codes to identify the pharmacy procedure or service. **However in another section, it listed qualities of the NCPDP Telecommunication Standard, which includes professional pharmacy services.** Refer to page 50331 of the Federal Register Volume 65, No.160.
>
> The NCPDP Telecommunication Standard Version 5.1 clearly supports HCPCS J-codes as a qualifier. The rule named the ASC X12N 837 Health Care Claim: Professional, Version 4010 transaction. NCPDP members requested a change and continue to work to have Telecommunication V5.1 and Batch 1.0 (revised 1.1) added for retail pharmacy professional services.
>
> > **3/13/2001 Update** – HHS asked for assistance in defining professional pharmacy services. NCPDP's Work Group 10 Professional Pharmacy Services created a task group to assist in defining professional pharmacy services and provided the definition to HHS.

National Council for Prescription Drug Programs, Inc. ◆ 9240 East Raintree Drive ◆ Scottsdale, Arizona 85260-7519
Phone (480) 477-1000 ◆ Fax (480) 762-1042 ◆ www.ncpdp.org

7/28/2001 Update – NCPDP Work Group 10 Professional Pharmacy Services created a White Paper on the usage of the NCPDP transactions and the ASC X12N 837, as appropriate for billing of professional services. The recommendation is NCPDP Telecommunication Standard Version 5,1, Batch 1.1, and ASC X12N 837 Health Care Claim: Professional, Version 4010 are all appropriate transactions for billing professional services, for different business practices.

12/21/2001 Update – The white paper on billing of professional pharmacy services was submitted to HHS/CMS on October 1, 2001. NCPDP members continue discussions with CMS (Center for Medicaid and Medicare Services) for the naming of NCPDP Standards for billing of professional pharmacy services. In addition, member companies are working with other healthcare associations, government representatives and political contacts to support the NCPDP Standards for billing of professional pharmacy services. The paper can be viewed at http://www.ncpdp.org/frame_members_government_hipaa.htm

2/4/2002 Update – The white paper was shared with the DSMO for discussion within their organizations.

2/14/2002 Update – Change Request #574 was added to the DSMO Change Request System to request support for the NCPDP Standards for the billing of professional pharmacy claims.

4/31/2002 Update – Change Request #574 is adjudicated by the DSMO. Letters of support and letters of disapproval have been received by HHS and the DSMO. Discussions with industry stakeholders occurred as the DSMO adjudicated the request. In addition, support of the NCPDP Standards for use in professional pharmacy services when part of the pharmacy benefit, will be included in the NCPDP response to the correction NPRM.

7/15/2002 Update – Change Request #574 was published with the DSMO categorization of **"No Change"** and the recommendation of:

> **"The DSMO recommend that these types of claims should continue to be submitted as they are currently being submitted."**

2/20/2003 Update – The Final Rule incorrectly states that the DSMO are still evaluating a Change Request on the billing of professional pharmacy services. The DSMO completed their recommendation on the Change Request (see 7/15/2002 Update above). The Rule states that further guidance will be provided.

8/25/2003 Update – No official guidance on supplies or professional services has been issued. It may be published in a Spring 2004 NPRM as noted in the "Regulations Status".

9/16/2004 Update – No official guidance on supplies or professional services has been issued. It may be published in a Spring 2005 NPRM as noted in the "Regulations Status".

7/24/2005 Update – No official guidance on supplies or professional services has been issued. Other items have been added to CMS' list of what might be included in an NPRM and the date has been pushed out. It may be published in a Spring 2006 NPRM as noted in the "Regulations Status". With the advent of Medicare Part D providing medication therapy management, the item is once again under discussion at NCPDP's Work Group 10 Professional Pharmacy Services.

Professional Pharmacy Services Implementation Guide:

NCPDP does in fact support and distribute an Implementation Guide specifically for the implementation of pharmacy professional services using NCPDP PPS codes. The Professional Pharmacy Services Implementation Guides have been published by NCPDP in three different versions in July 1997, June 2000 and November 2003 in support of major revisions of the NCPDP Telecommunication Standards. Two of these versions were published before the publication of HIPAA TCS Rules. Since this point, the Professional Pharmacy Services Implementation Guide was incorporated into the Telecommunication Standard Implementation Guide.

It should be noted that since NCPDP Telecommunication Standard Version 3.2 (1992), the billing for services has been supported. The Telecommunication Standard Implementation Guide Version 5.1, named in HIPAA, specifically provides information on the billing of professional pharmacy services. The following is just one excerpt.

> **"Billing (Transaction Code B1)**
>
> Billing transactions require the submission of the following segments: header, insurance, claim and pricing. Up to four transactions per transmission are permitted, except for compound billings. Only one transaction per transmission is allowed when billing for a multi-ingredient prescription.
>
> In Version 5.Ø & 5.1, billings may be for products dispensed, DUR conflict resolution, or professional services rendered. Services may be correlated with a dispensing event or may be separate and unrelated to any particular prescription. Professional pharmacy services may include but are not limited to blood pressure monitoring, taking a patient history for a new disease or diagnosis, referring patients to other health care providers and counseling and education beyond the simple act of describing a medication's use and side effects."

NCPDP member organizations are ***still*** waiting on the NPRM to address the pharmacy DSMO Change Requests on professional pharmacy services and the billing of supplies. While NCPDP is not a covered entity and therefore not in violation of the Standards for Electronic Transactions, entities that submit and adjudicate professional pharmacy services have invoked contingency plans until the final rule is published addressing the industry's concerns.

In addition, NCPDP's Work Group 10 Professional Pharmacy Services continues to work with industry representatives and to provide guidance on the billing of medication therapy management services under Medicare Part D.

Any correspondence regarding this matter should be sent to
Lynne Gilbertson
Director of Standards Development
1803 Longview Drive
Mt. Juliet, TN 37122
(615) 754-0445
lgilbertson@ncpdp.org

Sincerely,

Lee Ann C. Stember

Lee Ann Stember
President
NCPDP
9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000
lstember@ncpdp.org

cc: NCPDP Standardization Co-Chairs

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6 Chestnut Street
Darien, Ct. 06820-4208
October 3, 2006
203-655-4124

Dr. McClellan, do you also have opinion?

Allen J. Taylor, M.D. FACC
American College of Cardiology
Heart House
2400 N Street NW
Washington, DC 20037

Dear Dr. Taylor,

Can you state the College's position on use of the 64 slice CT scan versus hospitalization?

Medicare is currently one of the few insurers covering this procedure, at a cost of approximately $1215.00, ($615 test, and $600 radiologist fee).

In an instance where a patient has gone to the ER with chest pains and numbness of hand, and EKG and preliminary enzymes tests, as well as most recent echocardiogram, show no major problem, is it not cost effective and good medicine to do the CCTA prior to hospital admittance?

It would seem Medicare is covering this test for cost effectiveness, and there are varying opinions among cardiologists as to use of the CCTA. So many complain about rising Medicare costs due to number of beneficiaries, which will continue to rise with aging Baby Boomers, that it would seem if costs can be cut, more people will be served, especially in instances where Medicare beneficiaries cannot afford the monthly Medigap premiums and do not have secondary insurance, yet do not qualify for programs such as Medicaid or QMB as supplemental coverage.

Does the College have a position statement on use of the 64 slice CT scan for Medicare beneficiaries prior to admittance to hospital?

Thank you in advance.

Sincerely,

Kathleen A. Bernadette, SFO

80

American Academy of Sleep Medicine

October 2, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1321-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: IDTF ISSUES

To Whom It May Concern:

The American Academy of Sleep Medicine (AASM), the professional medical society for clinicians, researchers and other health care providers in the field of sleep medicine, applauds CMS and their recommendation to incorporate supplier standards that Independent Diagnostic Testing Facilities (IDTF) must meet in order to obtain or retain their enrollment in the Medicare program. The AASM supports supplier standards that will protect and continue to allow Medicare beneficiaries to receive the highest quality of care.

As the national accrediting body for sleep disorders centers and sleep related breathing laboratories, the AASM is dedicated to setting standards and promoting excellence in sleep medicine health care, education and research. The AASM is acutely aware of IDTF's operating within the health care arena of diagnosing sleep related disorders. While many of the IDTF's operating in this sector are accredited by the AASM and meet the highest quality of standards relevant to the field of Sleep Medicine, we are cognizant of patients being seen in diagnostic facilities that stretch the standards set by State, Federal and local laws or AASM accreditation.

As patient demand increases it is possible for the safety of Medicare beneficiaries to be compromised. As a result of the increasing threat to patient safety the AASM requests that CMS incorporate into their final rule the requirement that those IDTF's who are providing sleep medicine diagnostic services to Medicare beneficiaries be accredited by the AASM.

Standards of AASM accreditation strictly adhere to evidence based practice parameters and are updated as new innovations and principles emerge in the field. Physicians at AASM accredited facilities must make recommendations consistent with evidence based standards of care and also regularly update their knowledge of sleep medicine by taking part in professional CME activities. Accreditation by the AASM assures quality patient care through comprehensive clinical evaluation and treatment by properly trained and educated staff.

One Westbrook Corporate Center, Suite 920, Westchester, IL 60154
Phone: (708) 492-0930, Fax: (708) 492-0943
www.aasmnet.org

Over the past several years there has been an increase in the amount of Medicare Local Coverage Determinations revised that require AASM accreditation as a prerequisite for reimbursement of sleep disorder testing. Medicare Region IV requires that a freestanding "center/laboratory must be accredited by and comply with the standards set by the AASM."

The accuracy of diagnostic sleep studies depends on the knowledge, skill, and experience of the technologist and the physician interpreting the studies. As a result IDTF's, centers and laboratories that specialize in sleep diagnostics must be capable of demonstrating documented training and experience. AASM accreditation provides patients the confidence that they are being treated by the highest qualified individuals for their sleep related disorder.

For your reference we have attached a copy of the AASM accreditation standards for your review. To further discuss our comments please contact AASM Government Relations Coordinator, Michael White at (708)492-0930 or mwhite@aasmnet.org.

Thank you,

Michael H. Silber

Michael Silber, MBChB
President

Vrajlal Rajyaguru
505W Vine Street, #301
Kissimmee, FL 34741-5055

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September 23, 2006

[recipient address was inserted here]

Dear Sir / Madam.

As a physician who takes care of Medicare beneficiaries and other patients, I write to urge you to take steps to prevent the scheduled 5.1% decrease to Medicare reimbursement for physicians in 2007. The impending physician payment cuts would be extremely detrimental to my practice and the patients I treat.

Currently, physician payment updates are driven by a flawed formula called the Sustainable Growth Rate (SGR). Instead of the SGR, payment updates should be based on increases in practice costs. If Congress does not pass legislation this year, Medicare payments to physicians will be cut by 5.1%. Some physicians may face cuts as high as 38% as CMS is using bottom-up methodology in calculating practice expense and improving reimbursement for evaluation and management services.

For years physicians have operated under a Medicare reimbursement system that does not keep track with inflation. While we support higher payment for evaluation and management services, substantial cuts in other areas are not acceptable. Physicians cannot continue to operate in an environment of such uncertainty, and as a result more and more doctors are electing to stop taking on additional **Medicare** patients, and an even more threatening issue, all other payers follow Medicare.

Congress must deal with this critical issue before it recesses for the elections. It is extremely frustrating to fight this battle each and every year. Please replace the 5.1% cut with a positive update that reflects increases in practice costs and stabilize Medicare physician payments.

Please take action to prevent these scheduled cuts to Medicare reimbursement for physicians and protect beneficiary access to healthcare.

Sincerely,

Vrajlal Rajyaguru, MD
(407)935-9404

C. Thomas Crooks, III, O.D.
President

American Optometric Association
243 N. Lindbergh Blvd • St. Louis, MO 63141 Blvd • (314) 991-4100
FAX: (314) 991-4101

October 3, 2006

The Honorable Mark McClellan, MD, PhD
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: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule (PFS) for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Doctor McClellan:

On behalf of its nearly 36,000 members, the American Optometric Association (AOA) is pleased to submit these comments related to the August 22, 2006 *Federal Register* publication of the proposed rule making revisions to payment policies under the Medicare physician fee schedule for calendar year 2007 and other changes to payment under Medicare Part B. In addition, we refer below to a fact sheet issued by CMS at the time the above proposed rule was issued, which announced CMS' plans to use new productivity data developed by the Bureau of Labor Statistics (BLS) in determining the 2007 Medicare Economic Index (MEI). This fact sheet notes that these new data, together with lower projections of inflation, are expected to lower the update factor under the Medicare physician fee schedule by 0.5 percentage points below the estimate contained in the President's Budget (to a negative 5.1 percent).

IMPACT

The proposed rule provides the usual impact analyses, which, among other things, assume that the physician fee schedule update factor for 2007 will be a negative 5.1 percent. A footnote accompanying one of the impact tables alludes to the fact that a new series of productivity data developed by the BLS will be used for the first time in calculating the MEI, and refers readers to the fact sheet mentioned immediately above. The proposed rule provides no other discussion of the factors that will affect the update factor for 2007. In contrast, the proposed rule published August 8, 2005 included a section devoted to sustainable growth rate (SGR) issues and inviting comments on them.

We believe that the proposed rule should have more explicitly discussed the changes being contemplated in calculating the update factor for 2007, especially since the planned changes in data and inflation assumptions would produce a further reduction in an update factor that is already slated to be significantly negative. This would have allowed CMS to more properly and more fully describe the new productivity data set and the changed inflation assumptions now being contemplated, state its belief that the agency has no alternative but to adopt the new BLS data set, and invite public comments on these issues. We believe that CMS' failure to do this is most unfortunate.

Much more importantly, AOA remains deeply concerned about the negative consequences that could arise with continued use of a flawed formula for updating the physician fee schedule conversion factor. Under the current SGR-based update formula, a negative update for 2007 would be followed by negative updates for many years to come. Reductions in Medicare payment rates for physicians' services, including those provided by the nation's optometrists, would contrast rather awkwardly with the rising costs of running an optometric practice (for example, the salaries and fringe benefits of professional, technical and administrative staff, office rents, the costs of supplies and equipment, rising energy costs, etc.), not to mention increases in inflation in the economy at large.

Data from the Medicare Payment Advisory Commission (MedPAC) suggest that some part of the recent growth in Medicare spending on physicians' services is associated with improved quality of care. The current Medicare physician payment update formula cannot coexist with a payment system that rewards improvement in quality. Incentive programs rewarding quality performance depend on greater physician adoption of information technology at a greater cost to physician practices. The flawed Medicare payment formula makes it difficult for physicians to make these health information technology investments.

Further, recent survey data suggest that sharp cuts to Medicare payment rates could soon affect physicians' willingness to accept new Medicare patients, or even to continue to care for established Medicare patients. Moreover, this past June, the Center for Studying Health System Change issued a report documenting the fact that average physician net income from the practice of medicine had declined about 7 percent between 1995 and 2003, after adjusting for inflation. This report went on to note that this decline "stands in sharp contrast to the wage trends for other professionals" and "likely is an important reason for growing physician unwillingness to undertake pro bono work, including charity care and volunteering to serve on hospital committees." All of this bodes ill for the longer-term.

This is why AOA believes very strongly that the current flawed update formula under the Medicare physician fee schedule needs to be permanently replaced by a methodology that properly takes into account the rising costs of caring for Medicare beneficiaries. We, therefore, urge CMS to work with the Congress to adopt a more reasonable update policy before the end of this calendar year, in time to affect the 2007 Medicare update factor.

PROVISIONS

Resource-Based Practice Expense (PE) RVU Proposals for CY 2007

AOA was pleased to see that information previously submitted regarding the pricing of certain supply and equipment items (nose pads, SJ076, and radiuscope, EQ271) was adequate to meet CMS's needs. This removes the risk that CMS might otherwise delete such items from its practice expense data base.

We hope the preceding comments are helpful. If you or your staff have any questions about them or would like AOA to be of additional assistance, please contact Ms. Kelly Hipp, Director of Professional Relations. Ms. Hipp can be reached at 703 837-1346 or email at KHipp@aoa.org.

Sincerely yours,

C. Thomas Crooks, III, OD

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American
Academy of
Home Care
Physicians
ACADEMY of HOME CARE
AMERICAN PHYSICIANS

October 5, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS—1321P
PO Box 8015
Baltimore, MD 21244-8015

Dear Dr. McClellan,

The American Academy of Home Care Physicians is pleased to submit these comments on the second proposed physician payment schedule rule released this August. The Academy represents physicians and other providers dedicated to provide house calls to some of Medicare's frailest and sickest beneficiaries.

Our comments follow those made earlier in response to the first proposed rule.

First, we want to briefly reiterate the introductory comments made in the first letter. We think attention to house calls is imperative for reasons of access to care, maintenance of quality and cost savings. Consideration of our proposal is also consistent with the primary care emphasis of this year's five year review. Finally, the changes to the house call codes would represent internal consistency within CMS and will support currently operating demonstrations which, we are confident, will further illustrate the cost and care effectiveness of house calls.

Second, we will make a substantive proposal for valuing work for house call and domiciliary care codes, 99341-99350 and 99324-99337 discussed with CMS staff by conference call, and note for the record PE corrections already reported to, and we understand changed by CMS staff.

1. **Work Values**

In our last letter, we argued that the work adjustments developed through the 5-year review process should apply equally to patients seen in their homes or

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in community-based congregate settings. We asked that work values for domiciliary care and home visit codes be adjusted upward on a percentage basis to reflect the newer values for comparable office codes, despite the fact that they were not part of the five-year review process, because the policy of CMS had been to use office visit codes as the base reference for these codes. Otherwise the actions of CMS will create code family anomalies that its efforts were intended to rectify.

The change is consistent with past CMS policy as this excerpt from the 1996 5-year review of the relationship of home care and domiciliary care services to other E/M services illustrates: (p. 20038 of May 3, 1996 Federal Register):

> **"CPT codes 99341 through 99353 (Home Services)**
>
> Our view is that the current relationship between the work RVUs for home visits and office visits should be maintained. The May 1992 refinement panel equated the home codes to office visit codes. Our position is that a home visit takes longer to furnish than a service with a similar content (level of history, examination, and medical decision making) in an office setting, thus, the home visits are equated with office visits of greater length. Therefore, we assigned new work RVUs to the home visit codes using the following relationships with the new work RVUs for office visits:
>
> <u>New patients:</u>
>
> CPT code 99341=CPT code 99203
> CPT code 99342=CPT code 99204
> CPT code 99343=CPT code 99205
>
> <u>Established patients:</u>
>
> CPT code 99351=CPT code 99213
> CPT code 99352=CPT code 99214
> CPT code 99353=CPT code 99215"

In 2005, the RUC approved and CMS accepted the policy that work and PE values for domiciliary care codes should be the same as for house call codes. We therefore request the same adjustment for work values be made to the current domiciliary care codes as are made as for house call codes.

The specific changes we propose are included in the table attached to this letter. You will note that no specific values are proposed for the highest level home visit new and established patient codes. This is because CMS assigned those values in 1997, using their sense of correct proportionality. We would suggest that, especially for the highest value established patient code, the trend line be used to pick a percentage by which to increase the work value. This is because this code is especially for care considerably beyond that of office practice.

2. Practice Expense

We agree with the CMS position to use direct inputs consistent with RUC/PEAC decisions. However, as reported to CMS staff, 99341, 99342 and 99343 and still missing 6 minutes each for pre-visit time. Also, 99341 is still missing SM025—specula tips, otoscope. We trust that these problems will be fixed in the final rule.

Conclusion

We believe our suggested actions are consistent with CMS' commitment to increased access to improved chronic care. Albeit of minimal economic impact per se, these changes will have tremendous significance to the house call physician industry struggling to grow within CMS guidelines. The changes will lead to better care for Medicare's sickest and frailest beneficiaries cared for both in fee for service and demonstration house call programs.

Please contact Constance Row, Executive Director AAHCP via email at aahcp@comcast.net or at 410-676-7966 for further information.

Sincerely,

Gresham Bayne, MD
President

AAHCP Proposed Work RVU Changes for Homecare and Domiciliary Codes										
HCPCS	Description	2006 Work RVU	2007 Work RVU Proposed (No budget neutrality adj)	Percent increase	Comp. Home Visit Codes	2006 Work RVU	2007 Work RVU AAHCP Proposal (No budget neutralityadj)	Comp. Domiciliary Visit Codes	2006 Work RVU	2007 Work RVU AAHCP Proposal (No budget neutralityadj)
99201	"Office/outpatient visit, new"	0.45	0.45	0.0						
99202	"Office/outpatient visit, new"	0.88	0.88	0.0	99341	1.07	1.07	99324	1.07	1.07
99203	"Office/outpatient visit, new"	1.34	1.34	0.0	99342	1.52	1.52	99325	1.52	1.52
99204	"Office/outpatient visit, new"	2	2.3	15.0	99343	2.27	2.61	99326	2.27	2.61
99205	"Office/outpatient visit, new"	2.67	3	12.4	99344	3.03	3.40	99327	3.03	3.40
					99345	3.78	*	99328	3.78	*
99211	"Office/outpatient visit, est"	0.17	0.17	0.0						
99212	"Office/outpatient visit, est"	0.45	0.45	0.0						
99213	"Office/outpatient visit, est"	0.67	0.92	37.3	99347	0.76	1.04	99334	0.76	1.04
99214	"Office/outpatient visit, est"	1.1	1.42	29.1	99348	1.26	1.63	99335	1.26	1.63
99215	"Office/outpatient visit, est"	1.77	2	13.0	99349	2.02	2.28	33336	2.02	2.28
					99350	3.03	*	33337	3.03	*
* CMS determination										

84-0
3

THE DIGESTIVE HEALTH CLINIC

Boise Gastroenterology Associates, P.A. & Idaho Endoscopy Center

September 22, 2006

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Dr. McClellan:

I am a private practice gastroenterologist who treats many Medicare patents. I am writing to express my grave concern with CMS's recent proposal to cut facility fees for endoscopies performed at ambulatory surgery centers.

In my practice, we see a large number of Medicare patients. Much of what I do is prevention colonoscopies for those who are at average risk for colorectal cancer, as well as colonoscopies for high risk patients who have been found to have polyps or cancers previously. Also, I see a lot of patients with other conditions—GI bleeding, inflammatory bowel disease, gastroesophageal reflux disease (GERD), and/or Barrett's esophagus for whom ready access to an appropriate, safe, cost-efficient site for GI endoscopy is critical.

Not incidentally, both the GAO and CMS have stated that the Medicare colorectal cancer screening benefit is underutilized. So, a proposal that pays ASCs significantly less than hospitals will reduce my ability to provide screening colonoscopies and other GI endoscopic procedures by forcing me to decrease the number of Medicare beneficiaries I see in my ASC because Medicare's payment level would drop so much that I would no longer be able to meet my expenses and render any reasonable return on investment.

Medicare seems to be ignoring both the stated priorities of the current Administration as well as the lessons of cost management in the private sector. ASCs are a more cost-effective environment than the hospital to receive key medical services. I know I charge patients much less for an endoscopy at my ASC that they're charged by hospitals for the same procedures. In fact, when private sector insurers have sought to reduce total health care costs, they have actively sought to encourage patients to receive their services in the ambulatory surgery center instead of in the hospital outpatient department. In a recent example, Blue Cross of California has announced that it will pay a 5% premium to physicians for

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every GI endoscopy that is performed in the ASC rather than in a hospital. This CMS proposal, which would always pay significantly more to hospitals and less to ASCs, is directly antithetical to the direction adopted by the private sector insurers.

The reality is that for every single case that moves from the hospital to the ASC under this expansion of the ASC approved list, the Medicare program will save money. This is so because at the current rates, ASC payments are always lower than, or at least never greater than the facility fee that CMS pays to hospitals.

Today, when a GI procedure such as a screening colonoscopy is performed in an ASC, that ASC receives a facility fee which on the average amounts to 89% of the facility fee the hospital gets for that same procedure. Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit.

Sadly, CMS has done everything possible to emasculate the utilization of that benefit. Since 1997, CMS has cut the physician fee schedule payment for screening/diagnostic colonoscopies by almost 40%--from a little over $300, to the current level of just around $200, and trending downward (these are raw dollars—if inflation were factored in the reduction would almost certainly be in excess of 50%). According to information from the American College of Gastroenterology, no other Medicare service has been cut this much.

Now, CMS issues a new proposal which would further undercut the prospects for Medicare beneficiaries to receive a colorectal cancer prevention colonoscopy. In terms of the specialty that would be hurt the most by the current proposal, once again, CMS has placed gastroenterology and colonoscopies for colorectal cancer screening in its cross hairs with the prospect of cuts from 89% of the hospital payment to 62%.

If CMS is bound to peg ASC payments at a percentage of hospital facility fees, it must adopt a bi-level approach, with ASCs in groups like GI and pain management at a higher tier of payment that is at or higher than the 89% we now receive, and then a second, lower tier as the facility fee percentage for ASCs in other specialties, which are not involved in life-saving preventive services such as colorectal cancer screening tests.

Here's what will happen if this CMS proposal is adopted:

For Patients:

Utilization of the Medicare colorectal cancer prevention benefit will be further devastated—the collision of false payment "savings" vs. sound preventive public health policy will be dramatic. Utilization of CRC screening will decline even more, cancers will go undetected, and many Medicare beneficiaries

will die unnecessarily because access to colonoscopy will be reduced as GI ASCs close, waiting times for screening will increase, and the overall rate of CRC screening will plummet farther.

For the Medicare System:

Medicare facility fee payments for GI services will increase, rather than decrease. Having dealt a death-blow to many GI ASCs by draconian reductions in payments, access of Medicare beneficiaries to GI ASCs will be markedly reduced. CRC screening colonoscopies will drop, but the volume of diagnostic colonoscopies and endoscopies will not decline.

With fewer participating ASCs, a larger proportion of all GI procedures will need to be performed in hospitals, where the facility fees CMS pays will be higher. So, total Medicare costs for GI facility fees will rise (although the per unit facility fee for decreased number of these performed in the ASC may well decline); available access by Medicare beneficiaries for GI procedures will decline; and more Medicare beneficiaries will die unnecessarily from colorectal cancer will increase as screening rates decline.

It is hard to believe that these are the results that CMS is seeking, but the only way to avoid this outcome is to modify this proposal so as to increase, not decrease, the facility fees to GI ASCs. This will avoid the closure of GI ASCs, and thus avoid a reduction in access and CRC screening rates. It will also prevent an increase in the number of GI procedures performed in the more costly hospital setting.

Respectfully submitted,

Robb Gibson

Robb F. Gibson, M.D.

85-07

Mark McClellan, MD
CMS - DEPT HHS
Attn: CMS-1506-P and CMS-1512-PN
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan,
As a U.S. citizen and taxpayer, I wish to voice my concern and opposition to the Center for Medicare and Medicaid (CMS) proposal to reduce the Medicare fee schedule. I also want to express my concern and opposition to the change in the payment structure for facility fees at ambulatory surgery centers (ASCs). It is unrealistic to reimburse ASCs 62% of what a hospital outpatient department gets reimbursed for performing the same service. I am especially concerned about CMS attempting to create incentives to steer patients from freestanding centers back into the more costly and less patient-friendly hospital environment. CMS should suspend its plans to implement the proposed changes and defer indefinitely the proposed new ambulatory surgery rules.

Sincerely,
(Name) Daniel J. McBride

(Address) 198 Sylvania Dr.

(City/State/Zip) Pgh PA. 15236-3535

NATIONAL OSTEOPOROSIS FOUNDATION

Standing Tall For You®

October 4, 2006

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
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 Rule

Dear Administrator McClellan:

Introduction

On behalf of the National Osteoporosis Foundation (NOF), thank you for the opportunity to comment on the Center for Medicare and Medicaid Services (CMS) Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B and the Proposed Rule. This letter's comments address "BONE MASS MEASUREMENT TESTS."

NOF is the nation's leading voluntary health organization solely dedicated to osteoporosis and bone health. Its mission is to prevent osteoporosis, promote lifelong bone health and help improve the lives of those affected by osteoporosis and related fractures and find a cure. NOF achieves its mission through programs of awareness, advocacy, public and health professional education and research. NOF is a leading authority for anyone seeking up-to-date, medically sound information and educational material on the causes, prevention, detection and treatment of osteoporosis.

In the United States, osteoporosis is a public health threat for 44 million Americans, 55 percent of the people 50 years of age and older. Ten million Americans are estimated to already have the disease and almost 34 million more are estimated to have low bone mass, placing them at increased risk for osteoporosis. Of the ten million Americans with osteoporosis, eight million are women and two million are men.

Osteoporosis often is called a "silent disease" because bone loss occurs without symptoms. People may not know that they have osteoporosis until their bones become so weak that a sudden movement causes a fracture or a vertebra to collapse. Collapsed vertebrae initially may be felt or seen in the form of severe back pain, loss of height, or spinal deformities such as stooped posture.

BONE MASS MEASUREMENT TESTS

NOF is pleased that Medicare is updating and finalizing the "Medicare Coverage of and Payment for Bone Mass Measurements" interim final rule it published June 24, 1998 because it is vital that Medicare coverage keep up-to-date with the scientific evidence on the prevention, assessment, and diagnosis of osteoporosis, a pervasive disease that often can have severe consequences. From its inception, NOF has advocated for appropriate Medicare coverage of bone mass measurement (BMM).

Definition
NOF agrees with CMS on the new definition of BMM and its reasoning that newer techniques of dual energy x-ray absorptiometry (DXA) are superior to single photon absorptiometry (SPA).

Conditions for coverage
NOF agrees with the newly proposed conditions for coverage as they incorporate current scientific evidence on using central DXA as the preferred measurement of bone mass density (BMD) in diagnosing and monitoring the effects of therapy and allow for future evidence to be incorporated, too.

Standards on frequency of coverage
NOF generally agrees with the proposed standards on frequency of coverage, but it has one area that it would like to clarify. One of the categories for beneficiaries who can be covered is an individual with primary hyperparathyroidism. According to the US Surgeon General's Report, this disease is relatively common in older people, especially postmenopausal women. "Typically cortical bone (for example, in the distal forearm) is affected to a greater extent than trabecular bone (for example, in the spine) in primary hyperparathyroidism (Silverberg et al. 1989). It is presumed that the reduction in bone mass is associated with the increased risk of fracture seen in these patients (Khosla and Melton 2002)."[i] A recent study in 2006 states: "Indeed, the distal part of the limbs are the most affected areas in PHPT (primary hyperparathyroidism) whatever the amount of cortical or trabecular bone."[ii]

Therefore, NOF proposes adding an exception under standards for frequency of coverage 410.31 (c) (2). This exception would describe an individual with primary hyperparathyroidism being covered when tested initially with DXA at the axial skeleton (hip and spine) under HCPCS 76075 (Healthcare Common Procedure Coding System) and at the appendicular skeleton (peripheral) (for

example, radius, wrist, and heel), under HCPCS 76075, to diagnose whether he or she has osteoporosis. Because there is a preferential loss of cortical bone in hyperparathyroidism, the results of testing bone density at one peripheral bone site (e.g. forearm) in addition to the hip and spine at the time provides a better picture of certain patients' actual medical condition. Therefore, we suggest that the following be included:

> (iii) initial testing for osteoporosis in patients with hyperparathyroidism by DXA on the axial and appendicular skeleton

Beneficiaries who may be covered
NOF agrees with the proposed change to beneficiaries who can be covered because glucocorticoid-induced bone loss develops quickly, leads to an increased risk of fractures, and fewer than 25 percent of patients prescribed oral glucocorticoids receive treatment to prevent or treat osteoporosis.[iii]

Use of national coverage determination process
NOF understands the rationale for proposing that the national coverage determination (NCD) process be used to identify additional BMM systems for purposes of 410.31(b)(2) and (b)(3). NOF agrees with this rationale providing that currently stated CMS policies are followed. These policies state that when there is a complete formal request for a new coverage determination, CMS will publicly track the process, allowing it to be transparent; provide an understandable decision memorandum prior to a NCD based on scientific and clinical evidence; offer adequate notice and opportunity to comment; be timely; and offer a reasonable mechanism for reconsideration.

Conclusion
Although NOF believes that Medicare coverage of bone mass measurement needs to be expanded so that the legal definition of qualified individuals keeps pace with additional current scientific and clinical evidence, it is aware that this change necessitates the passage of new legislation.

Thank you again for the opportunity to comment on the proposed final rule, and if we can assist you in any way, including implementation of the rule, please do not hesitate to contact Roberta Biegel, senior director of public policy and government relations, at 202-721-6364 or roberta@nof.org.

Sincerely,

Thomas Einhorn MD

Thomas A. Einhorn, MD
Co-chair, Advocacy Committee

Conrad Johnston MD

C. Conrad Johnston, Jr., MD
Co-chair, Advocacy Committee

CC: Bill Larson

Citations:

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[i] U.S. Department of Health and Human Services. *Bone Health and Osteoporosis: A Report of the Surgeon General.* Rockville, MD: U.S. Department of Health and Human Services, Office of the Surgeon General, 2004: 49.

[ii] Chappard C, et al. Bone status in primary hyperparathyroidism assessed by regional bone mineral density from the whole body scan and QUS imaging at calcaneus. Joint Bone Spine 2006 Jan; 73(1): 86-94.

[iii] McIlwain HH. Glucocorticoid-induced osteoporosis: pathogenesis, diagnosis, and management. Preventive Medicine 2003 Feb; 36(2): 243-9.

Cotrol 87-C

ADVANCED UROLOGY ASSOCIATES OF FLORIDA, P.L.

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VALERIE A. WARD, A.R.N.P.

October 3, 2006

Mark McClellan, M.D.,
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue
Washington, DC 20201
Attention: CMS-1321-P

2006 OCT -4 PM 5:18

RE: Medicare Program: Proposed Changes to Reassignment and Physician Self-referral Rules Relating to Diagnostic Tests as Noted in the Revisions to Payment Policies under the Physicians Fee Schedule for Calendar Year 2007 – CMS-1321-P

Dear Administrator McClellan:

Advanced Urology Associates of Florida, P.A. (AUAF) appreciates the opportunity to comment on the proposed rule for changes to reassignment and physician self-referral rules relating to diagnostic tests as noted in the revisions to payment policies under the physicians fee schedule for calendar year 2007, as published in the August 22, 2006 *Federal Register*. Specifically, we will comment on the proposed changes to (i) proposed changes to existing physician self-referral rules (the "Self-Referral Rule" or "Stark"), and (ii) existing Medicare reassignment rules (the "Reassignment Rule") (collectively, the Self-Referral Rule and Reassignment Rule as, "Proposed Rules"), which, if finalized, would have a chilling effect and substantial negative impact on the diagnosis and treatment, specifically in the area of neoplasms involving the genitor-urinary tract, which we provide to our patients. These proposed changes are found at Section V, Part 411-EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT, Subpart J-Financial Relationships Between Physicians and Entities Furnishing Designated Health Services (Section 411.351 Definitions *Centralized building* and *Physicians in the group practice*) and Part 424-CONDITIONS FOR MEDICARE PAYMENT, Subpart F-Limitations on Assignment and Reassignment of Claims (Section 424.80 (d)(2)(3) Prohibition of reassignment of claims by suppliers). The preamble language of the proposed changes to the Proposed Rules and their inclusive commentary accompanying those proposed changes clearly demonstrate that Centers for Medicare & Medicaid Services (CMS) views small centralized pathology laboratory arrangements ("pod laboratories"), described in Advisory Opinion 04-17, as significant fraud and abuse risks, although the overutilization of services referenced by CMS generally appears to be unsubstantiated.

CMS' position is that the proposed changes to the Self-Referral Rules and Reassignment Rules are designed to address two (2) separate but related concerns. First, CMS believes certain proliferating joint ventures that provide designated health services, which allow physician group practices to bill for services furnished by a contractor physician in a "centralized building" arrangement, are not within the intended purpose of physician self-referral laws. CMS specifically singled out centralized pathology laboratories, or pod laboratories, remotely located, whether in or out of the same state where the group practice is located, as such an arrangement. Second, CMS opines that recent changes to Medicare rules on

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reassignment have led to a "state of confusion" as to whether existing Medicare "anti-markup" rules also apply to situations in which a reassignment has occurred in accordance with a contractual arrangement. It is for these reasons CMS proposed the changes noted in the Proposed Rules that we now wish to comment on below.

I. Proposed Changes to Self-Referral's Definitions

This section of the Proposed Rules contains changes to two (2) specific definitions identified in Stark.[1] To the definition of "centralized building," CMS proposes to (i) introduce a square footage requirement and (ii) require that all equipment utilized to perform substantially all of the designated health services in that space must be permanent. It also clarifies that a "Physician in the group practice" must meet the requirements of the reassignment rules, as described in the CMS Internet Manual.

A. *Centralized Building*

CMS proposes to revise the definition of "centralized building" to require a minimum area of 350 feet square feet. The minimum area requirement would not apply to space owned or rented in a building in which no more than three (3) group practices both (i) own or lease space in the same building, and (ii) share the same "physician in the group practice" (meaning independent contractor physician). CMS clearly states that the purpose of this square footage area requirement and related exception is to prevent abusive arrangements such as pod laboratories, while not disqualifying legitimate, stand-alone physician offices that are unusually small.[2] We take exception. Whether a group practice that is a surgical or non-surgical specialty who has identified the need for and maintains an anatomical pathology laboratory for quality assurance purposes in addition to meeting OSHA standards and requirements either moves or develops the anatomical pathology laboratory site in a "centralized building" is irrelevant so long as the "centralized building" prong of Stark is satisfied. The 350 square feet proposed requirement of the "centralized building" prong is arbitrary and capricious. AUAF is a "busy" three (3) man urology practice on the Florida Treasure Coast. AUAF presently provides anatomic pathology services, in a pod laboratory setting in an area consisting of 280 square feet, for which the group practice directly bills and collects from Medicare and other third-party payors. Presently, AUAF processes approximately 350 slides per month for uro-pathology interpretation. We believe that the space requirement should be dependent on the number of pathology specimens (biopsies and/or cytology washings) and pathology slides processed per month and not fit a minimal requirement that "one minimal size fits all." In our particular model, the present 280 square feet is more than adequate to meet AUAF's needs. The histology technician, who is a leased employee, has no difficulty in processing and preparing the specimens in the space that is provided by the group practice. The pathologist, who once or twice per week performs interpretations and dictation in the space, is not hindered in any way from performing professional services. However, it is anticipated that as the urology group practice expands, additional space to process and prepare specimens may be required.

However, we do agree with CMS that space which is divided into "cubicles" (let us say for discussion purposes consisting of 36 square feet or less) is inadequate. Certainly any attempt to have a "centralized" area in a space of 350 square feet or more for the processing of specimens from multiple

1. CMS-1321-P at 189-209 and 321-324.
2. Id. at 206.

practices and cubicles within that space to be used exclusively by the pathologist for specimen interpretations of individual group practices would not fit an exception to Stark.

Over the past decade, through education, public announcements on both radio and television in addition to the press, an acute awareness of this deadly and debilitating form of cancer in men has gained momentum and has been brought to the forefront by the diagnosis and treatment of this disease in prominent government officials and in the entertainment industry. The general public has become acutely aware of the methods by which prostate cancer is diagnosed. This had led to an awareness and increase in the demand of early prostate detection procedures, such as blood tests (PSA), rectal examinations, family history of prior prostate cancer, race, age and other factors which are purely objective. Positive criteria and laboratory tests in male patients which indicate the possible presence of cancer of the prostate are not susceptible to overutilization and are thus "medically unnecessary" procedures. This marked increase of service requirement and the failure of the large commercial laboratories to service our needs led AUAF to conclude that there must be a more cost effective alternative.

AUAF became part of a consortium of urology group practices, through Uropath, a management service company who does not provide "similar services," to provide for the collection, processing and services of highly quality and trained specialized uro-pathologists who provide pathology reports on biopsies and uro-cytology specimens on a timely basis to improve the quality of care and treatment to our patients. Additionally, there were other factors other than "profit" which motivated AUAF to seek alternative anatomic pathology services in the presence of an increase of prostatic biopsy services. Among them but certainly not limited to are (i) the changing applicable medical standards for the number of prostate biopsy specimens for a single patient which are interpreted by pathologists; (ii) the growth of the span of the age population (no longer an old man's disease) in which cancer of the prostate can be diagnosed early and treated; and (iii) the subsequent use of prostatic biopsy procedures for prognostication purposes in alternative cancer treatment methodologies such as IMRT and cryotherapy to ensure positive outcomes.

AUAF, in compliance with Stark and with the assistance of Uropath, established a urology anatomic pathology laboratory utilizing the "in-office ancillary exception" in a "centralized building" prong. AUAF purchased and owns all the equipment for the processing and interpretation of urology specimens. AUAF's anatomical pathology laboratory is in operation six (6) days per week for the processing and interpretation of urology biopsy specimens.

Prior to entering into the creation of a urology anatomic pathology laboratory in compliance with Stark, AUAF submitted prostatic needle biopsies and complicated in-situ hybridization studies (FISH) to commercial anatomic laboratories. Under normal conditions, processing of specimens took on an average, four (4) to five (5) calendar days for needle biopsies and eight (8) to (9) days for FISH. Additionally, the interpreting pathologists were not "pure" uro-pathologists. Thus, when an issue was identified by the treating urologist in the staging and grading of a malignant neoplasm, the general pathologist who reviewed the tissue and submitted the report was not immediately available to respond to questions. Additionally, many times the general pathologist, who would perform the interpretations, could have been many states away and certainly not available by telephone or other means of communication due to time zone differences for instant response to questions regarding interpretations. AUAF's urologists became very frustrated. Even more was the frustration exhibited by their patients specifically relating to the diagnosis and classification of the neoplasm in question. Response time from

the interpreting general pathologist of record would result in an additional 24 to 48 hour delay in communicating with the patient. What is more "shocking" was the percentage of rejection by the commercial anatomical laboratory of FISH specimens of up to seventy-five percent (75%). Thus, the failure of the FISH specimen to be processed resulted in the inconvenience for the need to subsequently retest the patient, the additional expense, and more important, delay in the diagnosis and treatment of the patient. Since the inception in 2004 by AUAF of its urology anatomic pathology laboratory, AUAF's prostatic needle biopsies are processed and interpreted within two (2) days and FISH studies within five (5) days. Additionally, the rejection of FISH and the degree of hypo cellular rate by the group practice's "centralized building" anatomic pathology laboratory has reduced the rejection rate to twenty percent (20%), a very high process rate and well below the commercial anatomical laboratory "failure to process" rate of seventy-five percent (75%).

Finally, the uro-pathologist who has entered into a personal service agreement with AUAF is a pure uro-pathologist. AUAF's uro-pathologist is available to the group practice on a 24-7 basis. AUAF's uro-pathologist is an important member of the team. His expertise is utilized on a daily and ongoing basis for the diagnosis, treatment and prognostication of neoplasms involving the genitor-urinary tract, and certainly not for the sole purpose of "supervising" the processing of specimens. In fact, AUAF's uro-pathologist is well recognized by his peers as an expert in the field of uro-pathology and is consulted on a daily basis by other general pathologists throughout the State of Florida as well as the United States to consult and assist in the interpretation of complex urological specimens. What is more important, AUAF's uro-pathologist is credentialed by Uropath under its services agreement to ensure that the uro-pathologist, who has entered into a personal service agreement with AUAF and has assigned his benefits, is in compliance with state law, a requirement for billing Medicare.

The other changes to the definition of "centralized building" concentrate on the equipment and its use in the space.[3] Once more, the proposed language seems to focus on pod laboratories or similar arrangements in which equipment would be moved from one group's space (a cubicle or unit) to another group's space (in an adjoining cubicle or unit). We agree with CMS that each anatomic laboratory be independently equipped. In fact, under AUAF's present arrangement under their management company services agreement, compliance procedures, prohibits the sharing of laboratory equipment between urology group practices necessary for the provision of uro-pathology services. We also agree with CMS that there may be an occasional need to bring specialized equipment into a group practice's space on a temporary basis; however, the proposed ten percent (10%) portability of the equipment is arbitrary depending on the needs. What is more important is what is meant by specialized equipment and the "needs?"

In closing our comments of the Self Referral Proposed Rule, we oppose requiring that the group practice exclusively employ in the space a non-physician employee, such as a histology technician or independent contractor for at least 35 hours per week. Most available histology technicians, unlike radiology technicians, most of which are trained as medical assistants and are able to perform other duties for the group practice such as simple radiology services, in addition to assisting in simple office procedures, whether in the primary office or in a "centralized building" location, are contracted for their services as a leased employee or independent contractor from hospitals or free standing anatomical

3. Id. at 322 and 323.

pathology laboratories. This proposal would be restrict the availability of a trained histology technician to the group practice and to the medical profession in general. In fact, since not all medical practices that would utilize a histology technician are neutral in size and certainly not equal in the volume of surgical specimens or diagnostic cytology washings (pulmonary, gastroenterology, urology, dermatology, and general surgery), to maintain a full-time histology technician to perform a limited number of specimen preparations is not practical. We base our objections to this proposal for the following reasons: (i) it would place an undue burden on the diagnostic prong of the specialties, and (ii) access becomes fiscally impossible. Additionally, it would place an undue hardship on the education and training of medical assistants and histology technicians within the medical profession and certainly would not be cost effective. If anything, the process should be reversed. The sharing of this highly technological non-physician employee should be encouraged not discouraged.

B. *Physician in the Group Practice*

Under the Proposed Rule, CMS would expand on the definition of "Physician in the group practice" by adding verbiage that not only must an independent contractor's service agreement comply with the reassignment rules at 42 C.F.R. 424.80(d)(3) but also "section 30.2.9.1 of the CMS Internet-only manual, publication 100-04, Claims Processing Manual, chapter 1 on general billing requirements (as amended from time to time)."[4] These changes are directly linked to the proposed changes to the reassignment rules as discussed and commented on below.

II. Proposed Changes to the Reassignment Rules

More striking then the proposed changes to the Self Referral's definitions are the changes the Proposed Rules consider for the reassignment rules.[5] Specifically, CMS explains it's rational with respect to the reassignment changes as follows: "Recent changes to our rules on reassignment of the right to receive Medicare payments may have led to some confusion as to whether the anti-markup and purchased interpretation requirements apply to certain situations where a reassignment has occurred pursuant to a contractual arrangement."[6]

CMS' intent is to clear up any ambiguities and to make clear that the same requirements that apply to the "purchased diagnostic test" exception apply to the "contractual arrangement" exception. CMS believes that the broadening of the reassignment exception under Section 952 of the Medicare Modernization Act of 2003 ("MMA"), has allowed the proliferation of pod laboratories. CMS came to this conclusion without sound and identifiable evidence that pod laboratories are subject to fraud , waste and abuse. Specifically, the contractual arrangement exception would include the "anti-markup" requirements found in the purchased diagnostic test exception. CMS proposes to amend the reassignment regulations to provide that if the technical component ("TC") of a diagnostic test is billed by a physician or medical group under a reassignment which involves a contractual arrangement with a physician or other supplier who actually performs the service, the amount billed to Medicare by the billing entity may not exceed (i) the lower of the physician's net charge, or (ii) the billing physician's actual charge, or (iii) the physician fee schedule amount under Medicare regulations.[7] The Proposed Rule

4. Id. at 323.
5. Id. at 340-342.
6. Id. at189.
7. Id. at340-342.

regarding reassignment would also require that in order to bill for the TC of a diagnostic test, the billing entity must also perform the professional interpretation of the test (the "PC").[8]

The billing limitation in the Proposed Rules applies only in the case of a reassignment involving a non-member physician of the group practice or other supplier who performed the TC. The example provided by CMS in the Proposed Rule, which demonstrates program vulnerabilities is one in which a supplier itself employs a histology technician and pathologist, the supplier employees go from laboratory to laboratory providing the TC, and through a contractual reassignment the group practice bills for services provided by the supplier.

We agree with CMS that a laboratory in which the TC is performed by employees of a group practice, either leased or directly employed, and who is supervised by a physician who has a direct contractual relationship as a physician in the group practice, either as an independent contractor or employee, falls within the exception.

Additionally, in April, 2004 clarifications were made by CMS regarding the question of "leased employees and purchased tests," to the "anti-markup" requirements of the purchased diagnostic test exception. At that time, CMS specifically acknowledged that diagnostic tests provided by leased employees are not "purchased tests" for purposes of the rule.

As to the question of independent contractors in the Proposed Rules we comment as follows. First, Stark included an independent contractor as a "physician in the group practice."[9] A physician independent contractor may provide services for a group practice, provided those services are performed on the group's premises, and a personal services agreement between a physician independent contractor and a group practice complies with the Medicare reassignment regulations. Further, the "physician services" and "in-office ancillary services" exceptions to Stark expressly require that a group practice bill for services provided by such physicians under a reassignment of benefits. In fact, it would be inconsistent under both Stark and the Medicare regulations for a group practice to bill for services provided through its contracted physicians that are not compliant with the reassignment regulations. Second, this interpretation would prohibit a group practice from utilizing a "locum tenens" physician to provide the PC of diagnostic tests, since those tests would not be directly provided by the group practice. Thus, this would again prohibit a group practice from billing for the TC without providing the PC of the same test.

We further agree with CMS that a more reasonable interpretation is to require that a group practice that is billing for the TC of a diagnostic test be the same entity that is providing and billing for the actual interpretation, or the PC. Further, we agree that those services must be provided on the group practice's premises. This would eliminate existing arrangements in which a group practice outsources to a supplier the TC of a diagnostic test for which the supplier bills Medicare, and then independently will contract with a physician to provide the PC of that test for which the group practice bills under reassignment for a profit. It would also eliminate arrangements where a group practice contracts with a pathology group to provide technical staff and supervision for the TC of tests in the group practice's premises and for which the group practice bills, in exchange for the pathology group receiving an exclusive contract to provide and bill for the PC in the designated pathologists own name. AUAF further

8. Id. at 341.
9. 69 Fed. Reg. 16054-16146, 16077 (March 26, 2004).

believes both of these models are presently utilized by a number of commercial companies who have developed questionable pod laboratories. This new requirement would not implicate those "centralized building" arrangements in which a group practice globally bills for the diagnostic test in which the TC is provided by its leased employee and the PC is provided by its independent contractor pathologist.

Under AUAF's management services agreement with Uropath, the group practice leases employees at fair market value that has been arrived at through arms length negotiations, and whose leasing fee does not vary with the volume and value of referrals between the parties. What is more important in this equation, the management company does not provide nor is it capable of providing pathology services as an outsource supplier of services.

Additionally, CMS is considering, but has not proposed in this rulemaking, amending 42 CFR § 424.80(d) further limiting a group practice to bill for a PC provided by a physician independent contractor under a reassignment of benefits unless the following elements are met: (i) the test is ordered by an entity independent of both the physician and the group contracting with the physician; (ii) the physician and medical group contracting with the physician do not see the patient; and (iii) the medical group billing for the PC also performs the TC.

In response, AUAF opines this consideration to be overbroad and too restrictive. Further, the adoption of this rule would prohibit a group practice from billing Medicare for the reassigned PC of a diagnostic test relating to a self-referral, even if the self-referral was expressly permitted under Stark. Further, if a group practice was not able to bill Medicare for the PC, it will no longer be able to bill for the TC of the same test.

CMS has also requested that we comment on the following: (i) whether radiology and other imaging services should be excepted from these proposed revisions, (ii) whether the proposed revisions should apply only to pathology services, (iii) whether the provisions should apply to services performed on the premises of the billing entity, and finally (iv) how to define the premises.

We believe that until these questions which have been raised for additional comment are resolved, the Proposed Rules should be delayed in its implementation. Our rational for this proposal is that the Proposed Rules are unclear and certainly difficult to comprehend. In our view, some rules are considered, some rules are proposed, and other thoughts on additional changes to the rules are introduced for the first time for discussion and comment. Additionally, to this entire question of fraud, waste and abuse by CMS in "centralized building" arrangements, in 2005, the Department of Health and Human Services, Office of Inspector General ("OIG") launched an initiative in the Work Plan Fiscal Year 2005[10], a review of the physicians pathology services performed in physician's offices to address such a question. This project was carried forward into the Work Plan Fiscal Year 2006[11], and most recently has been extended into the Work Plan Fiscal Year 2007[12]. CMS proposes these rules, without a foundation, to address perceived program abuse which is the result of the pod laboratory concept. In fact, until the

10. HHS/OIG Work Plan Fiscal Year 2005, CMS, *(OAS: W-00-05035164)* at Page 11.
11. HHS/OIG Work Plan Fiscal Year 2006, CMS, *(OAS; W-00-05035164; various reviews; expected issue date:FY2006; work in progress)* at Page 8.
12. HHS/OIG Work Plan Fiscal Year 2007, CMS, *(OAS; W-00-05035164; various reviews; expected issue date:FY2006; work in progress)* at Page 9.

present OIG study has been completed, there exists no substantive evidence to support the premise that pod laboratories have resulted in the over-utilization and provision of unnecessary medical services, specifically prostatic biopsies, kickbacks, fee-splitting, or any other program abuses. In light of the on going study by the OIG, we strongly recommend that until the study is completed, implementation of the Proposed Rules should be delayed.

In summary, AUAF agrees with CMS that additional safeguards regarding joint venture arrangements under which pathology services are delivered are appropriate, especially in circumstances in which a group practice outsources to a supplier the TC of a diagnostic test for which the supplier bills Medicare, and then independently contracts with a physician to provide the PC of that test for which the group practice bills under reassignment for a profit. We would also eliminate arrangements where a group practice contracts with a pathology group to provide technical staff and supervision for the TC of tests in the group practice's premises and for which the group practice bills, in exchange for the pathology group receiving an exclusive contract to provide and bill for the PC in the designated pathologists own name. Below is a summary of our comments:

(i) AUAF agrees with CMS that an independent contractor physician of a group practice should only be able to provide professional or technical services on behalf of the group practice, and for which the group practice bills and collects, if the services are provided on the premises of the group practice. This rule would discourage that contractual reassignment of services by providers who have no physical relationship with the billing entity.

(ii) AUAF agrees with CMS that if a group practice intends to bill for the TC of a diagnostic service, the group practice must perform the PC of that same service. This is particularly true when the TC in question is performed under the supervision of the same physician. The Proposed Rules would eliminate arrangements in which a pathologist agrees to serve as an independent contractor of a group for purposes of supervision, in exchange for providing and billing for the PC of the same service in the physician's own name.

(iii) AUAF strongly agrees with CMS that any "centralized building" used for the provision of designated health services should contain the necessary equipment on a permanent basis to perform substantially all of the services that are performed in the space. We contend that this is a requirement of Stark under the "in office ancillary services" exception and existing CLIA regulations. No pod laboratory should be permitted to share equipment or supplies with another.

(iv) AUAF disagrees with CMS as to the minimum square foot requirement. We believe that this prong of the Proposed Rule is too ambiguous in addition to being arbitrary and capricious. Further, it is our contention that this proposed rule is intended solely to eliminate pod laboratories without any justification. There is no evidence that pod laboratories, especially under the model presented, present a fraud and abuse risk to the Medicare program. More important, there is no discussion in the Proposed Rule by CMS regarding the quality of pathology services that can be delivered by pod laboratories as compared with the outsourcing these services to a commercial anatomic laboratory. Contrary to what opponents to pod laboratories believe or assert, in our two (2) year clinical experience, AUAF has actually improved patient care, and in some cases have reduced costs to the Medicare program.

Should you have any questions concerning these comments, please contact me at your convenience.

Respectfully submitted by,

ADVANCED UROLOGY ASSOCIATES OF FLORIDA, P.A.

By: _____
JOSEPH P. CRAWFORD, M.D., FACS
Its: Managing Member

JPC/
cc: Robert Rappel, D.O., J.D.
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October 4, 2006

VIA HAND DELIVERY
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to Proposed Revision to Physician Fee Schedule for Calendar Year 2007: CMS-1321-P

To Whom It May Concern:

Uropath, L.L.C. ("**Uropath**") is a Texas limited liability company that assists professional urology group practices in developing and operating highly specialized pathology laboratories. Uropath provides managerial and operational expertise and efficiencies which permit a group practice to provide superior pathology services and better patient care. All services provided in Uropath-managed laboratories are provided and billed for compliant with all applicable laws and regulations.

On August 22, 2006, the Centers for Medicare and Medicaid Services ("**CMS**") published File Code [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* (the "**Proposed Rule**"). At Section II.I of the Proposed Rule, (pages 49054-57 of the August 22, 2006 edition of the Federal Register), CMS proposes: (i) changes to existing Medicare reassignment rules; and (ii) changes to existing physician self-referral regulations (collectively the "**Reassignment and Self-Referral Rule**").

Uropath submits the following comments to the Proposed Rule, and specifically to the Reassignment and Self-Referral Rule. Section I provides background information describing Uropath's business model and the quality of care benefits related to delivering urological pathology services in this manner. Section II includes specific comments to specific subsections of the Reassignment and Self-Referral Rule.

I. INTRODUCTION

Urology group practices are dedicated to the prevention, detection, and treatment of prostate cancer. Prostate cancer is one of the most common and fastest growing types of cancer

among American men. More than 70% of all prostate cancers are found in men over the age of 65.

Clinical indications of, and risk factors for, prostate cancer are substantially objective, and include: an elevated prostate-specific antigen blood test ("PSA"); the presence of prostatic nodules upon performance of a digital rectal examination; prior history of cancer; age; and co-morbidities (additional or coexisting diseases or conditions of the patient). When prostate cancer presents clinically, a prostate biopsy is often performed. A prostate biopsy is the removal of part of a patient's prostate tissue, which is sent to a pathology laboratory for examination. A single tissue specimen may not capture existing cancerous cells, so many (typically twelve) specimens are taken from a single patient. A pathologist examines the specimens to confirm the existence of prostate cancer, and to grade the severity of any existing cancer.

Pathologists grade prostate cancer according to the "Gleason System," which assigns each specimen a grade from 1 to 5. For a given patient, the two tissue samples with the highest grades are totaled to yield a Gleason score. The Gleason score is vital in assessing the existence and severity of prostate cancer, which is used by urologists to develop appropriate treatment options for the patient.

The Gleason System is by nature subjective because it relies on human grading. One doctor's "3" might be another doctor's "4." The more experience a single pathologist has in examining prostate biopsies for cancer, the more reliable and consistent the pathologist will become at grading prostate cancer. Further, patient care is greatly enhanced if the same pathologist examines samples for the same urologist and if that urologist is able to discuss with a pathologist particular aspects of a pathological examination. Finally, because the need for results can be urgent, patient care is enhanced when a urologist is able to prioritize with a pathologist the timing for the delivery of pathology results in order to minimize wait time for crucial samples.

Insurance companies pay for pathology services. Most insurance companies will reimburse a urology group for pathology services provided as an extension of their core urology practice, but if a urology group does not provide pathology services in-house, most insurance companies require that specimens be sent to a particular laboratory with which the insurance company has contracted. These may include national reference laboratories that employ a great number of pathologists. These laboratories picked up specimens locally and shipped them across the country to large pathology factories.

Historically, this arrangement produced unreliable pathology for several reasons. First, since specimens were shipped to several different labs, each with several different pathologists, there was no consistency of specimen grading. Second, because the national laboratories employed so many pathologists at a single location, there was no way for urologists to identify which pathologist examined their specimens, so there were little or no consultative benefits available to urologists. Third, because the urologists had no control over the pathologists' workload or priorities, there was either no way for a urologist to expedite the handling of particular specimens, or it could only be done at significant additional cost, which in many cases was not reimbursed by the insurance company.

These quality of care issues compelled urology group practices to form Uropath in May, 2003. Uropath assists group practices in developing, constructing, equipping, and operating

pathology laboratories dedicated almost exclusively to the detection of prostate cancer. A group practice that establishes its own pathology laboratory gains the following patient care benefits: (i) by using the same pathologist for all urological pathology work, particularly those related to potential cancer, a group practice is able to minimize inconsistencies in grading specimens inherent in using more than one pathologist; (ii) sources of potential grading error include a pathologist's education and experience, and by utilizing its own dedicated urology pathology physician, a group practice can minimize this source of error; (iii) by utilizing its own contracted pathologist, a group practice enjoys more meaningful consultative benefits with respect to specimens reviewed and interpreted; and (iv) a group practice is able to make special requests and prioritize sampling sent to the their own pathology laboratory without undue delay or expense.

Uropath assists a group practice in finding suitable office space for a laboratory. The group practice will have sole and exclusive rights to the premises for the purpose of operating an independent pathology laboratory. Uropath will likely manage several discrete, separately owned laboratories located in the same medical office building. Each laboratory will be separately owned, certified, and occupied by a separate and discrete group practice which will have sole and exclusive use of its leased or subleased premises. All laboratory and office equipment is owned by an individual group practice. Each group practice will independently contract with (i) a board certified pathologist for the provision of professional medical services, and (ii) Uropath, for the provision of non-professional medical, administrative and managerial services.

Each Group Practice uses its own pathology laboratory for all of its pathology services. Group practices do not refer pathology services to each other. Each group practice independently contracts with all professional staff and medical personnel that will provide professional medical services to its laboratory, though more than one Practice may independently contract with the same pathologist for the provision of such services. A pathologist will only provide services on behalf of a group practice while the pathologist is physically present in the Group Practice's Lab, and no laboratory will borrow or share any equipment necessary to perform pathology services.

CMS states that the Reassignment and Self-Referral Rule is designed to address two separate but related concerns. First, recent changes to Medicare rules on reassignment has led to confusion as to whether existing Medicare anti-markup and purchased interpretation rules apply to situations in which a reassignment has occurred pursuant to a contractual arrangement. Second, CMS believes certain business arrangements that are proliferating are not within the intended purpose of physician self-referral laws, which permit physician group practices to bill for services furnished by a contractor physician in a "centralized building."

CMS specifically identifies pathology laboratories such as those Uropath manages as an example of a suspect arrangement. CMS calls these labs "pod labs," and at 71 FedReg 49055 generally describes what it believes to be a couple of typical pod lab arrangements. CMS does not accurately describe a Uropath-managed laboratory arrangement but it is clear that eliminating Uropath-managed laboratories are a focus of the Reassignment and Self-Referral Rule. CMS writes at 71 FedReg 49057 that it believes the Reassignment and Self-Referral Rule will prevent abusive arrangements such as pod labs while preserving legitimate small physician offices.

II. COMMENTS: REASSIGNMENT AND SELF-REFERRAL

The Comments below address the Reassignment and Self-Referral Rule published in Section II.I of the Proposed Rule and located at 71 FedReg 49054-57. Section A addresses the decision of CMS to implement regulations intended to eliminate the existence of pod labs. Section B includes comments specific to the proposed reassignment regulations. Section C includes comments specific to the proposed self-referral regulations.

A. General Comments to Reassignment and Self-Referral Rule

The four pages of the Proposed Rule that address Reassignment and Self-Referral (pages 49054-57) are replete with references to pod labs as abusive arrangements that expose Medicare to risk of program abuse. Risks mentioned include: (i) the generation of medically unnecessary biopsies; (ii) kickbacks; (iii) fee-splitting; and (iv) prohibited self-referrals. Uropath expects that national pathology providers and special interest groups representing them will attack Uropath-managed laboratories because these entities and their members stand to lose significant revenue as more and more urology group practices operate in-office pathology laboratories. Uropath did not expect, however, that CMS would conclude, without any evidence of program abuse whatsoever, that pod labs are an abusive arrangement that should be regulated out of business.

Group practices that operate Uropath-managed laboratories provide pathology services compliant with all applicable laws and regulations. These laboratories do not rely on more flexible reassignment provisions to mask purchased services as reassigned services. Rather, they utilize expert technicians and contract directly with nationally renowned urological pathologists to provide technical and professional pathology services in their own centralized pathology laboratories. They did so well before the MMA made it easier for opportunists to profit off Medicare by purchasing and billing for services under a paper reassignment.

No fee-splitting or prohibited self-referrals occur in any Uropath-managed laboratory. All services are provided by employees and contracted physicians in a group practice's own facilities, utilizing solely the individual group practice's CLIA certified laboratory, equipment, and supplies, all in accordance with the group practice's policies and procedures. The structure under which these services are provided is completely consistent with applicable anti-markup provisions, limitations on the billing for purchased services, the Stark Law, and all other applicable law and regulations.

No kickbacks occur in any Uropath-managed laboratory. In 2005, pursuant to its 2005 Work Plan, the Office of Inspector General's Office of Audit Services conducted audits of three Uropath-managed pod labs (one in each medical office building where Uropath manages such labs). Groups provided medical records, utilization data, policies and procedures, and complete access to laboratories and personnel during operating hours. Uropath voluntarily provided substantial documentation to the OIG in connection with those audits, made itself available for personal interviews in San Antonio, Texas in the summer of 2005, and offered to assist the OIG in any way in connection with the its audits of Uropath-managed pod labs. To date, the OIG has provided none of those groups with any information suggesting that over utilization, the ordering of unnecessary services, fee-splitting, prohibited referrals, or any other program abuse is occurring. In fact, Uropath has never been contacted for any additional information, and to date no work plan audits of Uropath-managed labs have ever been released.

There is no data to support the accusation that pod labs facilitate the generation of medically unnecessary biopsies. Clinical indications for prostate biopsy are not subject to

manipulation, as any sincere urologist will attest. Internal data generated by group practices that operate Uropath-managed pod labs actually show a higher positive incidence of prostate cancer than before they owned their own laboratories. This is because their pathologists, who do nothing but urologic pathology, have become experts in the identification and grading of biopsies. Moreover, incidences of "atypia," or inconclusive pathological findings (which often require secondary biopsies and consults) are much lower in these labs for the same reason. In many cases, these group practices are performing fewer biopsies as a percent of patients seen, because they are better at it.

When CMS published its Final Rule adopting new Stark Law regulations related to electronic prescribing and electronic health records on August 8, 2006, CMS specifically referred to Congress's objective "of improving patient safety, quality of care, and efficiency in the delivery of care." Uropath-managed pod labs achieve all of these objectives. Yet while unsubstantiated accusations of program abuse in pod labs appears throughout the Reassignment and Self-Referral Rule, there is not one mention of the quality of care and efficiency in its delivery that are facilitated at these laboratories.

It is clear to Uropath that CMS has adopted the position of others that pod labs present substantial risk of program abuse. Uropath cannot discern the basis for CMS's hostility to pod labs, given that there has been no demonstrable evidence that pod labs result in any program abuse, and given that the quality of care benefits to patients are tangible and real. Uropath-managed pod labs do, however, generate permitted self-referrals which are subject to intense regulation, so Uropath-managed laboratories are vigilant of all changes in Medicare laws, rules and regulations that apply to the provision of pathology services.

The Proposed Rule seeks to eliminate pod labs. Uropath-managed pod labs are vital to the accurate detection and treatment of prostate cancer, and do not expose Medicare to undue risk of program abuse. Rather than attempt to adapt to changing rules intended to terminate pod labs, Uropath and its group practice clients welcome the opportunity to present data, information, statistics and outcomes to CMS that substantiate that pod labs provide superior urological pathology at lower cost to the Medicare program. Uropath believes if this rulemaking is postponed while that process is undertaken the result will be more comprehensive, meaningful rules that address actual and significant risks of program abuse.

B. Proposed Reassignment Regulations: 42 CFR § 424.80

CMS proposes to amend its reassignment regulations to clarify how the purchased tests and purchased test interpretation rules apply in the case of a reassignment made under the contractual arrangement exception set forth at 42 CFR § 424.80(d)(2). Uropath does not object to the proposed regulations but believes further clarity is unnecessary. Further, the proposed regulation themselves are ambiguous and unclear and may create uncertainty where clarity existed. Finally, the proposed regulations, the considered regulations, and the solicitations for comments regarding proposed and considered reassignment regulations, strongly suggest that CMS may not have a complete appreciation of exactly what problems it seeks to address or what consequences the proposed reassignment regulations would have on existing business arrangements.

1. Existing Regulations are Clear and Definite

Section 952 of the MMA amended the Social Security act to extend the reassignment exception to any contractual relationship, regardless of where the services are performed, subject to program integrity and other safeguards the Secretary deems appropriate. The Secretary subsequently amended 42 CFR § 424.80(a) to provide that "[n]othing in this section alters a party's obligations under . . . the physician self-referral prohibition (section 1877 of the Act) . . . the rules regarding physician billing for purchased diagnostic tests, . . . or any other applicable Medicare laws, rules, or regulations." This amendment clearly states that contractual reassignments are subject to all other Medicare rules, regulations, and safeguards.

In March, 2004, CMS issued final Stark Law Regulations, which became final in June, 2004. The Physician Services Exception and the In-Office Ancillary Services Exception to the Stark Law, set forth at 42 CFR § 411.355(a) and (b), except from the Stark Law's general self-referral prohibitions certain services provided by or under the supervision of a "physician in the same group practice" as the referring physician. A "Physician in the Group Practice" is defined at 42 CFR § 411.351 to include "an independent contractor physician during the time the independent contractor is furnishing patient care services for the group practice under a contractual arrangement with the group practice to provide services to the group practice's patients ***in the group practice's facilities***."

The interplay between the reassignment regulations (42 CFR § 424.80) and the Stark Law regulations (42 CFR § 411.351) is clear. The expanded reassignment regulation permits any Medicare enrolled entity to bill and collect for services provided by a supplier if there exists between the two parties a contractual arrangement under which the entity bills for the supplier's services. This general exception is subject to all other applicable Medicare law provisions to 42 CFR § 424.80(a). The Stark Law Regulation does not permit a group practice to refer "designated health services" (which includes diagnostic tests and related physician services) to an independent contractor physician who has reassigned rights to bill Medicare to the referring group practice unless the independent contractor physician is providing the services at issue on the premises of the referring group practice.

CMS states at 71 FedReg 49054-55 that it was concerned the MMA's expanded reassignment rules would create new fraud and abuse vulnerabilities, and commenters suggested that the expanded reassignment rules facilitated the development of pod labs. But the Stark Law regulations prohibit self-referral arrangements in which services are provided by an independent contractor physician in any location other than on the premises of the referring group practice. Moreover, the reassignment exceptions have long permitted a group practice to obtain a contractual reassignment from a pathologist that provides supervision and professional pathology services in the group practice's centralized laboratory facility. Uropath-managed laboratories have used this compliant model since long before the MMA expanded the reassignment exception. Technical services provided by employees or contractors of a group practice; in the group practice's facilities; using the group practice's equipment, supplies, and premises; and in accordance with the group practice's policies and procedures, have never been subject to the Medicare anti-markup provision simply because the physician supervising and performing professional services is an independent contractor, and not an employee, of the group practice.

The interplay between the Medicare anti-markup provision and the reassignment regulations is also clear. The expanded reassignment regulations permit a Medicare enrollee to bill Medicare for services purchased from an independent supplier under a contractual

arrangement that includes a reassignment. But the reassignment regulations provide that the reassignment does not alter a party's obligations under the rules regarding physician billing for purchased diagnostic tests. And the anti-markup provision prohibits the purchaser in such a situation from billing Medicare an amount in excess of the amount paid to the supplier.

CMS notes at 71 FedReg 49056 that commenters claimed some existing arrangements do not satisfy Medicare rules regarding purchased diagnostic tests and sought clarification on whether anti-markup and purchased test provisions applied in the contract of a contractual reassignment. Yet, 42 CFR § 424.80(a) specifically states that any reassignment permitted thereunder is subject to all applicable Medicare laws, rules, and regulations, specifically including "***rules regarding physician billing for purchased diagnostic tests***." There should be no confusion. The anti-markup provision applies to purchased technical services whether or not the selling entity has contractually reassigned the right to bill Medicare to the buyer.

2. The Proposed Reassignment Rules Create Ambiguity and Confusion

Uropath believes commenters that have lost pathology revenue to Uropath-managed laboratories have manufactured ambiguity in the existing rules in an effort to convince CMS to adopt regulations designed to terminate pod labs. Uropath has no objection to the proposed reassignment regulations, and if ignorant providers of Medicare reimbursed services are not complying with the Medicare laws, rules, and regulations that apply to the billing for reassigned and purchased services, then the proposed reassignment regulations may make patently clear to those entities that their business arrangements are suspect. Unfortunately, Uropath believes that the proposed reassignment rules will also create a great deal of new uncertainty for knowledgeable Medicare participants where currently none exists.

For example, 42 CFR § 424.80(d)(3) purports to apply anti-markup provisions to technical services billed by a medical group practice "following a reassignment involving a contractual arrangement with the physician or other supplier who performed the technical component." What is meant by the phrase "involving a contractual arrangement with a physician?" If the supervising physician is an independent contractor of a group practice but the technician performing the technical service is an employee of the group practice, is this rule implicated? If so, what would be the "supplier's net charge" or "billing entity's actual charge" for purposes of applying the new anti-markup provision, given that the billing entity and the "supplier" are the same entity?

Further, proposed 42 CFR § 424.80(d)(3)(iii) would require that, in order to bill for the technical component of a service, a "physician or medical group must directly perform the professional component of the service." It appears to apply to both an employee reassignment as well as a contractual reassignment. What does "directly perform" mean in this context? Presumably this would require the same entity to bill for the TC and the PC but that is not stated. If an employed independent contractor physician performs the professional component of a service on the group practice's premises using the group practice's equipment in accordance with the group practice's policies pursuant to a contractual arrangement with the group practice, is the group practice "directly performing" the service? If a group practice utilizes locums coverage, are those services "directly provided" by the group practice? The Stark regulations recognize that such physicians provide services on behalf of a group practice just as owners and employees do, as the definition of a "physician in the group practice" includes all these physicians, and in

fact requires that a group practice bill and collect for such services provided pursuant to a self-referral. *See* 42 CFR § 411.351; 42 CFR § 411.355. It would be anomalous if the Stark regulations required that a group practice bill for medical services that the reassignment rules did not consider directly performed by the same group.

3. The Proposed Reassignment Rules Seek More Guidance Than They Provide

The proposed reassignment rules propose two conceptual changes. First, application of anti-markup provisions to technical services purchased and billed for pursuant to a contractual reassignment. Second, requiring that a Medicare participant bill for the professional component of a service if the participant intends to bill for the technical component of the same service under a reassignment. As discussed above, these concepts are simple and positive, but the actual rules are difficult to understand and apply.

In addition, CMS states that it is considering, but not proposing, certain limitations on who can bill for the professional component of a reassigned diagnostic test. The considered provision is very similar to an existing rule found in Section 30.2.9.1 of the Medicare Claims Processing Manual, which governs when a participant can bill for a purchased professional interpretation of a diagnostic test. No regulation to accomplish this is proposed, and in fact one of the issues on which CMS invites public comment is the wording of such a proposed rule.

Finally, CMS seeks comment on the following additional issues related to the proposed reassignment rule:

(i) whether radiology or other imaging services should be excepted from any of the proposed or considered rules;

(ii) whether the proposed rules should apply only to pathology services;

(iii) whether the proposed rules should apply to services performed on the premises of the billing entity, and if so, how to define the premises appropriately;

(iv) proposed text of its considered limitations on the billing for purchased test interpretations; and

(v) whether an anti-markup provision should apply to purchased test interpretations, and if so, how to determine the correct amount that should be permitted.

These are not simple housekeeping issues, but are significant changes in the permitted provision of and billing for Medicare-reimbursed diagnostic services. The sheer number of issues on which CMS seeks industry guidance, as compared to those which CMS attempts to address in this rulemaking, strongly suggests that CMS may not have a complete understanding of the issues it seeks to address or the consequences of its proposed reassignment regulations. These changes would have significant impact on many diagnostic imaging arrangements, in ways that

cannot be fully appreciated. As discussed below, prudence mandates that CMS take a more deliberate and reasoned approach to this rulemaking.

4. Comments on Issues for which CMS Requests Specific Comment

Question: Should radiology and other imaging services be excepted from the proposed reassignment rules, or alternatively should the rules apply only to pathology services?

Answer: Uropath can discern no legitimate rationale for excepting imaging services or any other diagnostic service from rules intended to curb program abuses related to the provision of diagnostic tests. To the extent fraud and abuse risks are present with respect to existing reassignment rules, there is no basis to believe the contractual reassignment of imaging or other diagnostic services is less prone to abuse than the contractual reassignment of pathology services. In fact, global teleradiology service arrangements are much more prevalent and sophisticated than pathology arrangements. CLIA ensures that all providers of laboratory services are properly licensed, permitted, accredited, and supervised, but no such federal program exists with respect to radiology services. A prevalent and highly suspect imaging business arrangement involves a group practice purchasing professional interpretations from out of state (even out of country) radiologists who have no physical connection to the purchaser, at prices lower than the group is able to bill Medicare under the physician fee schedule.

The only logical reason for excluding imaging services from this rulemaking is that CMS's primary directive is to affect the financial viability of pod labs. CMS may seek to minimize the unanticipated consequences of these rules by limiting their application to the domain of pod labs. Uropath does not understand the basis for CMS's hostility to pod labs, given that there has been no demonstrable evidence that pod labs result in any program abuse, and given that the quality of care benefits to patients are tangible and real. Uropath and its group practice clients welcome the opportunity to present data, information, statistics and outcomes to CMS that substantiate that pod labs provide superior urological pathology at lower cost to the Medicare program. Uropath believes if this rulemaking is postponed while that process is undertaken, the result will be more comprehensive, meaningful rules that address actual and significant risks of program abuse.

Question: Should the proposed rules apply to services performed on the premises of the billing entity, and if so, how should premises be defined?

Answer: No, the proposed rules should not apply to services performed on the premises of the billing entity. There are no doubt abuses of the MMA reassignment exception occurring. The abuses involve Medicare participants masking a purchased service as a reassigned service by obtaining a contractual reassignment. In such cases, the only relationship between the provider and the billing entity is on paper.

In a Uropath-managed laboratory, an independent contractor pathologist works in a group practice's CLIA certified laboratory, supervises the group's technicians, uses the group's equipment, supplies, and computers, and provides services in accordance with the group's policies and procedures governing the provision of pathology services. This arrangement provides superior pathology services, was appropriate prior to the expansion of reassignment

exceptions, and should not be eliminated as a result of unsubstantiated concerns regarding potential program abuse. Even absent the proposed reassignment regulations, the Stark regulations provide that no physician or group practice may self-refer pathology services to a contracted physician unless the services are provided in the group's premises, which is an appropriate safeguard to address this perceived program risk.

That CMS is seeking comment on how to define the "premises" in this context is yet another confirmation that CMS seeks industry input on how to singularly impact the viability of pod labs. As discussed above, there is no evidence to support this hostility – only the baseless accusations of commenters who have lost and who stand to lose revenue to group practices that provide their superior pathology services in their offices.

Question: Should CMS adopt limitations on the billing for purchased test interpretations? Should CMS adopt an anti-markup provision that applies to purchased professional interpretations?

Uropath supports reasonable and appropriate restrictions on the billing for and the marking up of purchased test interpretations. None are published for review and comment in this rulemaking. Appropriate regulations should permit arrangements that improve quality of care while minimizing the risk of program abuse. It is clear to Uropath that CMS has concluded pod labs present substantial risk of program abuse without any demonstrable evidence. Uropath is concerned that any rulemaking in this environment will simply be aimed at eliminating pod labs, which Uropath strongly believes improve quality of care while minimizing cost and risk of program abuse. Uropath would respectfully request an opportunity to present to CMS data to substantiate these claims before CMS engages in this rulemaking.

C. Proposed Self-Referral Regulations: 42 CFR § 411.351

1. Square Footage Requirement

The Proposed Rule related to physician self-referral amounts to two principal changes to the "centralized building" prong of the In-Office Ancillary Services Exception in the Stark Law Regulations. First if a group practice contracts with a physician to provide professional services on its behalf in a centralized building, and that physician also contracts with more than two other group practices to provide professional services in the same building, the group practice's centralized building must be larger than 350 square feet. Presumably, CMS chose 350 square feet because it believed that pod labs are larger than that, though it has sought comment on whether the area requirement should be more or less than 350 square feet. If a group practice's lab is larger than 350 square feet, this change is irrelevant, and if a group practice's independent contractor pathologist contracts with fewer than four groups in the same building, the change is irrelevant.

CMS flatly states that "the purpose of the square foot minimum and the related exception is to prevent abusive arrangements such as pod labs." CMS has concluded that pod labs are an abusive arrangement without any demonstrable evidence to support the conclusion, and without ever having requested any information from pod labs which would assist CMS in appreciating potential risks and benefits of such arrangements. Uropath-managed laboratories could modify their footprints to ensure they are not implicated by this regulation. Alternatively, these

laboratories could ensure that their relationships with pathologists do not exceed the arbitrary limits on such relationships that CMS may implement. These short term solutions could permit Uropath-managed laboratories to continue to provide their unsurpassed pathology services in a manner compliant with laws that may change annually in an effort to destroy them.

A more reasoned approach is to withdraw these rules and permit Uropath to present data, information, statistics and outcomes to CMS that substantiate that pod labs provide superior urological pathology at lower cost to the Medicare program. Uropath believes if this rulemaking is postponed while that process is undertaken the result will be more comprehensive, meaningful rules that address actual and significant risks of program abuse.

2. Fully-Equipped Requirement

The proposed self-referral regulations also requires that a "centralized building" contain, on a permanent basis, the necessary equipment to perform substantially all of the pathology services that are performed on the premises. Uropath fully supports this requirement, and Uropath-managed Labs already comply with this new requirement because Uropath believes it is required by already existing laws and regulations. CLIA regulations require that certain equipment, materials, and supplies be permanently present and available in a pathology laboratory in order for it to be licensed to provide pathology services.

In addition, Uropath believes a reasonable and appropriate inference of the In-Office Ancillary Services Exception to the Stark Law is that a group practice's centralized building be independently equipped with all necessary equipment to provide the services it provides. It is for that reason that the compliance policy Uropath provides to all group practices, entitled "Provision of Services at Remote Pathology Labs Under Stark Law" requires that each laboratory be independently equipped, and that under no circumstances should a Lab share laboratory equipment necessary for the provision of pathology services. This policy was provided to the OIG in connection with its audit of a Uropath-managed laboratory in 2005.

3. Comments on Issues for which CMS Requests Specific Comment

The proposed self-referral regulations also seek comment on several specific issues. The specific comments to these issues are addressed separately below.

Question: Should there be a minimum square foot requirement for a centralized building, and if so, should it be more or less than 350 square feet?

Answer: No, there should not be a minimum square foot requirement. CMS flatly states that "the purpose of the square foot minimum and the related exception is to prevent abusive arrangements such as pod labs." Uropath-managed laboratories could modify their footprints to ensure they are not implicated by this regulation. A more reasoned approach is to withdraw these rules and permit Uropath to present data, information, statistics and outcomes to CMS that substantiate that pod labs provide superior urological pathology at lower cost to the Medicare program. Uropath believes if this rulemaking is postponed while that process is undertaken the result will be more comprehensive, meaningful rules that address actual and significant risks of program abuse.

Question: Should CMS impose a requirement that a centralized building permanently contain the necessary equipment to perform substantially all of the designated health services furnished in the "centralized building?"

Answer: Uropath believes it should be reasonably inferred from existing Stark Law Regulations that this is a requirement of a centralized building. To the extent CMS believes this clarification is appropriate, Uropath agrees.

Question: Should CMS require that, for space to qualify as a "centralized building," a group practice must employ in that building a non-physician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week?

Answer: This requirement, if imposed, would have far-reaching and devastating consequences on a variety of providers, specifically including but not limited to solo practitioners, small group practices, and rural providers. If the imposition of this requirement is yet another attempt to affect the financial viability of pod labs, Uropath would echo previous comments regarding the lack of demonstrable evidence of program abuse, and its request to present data to CMS to substantiate that pod labs provide superior urological pathology at lower costs.

Question: Should a group practice be allowed to maintain a "centralized building" in a state different from the states in which it has an office that meets the criteria of a "same building" as that term is defined at 42 CFR § 411.355?

Answer: Those critical of pod labs often mention that a group practice's pathology laboratory may be located several states away from the group practices clinical offices. There is an inference that this arrangement is somehow inappropriate or abusive. There no basis for such an inference.

Locating several pathology laboratories in a single location promotes higher quality pathology for all labs by giving urological pathologists personal consultative access to other urological pathologists located in the same medical office building. Most state licensing laws require that a pathologist be licensed in both the state where the service is provided and the state where the patient resides, and Uropath ensures that all pathologists comply with applicable state licensing law. CMS has generally left issues of geographical location to the States.

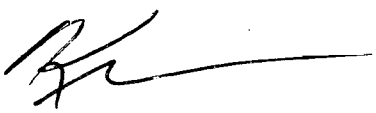
It should be noted that several national and regional pathology laboratories that compete with Uropath-managed labs collect prostate biopsies at the local level and then ship those biopsies to a single location several states away. At least two of these national laboratory companies claim to locate pathology-specific laboratories in Warren, Michigan, and in the state of Connecticut. Medicare reimbursement for CPT code 88305, the most commonly used prostate biopsy code in those locations is $112.55, and $116.24, respectively. Uropath-managed pod labs are located in the State of Florida and in San Antonio, Texas, where Medicare reimbursement for CPT code 88305 is $99.84 and $94.63, respectively. The national laboratory reimbursement rates are from 12% to over 20% higher than Uropath-managed lab rates. Forum shopping for the most lucrative national Medicare reimbursement rates profits national laboratories entirely at the expense of the Medicare program.

III. CONCLUSION

Uropath wishes to thank CMS for this opportunity to provide comments regarding the Proposed Rule. Uropath understands and appreciates CMS's mandate to protect the integrity of the Medicare program. Uropath believes it can continue to assist group practices in providing world class urologic pathology services in a manner that CMS is comfortable eliminates any undue risk of program abuse. Uropath would welcome the opportunity to openly discuss with CMS ways of achieving that goal.

If you have any questions or concerns about the comments we have submitted, we would be happy to discuss them with you.

Sincerely,



Ken Flowers, MBA, CHE
Chief Executive Officer

KF/dd

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315-253-7351 / Fax: 315-252-5345

October 2, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS – 1321 – P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: Federal Register, August 22, 2006, Proposed Rules for Blood Glucose Testing

Dear Sir:

I believe the proposed rule for blood glucose testing does not meet the spirit and intent of the Medicare program. The proposed regulation is unduly restrictive and contrary to the Act, the governing regulations, inconsistent with Medicare's National Coverage Decision (PM-AB-02-110) and contrary to standards of medical practice.

The NCD (PM-AB-02-110) recognizes that blood glucose testing is necessary for patients with diabetes and other defined medical conditions. The NCD specifically states that testing "using a device approved for home monitoring or by using a laboratory assay system using serum or plasma" is covered. It is also clear that this coverage determination encourages use of devices for home monitoring. The NCD goes on to say that the "convenience of the meter or stick color method allows a patient to have access to blood glucose values in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting (underline added). The NCD does not place any specific limitations on the frequency of testing. In fact the NCD simply states that "frequent home blood glucose testing by diabetic patients should be encouraged."

CFR 410.32(a) requires that in order for a diagnostic test to be considered reasonable and necessary it must be ordered by a physician and the ordering physician must use the result in the management of the beneficiary's specific medical problem. In the case of an SNF a physician orders blood glucose testing usually based on sliding scale for a month at a time. These explicit instructions to the attending RN to provide X amount of insulin for Y reading with instructions for immediate physician contact on outlier readings (unreasonably high or low readings). The physician review the results of these tests on his monthly visit, considering changes in patient's diet, change of

medications that may affect glucose levels, physical or cognitive issues etc. The physician either modifies or renews his testing and insulin orders a result of his review of the test results achieved. Thus it is quite clear that the physician utilizes these results in the patient's plan of care. It is ludicrous to expect a physician to be contacted several times a day to transmit test results and it is certainly contrary to current standards of medical practice.

CMS PUB 100-8 Chapter 13.5.1 states that in pertinent part that a service is considered reasonable and necessary when "furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition", is "ordered and furnished by qualified personnel" and "meets, but does not exceed, the patient's medical need." In an SNF the accepted standard of medical practice is for the physician to order these glucose tests to treat the patient. Orders are executed by an RN qualified to administer the test, read the results and act on the physician's orders to dispense insulin. These procedures are the "accepted standard of medical practice" today. For this proposed regulation to summarily state that physician's standing order will not be acceptable and necessary clearly violates Pub 100-8 Chapter 13.5.1.

It is interesting to note that CMS does not apply the above standard uniformly through out all the covered services paid by Medicare. For example, enteral services are paid under Medicare Part B. The doctor executes a Certificate of Medical Necessity (CMN) for a patient under his care that is in effect for as long as the patient remains on that service. The doctor is not required to constantly update this order. It is a standard medical practice to continue an order for a required service until such time as the service needs to be changed or terminated. Enteral services are required to keep the patient alive. Blood glucose services are needed to ensure that a patient does not go into diabetic shock. Both services are administered by nursing staff authorized and trained to do so. Both are required services to ensure the health and safety of the patient. Yet blood glucose has an unrealistic physician notification requirement.

The proposed regulations are also referring to doctor ordered blood glucose testing as "routine blood glucose monitoring". PRM I section 2203.1 and 2203.2 define routine and ancillary services respectively. The doctor ordered blood glucose test does not meet the definition of "routine" services. Routine services are defined as services routinely furnished to ALL patients such as room, dietary, medical social services, general nursing, general supplies, and equipment that is reusable and expected to be available in an SNF. While the definition of an ancillary service found in section 2203.2 are services directly identifiable to a patient, NOT generally furnished to most patients, are not reusable and represent a cost for each application. A blood glucose test meets ALL of these criteria in addition to being doctor ordered for the patient's specific medical need. The classification of these ancillary tests as "routine blood glucose monitoring" is erroneous and not consistent with Medicare regulations.

For the reasons cited above I respectfully request the CMS modify the proposed regulation to conform to the cited authorities and accepted standards of medical practice prevalent in the medical community today. To deny an SNF from availing itself to state of the art medical technologies and techniques to care for their residents in favor of a restrictive, not realistic, draconian approach to patient care effectively shifts the cost of practicing good patient care to the SNF. Instead CMS should be issuing instructions to their FIs through regulatory changes and updates to conform to the aforementioned NCD developed under the authority of the Negotiated Rulemaking Act.

Sincerely,

Karol Prayne

Karol Prayne
Administrator

Deborah R. Baum, M.D.
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5210 Linton Blvd.
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Delray Beach
Fl., 33484

September 24, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTENTION: CMS-1321-P
P.O.Box 8015
Baltimore MD. 21244-8015

To Whom It May Concern

RE: CMS1321-P Medicare Program Revisions to Payment Policies under the Physician Fee Schedule for Calendar year 2007 and other Changes to Payment under Part B.

I am writing to express my grave concern over the revisions proposed above. Apparently, these changes are meant to address concerns about the proliferation of 'Pod labs' which are pathology labs that have been set up side by side in a particular building by separate group practices. Each group then contracts with the same pathologist to interpret specimens obtained from all the separate practices. As a consequence there is often sharing of the same personnel and equipment. The allegation in this new proposal is that these labs will induce urologists, (or others) to perform unnecessary biopsy procedures so they can then benefit from the reading of the pathological specimens. This is apparently based on allegations by the American College of Pathology that ownership by urologists of pathology labs would then lead to more biopsies being done for profit. However, there has been no data to back up these allegations.

My concern here is that there the regulations are designed to change the definitions and applications of a '*centralized building*', '*physician in the group*' and '*reassignment of benefit*' concepts.

Changes to reassignment rules are unnecessary and unwarranted. Rules were deliberately liberalized to make logistical sense only 2 years ago. Groups throughout the country have relied on these changes to structure their affairs. Anecdotal allegations about potential abuse are entirely unfounded and not a proper basis to cause physicians everywhere to re-incur legal fees to unravel relationships structured to comply with recent, well-considered, regulations.

The Stark II, Phase II regulation published July 2004, contained specific, well considered provisions to permit the sharing of facilities for ancillary services by practices located in the same building. Many physicians, acting in direct reliance on these regulations, have

invested millions of dollars to establish these shared laboratory and imaging facilities and an alternative to more costly and complex formation of huge group practices. As intended, these shared facilities are both cost effective and convenient to patients, and many rely heavily on the 2004 'physician in the group' and reassignment of benefits regulations. To change these basic concepts at this time, in the absence of clear data demonstrating the need for change is unfair and places an unfair burden on physicians, who, in good faith, have entered into these shared facilities.

The cost effectiveness of shared ancillary facilities is obvious. Rather than duplicate capital expenditures for state-of –the art technologies like PET Scans, high speed CT scanners and MRI , and duplicate operating costs for personnel and facilities that would be underutilized, shared facilities allow practices to offer the most current technologies and best trained personnel. Further, these shared facilities will enable practices to continue to offer these advantages even if the drastic fee reductions proposed for January 2007 are fully implemented. Eliminating unnecessary overhead should be a goal of any efficient system, including those financed by CMS.

The proposed regulations would intentionally create unnecessary overhead by proposing minimum square footage, limitations on the number of practices in the 'same building' and using the same sub specialists, requiring non-physician personnel for at least 35 hours per week regardless of productivity and requiring 'permanent' equipment. The stated goal of creating artificial requirements is to 'make it not financially feasible for pod labs to exit, is illogical since the stated basis of this goal is that the organized pathology lobby alleges that they think allowing urologists to profit from labs might cause them to perform unnecessary biopsies. In virtually every scenario, the costs to the program are driven by the pathologists, not the clinician. Pathology determines numbers and types of studies/stains performed, which determines cost. Rather than pretend that the cost problem is driven by who owns the lab, a better approach would be to regulate how pathologist are allowed to be compensated (in the same manner as Stark currently prescribes compensation to other MDs based directly on value or volume of DHS referrals).

There seems to be inherent unfairness of changing already overly complex and misunderstood reassignment rules to preserve income levels for MDs who never even see patients, all as part of regulation to reduce compensation to those who actually treat them.

Thank you for your consideration

Sincerely,

Deborah R. Baum, MD, FCCP