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APMA
American Podiatric Medical Association

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October 4, 2006

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

RE: CMS-1321-P
Comments on Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (71 Fed. Reg. 48982, August 22, 2006)

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's foot and ankle physicians and surgeons, is pleased to provide comments on the proposed rule that addresses certain provisions of the Deficit Reduction Act of 2005 (DRA), as well as makes other proposed changes to Medicare Part B payment policy. The APMA offers the following comments:

Provisions

Payment for Splint and Cast Supplies (p. 48986)

We support the decision by the Centers for Medicare & Medicaid Services (CMS) to continue to pay for splint and cast supplies using the Healthcare Common Procedure Coding System (HCPCS) Q-codes. We agree that the majority of these supplies will be used in the management of fractures and dislocations but recognize that these supplies are also sometimes necessary for other reasons, including serial casting, wound care or protection. We appreciate that CMS has proposed a system that will continue to allow these medically necessary supplies to be paid separately.

According to CMS:

"Physicians would continue to bill the HCPCS Q-codes, in addition to the cast/strapping application procedure codes, to be paid for these materials. The following supplies would continue to be paid separately using the HCPCS Q-codes and would not be included in the PE database upon adoption of this proposal:

. Fiberglass roll
. Cast padding
. Cast shoe
. Stockingnet/stockinette
. Plaster bandage
. Denver splint
. Dome paste bandage
. Cast sole
. Elastoplast roll
. Fiberglass splint
. Ace wrap
. Kerlix
. Webril
. Malleable arch bars and elastics

The splint and cast supplies would not be included in the PEs for the following CPT codes:

. 24500 through 24685
. 25500 through 25695
. 26600 through 26785
. 27500 through 27566
. 27750 through 27848
. 28400 through 28675
. 29000 through 29750."

Based on the proposal by CMS, a "cast shoe" would now be included as part of the definition and value of the splint and cast supply Q-codes. In our opinion, "cast shoes" should be removed from the list. Since shoes, other than qualified diabetic shoes and shoes attached to a brace, are statutorily non-covered items, "cast shoes" should not be listed within defined items included in the "Q" splint and cast supply codes. Similarly, the same would hold true for cast shoes dispensed post-operatively following a surgical procedure or service as those shoes are not included "globally" with procedures or services.

Supply Items Needing Specialty Input for Pricing (p. 48989)

CMS has requested specialty society input on the Micro air burr. We believe this information already exists in the database as "drill system, surgical, small-micro (Stryker)". We are attaching information on what is included in the system, along with pricing information. We hope this information is sufficient but if it is not, we will be happy to continue to work with CMS in obtaining additional pricing information for this item.

DRA Proposals

Revisions to Payments for Therapy Services (p. 48997)

The APMA is concerned with the removal of the exceptions process for the therapy caps. While we appreciate that the implementation of an exceptions process was required by Congress for calendar year 2006 only, we believe that the process developed by CMS was fair and reasonable. We believe that prior to eliminating the exceptions process CMS should carefully assess how that process was utilized in 2006 so that Medicare beneficiaries needing access to medically necessary therapy services will continue to be able to receive those services.

CY 2007 Update and Proposed Revisions of the Medicare Economic Index (MEI) (p. 49069)

This year's proposed rule includes only a passing reference to the CY 2007 update and no discussion whatsoever of the MEI. This is a significant change from previous proposed rules when detailed information about the update and the MEI have been provided and comments from the public have been solicited. The only discussion in this year's proposed rule is in the section on the Regulatory Impact Analysis where it says: "Table 7 below shows the specialty level impact of section 5102 of the DRA and our most recent estimate (-5.1 percent) of the CY 2007 Medicare PFS update."

This number is 0.5 percent less than the estimate of -4.6 percent recently contained in the President's Budget. An explanation of the reduced update was included in the Fact Sheet on the Medicare Economic Index that was released on August 8, 2006 the same date that the proposed rule was released. According to the Fact Sheet, the lower MEI is due to the use of a new measure of productivity by the Bureau of Labor Statistics (BLS) and lower projections of inflation. Few details were provided and CMS did not request comments on the changes.

The impact of reducing the MEI by 0.5 percent is significant. We estimate that -0.5 percent reduction in the update will result in a $375 million cut in physician payments in 2007. Because of this impact and the fact that the revised MEI was not even discussed in the proposed rule, we believe it should be withdrawn.

We also dispute the new data allegedly showing increased physician productivity. This simply cannot be correct given the recently added burden of counseling Medicare beneficiaries on their new prescription drug and preventive services benefits. Our members have provided this counseling as a service to their patients and in response to explicit requests from Medicare that they do so. It should be obvious that taking time out of a busy schedule to provide counseling for which no separate payment is made would decrease, rather than increase a physician's productivity.

Finally, we believe that CMS may be in violation of the Administrative Procedures Act (APA). A proposed rule and the opportunity to submit comments must be provided by CMS. We recommend that CMS withdraw its proposed change in the MEI and include it in the proposed rule for CY 2008 which will be published in late Spring or early Summer of 2007.

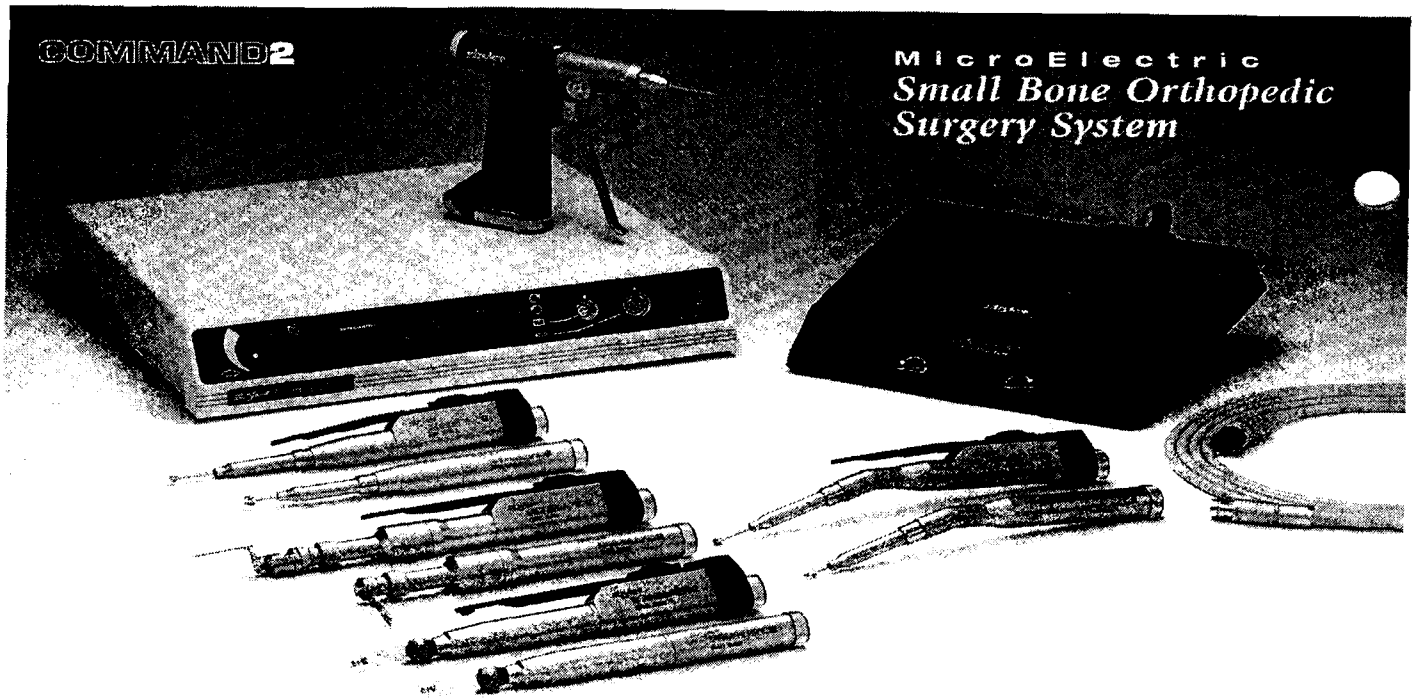
Conclusion

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

Sincerely,

David M. Schofield, DPM
President

Stryker customer service phone quote 1-800-253-3210:
surgical small bone drill system; Total: $8,979
drill with handswitch (#2296-210); $4,200
irrigation tube set (#260-901-50); $174
control console (#2296-1); $2,500
connectors/cord (#296-4); $605
auto irrigator pump (#296-1-284); $1,500



COMPLETE COMMAND2 MICROELECTRIC SYSTEM ORDERING INFORMATION

PRODUCT NUMBER	NAME
HANDPIECES	
2298-10	50K Drill
2296-210	50K Drill with handswitch
2296-12	20° 50K Drill
2296-212	20° 50K Drill with handswitch
2296-16	Spine Drill
2296-216	Spine Drill with handswitch
2296-34	Sagittal Saw
2296-234	Sagittal Saw with handswitch
2296-31	Oscillating Saw
2296-231	Oscillating Saw with handswitch
2296-37	Reciprocating Saw
2296-237	Reciprocating Saw with handswitch
2296-44	Dermabrader
2296-88	MicroDriver (includes wire collet 296-80-62)
2296-300	Impaction Drill
260-901-15	Implant Drill
296-80-110	Synthes® Chuck
296-80-112	Trinkle Chuck
296-80-62	Wire Collet (Accepts wires from .028-.078" dia.)
296-80-125	Pin Collet (Accepts pins from .078-.125" dia.)
296-80-131	Jacobs® Chuck with Key
2296-80-134	Command2 MicroElectric Sagittal Saw Attachment (Accepts all Command2 Precision™ Micro Blades)
296-80-150	High Torque Jacobs® Chuck with Key

PRODUCT NUMBER	NAME
COMMAND2 GENERAL ACCESSORIES	
260-901-19	Contra Head with External Irrigation
260-901-20	1:1 Contra Head
260-901-21	1:1 Reducer
260-901-23	16:1 Reducer
260-901-24	64:1 Reducer
260-901-25	256:1 Reducer
260-901-26	1024:1 Reducer
48-138	Luer Lock Connector Clip
260-901-54	Three-Way Luer Lock (Non-sterile, individual packages)
260-901-55	Irrigation Caps (Non-sterile, 10 per package)
260-901-531	Spend Reducer Tube Clip
260-901-532	External Irrigation Clip (For use with Implant Drill Heads)
260-901-533	Internal Irrigation Clip (For use with Implant Drill Heads)
260-901-556	Internal Irrigation Tubing Clip (For use with Implant Drill Heads)
260-901-739	ContraClean™
260-901-50	Irrigation Tube Set with Accessories
Tube Set Includes the Following Items which may also be Purchased Separately:	
260-901-51	Bag Spike Set
260-901-52	Irrigation Tube Set
260-901-53	Pump Insert with Tube
2296-175	Sterilization Case for Command2
296-3	I.V. Pole
2296-170	Sterilization Basket for Command2
2296-180	Command2 Carrying Case
2298-3-100	Office Handpiece Sterilization Rack

PRODUCT NUMBER	NAME
298-98-100	Accessory Organizer (for Burs and Blades)
2296-3-400	Oscillating Saw Adapter w/ Wrench
2296-1	Console
296-4	Connectors and Cord
2296-7	Unidirectional Footswitch
2296-8	Bidirectional Footswitch
296-1-284	Auto Irrigator Pump
2296-2	Command2 Pinch Valve (for 2296-1 Console)
296-2-20	Silicone Irrigation Tube Set for Pinch Valve (non-sterile)
296-2-22	Silicone Tubing for Auto Irrigator
296-2-25	PVC Irrigation Tube Set (pkg. of 10) (sterile)
296-2-28	Irrigation Holder for Auto Irrigator
296-2-30	Tube Set Clips
2296-101	Bur Guard
2296-301	Impaction Drill Bur Guard
2298-302	Impaction Drill Shield
2296-100-200	Irrigation Clip for 100K Drill (296-100)
2296-101-200	*Irrigation Clip for 100K II Drill with Bur Guard*
2296-10-200	Irrigation Clip for Command2 50K Drill
2296-12-200	Irrigation Clip for Command2 20° 50K Drill
2296-31-200	Irrigation Clip for Command2 Handswitch Oscillating Saw
2296-34-200	Irrigation Clip for Command2 Handswitch Sagittal Saw
2298-37-200	Irrigation Clip for Command2 Handswitch Reciprocating Saw
2296-300-200	Irrigation Clip for Impaction Drill with Shield
2296-301-200	Irrigation Clip for Impaction Drill with Guard
2296-400	Bur and Blade Rack
2296-401	Surgical Power Station

See Bur and Blade Literature for complete listing of blades and burs.

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Community Oncology Alliance

Dedicated to high quality, affordable, and accessible cancer care

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communityoncology.org

October 10, 2006

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

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

Dear Ms. Norwalk:

On behalf of Community Oncology Alliance (COA), we would like to provide commentary on the Centers for Medicare & Medicaid Services (CMS) proposed notice regarding revisions to payment policies under the physician fee schedule for calendar year 2007 and other changes to payment under Part B. COA membership is representative of approximately 85% of the cancer care delivery system in this country and as such, is truly the voice of community oncology.

As **Background**, we are very much aware of the proposed 5-year RVU modifications scheduled to become effective 1 January, 2007 and COA has submitted commentary in response to such proposed rule. Briefly:

1. The budget neutrality adjuster poses the potential of up to a 10% reduction in RVUs.
2. The Geographic Practice Cost Indices (GPCI) floor will be eliminated year end 2006 creating additional reimbursement reductions, especially in already compromised rural clinics.
3. A proposed Physician Fee Schedule (PFS) reduction of 5.1% further crippling oncology.
4. The possibility of a reduction in the conversion factor decreasing reimbursement further.
5. Failure of CMS to re-evaluate reimbursement rates on recently cross walked G codes will leave such under-valued for another six years.
6. Absence of an oncology demonstration project for 2007.
7. Four year Phase-In will reveal additional layers of flawed methodology.
8. Our ongoing concerns that the promises made under MMA have not been fulfilled. This includes the creation of oncology treatment planning code(s), reimbursement for pharmacy facilities costs and permanent corrections to cover the real costs associated with first and subsequent hours of chemotherapy administration. The first two items on this list are not covered. The latter item is covered at about 60% of actual cost.
9. PriceWaterhouseCoopers reports that MMA reduced payments to oncology by $13.7 billion over ten years – over three time's Congressional intent.

All of these things add up to disastrous consequences for community oncologists nationwide.

Provisions of the proposed rule present concerns as follows:

1. The absence of a review on temporary G codes recently converted to CPT codes in the current calendar year translates into an inaccurate valuation of critical administration codes for a further six year duration.
2. We note the assignment of work RVU's to three medical nutrition therapy (MNT) codes, as well as the creation of two temporary G codes to track MNT services following a second referral in the same year. Community Oncologists have been providing these services free of charge within their offices for years by necessity. Toxic chemotherapy and associated rescue agents demand strict nutritional adherence; a service never reimbursed in the community setting.
3. We have concerns about the incorrect valuation placed upon home health and hospice codes for clinical labor since calendar year 2004. What is the impact of these changes up or down and if an underpayment exists, will we be made whole?
4. Mention is made under Supply and Equipment Table 2 to include OSHA ventilated hood, code ER008 within the specialty of Radiation Oncology associated with CPT code 77334 carrying a 2005/6 price of $5,000. Do we assume that similar allowances will be made for all administration codes associated with drug administration within the specialty of Hematology/Oncology?

Geographic Practice Cost Indices (GPCI) as addressed raises these questions:

CMS indicates that it must review GPCIs at least every 3 years and make resultant adjustments over two years, implementing only one-half of any adjustment in the first year if more than one year has elapsed since the last GPCI revision. To date, there is no new census data, yet CMS is removing the floor of 1.00, reverting to the fully implemented value effective 1 January 2007. As reflected in Table 3: Payment Localities with Negative Percent Change, there are a number of areas that will be very much affected by this implementation. We are concerned that the Medicare beneficiary's access to care will be severely diminished. CMS looks to state medical societies as the impetus for change to these affected localities, yet does not have an algorithm that will produce fair and equitable adjustments. MEDPAC and GAO indicated a willingness to study this phenomenon to identify alternative methods of reconfiguration. It is our suggestion that the final adjustment slated for 1 January 2007 be delayed until such time as these agencies are able to discern a more legitimate method of calculating adjustments to various payment localities.

There is a vast amount of discussion regarding **Proposed Payment for Covered Outpatient Drugs and Biologicals (ASP Issues)**, and while we do realize that the manufacturer, wholesaler, distributor and pharmacy benefit managers must contribute largely to this section, Community Oncology Alliance is of the opinion that responses elicited by these representative groups will profoundly effect our ability as clinical oncologists, to supply and administer these life-saving drugs to our patient population.

CMS states that the implementation of Medicare Part D did not change Medicare Part B coverage. We simply do not agree with this statement, for it has profoundly changed not only how we procure drugs for our patients, but which drugs your Medicare beneficiaries have available to them via an ever changing formulary. Medicare Advantage Plans have become the consumer choice in specific geographic areas and have begun to dictate which drugs their members can avail themselves of via the physicians office versus the specialty pharmacy benefit manager, often times forcing treatment at home under the guise of other than oncology

certified nurses. Treatment modifications and treatment delays have been the net result of mountains of paperwork necessitated by insurance dictated pre-authorizations and letters of medical necessity.

There appears to be a tremendous amount of interest in arriving at a fair methodology for computing Average Selling Price (ASP), even going so far as to mention the inclusion of costs for handling, storage, inventory reporting, shipping, receiving, patient education, disease management and data borne by manufacturers. CMS, it seems, is considering revising the current calculation for deriving ASP, taking into account the fair market value of the aforementioned services. It strikes us as odd that this agency would hear and act upon the sentiment of manufacturer, yet ignore the claims by community oncology clinics for the very same services. Clinics must purchase, ship, store and inventory all drug products. And too, they must ascertain how to prepare the drug for administration, educate the patient and his family, monitor disease progression or regression and maintain and accumulate such data in a medical record, preferably electronic. Many, if not all, of the above are under-reimbursed or un-reimbursed by CMS. Creation of a pharmacy facilities management code and a treatment planning code would fill this void of Part B reimbursement quite effectively.

COA is encouraged to learn that CMS has genuine concerns as it relates to the validity and accuracy of calculating Average Selling Price (ASP). Manufacturers, Distributors, Group Purchasing Organizations (GPO) and Pharmacy Benefit Managers (PBM) have sought guidance from CMS on the topic of administrative fees, service fees and fees paid to PBMs in the calculation of ASP. Oncology clinics and the physicians who support them also have genuine concerns as to the response to be given to such and offer the following thoughts.

We feel it imperative that fees for bona fide services be excluded from the calculation of ASP. Any contractual arrangement between two parties wherein a service is provided at fair market value is simply that, an independent agreement between two parties. It is totally inappropriate to roll into the calculation for ASP any fees resulting from such relationship as such should not affect the ultimate price paid by the end user, the physician clinic. Further, a bona fide service should be left to the hands of those discerning the value or benefit derived from such, with fair market value ascertained by the two contracting parties, which is the route normally taken for all contractual arrangements. As you know, the value of such things as data is sometimes limited to a single source and CMS truly is not in a position to place a value on that. We therefore request that CMS abstain from determining what is and is not a bona fide service. However, should CMS decide to move forward with such determination, it is strongly suggested that any decisions regarding what actually constitutes a bona fide service fee be presented as formal rulemaking, rather than through a Program Transmittal. CMS must be cognizant of the fact that even the most minor of changes in ASP reporting can have devastating consequences on provider reimbursement and ultimate patient access and quality of care. Any proposed changes should have benefit of input from all stakeholders before implementation.

Many physician groups and clinics belong to GPOs for the explicit purpose of negotiating contracts with manufacturers; however, we do not believe that GPOs in general, purchase actual product themselves. In that they are not, in actuality, purchasers, fees paid to them by manufacturers should be ineligible insofar as ASP calculation is concerned. At times, a GPO may decide to share some portion of fees paid by a manufacturer with its members, the actual purchasers. Again, this is a business decision made by the GPO to a purchaser and such

reapportionment should not be incorporated in any ASP calculation, as not all end users have similar benefit.

COA is supportive of CMS' efforts to establish a uniform method of estimating lagged exempt sales. We are concerned that this number, as currently reported, is not truly reflective of actual realized ASP ineligible sales, which has greatly contributed to distorting the reimbursement paid to providers who simply cannot acquire said product at current ASP numbers. Specific focus should be directed at drugs purchased by Part D plans and state pharmaceutical assistance plans, which volume is increasing at a rapid rate. Many of our patients are given scripts to have their prescriptions filled at a local pharmacy under a Part D or state medical assistance plan. It is our understanding that these drugs are being removed from the ASP calculation, even though the initial sale to the specialty or retail pharmacy is an ASP eligible sale. Additionally, we suspect that drugs sold to qualified retiree plans are sometimes included, sometimes excluded in reporting. Clearly there is a problem and it is requested that CMS take immediate action to clarify estimation methodology, as the current "guesstimate" only further exacerbates the problems experienced by our physicians' inability to purchase drug at current ASP reimbursement.

COA would also like to contribute its thoughts as it relates to contract bundling and its impact on ASP calculation. We are deeply concerned that any apportioning methodology that potentially may be proposed by CMS, as it relates to discounts and rebates, will have a negative impact rather than a positive one on ASP. Physician clinics are being paid 80% of ASP+6. Given the "bad debt" situation, clinics are essentially under water for most cancer treatments. Clinics are concerned that the removal of these discounts will preclude purchase and administration of products currently included in these bundling type arrangements, resulting in the potential for even greater access issues for cancer patients. Bundling arrangements are common, and we are aware of similar bundling arrangements between manufacturers and hospitals and ambulatory care centers for medical devices, supplies, and drugs. Therefore, we are somewhat puzzled at CMS' motive for questioning such contracts only in the Part B setting. The vast majority of chemotherapy services are provided in the community clinic setting, and clinics currently are permitted to negotiate with manufacturers to secure discounts on the oncology products that they administer to their patients. If our ability to negotiate with the manufacturer is removed or substantially limited due to an apportioning methodology, many patients may be left without the potentially life-saving drugs that they require. Again, a very large potential for patient access issues exists if CMS chooses to remove or limit a physician's ability to negotiate with manufacturers for discounts.

Should CMS wish to pursue pricing policies and bundling price concessions in the near future, we respectfully request that such are presented in the form of a proposed rule, allowing all stakeholders to comment on this controversial issue.

We are grateful to CMS for modifications suggested in the frequency of testing for **Bone Mass Measurement Tests**, however, COA clinicians would like to see an exception made for those Medicare beneficiaries who have a history of, or who are currently receiving chemotherapy treatment, which is well known to cause bone degradation and/or exacerbation of osteoporosis. More frequent bone mass testing will allow physicians to prescribe the appropriate treatment for those conditions created or worsened by the use of toxic chemotherapy agents and complementary rescue agents and maintenance drugs and the current 23 month period is too long after chemotherapy initiation.

A **Regulatory Impact Analysis** must be prepared as it relates to the Physician Fee Schedule 2007 Proposed Rule because it is estimated that more than $100 million dollars will be redistributed as a result of its implementation. CMS is using paid claims processed and paid thru March 30, 2005 as the basis for estimated changes to the 2007 PFS, the net result of which is a supposed 3% increase derived from changes to Work and RVUs, culminating in 2011 with an actual decrease to 2%. However, we reiterate that this stated increase is deceptive in that reimbursement to community oncology clinics has actually decreased beginning in 2004 and continuing up to the present. Add to this, the pending reduction of 5.1%, the continual slide in ASP drug reimbursement and the ratcheting down of payment on drug administration and CMS has actually created a lose/lose situation for community oncology clinics and patients alike, with no salvation on the horizon. While Medicare Part B reimbursement continues its downward spiral, the cost of doing business continues its upward climb, forcing the closing of many clinics; rural, urban and suburban, the downsizing of practices, the retirement of outstanding physicians, the sale of private practices to outpatient hospital facilities, and the transfer of care from the community to the nearby university or community hospital. We sincerely doubt that this was the intention of MMA, but the sad truth remains. The cancer care system in this county is being dismantled, unbeknownst to those wielding the changes.

Proposed changes with respect to payment for covered outpatient drugs and biologicals, says CMS "will have NO impact on Medicare Expenditures". If this is indeed fact, then don't you agree that it is time to take a long hard look at the entire RBRVS system, adopted in January 1992 to, in theory, value physician work involved in face-to-face care with the patient. And, while RBRVS succeeded in decreasing the value of expensive and short procedures, it was ineffective in factoring in high overhead, low face-to-face procedures like drug therapy. Why? Our theory is that there was very little outpatient drug treatment actually performed in the physician office setting at the inception of this system of reimbursement. For the past fourteen years, professional societies with drug based payments have attempted to find a way to be paid fairly for their services using RBRVS, without additional drug reimbursement. Bottom line....RBRVS simply does not work for drug therapy administration. A further effort to lower the RVUs for these procedures with only one year of history, underscores that this is true!

Community Oncology Alliance implores CMS to consider the impact of the changes it is making. It may take a year or so, but the net result is almost cast in stone.....care will be impacted and patients will die.....the present situation with IVIG appears to be a harbinger of the full-fledged crisis that could face cancer care. We call upon CMS to keep the promises made under MMA and properly pay for the drugs and fully pay for the essential services to deliver chemotherapy. At present, both are underpaid; clinics and patients are adversely impacted.

Sincerely,

Frederick M. Schnell, MD, President
Community Oncology Alliance

PHYSICIANS
RightPath
The In-Practice Pathology Solution

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October 10, 2006

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

Attention: CMS–1321–P

Dear Sir or Madam:

Please accept these comments from Physicians RightPath regarding proposed amendments to **Reassignment and Stark Rules** relating to diagnostic tests. Physicians RightPath provides "in-practice" pathology laboratories for group practices. These practice-based pathology laboratories, which are organized as a component of each physician group practice, supply a complete range of tissue processing and diagnostic pathology services to each client groups' patients.

I. IN-SOURCED PATHOLOGY SERVICES PROVIDE NUMEROUS PATIENT BENEFITS AND COST EFFICIENCES; CMS LACKS CREDIBLE EVIDENCE TO SUPPORT ITS PROPOSED CHANGES

By in-sourcing pathology services, group practices can improve patient care through better control over the quality and scope of the diagnostic services they furnish. Accurate, timely and consistent pathologic diagnosis is a critical factor in determining patient outcome. In-sourced pathology integrates and streamlines related diagnosis and patient care services and enhances communication between the clinician and pathologist, resulting in faster reporting, more timely second opinions, and an overall team approach to patient diagnosis, treatment, and follow-up care.

However, in-sourcing pathology services in the same office space where patients are seen can be an expensive and sometimes impractical undertaking. The preparation of specimens for diagnosis necessitates the use of a variety of noxious and hazardous chemicals, which pose considerable ventilation and storage problems. Most medical offices buildings are not equipped to permit utilization of such chemicals. Moreover, the cost of most physicians' office space is much higher than the cost of space suitable for a pathology laboratory – cost efficiency in every respect, including rent, is a priority for many physician practices given diminishing Medicare reimbursement.

10421 University Center Drive, Suite 500-M □ Tampa, Florida 33612 □ 813.549.1050 □ Fax: 813.549.1051 □ www.PhysiciansRightPath.com

Physician RightPath enables group practices to more easily and efficiently locate pathology laboratories in "aggregated pathology environments," which are comprised of multiple, spatially separate, independent, self-contained pathology laboratories. Each such pathology laboratory, is solely owned by and licensed to a qualified physician group practice, and is located at a centralized location that is owned or leased by the group on a full-time basis (that is, 24 hours per day, 7 days per week), and is used exclusively by the group practice.

This aggregated pathology environment also creates a community of extremely talented pathology professionals from which group practices can draw to staff their laboratories. This distinctive pathology community stimulates intellectual curiosity and fosters a collegial exchange of scientific knowledge further enhancing the depth and quality of patient care. Collectively, the aggregated pathology environment represents an extremely efficient and cost effective alternative for laboratory location, space, and access to high quality technical and professional pathology personnel.

CMS's proposed regulations will undermine the ability of group practices that have developed such services in good faith reliance on existing Stark exceptions to in-source pathology services and consequently compromise patient care. Perhaps most disconcerting, CMS is inviting these consequences without adequate basis to substantiate its proposals. CMS claims that its proposed amendments and additional changes under consideration are prompted by concerns that pathology labs operated by group practices generate medically unnecessary biopsies, unlawful kickbacks, improper fee-splitting and referrals that should be prohibited by the Stark Law. However, there is no objective statistical or documented evidence that group practices with pathology pod labs utilize pathology services more than group practices without pathology laboratories, or that they even present a clear threat of overutilization. CMS has offered no evidence to substantiate these concerns, and therefore seems to be proposing significant changes based on bald assertions and unsupported complaints by some commenters. CMS should not propose amendments to its Stark regulations without first documenting clear evidence sufficient to support such changes. Likewise, CMS should not utilize its reassignment rules – which are intended to prevent abusive billing and coding practices, not anti-kickback violations – to address perceived kickback concerns which are presently and more appropriately being addressed by the Inspector General for the U.S. Department of Health and Human Services ("OIG").

For the policy reasons stated above, Physicians RightPath urges CMS to abandon these recommendations, at least until such time as the Agency is able to substantiate its perceived concerns. We likewise urge caution for the legal reasons stated below.

II. PROPOSED CHANGES AFFECTING GROUP PRACTICE BILLING FOR THE TECHNICAL COMPONENT OF DIAGNOSTIC TESTS

A. Proposed Amendment to the Reassignment Rules

CMS proposes to amend 42 C.F.R. § 424.80(d) to: (i) expand the anti-markup rule for diagnostic tests purchased by a physician or physician group to diagnostic tests billed pursuant to a reassignment involving a contractual arrangement between the physician or physician group and a diagnostic test supplier; and (ii) require that the billing physician or physician group directly

perform the professional component of the diagnostic test furnished by the practice pursuant to a contractual arrangement.

Comments: We are not aware of any group practices attempting to use the contractual arrangement reassignment exception to circumvent the more stringent requirements of the purchased diagnostic test exception and the anti-markup rule. Moreover, we believe that application of the contractual arrangement exception to technical component diagnostic testing is spurious. The test is either furnished by the group practice, or the test is purchased by the group practice. In the latter case, the purchased diagnostic reassignment exception and the anti-markup rule apply, and it is not apparent to us why CMS would need to amend the contractual arrangement reassignment exception to make this clear.

B. Proposed Amendments and Changes Under Consideration to the Stark Regulations

1. Proposed Amendment to the "Centralized Building" Definition. CMS proposes to amend the Stark definition of "centralized building" by adding two additional requirements. First, CMS proposes that, unless there are no more than three group practices in the "same building" utilizing the same "physician in the group practice," the space leased or owned by the group must be at least 350 square feet. Second, CMS proposes that 90 percent of the Stark DHS furnished in the space in a calendar year must be performed with equipment that is permanently located in the space (*i.e.* not moved into the space temporarily from other parts of the building or from outside the building).

Comments: Group practices have for decades properly furnished their patients with access to ancillary services, such as clinical laboratory services, pharmaceuticals, and imaging services, and, since the passage of Stark I and Stark II (over 10 years ago), properly furnished these ancillary services in compliance with the Stark in-office exception and the physician services exception. The purpose of CMS's "centralized building" definition was to prevent circumvention schemes by so-called groups-without-walls, disparate group practices loosely affiliating solely for the purpose of aggregating their referral volume and exploiting the Stark in-office exception. The "centralized building" definition presented a barrier to any shared DHS facility arrangements by multiple practices by requiring that the group practice have exclusive use of the space. This "exclusive use" standard has, as a practical matter, restricted off-site, group practice DHS facilities (including off-site pathology laboratories) to those facilities operated by group practices large enough to cover the cost of such a facility. In reliance on the "centralized building" definition, these larger groups have made a significant investment in space, equipment and staff. However, certain imaging and other diagnostic testing is not furnished efficiently with equipment that is permanently installed in the space. A multi-site group practice, for example, may very well rotate an ultrasound or echocardiography machine in and out of a "centralized building." Accordingly, we do not believe that CMS should finalize its amendments to the "centralized building" exception as proposed. This would unnecessarily disrupt the operation of many long-standing DHS facilities that have legitimately operated in reliance on the "centralized building" definition, in certain cases requiring closure of these facilities.

2. Changes to the "Centralized Building" Definition Under Consideration. CMS is also considering (and requested comments on) amending the Stark regulations to require that a group practice with an off-site DHS facility in a "centralized building" employ or contract with an individual who performs services exclusively for the group at least 35 hours per week in the facility. CMS is also considering whether to require that the "centralized building" be located in the same state where the practice maintains a full-time medical office (providing evaluation and management or therapeutic services), or require that the "centralized building" be located within a certain number of miles of the group practice's medical office.

Comments: CMS needs to keep in mind that there are very large group practices with large regional and rural service areas that have mobile and fixed site diagnostic facilities that operate in multiple states, many miles from the group's medical offices. For example, a large multi-specialty group practice might have a mobile echo unit that travels to remote, rural locations or moderately populated urban areas. But for these mobile units, the local primary care physicians would not have access to echocardiography, a primary cardiac diagnostic tool. These mobile units operate in reliance on the current "centralized building" definition. An in-state or mileage limitation would likely shut down some of these mobile outreach programs, impairing access to specialty care. Similar consequences could follow for other diagnostic testing services, including pathology laboratories.

In addition, full-time (35-hours per week) employment of an individual in the "centralized building" is a poor proxy for a "legitimate" centralized building. There is a short supply of qualified technologists and other staff to work in diagnostic testing and other DHS facilities. Part-time employment (only) may be necessary to staff a DHS facility in a centralized building. Further, while the "centralized building" definition has consistently required exclusive use, it has not required that the facility be open full-time (only that the space be leased full-time). By adding this "full-time" standard, CMS will effectively shut down facilities that cannot afford to remain open on a full-time basis. Accordingly, CMS should not adopt these concepts in the final rule.

Finally, we believe that CMS's comments (on page 71 *Fed. Reg.* 48,982, 49,056) on the applicability of the "centralized building" definition to the physician services exception to the Stark law are in error. Neither the physician services exception nor the definition of "physician in the group practice" have a site of service requirement for physician services furnished by owners and employees pursuant to referrals by another physician in the group practice. Only when the physician services are provided by an independent contractor to the group is there a site of service requirement by reference to the definition of "physician in the group practice." However, as CMS notes, the definition of "physician in the group practice" uses the phrase, "in the group's facilities," not in the "same building" or in a "centralized building." If CMS had meant "same building" or "centralized building," it could and should say so. Construing "in the group's facilities" to mean "same building" or "centralized building" suggests that CMS thinks that professional component DHS (*e.g.*, interpretations) billed by a group practice in reliance on the physician services exception is somehow dependent on compliance with the Stark in-office exception's location test, which is simply not true. These are distinct exceptions with their own

approach to site of service or location, and it is important to recognize the distinction.[1] Accordingly, we believe that CMS should note this error in its response to comments, lest it give the wrong impression that professional component DHS performed by an owner or employee of a group practice has to be provided in the "same building" or a "centralized building." If CMS should elect to create an "on the premises" exception to its contemplated prohibition on billing for professional interpretations by contractors under the contractual arrangement reassignment exception, we recognize the utility of defining "on the premises" consistent with the Stark "same building" or "centralized building" definitions. However, in such case, CMS should create an exception to accommodate professional interpretations performed in the hospital. Without it, a group practice would be prevented from billing for a professional interpretation performed by one of its physician employees or owners at the hospital, for example, if another physician in the group were the source of the referral.

III. PROPOSED REASSIGNMENT CHANGES AFFECTING GROUP PRACTICE BILLING FOR THE PROFESSIONAL COMPONENT OF DIAGNOSTIC TESTS

A. Proposed Changes to the Contractual Arrangement Reassignment Exception

CMS is considering amending the contractual arrangement reassignment exception that would effectively prohibit a group practice from billing for the professional component of a diagnostic test performed by an independent contractor if the practice is the source of the referral.

Comments: We understand why CMS would want to prevent the contractual arrangement reassignment exception from being used to circumvent the constraints of the purchased interpretation exception. However, we believe that CMS should make an exception for professional interpretations by an independent contractor performed on the premises of the ordering group practice. This would preserve the well-established and long-standing distinction between independent contractor services on and off the premises of a practice or clinic that was recognized by CMS for decades under the health care delivery system – clinic exception, which the contractual arrangement exception effectively replaced and expanded. CMS effectively recognized this distinction in its recent manual instructions on IDTF billing. See Program Integrity Manual, Chapt. 10, § 4.19.8.C. (Offsite Interpretations). That instruction states that an IDTF can only bill for an interpretation performed by an independent practitioner off the premises of the IDTF if the interpretation qualifies for the purchased interpretation reassignment exception. This instruction implies a decision by CMS to distinguish a purchased interpretation from a contracted interpretation by the site of service, a distinction that group practices have made for decades under the health care delivery system-clinic exception.

By adopting this distinction between "on-site" (or on the premises) and off-site (or off the premises) as the touchstone for distinguishing between a purchased interpretation and an interpretation performed pursuant to a contractual arrangement, which CMS could do through interpretation (manual instructions), not rulemaking, CMS could avoid additional notice-and-

[1] The "in-office exception" does not apply to professional interpretations, unless you take the odd position that a contractor physician who is interpreting test results does so under the supervision of another physician in the group practice. The physician services exception is clearly the more suitable Stark exception for professional interpretations.)

comment rulemaking and having to consider such drastic measures as an anti-markup rule for professional interpretations performed pursuant to a contractual arrangement.

We believe that, for purposes of the contractual arrangement exception (as applied to interpretations), "premises" should be defined as space in the "same building" or in a "centralized building," as those terms are currently defined by the Stark regulations. We oppose the proposed amendments to the "centralized building" definition for the reasons stated above in Part I.B and below in Part III. However, as noted above, CMS should create an exception for professional interpretations performed in the hospital pursuant to a referral by another physician in the group practice, which it can do through manual instructions.

B. Proposed Changes to the Employment Reassignment Exception

We note that CMS proposes amending the heading for Section 424.80(d) of the Medicare regulations from "Reassignment to an entity under a contractual arrangement: Conditions and limitations" to "Reassignment to an entity under an employer-employee relationship or under a contractual arrangement: Conditions and limitations," (emphasis supplied).

Comments: This proposed amendment suggests that CMS may be considering restricting a group practice from billing for the professional component of a diagnostic test performed by an employee of the practice if the practice is the source of the referral. We believe that any such changes to the employment reassignment exception would be highly controversial, and inconsistent with the well-established and long-standing rule that an employer can properly take reassignment from its employee without regard to the site-of-service. Further, CMS should not adopt any such change without full notice-and-comment rulemaking.

* * * * *

We appreciate your attention to these comments. Please call me at 877.446.7284 if you have any questions about Physicians RightPath or these comments.

Sincerely,

D. Russell Locke, M.D., MPC

D. Russell Locke, M.D.
President

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October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW, Room 445-G
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; INDEPENDENT LAB BILLING (71 Federal Register 48982), August 22, 2006.

Dear Dr. McClellan:

On behalf of our 4,800 member hospitals, health care systems and other health care organizations, and our 38,000 individual members, the American Hospital Association (AHA) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on laboratory billing for the technical component (TC) of physician pathology services provided for hospital patients.

CMS proposes to amend section 415.130 in the Medicare regulations so that an independent lab may not bill the carrier for physician pathology TC services furnished to a hospital patient after December 31, 2006. CMS states that allowing independent labs to bill for these services would result in the Medicare program paying twice for the TC service – first to the hospital treating the patient through the inpatient prospective payment system (PPS) rate, and again to the independent lab that performs the TC service. **However, the AHA believes this statement is based on flawed assumptions and urges CMS to continue to pay independent labs for services to hospital inpatients in the same manner as they do today.** Given the history of the development of the inpatient and outpatient PPS systems, and CMS' guidance with respect to pathology TC services, it clear that the **TC costs are not included** in the inpatient diagnosis-related groups (DRGs) created under the inpatient PPS.

BACKGROUND

The TC of physician pathology services includes the preparation of the slide involving tissue or cells that a pathologist will interpret. These services also include a pathologist's examination of tissue removed during surgery – such as tumors, inflammatory tissue and biopsies – to determine whether disease is present and, if so, which one(s). They are necessary in order to continue to provide many kinds of surgical services in hospitals.

Many hospitals elect to use physician pathology services provided by independent labs. Some hospitals enter into these arrangements because they lack the surgical volume necessary to support an in-house pathology practice. Others choose to send out specimens because, by taking in referrals from multiple sites, an independent lab can provide more sophisticated diagnostic services for a wider range of cases than a single hospital alone can afford for its patients.

Medicare had a long-standing history of paying labs directly for both the preparation and interpretation of the patient specimen under the physician fee schedule prior to 1999. That year CMS proposed eliminating separate billing and payment for these TC services. This would have created significant hardship for both labs and the hospitals they served. At the request of stakeholders, CMS delayed implementing this policy for one year to allow sufficient time for hospitals and independent labs to negotiate arrangements. Subsequent congressional action over the last six years has allowed for the continuation of separate billing for the TC services for a large number of hospitals that had arrangements with independent labs in place prior to CMS' 1999 proposal. Under the *Medicare Modernization Act of 2003* (MMA), Congress extended the "grandfathering" of these hospital arrangements through 2006.

IMPACT OF PROPOSED POLICY ON HOSPITALS

Allowing this provision to expire will harm all hospitals included in the grandfather provision, and would be especially burdensome for small and rural hospitals. Hospitals and independent labs will have to put into place costly and administratively complex new billing systems and procedures, stretching already scarce resources and potentially forcing them to reduce the variety of services they provide.

Under current direct billing arrangements, labs submit a single global bill to Medicare for both the TCs and the physician's professional component services. Without direct billing, the labs will be required to issue two bills – one to Medicare for the professional component and another to the hospitals for the TCs, thus doubling the lab's billing costs. Hospitals will in turn be required to set up systems to receive and account for these bills, and to pay the labs once payment has been received from the hospitals' fiscal intermediaries. Although hospitals established similar accounting systems years ago for other services that were bundled into the DRGs, they have never done so for physician pathology TC services. These new and unnecessary billing systems and administrative overhead requirements will be costly and burdensome.

This burden will be particularly acute for smaller hospitals, which often serve rural areas and rely heavily on independent labs for surgical pathology services. The primary alternative to outsourcing these services – creating internal capacity to perform anatomic pathology TC services – is out of reach for most small and rural hospitals.

TC COSTS NEVER INCLUDED IN INPATIENT PPS

The AHA strongly believes that the decision to end the current billing system is based upon flawed assumptions and assertions. CMS' policy overlooks important Medicare payment history that supports continuing the current grandfather provision.

According to CMS, the primary reason for changing the direct payment policy to independent labs is that Medicare is paying twice for the same service – once to the hospital as part of the DRG payment and once to the laboratory through the Medicare physician fee schedule. However, when PPS rates were developed in 1983, **Section 2802 of the *Provider Reimbursement Manual* instructed hospitals using independent labs not to include the costs of pathology services in their base period costs. This applied to all hospitals – urban, suburban and rural.** When the *Medicare Intermediary Manual* was updated in 1986, section 3618 included the same exception. In 1992 when the Medicare physician fee schedule was implemented, CMS reiterated that independent labs should bill Medicare directly for both the professional and technical component of physician pathology services furnished to hospital inpatients and outpatients. Again, this applied to urban, suburban and rural areas.

In 1999, the agency proposed changes that would prevent independent labs from billing Medicare directly for TC services provided to hospital inpatients. CMS assumed that the DRGs now included TC payments because separate urban and rural DRG rates were eliminated in 1995, and urban hospitals were likely to have included these costs in their base period costs that formed the DRGs.

However, all urban hospitals did not provide in-house pathology services when the DRGs were developed 1983. CMS acknowledged this in the 1999 proposed rule. In fact, a 2003 report[1] by the Government Accountability Office, formerly the General Accounting Office, on this topic acknowledged that urban hospitals outsource *more* pathology services under arrangements with independent labs than rural hospitals. Because these costs were never included in the base rate, budget neutral reweighting of hospital DRGs will never compensate for these increased costs. In addition, CMS does not propose adding any new dollars to the inpatient PPS base rate to account for the additional TC costs that hospitals will be required to bear if the grandfather provision is allowed to expire.

There are hospitals of all sizes in all geographic locations that have, based upon Medicare's long-standing payment policy, made arrangements with independent labs to provide pathology services. These beneficial arrangements reflect the medical care decisions reached by hospitals and responsible pathologists about the best way to provide needed services to patients in each community. Maintaining the current grandfather provision is a reasonable policy approach. It would cover only those hospitals that relied on these arrangements before the proposed policy change, allowing CMS to continue to implement its desired payment changes prospectively. Most importantly for patients, it would provide much needed stability for those hospitals that rely on independent labs for critical pathology services.

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[1] "Modifying Payments for Certain Pathology Services Is Warranted." General Accounting Office, GAO-03-1056, September 2003.

We urge CMS to allow these arrangements between grandfathered hospitals and labs to continue so that quality diagnostic testing may proceed without disruption and increased costs.

The AHA appreciates the opportunity to comment. If you have questions please feel free to contact me or Roslyne Schulman, AHA senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

Bellco HEALTH

Via Overnight Mail

October 5, 2006

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

Re: CMS-1321-P

Dear Dr. McClellan:

On behalf of Bellco Health, I would like to take this opportunity to provide our comments on the Proposed Rule CMS-1321-P, "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B" (the "Proposed Rule"). This rule was published in the Federal Register on August 22, 2006.[1]

Bellco Health is a $1.5 billion national pharmaceutical distribution and health services organization. The Bellco Health group of companies include: Bellco Drug Corp., a full-line, full service pharmaceutical wholesaler; Bellco Generics, a national generic drug distributor; American Medical Distributors, Inc., the country's leading distributor of biotech drugs and pharmaceuticals to the kidney dialysis market; Dialysis Purchasing Alliance, Inc., a group purchasing organization dedicated to kidney dialysis; and Clinical Outcomes Resource Application Corporation, a web-based clinical data collection, reporting, and benchmarking application. Bellco Health serves over 3,000 pharmacies and clinics throughout the country.

Bellco Health is a member of the Healthcare Distribution Management Association ("HDMA"). As part of our membership activities, we have reviewed the HDMA written comment letter to the Centers for Medicare and Medicaid Services (CMS), on the proposed rule referenced above. Bellco Health fully endorses the HDMA comments, and is, by submission of this letter, incorporating the HDMA comments by reference into our written comments for the record.

While we fully agree with all of the points raised in the HDMA letter, we wish to place special emphasis on two items addressed in the HDMA comment letter regarding Average Sales Price (ASP) Issues. First, Bellco Health especially encourages CMS to reconsider its opinion that

[1] 71 *Fed. Reg.* 48980 (Aug. 22, 2006).

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South Carolina
Society of Pathologists

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Comments of the South Carolina Society of Pathologists on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

[CMS-1321-P]

The South Carolina Society of Pathologists (SCSP) is pleased to have the opportunity to comment on the proposed revisions to payment policies under the physician fee schedule for calendar year 2007 (the "Proposed Rule"). 71 Fed. Reg. 48982 (Aug. 22, 2006). The South Carolina Society of Pathologists is a professional society of pathologists practicing in the state of South Carolina. The South Carolina Society of Pathologists' members perform a variety of services that are reimbursed under the physician fee schedule. Thus, the South Carolina Society of Pathologists' members will be significantly affected by the changes in the Proposed Rule. The South Carolina Society of Pathologists' comments on the Proposed Rule focus on the revisions to the reassignment and physician self-referral rules, and changes to the rules governing how anatomic pathology services are billed.

PROVISIONS

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

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

As CMS recognizes, there are two different, but related, means of curbing these practices: first, clarify the provisions of the prohibition on reassignment, which is designed specifically to prevent Medicare from paying physicians for work performed by others, except in limited situations and second, modify the Stark self-referral law, which is designed to prevent physicians from profiting by referring business to entities with which they have a financial relationship. As CMS notes, many pod arrangements are established either in contravention of these requirements or by taking advantage of ambiguities that exist. Generally, the South Carolina Society of Pathologists is supportive of the changes that CMS is making, but we are aware of additional helpful

proposals to clarify or more closely define the requirements set out by CMS, as well as to address the issue of part-time employees.

Changes to the Reassignment Rule

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

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

South Carolina Society of Pathologists position: **supports** applying current purchased-service limitations in situations of reassignment

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

South Carolina Society of Pathologists position: **no additional limitations** are necessary on PC purchase, beyond the need to apply the purchased-service rules that already exist and clarifying that they apply in the contracted reassignment setting

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

South Carolina Society of Pathologists position: **no comment**

Stark Self Referral Provisions

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

Part-Time Employment of Pathologists

The South Carolina Society of Pathologists is concerned that in response to the provisions in the Proposed Rule, existing and new arrangements may be restructured

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

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

We are aware of, and **support** suggested alternative regulatory proposals that would address this issue through the "substantially all" requirements for group practices under Stark. In essence, they would require that, in addition to the group practice as a whole having to perform at least 75% of its patient care services through the group, each individual member would need to perform at least one-half of its patient care services through the group. Such a provision could be limited to pathology services. Alternatively, CMS could, in the same provision of Stark establish a maximum number of group practices to which any one pathologist could belong. The South Carolina Society of Pathologists would strongly support this approach. These are more fully described in the comments of the American Clinical Laboratory Association, so they need not be repeated in detail here. Basically, if a pathologist arrangement did not meet this requirement, then the group practice would not be able to bill for pathology services that it refers to the pathologist. We believe that such a provision would limit restructuring that might be anticipated in response to the proposed changes in the contractor reassignment rules.

INDEPENDENT LAB BILLING

In the Proposed Rule, CMS states, "We continue to believe, however, that hospital prospective payment amounts already compensate hospitals for the TC of physician pathology tests and that additional payment under the PFS is inappropriate." *Id.* Therefore, CMS is proposing to amend § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

The South Carolina Society of Pathologists believes that the proposed rule misstates the intention of the proposal to discontinue the Grandfather provision, where it states "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient." We believe the intent was to state that "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the technical component of physician pathology services furnished to a hospital inpatient or outpatient." We urge CMS to correct this language if this concept is to appear in the final rule.

Given this major change to these historical billing rules, we strongly urge CMS to help hospitals understand their new obligations and move forward to address them to ensure that Medicare beneficiaries have full access to necessary clinical laboratory testing services.

CONCLUSION

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed changes to the physician fee schedule. Please do not hesitate to contact us should you have any questions about this information or need any further information.

Respectfully submitted,

Sally Self, MD

Sally Self, MD
President, South Carolina Society of Pathologists
October 9, 2006

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American Academy of Otolaryngology—Head and Neck Surgery

Working for the Best Ear, Nose, and Throat Care

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October 9, 2006

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

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 the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), I am pleased to submit the following comments on the "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 as a proposed notice on August 22, 2006. Our comments will address: (1) our previous recommendations for the 2007 physician fee schedule following publication of the June 29, 2006 proposed rule; (2) proposed reductions in payments for imaging services to the outpatient department payment amount; (3) the Sustainable Growth Rate (SGR); (4) the Geographic Practice Cost Indices (GPCIs); and, (6) the CY 2007 update and the proposed revisions of the Medicare Economic Index (MEI).

AAO-HNS Comments on the June 29, 2006 Proposed Rule

This is the second proposed rule that has been published for the CY 2007 fee schedule. The first proposed rule was published on June 29, 2006. We submitted the following comments and recommendations that we re-state here for consideration when CMS prepares the final rule for CY 2007:

- We strongly urge acceptance of the RUC recommended work RVUs for 8 head and neck procedures where CMS reduced the values recommended by the RUC.
- We support increased payments for E/M services but believe the proposed work RVUs are excessive and unsupported by the available data.
- We support the proposal to eliminate the non-physician work pool which will allow all of the special otorhinolaryngologic services to be valued in a consistent manner.

- We recommend that CMS issue clarifying instructions or an educational article on code 69210 *Removal of impacted cerumen* so that the code will be used in a consistent manner. As an example, the AMA's *CPT Assistant* article on this topic from June 2006.
- We recommend that CMS accept the RUC recommendations for the procedures whose RVUs were based in part on information in American College of Surgeons' National Surgical Quality Improvement Program (NSQIP) database and the Society of Thoracic Surgeons (STS) National Database.
- We strongly urge CMS to adjust the conversion factor rather than the work RVUs to maintain budget neutrality following completion of the 5-year review of physician work.
- We are generally supportive of the CMS "bottom-up" methodology for calculating practice expense RVUs.
- We recommend that CMS eliminate the use of Indirect Practice Cost Indices (IPCIs) in the calculation of revised PE RVUs.

Proposed Reductions in Payments for Imaging Services

Section 5102(b)(1) of the Deficit Reduction Act, requires CMS to cap the physician fee schedule (PFS) payment amount for the technical component of imaging services (including the technical component portion of a global fee) at the CY 2007 outpatient prospective payment system (OPPS) payment amount.

The DRA defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography.''

In order to implement section 5102(b) of the DRA, CMS needed to identify the codes that fall within the scope of ''imaging services'' defined by the DRA provision. The proposed list of codes identified by CMS as imaging services is in Addendum F of the proposed rule.

We believe CMS has erred by including on the list of "imaging services" certain codes that are never performed for diagnostic purposes alone. Two such codes are performed by our members. They are:

76942 Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
76555 Computed tomography guidance for stereotactic localization

These guidance codes, and others like them, should not be considered imaging in the context of the DRA. We recommend that they be deleted from the list of codes subject to the requirements of the DRA.

We also wish to express our opposition to this DRA provision. We recognize that the agency must implement laws that are passed by the Congress. However, this section of the DRA does not represent sound policy. The caps are completely arbitrary and they undermine the resource-based relative value scale (RBRVS). We urge CMS to make the Congress aware of these problems and to advocate for the repeal of the provisions in Section 5102 of the DRA.

The Sustainable Growth Rate (SGR)

Updates to Medicare physician payments are made each year based on a statutory formula established in section 1848(d) of the Social Security Act. The calculation of the Medicare physician fee schedule update utilizes a comparison between target spending for Medicare physicians' services and actual spending. The update is based on both cumulative comparisons of target and actual spending from 1996 to the current year, known as the Sustainable Growth Rate (SGR), as well as year-to-year changes in target and actual spending. The use of SGR targets is intended to control the growth in aggregate Medicare expenditures for physicians' services.

In many previous comments, we have joined the AMA and other physician specialty societies in describing the flaws in the SGR formula. In 2002, physicians received a 5.4% payment cut. Additional cuts in 2003 through 2006 were avoided only after Congress intervened. Consistent with the position of the American Medical Association (AMA), we identified several steps that could be taken that would significantly reduce the costs associated with a permanent legislative fix to the Sustainable Growth Rate (SGR) formula. Specifically, CMS must:

- Remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996;
- Ensure that government-induced increases in spending on physicians' services are accurately reflected in the SGR target; and,
- Ensure that the SGR fully reflects the impact on physician spending due to national coverage decisions

We are extremely disappointed that CMS has not made a single revision in the calculations for the update, despite the widespread support for change. In this proposed rule, CMS announced a 5.1 percent reduction in the 2006 conversion factor. Thus, the conversion factor will fall from $37.8975 in 2006 to $ 35.9647 in 2007.

If these cuts begin on January 1, 2007, the average payments will be less in 2007 than they were in 2000. These reductions are not cuts in the rate of increase, but are actual cuts in the amount paid for each service because an update of 0 percent does not account for substantial practice cost inflation. Many of our members cannot absorb these payment cuts and, unless CMS or Congress acts, they will be forced to reevaluate their relationship with Medicare. In some cases, they will be forced to avoid, discontinue or limit the provision of services to Medicare patients.

We recommend that that CMS act on the recommendations it already has received, especially the removal of the Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996.

The Geographic Practice Cost Indices (GPCIs)

The Medicare statute requires CMS to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three fee schedule components (physician work, practice expense and malpractice expense). The statute also requires CMS, in consultation with appropriate physician representatives, to review the GPCIs at least every 3 years and allows the agency to make adjustments based on its review.

The first review and revision was implemented in 1995 and the last GPCI revision was implemented in 2005. The next GPCI update is scheduled to be implemented in January 2008.

In addition, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established a floor of 1.0 for the work GPCI for any locality where the GPCI would otherwise fall below 1.0. This provision applied to payments for services furnished on or after January 1, 2004 and before January 1, 2007. As described in the proposed rule, CMS will remove the 1.00 floor beginning on January 1, 2007 and the work GPCI will revert to the fully implemented value. As a result of this change, payments for services in some payment localities will be decreased by as much as 3 percent. The localities most affected are shown in the table below:

Locality	Percent Change
Puerto Rico	-2.44%
Nebraska	-2.44%
Wyoming	-2.55%
Montana	-2.83%
Rest of Missouri	-2.97%
North Dakota	-3.16%
South Dakota	-3.35%

For the past 3 years, the GPCI floor of 1.00 has had a significant impact on payments to physicians practicing in rural areas such as those listed in the table above. We believe it has contributed to the recruitment and retention of physicians in these areas. These physicians now face a 3 percent cut in their 2006 payments on top of the -5.1 percent cut that is proposed for all physicians, regardless of their location. All the progress of the past 3 years will be quickly undone. We encourage CMS to work with the Congress to restore this important and highly successful public policy.

CY 2007 Update and Proposed Revisions of the Medicare Economic Index (MEI)

Unlike previous years when there have been extensive discussions of the upcoming year's update and the MEI, this year's proposed rule includes only passing reference to the update in the section on the Regulatory Impact Analysis and the MEI is not discussed at all. It says: "Table 7 below shows the specialty level impact of section 5102 of the DRA and our most recent estimate (-5.1 percent) of the CY 2007 Medicare PFS update." This number was unexpected because it is lower than the estimate of -4.6 percent recently contained in the President's Budget.

An explanation of the reduced update was included in the Fact Sheet on the Medicare Economic Index that was released on August 8, 2006, the same day that the proposed rule was released. The lower MEI was attributed to the use of a new measure of productivity by the Bureau of Labor Statistics (BLS) and lower projections of inflation. Few details were provided and comments on the changes were not requested.

We strongly object to the 0.5 percent reduction of the 2007 physician fee schedule update because it was not proposed or even discussed in the proposed rule. In addition, we believe that any new data showing physicians have become more productive in the past year is incorrect, especially given the added, unfunded burden of counseling Medicare beneficiaries on their new prescription drug benefits and their new preventive services benefits.

This counseling has been provided by our members and their employees as a service to their patients in response to specific CMS requests. Clearly, this free counseling has decreased, rather than increased, productivity and should be a factor in the determination of the MEI.

The impact of reducing the MEI by 0.5 percent is significant. Based on the impact table in the proposed rule that shows $75 billion of allowed charges under the physician fee schedule, a -0.5 percent reduction in the update will result in a $375 million cut in physician payments in 2007. A change of this magnitude should have been proposed in the Federal Register, not surreptitiously announced in a Fact Sheet. The agency's actions this year, in contrast to previous years, suggest it was attempting to hide this revision in the MEI for CY 2007.

We believe that CMS may be in violation of the Administrative Procedures Act (APA). This law requires publication in the Federal Register of most rules and a period for public comment. We recommend that CMS withdraw its proposed change in the MEI pending a full discussion of the issue in the Federal Register and the opportunity for the public to comment.

Conclusion

The American Academy of Otolaryngology—Head and Neck Surgery appreciates the opportunity to provide these comments and recommendations on behalf of behalf of our members. We trust you will find our comments compelling and that necessary and appropriate changes will be made in the final rule. If you require further information, please Ms. Linda Taliaferro, MHCM, Director of Health Policy at (703) 684-4286 or ltaliaferro@entnet.org.

Sincerely,

David R. Nielsen MD

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VIA FEDERAL EXPRESS

October 6, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1321-P
Mail Stop C-4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1321-P
Comments on Proposed Changes to
Reassignment and Physician Self-Referral
Laws Relating to Diagnostic Tests

To the Centers for Medicare & Medicaid Services:

The law firm of Horty, Springer & Mattern, P.C. devotes its practice exclusively to hospital and health care law. We work with health care providers throughout the country, consulting with hospital boards, hospital attorneys and medical staff leaders.

In our practice, we have learned that certain practices that CMS's current regulations permit under the physician self-referral laws and the Medicare reassignment rules may often have an adverse effect on patient care, increase medically unnecessary services, increase federal health care program expenditures and unfairly compete with services provided by hospitals, especially those in a rural area. In submitting these comments, we are not acting on behalf of any client.

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

We applaud the publication of the proposed changes to the reassignment and physician self-referral rules relating to diagnostic tests that were published in the August 22, 2006 Federal Register (the "Proposed Regulations"). The Preamble to the Proposed Regulations does an excellent job of describing some of the abusive arrangements that have arisen since the publication of the final regulations to the physician self-referral law, 42 U.S.C. §1395nn (Section 1877 of the Social Security Act) on March 26, 2004.

We agree with CMS that the so-called "pod lab arrangements" that were described in the Preamble to the Proposed Regulations, 71 Fed. Reg. 48982, 49054-49058 (August 22, 2006), can have the effect of generating medically unnecessary tests, kickbacks, fee splitting and referrals that should otherwise be prohibited under the physician self-referral statute. (71 Fed. Reg. 49055.) CMS is to be congratulated for first recognizing – in the November 15, 2004 Federal Register, 69 Fed. Reg. 66235, 66315 – that the changes in the Medicare reassignment rules that were necessitated by the Medicare Modernization Act have caused a significant growth of so-called "pod, salon, turnkey, mini-mall or condo labs" and for publishing the Proposed Regulations in order to take the first step necessary to rein in some of these abusive arrangements.

However, CMS should also be aware that the Proposed Regulations do not go far enough to address the manner in which some physician practices have been using, or are planning to use, a Centralized Building to establish abusive arrangements to provide ancillary services. We urge CMS to prohibit the abusive relationships that are being promoted to physicians across the country. We also urge CMS to re-examine the "in-office ancillary services exception" in more detail and to limit that exception to services that are truly ancillary to the professional services being provided to a program beneficiary by requiring that they be provided at the time the physician sees the patient, in the immediate vicinity of the physician's practice, by a competent practitioner.

CMS should also consider the fact that the Office of Inspector General for the Department of Health and Human Services (the "OIG") has found that certain in-office ancillary service arrangements that purportedly satisfied the in-office ancillary services exception (42 C.F.R. §411.355(b)) violated the Anti-kickback Statute. See, OIG Advisory Opinion 04-8 (June 23, 2004), discussed *infra*. CMS should also consider the fact that private insurers, such as Highmark Blue Cross, have adopted Provider Credentialing Guidelines (See https://www.highmarkblueshield.com/pdf_file/imaging/hbs-prof-priv-

guidelines.pdf#search=%22highmark%20privileging%20guidelines%20radiology%22), a copy of which has been attached for your convenience, in order to halt the proliferation of abusive in-office ancillary arrangements that have occurred due to CMS's failure to address this issue adequately and with clarity.

(a) Location of Centralized Building

The Proposed Regulations have resulted in some significant changes to the definition of a "Centralized Building" that is set forth in 42 C.F.R. §411.351. However, CMS must be aware of the fact that CMS's definition of the term "Centralized Building" does not require that the Centralized Building be within a certain distance of the ordering physician's practice. As a result, a physician practice may locate a Centralized Building at a significant distance from the location where the patient has received professional services. We are aware that some physicians have gone so far as to place a Centralized Building in a different state from the state in which the professional services were provided in order to avoid state Certificate of Need rules. In doing so, the use of a Centralized Building actually serves to inconvenience patients and to stretch the purpose of the use of the Centralized Building beyond the breaking point.

Therefore, CMS should further revise the definition of a Centralized Building to require that the Centralized Building be located within a certain defined distance of the location where the physician provided the professional services that gave rise to the ancillary services. One benchmark that may be used is the 250 yards used in the Medicare Provider-based rules to define a provider's "campus." (42 C.F.R. §413.65(a).) At a minimum, CMS should require the Centralized Building to be in the same state as the ordering physician's practice.

CMS's failure to require that the Centralized Building be in close proximity to the physician's office location permits arrangements intended to circumvent state law, allows for numerous types of abusive relationships and, most importantly, inconveniences Medicare beneficiaries. Therefore, in addition to the proposed minimum space requirement, we also recommend that CMS require proximity to the ordering physician's practice.

(b) Credentials of Physicians Who Interpret In-Office Ancillary Services

The in-office ancillary services exception requires the Physician Group to supervise the in-office services either through a Member in the Group Practice or by a Physician in the Group Practice. (See 42 C.F.R. §411.355(b)(3).) However, CMS does not describe the qualifications of the physician who must interpret the in-office ancillary service. This lack of specificity has led to situations where physicians are eligible to submit a claim for services to CMS that are performed

in their office that they would not be permitted to perform if that service was provided in a hospital.

Therefore, we urge CMS to consider credentialing requirements similar to those described in the attached Highmark Privileging Guidelines. At a minimum, CMS should adopt regulations that state that CMS will not pay a physician for a DHS that is performed as an in-office ancillary service if the physician who interprets the service does not possess the clinical privileges needed to interpret that service if it were performed at a hospital where the physician maintains clinical privileges.

(c) On-Site Versus Off-Site

A part-time leasing arrangement will not comply with the definition of a "Centralized Building" (42 C.F.R. §411.341) and, as such, is prohibited. The Proposed Regulations have wisely not altered this prohibition. Notwithstanding this clear prohibition of a part-time leasing arrangement in an off-site Centralized Building, the in-office ancillary services exception permits a provider of the ancillary services to lease space and equipment on a part-time basis to a physician or physician group practice that practices in the same building. CMS should consider revising the location-specific nature of part-time lease arrangements by prohibiting all part-time leasing arrangements regardless of whether they are provided in a "Centralized Building" or the "same building" as the ordering physician.

When discussing the scope of an "In-Office Ancillary Services exception," the Phase I Stark Regulations prohibited referrals to a part-time lease in a building that is not located in the same building in which the Physician Group practices, with the Preamble to those regulations stating "what will not be protected by Phase I of this rule-making are a number of part time, intermittent arrangements that functionally are nothing more than shared off -site facilities." (Emphasis added.) 66 Fed. Reg. 856, 881 (Jan. 4, 2001).

The Preamble to the Phase II Stark Regulations made it clear that the Phase II Stark Regulations specifically adopted this portion of the Phase I rule by stating "we are also retaining without substantive change the Phase I centralized building test for group practices under the In-Office Ancillary Services exception. To prevent abuse of off-site DHS arrangements such as part-time MRI or CAT scan rentals, Phase I provided that the group practice must have full-time, exclusive ownership or occupancy of the centralized space. While many commenters objected to this requirement, we are not changing the rule." 69 Fed. Reg. 16054, 16072. (Emphasis added.)

Therefore, both the Phase I and the Phase II Stark Regulations clearly state that DHS that are provided in an off-site "centralized building" pursuant to a part-time lease arrangement will not qualify as an in-office ancillary service. The Phase II Stark Regulations further describe the manner in which a "centralized building" has been defined in 42 C.F.R. §411.351 and by the rules governing the use of a "centralized building" in the in-office ancillary services exception. (42 C.F.R. §411.355(b)(2)(ii) and (iii).) This prohibition has not been altered in any way by the Proposed Regulations.

In the Phase II Preamble, CMS distinguished a part-time lease arrangement in an off-site Centralized Building from a part-time leasing arrangement that is located in the same building as the referring physician by stating that "Under the regulations, a solo practitioner may provide DHS through a shared facility as long as the supervision, location and billing requirements of the In-Office Ancillary Services exception are satisfied." 69 Fed. Reg. at 16071. Unfortunately, CMS failed to define what is meant by a "shared facility" and did not include any type of discussion that would provide any meaningful guidance as to what CMS meant by a "shared facility."

CMS's reference to a "shared facility" in the Preamble to the Phase II Stark Regulations and CMS's response to certain comments in the November 14, 2004 changes to the Medicare Reassignment Rules have resulted in a proliferation of various types of part-time lease arrangements in the same building as the Physician Group's practice even if the group maintains a primary practice in close proximity elsewhere and the referring physician or one or more members of the referring physician's group practice regularly practices medicine in that building a mere six hours per week pursuant to 42 C.F.R. §411.355(b)(2)(C)(3).

CMS has caused further confusion with a statement that was included in the Proposed Regulations' definition of a "Centralized Building." When referring to the 350 square feet limitation, CMS stated: "This limitation does not apply to space owned or rented in a building where no more than three group practices own or lease space in the 'same building' (as defined in this section) and share the same 'physician in the group practice' (as defined in this section)." 71 Fed. Reg. at 49081.

CMS should consider that in the Phase II Preamble, when discussing the fact that the same building requirement excludes mobile vans or other facilities not permanently affixed to the building, it observed "as we stated in the Phase I Preamble (66 F.R. 891) part-time rentals of DHS equipment are precisely the arrangements that Section 1877 of the Act was designed to restrict." 69 Fed. Reg. at 16074. If one reviews the section of the Phase I Preamble that is cited in this quote, one will find that among CMS's concerns with a mobile van were arrangements

that "would seem to be calculated to enhance physician revenue, rather than patient convenience, since patients would be encouraged, if not required, to schedule appointments on the day that the physician stands to profit from the services." 66 Fed. Reg. at 89.

The fact that (1) CMS references this section of the Phase I Preamble when discussing part-time leasing arrangements in the same building as the Physician Group, (2) the Medicare Purchased Service Rules will apply regardless of whether the test is performed at the physician's office or at another facility (Ch. 13 §20.2.4.1 of the Medicare Claims Processing Manual), and (3) in many instances, the effect of a part-time lease, whether in the "same building" or in a "Centralized Building," will be that beneficiaries "will be encouraged, if not required, to schedule appointments on the day that the physician stands to profit from the services," 66 Fed. Reg. at 891, should cause CMS to prohibit any part-time lease from qualifying for the in-office ancillary services exception, regardless of whether it is in a "Centralized Building" or in the "Same Building" as the physician practice. Regardless of the location, the effect of, and the intent in structuring such a part-time lease arrangement are to "enhance physician revenue, rather than patient convenience." 66 Fed. Reg. at 891. We urge CMS to halt these abusive relationships.

(d) Consistency with the Anti-Kickback Statute

Compliance with the Stark Regulations "sets a minimum standard for acceptable financial relationships" and the mere fact that an arrangement is permitted by the Stark Regulations does not mean that it will comply with the Medicare Anti-Kickback Statute. 66 Fed. Reg. at 863 and, more recently, 70 Fed. Reg. 4858, 4863 (January 31, 2005).

We recognize that CMS lacks the regulatory authority to comment on the Anti-Kickback Statute. However, CMS must take notice of the fact that many "same building" abusive part-time leasing arrangements that are permitted by CMS's arbitrary distinction between a "Centralized Building" and a "Same Building," besides being inconvenient for patients and difficult to manage, have been found by the OIG to potentially generate prohibited remuneration under the anti-kickback statute. See OIG Advisory Opinion 04-8 (June 23, 2004), where the OIG reached this conclusion after examining a leasing arrangement with an LLC that was located in the same building as a physician group that wished to lease the LLC's space, equipment, administrative services and, if requested by the physician group at an additional rental payment, physical therapy services.

Similarly, in OIG Advisory Opinion 4-17 (December 17, 2004), a company that arranged for the provision of in-office pathology laboratory services proposed entering into a series of contracts

with a Physician Group practice to operate pathology laboratories for each Physician Group in each Physician Group's office. Under the proposed arrangement, the pathology group intended to furnish all necessary management and administrative services, equipment, leasing, premises subleasing, technical, professional and supervisory pathology services and, if requested, billing services for each Physician Group that operated its own pathology lab which the OIG was told would be billed by the Physician Group as an "in-office ancillary service." The OIG was also informed that the proposed arrangement satisfied the in-office ancillary services exception to Section 1877 of the Social Security Act.

The location of the service was not a significant factor in the OIG's analysis of the compensation arrangement that was at issue in this Advisory Opinion. Rather, the OIG recognized that the actual financial and business risk for the group would be minimal or nonexistent because the physician group would have complete control over the amount of business the group would send to the lab and would in fact make substantial referrals to the lab. The OIG then ruled that the proposed in-office lab could potentially generate prohibited remuneration and that the OIG could potentially impose administrative sanctions under Sections 1128(b)(7) or 1128(a)(7) of the Social Security Act. (See also the Discussion in the OIG's Supplemental Compliance Program Guidance for Hospitals at 70 F.R. 4866.)

(e) Non-governmental Payor Policies May Affect Use

We recognize that CMS is not required to consider the payment policies of private payors. However, CMS should recognize that CMS's lax and ambiguous rules regarding the payment for in-office ancillary services have caused a proliferation of in-office ancillary services which has caused many private health plans to adopt, or to be in the process of adopting, payment policies that will prohibit a Group Practice from being paid by that plan for certain types of in-office ancillary services for which CMS's current rules will permit payment.

For example, one of the "additional provisions" in the attached Highmark Blue Cross/Blue Shield "Professional Provider Privileging Guidelines" states that the plan will "only reimburse providers for diagnostic imaging services if the services are provided on imaging equipment (i) owned by the provider or (ii) leased by the provider on a full-time basis. Owned or leased on a full-time basis is defined as (a) the provider has possession of the equipment on the provider's property and the equipment is under the provider's direct control and (b) the provider has exclusive use of the equipment, such that the provider and only the provider uses the equipment." These rules apply regardless of whether the ancillary service is provided in a Centralized Building or in the Same Building in which the referring physician practices.

Similarly, CMS should consider adopting a requirement that CT and MRI must be performed at a practice site that provides at least five additional enumerated imaging services, as well as a requirement for imaging providers that, as a condition of payment, the imaging provider must provide a written report to the ordering physician within 10 days of the date of service, except for mammography services, where the report must be completed within 30 days.

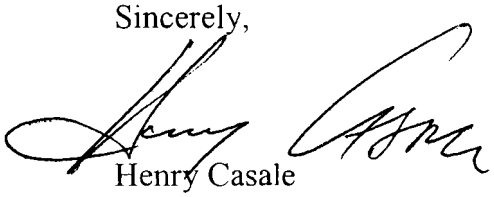
CMS should afford Medicare beneficiaries the same protection from such medically unnecessary ancillary services that are enjoyed by the enrollees of a private payor. Therefore, we urge CMS to consider similar requirements when formulating the final regulations that will describe the circumstances under which a physician or Group Practice will be reimbursed for in-office ancillary services that are provided to a Medicare beneficiary.

CONCLUSION

In his introductory remarks to Section 1877 of the Social Security Act, Congressman Stark stated that "the only way to protect health care consumers from unnecessary referrals is to impose a bright line rule." 139 Cong. Rec. E84-01 (January 6, 1993). Proposed changes to the reassignment and to the physician self-referral rules relating to diagnostic tests will help achieve some of the bright line clarity anticipated by Congressman Stark when Section 1877 of the Social Security Act was proposed. However, as long as CMS fails to address the proximity of a Centralized Building to the referring physician, does not require defined qualifications for the physician who interprets the service, and persists in making the arbitrary distinction between on-site versus off-site entities, abusive relationships will continue to be promoted to physicians.

As such, CMS should consider the restrictions that have been described above as well as those described in the enclosed Highmark Professional Provider Privileges Guidelines as a rational means of limiting in-office ancillary services to those services that are (i) medically necessary, (ii) conveniently located for Medicare beneficiaries, (iii) truly ancillary to the professional services being provided by the treating physician and (iv) provided by qualified physicians.

Sincerely,



Henry Casale

HC/pam

Enclosure

157580 1

Highmark
Professional Provider Privileging Guidelines

Purpose

The following guidelines are intended to promote reasonable and consistent quality and safety standards for the provision of imaging services. Highmark will not reimburse providers for imaging services performed if they do not satisfy the following guidelines. These guidelines affect all Highmark members except those covered under traditional indemnity plans.

General Requirements for Imaging Providers

- All imaging providers must provide a written report within 10 business days from date of service to the ordering provider. (Mammography reports must be completed within 30 days, per Mammography Quality Standards Act (MQSA) guidelines.)
- All imaging facilities must have a documented Quality Control Program inclusive of both imaging equipment and film processors.
- All imaging facilities must have a documented Radiation Safety Program and As Low As Reasonably Achievable (ALARA) Program.
- All imaging facilities utilizing equipment producing ionizing radiation must have a current (within 3 years) letter of state inspection, or calibration report, or physicist's report.
- Highmark Medical Policy will apply to the delivery of services detailed in the guidelines.
- All imaging providers must be Highmark credentialed (hereinafter referred to as "credentialed").

Guidelines Specific to Plain Films

- Providers must have a state certified or American Registry of Radiologic Technologists (ARRT) certified technologist on-site taking all films, or must arrange for a credentialed radiologist to over-read all films within 5 business days from date of service.
- At minimum, an automatic processor must be used to develop all analog plain films.

Guidelines Specific to Bone Densitometry

- Bone Densitometry must be performed by hospitals, or by credentialed radiologists, endocrinologists, rheumatologists, obstetricians/gynecologists, orthopedists, internists, and family physicians.
- Must be performed on an axial Dual Energy X-ray Absorption (DEXA) system or a Quantitative CT.
- At least one physician from each practice location must be a credentialed radiologist or achieve certification by the ISCD (International Society for Clinical Densitometry), and one technologist from each practice location must be ARRT certified or achieve certification by the ISCD (International Society for Clinical Densitometry) within one year of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Nuclear Cardiology

- Nuclear cardiology practices must employ at least one physician who is credentialed in diagnostic radiology, nuclear medicine or has received certification by the Certification Board of Nuclear Cardiology (CBNC).
- Nuclear cardiology practices that do not meet the above criteria will be considered for participation upon submitting evidence that at least one physician has satisfied the Level II training in Nuclear Cardiology as recommended in the American College of Cardiology/American Society of Nuclear Cardiology, Core Cardiology Training Symposium (COCATS) Training Guidelines.
- Nuclear cardiology imaging systems must have the capability of assessing both myocardial perfusion and contractile function (ejection fraction and regional wall motion).
- Cardiac stress tests must be performed under the direct supervision of a credentialed physician who has a current Advanced Cardiac Life Support (ACLS) certification.
- Nuclear cardiology practices must provide a copy of a Radioactive Materials License that indicates the practice address and the name of the nuclear cardiology physician(s) performing and/or

interpreting nuclear cardiology studies. The address and physician name(s) must be the same as those listed on the Privileging Application completed by the practice.

- Nuclear cardiology practices must use a technologist who is certified in Nuclear Medicine through the ARRT, Certified Nuclear Medicine Technologist (CNMT) or Nuclear Medicine Technology Certification Board (NMTCB) or licensed by the state in nuclear medicine technology.
- Nuclear cardiology practices must achieve accreditation by ICANL (Intersocietal Commission for the Accreditation of Nuclear Cardiology Laboratories) or the ACR (American College of Radiology) within two years of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Echocardiography/Stress Echocardiography

- Echocardiography must be performed by physicians credentialed in diagnostic radiology or cardiology, or under the personal supervision of a physician credentialed in diagnostic radiology or cardiology.
- Echocardiography systems must have Color Flow Doppler capability.
- Stress echocardiography must be performed under the direct supervision of a credentialed physician who has a current Advanced Cardiac Life Support (ACLS) certification.
- Echocardiography practices must achieve accreditation by ICAEL (Intersocietal Commission for the Accreditation of Echocardiography Laboratories) within two years of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Peripheral Vascular (PV) Ultrasound

- PV Ultrasound must be performed by physicians credentialed in diagnostic radiology, vascular surgery, cardiology or neurology, or under the personal supervision of a physician credentialed in diagnostic radiology, vascular surgery, cardiology or neurology.
- PV Ultrasound providers must employ a sonographer certified by the American Registry of Diagnostic Medical Sonographers (ARDMS) or ARRT.
- PV Ultrasound systems must have Color Flow Doppler capability.
- PV Ultrasound providers must achieve accreditation by ICAVL (Intersocietal Commission for the Accreditation of Vascular Laboratories) or the ACR (American College of Radiology) within two years of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Obstetrical/Gynecological (OB/GYN) Ultrasound

- OB/GYN Ultrasound must be performed by credentialed radiologists, obstetricians, gynecologists, and family physicians, or under the personal supervision of credentialed radiologists, obstetricians, gynecologists, and family physicians.
- Practices that achieve accreditation in Obstetrical and/or Gynecological Ultrasound by the AIUM (American Institute of Ultrasound in Medicine) or ACR (American College of Radiology) within one year of Provisional acceptance in the Privileging Program, are eligible to be reimbursed for certain imaging procedures as specified in the Obstetrics II Diagnostic Imaging Privileging (DIP) Level. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*
- Practices that do not achieve accreditation are eligible to be reimbursed for limited OB/GYN ultrasound procedures only.

Guidelines Specific to Urological Imaging

- Urological imaging must be performed by credentialed radiologists and urologists or under the personal supervision of credentialed radiologists and urologists.
- Contrast enhanced procedures must be performed under the personal supervision of a credentialed physician who has a current Advanced Cardiac Life Support (ACLS) or Advanced Radiology Life Support (ARLS) certification.

- Practices that employ a technologist or sonographer certified by the ARDMS or ARRT are eligible to be reimbursed for certain imaging procedures of the abdomen, pelvis and genitalia, as specified in the Urology II Diagnostic Imaging Privileging (DIP) Level.
- Practices that do not employ a technologist or sonographer certified by the ARDMS or ARRT are eligible to be reimbursed for prostate ultrasound only.

Guidelines Specific to Mammography

- Mammography facilities must have a current MQSA certificate issued by the FDA.
- Diagnostic mammography may only be performed under the personal supervision of a credentialed radiologist.

Guidelines Specific to Breast Ultrasound

- Breast Ultrasound may only be performed by a credentialed radiologist, or a credentialed surgeon who has breast ultrasound certification from the American Society of Breast Surgeons (ASBS).
- Practices that do not have a credentialed surgeon who has breast ultrasound certification from the ASBS, must achieve accreditation in breast ultrasound by the ACR (American College of Radiology). within one year of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Positron Emission Tomography (PET)

- PET must be performed by a hospital; or partially owned by a hospital as part of a joint venture or other partnership; or owned and operated by an oncology practice clinically affiliated with hospital or community based cancer treatment programs; or there is an access need.
- PET facilities must employ technologists certified in Nuclear Medicine through the ARRT, CNMT or NMTCB or licensed by the state in nuclear medicine technology.
- Only high performance full ring PET systems will be considered.
- PET scan providers must achieve accreditation by ICANL (Intersocietal Commission for the Accreditation of Nuclear Laboratories) or the ACR (American College of Radiology) within two years of provisional acceptance in the Privileging Program. *[Note: Facility must submit evidence of application for accreditation to NIA within 3 months of receipt of letter indicating Provisional acceptance.]*

Guidelines Specific to Fluoroscopy

- Fluoroscopy must be performed by, or under the personal supervision of, a credentialed radiologist.

Guidelines Specific to CT and MR

- CT, and MR must be performed at a practice site that provides at least five of the following modalities:
    - ✓ Plain Films or DEXA (either or both count as one)
    - ✓ General or OB/GYN Ultrasound (either or both count as one)
    - ✓ Peripheral Vascular (PV) Ultrasound
    - ✓ Echocardiography/Stress Echocardiography (either or both count as one)
    - ✓ Mammography
    - ✓ Computed Tomography (CT)
    - ✓ Magnetic Resonance Imaging/Angiography (MRI/MRA)
    - ✓ Fluoroscopy
    - ✓ Nuclear Medicine/Nuclear Cardiology
- Hours of operation requirement - Must offer diagnostic imaging services for a minimum of 40 hours per week.
- Must employ an appropriately licensed or certified technologist (state certified, ARRT, ARDMS, NMTCB).
- If offering MRI services, must also provide MRA capability.

- If offering MRI services, must achieve accreditation by the ACR (American College of Radiology) for MRI within one year of Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*
- Must be staffed on-site by a credentialed radiologist who has a current Advanced Cardiac Life Support (ACLS) or Advanced Radiology Life Support (ARLS) certification during the hours outlined in the hours of operation requirement and whenever contrast enhanced procedures or diagnostic mammography are performed (including during non-standard hours).
- The practice location is not required to have an on-site radiologist when the practice location utilizes teleradiology and meets the following requirements:
  - A Highmark credentialed physician:
    - √ is on-site during normal business hours (40 hours per week minimum).
    - √ is a member of the imaging provider group.
    - √ is available for patient, referring physician and teleradiologist consultation.
    - √ has a current ACLS or ARLS certification.
    - √ is on-site when contrast enhanced procedures or diagnostic mammography are performed.
  - The radiologist performing the imaging reading services via teleradiology:
    - √ is credentialed by Highmark and licensed in the state where the imaging site is physically located and where diagnostic services are rendered to the patient.
    - √ is a member of the imaging provider group.
    - √ is dedicated to providing radiology services via teleradiology during the practice location's normal business hours (40 hours per week minimum).
    - √ is available for consultation with the imaging practice, ordering physician and patient at the time of service during the practice location's normal business hours (40 hours per week minimum).
  - Images must be transmitted in a real-time or near real-time mode (< 2 minutes) to ensure that the interpreting radiologist can collaborate with the rendering physician and radiology technicians performing the studies.
  - At a minimum, sites must be connected via broadband or the necessary bandwidth to ensure real-time or near real-time image availability to the radiologist (< 2 minutes).
  - When a teleradiology system is used to render the official interpretation, there is no clinically significant loss of data from image acquisition through transmission for final image display.
    - Sites must have a PACS (picture archiving and communications system)
    - Sites must have minimum monitor resolution (matrix) of 512 x 512 at 8-bit pixel depth for MR, CT, nuclear medicine, fluorography and 2.5 lp/mn at 10-bit pixel depth for plain film.

- The above guidelines do not preclude credentialed cardiologists from performing echocardiography/stress, echocardiography, peripheral vascular ultrasound, arterial angiography, and nuclear medicine/nuclear cardiology diagnostic services at this practice site.

Guidelines Specific to Practices Specializing in Women's Health

- Must provide at least the following three modalities:
  - ✓ Mammography
  - ✓ OB/GYN Ultrasound
  - ✓ DEXA
- Facilities must have a current MQSA (Mammography Quality Standards Act) certificate issued by the FDA.
- Diagnostic mammography may only be performed under the direct supervision of a credentialed radiologist.
- Must employ an appropriately licensed or certified technologist (state licensed, ARRT, ARRT (M), ARDMS).
- Must achieve accreditation in Obstetrical and/or Gynecological Ultrasound by the AIUM (American Institute of Ultrasound in Medicine) or ACR (American College of Radiology) within one year of

Provisional acceptance in the Privileging Program. *[Note: Practice must submit evidence of application for accreditation within 3 months of receipt of letter indicating Provisional acceptance.]*

Providers Utilizing Mobile Services

Providers utilizing mobile services will not be considered for participation except as follows:

- FDA certified mobile mammography

Additional Provisions:

Highmark will only reimburse providers for diagnostic imaging services if the services are provided on imaging equipment (i) owned by the provider or (ii) leased by the provider on a full-time basis. Owned or leased on a full-time basis is defined as (a) the provider has possession of the equipment on the provider's property and the equipment is under the provider's direct control and (b) the provider has exclusive use of the equipment, such that the provider and only the provider uses the equipment.

"Personal supervision" means that the provider must be in the immediate vicinity so that he or she can personally assist in the procedure, or to assume the primary care of the patient, if necessary. (Source: Highmark Medical Policy Z-27)

All imaging providers are subject to unannounced site inspections. Those providers who are found to have misrepresented information on their Privileging Application may be subject to termination of imaging privileges.

The Highmark Professional Provider Privileging Guidelines are not intended to disadvantage any specialist from providing imaging services.

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October 6, 2006

VIA OVERNIGHT COURIER

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1321-P
REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

To Whom It May Concern:

As a partner at Reed Smith LLP who regularly advises scores of hospital-based radiology groups located throughout the United States on reimbursement and regulatory matters, I feel compelled to comment on the additional conditions CMS is considering imposing on the reassignment of professional component services and to suggest alternative language designed to achieve the goal of guarding against program abuse while doing so in a manner that will not unduly hinder the practice of radiology.

Specifically, CMS indicated in Section I of the Preamble to the Proposed Rule that it is considering further amending § 424.80(d) of the Medicare reassignment rules to specify that, in order for a physician or medical group to bill for the professional component of a diagnostic test performed by another physician pursuant to a reassignment, the billing physician or medical group must satisfy the same conditions as would apply if the billing physician or medical group had simply purchased the interpretation without taking reassignment from the interpreting physician.[1] These additional conditions include a requirement that "the physician or medical group billing for the interpretation must have performed the TC of the test." While we understand that this condition is intended, at least in part, to prevent the proliferation of "test brokers" who essentially have no role or involvement in the ordering or performance of a diagnostic test (other than to submit a claim for the services), adding such a condition to the reassignment rule for professional component services will substantially hinder hospital-based radiology practices from ensuring that the hospitals they serve are sufficiently staffed and adequately covered, in part by using highly qualified, subspecialized independent contractor radiologists, on a 24 hour per day, 7 day per week basis.

1 See 71 Fed. Reg. 48982, 49056 (Aug. 22, 2006).

Generally speaking, under most radiology service arrangements between hospitals and hospital-based radiology groups the hospital bills for the technical component of any imaging services performed for its patients and the hospital-based radiology group performs and bills separately for its professional services. It is my understanding based on discussions with my clients that many radiology groups across the country are experiencing difficulties with recruiting and retaining a sufficient number of board certified radiologists. This difficulty with recruiting is particularly taxing on hospital-based radiology groups and their physician members since those groups are typically responsible for ensuring that a hospital's radiology department is sufficiently staffed and call coverage provided on a 24 hour per day, 7 day per week basis. As a result, it is not uncommon for an understaffed radiology group to contract with an independent contractor physician or a teleradiology services company to perform professional interpretation services on behalf of the group and for the contracted physicians to reassign their rights to receive payment to group the in an effort to ease the burden on the group's employed physicians and ensure that the hospital is receiving the appropriate level of service.

Due to the great technological advances in electronic transmission of images, teleradiology arrangements also enable the hospital-based radiology group to gain access for their patients to contractor radiologists with subspecialty expertise in such fields as musculoskeletal, neuroradiology, thoracic and cardiovascular imaging. The result is a marked improvement in patient care for patients who previously never before benefited from access to such specialists.

If CMS imposed a new condition requiring that any medical group which bills for professional interpretation services pursuant to a reassignment must also perform the technical component of the diagnostic testing, such a condition would effectively prohibit hospital-based radiology groups from obtaining additional assistance or professional services through an independent contractor since the radiology group does not perform the technical component of the diagnostic tests it is responsible for interpreting. The inability of radiology groups to obtain professional services under contract would undoubtedly impose a substantial burden on radiology groups – most importantly those in rural or non-metropolitan areas who continually struggle to recruit new physicians.

In an effort to address CMS's concerns with protecting the program from abusive billing practices while at the same time protecting the ability of radiology groups to engage the professional services of an independent contractor, I propose that CMS consider creating an exception to the technical component condition for hospital-based radiologists. Specifically, I would like to propose the following language for consideration:

- The physician or medical group billing for the professional component must have performed the technical component or, if the technical component is performed and billed by a hospital, the physician or medical group must have been responsible for oversight and quality of such technical component.

I believe the above-language should sufficiently address CMS's concerns with respect to program abuse since, although broader than the original language, the condition would continue to require that the entity billing for the professional component have a reasonable nexus to and moderate

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participation in the performance of the technical component. The benefit is that the proposed language also addresses the concern that radiology practices retain the ability to contract for professional services.

I appreciate this opportunity to comment on the changes CMS is considering with respect to the reassignment rules for professional component services and can be reached by phone or email if a CMS staff member has any questions or wishes to discuss the above comments further.

Sincerely,

Reed Smith LLP

Thomas W. Greeson

TWG:HMZ:jap

October 10, 2006

BY ELECTRONIC MAIL AND OVERNIGHT DELIVERY

Anita Greenberg
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attn: CMS-1321-P
7500 Security Boulevard
Mail Stop C4-26-05
Baltimore, Maryland 21244

Re: **CMS–1321–P**: Medicare Program; Proposed Blood Glucose Testing Rule (42 C.F.R. § 424.24(f)), Included in the Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Ms. Greenberg:

The American Health Care Association ("AHCA") and the Alliance for Quality Nursing Home Care (the "Alliance") appreciate the opportunity to address several key issues raised by the proposed blood glucose monitoring requirements for Medicare Part B beneficiaries that reside in skilled nursing facilities ("SNFs"). These requirements are included in the proposed rule, *CMS-1321-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B*, issued by the Centers for Medicare & Medicaid Services ("CMS") on August 22, 2006. See 71 Fed. Reg. 48,981.

AHCA is a non-profit federation of affiliated state health organizations, together representing more than 10,000 non-profit and for-profit assisted living, nursing facility, developmentally-disabled, and subacute care providers that care for more than 1.5 million elderly and disabled individuals nationally. AHCA's ultimate focus is on providing quality care to the nation's frail, elderly and disabled, who are served by the long-term care professionals who comprise AHCA's membership. Similarly, the Alliance is a coalition of 16 national long-term care provider organizations that care for approximately 300,000 elderly and disabled patients each year in nearly 1,800 facilities across America. The Alliance is also dedicated to improving the quality of nursing home care in the United States through measured results and outcomes and to assuring the government resources necessary to provide high quality care and services. Since Medicare Part B beneficiaries comprise a significant portion of the patients residing in our member SNFs, members of AHCA and the Alliance are directly impacted by the

proposed changes to physician certification requirements for blood glucose testing services (the "Proposed Rule").[1]

As set forth below, the importance of effectively treating and managing diabetes in institutionalized Medicare beneficiaries cannot be understated. Current clinical evidence and medical literature clearly support the medical necessity and reasonableness of a physician-prescribed protocol of repeat blood glucose monitoring in diabetic patients. Accordingly, requiring physicians to individually order and certify the medical necessity of each "finger stick" blood glucose test administered to a Part B-eligible nursing home resident is inconsistent with the Medicare statute and regulations, as well as longstanding CMS policy. More importantly, CMS provides no clearly articulated rationale in support of the Proposed Rule, which deviates significantly from the current best practices in diabetes management and seeks to impose unnecessary burdens on Medicare providers and fiscal intermediaries.

We respectfully urge CMS to withdraw the Proposed Rule to ensure that our members' ongoing efforts to provide the highest quality of SNF care are not unnecessarily hindered. CMS has a key opportunity to establish effective treatment and reimbursement policies for treating and preventing diabetes, and we trust that CMS will pay serious attention to our comments as required by law. To that end, we have enclosed a proposed protocol for blood glucose monitoring that we believe best serves the critical needs of institutionalized Part B beneficiaries with diabetes. AHCA and the Alliance look forward to working with CMS in continuing to fight this debilitating disease and adopting as many of these recommendations as possible.

I. The Proposed Rule Is Inconsistent with Applicable Legal Authorities

A. The Medicare Statute and Regulations Support Coverage of Blood Glucose Monitoring

A physician-ordered protocol of blood glucose monitoring, which may include a prescribed series of blood glucose tests over a designated period of time, clearly meets the requirements of the Social Security Act (the "Act") and the Medicare regulations. The Act is the foremost authority for Medicare Part B coverage for blood glucose testing. The applicable section of the Act is the general requirement that the service be "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Under this requirement, blood glucose monitoring is reasonable

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1 Because we are only commenting on the blood glucose testing provisions of the Proposed Rule, references to the Proposed Rule in these comments refer solely to the preamble discussion and proposed regulation relating to blood glucose testing.

and necessary for the diagnosis or treatment of the blood glucose metabolism abnormalities that are the hallmark of diabetes. Necessarily then, a physician-prescribed protocol for blood glucose testing is also reasonable and necessary for detecting and treating diabetes, particularly considering that the frequency of testing is determined based upon the needs of the individual beneficiary.

In recognition of the fact that Congress provided for Medicare Part B coverage of blood glucose testing services, the Medicare regulations further describe the circumstances under which blood glucose testing is reasonable and necessary. The regulations define blood glucose testing with a device approved for home use as a "diagnostic laboratory test." 42 C.F.R. § 493.15. For Medicare beneficiaries residing in a SNF, coverage exists for diagnostic laboratory tests if they are "ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." Id. § 410.32(a). Thus, the only requirement in the Medicare regulations for blood glucose monitoring to be reasonable and necessary is an order by the treating physician for such testing. Nothing in the Medicare regulations imposes any additional requirements, and it would be inappropriate and inconsistent for CMS to implement a new rule – as proposed to be codified at 42 C.F.R. § 424.24(f) – that would require physician orders for each individual blood glucose test that is part of a reasonable and necessary protocol of blood glucose monitoring.

B. The National Coverage Determination Supports Coverage of Reasonable and Necessary Blood Glucose Monitoring

Effective November 23, 2001, CMS promulgated the National Coverage Determination ("NCD") to address Medicare coverage of blood glucose testing. The NCD specifically encourages frequent testing of blood glucose levels for diabetic patients and acknowledges that it is reasonable and necessary to measure quantitative blood glucose in stable, non-hospitalized patients who are unable or unwilling to do so. The NCD does not provide any specific limitations to testing. In plain language, the NCD acknowledges that specific diagnosis codes, such as diabetes, support repeat testing, especially where there is a confirmed continuing risk of glucose metabolism abnormality. Significantly, the NCD has been revised and expanded since its effective date of November 23, 2001, but the fundamental policy of covering and supporting blood glucose testing with a home-use device has not changed.

The NCD notes that using a device approved for home testing has become a standard of care for control of blood glucose, even in the inpatient setting. Importantly, the NCD neither requires nor suggests that frequent testing is unreasonable or lacks medical necessity for beneficiaries diagnosed with diabetes. Moreover, the NCD does not suggest that treating physicians must order individual blood

glucose tests in lieu of a carefully designed protocol of repeat blood glucose monitoring. Rather, the NCD merely limits coverage for beneficiaries with "nonspecific signs, symptoms, or diseases not normally associated with disturbances in glucose metabolism" (i.e. patients without a diagnosis of diabetes) to a single test unless the results are abnormal or there is a change in clinical condition. According to the NCD, specific diagnosis codes such as diabetes support repeat testing, especially where there is a "confirmed continuing risk of glucose metabolism abnormality." Diabetes is a disease that is not only "associated with" disturbances in glucose metabolism, but is defined as "a syndrome characterized by hyperglycemia [abnormally high blood glucose] resulting from absolute or relative impairment in insulin secretion and/or insulin action." See Merck Manual of Diagnosis and Therapy § 2, Ch. 13, pg. 1. Beneficiaries with a diagnosis of diabetes who reside in SNFs and other institutional settings almost always have such a continuing risk. Therefore, longstanding CMS policy, as reflected in the NCD, clearly supports coverage of claims for regular blood glucose testing of beneficiaries with a diagnosis of diabetes.

Specifically, the NCD states that "[f]requent home blood glucose testing by diabetic patients should be encouraged," and that "[t]he convenience of the meter or stick color method . . . has become a standard of care for control of blood glucose, even in the inpatient setting." 66 Fed. Reg. 58,846 (Nov. 23, 2001). The NCD also states that "[d]epending upon the age of the patient, type of diabetes, degree of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four times annually may be reasonable and necessary. . . . [R]epeat testing may be indicated where results are normal in patients with conditions where there is a confirmed continuing risk of glucose metabolism abnormality." Id. Taking into account the health factors of institutionalized diabetics, nowhere in the NCD are there specific limitations on the frequency of testing, and nowhere is there mention of requiring an order for each blood glucose test administered to patient with a "confirmed continuing risk of glucose metabolism abnormality." The NCD simply lists the number of maladies that may require blood glucose testing and reiterates that reasonable and necessary tests will be reimbursed. See id. at 58,846, 58,848.

Put simply, CMS should not break from its medically-sound and longstanding policy by requiring a physician to individually certify each blood glucose test administered to a beneficiary that, in the medical opinion of the physician, requires repeat blood glucose testing in order to diagnose and treat diabetes. A physician-prescribed protocol of repeat blood glucose testing services meets the NCD criteria when performed on a diabetic beneficiary who has a continued risk of glucose metabolism abnormality. The NCD clearly states that such testing should be encouraged. Such blood glucose

testing services also meet the reasonable and necessary criteria. They are ordered by the treating physician, furnished by qualified personnel, in an appropriate setting, and furnished in accordance with accepted standards of medical practice for the treatment of diabetes. Moreover, all such tests are performed at a frequency determined by the particular beneficiary's treating physician to meet his or her specific medical needs.

II. CMS Must Withdraw the Proposed Rule under the Administrative Procedures Act Because CMS Has Failed to Articulate Any Rationale or Basis for the Proposed Rule

In the preamble to the Proposed Rule, CMS asserts that the proposed blood glucose testing regulation is a codification of "long-standing policy" on the coverage of blood glucose monitoring services. See 71 Fed. Reg. at 49,065. Nonetheless, the only "authority" cited by CMS is Program Memorandum AB-00-108 (Dec. 1, 2000), and a CMS manual provision, Chapter 7 of the Medicare Claims Processing Manual (CMS Pub. 100-04), entitled "Skilled Nursing Facility Part B Billing." Neither of these documents provides any clinical or legal support for the Proposed Rule, and both are contrary to the legal authorities cited above.[2] Moreover, the preamble discussion references no scientific articles, technology assessments, clinical guidelines, statements from clinical experts, medical textbooks, claims data, or other indication of medical standards of practice that CMS considered before issuing the Proposed Rule. The Proposed Rule is also wholly inconsistent with the diabetes care initiatives established and promoted by the U.S. Department of Health and Human Services ("HHS"), as discussed further below. In sum, CMS has failed to articulate any rationale for its rule, the alternatives considered and ruled out, and, fundamentally, why such a restrictive policy is consistent with the statutory mandate that blood glucose testing services be "reasonable and necessary."

The complete absence of medical evidence or claims data to support the proposed regulation means that interested parties cannot offer meaningful comments to the substance of the Proposed Rule. Pursuant to the Administrative Procedures Act (the "APA"), federal agencies must "give interested

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2 Nonetheless, aspects of the Program Memorandum actually support coverage of physician-ordered protocols for repeated blood glucose testing. Specifically, the Program Memorandum program recognizes that "administration of the [blood glucose testing] service several times a day is common in order to maintain tight control of glucose to prevent heart disease, blindness, and other complications of diabetes." Program Memorandum AB-00-108 (Dec. 1, 2000), pg. 1. The Program Memorandum also discusses blood glucose testing services for Medicare Part B nursing home patients and states that payment cannot be denied on the basis that the service is routine care, which is only a consideration for Part A nursing home services. See id., pg. 3

persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. 553(c). Courts have consistently held that the public's right to participate in the rulemaking process requires an agency to "provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully." Florida Power & Light Co. v. United States, 846 F.2d 765, 771 (D.C. Cir. 1988). See also Home Box Office, Inc. v. FCC, 567 F.2d 9, 35 (D.C. Cir. 1977); United States v. Nova Scotia Food Products Corp., 568 F.2d 240, 251-52 (2nd Cir. 1977).

In order for parties to offer meaningful support or criticism under the APA's notice-and-comment rulemaking process, "it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules." Connecticut Light & Power Co. v. Nuclear Regulatory Com., 673 F.2d 525, 530-31 (D.C. Cir. 1982). See also Sierra Club v. Costle, 657 F.2d 298 (D.C. Cir. 1981). If the federal agency relies on an outside study in promulgating a rule, the agency itself must first examine the methodology used to conduct the study. City of New Orleans v. SEC, 969 F.2d 1163, 1167 (D.C. Cir. 1992). Furthermore, the technical complexity of the analysis does not relieve the agency of the burden to consider all relevant factors and there "must be a rational connection between the factual inputs, modeling assumptions, modeling results and conclusions drawn from these results." Sierra Club, 657 F.2d at 333. In Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973), the D.C. Circuit invalidated a final EPA regulation because the agency's failure to utilize sufficient research data in the Proposed Rule hindered the opportunity for meaningful public comment. The court held that it "is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data." Instead, the issuing agency "must disclose in detail the thinking that has animated the form of a Proposed Rule" and provide a reasoned analysis of the data. Id.

Like Portland Cement, CMS's failure to provide any evidence or data regarding blood glucose monitoring and the resulting absence of reasoned scrutiny provides no opportunity for the public to offer meaningful support or criticism of the Proposed Rule. It is also questionable whether CMS adequately revisited Program Memorandum AB-00-108 and Chapter 7 of the Medicare Claims Processing Manual – both of which clearly contradict the "reasonable and necessary" requirement of the Act and the NCD – before codifying their policies in the Proposed Rule. Consequently, CMS has disclosed neither a purposeful rationale nor any evidence that would lend credence to the restrictions set forth in the Proposed Rule. Accordingly, we respectfully request that CMS withdraw the proposed blood glucose

testing rule until such time that the agency obtains and considers sound clinical evidence, current best practices of medicine, and claims data such that the public may meaningfully contribute to the rulemaking process.

III. The Proposed Rule Does Not Comport with Current Best Medical Practices in Detecting and Treating Diabetes

As noted above, the preamble discussion accompanying the Proposed Rule does not discuss any clinical studies or medical articles about blood glucose testing or the health care needs of diabetic patients. Accordingly, it would appear that the proposed blood glucose regulation was developed without consideration of current medical literature and clinical authorities, which advocate regular blood glucose testing for institutionalized diabetics. We respectfully submit that a careful review of these authorities would lend no support for the position taken by CMS in the Proposed Rule.

A. Blood Glucose Testing is a Cornerstone of Diabetes Care

Blood glucose testing to monitor glucose levels in the blood, as performed by patients and health care providers, is considered a cornerstone of diabetes care. See Position Statement: Tests of Glycemia in Diabetes, American Diabetes Association, Diabetes Care 25:S97-S99, Supp. 1 (Jan. 2002), pg. S97. The results of these tests are used to assess the efficacy of therapy and to guide adjustments in medical nutrition therapy, exercise, and medications to achieve the best possible blood glucose control. See id.

Clinical authorities support the use of sliding scale insulin administration supported by glucose testing for nursing home residents, although prolonged use of sliding scale insulin is not recommended. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), pg. 26. This approach uses a base dose of intermediate or long acting insulin, and regular insulin, supplemented by regular insulin administered by the nurse based on the patient's blood sugar and the treating physician's orders. The established best practice is for the physician to set the frequency of the testing and a range for the blood glucose values of the specific patient. Blood glucose testing (or monitoring), a measurement of glucose in the blood that can be done at any time on a portable machine, has long been used to assess blood glucose levels for diabetics. Blood glucose testing is typically performed by placing a drop of blood on a reagent strip, which uses a chemical substance to react to the amount of glucose in the blood. The portable machine then reads the strip and displays the results as a number on a digital display. Physicians are notified when glucose values go above or below the specified parameters. Adjustments are made to the base (and supplemental) dose when necessary. This treatment protocol is essentially the same whether the patient

is being treated at home, as a hospital inpatient, or in a SNF, and is consistent with existing Medicare requirements and the policy established in the NCD.

This type of glucose testing is particularly important in elderly patients where their age has compromised the body's homeostatic ability to maintain a normal body state having stability and uniformity on its own. To help elderly diabetics maintain a homeostatic state, the clinical practice model of the AMDA recommends a blood glucose test on admission, bedside glucose testing several times a day (more frequently if the patient's glucose level is poorly controlled), daily blood glucose review, and physician alert when values fall below or above the recommended range or a range indicated in the physician-ordered protocol of blood glucose monitoring. See id. pgs. 11, 27-28, 39-42. The American Diabetes Association also recommends blood glucose testing of type 1 diabetics three or more times daily. See Standards of Medical Care in Diabetes, American Diabetes Association, Diabetes Care 2004, Vol. 27, pg. S20; Position Statement: Tests of Glycemia in Diabetes, American Diabetes Association, Diabetes Care 25:S97-S99, Supp. 1 (Jan. 2002), pg. S97. Such glucose testing should not be confused with screening tests, routine or standing orders. Regular testing, when prescribed as part of a treatment protocol specifically designed to meet the needs of the individual beneficiary, is medically necessary to avoid certain short and long-term complications of diabetes, and to assess the efficacy of ongoing treatment.

The medical literature clearly indicates that day-to-day control of insulin levels reduces the severity of existing consequences of diabetes, and can prevent the onset of new symptoms and complications. Diabetes is common in the nursing home setting, with over 18 percent of nursing home residents having this disease. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), pg. 2. The literature demonstrates that nursing home patients have a high prevalence of cognitive and physical impairment and need help in daily activities and maintaining recommended dietary and exercise regimens. The prevalence of these impairments is higher among diabetic nursing home patients than in the nursing home population as a whole, which increases the complexity of diabetes management, and makes it unlikely that these patients can manage their diabetes on their own. See id., pg. 3. Diabetic nursing home residents are susceptible to hyperglycemia (a condition that impairs cognition, decreases pain thresholds, impairs vision, increases the risk of infections and may increase the risk for falls) and hypoglycemia (which, untreated, can cause falls or permanent neurological impairment). See id. Nursing home residents are frequently unable to perceive or communicate hypoglycemic symptoms. See id. "Frequent monitoring of blood glucose levels is critical to avoid hypoglycemia and its consequences." Subacute Care for Seniors:

Management of Elderly Diabetic Patients In the Subacute Care Setting, A. Lee, MD, Clinics In Geriatric Medicine, 16:4 (Nov. 2000), reprinted at http://home.mdconsult.com, pg. 8.

Treatment guidelines for diabetes published by numerous medical societies establish that glucose monitoring is reasonable and necessary for the treatment of diabetes patients, and leave the frequency of the testing to the medical judgment of the treating physician, based on the patient's individual circumstances. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), see especially pgs. 39-41. Regular blood glucose testing is part of an overall, individualized treatment care plan for diabetes management, along with a meal plan, activity and physical therapy, treatment with oral antidiabetic agents and/or insulin, foot/wound care, and pain management. See id. pg. 16. Regular monitoring of blood glucose levels helps achieve target ranges for blood glucose control; reduce the risk of lower-extremity infections, ulcers, and limb loss; control pain and neuropathic symptoms; and reduce the progression of other diabetic complications. See id., pgs. 16-17.

The insulin needs of patients with diabetes can vary from one patient to another, from day to day, even from hour to hour. Most nursing home patients have type 2 diabetes but a sizable proportion have combined therapy with insulin orders for treatment. Regular testing is particularly important because blood glucose levels frequently vary depending on the time of day, as demonstrated in a study conducted by the National Institute of Diabetes and Digestive and Kidney Diseases and Social, and Scientific Systems, Inc., published in the December 27, 2000, Journal of the American Medical Association. See Diurnal Variation in Fasting Plasma Glucose, JAMA (Dec. 27, 2000), pg. 5; see also Merck Manual of Diagnosis and Therapy § 2, Ch. 13, pgs. 9-10 (discussing the "dawn phenomenon").

During the past decade, clinical trials have demonstrated the importance of glycemic control, as measured through regular blood glucose testing, to prevent and reduce the complications of diabetes. See The Importance of Tight Glycemic Control, J.E. Gerich, MD, The American Journal of Medicine, 118:9A (September 2005), reprinted at http://home.mdconsult.com, pg. 4. Several new therapeutic agents have become available to improve and monitor glycemic control in patients with type 2 diabetes, including less painful and continuous monitoring devices. See id. Although continuous monitoring is not at issue with respect to the Proposed Rule, the optimization of glycemic control by any means has been shown to be cost-effective. See id. Regular blood glucose testing with home use devices is less expensive in the long run than the costs of surgery and other treatments for patients who develop complications due to poor glycemic control. However, despite the advances in monitoring devices and therapeutic agents, at least one study suggests that there has not been a corresponding improvement in

glycemic control for diabetic patients. See id. The likely explanations for this include "lack of time and resources due to reimbursement considerations, for physicians to treat patients with diabetes," provide needed education, and other factors. Id.

CMS has a clear opportunity to place itself at the forefront of combating diabetes in the nursing home population. However, the Proposed Rule is precisely the type of reimbursement policy that discourages regular blood glucose testing. Rather than encourage the necessary monitoring of blood glucose levels in Part B SNF residents by covering these tests, the Proposed Rule establishes administrative burdens that would effectively deny coverage, creating a disincentive to perform these tests. Moreover, the Proposed Rule directly contradicts best practices and instead calls for an unworkable, misguided and impractical approach to treating diabetes. Although physicians and nursing homes will continue to use their best efforts to treat Medicare beneficiaries, the treatment protocol advocated by the Proposed Rule would be less effective than current best practices in preventing institutionalized diabetics from suffering heart attacks and strokes, developing blindness, requiring the amputation of limbs, and experiencing other complications that require costly medical intervention. The preamble to the Proposed Rule also includes no comparisons of the costs of regular blood glucose monitoring without the proposed physician certification requirement with the costs of hospital and rehabilitative care for these severe complications. CMS should withdraw the Proposed Rule for precisely these reasons and, instead, develop blood glucose monitoring policies that comport with current best practices in treating and preventing diabetes.

B. Requiring Orders for Each Individual Blood Glucose Test is Not Best Medical Practices

The established best practice is for the physician to set the frequency of the testing and a range for the blood glucose values of the specific patient. Physicians are notified when glucose values go above or below the specified parameters. Adjustments are made to the base (and supplemental) insulin dose when necessary. This treatment protocol is essentially the same whether the patient is being treated at home, as a hospital inpatient, or in a SNF, and is consistent with existing Medicare requirements and the policy of many fiscal intermediaries. As discussed below, there is no rational basis to apply a more restrictive policy to the administration of blood glucose testing to SNF residents than to ambulatory beneficiaries performing self-testing at home, particularly considering that SNF residents are less capable of such tasks – as reflected in the fact that they require 24-hour care in nursing homes that offer skilled nursing care and other services.

Adherence to the current best practices for glucose testing is particularly important in elderly patients whose age has compromised the body's ability to maintain stability and uniformity on its own. To help elderly diabetics maintain a homeostatic state, the clinical practice model of the AMDA recommends a blood glucose test on admission, bedside glucose testing several times a day (more frequently if the patient's glucose level is poorly controlled), daily blood glucose review, and physician alert when values fall below or above the recommended range or a range indicated in the physician's order. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), pgs. 11, 27-28, 39-42. These carefully designed clinical practices are clearly "reasonable and necessary" for the ongoing diagnosis and treatment of diabetes in institutionalized beneficiaries.

Clearly, physicians will and should follow the best practice in this area. Thus, compelling SNFs to phone a physician for each patient, sometimes up to three and four times a day, for an order for the next test to be done in a few hours (in order to achieve coverage under the rubric of the Proposed Rule) is in actuality telling physicians how to practice medicine, and more importantly, telling them how to practice it inappropriately and badly.[3] This is not acceptable. Accordingly, CMS should withdraw the Proposed Rule because it is contrary to the best practices of medicine, it is not patient-centered, contradicts the plain requirements of the Act, and is a marked departure from the long-standing policy of the agency.

C. The Proposed Rule is Inconsistent with Federal Initiatives to Treat and Prevent Diabetes

The Proposed Rule not only ignores current medical literature and clinical authorities, it is inconsistent with numerous federal initiatives to combat diabetes and prevent complications of the disease. A number of these programs recognize the value of having the physician prescribe supplies and document the frequency of self-testing, without requiring physician review before each testing event. Some of the key programs sponsored by the federal government include:

- The Centers for Disease Control and Prevention ("CDC") National Public Health Initiative on Diabetes and Women's Health (see http://www.cdc.gov/diabetes/projects/women.htm);

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3 The Social Security Act expressly mandates that federal agencies are not authorized to "exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." Social Security Act § 1801 (codified at 42 U.S.C. § 1395).

- The HHS Council on Health Disparities, which sponsors a number of programs designed to improve the health of minorities and underserved populations, including diabetes detection and prevention (see http://raceandhealth.hhs.gov); and

- The National Diabetes Education Program ("NDEP") (see http://www.cdc.gov/diabetes/ndep/index.htm).

When HHS launched NDEP in 2001, a joint federal program run by the National Institutes of Health and the CDC, the Secretary emphasized the importance of informing Medicare beneficiaries that they "can use their benefits to better monitor and manage their diabetes." See "HHS Launches Diabetes Education Program for Older Americans," HHS Press Release (May 3, 2001), reprinted at http://www.hhs.gov/news/press/2001pres/20010503.html, pg. 1. The NDEP supports routine monitoring of blood sugar levels by diabetics and their health care providers for use in an effective treatment plan for managing their disease. See id. These policies are even more important for diabetic patients residing in nursing homes considering the significant impact that diabetes can have on this vulnerable Medicare population.

Nonetheless, the Proposed Rule would frustrate the objectives of these vital federal initiatives by imposing additional hurdles to regular blood glucose testing in SNF residents. The Proposed Rule also runs counter to the recommendations of the American Diabetes Association that, given the importance of blood glucose testing to diabetes care, government and third-party payers "should strive to make the procedure readily accessible and affordable for all patients who require it." See Position Statement: Tests of Glycemia In Diabetes, American Diabetes Association, Diabetes Care 25:S97-S99, Supp. 1 (Jan. 2002), pg. S97. CMS should remain cognizant of the significant efforts that the federal government has undertaken to prevent and combat diabetes. Accordingly, the Proposed Rule should be withdrawn.

D. A Physician's Treatment Protocol Does Not Constitute a "Standing Order"

The proposed regulation would deem that a physician's "standing order" is not sufficient to order a series of blood glucose testing services. We are concerned that CMS is improperly interpreting a physician-prescribed protocol of blood glucose monitoring, including sliding scale insulin dosage determination by glucose monitoring, as a "standing order" or as "routine testing." If these general principles are misunderstood or misapplied, SNFs would be required to obtain a new physician order for each blood glucose test, which in many cases is done two to three times a day. In short, we believe that

any interpretation of physician-prescribed protocols of blood glucose monitoring as "standing orders" is in error. Moreover, we are extremely troubled that CMS is not correcting this misunderstanding and, as indicated by the Proposed Rule, may indeed be supporting it.

In diabetes management, "standing order prescriptions" are designed to control unplanned conditions. Conversely, prescriptions for glucose monitoring are patient-specific and are designed to maintain a homeostasis (to maintain stability/uniformity in the normal body state of the particular patient). The difference between these two medical treatment strategies is medical event management (standing orders) versus medical diagnosis and maintenance (glucose monitoring via sliding scale to determine insulin dose). Unlike "standing orders" aimed at management to control unplanned/acute conditions, glucose monitoring strives to maintain a homeostatic state which is particularly important in elderly patients where their age has compromised the body's ability to maintain stability. Moreover, a physician's determination that a series of blood glucose tests administered over a limited period time is reasonable and necessary to detect and treat glucose abnormalities should not be discounted as a "standing order" that would not qualify for reimbursement of the testing services.

The American Healthways, Inc. (formerly the Diabetes Treatment Centers of America) developed best practice guidelines for the inpatient management of patients with diabetes. In this model, "standing orders" consist of developing protocols for responding to hypoglycemia, intravenous insulin infusion instructions, perioperative diabetic assessments and insulin pump management. These standing orders are needed to address situations where abrupt or unplanned conditions precipitate deterioration of metabolic glucose control, resulting in acute complications like diabetic ketoacidosis, hypoglycemia, and other adverse outcomes. As is evident, there is significant difference between "standing orders" and a beneficiary-specific blood glucose monitoring and treatment protocol, yet CMS fails to recognize such a distinction in the Proposed Rule.

Even if CMS considers a blood glucose monitoring protocol to be a "standing order," such an order would continue to reflect a physician's independent judgment that the prescribed tests are "reasonable and necessary" to diagnose and treat diabetes and therefore covered under Medicare Part B. In its Compliance Program Guidance for Clinical Laboratories, the Office of Inspector General (the "OIG") for HHS clearly states that "standing orders are not prohibited in connection with an extended course of treatment . . . ." 63 Fed. Reg. 45,076, 45,081. The OIG does not suggest that laboratory testing performed pursuant to a "standing order", including blood glucose testing, is itself not reasonable and necessary. Rather, the OIG's concern is that, in some cases, a physician's initial determination that testing is medically necessary may not be adequately updated or reviewed. In the context of blood

glucose monitoring in SNFs, it is our experience that physicians who order glucose monitoring in connection with an extended course of treatment for diabetic nursing home beneficiaries are periodically monitoring those "standing orders." Thus, a carefully planned protocol for blood glucose testing, reviewed periodically by the treating physician, does not present the potential concerns highlighted by the OIG and, accordingly, would satisfy the "reasonable and necessary" requirements of the Medicare statute and regulations. Therefore, the Proposed Rule should be withdrawn or, at a minimum, amended to clarify that a protocol of blood glucose monitoring for a SNF resident may itself be reasonable and necessary, not just the individual tests that are administered pursuant to the prescribed plan of treatment.

E. CMS Should Adopt the AHCA or Highmark Protocol for the Administration of Blood Glucose Testing

The treatment and reimbursement policy established in the Proposed Rule does not comport with sound medical practices and, moreover, would not improve the health of diabetic Medicare beneficiaries that reside in SNFs. We believe that CMS has a key opportunity to improve diabetes care in this vulnerable population and firmly establish practice guidelines that can be adopted by physicians and institutional providers participating in the Medicare program. As discussed above, a series of clinical studies have demonstrated that tight control of glucose levels leads to significant decreases in the incidence of complications seen in many diabetic patients. Furthermore, the patient population in today's long-term care setting is substantially older and more medically complex than ever before, and current practices for treating diabetes in these patients must be adopted. We, therefore, urge CMS to take the logical next step by affirmatively establishing clinically-proven policies and protocols for combating diabetes in non-ambulatory residents of nursing facilities and other institutions.

To that end, we have enclosed with our comments two proposed protocols for "finger stick" blood glucose determinations that were designed, respectively, by the AHCA and Highmark Medicare Services ("Highmark").[4] See Exhibits A, B. The AHCA and Highmark protocols facilitate the identification of blood glucose trends, feedback of test results to facility professionals and physicians, and more timely decisions regarding the delivery of treatments that require glucose values (e.g., the precise amount of additional insulin to be administered pursuant to the physician's blood glucose monitoring protocol). Importantly, both the AHCA and Highmark protocols would further ensure that blood glucose testing services submitted for payment under Medicare Part B are reasonable and

4 The Highmark protocol presented here is in draft form, as it has not yet been adopted by Highmark.

medically necessary: first, they establish an immediate physician notification requirement for any substantial deviation of blood glucose levels, and; second, both protocols provide an appropriate timeframe for reporting patterns of beneficiary glucose results to the physician who prescribed the individual's blood glucose monitoring plan. In other words, once a physician determines that a series of blood glucose tests is reasonable and necessary for diagnosing or treating diabetes in the beneficiary, the physician will review the series of tests on a trended basis in order to determine whether another order for glucose monitoring is necessary.

Moreover, the AHCA and Highmark protocols both address CMS's apparent concerns about unending "standing orders" because they create a series of opportunities for the physician to periodically review the trended test results, the appropriateness of the treatment regime, and the frequency of monitoring for each individual patient. Each proposed protocol also creates a clear structure to distinguish between blood glucose determinations to assist in the management of unstable or at-risk patients and blood glucose determinations as part of routine monitoring of stable diabetic patients. Accordingly, adoption of either protocol would mitigate the risk of unnecessary blood glucose testing, a clear objective of the Proposed Rule, without the additional administrative burdens that a requirement for individual test certifications would impose. We invite CMS to review and comment on the proposed AHCA and Highmark protocols, and we look forward to working with the agency to establish a uniform and medically-sound policy for blood glucose monitoring in non-ambulatory Medicare Part B beneficiaries.

IV. The Proposed Rule Would Place Unnecessary Administrative Burdens On Providers And Physicians

The Proposed Rule's requirement that treating physicians certify each individual blood glucose test prescribed for a SNF beneficiary would undoubtedly create unnecessary administrative burdens for both physicians and SNF personnel. Treating diabetes using blood glucose testing in a hospital, SNF, or home, is best managed by trend analysis, not test-to-test adjustments. It is generally of little use to provide individual test results to, and obtain a new order from, the physician after each test, except when the results are outside the parameters set by the physician; in such cases, as with any significant change in condition, the physician would be promptly notified. Under current best practices, it is most useful for the physician to see trends of test results in order to determine whether dosage modification is medically necessary. See Managing Diabetes in the Long-Term Care Setting: Clinical Practice Guideline, American Medical Directors Association (AMDA) (2002), pgs. 28.

Nevertheless, the Proposed Rule would impose additional, unreasonable requirements that would not serve to improve the health of Medicare beneficiaries. Instead of adhering to current best practices, the Proposed Rule would require repeat communications between the SNF and the physician, as many as three or four times per day, for each diabetic SNF resident whose physician has prescribed a protocol of ongoing blood glucose monitoring. As one physician that treats diabetic Medicare SNF residents observes, it "would be impractical and, in my opinion, unnecessary for me to write a separate order for each blood glucose test to be administered to [my patient], or to be notified of the results of each test. It is my professional opinion, in keeping with standard medical practice, to review [my patient's] blood glucose test results on a bi-monthly basis and make appropriate adjustment to her plan of care."

The Proposed Rule would also create a tremendous burden on SNFs and their nursing staff and fails to take into consideration the realities of caring for Medicare beneficiaries who suffer from this common and debilitating disease. Most SNF residents have blood glucose testing schedules that follow similar time frames and, thus, the Proposed Rule would require nurses to call physicians for every diabetic patient at the same time. In other words, even if SNFs reported each individual test result to each diabetic resident's physician – and then waited for the physician to certify the next scheduled test – it is doubtful that this process would further the agency's ostensible goal of increasing physician involvement in diabetes management. Time taken to report individual tests also impedes necessary consultation and input from interdisciplinary care team members that have a critical role in the patient's diabetes management. Moreover, as discussed below, the requirement that each blood glucose test be supported by an individual physician order would impose a significant paperwork burden on providers and fiscal intermediaries. Consequently, the Proposed Rule would not serve to further the health needs of Part B beneficiaries, but would merely impose additional burdens on those practitioners and SNF personnel currently following best practices in treating diabetes in nursing home residents. CMS should encourage physicians and SNFs to continue using current best practices in treating Medicare Part B beneficiaries, not frustrate such efforts by imposing unnecessary administrative burdens on these providers.

V. The Proposed Rule Disparately Impacts Part B Beneficiaries Residing in SNFs

The Proposed Rule also improperly distinguishes between Medicare Part B beneficiaries based solely on their place of residence, and does not take into consideration the inherent differences in the medical needs of ambulatory diabetics and those who reside in nursing homes. As noted, blood glucose testing with a device approved for home use is covered under Medicare Part B as a "diagnostic laboratory test" when reasonable and necessary to diagnose and treat illness or injury. See 42 U.S.C. §

1395y(a)(1)(A); 42 C.F.R. § 493.15. In order to be covered by Medicare, therefore, a physician must certify that blood glucose monitoring is reasonable and necessary based upon the circumstances and needs of the individual beneficiary. However, the Proposed Rule attempts to create an arbitrary distinction between diabetic beneficiaries that reside in SNFs, and ambulatory beneficiaries that are capable of performing their own tests at home on a device similar, or even identical to, the device used by a nursing home to perform blood glucose monitoring. As such, the Proposed Rule would allow physicians to prescribe an ongoing blood glucose treatment monitoring plan for ambulatory Part B beneficiaries, but not for more vulnerable nursing home residents - who clearly require substantially more attention and care. This disparate impact on institutionalized Part B beneficiaries would be untenable.

In general, nursing home patients have a high incidence of cognitive and physical impairment and need help in daily activities. The prevalence of these impairments is higher among diabetic nursing home patients than in the nursing home population as a whole, which increases the complexity of diabetes management, and makes it unlikely that these patients can independently manage their diabetes. Diabetic nursing home residents are susceptible to hyperglycemia and hypoglycemia, and are frequently unable to perceive or communicate hypoglycemic symptoms to their caregivers. Nevertheless, CMS would impose additional administrative requirements – unwarranted by current clinical evidence and industry practices – on nursing homes and physicians that provide such critical services to Medicare beneficiaries. Given the increased vulnerability of diabetic nursing home residents, there is simply no rational basis for making it more difficult for such individuals to receive adequate blood glucose monitoring services than for those that can perform such services at home, without assistance. In the event that a physician fails to certify an individual blood glucose test for a nursing home resident, the Proposed Rule would effectively penalize the beneficiary for obtaining the necessary supervision and care that a Medicare-certified SNF can provide. Because the Proposed Rule presents an issue of national significance that cannot, and should not, be relegated to a general "one-size-fits-all" regulatory requirement, we urge CMS to withdraw the Proposed Rule.

VI. CMS Failed to Adequately Perform the Regulatory Impact Analysis

CMS's Regulatory Impact Analysis (the "RIA") of the Proposed Rule is also problematic, in part because it is devoid of rationale or evidence that could justify the Proposed Rule. Pursuant to a number of executive orders and acts of Congress, CMS is obligated to perform a RIA in order to examine the Proposed Rule's anticipated monetary effect on the Medicare program and, more importantly, estimate the impact on access and the quality of care provided to Medicare beneficiaries. The RIA must also

adequately describe the alternatives considered in developing the rule. In the case of the Proposed Rule, CMS not only failed to adequately complete these mandatory assessments, but does not mention the proposed blood glucose testing requirements at all in its RIA. See 71 Fed. Reg. 49,068-49,078. Consequently, the Proposed Rule must be withdrawn.

VII. The Proposed Rule Does Not Comport with the Paperwork Reduction Act of 1995

CMS has also failed to consider the extensive information collection and paperwork burden that the Proposed Rule's physician certification requirements would place upon Medicare providers and contractors. Congress enacted the Paperwork Reduction Act of 1995 (the "Paperwork Reduction Act") in order to minimize the paperwork burden for individuals, small businesses, and federal contractors, among others, that result from the collection of information by or for the federal government. 44 U.S.C. § 3501. Accordingly, the Paperwork Reduction Act requires CMS to publish a notice in the Federal Register to seek public comments on the proposed collection of information with a 60-day comment period, and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. Id. § 3506(c)(2)(A). While the agency has attempted to include such public notice in the preamble to the Proposed Rule, CMS asserts that only its proposed recordkeeping requirements for independent diagnostic testing facilities ("IDTFs") will impose an information collection requirement on the public. See 71 Fed. Reg. 49,068. CMS completely ignores the paperwork burden associated with the proposed blood glucose testing regulation and, thus, the public notice provided in the Proposed Rule is insufficient to meet the requirements of the Paperwork Reduction Act.

By requiring physicians to certify the medical necessity of each individual blood glucose test, the Proposed Rule would effectively impose a significant information collection requirement on physicians, SNFs, and the fiscal intermediaries that process Part B claims for blood glucose testing services. First, treating physicians would be required to render prescription orders for each glucose test administered to their patients (which could be three or four additional orders per day, per patient). Second, SNF personnel would be obligated to document each additional physician order in each patient's medical record, resulting in additional paperwork and written communications between the SNF and each prescribing physician. Lastly, the fiscal intermediaries processing the resulting Part B claims would be faced with vast amounts of additional paperwork, particularly when conducting desk audits or reviews to determine the medical necessity of each individual blood glucose test administered to a Medicare beneficiary residing in a SNF.

We find it alarming that CMS is attempting to implement a Proposed Rule that not only deviates from current best medical practices and the requirements of the Medicare statute, but would encumber providers and fiscal intermediaries with additional information collection requirements without the public notice proscribed by the Paperwork Reduction Act. Consequently, we strongly urge the agency to withdraw the Proposed Rule until CMS can adequately evaluate the additional burdens that will be placed on participating SNFs, physicians, and the agency's administrative contractors.

* * * *

AHCA and the Alliance appreciate the opportunity to present these comments to CMS. We hope our the information presented, including the proposed blood glucose monitoring protocol, will be useful to CMS in revisiting the policies set forth in the Proposed Rule and affirmatively developing appropriate diabetes treatment and management policies in the future.

Respectfully submitted,

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EXHIBIT A – AHCA PROTOCOL

MANAGEMENT OF DIABETES MELLITUS IN LONG TERM CARE FACILITIES: PROPOSED PROTOCOL FOR PHYSICIAN NOTIFICATION FOR FINGER STICK BLOOD GLUCOSE DETERMINATIONS

Purpose: To further address the Centers for Medicare and Medicaid Services (CMS) Program Memorandum (PM) AB-00-108, December 1, 2000 concerning sliding scale insulin dosage determination by glucose monitoring and the requirement to notify the physician after each finger-stick test result to obtain a prescription for continuation or modification of insulin dosage.

Goal: To establish a guideline for glucose monitoring using a sliding scale for insulin dosage with the frequency of physician notification in managing patients with Diabetes Mellitus (DM) in long term care facilities. The guideline is offered as an interim measure until a relevant professional association with expertise in this area (e.g. the American Medical Directors Association) develops a more definitive clinical practice guideline that is specific to patients with long-term, chronic care needs.

Date: March 20, 2002

INTRODUCTION:

Diabetes Mellitus (DM)/Type II is a disorder of carbohydrate metabolism that leads to abnormalities of fat and protein metabolism. It is the most common endocrinologic disorder and is the most prevalent endocrinologic disorder in individuals over the age of 55 years. According to statistics recently reported by David Eddy, M.D., Ph.D. at the 2001 Health Legacy Partnership Conference, Type II diabetes affects about 16 million people in the United States and it is estimated that approximately 6 million of these individuals have not yet been diagnosed. In addition, 20 million people have impaired glucose tolerance resulting in elevated fasting plasma glucose levels. The incidence of DM will increase over the next three decades as the graying of America continues. The impact of this disorder on quality of life and on economic costs is substantial.

A series of clinical studies have demonstrated that "tight" control of glucose levels leads to significant decreases in the incidence of complications seen over time in many diabetic patients. **It is important to note that the patient population in today's long term care (LTC) facility is substantially older and more medically complex than in the past ("older and sicker").** Today's LTC patient with DM is older and has more co-morbid conditions than the average LTC facility patient with DM a decade ago. According to a study published in the *Journal of Cardiovascular Nursing*, April 1, 2000, titled "Patient Problems and Nurse Interventions During Acute Care and Discharge Planning," the frequency of problems experienced by individuals over the age of 65 averaged 8.6 problems during the acute care stay that required nurse attention and care planning. In this study, 68% of the nursing interventions associated with these problems related to surveillance activities. The most frequently cited surveillance activity was drawing lab specimens. The number of patient problem discovered in this study is also consistent with the number of patient problems identified via the Resident Assessment Instrument (RAI) process.

In comments provided to the Centers for Medicare and Medicaid Services (CMS) on the Resident Assessment Protocol (RAP), the American Health Care Association (AHCA) reported that with each

Minimum Data Set (MDS) assessment, approximately 6 to 10 RAPs are generated. This constitutes about 50% of the RAI RAPs that can be triggered for care planning. In 6 of the 17 provided RAPs, DM is listed as an "internal risk factor." Among these six are the more commonly triggered RAPs. There is thus a current need for monitoring that is mandated by the RAI process and a growing need for more intense management of blood glucose levels for an increasing number of residents in LTC facilities who have DM.

BLOOD GLUCOSE MONITORING IN MANAGEMENT OF DM:

The technology now exists and can be effectively operated at LTC facilities to permit the staff at LTC facilities to determine blood glucose levels rapidly and accurately using blood obtained from a finger stick and processed by a simple to calibrate glucometer. This technology and approach facilitates feedback of the results of the blood glucose value to facility professional staff, the identification of trends, and more timely decisions regarding the delivery of treatments that require the glucose value to help determine the next steps (e.g. the precise amount of additional insulin, if any, that should be administered to the individual patient).

There are four levels of clinical situations where glucometer/finger stick glucose monitoring in LTC patients is indicated. These situations are based on patient acuity, clinical judgment, patient diet, patient activity levels and standards of practice for clinical management of patients with DM. Any attempt to codify this dimension of DM management must reflect both current medical knowledge and the need to ensure a reasoned level of accountability in the overall process. To accomplish these goals, we recommend that the physician's orders for the monitoring of patients with DM include the following five (5) components if the ordered finger stick glucose determinations are to be considered "covered tests" and reimbursable by CMS.

The order for finger stick monitoring should contain the following elements:

1. The specific hypoglycemic medication to be administered, the route of administration (oral or sub-cutaneous) and the specific dose of the medication related to the blood glucose value obtained;
2. The order should also specify the conditions under which the physician must be notified immediately for an abnormal value ((e.g. "Notify the physician immediately for any glucose value that falls outside a prescribed range (e.g. <60 mg% or > 300 mg%) or if patient exhibits any of the signs or symptoms of hypo or hyper-glycemia")) and the route of administration for the medication;
3. The level of instability of the DM patient (see below) and the frequency for staff to communicate to the physician all of the blood glucose determinations (to support use of these values in the real time management decisions of the treating physician);
4. The frequency for obtaining the blood glucose determinations; and
5. The duration of the order (a set time for the order to expire unless specifically extended as a new order for specified clinical reasons). This period should not exceed 10 days.

EXHIBIT A – AHCA PROTOCOL

The Protocol proposes using four (4) levels of DM patients. The Levels include:

A) Level I – Patients with unstable DM (blood glucose values of < 60 mg% or > 350 mg% or with signs and/or symptoms of hypo- or hyper-glycemia). These patients often require finger stick glucose monitoring to be performed at least 3 or more times per day. The physician orders for this level include specific circumstances that will mandate immediate physician notification (e.g. notify physician immediately for glucose levels less than 60 mg% or more than 350 mg%). The specific levels noted for immediate notification under such a "sliding scale" order are clearly dependent on individual patient characteristics and physician judgment.

The physician's order may also call for the administration of differing amounts of additional medications (e.g. insulin for blood glucose levels that are in certain ranges. That is to say, as an example, give no additional insulin for a determination of between 60 and 150mg%, give 4 units of regular insulin subcutaneous if blood glucose is between 151 and 250 mg% and give 8 units of regular insulin subcutaneous for a determination between 251 and 350mg%). If the glucose level is greater than 350 mg%, the physician would be called immediately and specific orders obtained for how best to respond.

In all these patients, the pattern of all the glucose determinations over time - and not the individual points along the time line - is of critical importance in the management of the patient's DM. The physician must review the pattern of these values over time to determine if the diet, activity level and/or hypoglycemic drug regime is appropriate or ought to be changed (or if the situation is stabilizing and monitoring frequency can be safely decreased). Hence, the physician's order for this category of individual with DM also should reflect that the facility staff shall notify the physician of all the individual determinations at a time interval specified in the physician's order for the individual patient/resident, whether or not any of the levels had previously triggered an immediate notification. For this level of monitoring intensity, the frequency of physician notification and review, in our view, should be every 24 to 48 hours. The more acutely ill (unstable) the patient, the shorter the frequency of notification. The more stable the patient, the less frequent the notification ordered within the above range.

B) Level II – Patients with a significant clinical risk for blood glucose instability, as determined by the attending physician, but who are more stable than the patients noted under Level I noted above. These individuals may or may not have any current fluctuation in glucose levels. For this level to be supported, the patient's glucose values would **either** be in the range of (>300 mg% but < 359 mg%) or (< 80 mg% but > 60 mg%) **or** the patient would have a specific medical reason for being at risk for blood glucose instability (e.g. acute urinary tract infection, steroid medications, etc.). The patients in this level may have blood glucose monitoring performed between one (1) and three (3) times per day. Again, as described above, the same type of sliding scale order may be written that allows immediate notification for levels that are very low or very elevated. At Level II, the physician would order notification of the pattern of blood glucose values for his/her evaluation in a range of (e.g.) every 2 to every 3 days.

C) Level III - Patients who are relatively stable, but still exhibit some risk for fluctuations in glucose control (although with less probability and/or lower magnitude of fluctuations). In these individuals, the monitoring frequency would be between one per day to twice per week. In this circumstance, the physician notification of all determinations would be at a frequency between every three 3 to 7 days, depending on the patient's stability and clinical context.

EXHIBIT A – AHCA PROTOCOL

D) Level IV: Routine Glucose monitoring for relatively stable patients with DM: These patients would demonstrate no blood glucose values outside the ranges noted above and would not exhibit any of the specific clinical factors that would generate a risk for such instability. These patients would have monitoring less than 2/week. **In these patients, the facility would not bill for the finger stick determinations and they would be considered part of a routine monitoring function.**

EXAMPLE: An individual who historically has relatively stable insulin dependent diabetes mellitus (blood glucose values normally in 150 to 180 mg% range). The physician's initial orders were to check blood glucose levels by finger stick once per week. This individual would be at Level IV under the proposed approach.

This individual then develops an acute urinary tract infection (UTI), with fever and an increased risk for glucose fluctuations. The individual would then transition to Level II, after the appropriate new orders are received from the physician. The physician orders that glucose values be measured three (3) times per day for clinical management during this period of increased risk. The order calls for notification of the physician immediately for specific glucose values that are in specified emergency ranges. The order also requires that the physician be notified of all the glucose values recorded at least every 48 hours. The blood glucose values for this resident over the next two days are in the 200 to 275 mg% range. None are in the "emergency" range, requiring "stat" notification.

This individual then progresses to develop signs and symptoms of hyperglycemia, with a blood glucose value of 375 mg% (in the "emergency range of >350 mg%). The physician is notified immediately by the staff, in accordance with the orders. A new order is received that calls for additional insulin to be administered immediately. In addition, the glucose values are to be obtained four (4) times per day. Notification of all the values is ordered to be communicated to the physician at least every 24 hours. The individual has filled the criteria for a Level I patient during this time period.

Over the next several days, the blood glucose values begin to improve, although they are still elevated (235 to 275 mg%). The fever has subsided and the individual is on appropriate antibiotics for the infection. The frequency of glucose determinations is reduced by a new order from the physician to three (3) times per day and notification of all results is ordered to be communicated to the physician at least every 2 days (Level III). This status is continued over a four-day period. During the last 72 hours of this period, the blood glucose values are generally in the 180 to 220 mg% range, with none >235 or <150 mg%. The patient appears to be making an uncomplicated recovery from the UTI. The physician then orders the frequency of blood glucose determinations to be reduced to two (2) times per week. (back to Level IV).

This clinical example is presented to demonstrate how this process can accomplish the following:

A) Ensure that good medical practice is supported by the overall framework and approach to patient management.
B) Ensure that the physician has access to all the information needed to make optimal clinical management decisions in a timely fashion, and
C) Ensure that there are easily understood criteria that will clearly distinguish between "routine monitoring" (analogous to the home setting for stable diabetic patients) and measurement of glucose values that are needed and used for real time management of the patient's disease when glucose instability is present or there is a documented increased risk of such instability occurring.

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Essentially, we concur that physicians should be expected to review all blood glucose determinations at intervals that reflect the relevant time frame within which clinical management decisions need to be made. The protocols discussed here -- immediate notification already required for any substantial deviation of blood glucose levels and the new proposed requirement that the pattern of values over the appropriate time frame should be communicated to the physician -- should ensure that tests submitted for payment under Medicare Part B regulations are medically necessary. The proposed approach also attempts to address the concerns expressed by CMS about avoiding "unending orders" and creates a clear structure to distinguish between blood glucose determinations to assist in the management of unstable or at risk patients and those who receive these determinations as part of routine monitoring of stable diabetic patients;

The framework outlined here for management of diabetic patients in the LTC population of increasingly frail individuals is consistent with accepted clinical practice. It creates a framework and expectation for effective communication between the physician and the facility staff concerning the relevant laboratory data. This approach also creates a series of opportunities for the physician to review the appropriateness of the treatment regime, dietary intake, activity level, clinical management and the frequency of monitoring required for each individual patient.

The use of the clinical situation level approach to glucose monitoring provides increased opportunity for the physician to review sequentially the on-going appropriateness of the management plan and the level of intensity of monitoring. This approach is in concert with quality clinical management and testing.

* * * *

The following physicians have participated in the development of this proposed protocol:

Jonathan Musher, MD
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EXHIBIT A – AHCA PROTOCOL

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EXHIBIT B – DRAFT HIGHMARK PROTOCOL

LOCAL COVERAGE DETERMINATION: 06-03
BLOOD GLUCOSE MONITORING IN A SKILLED NURSING FACILITY (SNF)

Contactor Name

Highmark Medicare Services

Contactor Number

00366

Contactor Type

Fiscal Intermediary

LCD Database ID Number

DL22369

LCD Title

Blood Glucose Monitoring in a Skilled Nursing Facility (SNF)

Contactor's Determination Number

06-03

AMA/CPT and ADA/CPT Copyright Statement

CMS National Coverage Policy

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

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

EXHIBIT B – DRAFT HIGHMARK PROTOCOL

Code of Federal Regulations, Title 42, Chapter 4, Parts 410.32 and 411.15

CMS On-line Manual Pub. 100-2, Chapter 15, Section 80.1 addresses coverage of clinical laboratory services.

CMS On-line Manual Pub. 100-4, Chapter 16 addresses billing of laboratory services.

CMS On-line Manual Pub. 100-8, Chapter 6, Section 6.1, "Medical Review of Skilled Nursing Facility Prospective Payment System (SNF PPS) Bills"

CMS On-line Manual Pub 100-3, Chapter 1, Section 190.20, "Blood Glucose Testing"

CMS Program Memorandum AB-00-108, Change Request 1362

CMS Transmittal 446, Change Request 3637

Primary Geographic Jurisdiction

Maryland
District of Columbia

Secondary Geographic Jurisdiction

Alabama, Arkansas, California – Entire State, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri – Entire State, Nebraska, Nevada, New Jersey, New Mexico, New York- Entire State, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, Washington state, and Wyoming

Oversight Region

III

CMS Consortium

Northeast

Original Determination Effective Date

06/15/2006

Original Determination Ending Date

Revision Effective Date

N/A

EXHIBIT B – DRAFT HIGHMARK PROTOCOL

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Compliance with the provisions in this policy may be monitored and addressed through data analysis and medical review audits.

Blood glucose determination may be done using whole blood, serum or plasma. It may be sampled by capillary puncture, as in the fingerstick method, or by vein puncture or arterial sampling. Meter assay of whole blood acquired through a finger stick using a device approved for home monitoring allows a patient to have access to blood glucose values on a digital display in a minute or less and has become a standard of care for control of blood glucose, even in the inpatient setting.

Blood glucose values are often necessary for the management of patients with diabetes mellitus, where hyperglycemia and hypoglycemia are often present. They are also critical in the determination of control of blood glucose levels in the patient with impaired fasting glucose (FPG 110-125 mg/dL), the patient with insulin resistance syndrome and/or carbohydrate intolerance (excessive rise in glucose following ingestion of glucose or glucose sources of food), in the patient with a hypoglycemia disorder such as nesidioblastosis or insulinoma, and in patients with a catabolic or malnourished state. In addition to those conditions already listed, glucose testing may be medically necessary in patients with tuberculosis, unexplained chronic or recurrent infections, alcoholism, coronary artery disease (especially in women), or unexplained skin conditions (including pruritis, local skin infections, ulceration and gangrene without an established cause).

Many medical conditions may be a consequence of a sustained elevated or depressed glucose level. These include comas, seizures or epilepsy, confusion, abnormal hunger, abnormal weight loss or gain, and loss of sensation. Evaluation of glucose may also be indicated in patients on medications known to affect carbohydrate metabolism.

The home glucose monitoring device is on the list of instruments that can be administered by providers registered under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), including providers registered with only a certificate of waiver.

The frequency of monitoring of blood glucose values should be determined by the physician on an individual basis while considering the following factors that affect glycemic control:

- Variations and degree of glycemic control as documented by hemoglobin A1C levels
- Treatment with insulin versus oral agents
- Frequency of symptoms of hypoglycemia
- Frequency of prior adjustments in therapy
- Motivation/ability for self-care and the presence of limitations such as language barriers and mental illness

- Presence of diabetic complications

Patients who have exhibited long-term control of blood glucose levels as evidenced by normal or steady A1C levels, minimal or no symptoms, minimal or no changes in therapy and no complications do not require frequent blood glucose monitoring.

Abnormal fasting glucose values may be defined as those below 70 mg/dL or above 125 mg/dL for a patient with diagnosed diabetes mellitus and below 70 mg/dL or above 100 mg/dL for a patient who has not been diagnosed with diabetes mellitus.

Abnormal random glucose values may be defined as those below 70 mg/dL or above 200 mg/dL for a patient with diagnosed diabetes mellitus and below 70 mg/dL or above 140 mg/dL for a patient who has not been diagnosed with diabetes mellitus.

Sections 42 CFR 410.32 and 411.15 specify that for a laboratory service to be reasonable and necessary, it must not only be ordered by the physician but the ordering physician must also use the result in the management of the beneficiary's specific medical problem. Implicitly, the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care; this includes the physician's order for another laboratory service. Compliance program guidance for laboratory services sets forth conditions under which a physician's order for a repeat laboratory service can qualify as an order for another covered laboratory service. A standing order is not usually acceptable documentation for a covered laboratory service.

Orders for continuing laboratory studies must be frequently updated. The medical record must reflect that the attending physician has evaluated the results of any laboratory study previously ordered. Orders for continuing lab work must have a reasonable cutoff time frame and be re-ordered as necessary. Any laboratory study ordered on a continuing basis without a cutoff time frame and without documentation in the medical record supporting that any previously ordered study was evaluated, will be considered a standing order and therefore, not reimbursable. Examples of acceptable time frames are as follows: daily times 4 days, weekly times 4 weeks, monthly times 3 months.

It should be noted that this policy does not prohibit a nursing home's Medical Director from authorizing services or procedures in emergency situations in a manner consistent with the Medical Director's obligations under state or federal law. In such instances, however, there must be documentation as to why the circumstances warrant intervention into the attending physician's role of caring for the patient.

As stated above, for a laboratory test to be covered, the result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care. The following are time frames for use in reporting the results of blood glucose testing to the physician.

<u>Reporting Abnormal Blood Glucose Results</u>

When reporting the abnormal values listed below, the time frame in which the blood glucose result must be reported to the physician is dictated by that result.

EXHIBIT B – DRAFT HIGHMARK PROTOCOL

The further outside the normal range the value is, the shorter the time frame for reporting it becomes.

Blood Glucose Value		**Time frame for reporting to physician**
Low	High	
60-70 mg/dl	200-299 mg/dl	Within 24 hours
50-59 mg/dl	300-400 mg/dl	Within 6 hours
Below 50 mg/dl	Over 400 mg/dl	Immediately

The above timeframes are appropriate for most patients. Depending on patient history and circumstances, shorter time frames may be clinically warranted.

When reporting an abnormal blood glucose value to the physician, the previous two or more results, as appropriate, should also be provided for trending purposes.

Reporting Blood Glucose Results within Normal Limits

In the absence of abnormal blood glucose results, the condition of the patient dictates the time frame for physician notification. The physician should be provided with a trending report consisting of the appropriate number of blood glucose values based on the frequency of monitoring.

Patient Category	**Time frame for reporting to physician**
A – most unstable – see below for details	Within 12 hours
B – unstable – see below for details	Within 24 hours
C – fairly stable – see below for details	Within 36 hours

Category A

Patients who:

- have unstable diabetes mellitus with unstable glucose levels or significant risk for alterations in glucose levels,
- have fingerstick glucose monitoring performed at least three (3) times per day, and
- may have orders for (additional) insulin administration on a sliding scale.

Category B

Patients who:

- have unstable diabetes mellitus with or without unstable glucose levels but are at risk for alterations in glucose levels,
- have fingerstick glucose monitoring performed one (1) to three (3) times per day,
- may have orders for (additional) insulin administration on a sliding scale.

Category C

Patients who:

- have diabetes mellitus which is not completely stable and are at some risk for alterations in glucose levels (although with less probability and/or lower magnitude of fluctuations), and
- have fingerstick glucose monitoring once (1) time per day or less.

Limitations

Blood glucose measurements without prompt physician notification as outlined above are not covered as diagnostic laboratory tests.

Coverage Topic

Lab Services

Bill Type Codes

22X SNF inpatient or HH visits (Part B only)
23X SNF outpatient, HHA-A

Revenue Codes

030X Laboratory – general classification

CPT/HCPCS Codes

82962 Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use

ICD-9 Codes that Support Medical Necessity

011.00-011.96	Tuberculosis
038.0-038.9	Septicemia
112.1	Candidiasis of vulva and vagina
112.3	Candidiasis of skin and nails
118	Opportunistic mycoses

EXHIBIT B – DRAFT HIGHMARK PROTOCOL

157.4	Malignant neoplasm of Islets of Langerhans
158.0	Malignant neoplasm of retroperitoneum
211.7	Benign neoplasm of Islets of Langerhans
242.00-242.91	Thyrotoxicosis
250.00-250.93	Diabetes mellitus
251.0-251.9	Disorders of pancreatic internal secretion
253.0-253.9	Disorders of the pituitary gland
255.0	Cushing syndrome
263.0-263.9	Malnutrition
271.0-271.9	Disorders of carbohydrate transport and metabolism
272.0-272.4	Disorders of lipoid metabolism
275.0	Disorders of iron metabolism
276.0-276.9	Disorders of fluid, electrolyte and acid-base balance
278.3	Hypercarotinemia
293.0	Delirium due to conditions classified elsewhere
294.9	Unspecified persistent mental disorders due to conditions classified elsewhere
298.9	Unspecified psychosis
300.9	Unspecified nonpsychotic mental disorder
310.1	Personality change due to conditions classified elsewhere
337.9	Unspecified disorder of autonomic nervous system
345.10-345.11	Generalized convulsive epilepsy
348.31	Metabolic encephalopathy
355.9	Mononeuritis of unspecified site
356.9	Unspecified hereditary and idiopathic peripheral neuropathy
357.9	Unspecified inflammatory and toxic neuropathy
362.10	Background retinopathy, unspecified
362.18	Retinal vasculitis
362.29	Other nondiabetic proliferative retinopathy
362.50-362.57	Degeneration of macula and posterior pole
362.60-362.66	Peripheral retinal degeneration
362.81-362.89	Other retinal disorder
362.9	Unspecified retinal disorder

EXHIBIT B – DRAFT HIGHMARK PROTOCOL

365.04	Ocular hypertension
365.32	Corticosteroid-induced glaucoma residual
366.00-366.09	Presenile cataract
366.10-366.19	Senile cataract
367.1	Myopia
368.8	Other specified visual disturbance
373.00	Blepharitis, unspecified
377.24	Pseudopapilledema
377.9	Unspecified disorder of optic nerve and visual pathways
378.50-378.55	Paralytic strabismus
379.45	Argyll-Robertson pupil, atypical
410.00-410.92	Acute myocardial infarction
414.00-414.07	Coronary atherosclerosis and aneurysm of heart
414.10-414.19	Aneurysm and dissection of heart
425.9	Secondary cardiomyopathy, unspecified
440.23	Arteriosclerosis of extremities with ulceration
440.24	Arteriosclerosis of extremities with gangrene
440.9	Generalized and unspecified arteriosclerosis
458.0	Orthostatic hypotension
462	Acute pharyngitis
466.0	Acute bronchitis
480.0-486	Pneumonia
490	Bronchitis, not specified as acute or chronic
491.0-491.9	Chronic bronchitis
527.7	Disturbance of salivary secretion
528.0	Stomatitis
535.50-535.51	Unspecified gastritis and gastroduodenitis
536.8	Dyspepsia and other specified disorders of function of stomach
571.8	Other chronic nonalcoholic liver disease
572.0-572.8	Liver abscess and sequelae of chronic liver disease
574.50-	Calculus of bile duct without mention of cholecystitis, without obstruction
574.51	Calculus of bile duct without mention of cholecystitis, with obstruction
575.0-575.12	Cholecystitis

576.1	Cholangitis
577.0	Acute pancreatitis
577.1	Chronic pancreatitis
577.8	Other specified diseases of pancreas
590.00-590.9	Infections of the kidney
595.9	Cystitis, unspecified
596.4	Atony of bladder
596.53	Paralysis of bladder
599.0	Urinary tract infection, recurrent
607.84	Impotence of organic origin
608.89	Other disorders male genital organs
616.10	Vaginitis and vulvovaginitis, unspecified
626.0	Absence of menstruation
626.4	Irregular menstrual cycle
628.9	Infertility, female of unspecified origin
648.00	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, unspecified as to episode of care or not applicable
648.03	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, antepartum condition or complication
648.04	Diabetes mellitus complicating pregnancy, Childbirth or the puerperium, postpartum condition or complication
648.80	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, unspecified as to episode of care or not applicable
648.83	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, antepartum condition or complication
648.84	Abnormal glucose tolerance complicating pregnancy, childbirth or the puerperium, postpartum condition or complication
656.60-656.63	Fetal problems affecting management of mother - large for-date of fetus
657.00-657.03	Polyhydramnios
680.0-680.9	Carbuncle and furuncle
686.00-686.9	Other local infections of skin and subcutaneous tissue
698.0	Pruritis ani
698.1	Pruritis of genital organs
704.1	Hirsutism
705.0	Anhidrosis
707.00-707.9	Chronic ulcer of skin
709.3	Degenerative skin disorders
729.1	Myalgia and myositis, unspecified

EXHIBIT B – DRAFT HIGHMARK PROTOCOL

730.07	Acute osteomyelitis of ankle and foot
730.17	Chronic osteomyelitis of ankle and foot
730.27	Unspecified osteomyelitis of ankle and foot
780.01	Coma
780.02	Transient alteration of awareness
780.09	Alteration of consciousness, other
780.2	Syncope and collapse
780.31	Febrile convulsions
780.39	Other convulsions
780.4	Dizziness and giddiness
780.71-780.79	Malaise and fatigue
780.8	Generalized hyperhidrosis
781.0	Abnormal involuntary movements
782.0	Disturbance of skin sensation
783.1	Abnormal weight gain
783.21	Loss of weight
783.5	Polydipsia
783.6	Polyphagia
785.0	Tachycardia, unspecified
785.4	Gangrene
786.01	Hyperventilation
786.09	Dyspnea and respiratory abnormality, other
786.50	Chest pain, unspecified
787.6	Incontinence of feces
787.91	Diarrhea
788.41-788.43	Frequency of urination and polyuria
789.1	Hepatomegaly
790.21-790.29	Abnormal glucose tolerance test
790.6	Other abnormal blood chemistry
791.0	Proteinuria
791.5	Glycosuria
796.1	Abnormal reflex
799.4	Cachexia
V23.0-V23.9	Supervision of high risk pregnancy
V58.63	Long-term (current) use of antiplatelets/antithrombotics
V58.64	Long-term (current) use of non-steroidal anti-inflammatories (NSAID)
V58.65	Long-term (current) use of steroids
V58.67	Long-term (current) use of insulin

V58.69	Long term current use of other medication
V67.2	Follow-up examination, following chemotherapy
V67.51	Follow up examination with high-risk medication not elsewhere classified
V77.1	Special screening for endocrine, nutrition, metabolic, and immunity disorders (use for 82947 only)

Diagnosis Codes that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

Any ICD-9 code not listed under the "ICD-9 Codes That Support Medical Necessity" section of this policy.

Diagnosis Codes that DO NOT Support Medical Necessity

Documentation Requirements

Documentation must be evident in the patient's medical record to substantiate the medical necessity of the testing performed. The ordering physician should retain in the patient's medical record, history and physical examination notes documenting evaluation and management of one of the Medicare covered conditions/diagnoses, with relevant clinical signs/symptoms or abnormal laboratory test results, appropriate to one of the covered indications.

Documentation must support that blood glucose monitoring was ordered by the physician and the laboratory result was reported to the physician promptly. The medical record must reflect the time the blood glucose result was obtained and the time the physician was notified. The documentation must also support that the results were used in the continuation or modification of care for the beneficiary's specific medical problem including changes/alterations in medications prescribed for the treatment of the patient's condition. Documentation must be submitted to Medicare upon request.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Sources of Information and Basis for Decision

HGSAdministrators LCD V-42

Associate Contractor Medical Director

HGSAdministrators Medical Director

EXHIBIT B – DRAFT HIGHMARK PROTOCOL

Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the appropriate specialty (ies).

Start Date of Comment Period

01/20/2006

End Date of Comment Period

03/08/2006

Start Date of Notice Period

04/27/2006

Revision History Number

06-03

142

Precision Therapeutics

The Science of Individualized Cancer Therapy

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

VIA FED EX

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

COMMENT TOPIC: CLINICAL DIAGNOSTIC LAB TESTS (DOS) FOR STORED SPECIMENS

Background

These comments are submitted by Precision Therapeutics, Inc. We are an independent laboratory located in Pennsylvania and provide a test in a category generally known as chemoresponse tests. The selection of chemotherapy as a treatment for cancer is a choice made between the patient and the treating physician based on a range of factors. These tests provide guidance to help evaluate which chemotherapeutic agent may be used when chemotherapy is the treatment of choice. Currently, these tests are used most frequently in the treatment of gynecologic cancers. Our own clinical data has shown that women treated with a drug identified as "responsive" experience a 2-3 times longer progression-free interval than those treated with a drug identified as "resistant". To date, CMS has paid for this type of testing through the Part B program.

We are commenting on section II.N.3.c. Other Lab Issues--Proposed Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens. In the Proposed Rule, CMS proposes to add a new regulatory section, § 414.410, to address concerns that have been raised regarding the date of service ("DOS") for some clinical diagnostic laboratory tests. While we believe that the proposed rule was likely meant to clarify billing instructions related to fixed tissue archival specimens, there is confusion on whether or not the ruling would apply to tests such as ours. Should it apply, it would effectively move a service that has been paid for as a Part B service for years, and move it into the Part A program.

Chemoresponse testing has never been provided as a hospital inpatient service. Hospitals do not provide the service and it has never been reflected in hospital costs. The

prospective payment system for hospital inpatient services does not and has never accounted for this technology. Should CMS take the position that fresh tissue falls into the proposed rule, **a service that is currently available to women in the Medicare system will become unavailable.** Hospitals do not have the incentive money to pay for these types of tests out of their current Medicare DRG payment. Additionally, Medicare will not allow women to pay for these services themselves on a private pay basis since it would be an illegal "unbundling" based on Medicare's insistence that it was a hospital Part A service.

Discussion

We access pathological excess fresh tumor from a surgical event. The tumor specimen comes to our lab, and a cell culture is started to keep the cells alive for possible testing. Typically, five to fourteen days post-receipt of the original specimen, we receive confirmation of the patient diagnosis, an order from a treating physician to test the cancer cells against a set of chemotherapeutic agents being considered for that particular patient, and a separate assignment of benefits from the patient for the test. At that time, cells are harvested from the original cell culture for testing. The only service related to the assay that was provided to the inpatient is harvesting the specimen which is done in conjunction with and not in addition to or independent of a surgical procedure. The cells are held in our facilities for potential testing, and extracted for testing purposes typically after the patient has already been already discharged from the hospital.

Medicare Part B covers many categories of benefits, including according to SSA § 1861(s) "medical and other health services." Among these medical and other health services are laboratory tests performed in an outpatient setting. Medicare contractors have paid for chemoresponse testing through Part B for approximately ten years. There are good reasons for why this has been the case:

- They are utilized for the post-hospital management of the patient
- The testing is unrelated to the underlying hospital stay
- They are provided by a provider different from the hospital
- They are not routinely performed for every patient (i.e. they are only used in particular cases)
- They are generally completed after discharge

The scientific requirements of chemoresponse testing are such that fresh tumor tissue is an absolute necessity. If the decision to hold the issue for possible testing is not made at the time of surgery, the opportunity for later testing is lost. This process is necessary because live tissue cannot be stored in the same way that paraffin-embedded specimens can be stored.

Recommendation

CMS should clarify that the proposed regulation applies to fixed tissue samples and continue to recognize the unique aspects of fresh tissue testing which makes it a Part B service despite the fact that the tissue emanates from a hospital stay.

We appreciate the opportunity to provide these comments and hope that future clarifications will that Medicare patients can continue to realize the clinical benefits offered by chemoresponse testing. Please let us know if we can answer any further questions.

Sincerely,

Sean McDonald
President and CEO
Precision Therapeutics, Inc.

The Fusion of Clinical Data and 3D Imaging

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

VIA FED EX

Re: CMS-1321-P -- Comments on the Proposed Rule for Calendar Year 2007 Payment Policies Under the Physician Fee Schedule
REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

To Whom This May Concern:

M2S appreciates this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) concerning the 2007 Medicare Physician Fee Schedule proposed rule.[1] Specifically, we wish to comment on the proposed requirement that in order for a billing entity to bill for the technical component (TC) of a service (under a reassignment involving a contractual arrangement between the billing entity and physician or other supplier who performs the service), the billing entity would be required to perform the interpretation.[2]

Recently, we commented on the CMS practice expense proposed notice's[3] treatment of three-dimensional pre-operative and post-operative computer-aided

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[1] See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other changes to payment under Part B, 71 Fed. Reg. 48982 (Aug. 22, 2006).

[2] Id. at 49056.

[3] See Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology, 71 Fed. Reg. 37,170 (June 29, 2006).

measurement planning and simulation (3D-CAMPS) technology, which currently is reported under the physician fee schedule by HCPCS code G0288: "Reconstruction, computed tomographic angiography of aorta for preoperative planning and evaluation post vascular surgery."

As we have conveyed to CMS in a number of other contexts, 3D-CAMPS refers to a specific and unique type of health information technology service that enables vascular surgeons to deliver the highest quality care for abdominal aortic aneurysms (AAAs) and thoracic aortic aneurysms (TAAs). Congress recently recognized the significance of this condition and coverage for ultrasound screening of AAAs is now included in the Medicare Act. MMS created the first commercially marketed 3D-CAMPS service, which is a software technology that delivers precise anatomical measurements and three-dimensional modeling in conformance with a specific suite of measurements endorsed by the Society for Vascular Surgery and recognized by the Food and Drug Administration (FDA) as adequate for postmarketing surveillance of stent grafts.

We continue to be dismayed by the extremely severe decrease in the practice expense (PE) RVUs for G0288. In 2006, the non-facility practice expense RVUs for G0288 is 10.64. Under the proposed changes to the practice expense methodology, the fully implemented non-facility PE RVUs for G0288 is 0.99. This change is a 91% decrease in the PE RVUs, and is simply incompatible with offering this highly valuable imaging technology to Medicare beneficiaries. We are concerned that the revision of the practice expense RVUs for G0288 is likely arbitrary and not based on data similar to that collected for CPT codes because G0288 has never been evaluated by the relevant RUC practice expense subcommittees such as the PEAC or the PERC. We renew our request that CMS reconsider the PE decrease for G0288 as a 91% decrease is invalid and inconsistent with the costs of performing the service. CMS should perform a careful analysis and acquisition of an accurate database of resource inputs to ensure that the practice expense for G0288 is accurate and that Medicare beneficiaries and their physicians can continue to benefit from the use of 3D-CAMPS technology.

Reassignment and Physician Self-Referral

CMS is appropriately concerned about fraud and abuse issues surrounding the recent changes in the reassignment rules. We generally support the proposed change to 42 C.F.R. § 424.80(d) that in order for a billing entity to bill for the TC of a service (under a reassignment involving a contractual arrangement between the billing entity and physician or other supplier who performs the service), the billing entity would be required to perform the interpretation. This approach helps to ensure that there is an appropriate nexus between the billing entity and the supplier that performs the technical component of the service.

However, there has been confusion among some of the Medicare contractors regarding codes that represent the technical component of a test but which have the corresponding interpretation or professional component bundled into another code. For

example, the G code described above, G0288, is not assigned work RVUs because the work for interpreting the images and data generated by the service described by G0288 is included in another code.

This splitting of the technical and professional RVUs for the G0288 service has created confusion among certain Medicare contractors. Therefore, it is important that CMS clarify in the final rule that while the billing entity must perform the interpretation in order to bill for the technical component (under its proposal), that in certain instances with certain codes (such as G0288) the interpretation or professional component is built into a different code than the code that is billed for the technical component, and that as long as the interpretation is performed by the billing entity (even if the interpretation is bundled into a different code than the code that is used for the technical component), then the technical component can properly be billed by the billing entity.

We appreciate the opportunity to provide these comments and are eager to work with CMS to ensure that physicians and patients continue to realize the clinical benefits offered by 3D-CAMPS. Please let me know if I can be of further assistance.

Sincerely,

M. Weston Chapman

M. Weston Chapman
Chairman and Chief Executive Officer

12 Commerce Avenue | West Lebanon, NH 03784 | p: 603.298.5509 | f: 603.298.5055 | www.m2s.com

Fresenius Medical Care

October 6, 2006

BY HAND DELIVERY
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: Federal Register Vol. 71, No. 162/August 22, 2006/Proposed Rules ESRD Provisions

Dear Sir or Madam:

The Puerto Rico Operations Division of Fresenius Medical Care North America appreciates the opportunity to comment upon certain aspects of the above-referenced proposed rule which directly impact reimbursement rates for dialysis care furnished in Puerto Rico. If the proposed update is implemented, the effect of changes in the wage index calculation will be a –1.7%. The overall effect, once the reimbursement changes for medications are factored, is a –1.1%. Medicare is the primary source of coverage for over 85% of the approximately 3,700 dialysis patients receiving dialysis care in Puerto Rico. Therefore, these negative updates have an increased effect upon providers based in Puerto Rico.

The proposed rule seeks to reduce the wage index floor for calculating the ESRD composite rate to .80, from a current .90. CMS intends to continue reassessing and adjusting the floor on a calendar year basis, although the drafters recognize that an immediate elimination of the floor could adversely affect ESRD beneficiary access to care. This continuous reduction in the floor, however, negatively updates reimbursement in Puerto Rico because wage index values have not been realistically updated in quite some time, thus negatively impacting reimbursement on a yearly basis. We do not agree with the agency's proposed continuous reductions, and are amenable to engaging in a dialogue in search of other alternatives that do not imply further negative reimbursement updates.

Such negative updates adversely impact what is already a difficult climate from a reimbursement perspective. A number of recent changes, in sequence, have impacted the ability of providers, such as Fresenius Medical Care, to maintain their revenue stream and continue to provide state-of-the-art quality care. The case-mix adjusted payment system, which included case-mix adjustments to the composite rate for age, low body mass index and body surface area negatively impacted reimbursement in Puerto Rico, because of the genetic composition (shorter and narrower body frame) of the average dialysis patient. Further, there have been a number of increases in local operational costs, such as mandated nurse wage increases, and steep water and electric bill rate increases. Although justifiably deserved, the mandated nurse wage increases alone will total $2.5M over a period of three years, starting in July of 2005.[1] Simultaneously, the utilities rate increases have

[1] Fresenius Medical Care employs over 400 Registered Nurses in Puerto Rico, since only Registered Nurses can provide dialysis care. The vast majority of nurses qualified for the mandated wage increase. The average hourly wage will increase from $8.65 to $13.11 over the three year period starting in July 2005.

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Fresenius Medical Care

increased operational costs by 2-3%, or approximately $1M per year. Water costs alone have risen by anywhere from 166% to 387% over the last two years and electricity costs have risen approximately 24% between calendar year 2005 and 2006.[2] Transportation costs into Puerto Rico are estimated at approximately 15% higher than in the US. All equipment and supplies used for dialysis services have to be imported since there is no local manufacturing. Additionally, the Commonwealth will impose a 7% sales tax effective November 15, 2006. Together, these elements add up to a significantly higher cost of delivering services than what may be contemplated by the drafters of the proposed rule.

Puerto Rico has a high incidence of ESRD for a number of historical and socio-economic factors, which deserve a detailed and studied analysis that is beyond the scope of these comments. However, the cost factors detailed above, combined with the fact that dialysis providers do not receive full reimbursement for the totality of the services provided to the dual-eligible population in Puerto Rico (this group comprises approximately 70% of the ESRD patient census in Puerto Rico), have severely constrained investment in new facilities and availability of care (long waiting lists are common) on an outpatient basis throughout the island.

Fresenius Medical Care has been a proactive voice and its representatives have been in communication with Commonwealth and federal authorities regarding the totality of the circumstances surrounding the incidence of ESRD and the quality and access to care for this segment of the Medicare population. However, in the face of proposed additional reimbursement cuts, combined with the operational cost increases detailed above, providers are being faced with a number of challenges, which ultimately may jeopardize and compromise the quality and frequency of attention that ESRD Medicare beneficiaries receive in Puerto Rico.

Therefore, we believe that the proposed wage index floor reduction should be suspended for calendar year 2007 and that the impact of any further floor reductions be considered thoroughly before implementation.

Additionally, we would like to suggest an update to the chart on page 49075. It states that there are 27 dialysis facilities performing 400,000 treatments a year. However, as of today there are 31 outpatient facilities performing approximately 550,000 in-center treatments per year.

We are available to discuss these comments in further detail. My telephone number is 787 764 3172 and my electronic mail address is arturo.villamil@fmc-na.com.

Sincerely,

Arturo Villamil
Vice President, Operations
Puerto Rico Region

Cc: James Kerr, CMS Regional Administrator, Region II
Delia Lasanta, Director, CMS Puerto Rico/USVI District Office
Hon. Luis Fortuño, Resident Commissioner

[2] As an example, the average kilowatt hour in Puerto Rico for the year 2003 was 12.61 cents, while the same kilowatt hour in the US cost an average of 7.42 cents.

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Focusing on Excellence in Medicine

SINCE 1921

Comments of the Texas Society of Pathologists on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

[CMS–1321–P]

The Texas Society of Pathologists (TSP) is pleased to have the opportunity to comment on the proposed revisions to payment policies under the physician fee schedule for calendar year 2007 (the "Proposed Rule"). 71 Fed. Reg. 48982 (Aug. 22, 2006). TSP is a professional society of pathologists practicing in the state of Texas. TSP members perform a variety of services that are reimbursed under the physician fee schedule. Thus, TSP members will be significantly affected by the changes in the Proposed Rule. TSP's comments on the Proposed Rule focus on the revisions to the reassignment and physician self-referral rules, and changes to the rules governing how anatomic pathology services are billed.

PROVISIONS

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

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

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

Changes to the Reassignment Rule

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

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

TSP position: **supports** applying current purchased-service limitations in situations of reassignment

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

TSP position: **no additional limitations** are necessary on PC purchase, beyond the need to apply the purchased-service rules that already exist and clarifying that they apply in the contracted reassignment setting.

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

TSP position: no comment

Stark Self Referral Provisions

As CMS recognizes, in order to limit these types of practices in all areas, it is also necessary to further clarify certain specific provisions or exceptions in the Stark self-referral law. TSP agrees that this is imperative. We are especially

concerned that in response to changes in the reassignment rules, discussed above, many pod arrangements will simply restructure and hire pathologists as part-time employees, which could circumvent the purpose of many of these changes. TSP believes that the Stark law may provide the most direct way of curbing these new abuses. Therefore, before discussing the other changes proposed by CMS to the Stark provisions, we wish to make one additional proposal designed to limit part-time pathologists.

Part-Time Employment of Pathologists

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

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

We are aware of, and **support** suggested alternative regulatory proposals that would address this issue through the "substantially all" requirements for group practices under Stark. In essence, they would require that, in addition to the group practice as a whole having to perform at least 75% of its patient care services through the group, each individual member would need to perform at least one-half of its patient care services through the group. Such a provision could be limited to pathology services. Alternatively, CMS could, in the same provision of Stark establish a maximum number of group practices to which any one pathologist could belong. TSP would strongly support this approach. These are more fully described in the comments of the American Clinical Laboratory Association, so they need not be repeated in detail here. Basically, if a pathologist arrangement did not meet this requirement, then the group practice would not be able to bill for pathology services that it refers to the

pathologist. We believe that such a provision would limit restructuring that might be anticipated in response to the proposed changes in the contractor reassignment rules.

INDEPENDENT LAB BILLING

In the Proposed Rule, CMS states, "We continue to believe, however, that hospital prospective payment amounts already compensate hospitals for the TC of physician pathology tests and that additional payment under the PFS is inappropriate." *Id.* Therefore, CMS is proposing to amend § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

TSP believes that the proposed rule misstates the intention of the proposal to discontinue the Grandfather provision, where it states "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient." We believe the intent was to state that "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the technical component of physician pathology services furnished to a hospital inpatient or outpatient." We urge CMS to correct this language if this concept is to appear in the final rule.

Given this major change to these historical billing rules, we strongly urge CMS to help hospitals understand their new obligations and move forward to address them to ensure that Medicare beneficiaries have full access to necessary clinical laboratory testing services.

DEFINITION OF SAME BUILDING AND CENTRALIZED BUILDING

The issue of the DHS service being furnished in the "same building" or "centralized building" needs to be more strictly defined to help prevent abuse. The TSP supports the proposal of a minimum space requirement for a number of reasons including safety, but the TSP believes a specific geographical boundary would be prudent to implement as well. There may be localities close to state borders and practices may serve patients with offices in different states. As such these situations should not be penalized because of their proximity to a state border. However, a more defined boundary such as a mileage radius, population statistical defined area, or some other identifiable definition should be considered and implemented in order to prevent the concerns raised by CMS. For example, Amarillo, Texas is close to the Oklahoma border and practices may serve patients in Oklahoma, and thus, a Urology practice with offices in Amarillo, Texas and Oklahoma should not be prevented from having a lab in Amarillo providing services to the Oklahoma patients. However, the lab should be based in Amarillo rather than San Antonio, Texas, which is close to 600 miles from the practices' clinical patient facilities. How can a Urology practice

in the Dallas-Fort Worth Metroplex have an "in office" lab 250 miles away in San Antonio? The same question can be asked about a Urology practice in Lubbock, Texas with an "in office" lab over 400 miles away in San Antonio, or a Urology practice in the Rio Grande Valley region of Texas with an "in office" lab 250 or more miles away in San Antonio. A more restrictive definition of the location of the centralized building is appropriate to make sure the spirit of the Medicare regulations is not being abused. Restricting the location of a pod lab to the locality to where the group has a patient clinic is appropriate.

CONCLUSION

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed changes to the physician fee schedule. Please do not hesitate to contact us should you have any questions about this information or need any further information.

Respectfully submitted,

Michelle Hebert, M.D.

Michelle Hebert, MD
President, Texas Society of Pathologists
October 9, 2006

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October 10, 2006

BY HAND DELIVERY

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

Re: Comments on CMS-1321-P (ASP Issues)

Dear Ms. Norwalk:

International Physician Networks, LLC ("IPN") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' Proposed Rule on Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (the "Proposed Rule"). Due to the nature of IPN's business and its fundamental function as a specialty-physician group purchasing organization, we are focusing our discussion in these comments to addressing the ASP reporting issues related to fees paid to Group Purchasing Organizations (GPOs) as further clarified by CMS in the Proposed Rule.

As discussed in detail below, IPN applauds and agrees with CMS' position that fees paid by manufacturers to GPOs as part of their group purchasing arrangements should not be included in the calculation of ASP so long as they are not passed along to customers or clients. IPN, however, suggests that payments by manufacturers to GPOs should not be subject to the proposed qualifying definition of bona fide service fees because GPOs are not buyers under the applicable law. Further, IPN recommends that if CMS determines that payments to GPOs may be a factor in calculating ASP, and therefore should be subject to the qualifying definition of bona fide service fees in order to be excluded from the ASP calculation, CMS should further clarify its position related to determining the fair market value of such GPO fees. Specifically, we urge CMS to clarify that it is appropriate to determine fair market value based on fixed percentage fees of units of product sales to GPO members consistent with the applicable governing regulations.

Overview of International Physician Networks (IPN)

IPN, a wholly owned subsidiary of AmerisourceBergen Corporation, is the leading physician specialty group purchasing organization with membership of over 10,000 community-based medical specialists. IPN members range from solo practitioners to some of the country's largest and most renowned private practices -- all committed to improving the quality of patient care in their own communities. IPN's physician membership is comprised of medical specialists who perform a significant volume of drug administration services, including oncologists/ hematologists; urologists, rheumatologists; and gastroenterologists.

IPN serves as a GPO for its members in an effort to ensure that they receive the pharmaceutical products necessary for high-quality patient care at the lowest possible costs. It believes that these group purchasing arrangements are critical in ensuring that medical specialists operate their practices at optimum efficiency, and that patients continue to have access to the highest quality of care in community settings. In addition to negotiating and administering group purchasing arrangements, IPN provides a variety of related practice management and clinical educational services to its members in an effort to enhance the efficiency of their practices and the quality of care received by their patients. These services include facilitating participation in clinical trials, developing timely clinical and scientific education programs, and providing information related to various practice management support services. By bringing clinical research, educational symposia, information systems, and other innovative services to the local oncology community, IPN provides tools to physicians that can help maintain a level of expertise so needed in the rapidly changing medical environment.

IPN provides a variety of services on behalf of its vendors in return for administrative fees that are paid pursuant to the applicable safe harbor regulations governing health care group purchasing arrangements. Although the exact nature of the work IPN performs varies for each vendor, generally, IPN provides the following services to pharmaceutical companies in exchange for its GPO administrative fees:

- Negotiating and administering the purchasing agreement on behalf of its physician members;
- Informing its members of the vendors' services and programs related to particular products;
- Distributing educational material to its members on behalf of the vendors;
- Assisting the vendors with data collection efforts related to its members' utilization of products and services;
- Providing vendors with logistical and administrative support related to conducting Advisory Boards, and providing other assistance related to gathering feedback from its members related to vendors' products and services; and
- Publishing both clinical and marketing materials in ION publications on a regular basis.

IPN, and other physician-based GPOs, serve a valuable and beneficial role in ensuring quality healthcare by providing significant assistance and services to community-based practitioners, and the vendors who provide them necessary products and services.

Administrative Fees Paid to GPOs Should Not Be Considered in Calculating ASP

IPN suggests that CMS should not require that payments made to GPOs, and other service providers who are not purchasers, be subject to the proposed qualifying definition of bona fide service fees[1] because these payments represent compensation for negotiated arms-length service arrangements, and are in no way related to price concessions received by a purchaser. Instead, the definition of bona fide services set forth in the proposed rule should be utilized to identify situations where payments made by manufacturers to ***buyers*** for services should be excluded from the ASP calculation, and service agreements between manufacturers and non-buyers should be governed by the terms of the negotiated, arms-length agreement between the manufacturer and the non-purchasing service provider.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) instituted the ASP methodology to determine the average price paid by physicians for Part B drugs and biologicals. Congress reformed the existing law in order to limit the "spread" -- the differential between a provider's cost of acquiring a drug or biologic and the amount the government paid for that product. To this end the statute, and CMS, is focused on the sale price made to purchasers of drugs and biologics.

Section 1847A(c)(1)(A) of the Social Security Act provides that ASP be calculated using the "*manufacturer's sales to all purchasers*" in the United States. Section 1847A(c)(3) of the Social Security Act requires that in calculating ASP, a manufacturer must include "*volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates.*" Under the statute the Secretary may also consider "*other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.*"

The focus on the price paid by the purchaser is made clear by the MMA's use of the term "widely available market price." CMS defines the term in Section 1847A(d)(5) as:

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[1] Section 414.802 of the Proposed Rule states that:

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

As discussed in detail below, IPN is concerned with the application of this definition to typical group purchasing arrangements.

the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

Consistent with this guidance, administrative fees paid to GPO service providers should not be viewed as a price reduction, but rather as compensation for a service that has been rendered to a non-purchasing provider. GPOs are not entities whose sales are included in the calculation of ASP, and their fee arrangements with manufacturers do not affect the separate and distinct price realized on any pharmaceutical products by the manufacturers.

Accordingly, any administrative fee between a GPO and a manufacturer should not be included as part of the manufacturer's sales price to purchasers, and therefore, should not be considered as part of the ASP calculation methodology. Because these payment arrangements between manufacturers and GPOs do not involve any price concessions, and the payment of fees to GPO service providers does not affect the price realized by the manufacturer, IPN believes that these fees should not be subject to the qualifying definition of bona fide service fees set forth in the Proposed Rule. Instead, that definition only should be applied to identify service payments that are made by a manufacturer to buyers, and to distinguish those payments made to buyers from price concessions they may receive, which should be included as part of the ASP calculation.

Appropriateness of GPO Fees

Again, IPN agrees with CMS' determination that fees paid to GPO service providers should not be included in the calculation of ASP. As stated above, because those service payment arrangements do not involve price concessions provided to any buyers, IPN does not believe they should be subject to the bona fide service definition set forth in the Proposed Rule. If, however, CMS determines that it is necessary to subject fee arrangements between manufacturers and entities that do not purchase their products to the qualifying definition of bona fide service fees, IPN urges the Agency to include additional clarification in the Final Rule stipulating that group purchasing percentage fee arrangements are an acceptable methodology for determining the fair market value of a GPO's services.

IPN believes this clarification is necessary to address certain inconsistencies between typical GPO fee arrangements and the proposed definition of bona fide service fees at 42 C.F.R. §414.802, and asks that CMS provide further clarification on this issue. Specifically, the proposed rule defines bona fide service fees as:

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

IPN believes that CMS should provide additional clarification that fixed fees and/or fees paid to GPOs based on revenue generated by product sales represent fair market value for the purpose of identifying bona fide service fees that are excluded from the calculation of ASP. IPN believes that this clarification is necessary to ensure that payments made by vendors to GPOs under typical group purchasing arrangements consistent with the well-established Congressional protection are excluded from ASP calculations.

GPO arrangements receive statutory protection under the Federal Anti-Kickback Law so long as certain conditions are satisfied. The statute states that prohibited remuneration arrangements does not apply to:

> any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal healthcare program if –
>
> (i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract ....

42 U.S.C. §1320a-7(b)(b)(3)(C). See also 42 C.F.R. §1001.952(j).

According to the Congressional protection and implementing Department of Health and Human Services regulations governing group purchasing arrangements, it is acceptable for GPO fees to be determined based on fixed amounts, or fixed percentages of the value of product sales to a GPO's members.

IPN, and to its knowledge, virtually all health care group purchasing organizations, routinely receive fees that are based on fixed percentages of units purchased by its members pursuant to the GPO's negotiated group contract, and otherwise consistent with the statutory protection governing such arrangements. We believe that it is necessary for CMS to clarify in the final rule that such payments based on designated percentages of units sold to members of a GPO qualify under the definition of bona fide service fees for the purpose of calculating ASP.

If CMS fails to provide this clarification, IPN is concerned that the health care GPO industry could be subject to significant costs and operational burdens related to justifying and calculating fees that are currently received as part of the typical course of business for the entire industry, and are otherwise consistent with the applicable Federal laws and implementing regulations. In establishing the GPO exception under the Federal Anti-kickback law, Congress determined that the benefits of GPO arrangements were substantially more significant that any minimal risk of abuse related to such arrangements.[2] Further, the Department of Health and Human Services promulgated the implementing regulations that govern health care GPO

[2] House Report No. 99-727, p. 445, July 31, 1986.

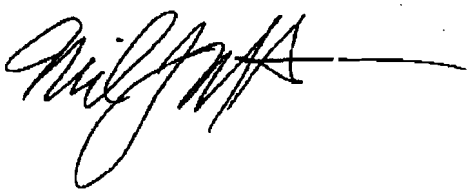
operations and did not deem it necessary to impose any additional requirements related to the calculation of fair market value beyond the establishment of payments based on fixed percentages of units sold, even though other safe harbors related to the provision of services include specific, additional requirements related to determining fair market value.[3] If CMS does not clarify that it is acceptable to determine fair market value based on these types of fee arrangements, it risks imposing an additional burden and cost to GPO operations by requiring them to undergo extensive third-party and market valuations in order to support fees that are excluded from the ASP calculation. This type of an approach would be unique to CMS and inconsistent to Congress' protection for group purchasing arrangements and the OIG's regulation of these arrangements, and could adversely affect the ability of health care GPOs to continue providing benefits to health care providers and the patients they serve.

Given the fact that CMS has acknowledged the benefits of GPOs by encouraging physicians to join purchasing groups in an effort to decrease drug acquisition costs and improve their practice efficiencies in response to the implementation of ASP reimbursement,[4] IPN believes that clarification on this specific issue in the Final Rule is necessary to protect these beneficial arrangements. We urge CMS to clarify that GPO fees that are not passed along to end users should not be included in the calculation of ASP so long as they are earned and paid consistent with the safe harbor protection under the Federal fraud and abuse rules, and to otherwise stipulate that it is acceptable to determine fair market value based on fixed percentages of revenue generated by product sales for the purpose of identifying bona fide service fees.

IPN appreciates the opportunity to comment on this important issue, and we look forward to working with CMS to ensure that Medicare beneficiaries continue to have access to critical drug and biological therapies. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions. Please feel free to contact Robert Wells, IPN Director of Compliance/Legal Affairs at 410-843-3426, if you have any questions regarding these comments.

Thank you for your attention to this very important matter

Respectfully submitted,



Mike Martin
President

[3] See e.g. 42 C.F. R. §§1001.952 (b)-(d)(space rental, equipment rental, and personal services).

[4] See, e.g. CMS: Revisions to Payment Policies Under Medicare, 69 Fed. Reg. at 66300-66301 (November 15, 2004

Comments of the Arkansas Pathology Society on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

[CMS–1321–P]

The Arkansas Pathology Society (APS) is pleased to have the opportunity to comment on the proposed revisions to payment policies under the physician fee schedule for calendar year 2007 (the "Proposed Rule"). 71 Fed. Reg. 48982 (Aug. 22, 2006). The APS is a professional society of pathologists practicing in the state of Arkansas. Our members perform a variety of services that are reimbursed under the physician fee schedule. Thus, our members will be significantly affected by the changes in the Proposed Rule. APS's comments on the Proposed Rule focus on the revisions to the reassignment and physician self-referral rules, and changes to the rules governing how anatomic pathology services are billed.

PROVISIONS

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

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

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

Changes to the Reassignment Rule

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

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

APS position: **supports** applying current purchased-service limitations in situations of reassignment

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

APS position: **no additional limitations** are necessary on PC purchase, beyond the need to apply the purchased-service rules that already exist and clarifying that they apply in the contracted reassignment setting

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

APS position: **no comment**

Stark Self Referral Provisions

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

Part-Time Employment of Pathologists

APS is concerned that in response to the provisions in the Proposed Rule, existing and new arrangements may be restructured so that pathologists will be retained as part-time employees rather than independent contractors. For example, a pathologist could become a part-time employee of several different groups under arrangements that potentially satisfy both the reassignment rules and the physician service or in-office ancillary services exceptions to the Stark self-referral provisions. From the standpoint of the group practice and the retained pathologist, the arrangement

need not differ significantly from an independent contractor relationship. Thus, APS considers it to be essential that CMS address both structures in its rulemaking.

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

We are aware of, and **support** suggested alternative regulatory proposals that would address this issue through the "substantially all" requirements for group practices under Stark. In essence, they would require that, in addition to the group practice as a whole having to perform at least 75% of its patient care services through the group, each individual member would need to perform at least one-half of its patient care services through the group. Such a provision could be limited to pathology services. Alternatively, CMS could, in the same provision of Stark establish a maximum number of group practices to which any one pathologist could belong. APS would strongly support this approach. These are more fully described in the comments of the American Clinical Laboratory Association, so they need not be repeated in detail here. Basically, if a pathologist arrangement did not meet this requirement, then the group practice would not be able to bill for pathology services that it refers to the pathologist. We believe that such a provision would limit restructuring that might be anticipated in response to the proposed changes in the contractor reassignment rules.

INDEPENDENT LAB BILLING

In the Proposed Rule, CMS states, "We continue to believe, however, that hospital prospective payment amounts already compensate hospitals for the TC of physician pathology tests and that additional payment under the PFS is inappropriate." *Id.* Therefore, CMS is proposing to amend § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

APS believes that the proposed rule misstates the intention of the proposal to discontinue the Grandfather provision, where it states "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient." We believe the intent was to state that "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the technical component of physician pathology services furnished to a hospital inpatient or outpatient." We urge CMS to correct this language if this concept is to appear in the final rule.

Given this major change to these historical billing rules, we strongly urge CMS to help hospitals understand their new obligations and move forward to address them to ensure that Medicare beneficiaries have full access to necessary clinical laboratory testing services.

CONCLUSION

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed changes to the physician fee schedule. Please do not hesitate to contact us should you have any questions about this information or need any further information.

Respectfully submitted,

Patrick D. Walker, M.D.
President, Arkansas Pathology Society
October 9, 2006

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From the desk of Seth A. Stabinsky, M.D.

October 5, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8010

Original plus Two Copies via Federal Express

RE: CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2007 and Other Changes to Payment Under Part B, Specifically **"Provisions Regarding Resource-Based Practice Expense (PE) RVU Proposals for CY 2007."**

Dear Dr. McClellan:

I am writing to you from my office-based Gynecology practice in San Jose, CA. with great concern over the above referenced proposed payment schedule change. In particular, I believe that by CY2010, there will be a significant negative effect from these changes on the practice expense RVUs for both **CPT code 58565 – Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants** as well as for **58356 – Endometrial cryoablation with ultrasonic guidance, including endometrial curettage when performed**.

I am aware that major changes to the PE methodology for CY 2007 were discussed in the June 29, 2006 proposed notice. By the end of the transition period in CY 2010, it seems clear that the specific, proposed practice expense RVUs published in the regulation for these two CPT codes will decrease patients' office-based access to these procedures. I fear this will lead to decreased access for women to such minimally invasive procedures in general and to increased expenses for CMS and other payers as pressure from unfavorable reimbursement will inevitably shift the treatment venue back to the much more expensive operating room environment.

CMS' proposed method uses budget neutrality adjustors in three separate steps. Practitioners cannot continue to absorb these under-valuations, especially as our practices face 37% in Medicare payment cuts over the next nine years, as projected by the Medicare Trustees. For example, the impact of the budget neutrality adjuster on the direct expenses means over $350 of the direct costs for CPT code 58565 are not included as part of the practice expense valuations for

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HealthPartners®

October 6, 2006

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

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 Dr. McClellan:

On behalf of HealthPartners Medical Group, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the calendar year 2007 Physician Fee Schedule proposed rules. HealthPartners Medical Group (HPMG) is a physician led, multi-specialty group practice with nearly 610 physicians serving patients at more than 50 clinic locations throughout the Twin Cities metropolitan area. HPMG is part of a consumer-governed family of nonprofit Minnesota health care organizations focused on improving the health of its members, its patients and the community. HealthPartners and HPMG are long term partners with CMS in serving Medicare beneficiaries. Our promise to patients is to deliver break-through experience through exceptional care and service that is safe, timely, effective, efficient, equitable, and most importantly, patient-centered. As such, the proposed provisions of the 2007 Physician fee schedule rule are of significant interest to us.

The rule proposes an overall decrease in the Physician Fee Schedule for 2007 in compliance with SGR requirements. We are disappointed to see, yet again, that the proposed fee schedule revision does nothing to address Medicare's underlying payment structure which continues to undervalue the quality of care provided to patients and perpetuates regional payment inequities. In particular, we encourage you to consider more fundamental change than an incremental approach with coding changes or SGR revisions. Some suggestions are described below. Minnesota, as well as much of the upper Midwest, has long been recognized as an area in which physicians and others provide higher quality care at a lower cost and reimbursement. One would expect the opposite – that those who perform best would be rewarded accordingly. However, Medicare physician

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Comments of the Florida Society of Pathologists on the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007

[CMS–1321–P]

The Florida Society of Pathologists (FSP) is pleased to have the opportunity to comment on the proposed revisions to payment policies under the physician fee schedule for calendar year 2007 (the "Proposed Rule"). 71 Fed. Reg. 48982 (Aug. 22, 2006). FSP is a professional society of pathologists practicing in the state of Florida. FSP members perform a variety of services that are reimbursed under the physician fee schedule. Thus, FSP members will be significantly affected by the changes in the Proposed Rule. FSP's comments on the Proposed Rule focus on the revisions to the reassignment and physician self-referral rules, and changes to the rules governing how anatomic pathology services are billed.

PROVISIONS

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

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

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

Changes to the Reassignment Rule

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

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

FSP position: **supports** applying current purchased-service limitations in situations of reassignment

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

FSP position: **no additional limitations** are necessary on PC purchase, beyond the need to apply the purchased-service rules that already exist and clarifying that they apply in the contracted reassignment setting

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

FSP position: **no comment**

Stark Self Referral Provisions

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

Part-Time Employment of Pathologists

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

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

We are aware of, and **support** suggested alternative regulatory proposals that would address this issue through the "substantially all" requirements for group practices under Stark. In essence, they would require that, in addition to the group practice as a whole having to perform at least 75% of its patient care services through the group, each individual member would need to perform at least one-half of its patient care services through the group. Such a provision could be limited to pathology services. Alternatively, CMS could, in the same provision of Stark establish a maximum number of group practices to which any one pathologist could belong. FSP would strongly support this approach. These are more fully described in the comments of the American Clinical Laboratory Association, so they need not be repeated in detail here. Basically, if a pathologist arrangement did not meet this requirement, then the group practice would not be able to bill for pathology services that it refers to the pathologist. We believe that such a provision would limit restructuring that might be anticipated in response to the proposed changes in the contractor reassignment rules.

INDEPENDENT LAB BILLING

In the Proposed Rule, CMS states, "We continue to believe, however, that hospital prospective payment amounts already compensate hospitals for the TC of physician pathology tests and that additional payment under the PFS is inappropriate." *Id.* Therefore, CMS is proposing to amend § 415.130 to provide that, for services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient.

FSP believes that the proposed rule misstates the intention of the proposal to discontinue the Grandfather provision, where it states "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to a hospital inpatient or outpatient." We believe the intent was to state that "For services furnished after December 31, 2006, an independent laboratory may not bill the carrier for the technical component of physician pathology services furnished to a hospital inpatient or outpatient." We urge CMS to correct this language if this concept is to appear in the final rule.

FSP strongly disagrees with CMS' assertion that hospital prospective payment amounts already compensate hospitals for the TC of these tests. We are not aware of

any documentation available to the public to support this assertion. Therefore, **we do not support** the implementation of these changes.

Given this major change to these historical billing rules, we strongly urge CMS to help hospitals understand their new obligations and move forward to address them to ensure that Medicare beneficiaries have full access to necessary clinical laboratory testing services.

CONCLUSION

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed changes to the physician fee schedule. Please do not hesitate to contact us should you have any questions about this information or need any further information.

Respectfully submitted,

Patricia A. Gregg, MD, FCAP

Patricia A. Gregg, MD, FCAP
President, Florida Society of Pathologists
October 9, 2006

MGI PHARMA

October 9, 2006

Terence Green
Vice President, Assistant General Counsel
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By Overnight Mail
Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

MGI PHARMA ("MGI") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Service ("CMS") proposed rule on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B (the "Proposed Rule"). MGI is an oncology and acute care-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of patients in the United States. Aloxi® (palonosetron hydrochloride) injection and Dacogen™ (decitabine) are among the products covered by Medicare Part B that MGI makes available to beneficiaries.

Our comments concentrate on the average sales price ("ASP") provisions of the Proposed Rule. In general, we appreciate that CMS seeks to clarify a number of operational issues arising under ASP reporting requirements. We agree that it is appropriate to address such issues in the context of a rulemaking so that the public has the opportunity to provide comments and recommendations. Below we offer a number of suggestions for improving and further clarifying the proposed ASP changes.

"ASP Issues"

I. Fees Not Considered Price Concessions

CMS proposes to clarify that bona fide service fees that are paid by a manufacturer to an entity, whether or not the entity takes title to the drug, are not considered price concessions for ASP reporting purposes. CMS proposes to define bona fide service fees as fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug. Further, CMS proposes to clarify that fees, including service fees, administrative fees and other fees, paid to GPOs or PBMs are not considered price concessions if they meet the proposed definition of a bona fide service fee.

We appreciate CMS's attempt to provide additional guidance regarding bona fide service fees. We are concerned, however, that aspects of the definition as proposed do not adequately reflect current contracting arrangements and could unduly complicate reporting obligations.

For instance, we recommend that CMS *not* apply the bona fide service fee standards to entities such as GPOs and PBMs when they do not take title of the product. Fees to GPOs and PBMs are service fees that typically do not affect the price realized by manufacturer. The ASP statute and reporting obligations are triggered by sales to purchasers, so there is no statutory basis for including fees that are not predicated on the transfer of title.

We also are concerned that CMS is proposing to require that a manufacturer determine whether an entity such as a GPO or PBM has passed on any portion of a service fee to that entity's own clients. While situations may arise in which a GPO or PBM shares a portion of a fee with its members who ultimately are purchasers, the manufacturer typically is not in control of, or even aware of, any such arrangement. It is even less likely that the manufacturer would have information about such down-stream transactions that is sufficiently detailed (i.e., apportioned to specific drugs) and timely on which to file accurate ASP reports.

Instead, we believe that the safe harbor for GPOs provides a more suitable and flexible framework for assessing the reportability of fees paid to GPOs and PBMs and that CMS should look to those standards. That is, CMS should not consider as discounts for ASP reporting purposes those fees that meet the GPO safe harbor. Likewise, CMS should not require manufacturers to demonstrate that a fee paid to an entity has not been passed back to a customer. Instead, it should be permissible for a manufacturer to exclude the fee from its ASP calculation if the contract between the manufacturer and the entity does not include any mandate that the fees be shared with the entity's customers.

CMS also requests comments on fair market value determinations for bona fide services. We urge CMS to proceed carefully in this area, in light of the agency's and the OIG's historical practice of not making bright line fair market value determinations. CMS should preserve a manufacturer's flexibility to use commercially-reasonable methods for determining fair market value in light of the complex contractual arrangements in the health care marketplace and the need to promote market efficiency. To the extent that CMS does offer additional guidance in this area, we recommend that the agency not unduly interfere with contracting arrangements and ensure that manufacturers are provided adequate time to comply with any new requirements.

We also request that CMS modify its proposed requirement that service fees represent fair market value for an *itemized service*. We believe that manufacturers should have the flexibility to pay a single service fee for an array of services, and that the manufacturer should be permitted to perform a fair market value analysis for the totality of services provided under the contract. Moreover, just as the GPO safe harbor provides for a presumption that a service fee that is 3% or less of the value of purchases may be considered fair market value, a threshold fair market value presumption for bona fide service fees could simplify the ASP reporting process for manufacturers and the review process for CMS.

II. Nominal Sales

CMS proposes to continue the current methodology for identifying and excluding nominal sales (i.e., sales that are exempt from the Medicaid best price calculation) from the manufacturer's calculation of the Medicare ASP. We support CMS's proposal, since using a single method to identify nominal sales under both ASP and Medicaid average manufacturer price ("AMP") reporting requirements ensures continuity and decreases reporting burdens.

We also recommend that CMS clarify the definition of safety net provider for purposes of nominal sales determinations. Under the Social Security Act, the Secretary may designate any facility or entity "that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate," based on factors enumerated in the statute. Currently, manufacturers cannot always readily determine whether an entity would qualify as a safety net provider. It would promote accuracy and consistency in ASP reporting if CMS maintained and posted a list of entities that the Secretary determines to be qualifying safety net entities for ASP reporting purposes.

III. Widely Available Market Price and AMP Threshold

Over the past several months, MGI PHARMA has become increasingly concerned that the current reimbursement policy for generic drugs under Medicare Part B results in (1) significant overpayments for generic drugs by the Medicare program and Medicare beneficiaries, and (2) financial incentives that could lead to prescribing practices that are not necessarily in the best interest of the patient, particularly cross HCPCS substitutions that could negatively impact clinical care. MGI PHARMA believes that CMS needs to take immediate action to protect beneficiary interests and better serve the Medicare program.

MGI PHARMA generally supports CMS' policies to incentivize provider utilization of generic products, but questions the manner in which the current ASP system attempts to achieve this goal. Current Medicare payment policy reimburses generic products for two quarters at the average sales price (ASP) payment rate established for the branded drug's payment code, until the generic drug's ASP can be incorporated into the volume-weighted ASP calculation for payment code. Therefore, while generic drugs may be purchased at a price significantly less expensive than their brand drug counterparts, generics are currently allowed to heavily discount behind the brand drug's price for six months to create a significant disparity between the brand ASP price and the generic market price (inclusive of discounts and rebates). The result is a significant drug margin – with Medicare often paying hundreds of dollars more than the actual price of these new generic products. There is no Medicare policy or Congressional mandate that justifies unnecessarily doubling or tripling the cost-sharing payments of Medicare beneficiaries.

In addition, this payment policy may even compromise patient treatment by promoting prescribing practices that are not necessarily the most efficacious treatment for the patient. For the first six months that a generic drug is on the market, there are significant financial incentives in place that unintentionally encourage physicians to make cross-HCPCS substitutions, not just choosing the generic option within a HCPCS code, in order to reap the financial benefit of prescribing the new generic product. In this scenario, it is not an issue of brand drugs competing with their generic counterparts – it is an issue of margins associated with new generic drugs driving physicians towards a specific therapeutic option regardless of the clinical considerations of the patients. MGI PHARMA agrees that CMS should use the ASP system to encourage competition between the therapeutically equivalent medications within a HCPCS code; however, the ASP system should not be used to drive providers to the drug with the highest margin, regardless of the implications to patient care.

The proposed rule provision dealing with bundling arrangements clearly demonstrates CMS' desire and authority to eliminate unintended financial dynamics created by the ASP system, particularly if those dynamics drive treatment decisions and raise

beneficiary and program costs. CMS is concerned that bundling arrangements may skew ASP calculations, potentially compromising patient access to appropriate care and resulting in higher costs to the Medicare program and its beneficiaries. In fact, CMS states in the proposed rule that its goal in reviewing bundling is "to ensure that the ASP is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives." These are the very same issues that are emerging in connection with reimbursement for new generic products entering the market.

In conclusion, the Medicare program is paying egregiously inflated prices for new generic drugs under the current ASP, not only overcharging beneficiaries but also potentially jeopardizing beneficiary access to clinically appropriate drug therapies because of these financial incentives. There is no question that these new generic entries will far surpass the 5 percent WAMP and AMP thresholds, but under the current ASP payment system, these drug margins are not only permitted, they are encouraged. Therefore, MGI PHARMA believes that CMS should make every effort to create a payment methodology for new generic drugs that (1) allows both Medicare beneficiaries and the Medicare program to more expeditiously reap the financial benefits when a new generic drug comes on the market, and (2) protects patient quality of care. We strongly recommend that CMS take a close look at the current reimbursement methodology to identify and address issues that could impact patient care and put unnecessary financial burdens on Medicare beneficiaries. We urge CMS to work with Congress to enact a remedy, which more rapidly recognizes the true market price of newly approved ANDAs. Some Members of Congress have considered requiring a market-entry ASP to be reported for a new generic product, allowing CMS to eliminate detrimental financial incentives that could impact patient care and allow beneficiaries to capture savings associated with lower cost generic alternatives. MGI PHARMA would ask CMS to support such a legislative change in policy.

IV. Bundling

CMS is considering providing guidance on the methodology manufacturers must use for apportioning price concessions across Part B drugs sold under bundling arrangements for purposes of the calculation of ASP. We agree that clear guidance in this area – particularly regarding the definition of a bundled sale -- is important to facilitate accurate, consistent ASP reporting. We recommend that CMS define a bundled sale for ASP reporting purposes as an arrangement involving the sale of multiple drugs that 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 would be consistent with the definition of a bundled sale under the Medicaid Rebate program, the discount safe harbor regulation to the anti-kickback statute, and as set forth through OIG Advisory Opinions. Establishing such a definition also is preferable to the agency attempting to catalogue all specific business arrangements that would be classified as a bundle, considering the evolving nature of such arrangements within the health care industry. Once CMS defines bundled sales, it

can set forth rules for allocating the bundled incentives to individual drugs in a way that ensures the accuracy of ASP-based reimbursement. The appropriate allocation of rebates and discounts will provide transparency and reflect true market costs of drugs and biologicals.

IV. Prompt Pay Discounts

MGI requests that CMS seek authority from Congress to exclude prompt payment discounts from the ASP calculation so that ASP better approximates provider acquisition costs. Currently, manufacturers are required to include prompt payment discounts as price concessions in the ASP calculation. We believe such an approach is problematic because providers typically do not purchase directly from the manufacturer and receive the benefit of a prompt pay discount. Accordingly, the current calculation methodology for ASP may not be an appropriate measure of provider acquisition costs. Further, as it currently stands, there is inconsistency in the treatment of prompt pay discounts between the Medicaid and Medicare programs. Congress recently amended the Medicaid rebate statute to exclude prompt pay discounts from the calculation of AMP. CMS should urge Congress to similarly amend the ASP statute to reduce confusion and provide greater consistency in the calculations.

* * * * *

MGI appreciates this opportunity to present these comments to CMS. Please do not hesitate to contact us if you have any questions.

Sincerely,

Terence Green
Vice President, Assistant General Counsel

Riverain MEDICAL

Early. Detection. Now.

October 9, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Office of the 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: CMS-1321-P, Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B

Dear Dr. McClellan:

Riverain Medical is pleased to submit the following comments to the Proposed Rule CMS-1321-P, "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B" (the "Proposed Rule") published in the *Federal Register* on August 22, 2006. As requested, we have keyed our comments to the issue identifiers in the Proposed Rule. We hope Centers for Medicare and Medicaid Services (CMS) finds our recommendations helpful as it finalizes the physician fee schedule for 2007.

Riverain Medical is a healthcare company that offers the only chest radiography computer-aided detection (CXR CAD) software for early lung cancer detection approved by the Food and Drug Administration (FDA). Riverain Medical is committed to being a leader and innovator in CAD and diagnostic technologies that significantly aid medical practitioners in the early-stage detection of diseases.

Riverain Medical wishes to comment on the Deficit Reduction Act (DRA) Proposals in the proposed rule.

DRA Proposals

The DRA requires the CMS to implement a payment cap for the technical component (TC) of certain imaging services. Specifically, if the amount determined under the physician fee schedule (PFS) is greater than the amount payable under the hospital outpatient prospective payment system (OPPS) for the same service, then CMS must substitute the OPPS amount for the PFS amount.

In its proposal on this issue CMS states that, "We also excluded all HCPCS codes for imaging services that are not separately paid under the OPPS since there would be no corresponding OPPS payment to serve as a TC cap."[1] The list of codes that CMS proposes to include under the DRA cap is printed in Addendum F of the proposed rule.

We note that CPT code 0152T, Computer chest add-on, is included in Addendum F. We wish to point out that 0152T has a status indicator of "N" in the OPPS, is not separately paid and that CMS is proposing in CMS-1506-P to maintain this packaged status for CY 2007.

We also note that imaging services for which separate payment is *not* made under the OPPS are proposed to be excluded from the DRA cap. Therefore, we request that CMS remove 0152T from Addendum F in the final rule.

We would like to point out that 0152T will be deleted as of January 1, 2007, and that it will be replaced by CPT codes 0174T and 0175T. We have requested that CMS assign 0174T and 0175T to APC 1492 with a status indicator of "S" or "Q" and a payment of $15.00. However, if CMS decides not to make separate payment for 0174T and 0175T and assigns them status indicators of "N," we request that both those codes not be included in Addendum F and that they not be subject to the DRA cap.

For your convenience the following are the CPT codes that are referenced above. The code that will be replaced has strikeout text:

~~+0152T Computer aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; chest radiograph(s) (List separately in addition to code for primary procedure)~~

+0174T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation

0175T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation

[1] 71 *Fed. Reg.* 48997.

We appreciate the opportunity to submit these comments on the Proposed Rule CMS-1321-P and would be happy to answer any questions you may have. I may be contacted at 800.990.3387 or my mobile phone at 330.284.3264.

Sincerely,

RIVERAIN MEDICAL

Sam D. Finkelstein

Sam D. Finkelstein
President
Riverain Medical

153

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MAHOMET, IL 61853-9734

October 9, 2006

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

RE: Comments on CMS-1321-P: Revisions to Payment Policies Under the Physician Fee Schedule for y 2007 and Other Changes to Payment Under Park B; "Independent Diagnostic Testing Facility (IDTF) Issues"

Dear Sir or Madam:

We are pleased to offer these comments on the proposed IDTF standards.

I am an owner of a physician practice that provides mobile diagnostic tests to patients who resided in Skilled Nursing Facilities (SNF's) or who are hospitalized and cannot easily travel to a hospital radiology department for the test they need. Equipment for the mobile services is leased and taken to the facility where the patient resides so that these tests can be provided to these patients who otherwise would not be able to have them. The tests are rendered at SNF's, hospitals and other settings where the patient resides. This practice model ensures that there is proper physician supervision of the tests as, in fact, the physician actually performs that diagnostic test. The services are billed to Medicare by the physician performing the tests. Whenever the patient is on a Medicare Part B stay, the physician bills the technical and professional components to Medicare. When the patient is on a Medicare Part A stay, only the professional component is billed to Medicare and, under consolidated billing, the SNF is billed to the Technical component and for any therapy which are consolidated. We have confirmed the appropriateness of our billing with the CMS Regional Office.

Recently, the local Carrier insisted that a lessor of equipment, my practice, had to become certified as an IDTF, even though the practice is an MD practice. Although we do not believe that all equipment lessors should have to be IDTF's, we have been certified as such, primarily under the Carrier's admonition that the services billed by our MD practice would be denied if we did not agree with the Carrier and Become certified. CMS's proposed standards should address more specifically, which entities must become certified as IDTF's. Specifically, physician should not need to become IDTF's and meet the new standards for tests that they offer personally.

We understand the Program's concern for the safety of equipment used by IDTF's. Even prior to becoming certified, we offered to permit carrier personnel access to all of our equipment which is calibrated and licensed by the state nuclear safety department. We suggest that, since all x-ray equipment must be certified by the FDA prior to sale and is licensed in every state and regulated by the state nuclear safety department, there is no need for CMS to empower the Part B providers attempting to deliver services to patients. CMS's proposed standards should defer to state agencies' calibration, testing, certification, and licensure requirements.

Under the new standards for IDTF's, we are concerned that the standards will be difficult to meet because all of our equipment is mobile. Although we have a physical plant for administrative purposes, we do not have a storefront. We do not believe that a storefront should be required in that context. The certification standards should address such scenarios. CMS's proposed standards should be modified to address those IDTF's whose inventory of equipment is made up of mobile equipment entirely.

In addition, the medical records to be maintained, should be limited to the studies performed by the IDTF. The patient records will be the physicians' or providers'. If the IDTF maintains a copy of the test results, that should be sufficient for the purpose of IDTF certification. (If the IDTF is billing Medicare directly, medical necessity standards might dictate where other records are to be maintained.) To impose on the IDTF the obligation to maintain other medical records, under HIPAA, would impose a significantly large paperwork burden on the IDTF's which is not addressed in the regulations, and would not advance the interest that CMS had in choosing to certify IDTF's. CMS should more carefully consider the record keeping obligations imposed under the IDTF standards in light of HIPAA privacy concerns and the paperwork burden involved.

Thank you for your consideration of these issues.

Sincerely,

Nae Y. Moon, MD

VIA FED EX

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ENDOCRINOLOGY
DIABETES
METABOLIC SUPPORT

October 9, 2006

Dr. Mark B. McClellan
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

Issue identifier- PROVISONS- MEDICAL NUTRITION THERAPY SERVICES

Dear Dr. McClellan:

I am writing in support of adequate work value for nonphysician medical nutrition therapy (MNT) services. This is necessary to foster a public health environment in which MNT is available to all patients requiring this intervention. Without adequate reimbursement, providers of MNT are not able to sustain viable practices and accessibility to all patients is not possible.

I am a physician nutrition specialist and a Past President of the American Board of Physician Nutrition Specialists. I am a consulting endocrinologist in private practice and on the voluntary staff at The Mount Sinai Hospital in New York. The overwhelming majority of my patients with diabetes are in need of MNT and the dedicated time a nonphysician nutrition specialist can provide. Other patients with renal disease, particularly with forms of malnutrition, are also in need of comparable MNT and counseling.

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I have reviewed the statements by Midtown Nutrition Care and support appropriate increases in the work value so that reimbursements to nonphysician MNT providers allow them to provide care to all patients.

Thank you for your time in reviewing my comments.

Sincerely,

Jeffrey I. Mechanick, M.D., F.A.C.E., F.A.C.P., F.A.C.N.
Director, Metabolic Support
Associate Clinical Professor of Medicine
Mount Sinai School of Medicine

MIDTOWN NUTRITION CARE
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October 6, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Issue Identifier: PROVISIONS—MEDICAL NUTRITION THERAPY SERVICES, CPT 97802-4, G0270-1 (II. Provisions of the Proposed Rule, A. Resource-Based Practice Expenses (PE) RVU Proposals for CY 2007, 3. Medical Nutrition Therapy Services)

Dear Sir or Madam:

On September 11, 2006 Midtown Nutrition Care submitted a comment that suggested that the work value for the medical nutrition therapy codes should be based on the work value of the15-minute Evaluation and Management consultation code CPT 99241. Our professional society, the American Dietetic Association, has suggested that the work value for the medical nutrition therapy codes could be based on the work value of the 15-minute and 30-minute Evaluation and Management office visit codes CPT 99213 and 99203. (71 FR 48987, second column).

The work value of an Evaluation and Management code appears to satisfy the statutory compensation (not scope-of-practice) language "85 percent of the amount determined...for the same services if furnished by a physician [emphasis supplied]" (Section 105(c)(2) of BIPA) because the text following CPT 97802-4 states: "For medical nutrition therapy assessment and/or intervention performed by a physician [emphasis supplied], see Evaluation and Management or Preventive Medicine service codes." (Preventive medicine codes would not be appropriate because Section 105(b) of BIPA states that Medicare medical nutrition therapy is only "for the purpose of disease management".)

However, if CMS does not agree that it is appropriate to crosswalk to the work value of an Evaluation and Management code, then an appropriate alternative would be a crosswalk to the work value of the 20 to 30 minute Insight Oriented, Behavior Modifying and/or Supportive Psychotherapy code CPT 90804, which has a current and proposed work value of **1.21**. This code does not include medical evaluation and management services, as does its companion code CPT 90805, which has a current and proposed work value of **1.37**. (70 FR 70442: 71 FR 49213).

The statutory definition of medical nutrition therapy services is "diagnostic, therapy and counseling services for the purpose of disease management" (Section 105(b) of BIPA) which matches well the definition of CPT 90804 services set forth in the third text paragraph prior to CPT 90804-90899: "Insight oriented, behavior modifying and/or

supportive psychotherapy refers to the development of insight or affective understanding, the use of behavior modification techniques, the use of supportive interactions, the use of cognitive discussion of reality, or any combination of the above to provide therapeutic change."

Because CPT 90804 is a 20 to 30 minute code, to determine its value range for a 15-minute increment we would first convert to one hour, then divide by 4:

At the beginning of the range, a 20-minute visit, we would calculate as follows:
1.21 X 3 = **3.63** per hour ÷ 4 = 0.9075 (**0.91**) per 15-minute increment.

At the end of the range, a 30-minute visit, we would calculate as follows:
1.21 X 2 = **2.42** per hour ÷ 4 = 0.605 (**0.61**) per 15-minute increment.

At the middle of the range, a 25-minute visit, we would calculate as follows:
1.21 X 2.4 = **2.904** per hour ÷ 4 = 0.726 (**0.73**) per 15-minute increment.

We suggest using the **0.73** value translated by the middle of the range (25 minutes). If the **0.91** value translated by the beginning of the range (20 minutes) were used it would certainly be acceptable, but it would be almost as high as the **0.92** proposed work value for the 15-minute office visit code CPT 99213. (71 FR 49232).

If the **0.61** value translated by the end of the range (30 minutes) were used it would be below the **0.67** current work value of CPT 99213 (70 FR 70458) and would create a total RVU of only **0.74**. (71 FR 49231). While this would increase reimbursement rates for medical nutrition therapy services, the resulting rates would barely be sufficient for us, and may not be sufficient to allow other registered dietitians to afford to become Medicare providers.

The **0.73** value translated by the middle of the range (25 minutes) is not only a logical value because it is in the middle of the 20 to 30 minute range, but would also generate a modest, but affordable, work value, being slightly higher than the **0.67** current work value for CPT 99213, yet considerably less than the **0.92** proposed work value for CPT 99213.

As discussed in detail in our September 11 comment, we submit that CMS should continue to follow the reasoning contained in the Calendar Year 2002 Final Rule that all time-based medical nutrition therapy codes would have the same hourly rate, so that the 15-minute individual codes CPT 97802, CPT 97803 and G0270 would have the same **0.73** work value and the work value for the 30-minute group codes CPT 97804 and G0271 would be equal to **0.73** times 2 divided by 5, or **0.29**. (66 FR 55280, first-second columns; 66 FR 55281, first column).

Sincerely yours,

Robert Howard, RD, JD
Managing Partner

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September 11, 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

Re: August 22, 2006 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

Issue Identifier: PROVISIONS—MEDICAL NUTRITION THERAPY SERVICES, CPT 97802-4, G0270-1 (II. Provisions of the Proposed Rule, A. Resource-Based Practice Expenses (PE) RVU Proposals for CY 2007, 3. Medical Nutrition Therapy Services, 71 FR 48987)

Dear Sir or Madam:

Midtown Nutrition Care (Midtown), a single specialty nutrition group practice with 7 registered dietitians, respectfully submits the following comments.

Table of Contents

Attachment B—July 2000 HCPAC Recommendations and August 1, 2000 transmittal memo (4 pages)

Attachment C—January 3, 2006 letter from ADA to CMS (4 pages)

Attachment D—March 24, 2006 letter from ADA to CMS (3 pages)

Attachment E—Section 105 of BIPA and Statement of the Manager For Section 105 (2 Pages)

Attachment F—March 2000 RUC Update Survey (24 pages)

Summary of Points

The work RVUs for the three individual 15-minute medical nutrition therapy codes CPT 97802, 97803 and G0270 should all be the same. The work RVUs for the medical nutrition therapy codes should be based on the 15-minute consultation code CPT 99241 rather than on the 15-minute and 30-minute physical therapy codes CPT 97110 and 97150.

Inadequate Reimbursement = Lack of Access

1. Last year, in the Calendar Year 2006 Proposed Rule, CMS proposed eliminating the nonphysician work pool, formerly known as the zero-work pool, and stated: "We recognize that there are still some outstanding issues that need further consideration, as well as input from the medical community. For example, although we believe that the elimination of the nonphysician work pool would be, on the whole, a positive step, some practitioner services, such as audiology and medical nutrition therapy, would be significantly impacted by the proposed change.... We, therefore, welcome all comments on these proposed changes..." (70 FR 45777, second column).

2. As members of the medical community Midtown submitted comments dated September 22, 2005 from our group and from the original sponsor of the medical nutrition therapy benefit bills, Congressman Jose Serrano. Comments were also submitted by our professional society, the American Dietetic Association (ADA).

3. These comments showed that even without further reduction current reimbursement rates are inadequate, and urged that appropriate work RVUs be assigned to the Medical Nutrition Therapy codes in order to give effect to the intention of Congress to provide adequate payment for these services, so that access to these services would become generally available to the Medicare beneficiaries entitled thereto, namely, patients with diabetes or renal disease.

4. That the access to care envisioned by Congress does not exist is shown by the following three items. First, prior to passage of the medical nutrition therapy benefit the Congressional Budget Office estimated the annual cost of medical nutrition therapy services to be 60 million dollars, but only a few million dollars have been spent annually since the benefit became available in 2002. Second, this represents visits by only about 250,000 beneficiaries out of an estimated 8 million beneficiaries with diabetes or renal disease. Third, only about 10% of dietitians (7,000 out of 65,000 nationwide) have become Medicare providers, compared with over 90% of physicians. For a discussion of these three items, see Journal of the American Dietetic Association, June 2005, p. 990 and p. 995 (footnote references).

5. In our case, as our September 22, 2005 comment showed, Medicare pays less than half the fees paid by insurers in our area that have independently valued these codes. Medicare's fees are well below our break-even level. Therefore we cannot afford to treat Medicare patients and none of us has become a Medicare provider. We turn away a couple of Medicare patients every day and most of these patients are unable to obtain medical nutrition therapy services because virtually none of the dietitians in our area accept Medicare.

6. In the Calendar Year 2006 Physician Fee Schedule Final Rule no decision was made regarding medical nutrition therapy work RVUs; that decision was put off to this year: "Because we are maintaining the NPWP for 2006, we are deferring our decision regarding work RVUs for audiology, speech language pathology and medical nutrition pending further discussions with the specialties." (70 FR 70134, first column).

7. In the Calendar Year 2007 Proposed Rule CMS stated it would establish work RVUs and remove clinical labor time in the practice expense direct input database: "Because we propose to add the work RVUs to these services, the MNT clinical labor time in the direct input database would be removed with the adoption of this proposal." (71 FR 48987, third column).

8. The assignment of work RVUs coupled with the removal of clinical labor time from the practice expense direct input database would raise the fully implemented non-facility total RVU of the 15-minute new patient visit code CPT 97802 from **0.48** to **0.58**, leave the 15-minute established patient visit codes CPT 97803 and G0270 total RVU of **0.48** unchanged, and raise the 30-minute group codes CPT 97804 and G0271 total RVU from **0.19** to **0.32**. (70 FR 70457, 70462; 71 FR 49231, 49235).

9. Given the approximately 10% adjustment required to preserve budget neutrality (71 FR 37241, first-second columns), this means that the new patient visit code would pay about 5% more than currently, the established patient visit codes would pay about 5% less than currently, and the group codes would pay about 50% more than currently. Although the group fees would be adequate, neither our practice nor the practices or employment settings of other dietitians have many group visits compared to individual visits. Therefore if these RVUs are carried over to the Final Rule our practice and other dietitians will still be unable to afford to treat Medicare patients, allowing the lack of access to care to continue.

The Work RVUs Should Be the Same for the Individual Codes

10. The proposed work RVUs are those recommended on an interim basis by HCPAC in July 2000, transmitted to CMS by memo dated August 1, 2000, a copy of which is attached as Attachment B.

11. These recommendations were based on a RUC survey conducted in March 2000 (Attachment F) for seven proposed, but never adopted, Medical Nutrition Therapy codes, 3 initial visit codes, 3 follow-up visit codes and 1 group visit code, modeled after the office visit code series CPT 99201-99205, 99211-99215.

12. Unlike the time-based codes that were adopted, these 7 codes were based on level-of-complexity. Thus the survey data showed that follow-up visits would have lower RVUs because at the same level of complexity the follow-up visit will take less time than the initial visit.

13. But because a shorter visit will take less time, it will also have fewer 15-minute increments. Therefore there is no need to value the 15-minute follow-up visit increment less than the 15-minute initial visit increment. In fact doing so amounts to a double reduction of the fee, first for fewer 15-minute increments, and then a lower RVU for the each increment.

14. HCPAC stated at the bottom of the first page of the July 2000 Recommendations (Attachment B): "This recommendation maintains the relativity of CPT code 97803 and 97804 as presented by the survey data and original work relative value recommendations from the American Dietetic Association." Somehow HCPAC overlooked the fact that the survey data was based on the never adopted level-of-complexity codes, while the adopted codes were purely time-based codes.

15. Using the survey data, HCPAC valued the15-minute follow-up increment 73% less than the 15-minute initial visit increment, estimating that the typical CPT 97802 visit would take 75 minutes (pre, intra and post visit time), while the typical CPT 97803 visit would take 55 minutes (pre, intra and post visit time), or 73% less time ($55 \div 75 = 73\%$).

16. All of the CPT codes that are time-based, other than the Medical Nutrition Therapy codes, use the same code for their initial and follow-up visits, so their initial and follow-up time increments will pay the same. See, for example, the preventive medicine counseling codes CPT 99401-99412 and the psychiatric therapeutic psychotherapy codes CPT 90804-90829.

17. In fact, were it not for CMS's need to use CPT 97803 and G0270 to keep track of the number of follow-up visits and change-of-diagnosis follow-up visits, it would need only one code for all individual visits. But just because CMS needs to use two additional follow-up visit codes is no reason to value the 15-minute increments of those codes less than the 15-minute increment of the initial visit code.

18. CMS recognized that initial and follow-up time-based medical nutrition therapy codes should be valued the same when CMS valued the later-created group change-of-diagnosis 30-minute follow-up code G0271 the same as the CPT 30-minute group code CPT 97804. (70 FR 70457, 70462).

19. But more to the point, the question of whether the individual 15-minute codes would be valued the same or differently was an issue once before, in the preparation of the Calendar Year 2002 Physician Fee Schedule. The Calendar Year 2002 Proposed Rule had proposed a lesser value for the 15-minute follow-up increments. The issue was fully discussed in the Proposed Rule, in comments thereto, and in the Final Rule, which concluded that all of the time-based Medical Nutrition Therapy codes should have the same hourly rate: "A commenter representing dietitians asked us to review the relativity of payment across the three medical nutrition CPT codes. The commenter indicated that payment for CPT code 97803 was set at 72.9 percent of proposed RVUs for CPT 97802 and 97804 was set at 31 percent of CPT code 97802. The commenter argues that, because reassessments are shorter than initial assessments, the proposed RVUs are actually discounted twice (that is, less payment per 15 minutes of time as well as less total time). They believe the value of CPT codes 97802 and 97803 should be identical.... We have reviewed the payments for CPT codes 97802 and 97803 and agree with the commenter that these two codes should have the same values. The essential difference between an initial and follow up medical nutrition therapy service is the time spent performing the service. Initial visits will be longer than follow-up visits and will likely involve Medicare payment for more increments of service. We will pay less for follow up visits because they will typically involve fewer 15-minute increments of time than an initial visit. The payment rate we are establishing in this final rule for CPT code 97803 will be the same as the proposed rate for CPT code 97802. We have also changed the payment rate for CPT code 97804 assuming that the code will normally be billed for 4 to 6 patients with the average of 5. Using the revised values, the payment rate for group medical nutrition therapy would approximate the hourly rate paid for other medical nutrition therapy services." (68 FR 55280, first-second columns).

20. That reasoning was sound and remains sound and should continue to be followed, rather than create a **0.08** less work RVU for CPT code 97803 and G0270 (0.45 – 0.37 = 0.08). (71 FR 49231, 49235).

Use the Work RVU of the 15-Mintue Consultation Code

21. CMS may accept or reject HCPAC work RVU recommendations. (71 FR 37173, third column). In this instance we submit that CMS should reject the July 2000 HCPAC interim recommendations, which base the medical nutrition therapy work RVUs on the 15-minute and 30-minute physical therapy codes CPT 97110 and 97150, and instead base the work RVUs on the 15-mnute consultation code CPT 99241.

22. The July 2000 HCPAC interim recommendations regarding the new Medical Nutrition Therapy codes were unusual in that they were initially submitted for the Calendar Year 2001 Physician Fee Schedule before CMS had the statutory authority to

value these codes for Medicare payment (71 FR 48987, first-second columns), because the law that created the medical nutrition therapy benefit was not enacted until later, in December 2000, and created the benefit for these services starting in the Calendar Year 2002. See PL 106-544, Appendix F, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Section 105, Coverage of Medical Nutrition Therapy Services for Beneficiaries With Diabetes or a Renal Disease, and the published legislative history set forth in the Statement of the Manager For Section 105, both attached as Attachment E.

23. When HCPAC was making its interim work recommendations, HCPAC did not know what the statute would eventually contain. Therefore HCPAC looked solely to the text of the Medical Nutrition Therapy codes CPT 97802-4 which describe medical nutrition therapy services in bare-bones terms as "assessment [or re-assessment] and intervention, individual [or group], face-to-face with the patient, each 15 [or 30] minutes." On the other hand the statute defines medical nutrition therapy services much more comprehensively as "diagnostic, therapy and counseling services for the purpose of disease management", Section 105(b) of BIPA, 42 U.S.C. 1395x(vv)(1), and provides that payment of 85% to dietitians be determined "for the same services if furnished by a physician." Section 105(c)(2) of BIPA, 42 U.S.C. 1395l(a)(1)(T).

24. Since HCPAC was recommending work RVUs when it was not even cognizant of what the statutory definition would be, HCPAC was able to compare the15- and 30-minute individual and group medical nutrition therapy codes to "other modality or treatment codes" (middle of the first page of the July 2000 Recommendations, Attachment B), in this case the 15- and 30-minute individual and group physical therapy codes CPT 97110 and 97150.

25. These treatment codes are poor comparisons given the (now known) statutory definition of medical nutrition therapy in Section 105(b), 42 U.S.C. 1395x(vv)(1), which includes diagnosis and counseling as well as therapy.

26. In the 2002 Physician Fee Schedule Proposed and Final Rules CMS had compared medical nutrition therapy services to the 15-minute preventive medicine counseling code CPT 99401: "Commenters...believe that medical nutrition therapy payment should not be based on comparison to a preventive medicine code (CPT code 99401) in the zero-work pool methodology. The commenters indicated that preventive medicine services omit the problem-oriented components of the comprehensive history, as well as other essential assessment points, such as the patient's chief complaint and history of present illness." (66 FR 55279, third column-55280, first column).

27. In prior submissions to CMS Midtown had also proposed that the work RVUs for the Medical Nutrition Therapy codes could be based on the 15-minute preventive medicine counseling code CPT 99401. However Section 105(b), 42 U.S.C. 1395x(vv)(1), defines medical nutrition therapy services as services provided "for the purpose of disease management", that is, for patients with established illness. So a crosswalk to CPT 99401 would not be appropriate, because the CPT text prior to Sections 99401-99429 states (third paragraph of text): "These codes [preventive medicine counseling codes] are not to

be used to report counseling and risk factor reduction interventions provided to patients with symptoms or established illness. For counseling individual patients with symptoms or established illness, use the appropriate office, hospital or consultation or other evaluation and management codes [emphasis supplied]."

28. A more appropriate crosswalk, according to the text quoted above, would be to the work RVU of an office visit or consultation code.

29. Section 105(b), 42 U.S.C. 1395x(vv)(1), provides that a medical nutrition therapy visit be "pursuant to a referral by a physician", to whom a report is sent post-visit. Therefore the visit could be considered a consultation. If so, the work RVU could be that of the 15-minute consultation code CPT 99241, which has a work RVU of **0.64** as of the 2006 Physician Fee Schedule, and the same **0.64** is proposed for the 2007 Physician Fee Schedule. (71 FR 37218, second-third columns; 71 FR 49232).

30. The medical nutrition therapy visit could also be considered an office visit. If so, the work RVU could be that of the 15-minute established patient office visit code CPT 99213, which has a work RVU of **0.67** as of the 2006 Physician Fee Schedule (70 FR 70458) and a proposed work RVU of **0.92** for the 2007 Physician Fee Schedule. (71 FR 37218, second-third columns; 71 FR 49232).

31. CMS could use either the work RVU of CPT 99241 or the work RVU of CPT 99213 as the work RVU for the 15-minute individual Medical Nutrition Therapy codes CPT 97802, 97803 and G0270; and as the basis for the work RVU for the 30-minute group codes CPT 97804 and G0271 in the same manner as was done in the Calendar Year 2002 Physician Fee Schedule Final Rule; that is, by multiplying the CPT 97802 RVU by 2 then dividing by 5. (66 FR 55281, first column).

32. The Calendar Year 2002 Physician Fee Schedule Final Rule, however, had rejected a valuation crosswalk to E/M codes, making the following analysis for the first time in the Final Rule, though not in the Proposed Rule (so no comments may have been received questioning such analysis): "We do not believe that it is appropriate to compare medical nutrition therapy provided by a registered dietitian to an E/M service provided by a physician. Registered dietitians do not take medical histories, they are not trained and do not perform physical examinations, nor do they make medical decisions. Furthermore, when physicians use an E/M code, they typically have also performed a medical history, physical examination, and engaged in medical decision making as part of that service. If such an individual performed a service that met the requirements of an E/M service, then it would be appropriate for him or her to report an E/M service [emphasis supplied]." (66 FR 55278, third column).

33. This analysis misread the statute, which specifies that the amount paid be determined by comparing medical nutrition therapy services provided by a physician, not by comparing medical nutrition therapy services provided by a registered dietitian. Section 105(c)(2), 42 U.S.C. 1395l(a)(1)(T), states "the amount paid shall be...85 percent of the amount determined ... for the same services if furnished [i.e., provided] by a physician".

(See the third sentence of the Statement of the Manager For Section 105, Attachment E, "... if such services were provided by a physician [emphasis supplied].")

34. CMS has acknowledged that: "Physicians will occasionally meet the statutory qualifications to be considered a registered dietitian or nutrition professional who can bill Medicare for medical nutrition therapy services. (66 FR 55279, second column).

35. If a physician who is also a dietitian has a medical nutrition therapy visit "for the purpose of disease management" the physician will perform the 3 key components, taking a medical history, performing a physical examination and engaging in medical decision making, as part of the service. In fact, the text following CPT 97802-4 states: "For medical nutrition therapy assessment and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes." (As noted above, since the Section 105(b), 42 U.S.C. 1395x(vv)(1), requires Medicare-covered visits to be for patients with established illness, only the office visit/consultation codes, not the preventive medicine codes, could be used for a Medicare-covered visit.)

36. To qualify for CPT 99241 or CPT 99213 these 3 components do not need to be at high levels. CPT 99241 is a level one E/M code that has the following, a problem focused history, a problem focused examination, and straightforward medical decision making; CPT 99213 is a level three E/M code that has the following, an expanded problem focused history, an expanded problem focused examination, and medical decision making of low complexity. (71 FR 37211, 37214).

37. Similarly, a registered dietitian who is not a physician will take a problem focused or expanded problem focused medical history, reviewing labs and other reports from the referring physician and interviewing the patient; will perform a limited medical examination, which will include anthropometric measurements, and could also include additional examination such as taking blood pressure or blood glucose, or examining affected body areas such as the skin for diabetic acanthosis nigricans, or for pressure ulcers that may be connected with protein-calorie malnutrition; and engage in straightforward or low complexity medical decision making, which will include prescribing or modifying nutrient and/or micronutrient intake, administration or supplementation, and could include additional medical decision making such as modifying insulin doses to match carbohydrate intake using carbohydrate counting/insulin ratios.

38. Because the levels of the history taking, physical examination and decision making in the visit (whether by a physician who is also a dietitian, or by a dietitian who is not a physician) are often low, the lower levels of medical history, physical examination and decision making contained in the 15-minute consultation code CPT 99241 make the work RVU of that code (current and proposed work RVU of **0.64**) more appropriate than the work RVU of CPT 99213, which has higher levels of history taking, physical examination and decision making (current work RVU of **0.67**, proposed work RVU of **0.92**). Therefore we recommend using the work RVU of CPT 99241.

39. It is also appropriate to use the work RVU of CPT 99241 because time may be the determining factor in assigning the level of the service. When time is the determining factor, the work RVU of CPT 99241 generates the lowest (and therefore most modest) work RVUs for visits lasting 15 minutes, 30 minutes or one hour.

40. The Evaluation and Management Service Guidelines state, under the heading "Levels of E/M Services": "The descriptors for the levels of E/M services recognize seven components, six of which are used in defining the levels of E/M services. These components are: History, Examination, Medical decision making, Counseling, Coordination of care, Nature of presenting problem, Time. The first three of these components (history, examination, and medical decision making) are considered the key components in selecting a level of E/M services."

41. However the Evaluation and Management Service Guidelines state later, under the heading "Select the Appropriate Level of E/M Services Based on the Following", "3. When counseling and/or coordination of care dominates (more than 50%) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), then time may be considered the key or controlling factor to qualify for a particular level of E/M services."

42. Although the definition of medical nutrition therapy services, Section 105(b), 42 U.S.C 1395x(vv)(1), includes three services, "diagnostic, therapy, and counseling services", counseling services will almost always dominate (more than 50%) the encounter. Therefore, time may be considered the key or controlling factor.

43. The following chart compares CPT 99241 to all other office visit/consultation codes that are 15 minutes or divisible by 15 minutes (all other codes are either less than 15 minutes or not divisible by 15 minutes). The chart shows that for both the current and proposed RVUs, the work RVU of CPT 99241 generates the lowest (most modest) work RVUs for visits lasting 15 minutes, 30 minutes or one hour. (70 FR 70458; 71 FR 37218, second-third columns; 71 FR 49232):

CPT Code	15-Minute RVU	30-Minute RVU	One-Hour RVU
99241	**0.64** Current	**1.28** (2 increments)	**2.56** (4 increments)
	0.64 Proposed	**1.28** (2 increments)	**2.56** (4 increments)
99213	**0.67** Current		
	0.92 Proposed		
99242		**1.29** Current	
		1.34 Proposed	
99203		**1.34** Current	
		1.34 Proposed	
99244			**2.58** Current
			3.02 Proposed
99205			**2.67** Current
			3.00 Proposed

The ADA Prefers Using an E/M Code RVU

44. All of the registered dietitians at Midtown are members of our professional society, the American Dietetic Association, and we have observed over the past 6 years that the ADA has consistently communicated its preference for work values based on E/M codes, in particular the level three, 15-minute and 30-minute, office visit codes CPT 99213 and 99203. As CMS observed, "the ADA compared work associated with their services to physician E/M services of CPT 99203 and 99213, which have respective work values of **1.34** and **0.67**." (71 FR 48987, second column).

45. Because CMS stated in the Calendar Year 2006 Final Rule that it was "deferring our decision regarding work RVUs for audiology, speech language pathology and medical nutrition pending further discussion with the specialties", ADA submitted a January 3, 2006 letter (Attachment C). In the letter ADA stated, at page 3, "there is external support for a far more transparent approach to MNT RVUs. AMA indicates in the CPT 2005 publication, 'for medical nutrition therapy assessments and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes.' If CMS believes the MNT statute for payment must be followed, then the agency should base the RD payment rate on 85% of the total physician RVUs for these codes (eg. E&M code 99203)." Nowhere in that letter are the HCPAC interim recommendations even mentioned.

46. In its March 24, 2006 follow-up letter to CMS (Attachment D), ADA again states its preference for E/M work values (bottom of page 1-top of page 2): "The most straightforward way to correct this anomaly is to establish work values for codes 97802, 97803 and 97804. CMS could crosswalk the work RVU from either the Evaluation and Management codes, or Preventive Medicine codes; the codes physicians are directed to use when they provide MNT services.... Alternatively, CMS could use the HCPAC interim work RVUs for the MNT codes. These values could be used but only with caution since they were not valued as physician services and therefore reflect a discounted service [emphasis supplied]."

47. CMS stated in the Calendar Year 2007 Proposed Rule: "More recently, the ADA requested us to reconsider our decision not to accept the HCPAC recommended work RVUs [emphasis supplied]." (71 FR 48987, second column). A more accurate statement would be: "More recently, the ADA requested us to reconsider our decision not to accept work RVUs."

48. When ADA wrote its March 24, 2006 letter it was not clear whether CMS would establish work values, so in an effort to make CMS comfortable with the concept ADA demonstrated to CMS that there were several sources upon which to base work values. ADA listed four such sources in the following order, first ADA's preference, an E/M code, then a preventive medicine code, then the 2000 RUC survey data, then the HCPAC interim recommended RVUs, if CMS "would adjust the HCPAC work professional services upward to recapture the value of the remaining 15%".

49. The HCPAC recommended work RVUs not increased by 15% were not even one of the alternatives! And the difference in compensation by not increasing by 15% (i.e. dividing by 0.85) is significant because the HCPAC recommended base RVU of **0.45** ÷ 0.85 = **0.53**, or **0.08** RVUs higher.

50. But even if increased by 15%, we submit that physical therapy code-based RVUs are not statutorily appropriate because the statute says that payment to dietitians should be 85% of the amount determined for the same services if provided by a physician.

CMS Not HCPAC Should Determine the Value of the Work RVUs

51. ADA has clearly expressed its preference for a comparison to E/M codes. However, even if ADA had no preference, we submit that CMS has the duty to make a reasoned analysis of whether E/M codes rather than physical therapy codes best describe what a physician who is also a dietitian would report for the service: "we retain the responsibility for analyzing any comments and recommendations received, developing the proposed rule, evaluating the comments on the proposed rule, and deciding whether and how to revise the work RVUs for any given service." (71 FR 37172, first–second columns).

52. If after a reasoned analysis CMS determines that medical nutrition therapy services are closer to physical therapy services than to office visit/consultation services, then so be it. But Midtown respectfully submits that CMS owes the public, the beneficiaries entitled to medical nutrition therapy services, and the registered dietitians and nutrition professionals who may provide such services, a thorough, reasoned analysis of the issue.

53. If CMS allows the HCPAC physical therapy code-based work RVU recommendations to become part of the Final Rule, the ADA will be forced to take the issue back to HCPAC. However, we strongly urge CMS to avoid this situation.

54. First, this will delay by at least one year the establishment of adequate work RVUs. And there is no guarantee that HCPAC will act in time for the 2008 Physician Fee Schedule. HCPAC may take 2 or even 3 years to act, prolonging the lack of access to care for 8,000,000 beneficiaries with diabetes or renal disease.

55. Second, now that these services are recognized as physician services there may be a jurisdictional question as to whether the regular RUC or RUC/HCPAC should decide the issue.

56. Third, CMS is fully competent to make its own determination.

57. Congressman Jose Serrano, the original sponsor of the medical nutrition therapy benefit bills, has reviewed this Comment and joins with our request that "you [CMS] perform a prompt, thorough, reasoned analysis of the appropriateness of the work value to be assigned, so that better access to care may be made available as soon as possible." (Attachment A).

Conclusion

58. The current and proposed malpractice RVU for all 5 Medical Nutrition Therapy codes is **0.01**. When added to the current practice expense RVUs, this makes the total current RVUs **0.48** and **0.19** for the individual codes and groups codes, respectively. (70 FR 70458, 70462; 71 FR 49231, 49235).

59. Midtown submits that the assignment of appropriate work RVUs to these codes should be based on the 15-minute consultation code CPT 99241, using its current and proposed RVU of **0.64** for the individual codes and 40% of that amount (multiply by 2 then divide by 5), or **0.25**, for the group codes. (66 FR 55281, first column).

60. If the proposed practice expenses of **0.12**, **0.10**, and **0.04**, for the individual initial visit, the individual follow-up visits, and the group visits (71 FR 49231, 49235), are added to work RVUs based on CPT 99241 (**0.64** and **0.25**), this would create (including the malpractice RVUs), total RVUs of **0.77**, **0.75** and **0.30**.

61. This would increase provider reimbursement rates for medical nutrition therapy services by about 50%, or perhaps a little less due to adjustments to preserve budget neutrality. (71 FR 37241, first-second columns).

62. With a 50% increase Medicare reimbursement would still be about 25% less than existing market rates but should be sufficient to allow us, and, we believe, the majority of other registered dietitians, to afford to become Medicare providers, and this should provide access to care for the Medicare beneficiaries entitled to these services.

Sincerely yours,

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October 6, 2006

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Issue Identifier: PROVISIONS—MEDICAL NUTRITION THERAPY SERVICES, CPT 97802-4, G0270-1 (II. Provisions of the Proposed Rule, A. Resource-Based Practice Expenses (PE) RVU Proposals for CY 2007, 3. Medical Nutrition Therapy Services)

Dear Sir or Madam:

On September 11, 2006 Midtown Nutrition Care submitted a comment that suggested that the work value for the medical nutrition therapy codes should be based on the work value of the15-minute Evaluation and Management consultation code CPT 99241. Our professional society, the American Dietetic Association, has suggested that the work value for the medical nutrition therapy codes could be based on the work value of the 15-minute and 30-minute Evaluation and Management office visit codes CPT 99213 and 99203. (71 FR 48987, second column).

The work value of an Evaluation and Management code appears to satisfy the statutory compensation (not scope-of-practice) language "85 percent of the amount determined...for the same services if furnished by a physician [emphasis supplied]" (Section 105(c)(2) of BIPA) because the text following CPT 97802-4 states: "For medical nutrition therapy assessment and/or intervention performed by a physician [emphasis supplied], see Evaluation and Management or Preventive Medicine service codes." (Preventive medicine codes would not be appropriate because Section 105(b) of BIPA states that Medicare medical nutrition therapy is only "for the purpose of disease management".)

However, if CMS does not agree that it is appropriate to crosswalk to the work value of an Evaluation and Management code, then an appropriate alternative would be a crosswalk to the work value of the 20 to 30 minute Insight Oriented, Behavior Modifying and/or Supportive Psychotherapy code CPT 90804, which has a current and proposed work value of **1.21**. This code does not include medical evaluation and management services, as does its companion code CPT 90805, which has a current and proposed work value of **1.37**. (70 FR 70442: 71 FR 49213).

The statutory definition of medical nutrition therapy services is "diagnostic, therapy and counseling services for the purpose of disease management" (Section 105(b) of BIPA) which matches well the definition of CPT 90804 services set forth in the third text paragraph prior to CPT 90804-90899: "Insight oriented, behavior modifying and/or

supportive psychotherapy refers to the development of insight or affective understanding, the use of behavior modification techniques, the use of supportive interactions, the use of cognitive discussion of reality, or any combination of the above to provide therapeutic change."

Because CPT 90804 is a 20 to 30 minute code, to determine its value range for a 15-minute increment we would first convert to one hour, then divide by 4:

At the beginning of the range, a 20-minute visit, we would calculate as follows:
1.21 X 3 = **3.63** per hour ÷ 4 = 0.9075 (**0.91**) per 15-minute increment.

At the end of the range, a 30-minute visit, we would calculate as follows:
1.21 X 2 = **2.42** per hour ÷ 4 = 0.605 (**0.61**) per 15-minute increment.

At the middle of the range, a 25-minute visit, we would calculate as follows:
1.21 X 2.4 = **2.904** per hour ÷ 4 = 0.726 (**0.73**) per 15-minute increment.

We suggest using the **0.73** value translated by the middle of the range (25 minutes). If the **0.91** value translated by the beginning of the range (20 minutes) were used it would certainly be acceptable, but it would be almost as high as the **0.92** proposed work value for the 15-minute office visit code CPT 99213. (71 FR 49232).

If the **0.61** value translated by the end of the range (30 minutes) were used it would be below the **0.67** current work value of CPT 99213 (70 FR 70458) and would create a total RVU of only **0.74**. (71 FR 49231). While this would increase reimbursement rates for medical nutrition therapy services, the resulting rates would barely be sufficient for us, and may not be sufficient to allow other registered dietitians to afford to become Medicare providers.

The **0.73** value translated by the middle of the range (25 minutes) is not only a logical value because it is in the middle of the 20 to 30 minute range, but would also generate a modest, but affordable, work value, being slightly higher than the **0.67** current work value for CPT 99213, yet considerably less than the **0.92** proposed work value for CPT 99213.

As discussed in detail in our September 11 comment, we submit that CMS should continue to follow the reasoning contained in the Calendar Year 2002 Final Rule that all time-based medical nutrition therapy codes would have the same hourly rate, so that the 15-minute individual codes CPT 97802, CPT 97803 and G0270 would have the same **0.73** work value and the work value for the 30-minute group codes CPT 97804 and G0271 would be equal to **0.73** times 2 divided by 5, or **0.29**. (66 FR 55280, first-second columns; 66 FR 55281, first column).

Sincerely yours,

Robert Howard, RD, JD
Managing Partner