May 13, 2008

United States Representative
The Honorable Charles A. Gonzalez
U.S. House of Representatives
Washington, DC 20515

Dear Representative Gonzalez:

Enclosed you will find a collection of Medicare topics that impact the small business as it relates to a physician practice. When asked to provide comments regarding the impact of Medicare regulations on the small business it seemed appropriate to invite our colleagues at South Texas Oncology and Hematology, PA to provide their perspective, concerns, comments and suggestions.

Sincerely,

Lynn F. Kuhn, CPA, COO
South Texas Oncology and Hematology, PA

And

Terry Allen, BBA
Director of Reimbursement
South Texas Oncology and Hematology, PA

Medicare Advantage Plans and the Small Business Impact

Medicare Advantage Plans and the perception of how they work:

Information is misleading and difficult to understand even for employees in the Health care industry. For Example, Medicare consumer web-pages state that an individual who elects to join a Medicare Advantage Plan is still in the Medicare Program and that "you don't need to buy Medigap policy[1]".

The reality appears to be that the Medicare member is in fact voluntarily dis-enrolling from the Medicare B Program, which in turn *voids* the Medigap insurance. Thus, there is no reason to buy the coverage or continue paying for the coverage.

Adding to the confusion, the enrollee must continue to pay the Medicare Part B premium thus the illusion is that the enrollee is still in the Medicare Part B program. If this is not an illusion, then why is Medigap policy now void?

Many argue that the Medicare Advantage Plan pays 100% of the Medicare Allowable which cover's the co-insurance. However, many plans pay 100% of the 80% and do not cover the co-insurance. Enrollees do not understand that when selecting a Medicare Advantage Plan they must chose a plan that is between F & J to fill the majority of Medicare Part B "gaps". It should be noted that with the introduction of Medicare Part D "J" type plans are harder to find and none are available to anyone over 65 on the Medicare Options Compare[2] site.

An example of the Medigap confusion is the Dual Eligible Medicare/Medicaid enrollees, South Texas Oncology and Hematology, PA has encountered numerous problems with beneficiaries who have enrolled into a nationally recognized Medicare Advantage Plan and are Medicaid beneficiaries as well. The Medicare Advantage Plan Pays 100% of the 80%; however, the 20% co-insurance is not paid. Upon billing Texas Medicaid, the co-insurance is declined, as Texas Medicaid does not recognize the Medicare Advantage Plan as a Part B plan. Texas Medicaid specifically stated, "According to our records, there is no indication that the above client had or currently has Medicare Part B. According to the 2007, Texas Medicaid Provider Procedures Manual (TMPPM) 4.5.1 indicates Medicaid pays the Part A and Part B Medicare deductibles and co-insurance liabilities. Medicare replacement policies refer to the Medicare Part C and we do not cover Part C at this time."[3] The practice was unable to pursue collection of the $5,000 co-insurance balance.

Administrative Burden on Practice:

Although the Medicare program may not be perfect, it is historically a predictable payor and thus requires minimum administrative attention. Medicare Strengths include:

- Average DSO for 90% of the claims billed is 20 days
- Claims are accepted electronically
- Claims are paid correctly the 1st time
- Appeals rule are clear and concise
- Questions are answered timely or appropriate follow-up is received upon escalation of the issue to Tier II.

Medicare Advantage plans are neither perfect nor or predictable as they have no historical performance indicators. The administrative management of these plans is high and claims often take months to resolve. Medicare Advantage plans weaknesses include:

- Contracts are not required between physician practice and insurance company; thus, there is no re-course for non-payment of claims.

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[1] http://www.medicare.gov/MPPF/Static/TabHelp.asp?language=English&version=default&activeTab=3&planType=MA

[2] http://www.medicare.gov/MPPF/Include/DataSection/MedigapDetails/MGAPPolicyChooser.asp

[3] TMPH A State Medicaid Contractor Letter dated October 8, 2007

- No business history with the vast majority of contracts; thus high risk for slow payment or non-payment.
- Plans do not understand billing codes thus; we're spending a significant amount of time sending them Medicare guidelines on how to process claims.
- Obscure plans are difficult to contact and resolve claims issues.
- Number of plans participating changes monthly and is burdensome to setup so many insurance companies to bill 1-2 claims especially since not all accept electronic claims
- Obscure plans are difficult to contact and resolve claims issues

Physician – Patient Issues:
South Texas Oncology and Hematology, PA has elected not to actively contract with any Medicare Advantage Plans due to the payment risk, co-insurance/supplemental insurance risk and administrative burden.

Existing patients are informed that we do not accept their new insurance and we are left explaining what their true benefits are and what that would mean to them and to us. Unfortunately, the majority of patients tell us the same thing… "I was told this is just like Medicare… It's even called the Medicare Advantage Plan". As our physicians have a long standing relationship and bond with these patients we typically agree to continue seeing these patients. However, we now have to ensure we find 'alternate' funding for the co-insurance. South Texas Oncology and Hematology, PA has hired the following positions:

- Two (2) Financial Counselors – Assists in qualifying and enrolling patients in co-insurance foundations, which is often drug specific and does not cover the entire co-insurance balance but any amount of money is helpful.
    - Practice Expense Associated with Salaries and benefits is $77,459.00 annually

- One (1) Full Time Collector – Collector actively watches patients with foundation benefits, audits accounts, reviews which drugs are eligible for foundation assistance, moves appropriate charges, bills foundation, performs follow-tasks, upon payment assures the correct drug co-insurance was paid, and then re-audits account to ensure patient is billed correctly for their remaining outstanding monies. This is time consuming DSO (days sales outstanding) is high 90 days where as Medicare is 20.
    - Practice Expense Associated with Salaries and benefits is $37,345.00 annually

The practice has numerous other expenses associated with Medicare Advantage plans but as you can see, we are expensing at a minimum $114,804 with no associated "new" revenue.

These additional expenses are not optional but are necessary for the small business owner survival. The full Medicare Allowable (80% from Medicare and 20% from co-insurance) must be collected to ensure the "cost" of the drug is met. The majority of our patients cannot afford 20% of their chemotherapy treatments. Nor can South Texas Oncology and Hematology, PA afford to write checks for each patients treatment.

The physicians at STOH recognize that the number of patients currently enrolled in Medicare Advantage plans is low; however, given that 23% Medicare beneficiaries in Texas are enrolled in a Medigap program[4] and 50% of our patient population is eligible for Medicare the associated risk is real and increasing on a daily basis.

Patient Issues:

- High pressure sales tactics
- "Deceptive and fraudulent sales practices"
    1. Texas Department of Insurance Issued - Consumer Alert – "Protect yourself against Medicare Advantage fraud"[5]
- Patients are being informed that their Physicians MUST take the insurance if they are Medicare Providers.

[4] 2005 Medigap in Texas Stats from www.medigapchoice.com – CMS enrollee data & NAIC Medigap data: 543,412 out of 2,390,053 Medicare Enrollee 23% of the Market

[5] Texas Department of Insurance – Consumer Protection Alert; Protect yourself against Medicare Advantage fraud, http://www.tdi.state.tx.us/rules/2007/parules.html

- Patients are calling our office with the insurance representative in their home because the sales representative is insisting they switch today.
- Although South Texas Oncology and Hematology, PA has elected not to contract with any Medicare Advantage Plans the sales representatives are quick to note, that the plan will pay out-of-network providers just as they would in-network providers.
- Texas Department of Insurance issued an Emergency Order Prohibiting Temporary Agents from marketing Medicare Advantage Health, Prescription Drug Plans on November 9, 2007 in direct response to "reports received by TDI, temporary insurance agents had solicited some Medicare beneficiaries to enroll in unsuitable Medicare Plans"[6]
- Medicare Advantage plans are renewed annually. If a company wishes to discontinue participation in the Medicare Advantage market, patients will be dis-enrolled and will need to re-enroll into another plan or back to the Original Medicare Plan. If the patient changes to the "Original Medicare Plan you might have a special temporary right to buy a Medigap policy, even if you have health problems. This is not automatic; the patient must request an application from the supplemental insurance company and has no more than 63 days to execute the enrollment.

In conclusion, there are over 705 Medicare Advantage companies contracted with Medicare as of December 2007 with over 26,246,908 enrollees. [7] Contracting with each one is not practical or an option given their lack of understanding regarding Medicare payment guidelines, and the exposure of patients not understanding that their new plan may not cover the 20% which has historically been covered by Medigap plans. It is twenty percent (20%) small business owners simply do not have and cannot afford to absorb the expense.

[6] Texas Department of Insurance – Emergency Orders – Prohibits Temporary Agents from Marketing; November 13, 2007

[7] Prepaid Medicare Advantage Plan contracts from the Monthly summary report_Dec 2007 11272007pdf

Medicare Information Structure

Newsletters:
Providers are obligated to understand and abide by all CMS regulatory requirements. However, even with the Medicare Paperwork Reduction Act, finding applicable regulations, new regulations and/or updates to existing regulations is difficult.

"Provider newsletters/bulletins are published at least quarterly and contain local and national policies and procedures, including significant changes to the program."[8] The Medicare Part B Newsletter published on February 28, 2009 is 80 pages long and may have pertinent data woven throughout the document. For example, update to the LCD Abarelix (Plenaxis ®) for Prostate Cancer –I78'LCD is between an update in Psychiatric Codes and Vascular Access for Hemodialysis.[9] A better format would group specialty related updates together. Thus, Cancer updates would be grouped under Oncology and Psychiatric under its specialty. Defined changes by Specialty would minimize the amount of time it took to find information and assist with more timely compliance.

Moreover, it would be helpful if newsletters were published by specialty. In other words, a Newsletter for Hematology, Medical and Radiation Oncology, Cardiovascular, Family Practice ECT… This request may sound daunting; however, Medicare information that is common to all specialties would be included in each newsletter thus the only additional work would be to re-organize the specialty specific data. The "common" newsletter would be the base platform with specialty specific information added to the specialty specific newsletter. Additionally, newsletters published electronically, would allow the common information to be displayed and specialty specific data would be available via links.

Local Coverage Determinations (LCD):
The LCD is a living document it is ever changing and updated. The frequency of the updates is not regular and is often proportional to the amount of political attention being given to a particular drug or vendor. Providers must review and implement changes to the LCD; these changes are published in the newsletters however not necessarily on a monthly basis.

An interesting issue recently arose; what do you do when audits span a period and the claims being reviewed span several bulletin updates. Audits are against the LCD language that was in effect for a particular date of service; however, as the LCD are living documents the published LCD's contain all the changes up to the current date. It would be helpful if a provider could request the LCD by Name and date of service. This would allow the provider to review the LCD, as it existed on that particular date. For now, though the provider must print and keep copies of each LCD to ensure they have access to the LCD as it was written for a particular DOS. This is burdensome, difficult to manage, and often times not possible. The alternative would be to print a current LCD and then redline out the updates as noted on the "revision" date page; this is not an easy task and the revision updates are a summary not a detailed list of what was actually changed.

[8] Trailblazer Health Enterprises Web Page, Publications, Newsletters page 1 paragraph 1
[9] Trailblazer Health Enterprises, Medicare Part B Newsletter No 08-077, February 29, 2008

Local Policies and the Treatment of Cancer:

"Act §1832(a) (1); see also 42 C.F.R. §410.3(a) (1). Coverage of medical and other health services is qualified by the overarching principles of sections 1862 (a) and 1833(e) of the Act. Section 1862(a) limits Medicare Payments to items or services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, "notwithstanding any other provision of Title XVIII of the Act. See also 42 C.F.R. §411.15(k) (1). Section 1833 (e) of the Act requires a claim for payment under Medicare part B to be supported by sufficient information and documentation. See also 42 C.F.R. §424.5(a) (6)…

The Medicare Benefit Policy Manual (Pub. 100-2) Chapter 15 §50.45 contains the CMS policy for Unlabeled Use for Anti-Cancer Drugs. It states in pertinent part, the following:

Contractors must not deny coverage based solely on the absence of FDA approved labeling for the use, if the use is supported by one of the following and the uses not listed as "not indicated" in any of the three compendia:

1. American Hospital Formulary Service Drug Information
2. American Medical Association Drug Evaluations
3. United States Pharmacopoeia Drug Information (USPDI)
4. A Use supported by Clinical Research that Appears in the Peer Reviewed Medical Literature in the absence of any of the three compendia…."[10]

In essence, if the Anti-Cancer drug meets the letter of the statute and/or regulation, then the drug should be accepted as covered across all states. This would reduce the administrative burden to small businesses and as well, as provide more consistent access to medically necessary care regardless of which state patients are receiving care.

A specific example of this is for the drug irinotecan (CPT-11) and the use of the drug for the treatment of Brain Cancer. The drug is considered reasonable and necessary and reimbursable in several states for the treatment of Brain Cancer, but not in Texas. Our claims are routinely denied at the first and second level of appeals; however, are the denials are overturned by the Administrative Law Judge.

It is unfortunate that the majority of providers (small businesses) will not provide the drug "off-label" because they are not willing to accept the risk of non-payment nor can they afford to pay for the drug without an expectation of payment for several months.

[10] ALJ Appeal No. 1-127970859; page 2 & 3 of 7, section A. Statutes and Regulations

Technology and the Treatment of Cancer:

Another arena where the disassociated review and implementation of regulatory guidance is with emerging technologies. CyberKnife and/or Stereotactic Radio Surgery are currently undergoing the same issues as the use of anticancer drugs mentioned previously. The overwhelming difference is CyberKnife is FDA cleared for the entire body; however LCD policies are retroactively determined after the small business has purchased the technology based on the FDA clearance for the entire body.

> "FDA – CDRH – PDF 510(k) SUMMARY date prepared May 3, 2007…
> Device Name: CyberKnife® Robotic Radiosurgery System Indications For Use:
>
> The CyberKnife® Robotic Radiosurgery System is indicated for treatment planning and image guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions *anywhere in the body* when radiation treatment is indicated."[11]

Radiation has been around for over 60 years, in essence the drug is same, but the method of delivery has become more precise over the years and with the introduction of new technologies. A more precise delivery mechanism spares healthy tissue, and reduces overall risk. It would make sense if Radiation is accepted treatment for cancer and the technology has been FDA approved for the entire body, then why are we now limiting reimbursement by state different approved sites?

Furthermore, there are currently no CPT codes that accurately reimburse for the resources utilized in treating patients with the CyberKnife in the freestanding setting. CMS has made the inaccurate assumption that the costs in a freestanding setting are lower than in a hospital outpatient setting which makes it very difficult for an independent or small center to function and treat patients. Again the reimbursement policy is site specific and diagnosis driven.

For example, please see the below letter written to Trailblazer Health Enterprises.

> April 28, 2008
>
> Trailblazer Health Enterprises
> Executive Center III
> 8330 LBJ Freeway
> Dallas, Texas 75243-1213
>
> Attention: Charles E. Haley, MD, MS, FACP - Medicare Medical Director
>
> ***RE: Robotic Stereotactic Radiosurgery – Payment for G-codes in the physician office***
>
> Dr. Haley,
>
> We would like to request that the coding and reimbursement for robotic stereotactic radiosurgery (SRS) performed in a physician's office be consistent with the OPPS guidelines. We ask that Trailblazer consider approving reimbursement of robotic SRS carrier-priced G-codes (G0339 and G0340) in the physician's office setting.
>
> Effective January 1, 2007, CMS granted coverage for radiosurgery procedures performed in free-standing centers under the physician fee schedule [CMS-1321-FC and CMS-1317-F].
>
> CMS recommends the use of the robotic radiosurgery G-codes for the hospital outpatient setting and has disallowed the use of the new CPT codes for robotic radiosurgery. The new G-codes G0339 and G0340 were created because CMS realized there were significantly different costs associated with delivering robotic radiosurgery vs. non robotic.

[11] FDA – CDRH – PDF 510(k) SUMMARY date prepared May 3, 2007 http://www.fda.gov/cdrh/pdf7/K071531.pdf

CMS has determined that HCPCS codes G0339 and G0340 are more specific in their descriptors than CPT codes 77371, 77372 and 77373.

The radiosurgery CPT codes included in the physician fee schedule do not accurately describe the service being provided.

- 77371-77373 CPT descriptors do not identify the procedure as **robotic** radiosurgery.
- 77371 and 77372 are specific to cranial lesions.

The reimbursement for these CPT codes in no way reflects the actually cost of the treatment.

- The reimbursement for 77373 is only $1583.37. This is significantly below the OPPS reimbursement for G0339 and G0340.
- For a three fraction treatment, the reimbursement using CPT 77373 is only $4750.11.
- Our cost for a three fraction treatment is three times that amount.

Several states have already approved reimbursement of G0339 and G0340 in the physician office setting. Those states and their respective Medicare carriers are:

- Upstate New York – Health Now, Part B Carrier
- California (San Francisco County, Ventura County, Los Angeles County, & Orange County) – NHIC, Part B Carrier
- Maine – NHIC, Part B Carrier
- Massachusetts – NHIC, Part B Carrier
- New Hampshire – NHIC, Part B Carrier
- Vermont – NHIC, Part B Carrier

We represent two physician practices in Texas that have a robotic radiosurgery system (CyberKnife). Our goal is to offer our patients the most appropriate therapy based on their diagnosis. Treatment with robotic SRS is more closely compared to surgical tumor removal and not traditional radiation therapy. For those patients who would receive better results from surgery vs. standard radiation therapy but who are not candidates for open surgery due to health risks or other factors, should have the option of receiving robotic SRS treatment.

We also noticed with the consolidation of the LCDs for the J4 MAC that prostate cancer is not mentioned in the LCD for Stereotactic Radiosurgery. This is of great concern to our practices because we are currently treating these patients with robotic SRS. It is less costly for the patient, requires fewer treatments and tends to have fewer side effects. We hope this is an oversight but if not, we would like to discuss this further because we believe it is in the best interest of the patient.

There are many benefits to treating a prostate cancer patient with radiosurgery vs. IMRT.

- Financial savings to Medicare - the cost for radiosurgery using the Medicare OPPS payment rate is about one half the cost of IMRT, which results in a 5-digit savings to the Medicare program per patient.
- Cost savings to patients – a very real and significant financial savings for elderly patients who, in addition to the out of pocket coinsurance costs, are having to travel great distances over many days (with the cost of gas being at an all time high) to be treated with IMRT.
- Potential for fewer side effects – the patient receives only five CyberKnife treatments vs. 40-45 IMRT treatments.

We would like the opportunity to meet with you to further discuss our recommendations regarding robotic SRS treatment in the physician's office and physician reimbursement of G0339 and G0340.

Sincerely,

Tammy Chambers, Director of Contracting
CHOP Board Member
The Center for Cancer and Blood Disorders, P.A.
800 W. Magnolia Ave., Fort Worth, Texas 76104
Phone 817-333-0126, Cell 817-269-0294
tchamber@txcc.com

Lynn F. Kuhn, C.P.A., Chief Operating Officer
CHOP Board Member
South Texas Oncology and Hematology, P.A.
7979 Wurzbach, Suite U 420, San Antonio, Texas 78229
Phone 210-616-5763, Cell 210-601-4610
Lynn.kuhn@stoh.com

"CyberKnife® Medicare Payment History

"Medicare has a responsibility to pay enough for beneficial new technologies to ensure beneficiary access to care, but must also be a prudent purchaser."
MedPAC
Report to the Congress
March 2003

When assigning codes to a new technology to allow Medicare payment in the Hospital Outpatient Prospective Payment System (HOPPS), CMS has two kinds of decision to make: how to describe the technology/service (Healthcare Common Procedure Coding System [HCPCS] codes), and what resources are used to obtain the technology and provide the service (Ambulatory Payment Classification [APC] groups). For a dramatically new technology, such as the CyberKnife ® (an image-guided robotic stereotactic radiosurgery [SRS] system), adequate data needed to make these decisions are often not available at the time of the decisions. This was the case with CyberKnife and, by its own admission, CMS made a number of significant initial errors in both HCPCS and APC determinations. As a result, the treatment process was not accurately captured and the procedures were significantly under-paid.

Over time, CMS improved both their description of the clinical characteristics of CyberKnife treatment and their understanding of the resource costs associated with treatment. Separate codes were created for robotic/ non-robotic systems and for one-session treatments/sessions two through five. However, inaccuracies remain in both the HCPCS code descriptors and the APC assignments, leading to possible under-payment for the CyberKnife technology and over-payment for older, less resource-intensive radiosurgery technologies.

Medicare payment for CyberKnife treatment was further complicated by the fact that treatment was soon being provided in freestanding settings, with the potential to reduce duplicative Hospital Outpatient Centers, but no appropriate codes available for billing. After a number of years, CMS made the HOPPS HCPCS codes available for billing in this setting, but continues to leave coverage and rate determinations to the local Medicare contractor. This results in coverage and payment discrepancies that could limit or deny access of Medicare beneficiaries to CyberKnife treatment in some regions of the country.

CMS originally assigned HOPPS HCPCS codes to CyberKnife because no Current Procedural Terminology (CPT) codes adequately captured the clinical characteristics or resource use of CyberKnife treatment. Although several CPT codes pertaining to radiosurgery services have been added in recent years, CMS has thus far judged these new codes to be inadequate for CyberKnife use. CMS has indicated that it is planning to reevaluate its decision not to move CyberKnife into the AMA-controlled CPT system this year.

The goal of every CyberKnife Center and the CyberKnife Coalition is to help ensure payments for CyberKnife treatment that are accurate and adequate: to protect Medicare beneficiaries' access to treatment while helping Medicare be a prudent purchaser."[12]

[12] Provided by the CyberKnife Coalition

Erythropoietin Stimulating Agents (ESAs) and the impact on Small Businesses and Patients:

CMS has drawn conclusions as to treatment guidelines using treatment parameters based on studies that clinicians have never and do not currently use. There are many private payers who are not following the CMS National Policy Guidelines on ESA's due to this inconsistency.

With the enforcement of the new guidelines there has been a direct correlation of reduced prescriptions written for chemotherapy drugs; although this may be adverse to the small business line, the true concern lies with the patients who may be receiving reduced or delayed chemotherapy treatments because of the decreased use of ESAs. The below letter from the physicians of South Texas Oncology and Hematology is submitted for your review and consideration:

June 1, 2007

Dear Sir/Madam:

Thank you for giving us the opportunity to comment on the proposed determination by CMS that "there is sufficient evidence to conclude that erythropoietin stimulating agent (ESA) treatment is not reasonable and necessary for beneficiaries with certain clinical conditions because of increased risk of adverse events, or because of a deleterious effect of the ESA on their underlying disease."

Changing ESA prescription practices throughout the nation would return care to an early 1990's timeframe, ignoring the reality that the most effective therapeutic regimens have changed dramatically since that time. These changes have, in large part, been made possible by the level of supportive care we have been able to deliver to our patients. It will be much more difficult, for instance, to treat breast cancer patients with standard polychemotherapy regimens.

It would be very difficult to treat breast cancer patients with TAC or dose dense therapy without ESA support. With TAC, 20 percent of patients will require transfusion without ESA support, and similar numbers of patients undergoing dose dense therapies often develop grade 3 hematologic toxicity requiring transfusion. Likewise, it will be difficult, if not impossible, to administer dose dense R-CHOP to elderly patients with large cell lymphoma. These treatments are generally regarded to be more effective than earlier regimens. Similarly, our ability to deliver ABVD for patients with Hodgkin's disease in a timely fashion is largely due to our use of growth factors and ESA support.

There are several studies proving that anemia increases radio resistance to cancer of the cervix. We used to transfuse these patients routinely in the past, prior to radiation. In general, anoxia in tumors is considered one of the factors that make patients fail radiation therapy. In these days where combination chemotherapy-radiotherapy has been proven to increase local response and control in many clinical settings, anemia is undesirable. The cheapest patient is the one we can cure. The most expensive is the one who fails and requires additional treatments. Clearly, the ability to use ESAs saves patient lives.

Use of hemoglobin < 9g/dl as a point to start treatment with ESAs will require transfusions that are otherwise avoidable because hemoglobin continues to fall for weeks after ESA use begins. Evidence suggests transfusion avoidance is better accomplished by early intervention at a higher hemoglobin level, and treatment at levels < 11g is superior to treatment at levels <10 g.

Further, a rule to stop treatment after four weeks if a 1 gm rise in hemoglobin is not achieved is not consistent with the clinical trial data. A number of studies show that 6-8 weeks of treatment may be required to achieve a 1 gm rise. Further, dose escalation can be critical with these agents. A significant number of patients who fail to respond to initial treatment with ESAs will respond to a dose 50% higher.

To impose a rule to limit treatment to 12 weeks per year will not meet the needs of many of our patients who have metastatic disease and who receive chemotherapy for many months.

We have no doubt that a severe restriction in ESA, as recently proposed, would result in a dramatic increase in the need for transfusion therapy as part of routine treatment protocols. If we increase the transfusion rate of patients, we increase expense to the system through blood banks, the hospital, and the cost of irradiated products to prevent the risk of graft-versus-host disease. We cost our patients precious time in undergoing the ordeal currently required to get a transfusion in the hospital.

Not so easily measured, but apparent to all of us who care for patients, is the benefit achieved for these patients with higher hemoglobins. It is true that causes of fatigue in the patient with cancer are multifactorial, but anemia is undoubtedly one of the factors and it is likely active in a significant number of patients. Opportunity lost to function in society and to relate to one's family at a high level is hard to measure, but exists, and will exert a tremendous cost to our patients if they do not have access to ESAs.

While the risk of hypertension, fluid retention, and thromboembolism due to a rapid rise in hemoglobin, high hemoglobin levels, and high ESA doses can all be addressed clinically, risks associated with transfusion are not nearly as predictable or as easily managed. Certainly, we will expose our patients, who undergo transfusion, to increased risk of error rates in the hospital and transfusion reactions and infection. Theoretical, but unproven, risk of stimulating tumor growth referenced in the CMS proposal are of concern and merit continued study. But evidence that certain cancer cell types express erythropoietin receptors comes from in vitro evidence. There is no evidence from clinical trials, if functional receptors actually exist, that treatment with ESAs stimulates tumor growth or reduces efficacy of treatment. However, just as troubling is the body of literature that suggests that those patients receiving transfusion during treatment for cancer are at increased risk for poor outcomes as a result of immunosuppression.

All of us involved in caring for patients with cancer would like to find more effective means of treatment, and accordingly, we support clinical trials. Most of these trials require a hemoglobin of 9 mg/dL or greater, and if this is the point below which ESA support may be started, access to clinical trials for our patients will be diminished. We fear that progress for finding better treatment will be delayed.

Further, to exclude patients receiving VEGF and EGFR inhibitors is not based on any clinical evidence and would likely have a dampening effect on the conduct of clinical trials with new agents.

There is no clinical data to support non coverage of patients with MDS and multiple myeloma and in some patients these agents are of life changing value.

Treatment with erythropoietin stimulating agents is expensive, but so is the potential expense, both direct and in opportunity lost, of limiting the availability of these agents. We hope that we do not return to the era of the 1990's, but rather use this important issue to serve as a platform for collaboration between oncologists, patients, and the pharmaceutical industry that will lead to a better understanding of the best way to use these important agents and to provide more focused care for our patients.

Thank you for your attention and consideration of this very important matter.

Sincerely,

Lon S. Smith, M.D.
Ardow R. Ameduri, M.D.
Ronald L. Drengler, M.D.
Keith E. Eyre, M.D.
Lisa M. Fichtel, M.D.
Allison M. Garner, M.D.
Joseph R. Holahan, M.D.
Steven P. Kalter, M.D.
Amy S. Lang, M.D.
Joaquin G. Mira, M.D.
Nena Mirkovic, M.D.
Kyriakos Papadopoulos, M.D.
Amita Patnaik, M.D.
Gladys I. Rodriguez, M.D.
Luis C. Rodriguez, M.D.
Anthony Tolcher, M.D.
Scott C. Ulmer, M.D.
A. J. White, M.D.

South Texas Oncology & Hematology, PA

May 14, 2008

United States Representative
The Honorable Charles A. Gonzalez
U.S. House of Representatives
Washington, DC 20515

Dear Representative Gonzalez:

I'm writing you to express my concerns about Medicare Coordination of Benefits. Medicare Coordination of Benefits is a process by which Medicare contractors gather enrollee benefit information in order to properly establish the order of claim payment to providers. Medicare Coordination of Benefit overpayments continue to cost Medicare and private insurance companies billions of dollars in unnecessary payments to providers annually.

I am a native resident of San Antonio, Texas and have been professionally employed in San Antonio's healthcare sector for fourteen years. My fourteen years of professional experience has been in the provider billing and reimbursement sector of the industry and the scope of my experience has included resolving Medicare Coordination of Benefits issues related to the population of patients served by the Practice.

The reason I'm very concerned about the issues surrounding Medicare Coordination of Benefits stems from discussions about the financial health and longevity of the Medicare program as we look at the baby boomer generation approaching Medicare eligibility and retirement. According to a February 10, 2008 publication by Walt Overfield of CNO and Associates, a private recovery auditing business that specializes in identifying overpayments for such federal programs as Medicare and Medicaid, $9.8 billion dollars in overpayments were reported in 2007 while over the last twelve years overpayments by Medicare were an astounding $188 billion dollars. While fraud and abuse account for a significant portion of the total Medicare overpayments, Medicare Coordination of Benefits overpayments cost the Medicare program significantly; these overpayments could be avoided if Medicare and private insurance contractors developed new regulations that called for the proactive monitoring of Medicare eligible/Medicare enrollees who are still working. In conjunction, the recovery of COB overpayments should be mandated within a much shorter period than what currently exists today. For health care providers, MSP is an integral component of the Medicare Coordination of Benefits process; Medicare Secondary Payer (MSP) is a tool, developed by Medicare, which health care providers can implement within their Practices to ensure coordination of benefits has been properly established. Yet, for most providers, the patient registration process has become a time consuming effort; HIPAA regulations have forced health care providers to implement additional forms into the normal course of business; requiring all Medicare enrollees to periodically complete MSP questionnaires could impact the flow of business in health care facilities across the country and those Practices, much like the one I work for, who already strive to proactively combat COB overpayments by conducting MSP evaluations are feeling the frustrations of patients who clearly do not understand the need for MSP. While Medicare enrollees continue to struggle with the concept of Medicare Secondary Payer, health care providers find it difficult placing qualified individuals in key patient registration positions who understand the complexities of Medicare Secondary Payer and Medicare's Coordination of Benefit guidelines. For patients and providers who identify Medicare COB issues, attempting to update records with Medicare seems to be a tedious task and the turnaround time on these updates could be greatly improved. Since its' establishment in 1965 under the historic Social Security Act, the Medicare program has provided health insurance for America's elderly and disabled. Since its' inception, health care costs have risen dramatically and with the wave of baby boomers reaching retirement, concerns over Medicare's viability is a huge concern; in the immediate, my concerns are for my family members and parents who are baby boomers, for my peers and those in the patient population fast approaching Medicare age, and for those already on Medicare. I cannot go without stating that my long term concerns focus on myself who, in about thirty or so years, will be of Medicare age and with talks about the Medicare Trust being depleted within in the next decade or so, what will happen to the health of Americans if health care costs are only going to continue to rise and Medicare or Medicaid may not be around to bridge the gap? These are very real economical and social concerns that if not addressed immediately will have an adverse effect on American life today, tomorrow, and in the future.

South Texas Oncology and Hematology, PA
7979 Wurzbach, Suite U436; San Antonio, Texas 78229

Medicare continues to need balanced health care reform and there is a vested interest in addressing Medicare's Coordination of Benefit processes as it relates to the solvency of the Medicare program. I am hopeful that I can count on your help to give this issue an opportunity to be heard and to receive the attention it needs. I would appreciate knowing your views on this matter and want to thank you for your time and consideration of this matter.

Sincerely,

Eric S. Orr, BSHCS, MHA
Billing Supervisor
South Texas Oncology and Hematology, P.A.
San Antonio, Texas
Office: 210.593.5927
Fax: 210.593.5899
Email: eric.orr@stoh.com

United States Representative
The Honorable **Charles A. Gonzalez (TX-20)**
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Gonzalez:

Thank you for the opportunity to speak on behalf of thousands of Medicare Beneficiaries. My name is Allina J. Rumfelt MA, PFA and I am the Admissions Manager for South Texas Oncology and Hematology in San Antonio Texas.[i] It is my role at STOH to research, educate and obtain resources for patients fighting the dreaded disease we call Cancer. It is also my responsibility to fill in any gaps patients and their physicians may experience as they go through this frightening journey.

I assist thousands of patients, family members, and staff members understand the complexities of medical coverage's and help them navigate through the myriad of rules and regulations applied to insurance and Medicare policies.

No doubt Medicare Part D has played an important role in this effort. At the onset of Medicare Part D in 2006 there was an expected adjustment period. However, as the private insurance industry continues to modify the administration of these polices, we are seeing even more complex requirements, more confused patients and increasing costs to a population vastly made up of citizens on fixed incomes.

More Complex Rules: More Confused Patients: Increased Costs: If I may elaborate:

- **Donut Hole Coverage**: While there are many plans that offer some drug coverage during the donut hole for generic prescriptions, there is not one free-standing Prescription Drug Plan (PDP) in Texas that pays for brand name drugs during the donut hole.[ii]
- **Pharmaceutical Assistance Programs**: Prior to Medicare Part D, beneficiaries were able to obtain assistance through PAP's. However, many assistance programs have specific exclusions if there is any prescription drug coverage at all.[iii]
- **Foundations:** Many pharmaceutical companies that continue to offer assistance through the donut hole redirect patients to a non for profit foundation that can take several weeks to get through the application process.[iv]
- **Formulary Finder:** Medicare Part D plans are not required to pay for all drugs and can change the drugs on their formulary during the course of the year as long as they comply with the 60 day notice to affected parties rule.
- **Exception and Appeals rules:** There are currently 55 Medicare Drug Plans available in Texas. Each drug plan has developed its own exceptions process. An unfavorable exception determination gets an enrollee into the appeals process, which further delays their treatment. If a patient's drug is dropped from the formulary in the middle of treatment patients either scramble to find a new plan that will cover their drug or pay out of pocket to continue care. In addition, non-formulary payments are not applied to the donut hole.
- **High Dollar Injectible and Infused Medications:** Many drug plans require enrollees to obtain certain biologicals and injectibles through a specialty care pharmacy. Drugs once overseen and administered under a physician's supervision are now shipped to the patient's home where they are expected to administer them on their own. [v]
- **Late Penalties: Cost Sharing: Income based Premiums:** Gray letters, orange letters, income based premiums, and lifetime penalties have created so much confusion. [vi]

Thank you again Congressman Gonzalez for the opportunity to speak on behalf of the thousands of cancer survivors who need legislative help in Medicare Part D reform.

Respectfully,

Allina J. Rumfelt CMA, PFA
Admissions Manager
South Texas Oncology and Hematology
7979 Wurzbach Ste. Z307
San Antonio, Texas 78229
Phone: 210-593-5957
Fax: 210-593-5906
Allina.rumfelt@stoh.com
www.stoh.com

[i] South Texas Oncology and Hematology. Also known as STOH
[ii] PharmacyChecker.com: Consumer research and information related to Medicare drug Plans
[iii] MGI Pharma Inc.: Novartis Pharmaceuticals: Roche Pharmaceuticals
[iv] Genetechaccesssolutions.com
[v] Wellcare Specialty Pharmacy: Pharmacare Specialty Pharmacy
[vi] Center for Medicare Advocacy, Inc. "A Potpourri of Part D".