NELTNER BILLING & CONSULTING SERVICES, INC.

ONCOLOGY MELTDOWN

NELTNER BILLING & CONSULTING'S RESPONSE TO THE GAO'S REPORT "PAYMENTS FOR COVERED OUTPATIENT DRUGS EXCEED PROVIDERS' COST"

PERSONAL STATEMENT

I have to admit it: at first, I was angry. Incensed. Outraged.

I began listening to the tape of the hearing, and reading the eagerly-awaited GAO report, and I was angry. Statements were being made about money and resources being wasted, about the elderly being taken advantage of, and about the "perverse incentives" resulting in abuse by providers and drug companies. At first, it seemed no one was addressing the problem or even aware of the issues related to the physicians. They were being cast as the "bad guys", as the instigators of the problems, rather than as victims themselves. In fact, the title of the hearing was "Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers," not "... a Broken System for Patients, Providers, and Taxpayers."

But then I read on, and I realized that there were some, if not all, members of the Subcommittee on Health and the Subcommittee on Oversight and Investigations, who "got it." As they stated at the onset of the hearing, "It is clear that this is not a simple problem that will not demand a simple conclusion." Many of the members made statements that clearly indicated they understood the reimbursement of drugs and the reimbursement of services were inextricably linked, and one issue could not be discussed or resolved without the other. I was pleased to hear members express their support and understanding for the difficulty and complexity of the work of oncologists.

Over the years, I have had the pleasure of working with and developing close relationships with oncologists. I strongly concur with Dr. Larry Norton's statement in his draft response to an article that appeared in the Chicago Tribune:

"Moreover, to suggest, as your article does, that oncologists would be tempted to overprescribe cancer drugs in order to reap additional profits is abhorrent. Oncologists care deeply about their patients, and are highly trained in the complexities of life and death decisions about cancer drug delivery." He goes on further to state, "Cancer drugs are administered according to the findings of rigorous clinical trials, and physicians have little leeway in determining drug, dose or frequency."

The purpose of this document is to present my response to the findings disclosed in the hearing and the GAO's report. Since many of the issues have already been brought to the attention of the committee members through the hearing, I will focus on those issues and/or details that were not addressed. It is my sincere hope that the information I provide will be valuable to the Congress in determining an appropriate course of action to rectify this situation.

THE LAW

As you well know, two laws were enacted to study the issue of reimbursement of drugs and physicians services related to outpatient cancer therapy. I contend that one or both of the laws were violated at least in spirit if not in letter by the focus of the hearing on September 21. Public law 106-113, Section 213 (which I will refer to as the practice expense study) and Public Law 106-554, Section 429 (which I will refer to as the drug study) explicitly state that two

studies were to be conducted, and the results of the drug study were to take into account the results of the practice expense study. As of the date of the hearing, the practice expense study had not even been released to the public!

The first of the two studies, the practice expense study, was authorized in 1999:

> *Public Law 106-113, Section 213: GAO study on resources required to provide safe and effective outpatient cancer therapy. The Comptroller General of the United States shall conduct a nationwide study to determine the physician and non-physician clinical resources necessary to provide safe outpatient cancer therapy services and the appropriate payment rates for such services under the Medicare program.*

The provisions of the practice expense study include a report to Congress: "The Comptroller General shall submit to Congress a report on the study conducted under sub-section (a). The report shall include recommendations regarding practice expense adjustments to the payment methodology under part B of title XVIII of the Social Security Act, including the development and inclusion of adequate work units to assure the adequacy of payment amounts for safe outpatient cancer therapy services. The study shall also include an estimate of the cost of implementing such recommendations."

In 2000, the second study was authorized:

> *Public Law 106-554, Section 429: Revised part B payment for drugs and biologicals and related services. The Comptroller General of the United States shall conduct a study on the reimbursement for drugs and biologicals under the current medicare payment methodology (provided under section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o))) and for related services under part B of title XVIII of such Act.*

There are provisions of the law that seem to have been fundamentally ignored in the issued report and hearing. For instance, the law requires the GAO to "determine the extent to which (if any) payment under such part is adequate to compensate physicians, providers of services, or other suppliers of such drugs and biologicals for costs incurred in the administration, handling, or storage of such drugs or biologicals."

The law also states that the report on the study should include recommendations for revised payment methodologies, and the Comptroller General may include in the recommendations "(i) proposals to make adjustments under subsection (c) of section 1848 of the Social Security Act (42 U.S.C. 1395w-4) for the practice expense component of the physician fee schedule under such section for the costs incurred in the administration, handling, or storage of certain categories of such drugs and biologicals, if appropriate; and (ii) proposals for new payments to providers of services or suppliers for such costs, if appropriate."

Finally, the law states that in making recommendations, the Comptroller General "shall conclude and take into account the results of the study provided for under section 213(a) of BBRA." In other words, the drug study was supposed to take into account the results of the practice expense study, which again has not yet been issued.

I fail to see how the law, which was enacted because Congress recognized the link between reimbursement for drugs and services for cancer therapy, was obeyed in the manner in which the report and hearing for the drug study were conducted. The link was severed; the issues were reported and discussed independently of one another, thereby thwarting any efforts to effectively resolve the situation.

THE HEARING

Let me state that I concur with the GAO's statement that "it should be a principle of Medicare payment policy to pay for each service appropriately and not to rely on overpayments for some services to offset inadequate payments for complementary services." In fact, I have encouraged my clients to focus on billing appropriately for the work they perform. I have also provided HCFA with documents recommending a course of action for billing drugs based on a modified "RVU" type system with commensurate increases in services payments.

I also strongly concur with Dr. Norton's statement that "under the current reimbursement system, the payments for drugs compensate for the underpayment or lack of payment for the related services, and all parts of the system must therefore be reformed at the same time."

THE FACTS

I would like to respond to specific statements made during the hearing.

DRUG REIMBURSEMENT AND COSTS

Mr. Bentley stated, "Medicare patients are defrauded because their 20% co-payment alone often exceeds 100% of the true cost of the drug." I would like to emphasize his use of the word "often". Deputy Inspector Grob even suggested, as one of his recommendations, to increase the discounting of the published AWP.

When Medicare proposed to reduce payments for drugs to 95% of AWP, I performed an analysis for my clients on the impact to their practices. At 80% of 95% of AWP, 35% of drugs were profitable (based on invoice costs alone) and 65% of drugs were paid below invoice cost. Only 11% of drugs were significantly profitable. 11% hardly defines "often". The data suggests that increasing the discounting of the published AWP is an inappropriate option.

Dr. Norton suggested drug payments should include an add-on amount of 10%.

I disagree with his suggestion. An add-on of 10% grossly underestimates the indirect costs of providing chemotherapy. Some of these costs include: meeting OSHA regulations,

managing drug inventory, meeting with drug reps, researching drug efficacies, and paying for nonbillable supplies.

In the tape of the hearing, the claim was made that "Vinkisar was sold to healthcare providers for $7.50 and then reported the price to Medicare as $740."

Our data indicates the quoted reported price is off by a factor of 10. The drug was sold for approximately $7.50 and then reported as $74.00. Although still a significant markup, it raises concerns about the GAO's collection and conversion of drug cost and AWP data.

Another claim was made at the hearing that the patient is putting up 200% of the cost of Doxorubicin, and 500% of the cost of Leucovorin Calcium.

Again, our data defies these claims. The patient is putting up not 200-500% of the cost, but 130-150%, which actually represents $1.00 to $2.00. Again, not a perfect system, but it raises concerns about the accuracy of the data presented.

PHYSICIAN SERVICES AND COSTS

Chairman Tauzin, among others, quoted the amount of money "wasted" in overpayments for drugs to healthcare providers. Since the practice expense underpayments were not specifically addressed during the hearing, it is inappropriate to quote any amount of money as wasted. Director Scanlon made recommendations that would add $51 million to practice expense payments. This amount represents only 5% of the alleged drug "overpayments" of about $1 billion.

This statement is grossly inaccurate. ASCO has provided data to CMS proving the payments for services are less than 25% of the actual practice expenses incurred. Based on the number of services provided, 55% of drug "overpayments" are necessary to cover practice expenses, not 5%, and not including compensation to the physicians for their work in managing the cancer therapy services.

Director Scanlon stated the practice expense study will "show that oncologists' payments relative to their estimated practice expenses, which include chemotherapy administration, were close to the average for all specialties."

This statement is only pertinent in that it indicates that all specialties are underpaid for their practice expenses. I attempted to provide data to the GAO that was relevant to their practice expense study. Iola D'Souza told my associate that the GAO was only reviewing the method for calculating practice expense, not practice expense data itself. I fail to see, in the absence of the actual report, how a focus on the method will resolve the problem if the practice expense data was inaccurate in the first place.

Director Scanlon admits that "oncologists have raised concerns about whether the data used to estimate their practice expenses constituted a representative sample of practices surveyed and

whether these data reflect current practices in delivering services. How improvements in the data to estimated practice expenses may affect payment levels is uncertain."

Dr. Norton stated, "The few types of chemotherapy that were first furnished in the office setting were relatively simple, but they established the basis for the low Medicare payment levels for chemotherapy administration services that continue to exist today. There has been no major revision, even though the complexity of chemotherapy furnished in the outpatient setting has increased enormously."

I would like to emphasize his further statement that "BBRA requires DHHS to conduct a study of the costs of furnishing chemotherapy in the office and assess whether payments were adequate, but the study was never conducted."

OTHER ISSUES

It is important for CMS to keep in mind that their payment policies guide the policies of non-Medicare carriers. In fact, there are now some markets where Medicare is the highest payer (Phoenix, for instance). Therefore, Medicare cannot implement policies assuming they are independent of other carriers, nor assuming that payments from other carriers will subsidize Medicare underpayments.

By the way, in the Phoenix market, the combined reimbursement system is so poor that physicians subsidize ancillary services through their professional services. The oncologists in private practice in Phoenix would make more money if they were hospital-based and did not assume the risks inherent in office-based chemotherapy treatments.

Let's take a realistic look at the situation. Oncologists spend half their time on direct patient care (billable) and the other half supervising chemotherapy treatments (non-billable). If CMS adopts a payment policy where oncologists "break even" on ancillary services (chemotherapy drugs and services), then oncologists will make less than their internal medicine counterparts (remember, oncologists see less patients per hour). How is this fair? The United States is the leader in health care delivery precisely because our health care delivery system provides incentives for high quality, cost efficient care. Take away those incentives from oncologists and you will have an oncology meltdown.

OUR RECOMMENDATIONS

We could recommend the following actions:

- Postpone regulatory action reducing drug payments until accurate practice expense data can be obtained and reviewed.
- Expand the scope of the practice expense report to include actual practice expenses incurred by specialty healthcare providers.
- Review the drug report in conjunction with the results of the modified practice expense report.

- Allow the CMS to respond to my report to Mr. Terrence Kay the Director of Practitioner and Ambulatory Care that will correct the historical payment policy, including assigning an RVU to the drugs. This report offers an opportunity for the Medicare program to participate in the savings that Oncologists realize when they purchase the drugs. This will correct the RVU issue of the Oncology codes so the GAO can perform their limited practice expense study to bring Oncologist into par with other specialist etc. The findings will also clarify many Medicare policies that will correct error in inappropriate bundling, down coding, etc.

Alternatively, we recommend CMS review NBC's proposal to establish an "RVU" type system for drugs and to increase payments for chemotherapy administration services.

ABOUT NBC

Neltner Billing & Consulting Services, Inc. is based in Newport, Kentucky. We are a full-service billing firm specializing in oncology practice management. In addition to our ongoing management support and physician billing services for forty-one practices (representing 119 physicians), we have also consulted with over 300 hospitals and oncologists. Since opening in 1985, our company has expanded to serve clients across the entire United States. We have consulted with several major corporations, including Caremark, National Health Labs, Baxter Healthcare, Amgen, et. al., and have assisted with the development of their oncology programs.

Among other services, we provide our clients with fee, coding, and financial analyses; preparation for capitation contracts and third party negotiations; practice mergers, acquisitions, and joint ventures; facilities administration--management and design; practice marketing and enhancement; cancer program development; and documentation reviews. Our president, Martin Neltner, has authored several valuable educational publications for physicians, has published several articles in journals, and has published newsletters that addressed major issues of concern to physicians.

Our consulting team incorporates knowledge and experience from all aspects of oncology practice management: financial, clinical, and administrative. We are unique in that we continually draw upon the vast amount of information supplied by our billing services. In this way, we have first-hand knowledge of the daily issues bombarding clinicians across the nation.

Our team members are acutely aware of the rapid flux in today's healthcare market. We seek not only to respond with effective programs, but also to act proactively in changing the direction of the market. NBC frequently lobbies for fair and consistent legislation regarding physician services. Among other ideas, we have developed an "RVU" table for the pricing of oncology drugs. Our firm has provided technical support to 22 state oncology societies; we founded the Ohio/West Virginia Oncology Society and served as its Executive Director. We established and managed NOPA, the National Oncology Practice Alliance, a network of over forty oncology practices dedicated to remaining small, independent practice.