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The Evolution of Community Oncology Care and its Threatened Extinction Due to Federal and Private Payment Reform

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ABSTRACT

Medical Oncology is a fairly new specialty, born in the early 1970s. In the following decades, a cascading series of changes in the pharmaceutical, diagnostic, and treatment components of cancer care led to a migration of care delivery systems from the inpatient setting to the physician office setting in individual communities. Funding mechanisms from the Federal Government were based upon significant errors, but allowed oncologists the freedom to develop the complex delivery systems required for this community based delivery model. Private insurers followed the Federal model.

Now, increasing financial pressures and visibility of the costs and growing utilization of cancer care have led to a spotlight on the errors in the funding mechanisms that have existed for years. It is time to repair those erroneous systems, but the debate and proposed solutions across both the Federal Government and the private sector may threaten to dismantle and render extinct the community based cancer care model that has evolved and become so successful in battling cancer.

This paper will explore the growth of community oncology and discuss some of the most damaging elements of proposed payment reform. With a basic understanding of the evolution of the payment methodologies and reform proposals, administrators should be better prepared to position their organizations against inappropriate payment reform proposals, and to begin to move their organizations into revisions that will better help them to survive the looming changes in payment reform – whatever their final form shall be.

INTRODUCTION

Cancer is a disease that has plagued mankind for centuries. Identified in papyrus writings as early as 2500 B.C.[1], substantial progress has been made in the diagnosis, treatment and management of cancer, but we cannot yet say that it has been cured. There have been remarkable advances in our understanding of the molecular basis of cancer and the events that can lead to cancer. The most rapid progress has been compressed into the last few decades. In those same decades, the way that we as a country pay for health care delivery has also evolved from an individual responsibility to a general perception that health care is a right. The bulk of the cost, though, is assumed to be paid by "someone else" – an insurer, an employer, or the government. Technological and treatment advances are now colliding with the unwillingness of those payors to pay for the rising costs of health care. Cancer care is caught now, in 2003, in the middle of a major payment reform – on both the private and governmental fronts. This reform could signal the beginning of a new era in the management of cancer as a disease, or, it could set cancer treatment back several decades, to a time when cancer care will no longer be readily accessible from physician offices in communities across the country. There are multiple reform proposals under consideration, and the challenge to the cancer care providers and payors is to collaboratively implement a successful reform that fairly addresses both the cost and treatment

issues. However, to better argue for what will be lost, we must first understand what we have gained in the physical treatment of cancer patients, and seek to understand how payment patters payment patterns have not kept pace with the treatment advances.

CANCER CARE AS IT EVOLVED THROUGH THE 1980S

Cancer has always been a challenging disease. Initially, physicians could only diagnose cancers with visible growths, or deal with clinical systems of a well-advanced fatal disease. Topical treatments, including unguents containing arsenic, were used from the eleventh to the 18th century[2]. By the late 18th century, pathology and physical diagnosis helped oncology to be recognized as a medical discipline. Treatment became coordinated in a few select hospitals, and basically consisted of radical surgical removal of the diseased body part, in the hopes that the cancerous cells were removed along with peripheral healthy tissue[3].

In 1865, a potassium arsenate treatment for chronic myelogenous leukemia emerged as one of the earliest examples of effective chemotherapy for malignant disease[4]. Arsenicals were used to treat leukemias into the 1930s, and were then discontinued until the introduction of arsenic trioxide in the late 1990s as a viable treatment for acute promyelocytic leukemia[5].

Radiation therapy and surgery dominated cancer treatment options, delivered in the inpatient hospital setting, during the early twentieth century, until the end of World War II. Growing public awareness of cancer as a disease and efforts by the American Society for the Control of Cancer pushed Congress into declaring the conquest of cancer as a national goal through the National Cancer Institute Act of 1937. This Act set aside cancer research funding and established a National Advisory Council to review all research. Specialty hospitals and academic medical centers continued to serve as the hub for cancer treatment[6].

World War I marked a milestone in the understanding of cancer – when it was inadvertently discovered that cancerous tumors in soldiers exposed to mustard gas responded to the gas. This discovery was not widely publicized for over a decade following the war, due to wartime classification of the studies. Several clinical studies during the mid to late 1940s led to a surge in investigation of nitrogen mustards and their application in clinical practice as anticarcinogenic agents[7]. ‘Researchers, encouraged by growing use of penicillin and other "wonder drugs" began

to investigate other drugs that might also serve as agents for treatment of localized cancer. Their successes firmly established chemotherapy as the third weapon (in addition to surgery or radiation therapy) against cancer.'[8]

Some drugs that were developed in this early spurt of research are still used as cornerstones of conventional chemotherapy, even into the twenty-first century, including chlorambucil (Leukeran), melphalan, busulfan (Myleran) and cyclophosphamide (Cytoxan). These successes drove a demand for more and better drug treatments. By 1955 Congress authorized funds for a national research effort, and the National Cancer Institute created a National Chemotherapy program devoted to testing chemicals that could possibly prove effective against cancer. More than 500,000 chemicals were investigated on animals through this National Chemotherapy program. Several hundred of these chemicals moved into clinical trials. It could take years for a drug go through the clinical trial process and come to market. However, by the late 1970s, approximately 45 chemicals had been approved by the FDA for 29 forms of cancer.

Oncology was growing as a profession. 'By 1964, the first professional organization focused solely on clinical oncology was established, the American Society of Clinical Oncology. This group was founded by a few physician members of the American Association of Cancer Research (AACR). ASCO [now in 2003] has more than 20,000 professional members worldwide. Its membership is comprised of clinical oncologists from all oncology disciplines and sub-specialties, oncology nurses and other health care practitioners. International members make up 26% of ASCO's total membership and represent more than 100 countries.'[9]

Insurance developments provided for cancer care. President Lyndon Johnson signed the law that created Medicare in 1965 – which established a health insurance program for the elderly. Medicare covers doctors, hospitals, other forms of health care, and drugs given to patients in the hospital or those associated with a visit to a physician's office, but Medicare does not cover outpatient prescription drugs (with the minor exception of a handful of oncology drugs for which there is an injectable equivalent). Oncology drugs delivered in oncologists' offices were covered, and still are, but are lumped into the physician practice expense pool, since they were not being widely used in the 1960s. Surgery was still the dominant methodology for dealing with cancer.

Movies like "Love Story" (1970) and "Brian's Song" (1975) dramatized the trauma of terminally ill patients leaving their homes and families to seek treatment, but more often concluding their lives in hospital beds, after having struggled with their illness and the side effects of cancer treatments. Around this time, patient advocacy groups were formed – lobbying for support for federal funding for research and increasing awareness of cancer and cancer treatment.

In 1971, President Nixon signed into effect the National Cancer Act of 1971, declaring war on cancer and the devastation it wreaked on American life. From this initiative, millions of dollars flooded universities and research centers. The number of research projects mushroomed, and bore fruit. Drugs were being discovered that had an effect on both the cancer cells themselves, and the side effects of other treatments. University cancer centers prospered from the influx of funding and manpower. Flourishing cancer research budgets were funded by a variety of public and private sources. The university cancer centers reached out to community hospitals as extensions of a national research machine.

By 1973, medical oncology programs were graduating a new breed of physicians specially trained in multidisciplinary oncology practice and clinical research. Surgeons had dominated cancer care during the 1950s and 1960s. But as drugs became a more prominent feature of cancer treatment, medical oncologists soon became the primary clinicians for patients with malignancies, coordinating multi-disciplinary care. Formal organizations were created to support the professional interaction, continuing medical education, and research networks of these community based physicians. The Association of Community Cancer Centers (ACCC) was founded in 1974. ACCC membership in 2003 now totals more than 650 hospitals, cancer centers, group practices and freestanding clinics as Institution/Group Practice Members. More than 400 physicians, nurses, administrators and other oncology professionals hold individual ACCC Memberships.

Cancer treatment was not easy on patients or their families. Dr. William Bobzien, III describes cancer care in eastern North Carolina, which can be assumed to be a fairly typical description of cancer care anywhere across the country in the late 1970s, early 1980s.

> ‘Aside from these few small pockets of care, most patients in the region had to travel to the Duke or the University of North Carolina (UNC) hospitals for any oncology care other than straight-forward surgery. This worked a considerable hardship on these patients, many of whom were seriously ill. Radiation and chemotherapy, of their very nature, often require frequent trips of extended residence away from home. And one must remember that in 1975 chemotherapy side effects, particularly nausea, were not well managed. Thus, trips were not only long but also often made in the company of acute symptoms of nausea and vomiting - a decidedly unpleasant prospect. To avoid this, a number of primary care physicians and surgeons in the region functioned as "good soldiers", delivering some chemotherapy under the direction of physicians at the medical centers.'[10]

By the late 1970s and early 1980s, community hospitals were forming dedicated oncology units, which became the hub of multidisciplinary cancer care. The very existence of three arms in the arsenal of treating cancer (surgery, radiation therapy and chemotherapy) dictated that a multi-disciplinary model would evolve and create a team atmosphere in these dedicated oncology units. Physicians working in the oncology inpatient unit grew accustomed to the involvement of oncology nurses, social workers, pharmacists, nutritionists, pastoral care givers, and other disciplines.[11] The complexity of the drugs, their side effects, and the conditions of the cancer itself, required a concentrated team approach to get the patients through their treatments.

> ‘The evolving culture for cancer care centered on clinical cancer research as the best therapy for patients and as such, something that needed to be made broadly available in the community. At the beginning of the 1980s about 5 percent of patients in National Cancer Institute trials were entered by community physicians. That percentage had soared to an excess of 60 percent by the end of the 1980s’.[12]

During the 1980’s, hundreds of new medical oncologists trained at university hospitals, and brought that knowledge and education out into the communities as they set up practice. The accepted approach to treating cancer had taken a dramatic shift, from a surgical focus to a concentration on innovation and rapid adaptation of constantly changing knowledge and treatments. Several new oncology journals emerged to provide ready community access for the

dissemination of new research. The research push from the 1970s had brought scores of new drugs into the treatment arsenal, including both chemotherapy and supportive care agents. These new drugs facilitated a massive shift in care from inpatient to the physician office outpatient setting, but the timing did not conveniently match changes in payment for cancer care. Nurses caring for oncology patients had to develop a unique and specialized knowledge of the drugs and their effects on patients. The Oncology Nursing Society (ONS) was established during these early years to meet the training and certification needs that were developing. 'ONS traces its origin to the first National Cancer Nursing Research Conference, sponsored by American Nurses Association and the American Cancer Society (ACS) in 1973. Following this conference, a small group of oncology nurses met to discuss the need for a national organization to support their profession. Since its official incorporation in 1975, ONS has become a leader in cancer care. ONS has, by 2003, become a professional organization of more than 30,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. It's also the largest professional oncology association in the world.'[13]

> 'The emigration of these physicians from the academic institutions in which they were trained to the community hospital setting would spark a transformation in cancer care delivery in the United States. These community oncologists soon found themselves set apart from the mechanisms that had supported them-nurses with specific knowledge of oncology, access to experimental therapies and clinical research, and a multidisciplinary approach to case management.'[14] Cancer care was at a crossroads in the early 1980s, but still badly in need of significant enhancements before being ready to make a successful transition into an outpatient setting.

Patients Forced to Leave the Hospitals - In the meantime, to further complicate matters the government instituted the Federal Tax Equity and Fiscal Responsibility Act in 1982, in an effort to make hospitals more efficient. This Act established an Inpatient Prospective Payment System (IPPS) to prospectively set global payments for inpatient hospital admissions (in about 500 diagnosis-related groups, or DRGs), rather than paying for the actual costs of each individual hospital admission. The chemotherapy DRG – DRG 410 – ended up being the lowest weighted of all DRGs. Inpatient treatment that would have been appropriately paid under the old system

was now being paid at an artificially set level intended solely to lower Medicare costs, and thus forced chemotherapy on an inpatient basis to become a loss to hospitals. Tens of thousands of cancer patients were forced to have their care shifted from the inpatient to the outpatient setting, thus also forcing these sick, debilitated and nauseous patients to endure daily travel to receive their care.[15]

Medicare patients were forced into substandard treatment scenarios as a direct result of governmental policy designed to save dollars – before measures were taken to understand the human impact the policy would engender. There were physical reasons why these patients were hospitalized for treatment. Chemotherapy regimens at the time mostly were limited to lengthy, 24-hour, continuous infusions. Patients were so debilitated from the toxicity of the agents themselves, in addition to the side effects caused by the treatment, that they were admitted for their own safety and out of medical necessity. Most oncologists working out of private offices also did not yet have the infrastructure required to support patients and their families with the education, treatment, monitoring and follow-up needed to support the chemotherapy regimens of the time.

Fortunately, almost nine years after this exodus caused by the hospital DRG system, the first of the anti-emetic drugs, Zofran, was developed and approved for use in 1991. Zofran, a Glaxo drug that reduced the nausea and vomiting side effects of chemotherapy treatments, revolutionized the lives of cancer patients and their medical support team. Patients were no longer as debilitated emotionally and physically from their treatments, and were able to return more quickly to normal daily function between treatments. Nurses who were caring for patients at the time tell poignant stories of patients whose outlook on life and ability to fight the cancer did a 180 degree turnaround. With better management of debilitating side effects, this paved the way for cancer care to move from an inpatient modality to the outpatient setting where it was both more cost effective and a better standard of care.

This and other supportive care agents (including growth factors addressing both red and white blood cell symptoms) made it easier for patients to tolerate the treatments by limiting the toxic side effects of chemotherapy – and for physicians to experiment with other, more effective, doses. In the words of Dr. Mitlesh Govil, as she reflected on the changes in treatment from those

early days…"These drugs prevented bone marrow toxicity of chemotherapy drugs. With the prevention of this most dangerous of the side effects of chemotherapy, we soon found that cancer patients could now not only receive chemotherapy without major nausea and vomiting, they could also prevent lowering of white blood cell counts, which places patients at high risk of life threatening infections. Prior to the availability of the blood cell agents "Neupogen" and "Leukine", patients on chemotherapy would end up hospitalized for days. They would also have serious ulcers in the mouth, diarrhea, weight loss, fungal infections and life threatening septicemia. This all became preventable with the use of these drugs, and this was achieved without hospitalization!"[16]

The stage was set for a clinically supported evolution of cancer treatment from a requirement of geographic proximity to major cancer centers concentrated in urban areas to true local, community-based care. No longer was there a two-tiered system of care for cancer patients across the country – one for those who happened to live near established cancer centers, or whose financial situation allowed travel to the centers, and one for those who were unable to reach such centers for care.

From the physician's office, oncologists could provide the clinical research opportunities so needed for innovative treatment, and manage symptoms and side effects in a manner that would keep patients comfortable and able to continue with their treatment regimens on an ambulatory basis.[17] Technological advances in portable infusion pumps allowed treatment regimens to be delivered on an ambulatory basis. As physicians were better able to manage the toxic side effects of chemotherapy drugs, they were also able to adjust dosages to better fit into ambulatory, rather than inpatient-based, regimens. Patients experienced fewer of the symptoms that would leave them vulnerable to infection or hospitalization for dehydration from nausea and vomiting.

CANCER CARE THROUGH THE 1990s

Those oncologists who started providing care in their offices quickly learned that providing safe, efficient, quality outpatient cancer care required an infrastructure and office set-up that was far different from other physician offices. Infusion suites and the supportive facilities are more on a par with acute care units in hospitals than with traditional physician office space. With the

migration of patients from the inpatient to the outpatient setting also came a migration of board-certified oncologists and oncology-certified nurses, as well as other oncology focused professionals comprising the treatment team.

> 'As care continued to migrate to the community outpatient setting, oncologists continued to optimize treatment protocols. The science of delivering cancer therapy changed with increasing understanding of precise timing of administration of active agents and supportive care. Cancer patients received specifically orchestrated regimens developed to maximize efficacy with fewer and more manageable adverse events. This required treatment protocols carefully tailored to each individual patient. Cancer care was often comprised of multiple pharmacologic agents and multiple treatment modalities that took into account the patient's unique clinical presentation and other social and economic considerations of the family. Even with scientific advancement in supportive care, chemotherapy remained a challenging process for the patient, which included pain, fatigue, and psychological challenges. During this time of rapid clinical advancement, community-based oncology practices developed the infrastructure to quickly adopt and incorporate new treatments, technologies, and clinical research capabilities into their practice patterns and manage the business of providing complex care in private office settings. This provided patients local access to the best available standard and research-based treatments without having to travel outside of their communities, and resulted in more than eighty percent of patients seeking their care in community outpatient practices.'[18]

The Government Starts to Investigate Payment Reform - This complexity of care and its variation from the traditional model caused the government to look at options for understanding and instituting payment reform over the years. As early as 1987, a section of the Omnibus Budget and Reconciliation Act required the Department of Health and Human Services to conduct a study of the costs of furnishing chemotherapy in the office and assess whether payments were adequate. The study was never conducted.[19] HCFA subsequently published a notice in the Federal Register requesting relevant data [53 Fed. Reg. 39644 (Oct. 11, 1988).] The notice recognized that Medicare payment for chemotherapy administration may be inadequate:

> "Changes in treatment methods and advances in technology now allow chemotherapy to be furnished to many patients in the physician's office, thus reducing the need for hospitalization to administer chemotherapy. Furnishing these services in the physician's office is more convenient for some patients and may provide other benefits as well..."
>
> "Current Medicare Part B payment rules for physicians' services, however, may fail to compensate adequately for these services because the usual reasonable charge methodology may not fully recognize the overhead costs involved in these procedures. Some sources of additional costs include employment of nurse oncologists, special patient rooms, and safety equipment required because of the toxicity of the chemotherapeutic agents and safety procedures issued by the Occupational Safety and Health Administration."

Possibly because there was little pre-existing data on the costs of chemotherapy administration, the Health Care Financing Administration (HCFA) never conducted the required study and never offered recommendations to Congress.[20]

The gradual growth of the community based oncology treatment model during the 1980s had repercussions throughout the payment community. As Medicare discouraged more costly hospital admissions, so soon did private insurers. Limitations were increasingly made on place of service for cancer treatments – essentially forcing the migration of care even faster into the community setting. The complex hospital oncology inpatient units were dismantled, and specially trained oncology staff that didn't leave the hospital's employment for the private setting were reallocated to other departments within hospitals. Diagnostic equipment and laboratory staff also shifted to the physician office setting, since timely analysis of a patient's health status is critical to accurate provision of chemotherapy treatment.

> 'By the late 1980s, the nation was witnessing an overall belt-tightening approach to health care spending. Between the mid-1980s and the early 1990s, the costs of health care and pharmaceuticals had risen at about twice the rate of general inflation. The payers of health care - the federal government, insurance companies, employers and the growing number of HMOs and managed care

> companies-sought to curb the rising costs of health care, primarily by changing the way health care was reimbursed. Prospective payment systems, gatekeeper mechanisms, and stricter definitions of coverage theoretically were intended to protect patients and enhance quality of care by improving efficiency and reducing inappropriate and/or "experimental" treatment. These measures have contributed to some extent to a higher level of efficiency and decreased health care costs. However, many hospitals and physicians -and patients- have held that too often these cost savings have been derived at the expense of patient care. For the first time, hospitals and oncologists found their decisions regarding patient treatment being weighed against the economic feasibility of carrying them out.'[21]

The entire furor over cost of care was additionally frustrating to physicians because the rate at which they were paid (and still are paid) was determined by the payor, not billed charges by physicians. At this time, physicians were paid by Medicare and other insurers for individual encounters and the drugs they used. From the outset of Medicare, physicians were paid according to each doctor's actual or customary fee for a service, or the prevailing fee in the area, whichever was less. Then, in 1989, the Omnibus Budget Reconciliation Act was passed by Congress in an attempt to basically set a ceiling on the total amounts paid by Medicare to physicians. Weights, defined as relative value units (RVUs), were established for physician services based upon estimates of the resources required to provide the services (physician "work" effort, practice expense allocations, and malpractice expenses). By law, the RVUs were paid at a single conversion rate that is adjusted from year to year as needed while still adhering to the "budget neutral" requirement that total payments paid under this system would not change from what had been paid in the prior year. **The essential error for oncologists was that the CMS basis for creating the RVUs depended upon data that was several years old; dating from a time when oncology wasn't predominantly delivered in physician offices, therefore it drastically underestimated appropriate physician reimbursement for the office setting. In addition, there was no recognition of the growing specialized types of nursing and chemotherapy administration services provided in physician offices that didn't directly involve the work of a physician.** An oncologist was paid for an intermediate office visit at the same rate as, for example, an internal medicine physician treating a strep throat infection. This posed a significant

problem because the RVU system focused on physician work effort, so a major aspect of the growing specialty of community oncology was essentially ignored in creating reimbursement methods.

The drug payments were also set by the government at this time, and were based upon a concept known as Average Wholesale Price (AWP). AWP is a number that is set primarily by external agencies, based upon numbers provided to them by manufacturers. A manufacturer would define their "Wholesale Acquisition Cost" (WAC). WAC is usually the one price at which manufacturers sell product directly to drug distributors. Drug distributors then take orders from physicians and pharmacies, pick and pack multiple drugs, and ship them out to the ordering source at a higher price to reflect their handling costs and own mark-ups. Depending upon the distributor used and the quantities the ordering source purchases, that higher price can vary widely.

Diverse Data Sources - There are two primary sources for the published AWP which have been used widely as the basis for drug reimbursement; Drug Topics Red Book (Redbook) published by Medical Economics Company Inc. and data files available from First Databank, Inc. (FDB). Both Redbook and FDB make their own adjustments to the manufacturer's WAC number (usually ranging in increases from 20% to 28%) and name that adjusted price as AWP. There are definable differences between the Redbook AWP and the FDB for most given drugs, but this was not historically an issue. Redbook is published on an annual basis with an additional subscription available for monthly updates. The cost of subscription was and is still relatively low and Redbook became the gold standard for AWP in the physician class of trade. The publications were accessible even to single physician practices and both Medicare and private insurers tied their reimbursement to the Redbook AWP. The data files that are produced by FDB are far more costly and unwieldy and were never practical for use in a physician's office. The FDB definitions of AWP become the gold standard for the pharmacy class of trade – completely unrelated to physician practice.

AWPS are published for each drug by National Drug Code (NDC) number. An 11-digit NDC number identifies the manufacturer or distributor of the drug, the particular drug, its strength, and its package size. The wholesale drug distributor functions as the middleman, not just for the

distribution of drug, but also for the reporting and tracking of drug volumes. Depending upon volume and other purchasing relationships, some (but not all) physicians were able to enter into contracts for specified prices for certain drugs. The numbers of drugs available for contracted prices was and always has been very small in comparison to the array of drugs available for use, and are usually found in small categories of care. Most oncology care involves unique drugs for which there are no competitive alternatives, and thus for which there are few opportunities for contracted pricing. The wholesale drug distributor (of which there are only 5 or 6 with national market coverage) would track purchase contracts and ensure that any reconciliations that needed to occur with the manufacturer to reach the end purchase price do occur, through a process called "charge backs".

Whereas AWP determined the reimbursement for the Medicare and private insurers (Aetna, Cigna, Blue Cross/Blue Shield, Humana etc.) part of the frustration growing among payors, including Medicare, was awareness that AWP was not the lowest price on the market. This had always been the case, but the increasing number of cancer drug treatments in physician offices and the high cost of each new drug coming to market were causing the payments for drugs to increase dramatically. Some other government agencies can purchase drugs through volume discounts or otherwise guaranteed best prices. Oncologists actually purchase the drugs intended or designed for their patients, place them into a centralized inventory, and often customize these treatments at the time the patient receives chemotherapy. Then the oncologists charge the insurer for the drugs actually used, at the reimbursement rates defined by each insurer (Medicare or private payor). By Medicare having set the reimbursement rate at a universal number like AWP, individual physicians were assured that even a one physician practice would be reimbursed at least at the rate it cost them to purchase the drugs on the open market. Drugs cannot be pre-ordered in advance of the patient’s arrival, since as many as two-thirds of planned treatments are adjusted on the day of care due to unanticipated changes in the patient’s health status on the day of the planned treatment. Oncologists must maintain a very expensive stock of oncology and other supportive care drugs on hand to be ready for most contingencies presented by patients on the day of treatment.

While AWP was typically somewhat higher than actual prices paid by physicians for drugs and the professional service fee payments under the RVUs were significantly lower than their

incurred costs, oncologists found that the net result was that the aggregate revenue stream was sufficient to cover their costs, as well as to allow them to build the infrastructure and employ the specialized professional team needed to provide office-based cancer treatment. As the clinical experience and research information on chemotherapeutic drugs grew, it became clear that single drug treatments didn't offer the same medical efficacy as combinations of therapy. However, each new combination of drugs brought with it a new set of treatment, management and monitoring issues…all related to toxicities, reactions, side effects, education, and supportive care and counseling. These added complexities placed additional burdens on the physician offices in terms of personnel, facilities, procedures and operations.

Complexity of Care Escalates, as does Cost - During the 1990s, the FDA issued 102 new drug approvals for cancer care. In those ten years, they approved 5 times the number of new approvals as during the 1980s and almost twice the number of new cancer drug use approvals granted by the FDA in the entire four decades since 1949.[22] Many of these approvals were for use in combination therapy regimens, comprised of multiple pharmacologic agents and multiple treatment modalities. Therapies would increasingly become sensitive to individual patient clinical status, and other social and economic considerations. Supportive care - either medical (such as use of anti-emetics or red or white blood cell growth factors to treat chemotherapy induced symptoms) or psychosocial (such as assistance with transportation, discussion groups, dietary and nutrition counseling, and even self-esteem issues on dealing with the physical side effects of treatment), both during and after treatment, sometimes for both patients and their families, became more essential to the success of the treatment. As therapies became more targeted, the sophistication of the infrastructure to support that care increased respectively, as did the costs. The toxic agents became subject to increasing OSHA and labor force handling requirements, especially for storage, mixing, administration and disposal of these bio-hazardous materials. Specialized equipment, safety gear, procedures, checking and double-checking of planned regimens before, during and after treatment all added to the costs of operation. Nurses and even non-medical personnel required more specialized training in the care of oncology patients, not to mention proper documentation and billing. This entire additional infrastructure was developed and funded by the oncologists as part of their office overhead because without it, they could not appropriately deliver care in the office setting. The funding for this infrastructure

was covered out of the combined payments received by physicians for professional services and drug payments.

Community Based Care Proves to be a Successful Model - By the late 1990s, the evolution was complete. The majority of cancer care was now delivered in private physician offices at the community level in towns across America, rural or urban. No longer were patients dependent for quality care upon their geographic location or financial resources. As was reported by Roberta Herzlinger in a recent study on the location of cancer care, "Our data analysis supports conclusively what anecdotal evidence had previously suggested; community-based oncology practices provide the overwhelming majority of cancer care in the United States. For each of the sample years, 1992, 1996, and 1999, as depicted in Table 1, over 80% of cancer encounters (diagnosis, treatment and monitoring) were concentrated in the community-based office setting. This percentage represents an annual average of nearly 7.6 million office visits for these cancer types alone. In short, more than four out of five cancer care encounters for the most common types of cancer occur in community-based treatment settings.[23]

Table 1: Location of Cancer Encounters – Prostate, Breast, Lung, and Colorectal

	1992	1996	1999	3-yr Average
Hospital Inpatient	7.4%	4.8%	5.8%	6.0%
Hospital Outpatient	11.3%	9.6%	10.9%	10.6%
Community-based Office	81.3%	85.7%	83.3%	83.4%

[24]

THE COLLISION BETWEEN COST AND PAYMENT

This evolution did not go unnoticed by the payors, both federal and private. With the rapid proliferation of new indications for established and new oncology drugs, the dollar volumes being paid for oncology care, and especially drugs in oncology offices, reached the radar screens

of those issuing the checks. On a periodic basis from 1987 on, Medicare and various administrations sought ways to reduce the amounts being paid 'for the relatively few pharmaceutical products that it [Medicare] covers, most of which are administered in physicians' offices to patients with cancer. Medicare spent $6.5 billion to purchase some 450 covered drug and biologic products in 2001; reimbursements to physicians accounted for about 75 percent of those expenditures.'[25] Additionally, 'investigations initiated by the Office of the Inspector General of the Department of Health and Human Services in the 1990s showed that the AWP was not an accurate reflection of the price that physicians and pharmacy suppliers actually paid for Medicare-covered drugs.'[26] Because the actual costs of providing chemotherapy and other cancer care was being funded by the total payment streams of both drug and professional payments, little solid information was known about the effect that solely changing drug payments would have on patient access to care in the physician offices. Over the next decade, several initiatives would start and fail due to Congress' concern about the potential adverse consequences of the financial actions.

A few existing reports well document the many eventually aborted attempts by various elements of Congress and various administrations to evaluate and change the oncology payment structure.[27, 28] Without going into great detail, most of these attempts concentrated on changing the rate of payment for drugs, without making any significant adjustments for professional costs or costs of delivery of the outpatient cancer care. Some of those initiatives resulted in conflicting summaries of the actual dollars involved and at risk, but also started to build the momentum for the current maelstrom surrounding change:

- The General Accounting Office, in 1992, came to the realization that treatment in the inpatient hospital setting was more expensive to Medicare than in the physician offices. They also reported that some oncologists were influenced by financial factors and inappropriately treated cancer patients in the hospital inpatient and outpatient settings, when clinical standards indicated that office setting treatments were suitable. The report included the following prophetic statements…'HCFA's response suggests that the agency does not adequately recognize the financial incentives created by its own regulations. As a result, future HCFA regulations are also likely to have the unanticipated consequence of

higher Medicare costs'.[29]

- HCFA proposed to survey a small sample of oncology practices in 1994 to determine acquisition costs of drugs so that an alternative to AWP could be created. Once HCFA realized the cost of making such a survey statistically significant, the project was dropped.

- Shortly after that, the Clinton Administration proposed another methodology for paying acquisition costs that was later abandoned, but by 1997 Congress had unilaterally dropped the existing 100% of AWP reimbursement down to 95% of AWP – in the absence of having been able to identify any better solution, and without calculating any potential effect on the physician practices.

- By 2000, Congress had directed the General Accounting Office (GAO) to study the adequacy of the payments for both drugs and the expenses physician offices incurred for treatment of Medicare patients. The GAO testimony to Congress on September 21, 2001 included the following comments:

  'Our study shows that there can be wide disparities between a drug's estimated acquisition cost and Medicare's payment for that drug….The discounts indicate that Medicare's payments for these drugs were at least $532 million higher than providers' acquisition costs in 2000.'[30]

- HCFA was also starting to recognize that there were costs of care incurred by oncologists that were being funded by the total revenue streams for drugs and professional services, and that there would be an adverse effect on cancer care should any correction not consider that situation. In a 2000 letter to Congress, HCFA stated:

  > '[W]e have concluded that Medicare payments for services related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate. . . . In next year's

physician fee schedule regulations, we intend to propose modifications to the practice expense formula or legislation that would increase payments for cancer chemotherapy administration. Our goal would be to have more accurate pricing for both chemotherapy drugs and chemotherapy administration in place at the same time.'[31]

- HCFA later acknowledged the range of uncompensated services furnished by oncologists that are being funded by the drug payments:

  '[S]ome practitioners have come to rely on inflated drug payments to subsidize associated, non-reimbursed costs, such as storage and administration, and, in some cases, to provide other important services that are not adequately compensated. Consequently, the administrative actions we take to reduce the price of a drug need to take such expenses into account.'[32]

- Also in 2001, the Office of the Inspector General estimated that Medicare beneficiaries would pay 'over $175 million less in coinsurance if Medicare paid for these drugs based upon catalog prices.'[33]

- Then, in early 2002:

  'Janet Rehnquist, inspector general of the Department of Health and Human Services, provided testimony on what she characterized as 'other potential adverse implications' of the use of AWP….because physicians and suppliers get to keep the difference between the actual price they pay for the drug and 95 percent of its AWP, this 'spread' serves as an inducement for suppliers or physicians to use one brand of the drug over another. Thus, publishing an artificially high AWP is used as a marketing device to increase a drug company's market share.'[34]

- HCFA did spend some time considering alternatives for calculation of costs in oncologist's offices, even publishing in the Federal Register on Nov. 1, 2001 an

analysis by a clinical expert panel (CPEP) of the direct costs associated with the principal chemotherapy administration codes. Although the CPEP process estimated direct expenses, the bulk of practice expenses are the indirect expenses, such as administrative staff, rent, and other overhead costs. Using the general ratio between direct and indirect expenses for all physicians,[35] the net total cost of the two principal chemotherapy administration codes is shown in the following table compared to the Medicare payment amount:

CPT 96408 (administration by push)	
Clinical staff	$ 50.69
Supplies	9.89
Equipment	0.40
Total direct costs	$60.98
Indirect costs	122.78
Total costs	**$ 183.76**
Medicare payment	**$ 39.02 (21% of cost)**

CPT 96410 (first hour of infusion)

Clinical staff	$ 60.14
Supplies	26.68
Equipment	1.84
Total direct costs	$ 88.66
Indirect costs	178.51
Total costs	**$ 267.17**
Medicare payment	**$ 62.36 (23% of cost)**

- As these totals indicate, Medicare pays less than one-fourth of the costs of the basic chemotherapy administration services.

- As recently as January 22, Tom Scully, [Center for Medicare and Medicaid Services] CMS Administrator, stated: 'There is a good argument….especially if you are an oncologist….that they have been artificially squeezed. And they've shown some data on that that we probably agree with….The government should try to pay for the right amount for their practice and the right amount for drugs'. In addition, the Chair of the House Ways and Means Health Subcommittee, Nancy Johnson, stated at an October 3rd, 2002, hearing on drug reimbursement that: 'Medicare does not reimburse oncologists for the practice expenses associated with providing treatment to cancer patients in outpatient settings.'

Charges of fraud begin - With increasing controversy regarding the rates paid for drugs to oncologists, the Office of Management and Budget (OMB), and the Office of the Inspector General (OIG) started investigations into possible fraudulent activity on the part of physicians, charging that by billing Medicare more than their costs of acquisition, physicians were committing fraud and abuse. Statements were even made regarding the fiduciary responsibility of the government to its Medicare beneficiaries to ensure that only the lowest prices were being paid. Accusations against oncologists reached the public venue, in publications such as the New York Times, USA Today and the Wall Street Journal.

Fraud charges not based in reality - Oncologists were caught somewhat off guard by all this, because as a group, they had been advocating balanced cancer payment reform for years, while the inability of Congress and the Administrations to develop a fair solution had led to decades of inaction. Now, a public hue and cry was building accusing doctors of profit-mongering and billing inappropriately under a system that ironically had not been set up by the doctors. In fact, the oncologists had been spending that last few years paying attention to building the necessary infrastructure to safely and appropriately deliver community based cancer care. The vast majority of oncologists had and still have no clue what an individual drug costs them to stock, let alone what the insurer will allow them to bill for the drug. They ordered the drugs needed for the care they felt appropriate to deliver, and let the rest of the dollars flow where they may. There also was little awareness of the costs of delivering care. Because the payment streams had no logic related to costs in and costs out, very little attention was focused on the individual elements, such as insurers underpaying for office costs and overpaying for drugs. As long as the bottom line covered the costs of service during the year, most oncologists spent their available time researching and developing new treatments and training their staff in handling chemotherapy regimens. That was, in hindsight, a very naïve position for oncologists to take, and unfortunately many in the insurance industry, including the federal government, were skeptical that physicians could be that naïve. As unlikely as it may seem to some, most oncologists had chosen that profession through a desire to conquer cancer and its symptoms, and that activity in itself had more than enough challenges to fill an oncologist's day.

In fact, most oncologists understood intuitively that Medicare, as a payor, was purposefully as low as possible, and that there were no profits being made in caring for Medicare patients, if any.

A study by Health Policy Alternatives actually proved in 1999 for the first time that oncologists were indeed losing money on current Medicare reimbursements. At that point, Medicare was considering a reduction in payment for drugs from 95% of AWP to 83% of AWP. "Table 1, which follows the executive summary, provides summary data of net Medicare revenue, Medicare-related operating costs and Medicare-related practice compensation in a side-by-side comparison of the three scenarios estimated: 100% of AWP as was the policy until 1998; current AWP minus 5%; and the proposed AWP minus 17%. … The analysis shows that under the policy in effect until January 1, 1998, whereby Medicare reimbursed for outpatient drugs at the AWP, oncology practices were realizing a small profit on their Medicare cancer business. A practice with utilization volume similar to that used in this analysis would realize $149,865 in profit, or an average of $21,409 per physician, or an average of $166 per Medicare patient. Under the current AWP minus 5 percent, the annual Medicare practice compensation is a **loss** of $162,058. For each of the 7 physicians in the practice, the average annual Medicare compensation is a **loss** of $23,151; or an average annual **loss** of $180 per patient. Under the proposed AWP minus 17 percent, the annual Medicare practice compensation drops significantly to a **loss** of $910,680. For each of the 7 physicians, the average annual **loss** would be $130,097, or a **loss** of $1,010 per patient.[36]

Despite the obvious confusion at the Congressional and Federal Administrative level regarding Medicare reimbursement for cancer care, there was a conviction that the drug payments were wrong and needed to be changed. There was some understanding, but less conviction that the other side of the revenue stream, costs of services essential to delivering that community-based care, were being significantly underpaid. Particularly at the Federal Level, it became easier to quantify the perceived overpayment, and to plan to convert that amount of money into "savings" that could be used to fund other Federal programs. Once the belief became pervasive that these were "savings" to which the government was entitled, it became easy to discount or dismiss statements by oncologists that those monies considered excessive were actually covering other costs integral to the delivery of cancer care, even when those statements agreed with public statements by governmental agencies in the past.

Other Payors jump on the bandwagon - It also became very easy for private insurers, such as Aetna, Cigna, Oxford, Human, etc., to pick up on the refrain being voiced in Washington, and to

seek out their own opportunities for savings. In different areas of the country, specific private insurers started implementing a variety of programs, all designed to achieve cancer care expenditures. These programs reached prominence in the late 1990s and early 2000s and included brownbagging (a general term for a diverse range of programs intended to separate the physician from the funding of the cancer drugs), disease management (a program designed to double-check choices made by physicians for inpatient and outpatient care against defined standards), mandatory vendor imposition (a program that chooses a for-profit third party to buy drugs instead of the physician, and simple decreases in amounts to be paid to physicians – with or without corresponding adjustments in the professional service fees. It is important to note that when many of these programs were proposed, oncologists to whom they were being proposed tended to reject them (on an individual practice basis) on the grounds of patient safety and access to care. These programs will be discussed in greater detail in another section.

Hospitals were no better off - Hospital cancer programs were and still are also experiencing their own funding disasters. The Balanced Budget Act of 1997 changed Medicare payment for hospital outpatient services based upon the outpatient prospective payment system (OPPS), which went into effect Aug. 1, 2000. The OPPS established payment rates based upon ambulatory payment classifications (APCs), similar in concept to the earlier hospital inpatient payment reform through DRGs. Like DRGs, the net effect of APCs was to lower reimbursement rates for hospital-based outpatient cancer care to below the costs of the services being delivered. In addition to the lower rates, the APCs were set up so as to not include appropriate payment methodologies for new cancer therapies.[37]

> 'With $60 billion spent on cancer care in the United States -- $35 billion of it on outpatient care – cancer centers have a big stake in how APCs will affect them and industry observers such as [Executive Director of ACCC Lee] Mortenson see hard times ahead. He says a study the association recently delivered to the Government Accounting Office showed that hospitals are getting 41 cents on the dollar for chemotherapy administration. In addition, he says, hospitals are losing 5% to 10% on the drugs themselves. For radiology, Medicare reimbursement for radiation oncology has dropped significantly – from $200 million in profits industry-wide to $132 million in losses. 'We're in trouble on the hospital side,' Mortenson says. 'The two major portions of

cancer programs are both losing money. That doesn't bode well.'...As have other groups, the ACCC argues that CMS used flawed numbers to analyze hospital costs and come up with payments under the new system…In 1996, only $2.8 million of supportive care drugs…were identified … in the CMS database. That same year, though, IMS Health, of Plymouth Meeting, PA, reported that $822 million in supportive care drugs were sold to U.S. hospitals. It's likely, association researchers day, that as much as $89 million – or 30 times the amount suggested by the CMS numbers – was spent on supportive care drugs in hospital outpatient settings during 1996. 'CMS records directly account for just 4% of the expected supportive care drug use.' Mortenson says. Given the continuous innovations in cancer care, and the fact that CMS data must continue to use data that are several years old to develop its APC relative prices, CMS data will always lag behind reality..'[38]

'Hospital cancer programs across the country have started closing their doors, ceasing to use the newest drugs (which don't have a mechanism for payment under Medicare currently), and others are tracking significant losses and deciding what steps to take. Examples of steps that hospitals are taking include: A large university hospital [in PA] is starting to cut many supportive care services... [it] is also seriously considering joining the exempt cancer center group because it does not believe it can maintain outpatient oncology operations under the current Medicare payment system…In May, this [Hawaii] hospital terminated all chemotherapy services due to poor reimbursement and an inability to continue sustaining financial losses. Patients must now commute outside the area to receive treatment at other hospital facilities (none of which are eager to accept the added patient volume…or, alternatively, to receive chemotherapy in their physician's private office…hospital [in Florida] no longer allows its doctors to order or administer new drugs…or it requires patients to pay cash or come up with a payment plan up front for the drugs. The Administration is developing a plan to remove the chemotherapy infusions from the hospital setting...The bottom line was that in 2002, hospitals were reimbursed at only about 80 percent of their costs for drugs in the outpatient setting. Incredibly, the final rule for 2003 reduced total payments by an additional $138 million.'[39]

PHYSICIAN OFFICE BASED COMMUNITY CANCER CARE - THE 2003 MODEL

There are many complexities to the successful delivery of cancer care out of the physician office model that, if not understood by those affecting changes in the payment programs, could cause the infrastructure that has developed so rapidly over the last few decades to collapse. An oncologist's office suite resembles a hospital acute care center far more than a typical physician office. Historically, insurer payment structures have been wedded to the encounter-based reimbursement philosophy: that the primary costs of a physician practice are those of the physician him/herself; that office based services are funded at basic levels; that procedures performed can be weighted and funded according to complexity of physician effort and time; and that support services and supplies are modest percentages of the costs of doing business. These encounter-based philosophies have no bearing on the realities of cancer care today, which demand the existence of an expensive infrastructure capable of reacting as needed to potentially fatal situations.

ASCO described some of the differences in the medical team and supportive care services in a white paper intended to illustrate the uniqueness of cancer care for those planning payment reform.

> 'Oncologists and their professional staffs typically furnish a variety of services to cancer patients for which there is no explicit reimbursement from Medicare and other insurers. These uncompensated services fall into two categories. The first category is composed of services furnished by non-physician staff that are indirectly related to chemotherapy administration and are an integral part of cancer treatment as it is furnished today. These services include nutrition counseling, social worker services, and psychosocial support. Social worker services encompass a variety of services intended to help patients carry out their therapy. These are functions such as helping patients with their health insurance, filling and refilling prescriptions, and obtaining prosthetics (e.g., breast prostheses and wigs); arranging physical therapy and transportation to and from the office for treatment; and implementing hospice referrals. Psychosocial support includes services such as counseling patients on their activities of daily living, support groups that meet in the physician's office, and grief counseling. These services are not offered by physicians who treat most types of illnesses, but they have become an integral part of cancer treatment.

The second category of services is physician services. Oncologists must frequently perform greater work before and after patient visits than is accounted for in the Medicare relative values for office visits, which assume that such pre- and post-visit work is the same for all specialties. Responding to patient e-mails and extended telephone calls with patients and their families about the side effects of treatment and the progress of the patients' condition are commonplace, as is in-person family counseling, but Medicare does not make any separate payment for these activities. Oncologists frequently consult by telephone with other physicians on treatment options and the availability of clinical trials. Treating cancer is a multidisciplinary exercise, and medical oncologists must often coordinate with radiation and surgical oncologists. Due to the severity of the disease, physicians treating cancer patients must also complete an extraordinary number of forms to document disability for insurance companies, support applications for family leave, obtain help with utility bills or handicapped license permits, deal with the Immigration and Naturalization Service or the Red Cross so foreign or military family members can visit the patient, and so forth. Medicare's implicit position that oncologists treating patients with cancer have the same amount of pre- and post-visit work as physicians treating relatively healthy patients does not reflect reality and results in a failure to compensate all of the work furnished by oncologists to Medicare patients.[40]

When a patient enters a physician office based community oncology practice, every member of the staff needs a specialized knowledge of oncology treatments and regimens, including the front desk staff in order to schedule return visits, and book appointments. Laboratory staff greet patients soon after arrival and run blood and other diagnostic tests essential for understanding the patient's health status and body chemistries as of that day. A cancer patient's health status can change rapidly and the chemotherapy treatments need to be finely tuned for that day's situation.

Physicians spend a great deal of time analyzing tests and medical records, understanding the patient's health and quality of life issues and discussing a variety of options before coming to a decision about treatment. Even after a decision to treat has been made, there are several alternatives to consider, literature to review, and patient needs to take into consideration before determining the most optimal therapy regimens. At this point, since most regimens are multiple drug combinations, dosing becomes another major decision-making process, and is carefully calibrated to the patient's health status and diagnostic results.

Finally, a patient is ready to receive treatment. Each time a patient comes in for treatment, medical personnel conduct an assessment of the patient's readiness for treatment that day, looking for changes in health status or symptoms or side effects from the treatments or the supportive care drugs intended to mitigate any side effects of the chemotherapy drugs. Chemotherapy drugs are designed to kill human cells, and target cancerous cells as much as possible not to affect too greatly any adjacent healthy human cells. As much as two thirds of the time, patients will present with issues that need to be addressed or co-morbidities that the physician needs to handle before proceeding with the cancer treatments.

The chemotherapy infusion center has to be simultaneously functional in a manner so as to make patients and their families comfortable for a stay of what is often several hours, and to enable the specially trained oncology nurses and provider team to safely deliver the therapy. Safe treatment also means that these staff and the facilities have to be able to respond in seconds to adverse reactions, which can be fatal. Expensive equipment that may only be used in emergencies must be readily available. Necessary staff training to deal with the daily treatment monitoring, patient assessment, family and patient counseling and education takes several hours each year.

Oncology nursing is highly specialized. It can take years for an oncology nurse to learn and become comfortable managing the different chemotherapy regimens. In a New England practice, a skilled I.V. nurse coming from a hospital intensive care unit had just barely reached a level of comfort with three year-old therapy combinations after almost a year of on-the-job training, but was not yet comfortable administering some of the new treatment regimens. Certification and maintenance of continuing medical education credits are important for physicians and nurses alike.

The storage, handling, mixing and administration of these toxic drugs add another whole dimension of facilities management. Chemotherapy drugs have a very low threshold for temperature and handling parameters, and when mishandled, can become more toxic or lose their effectiveness. The cost and variety of needed drugs is managed by one inventory storage process, which usually involves a specialized hardware and software inventory system (part of which is refrigerated). Practices order from a very limited number of drug distributors, and exercise caution to ensure that only reputable firms handle the delivery of the drugs in a reliable manner.

OSHA and CLIA regulations govern much of what is routinely done at an oncologist's office, including regulations targeted at handling the toxic chemotherapy infusions, as well as the mixing and administration process. Specialized equipment ranging from tiny $2-$3 vial pins to several thousand dollar laminar flow hoods under which the drugs are mixed is required. Supplies that are essential to the administration of chemotherapy regimens, like pumps, tubing, saline solutions, sterile water, bags, gloves, more expensive needle-less systems, etc., are an integral part of the treatment.

Almost none of the items, staff, training and specialized facilities mentioned in the paragraphs above are paid for or recognized by Medicare or private insurers. It is this infrastructure that has been funded out of the dual revenue streams for drugs and professional services, and if cancer care is to continue as a community based care delivery system, this is the infrastructure that must be funded in an appropriate manner as part of cancer payment reform.

It has taken 3 to 4 decades to create an environment where patients can walk in a physician office door, receive the supportive care and diagnostic services they need to enable them to receive toxic chemotherapy regimens and return to their home the same day, continuing to live their lives as uninterrupted as possible by the treatment of their disease. It looks easy, and oncologists may have done themselves and their patients a disservice by creating a system that works so seamlessly that it seems effortless (and therefore is easy for uninformed policy makers to dismiss as unimportant). Every element: the training, the cognitive process, the assessment, the monitoring, the watchfulness before, during, and after treatment, the after-hours follow-up care, the support systems, the guidance and counseling, the education of both patients and families, the coordination of multiple specialties and inter-disciplinary communication - all are critical and integral to community cancer care treatment in physician offices. The inability of physicians to pay for any element of this complex infrastructure under a revised payment system will lead to the complete collapse of that infrastructure.

CANCER CARE AT A CROSSROADS

Now, in 2003, we are seeing the result of a ten year shift in paradigm caused by the clash between advances in cancer care and the unwillingness of insurers to continue to fund the current delivery system as it has evolved over the last four decades. As early as 1991, industry observers were observing a shift in payment incentives.

> "The cancer treatment community is experiencing more than just a temporary lack of payment for new drugs. It is seeing changes in the patterns of care by physicians…as well as a shifting of incentives. Physicians who were trained to be innovators (or at least to stay current) now have strong incentives to be the last to adopt new technologies. These changes are pervasive and threaten to influence patient care negatively…In less than a decade we have moved from an era in which new technologies were heavily promoted to an era in which they are sometimes offered reluctantly and in which patients may have to sue their insurance companies to receive the new types of care…The ACCC recently surveyed oncologists across the nation about the prevalence and nature of reimbursement problems. The responses indicated that 90 percent of oncologists are spending more time than they were three years ago in attempting to get adequate third-party reimbursement, 90 percent said that they were having more difficulty getting reimbursed by managed care plans than 3 years ago, and 60 percent stated they were experiencing increasing difficulty within the last year receiving payment for previously reimbursed cancer therapies. Sixty percent indicated there had been a decline in reimbursement for cancer therapy over the previous year.[41]

While the above paragraph was written back in 1991, it is no less true in 2003. Since late 2001, Congress has been moving more quickly towards cancer payment reform. In September, 2001, Federal investigators called for changes in the way Medicare pays for certain drugs, claiming that overcharging by physicians and price manipulation by drug companies cost taxpayers $532 million and more last year.[42] The Office of the Inspector General, as well as General Accounting Office (GAO) Director William J. Scanlon, spoke of the need for sweeping changes to the Medicare drug reimbursement process. As private insurers watched those deliberations, some began jumping the gun and trying to implement their own versions of cancer payment reform,

but in an even more uninformed manner than Congress and CMS. Innovation in cancer care is threatened as never before!

The frequency of reform proposals by the federal government and private insurance increased rapidly in 2002 and 2003.[43] It seemed apparent that some correction, whether affected by Congress or the Administration through CMS, would be imminent. One of the major difficulties with movement toward a solution had been lack of information regarding costs of oncology care. Medicare has very specific regulations regarding the format, design, and handling of practice expense surveys, which was the reason that many industry analyses of the costs of the infrastructure essential to delivering community cancer care were ignored or dismissed by CMS.

> 'ASCO did fund a survey that followed the CMS constraints. Out of 999 responses, an unprecedented response rate, CMS found reasons to exclude all but about a quarter of them. Paul Bunn, MD, President of ASCO, referred to the results of this survey at a Congressional hearing in October 2002: ASCO has long asserted that past survey results [upon which federal policies were being based] were inadequate to capture true costs of oncology practices because they included only a small, unrepresentative group of oncologists. Therefore, in order to address the paucity of data, ASCO engaged Gallup to conduct a new survey of oncology practices that would provide more reliable answers. Gallup has now completed its survey, and the resulting data were forwarded to the contractor of the Centers for Medicare & Medicaid Services (CMS) for evaluation. The CMS contractor, the Lewin Group, has completed its analysis of the data and forwarded its conclusions to CMS.
>
> As analyzed by Lewin, the survey data show that CMS dramatically underestimated oncologists' practice expenses per hour; the survey, adjusted for inflation, reflects that oncologists' actual practice expense is roughly 90% higher than CMS' current assumptions. Additional analysis, still underway, may increase the gap between actual expenses and what Medicare assumes to be the case.'[44]

However, the governmental regulations governing handling of this survey also required that ASCO not receive the raw data for its own analysis. CMS received the data in the summer of

2002 and held it for months without public dissemination of their own analysis of changes this data might suggest. Periodic conversations and communications with CMS officials made it appear to oncology community representatives that the data had been analyzed internally and found to suggest a magnitude of under funded practice expense that was greater than CMS wished to admit. The software and methodology that converts practice expense data into RVUs for physician professional services billing codes is proprietary to CMS and is held in very close confidence.

When CMS and Congressional officials did start leaking information about the perceived underfunding gap for professional services, the amount ranged from $50 million to $190 million. This was usually presented simultaneously with projections of overpayment of cancer drugs to oncologists of $500 to $800 million per year. The difference between the underpayment and overpayment was the perceived "savings" that could be pulled out of cancer care and used for other federal projects, such as a prescription drug benefit.

Without access to the exact methodology that CMS was using to analyze the data, it became difficult for oncology professionals to address the vast difference between the CMS conclusions and the reality that they dealt with daily of the costs of providing the infrastructure required for delivering community cancer care. By the end of 2002, it became clear that rising attention to the antiquated dual payment stream that had been funding oncology care for decades was going to finally result in either Congressional or Administrative correction. Equally obvious was that there was a significant gap in knowledge on the part of those entities with regard to the realities of cancer care and the complexities that had evolved in the delivery system to allow the safe provision of care in physician office settings.

For the first time, physician members of the oncology industry conducted their own analyses to better understand the costs they incurred while caring for Medicare patients. US Oncology (a publicly held corporation with more than 870 physician members across the country) discovered to their surprise in 2002 that, at best, their practices were barely making a less than 2% positive margin on care delivered to Medicare patients. As a large purchasing group, US Oncology could achieve some economies of scale that would improve their efficiency – but there are limited opportunities for economies of scale in either the acquisition of oncology drugs or in the delivery

costs of what is a very meticulous, labor-intensive environment. ACCC also worked in 2002 with ten oncology practices to complete an unbiased accounting review of all revenues and costs of practice operations, and found that, on average, these representative community oncology practices were losing more than 1% on every Medicare patient, which echoed the findings by consultant Bart McCann from 1999. The Community Oncology Alliance (COA), a grassroots group of oncology practices founded in December 2002, conducted a study in 2003 that again did a clean accounting review of all dollars in and dollars out for over 47 oncology practices across the country This review showed that

> 'Medicare under-reimburses for all the essential services required by cancer patients by an estimated $718 million. Medicare over-reimburses for cancer drugs by $570 million. Community oncology practices, where over 80% of Americans with cancer are treated, lose an estimated $148 million treating Medicare patients. Additionally, the GAO and CMS estimates of drug reimbursement are artificially high because they are only based on acquisition cost, which is only a portion of the direct drug cost that also includes procurement, inventory, storage, pharmacy, and waste.' [45]

The election in November 2002 reshaped the profile of Congress by leaving the Republicans dominating the Presidency, House of Representatives, and the Senate, but with such a slim margin, particularly in the Senate, that controversial bills would have a difficult progress. Both parties saw a value to passing a Medicare prescription drug benefit package in 2003 prior to the next major election year in 2004, and when the 108th Congress convened in January, made that a high priority. The discussion regarding cancer payment reform became enmeshed in the prescription drug bill. Many proposals for cancer payment reform were floated but not finalized. It was clear to the oncology community that each of the proposals was grossly inadequate, and would leave cancer care in the community physician office setting severely under funded. This lack of resources would dramatically reduce access to cancer care for patients by removing the underpinnings of the infrastructure so essential to the provision of outpatient care of cancer patients.

Representatives Charlie Norwood (R-GA) and Lois Capps (D-CA) introduced HR 1622, The Quality Cancer Care Preservation Act in the House of Representatives on April 9, 2003. This

thoughtful legislation would reform the Medicare system for reimbursement of chemotherapy services through a comprehensive approach that addresses both payments for chemotherapy drugs and for practice expenses associated with chemotherapy administration. The Quality Cancer Care Preservation Act sought balanced reform which would align Medicare reimbursement for the chemotherapy drugs and services to actual costs. It proposed to set reimbursement for chemotherapy drugs at the manufacturer's sales price with an additional percentage to reflect the varying prices that practices of different sizes may pay for the drugs and for drug-related costs such as wastage and bad debt. It also required Medicare to fully reimburse for the costs of delivering chemotherapy, with the increase in reimbursement for services financed by savings from adjustments in payments for drugs. In addition, the legislation required Medicare to pay for essential patient support services that are integral to quality cancer care such as nutrition counseling, psychosocial services and social worker services.

ASCO, the Cancer Leadership Council, which represents cancer patients, providers and researchers, the Community Oncology Alliance, and many other groups representing oncologists, oncology nurses and cancer patients, endorsed this legislation. The bill attracted 117 co-sponsors in the house, and a companion bill S1303 in the Senate was introduced by Senator Brownback, [KS] on June 20, 2003 and it gathered 9 co-sponsors before being virtually replaced by activity on the Medicare prescription drug bill. In the House of Representatives, both the Energy and Commerce Committee and the House Ways and Means Subcommittee on Health were pursuing their own formulas for correction of cancer payment reform. The Senate saw that debate handled through the Senate Finance Committee. Each of these three committees developed very different solutions, none of which were judged by the oncology community to present sufficiently balanced reform as to allow for continuity in cancer care delivery.

Before either of the HR 1622 or S1303 bills reached full consideration by their governing bodies, rapid development of a Medicare Prescription drug benefit bill – eventually becoming H1 and S1 (The Medicare Prescription Drug and Modernization Act of 2003) basically swamped discussion of an independent cancer payment reform solution. This Act addresses a Medicare reform package that dwarfs the magnitude of the cancer payment budget. As Congresswoman Nancy Johnson, Chairwoman of the House Ways and Means Committee Subcommittee on Health, stated in several public forums: the cancer community is at a disadvantage, because in terms of

raw dollars, the prescription drug benefit bill could be perceived as a full desk, while the cancer issue is relatively the size of a quarter sitting on a corner of that desk. Buried under the hundreds of pages of each bill, were vastly different proposed solutions –each in their own way resulting in hundreds of millions of dollars being pulled out of cancer care.

The Senate introduced S1 (their version of the prescription drug bill) on June 11, 2003 and had passed it by June 27. By June 25, 2003, the two House Committees had resolved their differences in conference and presented H.R.1H. in the House for vote and the bill was approved in the wee hours of the morning, with substantial amendments. A panel of conferees was named to resolve the differences between the House and Senate Versions of H1 and S1. There was hope that any conflicts could be resolved before the July 4, 2003 break, and then before the August break. Published plans are for staffers and conferees to resolve outstanding conflicts and present a merged bill to the House and Senate for a vote before the close of the 108th Congress First Session (now scheduled for Oct. 3, 2003.)

CMS has its own role to play in cancer payment reform. Citing Office of Management and Budget and Judicial Department pressures to remove the "perverse" and "abusive" actions of physicians in billing for drugs at rates higher than they are paid, periodically Tom Scully, Administrator for CMS, issued several warnings that, should Congress not execute a timely solution to cancer payment reform, CMS would make those corrections for which it feels it has legal authority. Unfortunately, CMS also claims only to be able to adjust the drug payment component of the cancer payment stream, which would de facto result in some degree of loss or wash on the drug expenses physicians incur, with payment based on current rates for professional service fees netting out to about 25 cents on the dollar.

DETAILS OF THE PROPOSALS ON THE TABLE – SUMMER 2003

S1 – The Senate version of The Medicare Prescription Drug and Modernization Act of 2003 is the least developed of all the proposals. This bill proposes to reduce drug payments to 85% of AWP for two years and then to convert to a market based price (of unspecified origin). Some of the relevant sections are:

‘SEC. 433. BASING MEDICARE PAYMENTS FOR COVERED OUTPATIENT DRUGS ON MARKET PRICES.

`(4)(A) Subject to subparagraph (C), the payment amount specified in this paragraph for a year for a drug or biological is an amount equal to the lesser of--

> `(i) the average wholesale price for the drug or biological; or
>
> `(ii) the amount determined under subparagraph (B)

`(B)(i) Subject to clause (ii), the amount determined under this subparagraph is an amount equal to--

> `(I) in the case of a drug or biological furnished in 2004, 85 percent of the average wholesale price for the drug or biological (determined as of April 1, 2003); and
>
> `(II) in the case of a drug or biological furnished in 2005 or a subsequent year, the amount determined under this subparagraph for the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

`(C)(i) The Secretary shall establish a process under which the Secretary determines, for such drugs or biologicals as the Secretary determines appropriate, whether the widely available market price to physicians or suppliers for the drug or biological furnished in a year is different from the payment amount established under subparagraph (B) for the year. Such determination shall be based on the information described in clause (ii) as the Secretary determines appropriate.

`(ii) The information described in this clause is the following information:

> `(I) Any report on drug or biological market prices by the Inspector General of the Department of Health and Human Services or the Comptroller General of the United States that is made available after December 31, 1999.

`(II) A review of drug or biological market prices by the Secretary, which may include information on such market prices from insurers, private health plans, manufacturers, wholesalers, distributors, physician supply houses, specialty pharmacies, group purchasing arrangements, physicians, suppliers, or any other source the Secretary determines appropriate.

`(III) Data and information submitted by the manufacturer of the drug or biological or by another entity.

`(IV) Other data and information as determined appropriate by the Secretary.

`(iii) If the Secretary makes a determination under clause (i) with respect to the widely available market price for a drug or biological for a year, the following provisions shall apply:

`(I) Subject to clause (iv), the amount determined under this subparagraph shall be substituted for the amount determined under subparagraph (B) for purposes of applying subparagraph (A)(ii)(I) for the year and all subsequent years.

`(II) The Secretary may make subsequent determinations under clause (i) with respect to the widely available market price for the drug or biological.

`(III) If the Secretary does not make a subsequent determination under clause (i) with respect to the widely available market price for the drug or biological for a year, the amount determined under this subparagraph shall be an amount equal to the amount determined under this subparagraph for the previous year increased by the percentage increase described in subparagraph (B)(i)(II) for the year involved.[46]

`(5) `(E) The amount specified in this paragraph for a drug or biological for the year beginning after the year described in subparagraph (D) and each subsequent year is equal to the lesser of--

`(i) the average wholesale price for the drug or biological; or

`(ii) the amount determined--

`(I) by the Secretary under paragraph (4)(C)(i) with respect to the widely available market price for the drug or biological for the year, if such paragraph was applied by substituting `the payment determined under paragraph (5)(E)(ii)(II) for the year' for `established under subparagraph (B) for the year'; and

`(II) if no determination described in subclause (I) is made for the drug or biological for the year, under this subparagraph with respect to the drug or biological for the previous year increased by the percentage increase described in paragraph (4)(B)(i)(II) for the year involved.'.

S1 also makes provision for some adjustment of professional fee payments, but these are essentially based upon the CMS interpretation of the ASCO Gallup Survey, which is already known to be based upon outdated methodologies and policies that do not reflect the current cancer care delivery system. Some of the relevant sections are as follows:

‘(b) ADJUSTMENTS TO PAYMENT AMOUNTS FOR ADMINISTRATION OF DRUGS AND BIOLOGICALS-

(1) ADJUSTMENT IN PHYSICIAN PRACTICE EXPENSE RELATIVE VALUE UNITS- Section 1848(c)(2) (42 U.S.C. 1395w-4(c)(2)) is amended--

(A) in subparagraph (B)--

(i) in clause (ii)(II), by striking `The adjustments' and inserting `Subject to clause (iv), the adjustments'; and

(ii) by adding at the end the following new clause:

`(iv) EXEMPTION FROM BUDGET NEUTRALITY IN 2004- Any additional expenditures under this part that are attributable to subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2004.'; and

(B) by adding at the end the following new subparagraph:

`(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR DRUG ADMINISTRATION SERVICES FOR 2004- In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished in 2004, the Secretary shall, in determining practice expense relative value units under this subsection, utilize a survey submitted to the Secretary as of January 1, 2003, by a physician specialty organization pursuant to section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 if the survey--

`(i) covers practice expenses for oncology administration services; and

`(ii) meets criteria established by the Secretary for acceptance of such surveys.'.

(2) PAYMENT FOR MULTIPLE CHEMOTHERAPY AGENTS FURNISHED ON A SINGLE DAY THROUGH THE PUSH TECHNIQUE-

(A) REVIEW OF POLICY- The Secretary shall review the policy, as in effect on the date of enactment of this Act, with respect to payment under section 1848 of the Social Security Act (42 U.S.C. 1395w-4) for the administration of more than 1 anticancer chemotherapeutic agent to an individual on a single day through the push technique.

(B) MODIFICATION OF POLICY- After conducting the review under subparagraph (A), the Secretary shall modify such payment policy if the Secretary determines such modification to be appropriate.

(C) EXEMPTION FROM BUDGET NEUTRALITY UNDER PHYSICIAN FEE SCHEDULE- If the Secretary modifies such payment policy pursuant to subparagraph (B), any increased expenditures under title XVIII of the Social Security Act resulting from such modification shall be treated as additional expenditures attributable to subparagraph (H) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w-4(c)(2)), as added by paragraph (1)(B), for

purposes of applying the exemption to budget neutrality under subparagraph (B)(iv) of such section, as added by paragraph (1)(A).

(3) TREATMENT OF OTHER SERVICES CURRENTLY IN THE NONPHYSICIAN WORK POOL- The Secretary shall make adjustments to the nonphysician work pool methodology (as such term is used in the final rule promulgated by the Secretary in the Federal Register on December 31, 2002 (67 Fed. Reg. 251)), for the determination of practice expense relative value units under the physician fee schedule under section 1848(c)(2)(C)(ii) of the Social Security Act (42 U.S.C. 1395w-4(c)(2)(C)(ii)), so that the practice expense relative value units for services determined under such methodology are not disproportionately reduced relative to the practice expense relative value units of services not determined under such methodology, as a result of the amendments to such Act made by paragraph (1).'[47]

The consequences that would occur from passage of this S1 version of cancer payment reform are simple, and would be fairly immediate. Physician practices would be paid less than their cost of acquiring oncology drugs, and at about 25 to 45 cents on the dollar for the costs of services essential to the treatment of cancer in the physician office setting. Physicians would be forced to choose to send their patients to a hospital based cancer program, if one were still open in the community, or further away for care if the local hospital had closed its cancer treatment center.

An industry analysis of the impact of drug reimbursement margins set at 85% of AWP, shows that most cancer drugs cost more than the reimbursement rate. This version of S1 would drop drug reimbursement immediately down to a level where most oncology drugs would be reimbursed below most physician office's costs of acquisition. The following table is an excerpt from a national oncology practice survey conducted in early 2003. It shows the margin at two percentages of Redbook AWP for one practice left on a drug after paying for just the raw cost of the drug. The margin expressed as a percentage can also be deceiving, because most drugs with margins above 10% are less costly, and even one dollar can move the percentages widely on lower cost drugs. It is important to note that the direct cost of a drug includes far more than the raw cost of the drug: in order to acquire drugs, there are also margins paid to drug distributors, staff (usually nurses or pharmacists) needed to inventory, order and restock the drugs, the time

cost of money to acquire and keep in inventory drugs costing hundreds of thousands of dollars, and breakage, wastage, and spillage caused in drug handling. Drugs must be stored in locked and often refrigerated storage areas and stocked at a level sufficient to handle the emergent needs of patients as well as the planned treatment regimens. It is obvious that an 85% of AWP proposal will not cover the total costs of acquiring and inventorying oncology drugs.

This S1 proposal does not identify which definition of AWP will be used. There are significant differences in defined AWP depending upon source. While there is recognition that prices may be changed upon review, the prices of drugs rise monthly, with no advance notification. Physician offices pay hundreds of thousands of dollars out of pocket across the country each month for price increases that can go unrecognized by Medicare or private insurers for 3 months to as much as 18 months. Physician offices incur the costs of drugs up front, and await reimbursement according to payor policies. Many payors change their prices paid for drugs annually, and payments are not adjusted back to the date of the price increase, leaving the physician office at risk for the cost of the increases.

Comparison of AWP margins for commonly used oncology drugs.48

Drug	*95% of AWP Margin*	*85% of AWP Margin*
Anzemet	62.20%	57.70%
Aranesp	13.80%	3.60%
Campath	4.40%	**-6.90%**
Paraplatin (Carboplatin)	4.00%	**-7.30%**
Doxil	8.20%	**-2.60%**
Doxorubicin	78.30%	75.70%
Gemzar	8.00%	**-2.90%**
Herceptin	7.80%	**-3.10%**
Hycamtin	4.40%	**-6.90%**
Irinotecan	9.30%	**-1.40%**
Leucovorin	90.70%	89.60%
Lupron Depot	53.60%	48.20%
Navelbine	4.40%	**-6.90%**
Neulasta	15.00%	5.00%
Neupogen	16.80%	7.10%
Oxaliplatin	6.60%	**-4.40%**
Pamidronate	65.40%	61.40%
Procrit	11.20%	0.80%
Remicade	12.20%	1.80%
Rituxan	7.20%	**-3.70%**
Sandostatin-LAR	5.80%	**-5.20%**
Taxol (Onxol)	80.70%	78.50%
Taxotere	19.80%	10.40%
Zofran	24.60%	15.80%
Zoladex	56.30%	51.10%
Zometa	11.10%	0.60%
Velcade	0.40%	**-11.30%**

Professional services fees under S1 are left to the interpretation of CMS. Without appropriate recognition and payment for the myriad of services that are essential to safe delivery of physician office based cancer care, the staff and resources that provide that care will be released and dismantled, respectively.

H1 is the version of the Medicare Prescription Drug and Modernization Act of 2003 that has gone through the most revisions prior to final printing, and yet is still missing several key points. This bill is the result of a compromise between the House Energy and Commerce Committee and the House Ways and Means Committee Subcommittee on Health. It includes two options for payment for oncology drugs, and recognizes the same professional fee revisions (based upon CMS analysis of the ASCO Gallup survey), but also brings up the potential for oncologists to bill under established codes now used by other specialties for equivalent activities in their own specialty. Since the initial adjustment for billing these additional codes would be funded from the "drug payment" savings, this reform would not have any effect on other specialties or the amounts they are paid currently.

At this point, it is appropriate to mention that cancer payment reform being considered is being considered as a "non-budget neutral" event by Congress, and probably also by the CMS Administration. Federal regulations dictate that all physician payments are gathered in a "physician work pool" and that any changes made within the pool remain budget neutral to Medicare – thus ensuring that an increase in one area is funded by a decrease in another area. However, this oncology reform is an entirely different case since the monies in question are already being spent in the aggregate as drug reimbursements. Any increase in oncology professional services payments will be balanced by a corresponding (if not larger) decrease in payments for oncology drugs. Congresswoman Nancy Johnson has often described the process as redefining the drug payments and moving those savings into a separate, protected pool, from which will flow the assigned dollars to repair the professional services adjustments. It appears to be generally recognized that appropriate cancer payment reform will not allow adjustment of drug payments without simultaneous correction in professional service payments. The amount of net savings that will be left over from that adjustment is the key issue at question.

In sequential years, adjustments to the oncology physician professional payments will be handled under the budget neutral regulations, as would adjustments for other specialties without special dispensation. Future adjustment for drug payments are subject to several models, none of which recognize the physicians purchase drugs on the open market and manufacturer price increases are born by the oncologists until such time as the reimbursement process reflects the amount of the increase. If successful reform creates a scenario where oncologists are paid at basically cost for

drugs, and also paid just enough to cover their costs of operations for the professional care, any reimbursement policy that doesn't reflect real-time market price adjustments for drug price changes will force physicians to incur significant losses when drug prices change.

The relevant sections of H1 to this analysis are presented below. The first section addresses a new concept for Medicare, the introduction of a competitive bidding award, which would result in a mandatory vendor imposition on oncology practices for Medicare oncology drugs.

`COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS

`SEC. 1847A. (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION-

`(1) IMPLEMENTATION OF PROGRAM-

`(A) IN GENERAL- The Secretary shall establish and implement a competitive acquisition program under which--

`(i) competitive acquisition areas are established throughout the United States for contract award purposes for acquisition of and payment for categories of covered outpatient drugs and biologicals (as defined in paragraph (2)) under this part;

`(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program or under section 1847B; and

`(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

`(B) IMPLEMENTATION- The Secretary shall implement the program so that the program applies to--

`(i) the oncology category beginning in 2005; and

`(ii) the non-oncology category beginning in 2006.

This section shall not apply in the case of a physician who elects section 1847B to apply.

`(C) WAIVER OF CERTAIN PROVISIONS- In order to promote competition, efficient service, and product quality, in carrying out the program the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

`(D) EXCLUSION AUTHORITY- The Secretary may exclude covered outpatient drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the drugs or biologicals (or class) are not appropriate for competitive bidding due to low volume of utilization by beneficiaries under this part or a unique mode or method of delivery or similar reasons.

`(2) COVERED OUTPATIENT DRUGS AND BIOLOGICALS, CATEGORIES, PROGRAM DEFINED- For purposes of this section--

`(A) COVERED OUTPATIENT DRUGS AND BIOLOGICALS DEFINED- The term `covered outpatient drugs and biologicals' means drugs and biologicals to which section 1842(o) applies and which are not covered under section 1847 (relating to competitive acquisition for items of durable medical equipment). Such term does not include the following:

`(i) Blood clotting factors.

`(ii) Drugs and biologicals furnished to individuals in connection with the treatment of end stage renal disease.

`(iii) Radiopharmaceuticals.

`(iv) Vaccines.

`(B) 2 CATEGORIES- Each of the following shall be a separate category of covered outpatient drugs and biologicals, as identified by the Secretary:

`(i) ONCOLOGY CATEGORY- A category (in this section referred to as the `oncology category') consisting of those covered outpatient drugs and biologicals that, as determined by the Secretary, are typically primarily billed by oncologists or are otherwise used to treat cancer.

`(ii) NON-ONCOLOGY CATEGORIES- Such numbers of categories (in this section referred to as the `non-oncology categories') consisting of covered outpatient drugs and biologicals not described in clause (i), and appropriate subcategories of such drugs and biologicals as the Secretary may specify.

`(C) PROGRAM- The term `program' means the competitive acquisition program under this section.

`(D) COMPETITIVE ACQUISITION AREA; AREA- The terms `competitive acquisition area' and `area' mean an appropriate geographic region established by the Secretary under the program.

`(E) CONTRACTOR- The term `contractor' means an entity that has entered into a contract with the Secretary under this section.

`(3) APPLICATION OF PROGRAM PAYMENT METHODOLOGY- With respect to covered outpatient drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has not elected section 1847B to apply--

`(A) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

`(B) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the beneficiary involved; and

`(C) the payment under this section (and related coinsurance amounts) for such drugs and biologicals--

`(i) shall be made only to such contractor;

`(ii) shall be conditioned upon the administration of such drugs and biologicals; and

`(iii) shall be based on the average of the bid prices for such drugs and biologicals in the area, as computed under subsection (d).

The Secretary shall provide a process for recoupment in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

`(4) CONTRACT REQUIRED-

`(A) IN GENERAL- Payment may not be made under this part for covered outpatient drugs and biologicals prescribed by a physician who has not elected section 1847B to apply within a category and a competitive acquisition area with respect to which the program applies unless--

`(i) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and area; and

`(ii) the physician has elected such contractor under paragraph (5) for such category and area.

`(B) PHYSICIAN CHOICE- Subparagraph (A) shall not apply for a category of drugs for an area if the physician prescribing the covered outpatient drug in such category and area has elected to apply section 1847B instead of this section.

`(5) CONTRACTOR SELECTION PROCESS-

`(A) IN GENERAL- The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of covered outpatient drugs and biologicals for an area, by physicians prescribing such drugs and biologicals in the area of the contractor under this section that will supply the drugs and biologicals within that category and area. Such selection shall also include the election described in section 1847B(a).

`(B) INFORMATION ON CONTRACTORS- The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Department's Internet website or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

`(C) SELECTING PHYSICIAN DEFINED- For purposes of this section, the term `selecting physician' means, with respect to a contractor and category and competitive acquisition area, a physician who has not elected

section 1847B to apply and has selected to apply under this section such contractor for such category and area.

`(b) PROGRAM REQUIREMENTS-

`(1) CONTRACT FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS- The Secretary shall conduct a competition among entities for the acquisition of a covered outpatient drug or biological within each HCPCS code within each category for each competitive acquisition area.

`(2) CONDITIONS FOR AWARDING CONTRACT-

`(A) IN GENERAL- The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of covered outpatient drugs and biologicals within a category unless the Secretary finds that the entity meets all of the following with respect to the contract period involved:

`(i) CAPACITY TO SUPPLY COVERED OUTPATIENT DRUG OR BIOLOGICAL WITHIN CATEGORY-

`(I) IN GENERAL- The entity has sufficient arrangements to acquire and to deliver covered outpatient drugs and biologicals within such category in the area specified in the contract at the bid price specified in the contract for all physicians that may elect such entity.

`(II) SHIPMENT METHODOLOGY- The entity has arrangements in effect for the shipment at least 5 days each week of covered outpatient drugs and biologicals under the contract and for the timely delivery (including for

emergency situations) of such drugs and biologicals in the area under the contract.

`(ii) QUALITY, SERVICE, FINANCIAL PERFORMANCE AND SOLVENCY STANDARDS- The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including--

`(I) the establishment of procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries regarding the shipment of covered outpatient drugs and biologicals; and

`(II) a grievance process for the resolution of disputes.

`(B) ADDITIONAL CONSIDERATIONS- The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon--

`(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

`(ii) the exclusion of the entity under section 1128 from participation under this title.

`(C) APPLICATION OF MEDICARE PROVIDER OMBUDSMAN- For provision providing for a program-wide Medicare Provider Ombudsman to review complaints, see section 1868(b), as added by section 923 of the Medicare Prescription Drug and Modernization Act of 2003.

`(3) AWARDING MULTIPLE CONTRACTS FOR A CATEGORY AND AREA- In order to provide a choice of at least 2 contractors in each competitive acquisition area for a category of drugs and biologicals, the Secretary may limit

(but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

`(A) The bid prices for covered outpatient drugs and biologicals within the category and area.

`(B) Bid price for distribution of such drugs and biologicals.

`(C) Ability to ensure product integrity.

`(D) Customer service.

`(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

`(F) Such other factors as the Secretary may specify.

`(4) TERMS OF CONTRACTS-

`(A) IN GENERAL- A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

`(B) PERIOD OF CONTRACTS- A contract under this section shall be for a term of 2 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

`(C) INTEGRITY OF DRUG AND BIOLOGICAL DISTRIBUTION SYSTEM- The Secretary--

`(i) shall require that for all drug and biological products distributed by a contractor under this section be acquired directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

`(ii) may require, in the case of such products that are particularly susceptible to counterfeit or diversion, that the contractor comply with such additional product integrity safeguards as may be determined to be necessary.

`(D) IMPLEMENTATION OF ANTI-COUNTERFEITING, QUALITY, SAFETY, AND RECORD KEEPING REQUIREMENTS- The Secretary shall require each contractor to implement (through its officers, agents, representatives, and employees) requirements relating to the storage and handling of covered outpatient drugs and biologicals and for the establishment and maintenance of distribution records for such drugs and biologicals. A contract under this section may include requirements relating to the following:

`(i) Secure facilities.

`(ii) Safe and appropriate storage of drugs and biologicals.

`(iii) Examination of drugs and biologicals received and dispensed.

`(iv) Disposition of damaged and outdated drugs and biologicals.

`(v) Record keeping and written policies and procedures.

`(vi) Compliance personnel.

`(E) COMPLIANCE WITH CODE OF CONDUCT AND FRAUD AND ABUSE RULES- Under the contract--

`(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

`(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

`(F) DIRECT DELIVERY OF DRUGS AND BIOLOGICALS TO PHYSICIANS- Under the contract the contractor shall only supply covered outpatient drugs and biologicals directly to the selecting physicians and not directly to beneficiaries, except under circumstances and settings where a beneficiary currently receives a drug or biological in the beneficiary's home or other non-physician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not--

`(i) require a physician to submit a prescription for each individual treatment; or

`(ii) change a physician's flexibility in terms of writing a prescription for drugs for a single treatment or a course of treatment.

`(5) PERMITTING ACCESS TO DRUGS AND BIOLOGICALS- The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous sentence shall apply if the physicians can demonstrate to the Secretary all of the following:

`(A) The drugs or biologicals are required immediately.

`(B) The physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals.

`(C) The contractor could not deliver to the physician the drugs or biologicals in a timely manner.

`(D) The drugs or biologicals were administered in an emergency situation.

`(6) CONSTRUCTION- Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

`(c) BIDDING PROCESS-

`(1) IN GENERAL- In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the prices bid to acquire and supply the covered outpatient drugs and biologicals for that category and area and the other factors referred to in subsection (b)(3).

`(2) PRICES BID- The prices bid by an entity under paragraph (1) shall be the prices in effect and available for the supply of contracted drugs and biologicals in the area through the entity for the contract period.

`(3) REJECTION OF CONTRACT OFFER- The Secretary shall reject the contract offer of an entity with respect to a category of drugs and biologicals for an area if the Secretary estimates that the prices bid, in the aggregate on average, would exceed 100 percent of the average sales price (as determined under section 1847B).

`(4) BIDDING ON A NATIONAL OR REGIONAL BASIS- Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

`(5) UNIFORMITY OF BIDS WITHIN AREA- The amount of the bid submitted under a contract offer for any covered outpatient drug or biological for an area shall be the same for that drug or biological for all portions of that area.

`(6) CONFIDENTIALITY OF BIDS- The provisions of subparagraph (D) of section 1927(b)(3) shall apply to a bid submitted in a contract offer for a covered outpatient drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference--

> `(A) in that subparagraph to a `manufacturer or wholesaler' is deemed a reference to a `bidder' under this section;
>
> `(B) in that section to `prices charged for drugs' is deemed a reference to a `bid' submitted under this section; and
>
> `(C) in clause (i) of that section to `this section', is deemed a reference to `part B of title XVIII'.

`(7) INCLUSION OF COSTS- The bid price submitted in a contract offer for a covered outpatient drug or biological shall--

> `(A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and
>
> `(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

`(8) PRICE ADJUSTMENTS DURING CONTRACT PERIOD; DISCLOSURE OF COSTS- Each contract awarded shall provide for--

`(A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

`(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

`(d) COMPUTATION OF AVERAGE BID PRICES FOR A CATEGORY AND AREA-

`(1) IN GENERAL- For each year or other contract period for each covered outpatient drug or biological and area with respect to which a competition is conducted under the program, the Secretary shall compute an area average of the bid prices submitted, in contract offers accepted for the category and area, for that year or other contract period.

`(2) SPECIAL RULES- The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section 1847B to the use of a price for specific covered outpatient drugs and biologicals in the following cases:

`(A) NEW DRUGS AND BIOLOGICALS- A covered outpatient drug or biological for which an average bid price has not been previously determined.

`(B) OTHER CASES- Such other exceptional cases as the Secretary may specify in regulations, such as oral drugs under section 1861(s)(2)(Q) and immmunosuppressives under section 1861(s)(2)(J).

`(e) COINSURANCE-

`(1) IN GENERAL- Coinsurance under this part with respect to a covered outpatient drug or biological for which payment is payable under this section shall be based on 20 percent of the payment basis under this section.

`(2) COLLECTION- Such coinsurance shall be collected by the contractor that supplies the drug or biological involved and, subject to subsection (a)(3)(B), in the same manner as coinsurance is collected for durable medical equipment under this part.

`(f) SPECIAL PAYMENT RULES-

`(1) IN GENERAL- The Secretary may not provide for an adjustment to reimbursement for covered outpatient drugs and biologicals unless adjustments to the practice expense payment adjustment are made on the basis of supplemental surveys under section 1848(c)(2)(H)(ii) of the Social Security Act, as added by subsection (a)(1)(B).

(2) USE IN EXCLUSION CASES- If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D), the Secretary may provide for reimbursement to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1847B.

`(3) COORDINATION RULES- The provisions of section 1842(h)(3) shall apply to a contractor with respect to covered outpatients drugs and biologicals supplied by that contractor in the same manner as they apply to a participating supplier. In order to administer this section, the Secretary may condition payment under this part to a person for the administration of a drug or biological supplied under this section upon person's provision of information on such administration.

`(4) APPLICATION OF REQUIREMENT FOR ASSIGNMENT- For provision requiring assignment of claims for covered outpatient drugs and biologicals, see section 1842(o)(3).

`(5) PROTECTION FOR BENEFICIARY IN CASE OF MEDICAL NECESSITY DENIAL- For protection of beneficiaries against liability in the case of medical necessity determinations, see section 1842(b)(3)(B)(ii)(III).

`(6) PHYSICIAN ROLE IN APPEALS PROCESS- The Secretary shall establish a procedure under which a physician who prescribes a drug or biological for which payment is made under this section has appeal rights that are similar to those provided to a physician who prescribes durable medical equipment or a laboratory test.

`(g) ADVISORY COMMITTEE- The Secretary shall establish an advisory committee that includes representatives of parties affected by the program under this section, including physicians, specialty pharmacies, distributors, manufacturers, and beneficiaries. The committee shall advise the Secretary on issues relating to the effective implementation of this section.

`(h) ANNUAL REPORTS- The Secretary shall submit to Congress an annual report in each of 2005, 2006, and 2007, on the program. Each such report shall include information on savings, reductions in cost-sharing, access to covered outpatient drugs and biologicals, the range of choices of contractors available to providers, and beneficiary and provider satisfaction.[49]

Competitive bidding is a model that might work well for non-oncology drugs, but has too many issues within the implementation and execution of the concept to be safely adapted for use with toxic oncology drugs being used in chemotherapy treatments. The problems with mandatory vendor imposition are multiple and will be discussed in a section following this one sharing the details of the proposals.

The next section of the H1 bill presents as an alternative to the mandatory vendor imposition model, an acquisition pricing model. **The details in execution of this model, if corrected, could become a workable solution for both Medicare and the oncology community.**

`OPTIONAL USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

`SEC. 1847B. (a) IN GENERAL-

`(1) ELECTION- In connection with the annual election made by a physician under section 1847A(a)(5), the physician may elect to apply this section to the payment for covered outpatient drugs and biologicals instead of the payment methodology under section 1847A.

`(2) IMPLEMENTATION- This section shall be implemented with respect to categories of covered outpatient drugs and biologicals described in section 1847A(a)(2)(B).

`(3) COVERED OUTPATIENT DRUGS AND BIOLOGICALS DEFINED- For purposes of this section, the term `covered outpatient drugs and biologicals' has the meaning given such term in section 1847A(a)(2)(A).

`(b) COMPUTATION OF PAYMENT AMOUNT-

`(1) IN GENERAL- If this section applies with respect to a covered outpatient drug or biological, the amount payable for the drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance--

`(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 100 percent (or in the case of covered outpatient drugs and biologicals furnished during 2005 and 2006, 112 percent) of the amount determined under paragraph (3); or

`(B) in the case of a single source drug (as defined in subsection (c)(6)(D)), 100 percent (or in the case of covered outpatient drugs and biologicals furnished during 2005 and 2006, 112 percent) of the amount determined under paragraph (4).

`(2) SPECIFICATION OF UNIT-

`(A) SPECIFICATION BY MANUFACTURER- The manufacturer of a covered outpatient drug shall specify the unit associated with each

National Drug Code as part of the submission of data under section 1927(b)(3)(A)(iii).

`(B) UNIT DEFINED- In this section, the term `unit' means, with respect to a covered outpatient drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.

`(3) MULTIPLE SOURCE DRUG- For all drug products included within the same multiple source drug, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) computed as follows:

`(A) Compute the sum of the products (for each national drug code assigned to such drug products) of--

`(i) the manufacturer's average sales price (as defined in subsection (c)); and

`(ii) the total number of units specified under paragraph (2) sold, as reported under section 1927(b)(3)(A)(iii).

`(B) Divide the sum computed under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all national drug codes assigned to such drug products.

`(4) SINGLE SOURCE DRUG- The amount specified in this paragraph for a single source drug is the lesser of the following:

`(A) MANUFACTURER'S AVERAGE SALES PRICE- The manufacturer's average sales price for a national drug code, as computed using the methodology applied under paragraph (3).

`(B) WHOLESALE ACQUISITION COST (WAC)- The wholesale acquisition cost (as defined in subsection (c)(6)(B)) reported for the single source drug.

`(5) BASIS FOR DETERMINATION- The payment amount shall be determined under this subsection based on information reported under subsection (e) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

`(c) MANUFACTURER'S AVERAGE SALES PRICE-

`(1) IN GENERAL- For purposes of this subsection, subject to paragraphs (2) and (3), the manufacturer's `average sales price' means, of a covered outpatient drug for a NDC code for a calendar quarter for a manufacturer for a unit--

`(A) the manufacturer's total sales (as defined by the Secretary in regulations for purposes of section 1927(c)(1)) in the United States for such drug in the calendar quarter; divided by

`(B) the total number of such units of such drug sold by the manufacturer in such quarter.

`(2) CERTAIN SALES EXEMPTED FROM COMPUTATION- In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

`(A) SALES EXEMPT FROM BEST PRICE- Sales exempt from the inclusion in the determination of `best price' under section 1927(c)(1)(C)(i).

`(B) SALES AT NOMINAL CHARGE- Such other sales as the Secretary identifies by regulation as sales to an entity that are nominal in price or do not reflect a market price paid by an entity to which payment is made under this section.

`(3) SALE PRICE NET OF DISCOUNTS- In calculating the manufacturer's average sales price under this subsection, such price shall be determined taking into account volume discounts, prompt pay discounts, cash discounts, the free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927), that result in a reduction of the cost to the purchaser. A rebate to a payor or other entity that does not take title to a covered outpatient drug shall not be taken into account in determining such price unless the manufacturer has an agreement with the payor or other entity under which the purchaser's price for the drug is reduced as a consequence of such rebate.

`(4) AUTHORITY TO DISREGARD AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES- In the case of a covered outpatient drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug is not sufficiently available from the manufacturer to compute an average sales price for the drug, the Secretary may determine the amount payable under this section for the drug without considering the manufacturer's average sales price of that manufacturer for that drug.

`(5) FREQUENCY OF DETERMINATIONS-

> `(A) IN GENERAL ON A QUARTERLY BASIS- The manufacturer's average sales price, for a covered outpatient drug of a manufacturer, shall be determined by such manufacturer under this subsection on a quarterly basis. In making such determination insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology established by the Secretary based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks.
>
> `(B) UPDATES IN RATES- The payment rates under subsection (b)(1) and (b)(2)(A) shall be updated by the Secretary on a quarterly basis and

shall be applied based upon the manufacturer's average sales price determined for the most recent calendar quarter.

`(C) USE OF CONTRACTORS; IMPLEMENTATION- The Secretary may use a carrier, fiscal intermediary, or other contractor to determine the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program memorandum or otherwise, any of the provisions of this section.

`(6) DEFINITIONS AND OTHER RULES- In this section:

`(A) MANUFACTURER- The term `manufacturer' means, with respect to a covered outpatient drug, the manufacturer (as defined in section 1927(k)(5)) whose national drug code appears on such drug.

`(B) WHOLESALE ACQUISITION COST- The term `wholesale acquisition cost' means, with respect to a covered outpatient drug, the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data.

`(C) MULTIPLE SOURCE DRUG- The term `multiple source drug' means, for a calendar quarter, a covered outpatient drug for which there are 2 or more drug products which--

`(i) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of `Approved Drug Products with Therapeutic Equivalence Evaluations'),

`(ii) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

`(iii) are sold or marketed in the United States during the quarter.

`(D) SINGLE SOURCE DRUG- The term `single source drug' means a covered outpatient drug which is not a multiple source drug and which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application, or which is a biological.[50]

The H1 approach to payment for professional services is basically the same as is used in S1, in that it refers back to the CMS adjustments planned from analysis of the ASCO Gallup survey. Congresswoman Johnson is working with the House leaders on an amendment to bring in the other "expedited coding" for oncologists, but the first draft of the amendment was very rough and a more current copy of the working document is not yet publicly available. Below is the H1 section addressing professional fees.

‘SEC. 303. COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS.

(a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE-

(1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE VALUE UNITS- Section 1848(c)(2) (42 U.S.C. 1395w-4(c)(2)) is amended--

(A) in subparagraph (B)--

(i) in clause (ii)(II), by striking `The adjustments' and inserting `Subject to clause (iv), the adjustments'; and

(ii) by adding at the end of subparagraph (B), the following new clause:

`(iv) EXCEPTION TO BUDGET NEUTRALITY- The additional expenditures attributable to clauses (ii) and (iii) of subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2005.'; and

(B) by adding at the end the following new subparagraph:

`(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR 2005-

`(i) IN GENERAL- As part of the annual process of establishing the physician fee schedule under subsection (b) for 2005, the Secretary shall increase the practice expense relative value units for 2005 consistent with clauses (ii) and (iii).

`(ii) USE OF SUPPLEMENTAL SURVEY DATA- For 2005 for any specialty that submitted survey data that included expenses for the administration of drugs and biologicals for which payment is made under section 1842(o) (or section 1847A), the Secretary shall use such supplemental survey data in carrying out this subparagraph insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and insofar as such data are submitted to the Secretary by December 31, 2004.

`(iii) PROVISIONS FOR APPROPRIATE REPORTING AND BILLING FOR PHYSICIANS' SERVICES ASSOCIATED WITH THE ADMINISTRATION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS-

`(I) EVALUATION OF CODES- The Secretary shall promptly evaluate existing codes for physicians' services associated with the administration of covered outpatient drugs and biologicals (as defined in section 1847A(a)(2)(A)) to ensure accurate reporting and billing for such services.

`(II) USE OF EXISTING PROCESSES- In carrying out subclause (I), the Secretary shall use existing processes for the consideration of coding changes and, to the extent coding changes are made, shall use such processes in establishing relative values for such services.

`(III) IMPLEMENTATION- In carrying out subclause (I), the Secretary shall consult with representatives of physician specialties affected by the implementation of section 1847A or section 1847B, and shall take such steps within the Secretary's authority to expedite such considerations under subclause (II).

`(iv) SUBSEQUENT, BUDGET NEUTRAL ADJUSTMENTS PERMITTED- Nothing in this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2005.

`(v) CONSULTATION- Before publishing the notice of proposed rulemaking to carry out this subparagraph, the Secretary shall consult with the Comptroller General of the United States and with groups representing the physician specialties involved.

`(vi) TREATMENT AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION- The

enactment of subparagraph (B)(iv) and this subparagraph shall be treated as a change in law for purposes of applying subsection (f)(2)(D).'.

(2) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL REVIEW- Section 1848(i)(1) (42 U.S.C. 1395w-4(i)(1)) is amended--

(A) by striking `and' at the end of subparagraph (D);

(B) by striking the period at the end of subparagraph (E) and inserting `, and'; and

(C) by adding at the end the following new subparagraph:

`(F) adjustments in practice expense relative value units for 2005 under subsection (c)(2)(H).'.

(3) TREATMENT OF OTHER SERVICES CURRENTLY IN THE NON-PHYSICIAN WORK POOL- The Secretary shall make adjustments to the non-physician work pool methodology (as such term is used in the regulations promulgated by the Secretary in the Federal Register as of December 31, 2002) for determination of practice expense relative value units under the physician fee schedule described in section 1848(c)(2)(C)(ii) of the Social Security Act so that the practice expense relative value units for services determined under such methodology are not affected relative to the practice expense relative value units of other services not determined under such non-physician work pool methodology, as the result of amendments made by paragraph (1).'[51]

These two bills (H1 and S1) are being discussed in conference actively at the moment, and there has been no public disclosure of movement on various issues. All that the oncology community can do at the moment is to point out the details of the elements of the proposals which will lead to the dismantling of cancer care in the community, and to be available to collaborate on achieving better solutions.

Medicare has published a Notice of Proposed Rulemaking (NPRM) which outlines four different proposals for a CMS-implemented solution to the pricing of oncology drug payments. The continual threat is made that CMS will implement one of these solutions (pending review of comments received by October 14, 2003) as of January 1, 2004, unless Congress passes legislation that preempts an Administrative solution. In fact, both the Senate and the House bills include such language – but the current House bill has an inaccurate date preempting action after January 1, 2005.

The most relevant sections of the CMS NPRM are as follows:

> 'Given the serious and well documented flaws in the current Medicare payment system identified by the GAO, OIG, and our own analyses, we are seeking comments on four different approaches to revising the Medicare drug payment system:
>
> (1) Basing our reform efforts on the comparability provision in the statute;
>
> (2) applying an average list AWP discount to the list AWPs as of April 1, 2003;
>
> (3) utilizing existing sources of market-based prices and developing additional sources for market monitoring; and
>
> (4) establishing a competitive acquisition program and Average Sales Price system. We are proposing to select one of these options.

Option 1—Comparability Provision

One option we are proposing is to base our reform efforts on the ''comparability'' provision in the Act, section 1842(b)(3)(B) of the Act. Specifically, this provision limits Medicare payment for a drug to what our contractors pay when the same drug is provided to their private policyholders and subscribers under comparable circumstances. As described below, we are proposing additional guidance to our contractors in identifying comparable circumstances with respect to the drug payments they make in their private sector business. While comparability applies to all charge-based services, we are proposing to focus its application on drugs given the excessive payments by the Medicare program and our beneficiaries under the current

methodology, as reflected in several OIG and GAO reports. Section 1842 of the Act authorizes us to enter into contracts with carriers for the administration of Part B benefits. Section 1842(b)(3) of the Act mandates that each contract with a carrier provide that the carrier: ‘‘* * * will take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to policyholders and subscribers of the carrier * * *.’’

Section 1842 of the Act sets forth general provisions applicable to part B payment determinations, including drug payments. The comparability provision requires a carrier to take action, when necessary, to ensure that Part B charges are reasonable and ‘‘not higher than the charge applicable for a comparable service in comparable circumstances’’ to its own policyholders. This limitation is a principle set forth by the Congress at the outset of the Medicare program, providing that Medicare beneficiaries should not be charged more than private pay patients for a comparable service provided under comparable circumstances. To this end, the Congress mandated that, where payment for a service to a Medicare beneficiary is on a charge basis, as opposed to a cost basis, the carrier’s private plan, if it has one, should be assessed to determine whether the service in question and the circumstances under which the service is provided are ‘‘comparable’’ to Medicare. If the service is comparable, then the applicable charge under the carrier’s private insurance plan may serve as a limitation on the amount that we pay. In accordance with these provisions, we have broad authority to make comparability adjustments with respect to Part B payment determinations based on charges. At the time the Congress legislated the current drug payment methodology, it did not amend our authority to make comparability adjustments or provide any indication that the other provisions of section 1842(b) of the Act with respect to Part B payment calculations were no longer applicable. Section 1842(b)(3) of the Act requires carriers, including Durable Medical Equipment Regional Carriers (DMERCs), to limit payment rates for Medicare covered drugs to the amounts that the carriers pay when these drugs are provided to their private policyholders and subscribers under comparable circumstances. We are proposing to issue additional guidance to our contractors indicating that comparability would exist with drug payments made in the same geographic area under the carrier’s indemnity health insurance products or broad network

preferred provider organization (PPO) products that do not rely on selective contracting. We are seeking comments on this proposed guidance. Consistent with § 405.508(c), the responsibility for determining that a carrier's indemnity product or PPO product is comparable would in the first instance fall upon the carrier in reporting pertinent information about its programs to us. When the pertinent information has been reported, we will advise the carrier whether any of its products has comparability. If we determine that a carrier's lower private payment for a drug has comparability in a given locality, the lower private payment limit would apply to the Medicare payment in that locality. Contractors would inform physicians, suppliers and other impacted parties about the new lower payment limit through their usual means of provider education (for example, bulletins, newsletters, Web site postings.)

As an example of how this approach would apply to a specific drug using hypothetical data, we will examine docetaxol (J9170). Suppose the national payment limit for docetaxol in 2004 was $358. If one of our carriers was paying $325 for docetaxol in one of its localities in its comparable private side business, the Medicare payment limit for docetaxol in that locality would be set at $325. This lower payment amount would only apply in that locality and would not be the national payment limit. If, however, the carrier was paying $375 for docetaxol in this locality, the Medicare payment would be based on the current national limit of $358. We understand that to the extent private sector drug payments vary by geographic region, the application of comparability may result in regional variation in drug payments. We seek comment on this aspect of the policy. It is our understanding that historically many private insurers have focused more on payments for oral drugs and inhalation drugs than injectable drugs, although this is changing due to the rapid growth in expenditures for injectable drugs. MedPAC discussed this in their June 2003 report to Congress titled ''Report to the Congress: Variation and Innovation in Medicare,'' which stated that ''Only as expenditures have sharply increased in the past few years have payers begun to focus on more efficient methods of paying for these drugs.'' We are seeking information on these new methods of paying for injectable drugs and comments on any implications for Medicare drug payment limits under the comparability provision.

Option 2—Average AWP Discount

a. Existing Drugs

Another option we are proposing is to apply an average AWP discount to the AWPs published in commercial compendia as of April 1, 2003. Specifically, we would lock-in and reduce the AWP published as of April 1, 2003 in the national drug pricing compendia by an average price discount from AWP. Our analysis of the available data from the GAO and OIG studies indicates that the majority of drugs examined had a discount of approximately 10 to 20 percent off of the AWP, with the remaining drugs having larger discounts. The Medicare payment limit, therefore, would be set at between 80 percent and 90 percent of the AWP published as of April 1, 2003. We are seeking comment on the appropriate uniform reduction to make in this range. This policy would be effective January 1, 2004. In future years, these prices would be updated on an annual basis by the increase in the consumer price index for medical care for the 12-month period ending June of the prior year.

As an example of how this approach might apply to a specific drug assuming an average AWP discount of 15 percent, we will again examine docetaxol (J9170). The April 1, 2003 AWP published in the commercial compendia for docetaxol is $377. Applying an average AWP discount of 15 percent, the Medicare 2004 payment limit for J9170 would be $320. Assuming a 4.0 percent increase in the consumer price index (CPI) for medical care for the 12-month period ending June 2004, the 2005 payment limit for J9170 would be $333, regardless of the list AWP at that time.

b. New Drugs and Drugs With Patent Expirations

The reimbursement rate for new drugs and drugs coming off of patent would be determined for the first year based on our review of information provided by the manufacturer about the expected widely available market price for that year. As a condition of obtaining a HCPCS code for billing purposes (in the case of new drugs) or continuing to recognize a HCPCS code for billing purposes (in the case of drugs coming off patent), manufacturers would be required to provide information on the anticipated widely available market price that a prudent physician or prudent supplier would pay for the drug and a rationale for the new price. We expect that drug manufacturers in the normal course of conducting their business have determined the prices that

physicians and suppliers would pay for the drug when sold through a distributor or via direct distribution. If we suspect that a manufacturer has knowingly supplied misleading pricing information to generate or maintain a ‘‘spread’’ between Medicare payment and the widely available market price, we will refer the matter to the OIG. As stated by the OIG in their Office of Inspector General’s Compliance Program Guidance for Pharmaceutical Manufacturers (68 FR 23737) that was published on May 5, 2003:

> ‘‘If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers’ profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller’s immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the ‘spread’ to induce customers to purchase its product.’’ During the first year the HCPCS code is used for billing, the manufacturer would provide updated information to us on the actual prices that physicians and suppliers are paying to purchase the drug. Again, we expect manufacturers would collect this information in the normal course of conducting their business.

We would review this data and other available data sources on the widely available market price of the drug to determine if an adjustment to the Medicare payment limit would be required for the second year. In the absence of a second year adjustment, the first year payment would be updated by the increase in the medical component of the CPI for the 12-month period ending six months prior to the year. For the third year and all subsequent years, the Medicare payment limit would be updated on an annual basis by the increase in the CPI for medical care for the 12-month period ending June of the prior year.

Option 3—Market Monitoring Another option we are proposing is to utilize existing sources of market-based prices in developing Medicare payment limits and to develop additional sources of

this information for market monitoring. Under this option, we would define AWP to be the widely available market price. Initially, we would use the market analyses available to us from GAO and OIG studies to transition widely available market prices into the Medicare payments. As discussed below, over time we may expand our data sources for these market prices. Although the GAO and OIG performed market analyses on drugs covering the majority of Medicare expenditures, they did not study all of the approximately 450 Medicare drugs. As described earlier in section I.B, Medicare drug spending is concentrated in relatively few drugs; 33 drugs account for 86 percent of the spending. Initially, for those drugs where we do not have GAO and OIG information on which to base a market price, we would proceed as in option 2 and base the payment limit on an average AWP discount off of the list AWP reported to the commercial compendia as of April 1, 2003.

a. Definition of Average Wholesale Price

In implementing sections 1842(o) of the Act and 429 of BIPA, we propose to define the AWP of a drug to be the widely available market price. The widely available market price would be the price that a prudent physician or prudent supplier would pay when purchasing the drug from common sources. Common sources that a prudent physician or supplier might utilize when purchasing a drug include, but are not limited to, wholesalers, manufacturers, repackagers, physician supply houses, pharmacies, specialty pharmacies, and group purchasing organizations. The widely available market price would not be a list price that is commonly discounted, but would be the purchase price net of discounts, rebates, and price concessions routinely available to prudent purchasers. The widely available market price would reflect prices in programs where a manufacturer, a manufacturer's subsidiary or related company, or a repackager sells drugs to physicians and suppliers directly or through buying groups or other mechanisms. For example, if a drug manufacturer establishes a buying group easily accessed by prudent physicians, the lower price offered to the buying group should be reflected as the widely available market price. It is not our intent to set the Medicare payment limit below the widely available market price. Under the current system, the Medicare allowed charge is the lower of the actual charge and 95 percent of the AWP. Using the authority granted to the Secretary under section 429(b) of BIPA, the Medicare allowed charge in a fully phased-in revised payment methodology would be the lower of the actual charge or the widely available market price. We would not pay at 95 percent of the

widely available market price since we wish to consider further the issue of beneficiary access at 95 percent of the widely available market price. As described in section II.D, we do not expect any beneficiary access issues with payment at the widely available market price.

b. Use of existing sources of market based prices

As described earlier in section I.F, both the GAO and OIG have performed market analyses of the widely available market prices for the top Medicare drugs in terms of expenditures. While the market analyses differed in their methodologies, for example the GAO used averages of drug prices from their data sources and the OIG used medians, in general the results were consistent for these drugs. To begin to incorporate this information into the Medicare payment limits for the drugs that have been studied, we would take the average discount between the GAO and OIG data for the drug and apply it to the list AWP reported in the published compendia as of April 1, 2003. Although as noted the results of the GAO and OIG market analyses are generally consistent, we seek comment on our proposed approach of averaging these two data sources. For example, one drug studied by both the GAO and OIG is rituximab (J9310). The April 1, 2003 list AWP published in the commercial compendia for rituximab is $501.13 for 100 mg. The GAO study indicates the average market price for rituximab is 81 percent of the list AWP. The OIG study indicates the average market price for rituximab is 80 percent of AWP. The average of these two data sources rounded to nearest percent is 81 percent of the list AWP. Under this option, the Medicare payment limit for J9310 would be $405.92 (that is, 81 percent of $501.13) effective January 1, 2004. Clotting factor was the subject of a separate GAO report entitled ‘‘Payment for Blood Clotting Factor Exceeds Providers’ Acquisition Costs’’ (GAO– 03–184). This report found that the market price for clotting factor was 59 percent of list AWP for hemophilia treatment centers and 69 percent of list AWP for homecare companies. We are proposing to transition these market prices into the Medicare payment limit for clotting factor at the average of these two figures, 64 percent, with an initial transition amount of 80 percent in 2004. (*see* section 3.f. for further discussion on the transition to market prices). We are requesting comments on the appropriate payment limit rate. The limit would apply for all clotting factor HCPCS codes, including both the human and recombinant forms.

c. Drugs Without Market-Based Price Information

Initially, for those drugs where we do not have GAO and OIG information on which to base a market price, we would proceed as in option 2 and base the payment limit on the average AWP discount off of the list AWP reported to the commercial compendia as of April 1, 2003. As an example of how this approach might apply to a specific drug assuming an average AWP discount of 15 percent, we will examine ifosfamide (J9208). The OIG and GAO did not study ifosfamide. The April 1, 2003 list AWP published in the commercial compendia for ifosfamide is $158. The Medicare payment limit for J9208 would be $135 (that is, 85 percent of $158) effective January 1, 2004.

d. Exceptions Process for First Year Reductions

A manufacturer could seek an exception from the application of these reductions on January 1, 2004 to one or more of its drugs if it would furnish us before October 1, 2003 with verifiable data on the widely available market price, as described earlier in section II.A.3.a, of the drug as of April 1, 2003 and certify the accuracy of this data. We will review the data and determine if it should be incorporated into the Medicare payment limit. Note that all data submitted as part of comments on this proposed rule would be available to the public. Also note that we would base any changes to our proposed payment policy only on data that we could make available to the public.

e. Future Years

As discussed in section 3.f below, we expect to develop additional sources of market-based prices in future years for the purpose of market monitoring. We also recognize that the OIG may perform updated market analyses on drugs previously studied or additional drugs. If the OIG performs a new market analysis, we expect to incorporate this information into the Medicare payment limits. As we develop additional sources of widely available market prices and sufficient new valid information becomes available from these sources, we expect to incorporate this information into the Medicare payment limits based on the methodology described above. In the absence of additional valid data sources indicating a change in the widely available market price, the Medicare payment limits would be updated on an annual basis by the increase in the CPI for medical care for the 12-month period ending June of the prior year.

f. Transition for Existing Drugs

For existing drugs where the widely available market price based on the OIG and GAO studies is less than 80 percent of list AWP, we would transition to the market-based payment in 15 percentage point increments. This is similar to the approach taken by the Congress in specifying the incremental payment changes under the inherent reasonableness authority (section 1842(b)(8) of the Act). For example, one drug studied by both the GAO and OIG is ipratropium bromide (J7644). The April 1, 2003 AWP published in the commercial compendia for ipratropium bromide is $3.52. The GAO study indicates the average market price for ipratropium bromide is 33 percent of list AWP. The OIG study indicates the average market price for ipratropium bromide is 34 percent of list AWP. The average of these two data sources rounded to the nearest percent is 34 percent of AWP. Because this is lower than 80 percent of list AWP, the Medicare payment limit for ipratropium bromide effective January 1, 2004 would be 80 percent of the list AWP or $2.82. The Medicare payment limit for ipratropium bromide effective January 1, 2005 would be 65 percent of the list AWP published in the commercial compendia as of April 1, 2003 updated by the medical CPI. The Medicare payment limits for CY 2006 and CY 2007 would be 50 percent and 35 percent, respectively, of the April 1, 2003 list AWP updated by the medical CPI. In 2008, the transition to the widely available market price would be complete and the payment limit would be 34 percent of the April 1, 2003 list AWP updated by the medical CPI. To the extent that the OIG performs a new market analysis or additional data sources are developed as described in section 3.h, the target widely available market price might change.

g. New Drugs and Drugs with Patent Expirations

The payment limit for new drugs and drugs coming off of patent would be determined as described under option 2.

The only difference would be that under the market monitoring approach the out year payment limit might change to the extent that the OIG performs a market analysis or additional data sources are developed as described in the next section.

h. Additional Sources of Market- Based Prices

We are considering additional sources of market-based price information. These sources could include drug distributors (for example, wholesalers, physician supply houses, specialty pharmacies, retail pharmacies, manufacturers, repackagers) physicians, suppliers, and group purchasing organizations (GPOs). To the extent that payments by private insurers and health plans reflect widely available market prices, we are considering inclusion of these sources. The general approach we will use is to take the median price among valid available sources of information on widely available market prices, after making any adjustments required to make the information comparable. We are considering whether to restrict the median calculation to those information sources that reflect significant market share. We are proposing to rely on a single information source if we determine that the source is representative of the widely available market price for a drug. We are considering the acquisition of this market-based price information through market research firms, contractors, consultants, the OIG, and/or by directly obtaining such data. If we obtain additional sources of market-based prices and if we determine these sources are valid for the purposes of determining payment limits based on widely available prices, we will provide an opportunity for public comment on the sources.

1. Data from Distributors and Manufacturers

We would seek to acquire data from drug distributors and manufacturers. Although there may be many distributors for a given drug, our understanding is that most physicians and suppliers tend to use the same distributors over a given time period and that the majority of these purchases, at least for injectable drugs, are concentrated in a small number of distributors. We are considering whether to focus our efforts initially on these distributors and we are seeking comment on this focused approach. Our market analyses would also include pricing information from manufacturers' direct distribution programs since, as discussed earlier, we understand that many of these programs are easily accessible to physicians and suppliers and that the prices offered in these programs are often lower than the prices available through other distribution channels.

2. Data From Physicians and Suppliers

We would also seek to obtain acquisition cost information from physician and suppliers. Although individual invoice pricing may not necessarily be reflective of the widely available

market price, for example due to the presence of volume related rebates and price concessions, this information could be informative in developing the widely available market price. While issues have been raised in the past concerning the use of invoice prices due to the potential presence of volume discounting, we note that the GAO study found that physicians who billed for low amounts of chemotherapy drugs were still able to obtain significant price discounts. We seek comment on this issue.

3. Data from Private Insurers and Health Plans

We are considering obtaining data from private insurers and health plans, including Medicare carriers' private businesses. As discussed earlier, it is our understanding that while many private insurers pay widely available market prices for oral drugs and inhalation drugs, they have not historically paid widely available market prices for injectable drugs. Given this, we are considering initially seeking private business prices for oral and inhalation drugs. For example, we are considering whether to request our four DMEPOS contractors to supply us with oral and inhalation drug pricing and related information from their private side business. For injectable drugs, as private insurers develop alternative payment approaches that reflect widely available market prices, we could seek this information from them. For example, similar to the approach suggested for oral and inhalation drugs, we are considering asking our carriers to furnish us with their private business payments for these drugs.

4. Approaches to Acquiring Market- Based Pricing Information

We are considering the acquisition of this market-based price information through market research firms, consultants, contractors, the OIG, and/or directly obtaining such data. It is our understanding that many manufacturers use market research firms to gather information on their products. For example, they conduct surveys of physician practices and compile pricing information. We are considering contracting with one of these firms to perform a market analysis of physician practices. We also understand that a few private health plans have begun to use consultants, at least for injectable drugs, to assist them in developing market based payment structures. We are considering contracting with these consultants. We are considering an attempt to obtain pricing information directly from distributors using full or part-time CMS employed or

contracted physicians. We are considering the selection of one or more contractors to acquire this information for us and maintain updated pricing information. The OIG may also update market analyses of drugs they have previously studied and examine additional drugs.

Option 4—Competitive Acquisition Program and Average Sales Prices

A fourth option we are considering is the establishment of a competitive acquisition program for drugs covered under section 1842(o) of the Act coupled with the establishment of a process for determining Average Sales Price (ASP). Under this option, we would establish competitive acquisition areas and entities would bid to supply drugs to physicians in one or more of these areas. A physician could choose annually to acquire drugs from one of these entities and the entity would be responsible for billing Medicare. Alternatively, a physician could choose to purchase drugs and bill Medicare. If a physician elected to purchase drugs, we would pay the physician the ASP for the drug. Manufacturers would be required to furnish us with the ASP for each of their drugs quarterly. This option is consistent with the GAO's recommendation that we evaluate expanding competitive bidding approaches to obtain lower drug prices (GAO–01 1118, p.5) and is consistent with our understanding of Congressional intent with respect to section 429 of BIPA. Below we describe our proposed competitive acquisition program and ASP-based payment systems. We seek comment on any additional elements that need to be considered in the establishment of these payment systems. We also note that for some drugs, such as those currently provided directly from the manufacturer to the physician, we may be potentially introducing an additional distribution level in the form of the bidding entity. Therefore, we have explicitly identified safeguards under the competitive acquisition program that are more implicit under our alternative payment reform proposals. While we believe that section 429 of BIPA contemplates (and section 1842(o) of the Act could be defined to permit) the use of such a competitive acquisition model, coupled with the implementation of an ASP setting function described below, we specifically solicit comments on the extent of the authority to implement the option set forth below either in its entirety or in a modified fashion.

A. Competitive Acquisition

1. Categories of Drugs

Under this proposal, we would bid two categories of drugs in each competitive acquisition area: oncology and non-oncology. The oncology category would consist of covered drugs typically billed by oncologists or otherwise used to treat cancer. The nononcology category would consist of all other covered drugs with the exception of DME drugs, clotting factors, drugs furnished to individuals in connection with the treatment of end stage renal disease, and vaccines. Payment for excepted drugs would be based on the ASP. We may propose subcategories of non-oncology drugs in the future. We seek comment on any additional categories of drugs that may be inappropriate for competitive bidding due to low utilization, a unique method of delivery, or similar reasons.

2. Bidding Entity Qualifications

a. Capacity Bidding entities would be required to demonstrate sufficient capacity to supply the drugs in the drug category in accordance with all applicable state requirements and pharmacy laws. The entity would need to have sufficient arrangements to acquire and to deliver drugs within the category at the bid price for all physicians that may elect such entity in a competitive acquisition area.

b. Shipment

Bidding entities would be required to have arrangements in effect for the shipment of drugs at least 5 days each week and for the timely delivery (including emergency situations) of drugs in the competitive acquisition area. The shipments would be made to the physician and not directly to the beneficiary, except under circumstances where a beneficiary currently receives the drug in the home or other nonphysician office setting. The contractor would not deliver drugs to a physician except upon receipt of a prescription.

c. Integrity of the distribution system.

Bidding entities would need to demonstrate that the drugs provided in the competitive acquisition program would be acquired directly from the manufacturer or from a distributor that has acquired the drugs directly from the manufacturer.

d. Inquiries and dispute resolution.

Bidding entities would be required to establish procedures for the prompt response and resolution of physician and beneficiary inquiries regarding the shipment of drugs and to establish a grievance process for the resolution of disputes. For disputes that are not resolved at the bidding entity, we propose to establish a national ombudsman to oversee and review complaints under the competitive acquisition program.

3. Bidding Process

a. Evaluation of bids.

We propose to select one or more winning bidders for each category based on the bid prices for the drugs, the ability to ensure product integrity, customer service, and past experience in the distribution of drugs. We also propose to reject any bid that we estimate would result in aggregate payments that exceed the payments that would have been made if the drugs in the category were paid at the ASP.

b. Timing of bidding process.

We expect to have the initial bidding process complete and the winning entities selected in time for the competitive acquisition program to be implemented for oncology drugs beginning in 2005 and non-oncology drugs beginning in 2006. We propose to select subsequent contractors on a periodic basis and seek comment on the appropriate time between bidding periods and the appropriate length of the contracts.

c. Bid prices.

The prices bid by an entity would be the prices in effect and available for the supply of contracted drugs in the area through the entity for the entire contract period. The bid price would not vary within a competitive acquisition area. The bid price would include all costs related to carrying out the contract provisions, including costs related to the delivery, dispensing, and shipping of the drug.

d. Bidding on a national or regional basis.

We would propose, but not require, entities to bid for contracts in more than one competitive acquisition area.

4. Competitive Acquisition Areas

We seek comment on the appropriate geographic regions to establish for a competitive acquisition program.

5. Billing and Coinsurance Under Competitive Acquisition

We propose that a successful bidder would be responsible for billing Medicare and collecting coinsurance for the drugs they supply that are subsequently administered to Medicare beneficiaries.

B. Average Sales Price

Under the competitive acquisition model option, a physician would make an annual election to obtain drugs in a given category through a winning bidder or could purchase the drugs and bill Medicare. If a physician chooses to purchase drugs, they would be paid under the ASP-based system described below. Manufacturers would be required to report the ASP to us on a quarterly basis.

1. Definition of Average Sales Price

Under this proposed option we would propose to define the ASP for a drug for a quarter as a manufacturer's total sales for the quarter less any sales exempted from the ASP calculation divided by the total number of units of such drug sold by the manufacturer in such quarter less any units from sales exempted from the ASP calculation. We seek comment on this definition as well as on the appropriate categories of sales that should be exempted from the ASP calculation.

2. Discounts

Under this proposal, in calculating the ASP, the manufacturer would take into account volume discounts, prompt pay discounts, cash discounts, the free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927), that result in a reduction of the cost to the purchaser. A rebate to a payor or other entity that does not take title to a covered outpatient drug shall not be taken into account in determining such price unless the manufacturer has an agreement with the payor or other entity under which the purchaser's price for the drug is reduced as a consequence of such rebate.

3. Payments.

We propose to pay for multi-source drugs at an appropriate markup above ASP and seek comment on a markup in the range of 101 to 112 percent of ASP. We propose to pay for single source drugs at the lesser of an appropriate markup of ASP in the range of 101 to 112 percent or the Wholesale Acquisition Cost (WAC). *Wholesale Acquisition Cost (WAC).* Under this competitive acquisition model option we would propose defining the WAC as the manufacturer's list price for the drug to wholesalers and direct purchasers in the United States as reported in wholesale price guides or other publications of drug pricing data. The WAC would not include prompt pay or other discounts, rebates or reductions in price.

B. Increases in Payments Related to the Costs of Furnishing or Administering Drugs

As described earlier, section 429(b) of BIPA requires us to revise the Medicare payment methodology for drugs under section 1842(o) of the Act based on the GAO report to the Congress. Under section 429(b), to the extent the Secretary determines appropriate, the Secretary may make adjustments to the practice expense component of the physician fee schedule for costs incurred in the administration, handling, or storage of certain categories of such drugs and biologicals. Section 429(b) also authorizes the Secretary to make proposals for new payments to providers of services or suppliers for such costs, if appropriate. However, the estimated aggregate payments for drugs under the revised system (including additional payments for related costs of furnishing or administering the drug) cannot exceed payments as projected by the Secretary under the current system.'[52]

CMS does go on to propose some limited changes in the professional service payments to physicians for the work done by the doctors and other medical professionals in the oncology offices during the course of treatment.

‘Below, we discuss payment issues associated with furnishing or administering Medicare covered drugs. To the extent appropriate, we are proposing increased payments for the administration of drugs or new payments to providers or suppliers for furnishing Medicare covered drugs and seek comment on the applicability of these payments under each of our four options for reforming the current payment system.

1. Proposed Changes in Physician Fee Schedule Payment for the Administration of Medicare Covered Drugs

a. SMS and Supplemental Survey Data

An important element in calculation of the practice expense relative value units (RVUs) for all services paid using the physician fee schedule is specialty specific practice expenses per hour of patient care. We use the American Medical Association’s (AMA’s) Socioeconomic Monitoring System (SMS) survey of actual aggregate cost data by specialty as the major source of data for these expenses per hour. However, not every specialty is included in the SMS data and several other specialties have commented that the SMS data were not adequately representative of the costs incurred by their specialty. (63 FR 58824–58826) Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) directed us to establish a process under which we would accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by organizations.

In an interim final rule published on May 3, 2000 (65 FR 25664) we set forth our criteria for accepting such supplemental surveys. In the December 31, 2002 **Federal Register** that contained the 2003 physician fee schedule final rule (67 FR 79972), in response to comments, we made some modifications to these criteria. In this year’s physician schedule proposed rule (68 FR 49030), we proposed changes to the deadline for submitting supplemental survey information to our contractor, the Lewin Group. Using the SMS data, we calculated a total practice expense per hour of $99.30 for oncology. We are currently using this practice expense per hour for CMS

specialty codes 83 (Hematology/ Oncology) and 90 (Medical Oncology). However, the American Society of Clinical Oncology (ASCO) submitted a supplemental survey in 2002 with a practice expense per hour of $189.00. In the 2003 physician fee schedule final rule (67 FR 79973), we discussed the practice expense survey submitted by the ASCO. Although the survey met our stated criteria, we did not use it in the calculation of the 2003 practice expense RVUs because of concerns about the data. Our contractor, the Lewin Group evaluated the data and indicated that average compensation (including salaries and fringes) for clinical and administrative staff reported in the ASCO survey averaged $71,014 and $87,253 respectively and appear inconsistent with other available data on wage rates for such staff. Furthermore, the Lewin Group indicated that the category of ‘‘other professional expenses’’ was 349 percent higher than the SMS survey. The Lewin Group suggested that we seek an explanation for the high values in the ASCO survey before incorporating it into the practice expense methodology.

In the December 31, 2002 physician fee schedule final rule we indicated that we intended to meet with ASCO to discuss our concerns and that we would consider using the data in the future if our concerns were addressed. We have subsequently held such discussions with ASCO and understand that the high values for average compensation for clinical and administrative staff are largely due to a limited number of practices with very high values that raise the average values calculated across all respondents to the survey. At this time, we are proposing to incorporate the survey into the methodology. Since our practice has been to use all survey data and not eliminate practices with high values, we are including all respondents in the supplemental practice expense per hour. As we note in more detail below, section 429(b) authorizes the Secretary to provide for adjustments to payments for the costs incurred in the administration of certain categories of drugs.

While we believe the provision allows the Secretary to make changes to practice expense payments in a nonbudget neutral manner, we also believe that it anticipates that the Secretary will make adjustments to payments for drug administration services at the same time the Secretary revises the payment methodology for drugs. Otherwise, we would be unable to compare the aggregate costs of the changes authorized by section 429. We are, therefore, proposing only to incorporate the oncology survey data into the practice expense methodology at the same time proposed changes in Medicare payment for drugs are adopted. ASCO, the GAO,

and OIG have all indicated that Medicare overpays for drugs and revisions to the payment methodology for drugs should coincide with increase in practice expense payments for drug administration services.

In testimony before the House Ways and Means Committee on October 3, 2002, ASCO acknowledged the need for comprehensive reform of Medicare payment for drugs and physician practice expenses. ASCO testified: We do not relish being targets for those who correctly point out that some drugs are reimbursed by Medicare at a rate that exceeds the acquisition cost * * * reform must be comprehensive, encompassing both overpayments for drugs and underpayments for the costs of administering the drugs. The GAO echoed this view in testimony before the House Energy and Commerce Subcommittee on Health Oversight and Investigations on September 21, 2001 testifying: ‘‘it should be a principle of Medicare payment policy to pay for each service appropriately.’’ OIG testified: Our reports have shown time after time that Medicare pays too much for drugs * * * We agree that physicians need to be properly reimbursed for patient care. However, we do not believe that the payment of artificially inflated drug prices is an appropriate mechanism to compensate them. At the same hearing, Subcommittee Chair James C. Greenwood stated: We will need to develop a solution that results in Medicare paying prices for drugs that are closer to the actual prices paid by health care providers. Similarly we will need to take steps to ensure that health care providers are sufficiently reimbursed for all of their services. Furthermore, we remain concerned about high practice expense per hour values from the ASCO survey. Even when practices with extremely high values are eliminated from the calculations, the supplemental survey practice expense per hour would remain 174 percent higher than the all physician average and more than 45 percent higher than the next highest specialty. We will continue investigating why oncology practice expenses would be so far above other specialties. For the reasons above, we believe the supplemental survey should only be incorporated into the practice expense methodology at the same time that Medicare revises the payment methodology for drugs. b. Weight Averaging Supplemental Survey and SMS Data.

When we use supplemental survey data, we have generally blended the supplemental data with SMS data for the specialty in order to use the maximum number of survey responses in calculating a practice expense per hour. However, the argument has been made that specialty societies would only undertake a survey because of the belief that the existing SMS data were

not sufficiently representative of the specialty's practice expenses. According to this argument, blending the supplemental data with existing SMS data were not appropriate. We agree and propose to use supplemental survey data without blending it with the SMS data. On only one previous occasion have we used blended data in the calculation of a specialty's practice expense per hour. In the 1999 physician fee schedule final rule (64 FR 59391), we blended the survey data from the Society of Thoracic Surgeons (STS) with the older SMS data for cardiac and thoracic surgery. Consistent with the proposed change to use supplemental survey data for oncologists' practice expenses without blending it with the SMS data, we are proposing to recalculate the practice expense per hour for cardiac and thoracic surgery using the data from only the STS survey which will result in a modest increase in their practice expense per hour. We are proposing to use the following revised data for oncology and cardiac and thoracic surgery:

REVISED PRACTICE EXPENSE PER HOUR [Dollar]	Specialty Clin. Staff	Admin. staff	Office expense	Med. supplies	Med. equip	Other	Total
Cardiac/Thoracic	19.5	18.0	17.2	2.1	2.1	14.2	73.1
Oncology	53.4	34.7	34.4	16.9	7.4	42.2	189.0

c. Nonphysician Work Pool The nonphysician work pool is a special methodology that we used to determine practice expense RVUs for many services that do not have physician work RVUs. We created the nonphysician work pool as an interim measure until we could further analyze the effect of the basic practice expense methodology on Medicare payment for services that do not have physician work RVUs. While the nonphysician work pool is of benefit to many of the services that were originally included, we have allowed specialties to request that their services be removed from the pool. Because the nonphysician work pool includes a variety of services performed by many different specialties, we use the ''all physician'' average practice expense per hour in place of a specialty-specific practice expense per hour.

Oncologists currently receive approximately 23 percent of their Medicare physician fee schedule revenues from drug administration services that are in the nonphysician work pool. For drug administration codes to benefit from the increase in oncology's practice expense per hour, it would be necessary to remove them from the nonphysician work pool and use the general top-down methodology to establish their practice expense RVUs. For this reason, we are proposing to remove therapeutic and diagnostic infusions (CPT codes 90780 and 90781), therapeutic, prophylactic or diagnostic injections (CPT codes 90782 through 90788) and chemotherapy administration (CPT codes 96408 through 96549) from the nonphysician work pool. Practice expense RVUs for these services will be computed utilizing the standard practice expense methodology used for computing practice expense RVUs for other services outside the nonphysician work pool. (CPT code 96400, chemotherapy injection, is not listed above because it has already been removed from the nonphysician work pool at the request of the American Urological Association. See the December 31, 2002 final rule, 67 FR 79981. This service is primarily provided by urologists and increased in payment by 640 percent between 2002 and 2003 as a result of being removed from the nonphysician work pool).

As we state above, we use the all physician average practice expense per hour in calculating the aggregate practice expense pool for services included in the nonphysician work pool. Once drug administration services are removed from the nonphysician work pool, nearly 98 percent of Medicare allowed charges for services affected by the nonphysician work pool calculations are diagnostic tests provided by radiologists, cardiologists and internists and therapeutic radiation oncology services. Because there is a less heterogeneous group of services remaining in the nonphysician work pool once drug administration services are removed and to minimize the impact of the removal of these services, we are proposing to revise the practice expense per hour based on a weighted average of the specialties that perform the services affected by its calculations. We are proposing to use the following revised data in the practice expense methodology for services remaining in the nonphysician work pool:

REVISED PRACTICE EXPENSE PER HOUR [Dollar]	Specialty Clin. Staff	Admin. staff	Office expense	Med. supplies	Med. equip	Other	Total
Nonphysician Work Pool	$15.8	$17.4	$21.5	$7.9	$4.9	$15.0	$82.6

In the practice expense methodology, the practice expense per hour for each category of costs is multiplied by the physician time per procedure and summed to the specialty level to create aggregate cost pools. By definition, nonphysician work pool services do not involve the physician and have no physician time. To create the nonphysician work pool, we have used clinical staff time per procedure in the computation. In the June 28, 2002 proposed rule (67 FR 43851), we proposed to use the maximum staff time where multiple staff are involved in providing the service. By using the maximum staff time, we are assuming that clinical staff are working concurrently. However, it is possible that clinical staff are working sequentially and it would be appropriate to use the total staff time for each service. We believe the staff time arrangement will likely differ based on the specific service and it is not possible to adopt a rule that will address every situation. Nevertheless, we are proposing to use the total staff time in place of the maximum staff time for developing the 2004 physician fee schedule. As we stated earlier, the nonphysician work pool was adopted as an interim step until we could further analyze the effect of the top-down methodology on non physician work pool services.

We have performed these analyses and are optimistic about being able to address nonphysician work pool issues as part of developing the 2005 physician fee schedule. At that time, we will no longer need to use staff time in the creation of the aggregate cost pools and this issue will be resolved. We have modeled the effect of removing drug administration services from the nonphysician work pool in combination with the change to the practice expense per hour and clinical staff time changes described above. These changes will increase the practice expense

RVUs for the nonphysician work pool by approximately 3 percent relative to the practice expense RVUs shown in the physician fee schedule proposed rule published on August 15, 2003.

d. Crosswalk Issues

As stated above, we are currently using the oncology practice expense per hour for CMS specialties 83 (Hematology/Oncology) and 90 (Medical Oncology). We have reviewed 2002 Medicare data for specialty 82 (Hematology). The mix of services provided by physicians billing under specialty 82 is similar to those of specialties 83 and 90. For this reason, we are proposing to change the specialty practice expense per hour crosswalk for specialty 82 from internal medicine to oncology.

e. Issues Related to Budget Neutrality

Section 1848(c)(2)(B)(ii)(II) of the Act requires that the additional expenditures resulting from changes in RVUs be budget-neutral. We normally adjust the practice expense RVUs so that the aggregate amount of expenditures is the same before and after a change to the methodology or data that are used to develop the practice expense RVUs. However, section 429(b)(1) of the BIPA indicates that, ‘‘Notwithstanding *any* other provision of law’’ * * *. (emphasis added) the Secretary is required to revise payments for drugs and is allowed to provide for adjustments to payment amounts for the practice expense component of the physician fee schedule (or new payments to providers or suppliers) for the costs incurred in the administration, handling, or storage of certain categories of drugs and biologicals).

The additional physician fee schedule payment and the new payments to providers and suppliers cannot exceed savings from revising payments for drugs. We believe that BIPA section 429(b) provides authority for us to increase physician fee schedule expenditures (that is, not apply the budget-neutrality requirement in section 1848(c)(2)(B)(ii)(II) of the Act) for adjustments made to the practice expense RVUs for drug administration.

We have modeled all of the changes described above and determined that payments for the drug administration services will increase by $190 million ($150 million to oncologists and $40 million to other specialties that provide drug administration services such as rheumatology,

gastroenterology and infectious disease). Because section 429(b) of BIPA provides authority to increase physician fee schedule expenditures for the adjustments to the practice expense RVUs for drug administration services, the proposed adjustments to practice expense RVUs will increase physician fee schedule allowed charges by $190 million or the amount of increased payments for drug administration services.

In general, the proposed adjustments to practice expense RVUs will result in increases in payment for those specialties that provide drug administration services and minimal net payment effects on other specialties. We believe that BIPA allows us not to apply the physician fee schedule budget-neutrality requirements in the context of revising payment rates for drugs and only if the additional expenditures from these and other changes described below do not exceed savings from revising prices for drugs. If we increased physician fee schedule expenditures for the adjustments made to the practice expense RVUs for drug administration without simultaneously revising payments for drugs, we would be spending more on Medicare drugs and drug administration services than we would be in the absence of making the payment changes. Such a policy is clearly prohibited by BIPA. As we stated earlier, we believe the statute anticipates that we would make drug administration payment changes in conjunction with adopting a revised payment methodology for Medicare drugs. Therefore, we are also proposing not to make the drug administration payment changes, even if we were to make them budget neutral under section 1848(c)(2)(B)(ii)(II) of the Act with respect to other physician fee schedule service unless the drug payment changes are also made. If these proposed changes are adopted the increased costs will be reflected in the sustainable growth rate.

f. Multiple Pushes

In the November 25, 1991 **Federal Register** (56 FR 59541), we indicated that Medicare will allow CPT code 96408 (Chemotherapy administration, intravenous; push technique) to be reported only once per day even if the physician administers multiple drugs. Since this code is in the nonphysician work pool, its payment amount is established based on charge-based practice expense RVUs. However, because we are establishing resource based practice expense RVUs and there are additional resources involved in administering each subsequent drug, we are proposing to change our policy and allow for 96408 to be reported once per day for each drug

administered. Using 2002 Medicare utilization data and the payment amounts resulting from the proposed changes described above, we estimate a $25 million increase in Medicare allowed charges to oncologists. We will reflect any increased costs associated with paying for multiple drug administrations on the same day in the sustainable growth rate. However, as discussed previously, we do not believe the statute permits us to adopt this proposal without revising Medicare's payment methodology for drugs since aggregate payments for drugs and drug administration services would exceed payments that would be made in the absence of such changes.

g. Summary of Physician Fee Schedule Proposals We are proposing to:

(1) Use the ASCO survey data without blending it with existing SMS data to determine practice expenses per hour for use in the top-down methodology (resulting in increased payment rates for drug administration codes provided by oncologists, rheumatologists,

gastroenterologists, infectious disease specialties and all other physicians that provide these services);

(2) revise the cardiac/thoracic surgery practice expense per hour to use supplemental survey data without blending with SMS data;

(3) remove drug administration codes from the nonphysician work pool and instead use our general top-down methodology to establish practice expense relative values units (RVUs);

(4) revise the practice expense per hour and clinical staff time used to determine the nonphysician work pool;

(5) change the specialty practice expense crosswalk for specialty 82 (Hematology) from internal medicine to oncology;

(6) increase physician fee schedule expenditures for the adjustments made to the practice expense RVUs for drug administration services (but only if there are accompanying revisions in payment for drugs discussed elsewhere in this proposed rule) resulting in minimal net payment effects on any specialty that does not provide drug administration services; and

(7) revise our policy on payment for multiple pushes.

We have modeled the above proposals as though they were in effect in 2002 to determine the specialty-level impact on Medicare revenues for oncologists. In 2002, oncologists received approximately $3.8 billion in Medicare revenues for drugs, $1.1 billion for physician fee schedule services and $0.1 billion for all other services. Taken together, oncologists received approximately $5.0 billion in 2002 Medicare revenues for all services. Using 2002 utilization, we estimate that total physician fee schedule payments to oncologists would have increased by $150 million as a result of using oncology survey data and other changes to the practice expense methodology. Allowing payment for multiple drug administration by the push technique would have increased oncology payments another $25 million. The estimated additional payment of $175 million to oncologists represents a 17 percent increase in their physician fee schedule revenues and a 58 percent increase in their payments for drug administration services. If we had adopted one of the proposals described above to revise drug payments in 2002, Medicare revenues to oncologists would have increased $80 million or 2 percent from applying comparability. Medicare revenues to oncologists would have declined by $570 million or 8 percent from applying an average list AWP discount of 80 percent.'[53]

Each of the three approaches in the Senate, the House and the Administration through CMS is seeking a solution to cancer payment reform which is driven by one goal – reducing the amount paid for cancer care. None of these proposals recognize the need for reform in the manner that the oncology community seeks it – revise the payment system to more appropriately match payments for professional and supportive services essential to community oncology care with the costs of providing that care (including mixing and administering drugs essential for cancer treatment), and payment for those drugs that recognizes the costs of acquiring, storing, and handling those drugs up to the point of mixing and administration. That basic difference lies at the crux of the concerns that the oncology community raises about each solution, since none of the solutions – as now proposed – will cover the essential costs of providing cancer care, and will thus cause the unintended, but inevitable collapse of a very efficient and patient-focused care infrastructure.

THE INEVITABLE CONSEQUENCES OF THE PROPOSED REFORMS

There are common themes to the proposed reforms: movement toward some average selling price – defined (or not), placement of a third party (via competitive bidding) into the process between the physicians and the insurer (Medicare), creation of a defined discount off some new definition of AWP, and use of the CMS analysis of the oncology Gallup survey to revise oncology practice expense reimbursement. Since none of the reforms will become the final solution in their current form, this paper will address specific concerns with the themes, rather than attempt a line by line review of each proposal.

Use of an Average Selling Price to set Drug Reimbursement

The majority of cancer care in the United States is delivered in physician office settings. These physician offices are not large corporate entities, and do not have vast financial cushions. Most are smaller, standalone businesses. Any use of an average or mean calculation to determine financial reimbursement for drugs for physicians by definition means that those purchasing above the set rate will lose money on every drug purchase.

'If further financial pressures were levied on community-based oncology practices in the form of payment reductions, many could be forced to close and/or consolidate. The vulnerability of community-based care settings to reimbursement pressure is due in large part to their relatively small size. According to the American Society of Clinical Oncology (ASCO), the average size of a cancer practice in the United States is three to five physicians, and office practices frequently consist of only one or two oncologists. Due to the limited overhead carried by these small practices, they have few options to reduce their costs. Rather than respond to reimbursement pressure by reducing an offsetting portion of overhead, therefore, many of these sites would be faced with the necessity of terminating on-site chemotherapy services or even closure.[54]

The flaw in this theory, besides the financial ramifications, is that use of oncology drugs can be appropriately and safely driven by the price of drug. The nurses and physicians who deliver the care need the flexibility to choose the drugs they feel are right for each individual patient. Third parties and policies inserted into the process for the purpose of choosing drugs solely from a price list could actually be endangering that patient. Physicians should not be forced to accept what he/she feels to be an inappropriate drug, or worse, to delay treatment while having to

explain why a drug that costs a little more than the lowest cost alternative is better for the patient. Management of chemotherapy drugs from a distance by looking solely at the purchase price is not appropriate or prudent in the case of these toxic and life-changing drugs.

Not all drugs are equal, even if they use the same active ingredients, use the same generic name, and are billed under the same drug classification. The differences in preservatives, solubility, administration, mixing and preparation, storage temperatures, and even packaging can become significant when being considered for use in a multiple agent chemotherapy treatment regimen. One version of two seemingly identical product types (manufacturer X's version of a drug versus manufacturer Y's version) might far less soluble during mixing and leave precipitate in the bag or vial – thus bringing into question the strength of the drug actually reaching the patient.

Chemotherapy is still a very delicate balance of art and a science, and when dealing with combinations of therapies that involve very toxic drugs, the effect of any margin of error can be dramatic. The tolerances for variation in dosing can be very small, and inaccurate strengths or usable drug, especially if undetectable to the human eye, could wreak havoc on planned chemotherapy treatment and the ultimate success or failure of the treatment in dealing with the cancer. Treatment by lowest cost alternative would not make a significant difference to a general practice patient with an earache, but could have a dramatic effect on the quality of life and health status of a cancer patient.

Since oncology care is so time sensitive based upon patient health status, oncologists must maintain drug inventories, which become the largest single cost category of the medical practice. Hundreds of thousands of dollars are tied up daily in drug inventory. Oncologists understand this as a basic cost of doing business, since chemotherapy can't be safely delivered to patients in the community under any other model other than having a sizeable arsenal of treatment readily available. That does not mean that doctors should be penalized by insurers for choosing the drugs they feel are right. Insurers, especially with the volume of a Medicare, should seek price controls for net drug prices by appropriately paying physicians for their own acquisition costs and then track drugs by manufacturer and seek net prices after use from manufacturers. Physicians are in danger of being caught in the middle of two financial rates they cannot control – cost and

reimbursement – and either medical quality or access to care will suffer if any of the currently proposed solutions are implemented.

Oncology practices have already proven that the financial margins involved in providing cancer care for Medicare patients are extremely tight. Oncologists must purchase drugs on the open market. Despite beliefs by Congress and the Administration to the contrary, group purchasing organizations that are available to physicians are of limited value for the majority of drugs used in chemotherapy treatment – the single source drugs. Physicians incur costs of acquisition of drugs that are greater than the mere market price of the drug. Highly trained nursing professionals manage the inventory and determine reorder quantities depending upon patient load. It takes time to monitor drug usage and what is needed for restocking. Even automated drug inventory management systems need care and feeding and modification. Choosing a source for the drugs and managing the order, shipping and unpacking of product takes staff resources. The inevitable breakage and spillage of managing an inventory becomes significant with an inventory where one small glass vial can represent hundreds or thousands of dollars. The time value of money tied up in ordering and inventory is significant. Oncologists do not buy direct from manufacturers – they purchase from a limited number of oncology drug distributors, who themselves purchase from manufacturers at Wholesale Acquisition Cost (WAC) and then resell to physicians at a price adjusted to reflect their own costs of handling and margins. All these are essential components to any calculation of "acquisition cost of drugs". All the proposals at hand would seem to address a basic price of drugs plus a margin to cover the additional acquisition costs. However, the details are key. Some proposals seek to set the WAC costs paid by the distributor as the base rate – which actually might be the most logical solution, if the percentage added to the base rate appropriately covered not only the components of acquisition costs in the physicians office as well as the distributor’s markup to physicians. Some proposals would seek out information on all prices net of all discounts and rebates charged for drugs by manufacturers, without regard for different pricing levels across classes of trade (i.e., physicians, hospitals, retail pharmacies, HMO’s and managed care, etc.). Each drug is unique and setting average prices across multiple drugs in one classification unfairly penalizes physicians who need to use the more expensive drugs based upon their professional medical opinion of the effect of using that drug versus another on an individual patient.

Third Party Intrusion (also known as competitive bidding, mandatory vendor imposition (MVI), etc.)

The hope for competitive bidding (from the insurer's and Medicare's viewpoint) is that by allowing a third party to buy drugs in volume and deliver them to oncologists upon receipt of a prescription, they can achieve greater volume discounts on drugs (translating into savings for the Medicare program) and also gain greater control over physician choice of treatments, even over selection of specific drugs. However, these hopes are not supported by the realities of cancer care. Volume purchasers within the physician class of trade can achieve limited incremental savings over current market pricing to oncologists. Adding a third party will incur additional administrative overhead at all levels of the care and payment process. This third party will take its fees out of the existing monies available for cancer care.

Oncologists now absorb from 20% to 30% of bad debts resulting from patient's inability to pay co-payments. These patients continue to receive their cancer care regardless of their account status. Some proposals would make the third party responsible for collecting patient co-payments. It is not realistic to assume that a for-profit third party would allow treatment to continue for patients already in arrears from previous treatments.

Physician offices care for patients of several insurers. The current drug management system works well, allowing physicians to stock expensive drugs in quantities measured to meet their overall patient demand. Turnover of drugs before expiration dates apply is critical to efficient pharmaceutical management. Space is often at a premium, especially for drugs with security or temperature control concerns. Personnel specially trained in the mixing and management of these toxic treatments are often in short supply. Each insurer that requires MVI, just by inserting this third party into the process, imposes substantial increased demands on staff, space and practice resources. Physicians would have to order drugs on a patient-by-patient basis, provide patient-specific shelf and refrigerator space for drugs, monitor multiple small shipments from a multitude of vendors and match each vial of those shipments to individual patients, and assure that individual drugs for a given patient arrive and are replaced on a time basis relative to the patient's treatment schedule. Consequently, un-reimbursed overhead in physician based cancer centers will skyrocket. Physician practices are routinely abstaining from participating in MVI

supported contracts for these very reasons – including the increased risk to patients of medication errors caused by the increased complexity of the drug management process.

Oncologists currently have very tightly controlled and highly efficient staff and facility management of drug inventories. They are able to, across their whole patient population – regardless of individual insurer – stock enough of the commonly and even "rarely-used-but-must-be-stocked-for-emergency-purposes" drugs. If forced to obtain Medicare drugs from a given vendor, these offices would essentially be required to double the inventory management processes, since separate ordering, inventory, storage, and handling would be critical to manage this duplicate inventory. The drugs would need completely separate storage, including refrigeration, since there are laws against using drugs ordered specifically for one patient for any other patient. Oncology care cannot be delivered safely or efficiently in a prescription delivered setting. In addition to the points listed here, this review of mandatory vendor imposition and the failures that MVI has already caused in Florida prove beyond a shadow of a doubt that this is not an appropriate solution for cancer care.

- About 80% of the treatments cancer patients receive consist of multiple drugs, which under this system may come from multiple sources. The logistics of ordering from multiple sources for multiple patients, then hoping all of the treatment regimen arrives on time for mixing and administration, along with the storage and replacement and pre-treatment planning will be an extraordinary burden on the resources of oncology practice.
- **MVI Threatens the Quality of Cancer Care by disrupting delicately timed cancer treatment –**One element that makes oncology care unique in the physician office setting is the flexibility of care and how it can be tailored for immediate patient needs. Oncology is not a prescription manageable specialty. Physicians need to stock the appropriate mix of drugs at hand for use by any patient in order to provide quality cancer care. Patients often come in presenting symptoms and side effects that need immediate treatment – oncologists cannot tell a severely emetic patient, or one whose blood cell counts have taken a turn for the worse that they must wait 24 – 48 hours for their prescription to be received and sent to the physician's office so that the physician could then provide the treatment. Cancer treatment may be planned, but it is individually modified on a daily basis when the patient presents for treatment in a way that is based upon the patient's

health status at that moment. Under MVI, physicians do not maintain their own inventories (and may not be able to afford to maintain the same staffing and practice resources), and thus are prevented from tailoring treatments to the current medical status of their patients in a timely manner.

- **The logistical costs to a practice if forced to convert to a patient based drug inventory system would be staggering**. Management of drug inventory, ordering and receiving would become so complex, and storage and staff requirements would become so great that the practice simply could not deliver safe or appropriate care under those burdens. At a time when practices are already facing critical shortages of staff qualified to handle oncology drugs correctly, a burden like this becomes untenable.
- **Lessons to Be Learned From Florida Activities** - Some private insurers are prematurely developing their own uninformed solutions, including MVI programs, that don't cover the costs of quality cancer care in aggregate, and put the entire community cancer delivery system at risk as a result for their members. This has been particularly prevalent in parts of Florida.
- **In south Florida, oncologists have been battling MVI and drug replacement programs for the last four years.** Blue Cross and Blue Shield Health Options, United and Aetna all have MVI programs for cancer drugs. The payors have ignored physician concerns with these programs.
- In central and northern Florida, physicians have been able to discuss with payors how detrimental MVI programs are, and so far, MVI programs have been made optional, rather than an absolute requirement.
- **MVI also threatens the safety of cancer drugs** – Physicians choose the source carefully before acquiring the drugs used for treating cancer patients. There are strict clinical and handling controls that must be followed from the point of manufacture right up to the moment of treatment. Most of these drugs have very narrow margins for temperature, storage and handling variation. MVI removes these controls and forces physicians to accept product about whose history they know nothing. MVI is fraught with incentives to solicit lowest cost bids for product supply, and to create shortcuts that can eliminate the strict clinical and handling controls for the sake of saving money. MVI substantially increases the risk of drug dilution, tampering, counterfeit products, and contamination of

product. When insurers select PBMs who promise to reduce the cost of cancer drug payments made by the insurer, neither the insurer nor the physician actually know the source chosen by the PBM for the drug. Unfortunately, Florida became a hotbed of MVI activity in the last few years, and we are just now seeing the magnitude of the compromised patient care that has followed behind that trend.

- **The following are excerpts from recent articles (May 2003) filed for the South Florida Sun-Sentinel, written by Bob LaMendola and Sally Kestin (Several other articles from this well-documented series are referenced in the bibliography).**
  - 'At pharmacies and hospitals around the country, fake, diluted, stolen and expired medications are slipping into the nation's drug supply, many via unscrupulous brokers in South Florida…… [55]
  - A proliferation of largely unregulated drug wholesalers –1,400 selling in Florida alone – has created a multimillion-dollar industry for illegal pharmaceuticals…..[56]
  - The unsuspecting victims are among the sickest – cancer and AIDS patients who depend upon costly injection drugs that are the most profitable to counterfeit.[57]
  - "Every possible scheme is going on," said Robert Penezic, a statewide prosecutor overseeing a Fort Lauderdale-based grand jury investigating the problem. "It's all right here in South Florida, and it's scary."[58]
  - The criminal element in the business has formed a network of companies trading hundreds of millions of dollars in medications, some of it phony, diluted, expired, relabeled, or improperly handled, according to documents and state and federal officials investigating the industry.[59]
  - These outfits also have built connections to supply other local wholesalers who sell to the nation's largest pharmaceutical distributors, turning South Florida into a major source of counterfeit and adulterated medications tainting the mainstream drug supply.[60]
- The Florida Legislature has recently passed legislation (now awaiting signature by the Governor) tightening up rules for wholesalers and their operations in the state, and requiring "pedigree papers" documenting drug sales history from the manufacturer to the patient. However, this is a limited measure – it only applies to a select list of "high risk" drugs until 2006, and only to drugs sold in Florida.

- MVI, by definition, disrupts treatment with delays in delivery, problems with shipping orders, loss, criminal activity and negligence. Third party competitive bidders have an inherent incentive to save money – which can be accomplished one of two ways – to shift monies now being invested in cancer care into their pockets as for-profit entities, or to cut corners by choosing to buy drugs from lowest bidders (who often are small wholesalers). Small wholesalers in Florida are being investigated for criminal activity, dilution and counterfeiting of drug, and repackaging of drug below manufacturer standards. MVI also increases the risk of medication errors due to its interference with clinical controls and the direct communication that allows the medical care team to ensure the safety and use of drugs. Cancer patients are exposed to serious medical complications, increased emergency hospitalizations, possible failures of planned treatment, and, at the extremes, unnecessary death.
    - A physician in Jacksonville FL prescribed Neupogen from days 14 through 24 of a patient's chemotherapy cycle. Timing of this supportive care drug was critical in managing side effects of the toxic chemotherapy drugs being used to treat the patient's cancer. The patient's insurer required that the drug be provided from its PBM and delivered directly to the patient's home. The drug arrived late, and no more active than sugar water – rendered completely useless by the Florida heat. The medicine required careful temperature controlled handling and transportation – which was not provided by the insurer's chosen discount pharmaceutical supplier or its source. As the patient's white blood cell counts dropped, his physician complained "When are insurance companies going to realize that they can kill people trying to save money this way"
    - Sometimes drugs are required to be sent to patient's homes, either for self-administration or to be brought to the doctor's office at the next visit. Horror stories abound across Florida and in other parts of the country of patients who didn't follow directions and over- or under-dosed on medications, and patients with drug piled in basements, in glove compartments of cars, or left on counters as a reminder to bring it in the next day. In every one of these circumstances, the patient's health was compromised by inappropriate levels of medication, or, worse, by drug made more potent or less effective (or toxic) by mishandling.

- Even if the drug makes it to the patient on time, the patient's confidence in the drug can be shaken. In Colorado in December 2002, a patient received his shipment of Neupogen as required from a supplier chosen by the PBM contracted by his insurer. In that package was the drug, but also two large boxes of diet pills, and trinkets such as a silver earring, a dream catcher, and an onyx frog fetish carving. The diet pills were labeled in Spanish. The package had clearly been shipped from Mexico – leaving the whole package open to suspicion for quality.
- On a December 22, 2002 edition of CBS's 60 Minutes (Volume XXXV, Number 13), an AIDS patient tells how she received a counterfeit version of Serostim, a drug that had given her positive results for a year before she became very sick, very fast on the counterfeit version, and that she is now too afraid to take the drug any longer. Out of fear of the devastating effects of receiving the counterfeit version, she is no longer taking the drug that was helping her most.

MVI Threatens the Cost and Efficiency of Cancer Care – MVI requires drugs to be ordered and paid for a specific patient. Since patient status changes routinely necessitate significant adjustments in treatment regimens, preordered drugs that no longer meet the patient's needs must be thrown away, even if there is another patient in the office that could have used that product that day. The costs to the healthcare system multiply under MVI, since the wasted drug and the adjusted drug for the original patient must be paid for, as well as the drug for the second patient. Increased drug waste also generates increased hazardous waste volume and thus disposal costs for that hazardous waste.

MVI increases provider and payor liability exposure – Currently, physicians operate within a clinically controlled system that protects the safety and reliability of the drug therapies they provide to their patients. MVI breaks this chain of custody, imposes unnecessary and dangerous delays in treatment and increases the opportunity for adulteration, spoilage or counterfeit replacement of drugs. This, in turn, increases provider liability for problems that occur as a result of MVI and the malpractice coverage costs that providers must bear. Physicians are unwilling to expose their patients to these risks. Insurers suggesting MVI programs to oncologists have been asked by those physicians to provide waivers of liability so that the risk for drug related liability moves from the physician to the entity intruding upon the drug selection process. Not

surprisingly, few payors want to accept that type of liability, but at the same time, they have no trouble making the decisions about saving money that lead to that increase in risk for their enrollees.

Florida is, unfortunately, a prominent laboratory in which we can look and observe the dangers of MVI and the havoc it can create in the treatment of cancer. We need to heed this lesson and understand why MVI is not a viable solution in cancer care for American citizens.

Defined Discounts off AWP – including definition of AWP

These approaches are driven more by the insurer's intention to reduce the amounts being spent upon cancer care than the care being delivered. This is one of the most insidious solutions to cancer payment reform because it seeks to set a limited financial solution on a medical process without regard to the realities of the costs of acquisition of the essential drugs. As has been noticed, there is no consistent definition of AWP. WAC is a more consistent number used throughout the industry. AWP is subject to definition and then not all definitions are readily available. There is a great conflict growing since the insurer population, including Medicare, is moving toward the First Data Bank definition (which is lower than the Redbook version). Physicians, however, do not have access to the First Data Bank versions. All the approaches being proposed seek to set some average number for a new AWP, which merely sets the stage for the same problems already stated for average payment solutions.

Again, physician practices have already proven that the financial margins involved in providing cancer care for Medicare patients are extremely tight. This situation exists under the current reimbursement of 95% of AWP. Proposals that merely redefine AWP or change the percentage are not truly addressing reform, just creating savings on the backs of Medicare cancer beneficiaries.

CMS Practice Expense analyses

The CME estimates for practice expense are, to put it bluntly, wrong. Numerous studies (now several years old) of oncology practice expenses, both Federal and industry, have shown a

ballpark of only 25% of actual practice expenses being paid. That would indicate that at least a four-fold increase in current Medicare professional payments would be appropriate to cover costs already being incurred but unfunded. The CMS proposed reimbursements of $150 million to $255 million are woefully understated, and if those solutions are made official policy, it will result in almost immediate collapse of the cancer care delivery system in the communities. Cancer patients will have to turn to hospitals in droves for care (if they wish to travel to hospitals) and the hospitals are unable to provide care for that volume of patients. This is not a threat, but a financial reality. No business can survive being paid less than its costs of operation.

The services not now being reimbursed by Medicare are not fluff, and are truly integral to the delivery of quality cancer care. These services cannot be compared to support services delivered by other specialties. Cancer patients are overwhelmed with the logistics of their care and side effects, and appropriate counseling, education and supportive care help empower them to not only maximize the value of their treatment, but in many circumstances, enable them to continue with their planned treatment rather than dropping out of a regimen. These are the services now funded, along with unreimbursed practice operational costs, by physician practices out of the net combination of drug and services payments. It is impossible to take hundreds of millions of dollars out of the cancer delivery system that is now paying for operational practice expense and service integral to cancer care, and leave practices able to care for Medicare patients. The math just doesn’t work!

Cancer payment reform should mean actual reform, not just another band aid. Cognitive services and integral support, education and counseling services should be properly labeled and reimbursed under their own merit. These services are unique to oncology and NOT comparable to services provided in other specialties. Lumping payment for these services onto existing codes merely replaces the inappropriate current payment system for another inappropriate system. Cancer care is an evolving specialty, and the sooner that we appropriately identify delivered services, the more flexible we leave the system to adapt to changing delivery methodologies as new solutions are proven successful. Cognitive cancer management and supportive services will still be needed even if cancer care eventually evolves into something other than chemotherapy administration.

PRIVATE INSURERS ARE JUMPING THE GUN/OR CHAMPING AT THE BIT

Private insurers across the country have been trying to implement various aspects of these proposed reforms, but in a vacuum. CMS holds the proprietary software for converting practice expense information into relative value units for coding purposes. Without a CMS proposed series of changes to the professional services billing codes, neither individual private insurers nor private oncology practices can develop a viable balanced solution on the practice expense side.

Most of these insurers are seeking to make reductions solely in the payments for drugs or to implement MVI-type programs, which would leave practices either unable to provide care they feel safe about and can trust, or unable to fund the other essential services necessary for the chemotherapy treatments. Practices across the country are facing the dilemma of accepting insurer programs that they know can't cover the costs of care OR having to tell patients that the practice will not be able to provide the care under their insurance program and then helping their patients seek alternative sites for treatment.

United, Aetna and Oxford all have in the last four months, announced changes in the way they will pay for cancer care. They have said publicly and privately that the programs being developed in New England will serve as pilots for change in other states. Their programs vary in minor details, but since at least two of those companies are using the same consultant, it is not an accident that their programs look almost identical and were announced within days of each other.

Public hearings were held by New York state legislators to understand the reductions in care being faced by their constituents. Hundreds of patients were informed by physicians in Connecticut, New York and New Jersey that the revised cancer payment policies of Aetna, Oxford and United were forcing physicians to resign from the programs rather than provide care that didn't allow for the funding of essential cancer services. One patient caregiver told a heartbreaking story of the difference in convenience and confidence in the care his wife received in her oncologist's office, and the next month in the hospital where she was forced to go due to changes in her insurer's cancer payment policies.

WHAT CAN COMMUNITY ONCOLOGY PRACTICES DO?

There has been an upwelling of activity in the community oncology community to educate the legislators and administrators of both Medicare and private insurance about the realities of oncology care. ASCO, ACCC, ONS, and various patient advocacy groups have been working behind the scenes tirelessly to promote balanced cancer payment reform. Unfortunately, this is a battle that has to be fought one person at a time. Unless those involved in the decision-making process have had first hand experience in visiting a community oncology practice, the perception is usually that of a general medicine practice, with no concept of the specialized equipment, professional training, emergency procedures, complex drug handling and mixing requirements, the hours of double and triple checking planned doses versus mixed drugs, etc. that is involved. Without an understanding of all those complexities, it is easy for an uninformed person to make quick judgements regarding drug pricing and interchangeability, or assume that practice expenses should be comparable to those of other physician specialties.

The Community Oncology Alliance was created by practicing community oncologists in December 2002 to add its voice to the more established professional organizations. It enlisted the support of former Congressmen Harold Ford, Sr. and Robert Livingston as lobbyists to help navigate the political labyrinth of Congressional and Administrative policy-making.

All these voices have had to address several fluctuations of potential proposals over the last few years – speaking up with the concerns and information about the unintended consequences of each proposal. This has been an exhausting process, but the end may soon be in sight. All indications are that either a Congressional or CMS solution will be implemented for either January 1, 2004 or January 1, 2005. The challenge for community oncology practices is that every one of the current proposals, in their current forms, will leave the essential services of cancer care unfunded, and thus will force the collapse of the existing cancer delivery system.

Unfortunately, until they have seen firsthand the realities of cancer care, those in the decision-making positions have very firmly held convictions that the "overpayments" on drugs are the result of a deliberate and profit-mongering initiative by oncologists, and that no significant adverse effects will actually occur should cancer payment reform pull millions of dollars out of the cancer care system as it is currently devised. Oncology administrators and physicians can join the education process by visiting two key web sites, ASCO at **www.asco.org**, and the

Community Oncology Alliance, at **www.communityoncology.org**, to learn more about the current issues and to whom messages need to be delivered and what they need to hear. This is a rapidly changing situation, and the fall of 2003 will bring many challenges and surprises.

Oncologists have quietly built up an efficient and scientifically sound environment for delivering toxic chemotherapy agents in a readily accessible and convenient manner. Because this environment was created free from the conventional bonds of encounter-based medicine, the necessary team and infrastructure was able to evolve driven by patient needs and the peculiarities of the constantly evolving treatment options. During this current period of transition in payment structures, it would be very easy for the scales to tip in either direction – preserving the delivery system that has brought hope and comfort to cancer patients, or causing its complete collapse and eventual extinction as an option for cancer patients.

Given the decades of war against cancer that have been waged, and the major scientific advances being made in this decade towards understanding the biology of cancer and developing biotechnology targeting cancers, it would be a disaster to decimate the community delivery system at this point. Cancer treatment is improving almost daily in its ability to better target just the cancerous cells, but still involves using drugs basically meant to kill human cells. The ordering, handling, storage, mixing, and administration of these highly toxic drugs and the supportive medicines that address their side effects are extremely complex and require close attention at every step in the process. The patient's oncologist assumes the legal risk for the appropriate management of the cancer treatment and the process that goes into delivering it.

Oncology practices across the country are accepting the challenge of educating those who need to know about the realities of cancer care and the unintended consequences of these proposals. By inviting Congressmen and Congresswomen into their offices, by writing opinion editorials and working with local and national media to tell their story, and by helping their patients to understand the risks of the current proposals, there is a growing national awareness of the dangers of instituting a decision that would harm the current delivery system. The Bibliography contains listings of a wide variety of articles that have hit the national and local media in an attempt to bring heightened awareness.

During visits to the offices, practices can walk Congressmen and others through the process of cancer care. Such tours showcase the one on one service, the attention to detail and accuracy needed through every step of the medical care, the expensive equipment and the complexities of mixing and handling the drugs. All of these are important in communicating what makes the care delivery infrastructure so critical to the safe treatment of cancer in the physician office setting.

The reality is that if the final cancer payment reform does not present a balanced solution, and millions of dollars are removed from a cancer system that is already at breakeven or losing money on Medicare cancer beneficiaries, the day that the new reform is implemented will see a vastly changed national cancer program. Physician offices will have made significant staffing and facility reductions, and supportive care services and programs will no longer be readily available. Oncologists will continue to see patients and diagnose their cancers and develop their treatment plan, but patients would have to seek that treatment plan from the remaining hospital outpatient and inpatient centers that are still open. Hospitals will continue to assess their operating losses from cancer care and scores of community hospital cancer programs will close. Accruals in clinical trials across the country will dry up, as physician practices lose funding for their nurses and offices and are forced to close their doors to the majority of the patients now being treated in those facilities.

There are a handful of academic cancer centers, like Fox Chase in Pennsylvania and MD Anderson in Houston, that are exempt under Federal law from the recent Medicare changes in hospital inpatient and outpatient reimbursement. These few centers are still thriving. If the community cancer delivery system in physician offices is rendered extinct by future Medicare funding changes, we may find that this handful of academic cancer centers will once again rise as the source for cancer care – at least for those fortunate enough to be able to make the trip to that geographic region for care.

Several years ago, Congress and the Administration established a process defining how physicians were to be paid for the care they delivered. This system set specific rates for physician services, and defined a series of billable codes that were to be used for identifying drugs and supportive services. Oncologists were thus required to bill for drugs and the other billable items of their practices at rates set outside of their office through a process developed

and endorsed by the Federal Government. There was a significant error made in the identification of costs to provide cancer care in physician offices, since the services delivered by non-physicians (including specially trained oncology nurses, other medical personnel, and the operational costs incurred in the ordering, handling, storage, mixing and administration of cancer treatments) were NOT included in identifying the practice costs. Oncologists learned to make do with the rates they were assigned, and managed to provide all that supportive care under the limits of the rates they were allowed to bill for physician services and drugs.

We have now reached a point where all involved in cancer care understand that that old methodology is inaccurate and needs to be fixed. The rates that were set for physician services barely cover ¼ of the costs to run an oncology practice, a situation that has been verified by the Federal Government years ago and documented in the Federal Register. The process for billing drugs is linked to billing units, and Average Wholesale Price (AWP), and payments are not linked to the amount physicians actually pay to acquire the drugs. However, the difference (sometimes larger, sometimes smaller) in aggregate has been paying for the myriad of operational costs inherent in delivering cancer care that have not been paid under any other system.

There is a major push within Congress and the Administration, in concert with the oncologists, patients, nurses, and advocates of the cancer care community to fix this payment structure in the next six months. There is universal acceptance that any adjustment to reduce payment for cancer drugs must be balanced with a simultaneous increase in payments for physician services. The magnitude and methodology of changes on both sides of the issue are in the middle of analysis and consideration at all levels of Congress and the Administration, in close concert with key leaders in the oncology community.

We are years, if not decades, away from any meaningful cure for cancer. Progress is being made in incremental steps, but at best, we have learned how to identify the disease, and how to gradually make slight improvements in the survival and response rate for individual cancers. At some point, we may be able to manage cancer as a chronic disease. Now, even the newer targeted therapies are used in conjunction with long-established therapies, and the risk of side effects and adverse reactions is still high. Cancer treatment is labor intensive and costly to

administer. We as a society are at a crossroads in determining whether we are still willing to shoulder the costs of the community-based delivery system which has served so well at advancing cancer care or to sacrifice it to the budgetary whims of politicians.

The evolution of the cancer system has been remarkable. What the oncologists and oncology nurses have accomplished with the drugs that are available is commendable. Despite the cynics, this is a specialty based upon hope, hope that the next day will bring a new discovery that will help today's cancer patient – or their survivors. That hope is why cancer patients have grown to trust that their physicians will provide them the care that they need, regardless of their ability to pay. The current system supports the oncologist's care infrastructure and allows that flexibility. The burning question is, will our reforms allow the future system to continue offering such a high standard of care?

Bibliography

Books

"Chapter 4 - Public Policy and Access to New Drugs: The Case of Cancer Chemotherapy", by Lee Mortenson, The Changing Economics of Medical Technology, National Academies Press (1991), Pgs. 53 – 68.

Interviews – June and July 2003

Presant, Cary, M.D., Private Oncologist in CA, President, Association of Community Cancer Centers, 11600 Nebel Street, Suite 201 * Rockville, MD 20852

Mortenson, Lee, D.P.A., Executive Director, Association of Community Cancer Centers, 11600 Nebel Street, Suite 201 * Rockville, MD 20852

Bailes, Joseph, M.D., Executive Vice President, US Oncology, 16825 Northchase Drive, Suite 1300, Houston, Texas 77060

Publications

"Bad Medicine", Produced by Catherine Olian, Frank Koughan, CBS News 60 Minutes Transcript, December 22, 2002, Volume XXXV, Number 13, CBS News, 524 West 57th Street, New York, NY 10019

"Cancer Care in America: Description and Implications of Outpatient Community-Based Cancer Care, March 2002, by Regina E. Herzlinger, DBA, Boston Healthcare Associates, Inc.

"Cancer Economics: Cancer Economics: Hospitals – What's Happening to Their Cancer Programs?", Albert B. Einstein, Jr., MD, **http://www.moffitt.usf.edu/pubs/ccj/v4n4/department1.html.**

"Financial Analysis of Community Oncology Practice Operations", Prepared and released June 23, 2003; Community Oncology Alliance, Memphis, TN **http://www.communityoncology.org.**

"How has the practice of Oncology changed over the past 20 years?", paper written for patients, Mitlesh Govil, MD, New London Cancer Center, New London, CT 06320, 2001

"The Impact of Medicare Payment Policies on Patient Access to Quality Cancer Care", Barton C. McCann, M.D. and Julia James, June 1999, Health Policy Alternatives, 444 North Capitol Street, NW, Suite 821, Washington, D.C. 20001-1512.

"Medicare and Drug Pricing", John Iglehart, The New England Journal of Medicine, Volume 348:1590-1597, April 17, 2003, Number 16.

"Medicare Program; Payment Reform for Part B Drugs; Proposed Rule", Department of Health and Human Services Centers for Medicare and Medicaid Services 42 CFR Part 405, 50437 Federal Register / Vol. 68, No. 161 / Wednesday, August 20, 2003 50428-50452.

"Patient Advocate Foundation Survey: Patient and Consumer Views of Browng Bagging and Mandatory Vendor Imposition", Report Prepared by the Lewin Group, Inc., January 24, 2003

Prepared Witness Testimony, Mr. William J. Scanlon, Director, Health Care Issues, General Accounting Office, Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, Subcommittee on Oversight and Investigations, Subcommittee on Health, September 21, 2001

"Reform of the Medicare Payment Methods for Cancer Chemotherapy", May 200, American Society of Clinical Oncology, Alexandria, VA 22314.

Articles

"'Alarming Percentage' of Wholesale RX Drugs Obtained Illegally, Grand Jury Says in Report", BNA's Health Care Daily Report, Volume 8 Number 41, Monday, March 3, 2003, ISSN 1091-4021, The Bureau of National Affairs, Inc., Washington, D.C.

"Anti-cancer drugs cut by Medicare", Bob Cusack, August 13, 2003, The Hill, 733 Fifteenth Street, NW Suite 1140, Washington, DC 20005 **http://www.thehill.com**

"APCs hitting cancer centers hard, more pain to come", APC Advisor, Volume 2, Number 8, August 2001, Pages 113 – 128.

"Cancer Care in Eastern North Carolina", 1975-2000, William F. Bobzien, III, MD, North Carolina Medical Journal, January 2002, Volume 62 Supplement, Page S46 - S50

"Cancer Drugs Face Funds Cut in a Bush Plan", Robert Pear, The New York Times, August 6, 2003, **http://www.nytimes.com/2003/08/06/politics/06DRUG.html**

Brown Bagging Chemotherapy Drugs...Part I, II and III, Astara March, July - August, 2002, Oncology Issues, Association of Community Cancer Centers, 11600 Nebel Street, Suite 201 * Rockville, MD 20852

"Congress Mulls MVI", Eric Berger, Legislink, A Community Service of US Oncology, March 21, 2003, US Oncology, 16825 Northchase Drive, Suite 1300, Houston, TX 77060, **www.usoncology.com**

"Drug bill may hit cancer patients Medicare reform could force them into hospitals for their chemotherapy", Lawrence M. O'Rourke, Bee Washington Bureau, July 16, 2003,

"Fake drugs find their way into Rx supply", Sally Kestin and Bob LaMendola Staff Writers, May 25, 2003, *Copyright © 2003,* *South Florida Sun-Sentinel*, **http://www.sun-sentinel.com/news/opinion/editorial/search/sfl-drugmain25may25.story**

"Former convicts try a safer venture: Pharmaceuticals", Sally Kestin and Bob LaMendola Staff Writers, May 26, 2003, *Copyright © 2003,* *South Florida Sun-Sentinel*, **http://www.sun-entinel.com/news/opinion/editorial/search/sfl-drugplayers26may26.story**

"Deep in Medicare Bill, a Drug Fight, Doctors Mobilize Over Their Latest Plan to Cut Reimbursements, but This Time They May Lose", Leila Abboud, Staff Reporter of THE WALL STREET JOURNAL, June 19, 2003, The Wall Street Journal, **http://online.wsj.com/article/0,,SB105597264583566600,00.html**

"Medicare bill may threaten cancer treatment", Julie Bryant, Staff writer, From the August 8, 2003 print edition of the Atlanta Business Chronicle, **http://www.bizjournals.com/industries/health_care/hospitals/2003/08/11/atlanta_story4.html**

"Medicare Payment for Cancer Drugs Is Seen as Likely", Robert Pear, The New York Times, April 29, 2003, **http://gateway.proquest.com/openurl?ctx_ver-Z39.88-2003&res_id=xri:PQD&rft_val_fmt=ori:fmt:kev:mtx:journal&genre=article$rft_id=xri:PQD:DID=0000001167798**

"New Medicare bill concerns doctors Legislation would cut cancer care", Gigi Wood, Iowa City Press-Citizen, July 17, 2003

"Origins of Cancer Therapy", Rose Papac, Yale Journal of Biology and Medicine 74 (2001), pp. 391-398.

"U.S. officials scrambling to fight counterfeit medicine", Lauran Neergaard, Associated Press, via Chicago Tribune, June 18, 2002,

Three S. Florida men accused of selling bogus AIDS, cancer medicine, ", Sally Kestin and Bob LaMendola
Staff Writers, May 22, 2003, *Copyright © 2003,* South Florida Sun-Sentinel, **http://www.sun-sentinel.com/news/local/southflorida/sfl-baddrugs22may22,0,4250988.story?coll=sfla%2Dnews%2Dsfla**

"An Update on Brown Bagging", Astara March, Oncology Issues, March/April 2003, Association of Community Cancer Centers, 11600 Nebel Street, Suite 201 * Rockville, MD 20852

"Who's Mixing Your Drugs? Bad Medicine: Pharmacy mix-ups a recipe for misery, some drugstores operate with very little oversight", Erin Hallissy, Sabin Russell, San Francisco Chronicle Staff Writers, Sunday June 23, 2002, San Francisco Chronicle

Internet Sources

"Advances begin to tame cancer", Raja Mishra, Boston Globe staff, 7/6/2003, **http://www.boston.comdaily globe2/187/metro/Advances_begin_to_tame_cancerP.shtml**

"After the National Cancer Act of 1971 Twenty Five Years of Advances Against Cancer, National Cancer Institute, **http://rex.nci.gov/massmedia/CANCER-RESRCH-WEBSITE/JNCI.html** 5/17/03

"ANCO Responds to Slanted NY Times Article About Drug Reimbursement and Cancer Doctors", John A. Keech, Jr., D.O., José Luis González, Association of Northern California Oncologists, California Oncology Consortium, January 28, 2003, **http://www.californiaoncology.org/assns/ancoresp12603.htm**

"Approved Claims Per Year", Oncology Approval Statistics 1949 – 2003, Center for Drug Evaluation and Research, Federal Drug Administration web site, **http://www.accessdata.fda.gov/scripts/cder/onctools/statistics.cfm**

"ASCO Profile", American Society of Clinical Oncology (ASCO), ASCO Web Site, www.asco.org, **http://asco.org/asco/shared/asco_print_view/1,1168,_12-002013-00_18-0010082,00.html**

"ASCO Testimony at House Committee on Energy & Commerce Subcommittee Hearing (September 21, 2001), ASCO Web site, **http://www.asco.org/shared/asco_print_view/1,1168,_12-002171-00_18-001715-00…**

"CLC Urges President Bush to Ensure Fair Medicare Payment for Cancer Care", Cancer Leadership Council, May 23, 2002, CLC Policy Issues: Medicare Payment, **http://www.cancerleadership.org/policy/medicare_payment/020523.htm**

"Closing in On Cancer", National Cancer Institute, Web Site, **http://rex.nci.nih.gov/behindthenews/cioc**.

"The First Twenty-Five Years", Association of Community Cancer Centers, About ACCC web page, **http://www.accc-cancer.org/about/25.asp**

H.R.1 Medicare Prescription Drug and Modernization Act of 2003 (Received in Senate from House), Library of Congress Web Site, Thomas Search Engine,**http://thomas.loc.gov/cgi-bin/query/D?c108:4:./temp/~c108FyRYND**::

"Hospital Outpatient Prospective Payment Rule Announced by CMS", August 13, 2002, Press Release, Association of Community Cancer Centers, ACCC Web Site, **http://www.accc-cancer.org/news/hopps.asp**

"How Medicare Payment Cuts Have Affected the Delivery of Cancer Care", Published July 28, 2003, Copyright 2003, Association of Community Cancer Centers, ACCC Website, **http://www.accc-cancer.org/news/medicare0728.asp**

"How Medicare Reimbursement Affects Our Patients", Edward L. Braud, M.D., Oncology Issues, 18(3):23-24, 2003, Association of Community Cancer Centers, posted 06/30/2003 on Medscape, **http://www.medscape.com/viewarticle/456826**

"Legislative Alert – Message to Congress: Pass Balanced Medicare Reform!, Eric Berger, US Oncology Web Site, **http://ww.usoncology.com/CompanyInfo/article.asp?aid=486**

S.1 Prescription Drug and Medicare Improvement Act of 2003 (Reported in Senate), Library of Congress Web Site, Thomas Search Engine, **http://thomas.loc.gov/cgi-in/query/D?c108:3:./temp/~c108HTPZAk**::

S S.1 Prescription Drug and Medicare Improvement Act of 2003 (Reported in Senate), Library of Congress Web Site, Thomas Search Engine, **http://thomas.loc.gov/cgi-in/query/D?c108:3:./temp/~c108HTPZAk**::

"Significant Research Achievements: 100 Years of Advances Against Cancer", National Cancer Institute, **http://cra.nci.nih.gov/2_accomplishments/1970s.htm**

Statement of Paul Bunn, M.D., Director, Cancer Center, University of Colorado, Denver, Colorado, and President, American Society of Clinical Oncology, Alexandria, Virginia, Testimony Before the Subcommittee on Health of the House Committee on Ways and Means, Hearing on Medicare Payments for Currently Covered Prescription Drugs, October 3, 2002, U.S. House of Representatives Ways and Means Committee Subcommittee on Health Web Site, **http://www.ons.org, http://www.ons.org/xp6/ONS/Information.xml/About_ONS.xml/Mission_Statement_and_**...

Reference Citations

[1]Seven papyri, discovered and deciphered late in the 19th century, provided the first direct knowledge of Egyptian medical practice. Two-known as the "Edwin Smith" and "George Ebers" papyri,--contain descriptions of cancer written about 1600 B.C. and are believed to date from sources as early as 2500 B.C., "Closing in On Cancer", National Cancer Institute, Web Site, **http://rex.nci.nih.gov/behindthenews/cioc.**

[2] "Origins of Cancer Therapy", Rose Papac, Yale Journal of Biology and Medicine 74 (2001), pp. 391-398.

[3] 1733-1788 Oncology's Arrival in the "Age of Reason", "Closing in On Cancer", National Cancer Institute, Web Site, **http://rex.nci.nih.gov/behindthenews/cioc.**

[4] "Origins of Cancer Therapy", Rose Papac, Yale Journal of Biology and Medicine 74 (2001), pp. 391-398.

[5]"Origins of Cancer Therapy", Rose Papac, Yale Journal of Biology and Medicine 74 (2001), pp. 391-398.

[6]1930-1950 "Cancer Chemotherapy on the Horizon", "Closing in On Cancer", National Cancer Institute the "Age of Reason", Web Site, **http://rex.nci.nih.gov/behindthenews/cioc**.

[7] "Origins of Cancer Therapy", Rose Papac, Yale Journal of Biology and Medicine 74 (2001), pp. 391-398.

[8] 1930-1950 "The National Cancer Institute is Founded, "Closing in On Cancer", National Cancer Institute the "Age of Reason", Web Site, **http://rex.nci.nih.gov/behindthenews/cioc.**

[9] "ASCO Profile", American Society of Clinical Oncology (ASCO), ASCO Web Site, **www.asco.org, http://asco.org/asco/shared/asco_print_view/1,1168,_12-002013-00_18-0010082,00.html**

[10] "Cancer Care in Eastern North Carolina", 1975-2000, William F. Bobzien, III, MD, North Carolina Medical Journal, January 2002, Volume 62 Supplement, Page S46 - S50

[11] "The First Twenty-Five Years", Association of Community Cancer Centers, About ACCC web page, **http://www.accc-cancer.org/about/25.asp**.

[12] "Chapter 4 - Public Policy and Access to New Drugs: The Case of Cancer Chemotherapy", by Lee Mortenson, The Changing Economics of Medical Technology, National Academies Press (1991), Pgs. 53 – 68.

[13] "What is ONS?" Oncology Nursing Society, ONC website – **http://www.ons.org, http://www.ons.org/xp6/ONS/Information.xml/About_ONS.xml/Mission_Statement_and_...**

[14] "The First Twenty-Five Years", Association of Community Cancer Centers, About ACCC web page, **http://http://www.accc-cancer.org/about/25.asp**.

[15] "Chapter 4 - Public Policy and Access to New Drugs: The Case of Cancer Chemotherapy ", by Lee Mortenson, The Changing Economics of Medical Technology, National Academies Press (1991), Pgs. 53 – 68.

[16] "How has the practice of Oncology changed over the past 20 years?", paper written for patients, Mitlesh Govil, MD, New London Cancer Center, New London, CT 06320, 2001

[17] "Cancer Care in America: Description and Implications of Outpatient Community-Based Cancer Care, March 2002, by Regina E. Herzlinger, DBA, Boston Healthcare Associates, Inc.

[18] "Cancer Care in America: Description and Implications of Outpatient Community-Based Cancer Care, March 2002, by Regina E. Herzlinger, DBA, Boston Healthcare Associates, Inc.

[19] "ASCO Testimony at House Committee on Energy & Commerce Subcommittee Hearing (September 21, 2001), ASCO Web site, **http://www.asco.org/shared/asco_print_view/1,1168,_12-002171-00_18-001715-00….**

[20] "Reform of the Medicare Payment Methods for Cancer Chemotherapy", May 200, American Society of Clinical Oncology, Alexandria, VA 22314.

[21] "The First Twenty-Five Years", Association of Community Cancer Centers, About ACCC web page, **http://www.accc-cancer.org/about/25.asp**

[22] "Approved Claims Per Year", Oncology Approval Statistics 1949 – 2003, Center for Drug Evaluation and Research, Federal Drug Administration web site, **http://www.accessdata.fda.gov/scripts/cder/onctools/statistics.cfm**

[23] "Cancer Care in America: Description and Implications of Outpatient Community-Based Cancer Care, March 2002, by Regina E. Herzlinger, DBA, Boston Healthcare Associates, Inc.

[24] ibid.

[25] "Medicare and Drug Pricing", John Iglehart, The New England Journal of Medicine, Volume 348:1590-1597, April 17, 2003, Number 16.

[26] "Medicare and Drug Pricing", John Iglehart, The New England Journal of Medicine, Volume 348:1590-1597, April 17, 2003, Number 16

[27] "Medicare and Drug Pricing", John Iglehart, The New England Journal of Medicine, Volume 348:1590-1597, April 17, 2003, Number 16.

[28] "Reform of the Medicare Payment Methods for Cancer Chemotherapy", May 200, American Society of Clinical Oncology, Alexandria, VA 22314.

[29] "Medicare and Drug Pricing", John Iglehart, The New England Journal of Medicine, Volume 348:1590-1597, April 17, 2003, Number 16.

[30] "Medicare and Drug Pricing", John Iglehart, The New England Journal of Medicine, Volume 348:1590-1597, April 17, 2003, Number 16.

[31] "Reform of the Medicare Payment Methods for Cancer Chemotherapy", May 200, American Society of Clinical Oncology, Alexandria, VA 22314.

[32] "Reform of the Medicare Payment Methods for Cancer Chemotherapy", May 200, American Society of Clinical Oncology, Alexandria, VA 22314.

[33] "Medicare and Drug Pricing", John Iglehart, The New England Journal of Medicine, Volume 348:1590-1597, April 17, 2003, Number 16.

[34] "Medicare and Drug Pricing", John Iglehart, The New England Journal of Medicine, Volume 348:1590-1597, April 17, 2003, Number 16.

[35] According to HCFA, the AMA survey indicates total practice expenses of $67.50 per hour of physician work, of which $22.40 is direct expenses (clinical staff, supplies, and equipment) and $45.10 is indirect expenses (clerical staff, office expense, and other expense). 63 Fed. Reg. 30818, 30830 (June 5, 1998). Thus, indirect expenses are 66.8% of total expenses.

[36] "The Impact of Medicare Payment Policies on Patient Access to Quality Cancer Care", Barton C. McCann, M.D. and Julia James, June 1999, Health Policy Alternatives, 444 North Capitol Street, NW, Suite 821, Washington, D.C. 20001-1512.

[37] "Hospital Outpatient Prospective Payment Rule Announced by CMS", August 13, 2002, Press Release, Association of Community Cancer Centers, ACCC Web Site, **http://www.accc-cancer.org/news/hopps.asp**

[38] "APCs hitting cancer centers hard, more pain to come", APC Advisor, Volume 2, Number 8, August 2001, Pages 113 – 128.

[39] "How Medicare Payment Cuts Have Affected the Delivery of Cancer Care", Published July 28, 2003, Copyright 2003, Association of Community Cancer Centers, ACCC Website, **http://www.accc-cancer.org/news/medicare0728.asp**

[40] "Reform of the Medicare Payment Methods for Cancer Chemotherapy", May 200, American Society of Clinical Oncology, Alexandria, VA 22314.

[41] "Chapter 4 - Public Policy and Access to New Drugs: The Case of Cancer Chemotherapy", by Lee Mortenson, The Changing Economics of Medical Technology, National Academies Press (1991), Pgs. 53 – 68.

[42] Prepared Witness Testimony, Mr. William J. Scanlon, Director, Health Care Issues, General Accounting Office, Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, Subcommittee on Oversight and Investigations, Subcommittee on Health, September 21, 2001.

[43]Aetna, Oxford and United were private insurers who notified oncologists in CT, NY and NJ that significant cancer payment reform programs were being implemented in the first quarter of 2003.

[44] Statement of Paul Bunn, M.D., Director, Cancer Center, University of Colorado, Denver, Colorado, and President, American Society of Clinical Oncology, Alexandria, Virginia, Testimony Before the Subcommittee on Health of the House Committee on Ways and Means, Hearing on Medicare Payments for Currently Covered Prescription Drugs, October 3, 2002, U.S. House of Representatives Ways and Means Committee Subcommittee on Health Web Site, **http://www.waysandmeans.house.gov/legacy/health/ 107cong/10-3-02/10-3bunn.htm.**

[45] "Financial Analysis of Community Oncology Practice Operations", Prepared and released June 23, 2003; Community Oncology Alliance, Memphis, TN **http://www.communityoncology.org.**

[46]S.1 Prescription Drug and Medicare Improvement Act of 2003 (Reported in Senate), Library of Congress Web Site, Thomas Search Engine, **http://thomas.loc.gov/cgi-bin/query/D?c108:3:./temp/~c108HTPZAk::**

[47] S S.1 Prescription Drug and Medicare Improvement Act of 2003 (Reported in Senate), Library of Congress Web Site, Thomas Search Engine, **http://thomas.loc.gov/cgi-bin/query/D?c108:3:./temp/~c108HTPZAk::**

[48] "Financial Analysis of Community Oncology Practice Operations", Prepared and released June 23, 2003; Community Oncology Alliance, Memphis, TN **http://www.communityoncology.org.**

[49] H.R.1 Medicare Prescription Drug and Modernization Act of 2003 (Received in Senate from House), Library of Congress Web Site, Thomas Search Engine, **http://thomas.loc.gov/cgi-bin/query/D?c108:4:./temp/~c108FyRYND::**

[50] *H.R.1 Medicare Prescription Drug and Modernization Act of 2003*(Received in Senate from House), Library of Congress Web Site, Thomas Search Engine, **http://thomas.loc.gov/cgi-bin/query/D?c108:4:./temp/~c108FyRYND**

[51] H.R.1 Medicare Prescription Drug and Modernization Act of 2003(Received in Senate from House), Library of Congress Web Site, Thomas Search Engine, **http://thomas.loc.gov/cgi-bin/query/D?c108:4:./temp/~c108FyRYND::**

[52] "Medicare Program; Payment Reform for Part B Drugs; Proposed Rule", Department of Health and Human Services Centers for Medicare and Medicaid Services 42 CFR Part 405, 50437 Federal Register / Vol. 68, No. 161 / Wednesday, August 20, 2003 50428-50452.

[53] "Medicare Program; Payment Reform for Part B Drugs; Proposed Rule", Department of Health and Human Services Centers for Medicare and Medicaid Services 42 CFR Part 405, 50437 Federal Register / Vol. 68, No. 161 / Wednesday, August 20, 2003 50428-50452.

[54] "Cancer Care in America: Description and Implications of Outpatient Community-Based Cancer Care, March 2002, by Regina E. Herzlinger, DBA, Boston Healthcare Associates, Inc.

[55] "Fake drugs find their way into Rx supply", Sally Kestin and Bob LaMendola Staff Writers, May 25, 2003, *Copyright © 2003, South Florida Sun-Sentinel*, ***http://www.sun-sentinel.com/news/opinion/editorial/search/sfl-drugmain25may25.story***

[56] "Fake drugs find their way into Rx supply", Sally Kestin and Bob LaMendola Staff Writers, May 25, 2003, Copyright © 2003, South Florida Sun-Sentinel, ***http://www.sun-sentinel.com/news/opinion/editorial/search/sfl-drugmain25may25.story***

[57] "Fake drugs find their way into Rx supply", Sally Kestin and Bob LaMendola Staff Writers, May 25, 2003, Copyright © 2003,South Florida Sun-Sentinel, ***http://www.sun-sentinel.com/news/opinion/editorial/search/sfl-drugmain25may25.story***

[58] "Fake drugs find their way into Rx supply", Sally Kestin and Bob LaMendola Staff Writers, May 25, 2003, Copyright © 2003, South Florida Sun-Sentinel, ***http://www.sun-sentinel.com/news/opinion/editorial/search/sfl-drugmain25may25.story***

[59] "Former convicts try a safer venture: Pharmaceuticals", Sally Kestin and Bob LaMendola Staff Writers, May 26, 2003, Copyright © 2003, South Florida Sun-Sentinel, ***http://www.sun-sentinel.com/news/opinion/editorial/search/sfl-drugplayers26may26.story***

[60] *"Former convicts try a safer venture: Pharmaceuticals Sally Kestin and Bob LaMendola Staff Writers, May 26, 2003, Copyright © 2003, South Florida Sun-Sentinel,* ***http://www.sun-sentinel.com/news/opinion/editorial/search/sfl-drugplayers26may26.story***