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AWPs and the Campaign to Cut Drug Margins

October changes may end access to cancer chemotherapy and supportive care drugs for elders and others

by Lee E. Mortenson, D.P.A., Teri U. Guidi, M.B.A., F.A.A.M.A., and Mary Lou Bowers, M.B.A., L.C.S.W.

Recently the Secretary of the Department of Health and Human Services and the Administrator of the Health Care Financing Administration announced significant cuts in Medicare payments to providers for 50 drugs, 16 of which are commonly used chemotherapy and supportive care drugs. In this article, the authors examine the impact of these cuts on physician practices and hospitals and conclude that the cancer care delivery system is in danger of collapsing.

Over the past several years a number of industries have suddenly confronted collapse as the federal government has cut off vital payments. Although these industries and their patients advocated against these cuts, they were accused of "crying wolf." Now, as Congress considers how it can save failing skilled nursing facilities and home health agencies, recent unilateral actions by the Health Care Financing Administration (HCFA) and rumors of similar congressional action threaten to add another "unintended consequence" to the stack. In this case, it is the fragile cancer care delivery system.

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A STATEMENT OF THE PROBLEM

Recently the Secretary of the Department of Health and Human Services (DHHS) and the Administrator of HCFA made twin announcements that HCFA will encourage Medicare intermediaries to begin reimbursing hospitals and physicians treating Medicare patients according to a drug pricing survey conducted by the Department of Justice (DOJ) during an ongoing investigation of Medicaid drug pricing. HCFA hopes to "encourage" this change without any formal rule or comment by October 1 of this year. This method of reimbursement is being substituted for the traditional reimbursement for drugs at the average wholesale price (AWP) as reported in the *Red Book* and other commercially available resources, which serve as DHHS's current reference source. DHHS contends that it has been surprised to find out that physicians and hospitals pay less than these published wholesale prices. It wishes to move to "correct" this newly discovered disparity by unilaterally substituting the DOJ survey for the prevailing AWP.

The DOJ drug pricing survey includes 16 commonly used chemotherapy and supportive care drugs (some listed by generic name and some by trade name, Table 1) and a number of other drugs that are occasionally used in hospital and office settings. The Department of Justice in conjunction with the states attorneys general has pressured state Medicaid plans to immediately lower their reimbursements to providers on the basis of the survey data. Unfortunately, our analysis of hospital and practice data indicates that adoption of these survey data as a substitute method of "fair" payment underreimburses providers of cancer care and generates significant losses. Providers who continue to administer drugs to Medicare and Medicaid cancer patients in hospital and office settings at these rates will quickly go out of business.

A brief look at the differences between current and proposed reimbursements shows dramatic changes. Two drugs, granisetron (Kytril) and ondansetron (Zofran), are reimbursed in the DOJ report at prices that are equal to AWP minus 28 percent and AWP minus 30 percent, respectively. Three other drugs (Bleomycin, Flourouracil, Lupron Depot) are reimbursed at a price that is roughly equivalent to AWP minus 50 percent. The balance is reimbursed at prices that range between AWP minus 65 percent to AWP minus 99 percent.

ASSESSING THE IMPACT ON HOSPITALS AND PRACTICES

To study the actual impact of these changes on hospitals and cancer practices, ELM Services, Inc. selected data from three representative hospital outpatient cancer care facilities and two four-person medical oncology practices for analysis. While there are a number of methodological issues with this approach, the authors have worked with hundreds of hospitals and practices and focused on selecting facilities that had provided high-quality recent data on drug use and which were believed to be broadly

Table 1. Department of Justice Survey: Price List for Oncology Drugs

DRUG NAME	UNITS	UNITS/ PKG	PRICE/ UNIT
ADRIAMYCIN PFS	2MG/ML VIAL	5	1.69750
ADRIAMYCIN PFS	2MG/ML VIAL	10	1.67375
ADRIAMYCIN PFS	2MG/ML VIAL	25	1.51200
ADRIAMYCIN PFS	2MG/ML VIAL	100	1.50862
ADRIAMYCIN PFS	2MG/ML VIAL	375	1.58906
ADRIAMYCIN RDF	10MG VIAL	1	8.24250
ADRIAMYCIN RDF	50MG VIAL	1	37.14500
ADRIAMYCIN RDF	150MG VIAL	1	113.75000
ADRUCIL	50MG/ML BULK VIAL	50	0.16300
ADRUCIL	50MG/ML BULK VIAL	100	0.14437
ADRUCIL	50MG/ML VIAL	10	0.14725
ANZEMET	20MG/ML VIAL	5	14.81500
BLENOXANE	15U VIAL	1	255.38667
BLENOXANE	30U VIAL	1	509.29000
BLEOMYCIN SULFATE	15U VIAL	1	156.66667
BLEOMYCIN SULFATE	30U VIAL	1	322.00000
CISPLATIN	1MG/ML VIAL	50	3.01950
CISPLATIN	1MG/ML VIAL	100	3.01500
CISPLATIN	1MG/ML VIAL	200	3.01750
CYTARABINE	20MG/ML VIAL	25	0.50500
CYTARABINE	20MG/ML VIAL	50	0.78000
CYTARABINE	100MG VIAL	1	4.15500
CYTARABINE	100MG VIAL	10	0.35000
CYTARABINE	100MG VIAL	10	0.35000
CYTARABINE	1GM VIAL	1	21.37000
CYTARABINE	1GM VIAL	1	22.00000
CYTARABINE	2GM VIAL	1	43.53000
CYTARABINE	2GM VIAL	1	44.00000
CYTARABINE	500MG VIAL	10	1.06100
CYTARABINE	500MG VIAL	10	1.05000
CYTARABINE	500MG VIAL	1	12.14333
CYTOSAR-U	100MG VIAL	1	4.06000
CYTOXAN LYOPHILIZED	100MG	1	4.18333
CYTOXAN LYOPHILIZED	200MG	1	7.02667
CYTOXAN LYOPHILIZED	500MG	1	11.59333
CYTOXAN LYOPHILIZED	1GM	1	23.18667
CYTOXAN LYOPHILIZED	2GM	1	45.82667
DOXORUBICIN	2MG/ML VIAL	5	1.47000
DOXORUBICIN	2MG/ML VIAL	5	2.52666
DOXORUBICIN	2MG/ML VIAL	5	2.07000
DOXORUBICIN	2MG/ML VIAL	5	1.47000
DOXORUBICIN	2MG/ML VIAL	10	1.47000
DOXORUBICIN	2MG/ML VIAL	10	2.02000
DOXORUBICIN	2MG/ML VIAL	10	1.47000
DOXORUBICIN	2MG/ML VIAL	25	1.47000
DOXORUBICIN	2MG/ML VIAL	25	1.40000
DOXORUBICIN	2MG/ML VIAL	25	1.51866
DOXORUBICIN	2MG/ML VIAL	25	1.36000
DOXORUBICIN	2MG/ML VIAL	100	1.40000
DOXORUBICIN	2MG/ML VIAL	100	1.42000
DOXORUBICIN	2MG/ML VIAL	100	1.39750
DOXORUBICIN	2MG/ML VIAL	100	1.17170
DOXORUBICIN	10MG VIAL	10	0.96700
DOXORUBICIN	20MG VIAL	10	1.64750
DOXORUBICIN	50MG VIAL	1	35.91667
ETOPOSIDE	20MG/ML VIAL	5	1.40000
ETOPOSIDE	20MG/ML VIAL	5	1.69000
ETOPOSIDE	20MG/ML VIAL	25	1.80000
ETOPOSIDE	20MG/ML VIAL	25	1.80500
ETOPOSIDE	20MG/ML VIAL	50	1.57260
ETOPOSIDE	20MG/ML VIAL	50	1.74850
FLOUROURACIL	50MG/ML VIAL	10	0.12000
FLOUROURACIL	50MG/ML VIAL	20	0.13000
FLOUROURACIL	50MG/ML VIAL	50	0.12000
FLOUROURACIL	50MG/ML VIAL	100	0.11000
KYTRIL	1MG/ML VIAL	1	139.03750
KYTRIL	1MG/ML VIAL	4	138.91750
LEUCOVORIN CAL	10MG/ML VIAL	10	0.38500
LEUCOVORIN CAL	10MG/ML VIAL	25	0.34700
LEUCOVORIN CAL	50MG VIAL	10	0.27625
LEUCOVORIN CAL	100MG VIAL	1	3.49333
LEUCOVORIN CAL	100MG VIAL	10	0.32375
LEUCOVORIN CAL	200MG VIAL	1	8.18750
LEUCOVORIN CAL	350MG VIAL	1	15.83333
LEUCOVORIN CAL	350MG VIAL	1	14.58333
LUPRON DEPOT	3.75MG KIT	1	406.00000
LUPRON DEPOT	7.5MG KIT	1	482.52250
LUPRON DEPOT	30MG VIAL	1	1903.80333
METHOTREXATE	1GM VIAL	1	45.96667
METHOTREXATE	25MG/ML VIAL	2	1.31666
METHOTREXATE	25MG/ML VIAL	2	1.71250
METHOTREXATE	25MG/ML VIAL	4	0.91250
METHOTREXATE	25MG/ML VIAL	8	0.62916
METHOTREXATE	25MG/ML VIAL	10	0.57000
METHOTREXATE LPF	25MG/ML VIAL	10	0.71000
METHOTREXATE LPF	25MG/ML VIAL	2	1.45625
METHOTREXATE LPF	25MG/ML VIAL	4	1.07937
METHOTREXATE LPF	25MG/ML VIAL	8	0.72968
MITOMYCIN	5MG VIAL	1	51.83333
MITOMYCIN	20MG VIAL	1	146.66667
MITOMYCIN	20MG VIAL	1	134.00000
NEOSAR	100MG VIAL	1	3.92000
NEOSAR	200MG VIAL	1	5.06000
NEOSAR	500MG VIAL	1	7.33250
NEOSAR	1GM VIAL	1	11.23750
NEOSAR	2GM VIAL	1	21.60250
TOPOSAR	20MG/ML VIAL	5	1.89333
TOPOSAR	20MG/ML VIAL	10	1.90000
TOPOSAR	20MG/ML VIAL	25	1.76000
VEPESID	20MG/ML VIAL	5	6.86000
VEPESID	20MG/ML VIAL	7.5	6.86000
VINBLASTINE	1MG/ML VIAL	10	0.90000
VINBLASTINE	1MG/ML VIAL	10	1.09250
VINBLASTINE SULF	10MG VIAL	1	7.95000
VINCASAR PFS	1MG/ML VIAL	1	5.10000
VINCASAR PFS	1MG/ML VIAL	2	4.17500
VINCRISTINE	1MG/ML VIAL	1	4.33750
VINCRISTINE	1MG/ML VIAL	2	3.80000
ZOFRAN	2MG/ML VIAL	2	11.30500
ZOFRAN	2MG/ML VIAL	20	8.45300
ZOFRAN	32MG/50ML BAG	50	2.56175

representative of their type. Several of the oncology wholesalers and the practices and hospitals themselves were approached to assure that they had provided the most recent prices.

Since the objective was to calculate the effect of only those reimbursement changes that have been announced to date (i.e., only those 16 oncology drugs listed in the DOJ survey), the margins on other oncology drugs (e.g., they were computed as being reimbursed at AWP minus 5 percent) were left untouched. It should be noted that the margins between acquisition and AWP minus 5 percent on single-source drugs are, in general, considerably lower than the margins on multi-source drugs.

For each hospital and practice, the usage for each drug was multiplied by 1) its current reimbursement, 2) cost (using current price lists or direct cost data reported by the hospital or practice), and 3) the proposed reimbursement. To assure that the effect was only being measured on the Medicare/Medicaid population, all patients seen were converted to the Medicare pricing schedule. While this does not take into account differences in payer mix or price shifting, it demonstrates the likely impact of these policy changes on the Medicare and Medicaid patient populations, which are 50 to 65 percent of the current cancer care population. Assuming that other payers are likely to adopt the Medicare/Medicaid pricing schedule, a universal conversion is appropriate.

Table 2 summarizes the findings for hospitals. Given that Medicare cost reports indicate that hospitals "break even" at AWP minus 5 percent (see our discussion in this article), the three sample facilities all face significant losses. Of course, this analysis does not calculate losses that would be generated by a broader policy shift to this type

Table 2. Variance in Hospital Reimbursement at AWP-5% vs. DOJ Reimbursement Rates

	Large University Hospital	Large Community Hospital	Small Community Hospital
in dollars	$ (2,127,221.41)	$ (531,309.00)	$ (869,048.00)
as percent	-6.50%	-9.70%	-28.08%

All three hospitals demonstrated significant reductions in payment from losses generated by the 16 oncology drugs in the Department of Justice survey.
NOTE: The smaller the hospital the greater the percentage loss generated, probably because smaller hospitals buy at smaller quantities.

Source: ELM Services, Inc.

Table 3. Oncology Practice Losses Under DOJ Reimbursement Rates

	4-person medical oncology practice #1	4-person medical oncology practice #2
Practice Loss for All Drug Acquisitions with DOJ Rates for 16 Drugs		
in dollars	$ (100,464.43)	$ (56,613.02)
as percent	-5.00%	-2.82%
Variance in Practice Reimbursement with DOJ Rate Reductions		
in dollars	$ (621,238.58)	$ (468,493.14)
as percent	-24.55%	-19.34%

Both practices are unable to acquire drugs at the Department of Justice prices. The underpayments are so severe, they drag all of the group practice costs below break even. Given losses on acquisition and an inability to use the margin to support nurses, extra space, inventory, and other extra costs for providing chemotherapy in offices, these practices are likely to stop providing drugs to Medicare, Medicaid, and other cancer patients.

Source: ELM Services, Inc.

Table 4. A Comparison of APC Payments* for Chemotherapeutic Agents with AWP-5%

APC	Total Cost Report Payment	Total AWP	Total AWP-5%	Total Cost Report Payments vs. Total AWP-5%
061 Level I Agents	$31,018,290	$ 5,444,549	$ 5,172,322	$25,845,968
062 Level II Agents	$22,006,281	$28,321,351	$26,905,283	-$ 4,899,002
063 Level III Agents	$31,135,449	$31,284,679	$29,720,445	$ 1,415,004
064 Level IV Agents	$12,816,793	$17,640,539	$16,758,512	-$ 3,941,719
Total	$96,976,813	$82,691,118	$78,556,562	$18,420,251

*APC payments are constructed from finalized hospital cost reports and include acquisition costs and costs associated with drug delivery.

This analysis illustrates that the initial APCs for chemotherapy (which were constructed by HCFA based on actual hospital costs) and AWP-5% were comparable in 1996 dollars. Although it appears that AWP-5% is actually below the proposed APC reimbursement, the AWP totals do not include new drugs coded with a J9999 (unknown) code. When those drugs are included, the difference is less than $2 million.

Source: Analysis by The Lewin Group and Orion Consulting

of pricing, i.e., lower reimbursement on other oncology drugs. However, with *just these initial changes in reimbursement for 16 drugs, it is clear that many hospitals will have to close their oncology chemotherapy units to avoid substantial losses.*

It is important to note that the larger the facility the more likely it is to obtain favorable pricing. Yet, even the largest facility used in this analysis will still have significant percentage losses, which will translate to significant dollar losses. The smallest hospital has significant losses: more than 25 percent below the average costs.

The data are equally compelling at the physician-practice level and call into question the validity of the DOJ survey methodology. As Table 3 illustrates, physician practices will take significant cuts in their total reimbursement for cancer drugs with the implementation of this new policy. In the case of the two four-person oncology groups studied, the underpayment of the 16 drugs *without additional cuts* caused medical oncology drug reimbursement to generate a substantial loss to the entire practice. In both of these cases, the lower reimbursement for the 16 drugs is so far below the costs to acquire these 16 drugs that the *total* Medicare reimbursement for the practice would fall below acquisition costs. Astonishingly, in none of the five cases could the hospitals or practices match the pricing schedule proposed by the DOJ survey. Indeed, the authors have heard from many medical oncologists and hospital administrators who wish to know who the DOJ surveyed, since they cannot obtain these prices. At this point, the DOJ, immersed in a lawsuit, is unwilling to discuss its survey methodology, leaving many hospitals and physicians baffled.

Given these results, it is likely that the hospitals and medical oncology practices will downsize their staff, eliminating oncology nurses, diverting patients to other locations for chemotherapy and supportive drugs, and, depending on the response of other insurers, perhaps stop providing chemotherapy to all cancer patients. Given the size of the losses, it is likely that the minimum response of the two four-person medical oncology groups would be to give Medicare and Medicaid patients a script for their infusions and urge them to find treatment elsewhere.

DATA PROVIDE INSIGHTS INTO THE VALIDITY OF AWP MINUS 5 PERCENT

Cancer care drug delivery is clearly different from many other forms of prescription drug usage. Instead of going to a local pharmacy for pills with minor side effects, cancer patients receive most of their drugs by infusion or injection or both. Even their oral drug usage requires extensive education and follow-up, since most cancer therapeutic drugs are lethally toxic if handled improperly. Used by only a limited number of patients, cancer therapeutic and supportive care drugs require precision in mixing based upon the patient's body surface area, and, as biohazards, require special disposal, mixing and administrative procedures. Patients and their caregivers require an inordinate amount of

Where Patients Receive Chemotherapy

To provide chemotherapy in their offices, medical oncologists support a facility and staff that differ from most medical specialties. In addition to exam rooms, billing staff, and the other typical requirements of private practice, medical oncologists require a higher level of nursing support to mix and administer these toxic agents. These nurses have to provide a higher level of patient education, giving patients and their families explicit information about medications, when they should call the office, or when they should take other actions. Moreover, providing chemotherapy requires medical oncologists to make a variety of special purchases. These include specialized chairs where patients spend long periods of time receiving an infusion; refrigerated space for a large inventory of chemotherapy agents that are not readily stocked at local pharmacies; and mixing hoods, under which the chemotherapy "cocktails" can be mixed in the proportions appropriate to the physician's orders and the patient's body size. In addition, medical oncologists must rent extra space to deliver the chemotherapy. Finally, they must dispose of hazardous waste, including the extra chemotherapy not used by an individual patient.

Thus, in many ways, medical oncology offices replicate the space, equipment, staffing, and service requirements of a specialized outpatient hospital chemotherapy area. Of course, none of these extra costs for nursing, inventory, space for delivery of chemotherapy, specialized equipment (chemotherapy chairs and hoods) are within the typical formula for RBRVS reimbursement. Medical oncologists have been able to support these costs at least in part through the difference between acquisition costs of drugs and actual reimbursement by payers. Hospitals have been able to support at least part of these costs through a facility fee, but there is no equivalent in private practice.

Over the course of the two decades since the advent of a prospective payment system for inpatient hospital use (diagnosis-related groups, or DRGs), chemotherapy has moved from an inpatient basis to a 90 percent outpatient basis, with 60 percent of all chemotherapy delivered in physician offices and 30 percent delivered in hospital outpatient cancer centers.

This change over the past two decades has altered the availability of cancer chemotherapy and supportive care drugs. At the beginning of the 1970s there were few locations and few therapies with which cancer patients could be treated. At the beginning of the 21st century, however, we have a significantly advanced armamentarium, with more than 300 new drugs and biologicals under development and a delivery system that assures that any patient requiring cancer drugs will find them within an easy drive of their home.

education especially since their ability to comprehend and remember instructions under this type of stress is often diminished. It is not surprising that under the current system of reimbursement, many costs of delivering chemotherapy and supportive care drugs are not absorbed. Indeed, it has been well recognized by Congress and DHHS (until recently) that the margin between the price that practices and hospitals pay for chemotherapy and supportive drugs and the payment they receive from Medicare reimbursement allows both practices and hospitals to pay for these extra costs of cancer care delivery. Yet, throughout the last eight years under the current Administration there have been a number attacks on this system of reimbursement. Members of the Administration and Congress have asked: Why should the drug margin not be eliminated and replaced with an incentive-neutral system that reimburses hospitals and medical oncologists for their actual costs of giving chemotherapy in an outpatient setting?

Although many in the cancer care community agree that a different system of paying for care would be valuable, they are extremely anxious about the current proposals. They are concerned because the margin is being eliminated without any real consideration or understanding that the cancer care delivery system *cannot cover these costs in other ways.* The usual suggestion has been that we eliminate the margin on drugs now and figure out how to cover the costs for care delivery later. Obviously, cancer care providers fear the very action that has now been unilaterally implemented by HCFA.

The premise on which many of these discussions are based is that there is "fat" in the system. This excess is seen as a savings opportunity, something that is going to physicians or hospitals as an unnecessary profit. The individuals who pose this scenario of eliminating the excess also assume that physicians and hospitals will continue to give these drugs (in appropriate amounts) without any profit or margin. The core argument is a simple sound bite: there is excess in the drug margins, which should be eliminated. Our findings call into question the premise that there exist excesses that can be eliminated without jeopardizing the viability of the cancer care delivery system.

During the recent debate on the implementation of the outpatient prospective payment system (OPPS) for hospitals, we examined data from HCFA's hospital data tapes and engaged The Lewin Group and Orion Consulting to simulate the creation of HCFA's ambulatory payment classifications (APCs). These records displayed a close alignment between Medicare payments for hospitals administering chemotherapy and supportive care drugs in the hospital outpatient environment and the then-prevailing method of paying physicians in their offices (i.e., 95 percent of average wholesale price, or AWP minus 5 percent).

To construct the APCs, HCFA used finalized hospital cost reports, which provide actual costs associated with each hospital outpatient procedure. For chemotherapy drugs, for example, these cost reports provide HCFA with the non-billable costs that are associated with giving the drugs in addition to their acquisition costs for the drugs themselves. Since it takes a while for HCFA and the hospital to finalize these reports, the most recent data that HCFA has available for the construction of the APCs is from 1996. Table 4 displays the initial ambulatory payment classification group payments proposed for hospital outpatient care. While it appears that the APCs (i.e., the reported hospital costs) exceeded AWP minus 5 percent in 1996 dollars, the APCs included payment for all the new therapeutic drugs (those available and recorded in 1996), and the AWP minus 5 percent calculation does not. Since J9999 (unknown) codes were used for all of these new drugs, it was impossible to ascertain the average wholesale price. However, the value of these drugs, as reported on these finalized Medicare hospital cost reports, is approximately $20 million. When this amount is added to the AWP column or subtracted from the APC column, the difference in the two columns is minimal (less than $2 million nationally). *Thus, the actual cost to hospitals for providing chemotherapy and supportive care, documented in the finalized Medicare cost reports, was equivalent to average wholesale price minus 5 percent* (AWP-5 percent).

Based on these data, last fall ACCC recommended that Congress adopt AWP minus 5 percent as a "level playing field" for both hospitals and physicians' offices and a substitute for the original APC categories which underpaid new cancer therapeutic drugs and supportive care drugs by as much as 50 percent.

The planned HCFA reductions in payments below AWP minus 5 percent (as it is currently defined) will cause hospitals to evaluate their oncology units as unprofitable in relation to other service lines, unless hospitals are generating significant payments from the administration of chemotherapy or an allied service, such as radiation oncology to offset the losses.

We are able to comment on this possibility given new data that we have recently reviewed in preparation of the Association of Community Cancer Centers' (ACCC) comments to HCFA on its final regulations for the revised APCs issued this spring. Once again we engaged The Lewin Group and Orion Consulting to simulate the data that HCFA used in creating the APC groups. In the case of chemotherapy administration, we found a $3 million shortfall below costs. In the case of radiation oncology, the number was more dramatic: $136 million below costs. With the addition of losses in chemotherapy reimbursement being proposed for October 1, it appears that every aspect of the oncology product line generates a loss for hospital outpatient cancer care.

COMMENTARY: A LOSS OF ACCESS TO CANCER CARE

With the cuts that have already been announced, it appears likely that HCFA will shut down the nation's cancer care delivery system in a matter of weeks or months. While HCFA staff often maintains that hospitals can support losing services with the margin on winning services, history does not support this view. Hospital

administrators, already under financial strain from managed care and reductions in Medicare and Medicaid reimbursement, are forced to concentrate their resources on service lines that are economically viable and prune those service lines that generate losses.

Of course, it will still be possible for some hospitals and practices in some locations to provide chemotherapy services to some patients. However, it is clear that the sudden loss of revenues from those cuts that the Secretary has already imposed will be sufficient to generate rapid closings of many offices and hospital outpatient programs throughout the country. Without question, Medicare and Medicaid patients will have huge access problems, with the loss of many providers of cancer care literally overnight. Given the absence of Medicare and Medicaid patients, who make up the majority of cancer patients seen in the average hospital or practice population, these facilities may also not be able to sustain a treatment service for private-pay patients.

In the halls of Congress, at DHHS, and in physician offices and hospitals, the question is the same: what is an appropriate way to cover the costs of delivering chemotherapy and supportive care to cancer patients? Everyone would like a simple answer. Members of Congress and the Administration would like there to be a cost savings that they could use to fund other programs. Unfortunately, there are a number of issues that need to be considered, some of which will arise automatically if the Secretary's actions are not reversed.

The first issue critical to this debate is the access to cancer care. Over the past 25 years, cancer care, especially chemotherapy and radiation oncology, have moved from a few university-based cancer centers to the neighborhoods of America. Where patients once had to fly with their family to a distant city for life-saving treatments, they can now drive to a local physician's office or hospital outpatient cancer center in their neighborhood. Patients' families now experience much less disruption in their everyday activities. Patients themselves can maintain a close to normal life in the familiar surroundings of their own home and community.

This dissemination of cancer care throughout all regions of the nation was not a planned event. Medical oncologists set up offices where there were little or no cancer services, first in urban areas, then in increasingly rural areas. Hospitals recognized the coming surge in cancer patients as the nation's "boomer" generation aged and established oncology inpatient programs. When Medicare payment for inpatient chemotherapy dived below existing costs, hospital outpatient cancer centers and medical oncologist offices suddenly became a significant addition to the locations where patients could receive this complicated therapy.

The result of this unplanned expansion and change in inpatient reimbursement is a network of hospital outpatient cancer centers and physician offices where cancer patients have ready access to chemotherapy under the supervision of their medical oncologist, who can supervise their progress and their therapy. In their physician's office or their neighborhood hospital outpatient cancer center, cancer patients and their families can find a comfortable, convenient, and safe location where they can have these toxic chemicals administered under the supervision of trained oncology nurses who know how to handle the complications, teach while they treat and help patients access all of the other resources they and their families need when facing this dread disease.

If we wish to support this cancer care delivery system, we must support the costs of delivering chemotherapy and supportive care at both hospitals and physicians' offices. A reduction in payment for oncology drugs—without an offsetting increase in other fees to physicians and hospitals—will eliminate the current provider network in oncology as well as 95 percent of the infrastructure for clinical cancer research. The care of cancer patients will return to those few facilities that can remain open. While it is cruel, it should be mentioned that many previous studies have shown that limiting access saves money because many patients and families will not or cannot support the logistics and disruptions that accompany seeking treatment at a distance from home. If this is the policy, we must bear the consequences...higher mortality from cancer at the same time that politicians are trumpeting the successes of research.

On a more practical note, we have worked on several models to see if we could construct a "bottom up" method of reimbursing chemotherapy and supportive care drugs and have been confronted with a number of daunting issues. First, in the hospital model, we know that "break even" for hospitals is the current level of reimbursement: AWP minus 5 percent at *Red Book* levels. We do not know break even in the practice setting, although it is clear that the losses incurred by the proposed changes drag down the entire reimbursement in a practice to the point where its total costs for all cancer drugs are below break even. This means that there is no margin for the other necessities of giving the drugs.

Second, if one is going to construct a model that returns a hospital or practice to a sufficient level of surplus above the drug acquisition costs to cover their extra costs for administration of the drug, storage, inventory, losses, and other costs of doing business, one must start with a "base" and have a target in mind. The issue of the base is a core issue. The DOJ survey was done for a lawsuit. The fact that none of the hospitals and providers in our analysis is able to acquire many of these drugs at DOJ rates calls into question their methodology. Perhaps these methods will serve for a one-time legal case, but does the Department of Justice intend to go into the quarterly survey business? Does DHHS assume that there will henceforth be no price increases? Currently there are several commercial sources that provide AWP, and the Justice Department is leaning on them to use DOJ prices. This seems inappropriate, economically unsound, and ill advised. Again, who will update these prices using which methodology?

Third, the Secretary of DHHS and the Administrator of HCFA

have made it clear that they intend to find other mechanisms to make other substitutions for AWP. Thus, other drugs will be affected, although we do not know which mechanisms will be used or the amounts the Secretary will cut. For example, the Secretary in her recent letter to Chairman Tom Bliley of the House Commerce Committee, indicated that she wished to use a rule called "Inherent Reasonableness," which would allow her to unilaterally cut prices by up to 15 percent per year. If she uses this on newer, single-source drugs, their reimbursement could go down a different amount than the reductions in the multi-source drugs. It should be noted that newer, single-source drugs have a much smaller margin than the multi-source drugs cited in the DOJ survey. Thus, we do not know if these cuts will be across the board or selective and what the basis for the cuts might be.

Fourth, assuming that we shift away from the Department of Justice one-time survey, shall we use manufacturers' list price or acquisition costs? Acquisition costs will require every provider to send bills to Fiscal Intermediaries and Medicare Carriers. This will eliminate electronic billing, lengthen cash-flow cycles, and in and of itself cause many locations to stop providing chemotherapy because they will not be able to finance the costs of $500,000 to $650,000 in drug inventory for each medical oncologist.

If we select manufacturers' list price, which manufacturer list? To whom are these prices being offered? The DOJ list purports to be a manufacturer's list price, but none of the offices and hospitals whose data we have seen can match these prices.

The next question is what is the target we are trying to reach? Should we build models with or without trained oncology nurses? How much rent should we allocate for the space where patients receive their chemotherapy? What about the specialized chemotherapy chairs themselves and the drug mixing hoods? What about storage facilities, including the need for refrigeration? Should we factor in state sales taxes, which many oncologists currently pay for chemotherapy and supportive care drugs? How much should we allocate for the inventory carrying costs on $500,000 to $650,000 in drugs? What about losses due to uncollected co-pays? With hard work some oncologists may obtain up to 90 percent of the co-pays, but in various parts of the country, hospitals and physicians can hope to collect no more than 50 percent. What about the disposal taxes for the hazardous waste that many oncologists pay? What about the gross receipts tax that some states charge? According to one study by former HCFA staffer Bart McCann, M.D., medical oncologists lose on average $180 over the course of a year for every Medicare patient they treat. Do we maintain that loss, reduce it, or increase it? Are we trying to preserve access for Medicare patients to chemotherapy in physicians' offices and/or hospitals or end it?

POSSIBLE SOLUTIONS

What type of fix should be developed? One suggestion is that Congress pass a change to the medical oncologists' practice expense component of their current reimbursement through the resource-based relative value system (RBRVS). If this is done, it will be the first time that Congress has inserted itself into the American Medical Association's Resource Utilization Committee process. While medical oncology has approached this committee requesting changes in the practice expense component of their reimbursement, which would make up part of the difference, they have faced other specialties that recognize any addition to one specialty is a subtraction of money available to other specialties. Congressional intervention in this area would cause great discord between the specialties even if new dollars were added to the pot, since the process by which it has allocated resources would suddenly become a process that could be influenced by politics.

When faced with the prospect of hospital margins decreasing in concert with physician offices, one congressional staffer suggested that all hospital drug bills would then be "covered" by outlier payments. However, outlier payments would require that each cancer patient bill be reviewed as an outlier. Then, hospitals could expect to recover only 75 percent of the difference of the payment and AWP minus 5 percent (e.g., their cost). Thus, a hospital administrator would be faced with the prospect of adding additional personnel to qualify every cancer patient's bill as an outlier and then expect to be reimbursed at less than the actual costs by the resulting partial payment.

Another congressional staffer suggested that a solution to the dilemma might be to pay hospitals according to one AWP source, while practices are paid according to another. While this may work for hospitals, the dichotomy is clear: the "level playing field" that has been an objective of lawmakers and administrators once again disappears.

Yet another solution might be a combination of some uniform mark-up on drugs, based on a standard manufacturer's list price and perhaps a facility or preparation fee.

Patients, HCFA staff, Congress, and providers might each have their own answers to the many questions posed in this article. However, it is clear that these first cuts will result in causing the collapse of the current cancer care system. Given this impending dislocation of care and the lack of clarity around a solution, it appears that a sensible short-term solution might be for Congress to call a "time out." Congress could require the oncology community and HCFA to develop a sound methodology to answer the question of a substitute approach to covering these extra expenses for the provision of care. While there is no guarantee that any "savings" can be found, this intermission would assure that Medicare, Medicaid, and other cancer patients continue to have access to cancer therapeutic and supportive care drugs while an appropriate solution is researched.

The hard question that faces us after October 1, 2000, is: where will these patients and their families receive chemotherapy and supportive care treatments? Perhaps we have decided that their care is less important than the "savings."