United States General Accounting Office

GAO

Report to the Chairman, Committee on Finance, U.S. Senate

July 1992

MEDICARE

Reimbursement Policies Can Influence the Setting and Cost of Chemotherapy

GAO/PEMD-92-28

GAO

United States
General Accounting Office
Washington, D.C. 20548

Program Evaluation and
Methodology Division

B-248953.1

July 17, 1992

The Honorable Lloyd Bentsen
Chairman, Committee on Finance
United States Senate

Dear Mr. Chairman:

In a previous U.S. General Accounting Office (GAO) study on off-label drug use, oncologists reported admitting patients to hospitals to avoid reimbursement problems associated with treatment in the office setting.[1] In light of that finding, in February 1991 you asked us to identify and report on factors that influence where oncologists treat Medicare patients and the potential cost to the federal government of treatment in different settings. We briefed members of the committee staff on our preliminary findings in June 1991 and document our results in this report.

The Health Care Financing Administration (HCFA) has a mandate to control costs and ensure that high-quality care is provided to Medicare beneficiaries. However, despite its efforts, Medicare spending continues to rise. As a result, the history of payment policy in the Medicare program has largely been an attempt to constrain the growth in expenditures.

Our review showed that (1) some oncologists have treated cancer patients in hospital inpatient and outpatient settings when, by clinical standards, they could have received treatment in the office; (2) financial factors influence the oncologist's choice of treatment setting; and (3) treatment in the hospital inpatient setting was most expensive to Medicare in three case studies.[2]

These results indicate that HCFA's reimbursement policies can have consequences beyond their intent. That is, whether and how much physicians are reimbursed by Medicare can affect the oncologist's choice

[1]See Off-Label Drugs: Initial Results of a National Survey, GAO/PEMD-91-12BR (Washington, D.C.: February 1991), and Off-Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies, GAO/PEMD-91-14 (Washington, D.C.: September 1991). The Food and Drug Administration (FDA) designates the clinical indications for which a drug has been proven effective on a label insert for each approved drug. "Off-label" drug use occurs when physicians use a drug to treat conditions other than those listed on the drug's label.

[2]The three treatment settings included in our case studies are hospital inpatient facility, hospital outpatient department, and physician's office. Case studies of these settings were conducted in three cities.

of treatment setting and, as a result, can also have a deleterious effect on Medicare expenditures.

Objectives, Scope, and Methodology

Most of the oncologists responding to our off-label drug survey reported "admitting patients to a hospital because a third party payer would not reimburse for the outpatient administration of anticancer drugs." The issue of where care is provided was not a central focus of the off-label drug project and the magnitude of this response indicated that more work on the issue might be warranted. Therefore, we focused this follow-on work on the relationship between reimbursement policies and the setting of care. Our objectives were (1) to determine if oncologists treat patients outside the office setting, (2) to determine why oncologists treat patients outside the office setting, and (3) to explore the potential effect on Medicare costs.

We examined each of these questions with different methods. To determine the factors that influence oncologists' choice of treatment setting, we interviewed oncologists and developed a model that illustrates the decisionmaking process. The model was developed and refined with the input and review of experts in the field.[3] To explore Medicare cost implications, we conducted case studies in three cities—Albuquerque, New Mexico; Cleveland, Ohio; and Santa Monica, California.[4] The case studies were limited to one type of cancer with one treatment regimen for one patient profile. In addition, to clarify whether oncologists treat outside the office for nonclinical reasons, we resurveyed respondents to GAO's earlier off-label survey. Greater detail on our methodologies is presented in appendix I.

Oncologists Treat Patients Outside the Office Setting

Individuals and representatives of organizations we briefed on our off-label drug use survey expressed doubt about the accuracy of oncologists' reports that they have admitted chemotherapy patients to hospitals when treatment could have been provided in the office setting. They believed that survey respondents may have been confused by the question's wording; for example, respondents may have interpreted the phrase "admit to the hospital" as meaning treatment in either the hospital inpatient or hospital outpatient setting.

[3]To help us refine the model, we met with officials and members of the American Society of Clinical Oncologists (ASCO), the Association of Community Cancer Centers (ACCC), and HCFA.

[4]For details on how the locations were selected, see appendix I.

When we surveyed the respondents to our original study, the majority confirmed that they admit patients (who, by clinical standards, could be treated in the office) to the hospital inpatient setting for treatment because of financial considerations. In addition, oncologists said they treated such patients in the hospital outpatient setting.

Why Oncologists Treat Outside the Office Setting

Professional standards require physicians to place the health and welfare of their patients above all other considerations in determining the most appropriate treatment. The off-label drug use study showed, however, that financial factors may also influence treatment decisions. To better understand how financial factors affect where cancer patients are treated, we conducted a series of interviews with oncologists and professional society representatives. In each interview, we were interested in situations in which the welfare of the patient or quality of care would not be compromised by the oncologist's decision regarding setting of care; that is, the outcome for the patient would be the same regardless of where treatment was provided.

We learned that many factors, such as the distance a patient must travel to receive treatment and whether the patient has support at home, can influence whether a patient is treated in the oncologist's office or elsewhere. However, oncologists we interviewed consistently stated that their choice of treatment setting (once patient welfare is taken into account) often hinges on whether they expect reimbursement to be adequate if treatment is provided in the office setting.

For example, oncologists told us they may decide to treat outside the office setting if they expect to lose money because of reimbursement denial for off-label drug use or because of what they consider inadequate reimbursement for labeled drug use. Oncologists in private practice typically maintain costly drug inventories. Therefore, reimbursement below a drug's cost or reimbursement denial could represent a considerable financial loss.

Oncologists also told us they may treat outside the office setting if they expect a patient to be unable to pay the required insurance deductibles or copayments. Regardless of the treatment setting, Medicare requires that the patient pay a portion of the physician's approved charges. The amount of the patient's liability, however, frequently varies depending on where the treatment is provided. Generally, Medicare deductible and coinsurance would be lowest in the office setting.

Oncologists generally incur higher costs when treatment is provided in the office setting because they typically provide all the services and drugs associated with treatment. (In a hospital setting, the oncologist usually provides only professional services.) Consequently, the patient's liability to the doctor is often highest in the office setting. Oncologists who believe a patient cannot meet this liability may avoid the potential financial loss and decide to treat outside the office setting.

To maintain a viable private practice, an oncologist would logically consider the potential for financial profit or loss (after patient welfare is taken into account) when deciding where to treat chemotherapy patients. As can be seen from the model presented in appendix I, when oncologists expect reimbursement to be inadequate in the office setting, they are likely to provide chemotherapy in another setting.

Medicare Costs for Three Treatment Settings

To explore whether oncologists' treatment-setting decisions affect Medicare costs, we conducted case studies in three locations. We used a case study methodology because of the difficulties associated with using several HCFA data bases to generalize costs. To focus on cost variations stemming specifically from treatment setting, we targeted the cases on one type of cancer, one treatment regimen, and one patient profile. The results are, of course, illustrative because case study results cannot be generalized.

For all three case studies, we used a patient profile and treatment regimen developed with the assistance of the National Cancer Institute (NCI) to estimate the cost to Medicare of providing chemotherapy in each setting—hospital inpatient facility, hospital outpatient department, and physician's office.

In all three locations, Medicare's cost was highest for treatment in the hospital inpatient setting. In two of the locations, the hospital outpatient setting was least expensive; in the third, Medicare's cost for treatment in the physician's office was lowest.

The hospital inpatient setting was most expensive regardless of whether off-label drug use was reimbursed or denied in any setting. However, reimbursement or denial for off-label drug use did affect whether the hospital outpatient or physician's office setting would be the least costly to Medicare. Detailed case study results are presented in appendix I.

Conclusions

Our results indicate that oncologists treat patients in the hospital inpatient and outpatient settings when, by clinical standards, they could receive treatment in the office. In addition, oncologists' choice of treatment setting (once patient welfare has been considered) often depends on whether they expect reimbursement to be inadequate for treating a chemotherapy patient in the office setting. Finally, for each of our three case studies, the estimated Medicare cost for chemotherapy treatment was more expensive in the hospital inpatient setting than in other treatment settings.

Determining the exact cost implications of these results is difficult because oncologists may use hospital inpatient or outpatient settings when they fear inadequate reimbursement for treating patients in their offices. Our case studies demonstrate that Medicare costs can be highest for hospital inpatient care but may be lowest for hospital outpatient care.

What is clear from our results, however, is that HCFA's reimbursement policies for chemotherapy have unintended consequences that extend beyond whether and how much oncologists are reimbursed by Medicare. Specifically, the policies may affect where a cancer patient gets treated and, as a result, Medicare costs for that patient's care.

HCFA Comments

HCFA provided written comments on an earlier draft of this report. Both HCFA's comments and our responses to them are presented in appendix II. The agency does "not disagree" with the general conclusion that Medicare payments to physicians for chemotherapy and for the off-label use of certain drugs may affect where cancer patients are treated. However, HCFA's comments ignore the resulting influence on Medicare costs and characterize our conclusions as "benign." We cannot agree. We believe that any finding that Medicare costs may be unnecessarily inflated should not be considered benign.

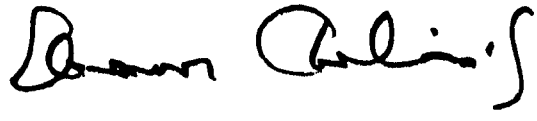
We had hoped that HCFA would express a commitment to analyze all future agency regulations for unanticipated consequences of higher costs and to conduct studies of the financial incentives created by regulations. Instead, HCFA's response suggests that the agency does not adequately recognize the financial incentives created by its own regulations. As a result, future HCFA regulations are also likely to have the unanticipated consequence of higher Medicare costs.

Our work was performed between October 1990 and June 1991, in accordance with generally accepted auditing standards.

Unless you announce the contents of this report earlier, we plan no further distribution of it until 30 days from its date. We will then send copies to the Secretary of the Department of Health and Human Services and the Director of the Office of Management and Budget. In addition, we will make copies available to interested committees and organizations and to others upon request.

If you have any questions or would like additional information, please call me at (202) 275-1854 or Robert York, Director of Program Evaluation in Human Systems Areas, at (202) 275-5885. Other major contributors to this report are listed in appendix III.

Sincerely,



Eleanor Chelimsky
Assistant Comptroller General

Contents

Abbreviations

ACCC	Association of Community Cancer Centers
ASCO	American Society of Clinical Oncologists
FDA	Food and Drug Administration
GAO	U.S. General Accounting Office
HCFA	Health Care Financing Administration
NCI	National Cancer Institute

Methodology and Results

This appendix provides additional details on the methodology used to address each objective of the assignment. It also presents detailed results.

Objective 1: Determine If Oncologists Treat Patients Outside the Office Setting

To determine whether oncologists treat chemotherapy patients in other settings when, clinically, they could be treated in the office setting, we mailed a survey in March 1991 to oncologists who had responded to an earlier GAO survey on off-label drug use.[1] The second survey consisted of a form letter with questions. The form letter explained that the results of one question on the off-label drug use survey—which asked oncologists whether they admitted patients to hospitals to avoid outpatient reimbursement problems—were unexpected and that follow-up discussions led us to suspect that oncologists might have been confused by the question's wording. The letter asked oncologists to help us clarify the issue by answering a reformulated version of the question.

Figure I.1 reproduces the off-label drug use survey question that the second survey was intended to clarify, and figure I.2 reproduces the letter included in the second survey.

Figure I.1: Off-Label Drug Use Survey Question

Of your cancer patients who could normally receive outpatient treatment, approximately how many, if any, has this individual practice admitted to a hospital in the **last three months** because a third party payer would not reimburse for the outpatient administration (e.g., by infusion) of anticancer drugs? *(Check one)*

37.9%	1. ☐ None
35.5%	2. ☐ 1 to 5 patients
13.6%	3. ☐ 6 to 10 patients
5.5%	4. ☐ 11 to 15 patients
2.6%	5. ☐ 16 to 20 patients
4.9%	6. ☐ More than 20 patients
100.0%	n = 586

[1]Recipients of the off-label drug use questionnaire included a randomly selected and nationally representative sample of members of ASCO.

Figure I.2: Letter to Oncologists

GAO

United States
General Accounting Office
Washington, D.C. 20548

Program Evaluation and
Methodology Division

March 29, 1991

Dear ASCO Member:

Enclosed is a report on the initial results of the General Accounting Office (GAO) Survey of Off-Label Drug Use. We appreciate your assistance with this study last March and hope you'll find the results interesting and informative. If you want to receive the full report on this study, please complete the address block at the bottom of the enclosed page.

One question--number 52 on page 23 of the enclosed report --yielded some very unexpected results. Specifically, 62 percent of respondents said they had admitted at least one patient to a hospital in order to avoid outpatient reimbursement problems. Follow-up discussions have led us to suspect that there might have been confusion about how the terms "outpatient" and "admit to a hospital" were interpreted. Consequently, we have reformulated question 52. Enclosed please find the restated version of this question. We hope that your answers will help us clarify the earlier results.

Your assistance with our Off-Label Drug Use survey was invaluable, and the clarification we are requesting is especially important in light of the ramifications associated with different treatment settings. As I am sure you realize, the accuracy of our understanding depends on what you can tell us.

Please return your responses in the enclosed pre-addressed envelope as quickly as possible, since we have a short time frame within which to respond to Congress' needs. All responses will be kept completely confidential. If you have any questions or comments, please call Cynthia Walford, Project Manager, at (505) 845-5371. Thank you for your assistance.

Sincerely,

George Silberman
Assistant Director

The second survey was mailed to 661 oncologists. Of those who responded, 79 percent met our criteria; that is, they were in private practice and treated chemotherapy patients. Thus, the survey's response rate was 54 percent (284 oncologists).

The first question of the survey asked oncologists whether they had treated chemotherapy patients in the last 3 months in a setting outside the private office who, by clinical standards, could have received treatment in the office. Two additional questions asked how often the oncologist admitted these patients to the hospital as inpatients and how often they were sent to a hospital outpatient department. Figure I.3 shows the survey questions and results.

Figure I.3: Results of Second Survey of Oncologists

Within the last 3 months, have you treated chemotherapy patients in a setting outside of your PRIVATE OFFICE who, by clinical standards, could have received treatment in your office?

n=103 No (If no, please do not continue)
n=181 Yes

If yes, how often did you admit these patients to a hospital on an INPATIENT basis (that is, in a patient room for 24 hours or more):

n=26 Regularly (more than 50 percent of the time)
n=17 Frequently (between about 25-50 percent of the time)
n=47 Occasionally (between about 10-25 percent of the time)
n=58 Rarely (probably less than 10 percent of the time)
n=31 Never

Again, if yes, how often did you send these patients to a hospital OUTPATIENT department for chemotherapy treatment?

n=48 Regularly (more than 50 percent of the time)
n=29 Frequently (between about 25-50 percent of the time)
n=26 Occasionally (between about 10-25 percent of the time)
n=35 Rarely (probably less than 10 percent of the time)
n=41 Never

In the 3 months prior to our survey, 64 percent of respondents (181 oncologists) treated chemotherapy patients outside the private office. When specifically asked where their patients were treated, 148 of the oncologists who responded (52 percent) reported admitting patients to the hospital inpatient setting at least once, 32 percent saying they did so at least 10 percent of the time. Also, 138 of the oncologists who responded (49 percent) reported sending patients to the hospital outpatient department for chemotherapy treatment at least once, 36 percent saying they did so at least 10 percent of the time.

Objective 2: Determine Why Oncologists Treat Patients Outside the Office Setting

To examine the factors affecting where cancer patients are treated, we conducted a series of interviews with oncologists, cancer center administrators, and representatives of ASCO and ACCC. In each interview, we made it explicit that the welfare of the patient would not be compromised by any decision regarding setting of care.

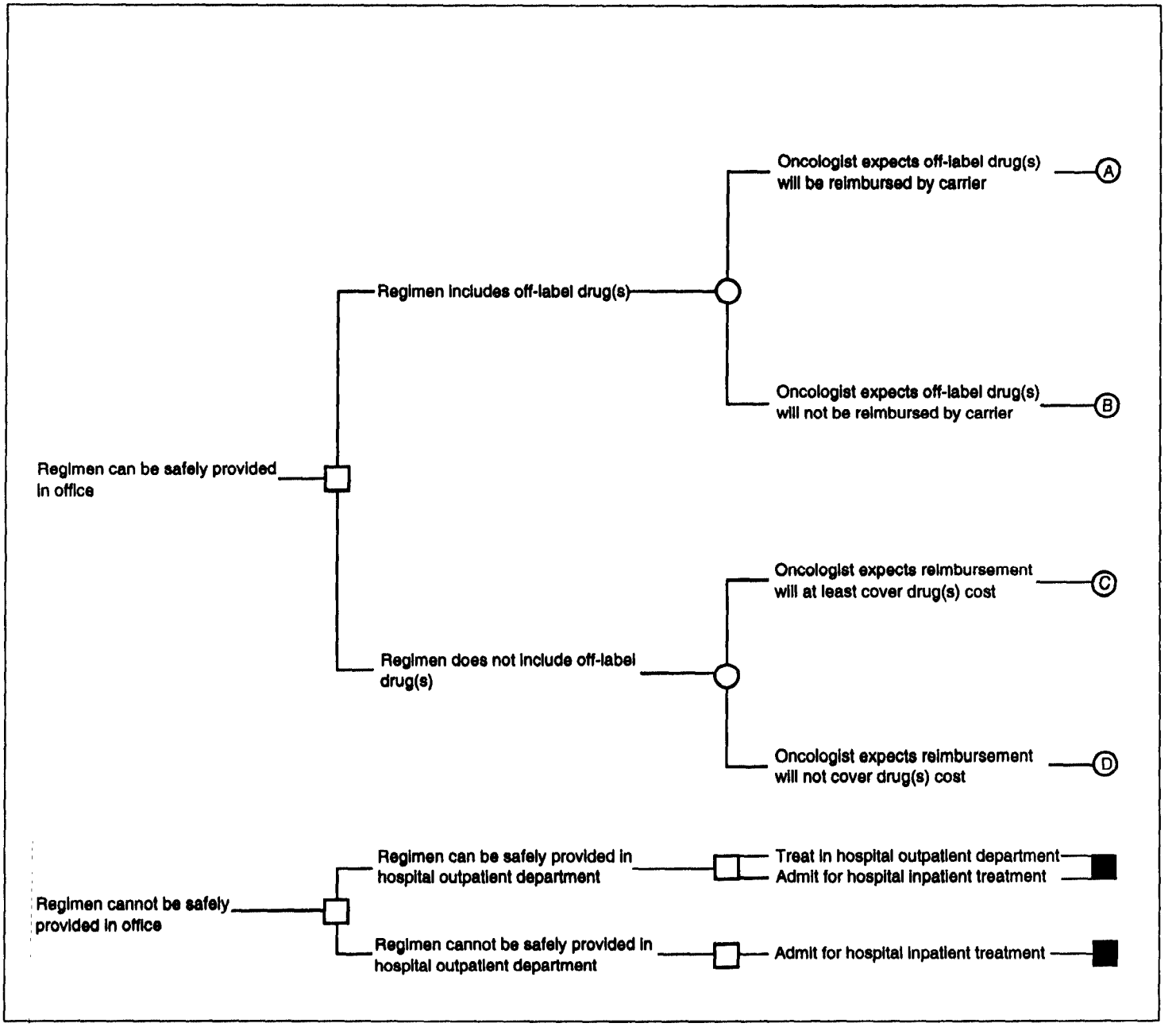
Oncologists told us that many factors can influence whether a patient is treated in the oncologist's office or elsewhere, including the distance a patient must travel to receive treatment and whether the patient has support at home.[2] However, the oncologists consistently cited financial factors—denied or inadequate drug reimbursement and patient copayments—and said their choice of treatment setting (once patient welfare is taken into account) is often based on whether they expect reimbursement to be inadequate for treatment in the office.

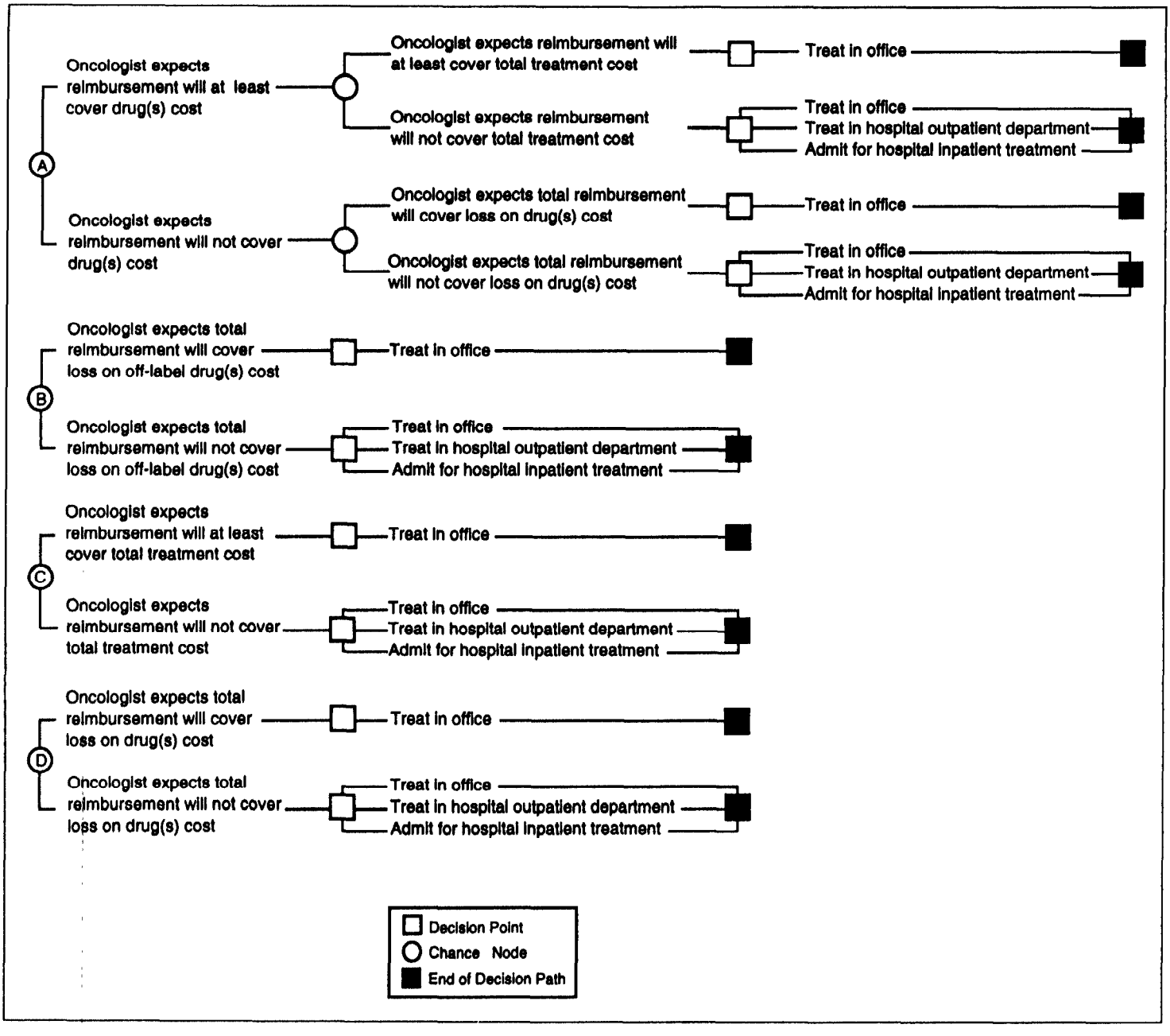
Oncologists typically purchase and maintain an inventory of chemotherapy drugs, representing a considerable investment. Oncologists who expect that reimbursement for drugs will be denied or will be insufficient to cover their cost may avoid the potential financial loss by treating patients outside the office setting. Oncologists told us they are generally willing to take a financial loss when it involves only their own time; however, the potential for losing money on expensive chemotherapy drugs is more likely to encourage them to treat patients outside the office.

We used the information obtained in our discussions to develop a model illustrating the factors that influence the decisionmaking process oncologists follow when choosing treatment settings. The model was presented to a panel of oncologists convened by ASCO and considered to be representative of its membership. The ASCO panel members reiterated what other oncologists had told us—that many factors influence their treatment-setting decisions—and suggested that including them all would show that the decision can be even more complex than the model illustrates. In general, however, the panel members agreed that their choice of treatment setting (once patient welfare is taken into account) often hinges on whether they expect reimbursement to be inadequate for treatment provided in the office setting. The model presented to the panel members is provided in figure I.4.

[2]In addition to these considerations, the relationship of the oncologist with the referring physician was mentioned as a factor that might affect where patients are treated. That is, oncologists who thought that future referrals might depend on whether the patient was treated in the office might be willing to accept the risk of a financial loss to satisfy the referring physician.

Figure I.4: Oncologist Decision Model




A
Oncologist expects reimbursement will at least cover drug(s) cost
Oncologist expects reimbursement will at least cover total treatment cost
Treat in office
Oncologist expects reimbursement will not cover total treatment cost
Treat in office
Treat in hospital outpatient department
Admit for hospital inpatient treatment
Oncologist expects reimbursement will not cover drug(s) cost
Oncologist expects total reimbursement will cover loss on drug(s) cost
Treat in office
Oncologist expects total reimbursement will not cover loss on drug(s) cost
Treat in office
Treat in hospital outpatient department
Admit for hospital inpatient treatment
B
Oncologist expects total reimbursement will cover loss on off-label drug(s) cost
Treat in office
Oncologist expects total reimbursement will not cover loss on off-label drug(s) cost
Treat in office
Treat in hospital outpatient department
Admit for hospital inpatient treatment
C
Oncologist expects reimbursement will at least cover total treatment cost
Treat in office
Oncologist expects reimbursement will not cover total treatment cost
Treat in office
Treat in hospital outpatient department
Admit for hospital inpatient treatment
D
Oncologist expects total reimbursement will cover loss on drug(s) cost
Treat in office
Oncologist expects total reimbursement will not cover loss on drug(s) cost
Treat in office
Treat in hospital outpatient department
Admit for hospital inpatient treatment
Decision Point
Chance Node
End of Decision Path

Assumptions underlying the model in figure I.4 are as follows.

1. "Safe" treatment includes consideration of

- the chemotherapy regimen (that is, the drug is not so toxic as to require hospital admission),
- the patient's condition (that is, the patient has no comorbidities, is not frail, and does not require around-the-clock care), and
- the capability of the office (that is, the office has appropriate equipment and staff to perform chemotherapy).

2. The oncologist can change the chemotherapy regimen to make it safe for the office setting but cannot change the patient's condition or the office's capability. The alternative regimen must be as safe and effective as the original or else the oncologist will not use it.

3. The patient prefers to be treated and the oncologist prefers to provide treatment in the office setting. The oncologist has no preference between the hospital inpatient and hospital outpatient settings; selection of either depends on availability, capability, and patient preference.

4. The patient is insured only by Medicare. Whether the oncologist accepts assignment may influence the patient's copayment and, therefore, the path selected by the oncologist.[3]

Objective 3: Explore Potential Effect on Medicare Costs

To examine the potential effect of the choice of treatment setting on Medicare costs, we conducted case studies in Albuquerque, New Mexico; Cleveland, Ohio; and Santa Monica, California. In each location, we obtained the Medicare reimbursement amount for a chemotherapy treatment provided in the three treatment settings included in our scope—the physician's office, hospital outpatient department, and hospital inpatient facility.

To select the locations, we used HCFA reimbursement data for a particular physician service.[4] We grouped the normally distributed data into thirds—representing high, medium, and low Medicare reimbursement

[3]A physician who accepts assignment from Medicare agrees to accept Medicare's fee schedule amount as full payment. A physician who does not accept assignment may bill the patient for a higher amount (limited to 120 percent of the fee schedule amount in 1992 and decreasing to 115 percent thereafter).

[4]HCFA data were obtained for two physician service codes for chemotherapy administration.

amounts—and selected a location from each group. Santa Monica was selected from the low reimbursement group for the selected physician service, Albuquerque from the medium reimbursement group, and Cleveland from the high reimbursement group. In each location, we sought the assistance of an oncologist in private practice and the cancer center administrator of the hospital where the oncologist has privileges.[5]

With the assistance of NCI, we selected a prevalent type of cancer that is treated with chemotherapy—extensive small-cell lung cancer. NCI also helped us develop a hypothetical patient profile and a typical chemotherapy treatment regimen for use in gathering Medicare cost data. The regimen was designed so that it could, hypothetically, be safely administered in any of the three treatment settings. Table I.1 describes the hypothetical patient and chemotherapy treatment regimen.

Table I.1: Case Study Patient Profile and Chemotherapy Treatment Regimen

Profile and regimen	Details
Disease	Extensive-stage small-cell lung cancer
Patient profile	65 years old; 1.7 m^2 body surface area; healthy; no comorbidities (gender not a factor)
Treatment regimen[a]	First day[b] —consultation —treatment planning —laboratory tests Second, third, and fourth days[c] —100 mg/m^2 carboplatin[d] —100 mg/m^2 etoposide

[a]The regimen represents one cycle of chemotherapy. The cycle would be repeated every 3 weeks for six cycles.

[b]For all treatment settings, the first day of the regimen is performed in the physician's office.

[c]Oncologists who participated in our case studies were given the discretion to modify the regimen as they saw fit. The two chemotherapy drugs listed here were included in all three cases. However, two different antinausea drugs were used. In the Santa Monica and Albuquerque cases, prochlorperazine was prescribed; in Cleveland, a more expensive antinausea drug, Zofran, was prescribed.

[d]At the time of our study, the Food and Drug Administration had not labeled carboplatin for use for small-cell lung cancer; therefore, use of the drug to treat small-cell lung cancer is considered off-label.

[5]Each hospital selected is a member of ACCC; each oncologist selected is both the ACCC medical oncology contact for the hospital and a member of ASCO.

For each case study, the oncologists and hospital representatives generated lists of charges associated with providing treatment in each setting. At our request, the appropriate claims-processing contractors calculated the Medicare reimbursement amount. Case study results are provided in table I.2.

Table I.2: Medicare Reimbursement for Three Case Studies

Location	Hospital inpatient	Hospital outpatient	Physician's office
Albuquerque, N. Mex.	$2,060.13	$1,351.19	$1,624.82
Cleveland, Ohio	2,351.72	658.53	1,797.35
Santa Monica, Calif.	2,416.38	1,263.92	944.85

The table shows that treatment in the hospital inpatient setting was most costly to Medicare in each case. This was true regardless of whether off-label use of the drug carboplatin was reimbursed or denied in either of the other settings. However, reimbursement or denial for carboplatin did affect whether the hospital outpatient setting or physician's office was least costly to Medicare.

In Albuquerque, where the use of carboplatin was reimbursed in all settings, treatment in the hospital outpatient setting was least expensive to Medicare. Treatment provided in the inpatient setting was most expensive—52-percent more costly than the hospital outpatient setting and 27-percent higher than for treatment in the physician's office.[6]

In Cleveland, treatment in the hospital outpatient setting was also least expensive to Medicare but substantially so because reimbursement was denied for the off-label use of carboplatin in that setting.[7] Treatment in the hospital inpatient setting was again the most expensive—257-percent higher than the hospital outpatient setting and 31-percent higher than treatment in the physician's office.

[6]Claims-processing contractor representatives told us the policy was recently changed to allow reimbursement for carboplatin when administered in the physician's office.

[7]Oncologists told us the likelihood that reimbursement for off-label drug use will be denied is greatest when treatment is provided in the physician's office and least when provided in the hospital inpatient setting. It is interesting to note that in the Cleveland case study, reimbursement for off-label drug use was allowed in the physician's office but denied in the hospital outpatient department. (In Cleveland, different contractors process claims for hospital outpatient and physician's office services.) Such seeming inconsistencies are possible because HCFA's policy on off-label drug use, at the time this study was conducted, permitted Medicare contractors to determine whether they will allow or deny reimbursement.

Medicare's cost for treatment in the physician's office was the least expensive in Santa Monica. This is in part because reimbursement was denied for the off-label use of carboplatin in the physician's office.[8] In Santa Monica, treatment in the hospital inpatient setting was 91-percent more costly to Medicare than treatment in the hospital outpatient setting and 156-percent more expensive than the physician's office.

[8]At the time of our review, the Medicare contractor for physician claims for the Santa Monica case study was reviewing its policy but did not allow Medicare reimbursement for the use of carboplatin to treat small-cell lung cancer. We later learned that the policy was changed in July 1991 to allow reimbursement for carboplatin when used for any cancer diagnosis.

Comments From HCFA

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Memorandum

Date FEB 4 1992

From Gail R. Wilensky, Ph.D.
Administrator

Subject GAO Draft Report, "Medicare: The Consequences of Reimbursement Policies for the Location and Cost of Cancer Chemotherapy" -- INFORMATION

To Eleanor Chelimsky
Assistant Comptroller General
General Accounting Office

We have reviewed the draft of GAO's proposed report to the Chairman, Senate Committee on Finance. It discusses the factors that influence where oncologists treat Medicare patients and the potential cost to the Federal Government of treatment in different settings.

We do not disagree with the general conclusions reached by GAO on page 9 of the report. It is possible that Medicare's payments to physicians for chemotherapy and for payment for the off-label use of certain drugs may have an impact on the choice of where a patient receives the chemotherapy treatment. However, the small sample size and benign nature of the conclusion in the report do not provide us with any significant additional information.

In addition, starting January 1, 1992, a new payment system was put into effect for physicians' services and for the payment for drugs. At this time, it is unclear whether this new system will continue to influence physicians in the same way as the former reasonable charge system. It would be useful if the report would address whether payments under the new fee schedule affect a physician's choice of the chemotherapy treatment site. Also, it would be equally useful if the study were broadened to offer more specific policy solutions.

The report seems to assume that Medicare will pay for hospital care even if the patient does not require services that must be given on an inpatient basis. Inpatient hospital stays are reviewed by Utilization and Quality Control Peer Review Organizations (PROs) to ensure that they are medically necessary. In those cases in which a PRO decides that an inpatient hospital stay was not medically necessary, Medicare payment is disallowed. Thus, Medicare would not pay for an inpatient hospital stay if the services that the patient received could have been appropriately provided in an outpatient setting.

It appears that the evidence generated by the survey of the oncologists was anecdotal. The objectivity of the responses may have been influenced by oncologists knowing that their responses would be kept confidential and their being able to ascertain what type of responses would most likely support the conclusion that Medicare should increase drug coverage and payment in the outpatient setting.

The report mentions that oncologists purchase and maintain an inventory of chemotherapy drugs, representing a considerable investment. The effect of this is unclear. Instead of Medicare's policy on unlabeled drug indications being the cause for physicians arranging for provision of chemotherapy in settings other than their offices, it may be in some instances they are using settings other than their offices in order to avoid the cost of maintaining an inventory of drugs. This possibility deserves to be explored.

We appreciate the opportunity to review the report; should you have any questions or require any additional information, kindly contact Ron Miller of the Executive Secretariat on (301) 966-5237.

The following are GAO's comments on the February 4, 1992, HCFA letter.

GAO Comments

HCFA's first qualification of our conclusions is that it is unclear at this time whether the new payment system for physicians' services and drug payments will continue to influence physicians' choice of chemotherapy treatment setting. In addition, HCFA suggests that a broader study might offer more specific policy solutions. We agree with both of HCFA's points and invite the agency to support its own evaluations of the effects of the new payment structures on physicians' behavior. Indeed, our findings, at minimum, make a strong case for the agency to pay close attention to the unintended consequences of its new policies.

Another HCFA comment suggests that utilization and quality control peer review organizations would have disallowed payment for the inpatient treatment setting because admission was not medically necessary. However, peer review organizations do not review all hospital admissions, and our previous work has shown that the likelihood is relatively small that their review procedures would identify most inappropriate admissions. Further, even if a hospital stay is denied, Medicare would generally still pay for chemotherapy at the hospital's outpatient rate.

HCFA also raises several methodological concerns. First, the agency notes the study's "small sample size." This criticism ignores the fact that our findings are based on two surveys. The first is of a nationally representative group of oncologists and cannot be characterized as small. The second survey was conducted to ensure that all respondents to the first survey (661 oncologists) understood exactly what was being asked of them in one specific question. Given the intent of the second survey, the mailing list is appropriate.

Second, HCFA characterizes our evidence as "anecdotal." We disagree with this characterization. The responses from the survey are self-reports of behavior and to refer to them as "anecdotes" implies that all surveys are based on anecdotal information.

Third, HCFA suggests that the confidential nature of our survey led respondents to provide biased answers. This is unlikely because most of the respondents identified themselves, even though there was no need to do so. Distortions from anonymity have little credibility when so many respondents waive confidentiality and openly admit that they engaged in

what might be considered questionable practice (admitting patients to the hospital who do not need to be there).

HCFA's final comment is that oncologists may use settings other than their offices to avoid the cost of maintaining a drug inventory. This is consistent with our finding that financial considerations affect the site of care. Our study was not designed to determine which factor—the level of reimbursement denials for unlabeled drug use or the cost of maintaining a drug inventory—was the most important in the decision of where to treat patients. In all likelihood, both played some role in this decision. We agree with HCFA that the implications of the costly inventories maintained by oncologists deserve to be explored.

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