

**STATEMENT OF LARRY NORTON, M.D.**  
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**BEFORE THE**  
**SENATE COMMITTEE ON FINANCE**  
**SUBCOMMITTEE ON HEALTH**  
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My name is Larry Norton. I am head of the Division of Solid Tumor Oncology at Memorial Sloan-Kettering Cancer Center in New York, specializing in breast cancer, and am presently serving as President of the American Society of Clinical Oncology (ASCO). ASCO is the medical society representing physicians who specialize in cancer treatment and clinical cancer research. Its 18,000 membership is international in reach and includes many nonphysician healthcare professionals.

I appreciate the opportunity to appear before the Finance Committee today to address issues of great concern to cancer physicians and their patients. Two of these issues—coverage by Medicare of oral anti-cancer drugs and payments by Medicare for chemotherapy drugs and services furnished in physician offices—have an inevitable link to quality cancer care for Medicare beneficiaries. They are thus highly appropriate and timely topics for consideration by this Committee.

I want to thank Senator Rockefeller and Senator Snowe for convening this hearing. Both Senator Rockefeller and Senator Snowe have commendable legislative records in support of quality cancer care. It was Senator Rockefeller's 1993 legislation that established a precedent for Medicare coverage of oral anti-cancer drugs by covering oral drugs that have an injectable version, and Senator Snowe has long been an advocate for coverage of oral breast cancer drugs.

The cancer community is pleased that you are still pressing for these important coverage provisions and feels confident that you will provide thoughtful leadership on the overarching question of how to ensure Medicare beneficiaries access to quality cancer care.

### **Medicare Coverage of Oral Anti-Cancer Drugs**

As I mentioned earlier, at Memorial Sloan-Kettering, I specialize in the treatment of breast cancer. With the benefits of screening and early diagnosis as well as improvements in therapy, mortality from breast cancer is declining, though not nearly so fast as we would like. One of the important drug therapies that has improved the chances for women diagnosed with breast cancer is tamoxifen, a hormonal agent that has been demonstrated to prevent the recurrence of breast cancer. I have prescribed that drug for my patients for years and have seen its benefits.

It is truly shocking that such an effective therapy is not covered by Medicare, leaving patients to fend for themselves for the five years that the drug is typically prescribed. Yet tamoxifen is just one of a number of anti-cancer drugs not covered by Medicare solely because they are not available in an injectable dosage form.

Noncoverage of oral anti-cancer drugs has long been a gap in quality cancer care for Medicare beneficiaries. Last year that gap became even more noticeable with the approval of the first in what we hope will be a series of targeted anti-cancer drugs that are less toxic than current treatment as well as more effective. But, because many of these drugs are available only in oral form, they will not be covered by Medicare unless Congress passes the Access to Cancer

Therapies Act, introduced as S. 913 by Senators Rockefeller and Snowe and co-sponsored by many others in both the Senate and the House of Representatives.

The first of these targeted oral drugs is known as STI-571, or Gleevec. The drug was tested in patients with chronic myeloid leukemia (CML) because it has the ability to block the effect of a protein that had been shown through basic research as essential to the growth of CML cells. Clinical trials have shown thus far that the drug has remarkable ability to induce remission in CML patients. As such, this drug's success is an important "proof of principle" that drugs targeting specific protein interactions or other cellular mechanisms can in fact be used effectively to treat cancer with fewer side effects than with traditional chemotherapy drugs. Additionally, this drug has just been approved for use in gastrointestinal stromal tumors (GIST), which was a previously untreatable and fatal disease.

Other targeted oral drugs are in the product pipeline and are showing impressive results in clinical trials. Within the next few years, we should see such products used for the treatment of a variety of cancers, not just cancers of the blood like CML but also solid tumors of the breast, colon, lung, pancreas and prostate. The anticipated success of these drugs is a resounding confirmation of this country's strategy of funding biomedical research. Through outstanding translational and clinical research, and with the continued efforts of industry, we now can create patient benefit from the many basic science discoveries of the past several decades.

As these new drugs increasingly take the place of drugs covered by Medicare, it will become obvious to beneficiaries with cancer that, while cancer research is doing more for them, the

Medicare program will be doing less. For example, the new drug for CML can be used by many patients in place of bone marrow transplantation or high-dose interferon, both very costly and very toxic treatments and both of them covered by Medicare in appropriate circumstances. Most patients will choose the new drug, but that means Medicare will not cover much of the cost of their care even though it would cover the perhaps less optimal therapies.

At present, most cancer treatment of Medicare beneficiaries is covered because it is administered by providers and drug costs are covered as incident to the provider service. As drug therapy is increasingly delivered in oral form, however, the financial burden will be shifted from the Medicare program to the individual beneficiary. This is clearly not an acceptable trend.

Medicare policy must be reformed to ensure that continued advances in cancer treatment that may result in less toxic, more effective and more cost-effective therapies are not stymied by coverage limitations that deny access to patients.

### **Need to Preserve Outpatient Chemotherapy**

As we consider the prospect of improved cancer therapies that can be administered orally, it is also important to preserve the current system of outpatient chemotherapy administration in physician offices and hospital outpatient departments. There has been much discussion over a number of years about Medicare payment of the drugs and related services furnished in outpatient cancer treatment.

As President of ASCO, I want to make clear our belief that the payment methodology should be reformed, but it must be done without disrupting patient care. ASCO agrees that Medicare payment for both drugs and related services should be restructured to more closely align payment amounts with the cost of providing care. Payments for drugs should be reduced; payments for related services should be increased. Reform should be comprehensive with simultaneous changes to drug payments and to payments for related services so as to ensure that treatment for beneficiaries with cancer is not threatened.

Chemotherapy is central to modern cancer treatment and is likely to be even more important in the coming years. Chemotherapy once required extensive hospital stays. Now, with better drugs to control side effects, patients can receive treatments in outpatient settings most convenient for them – and for their families. This is usually in physician offices.

In restructuring the Medicare payment system for chemotherapy, the net result must be aggregate payment amounts that enable physicians to continue offering office-based chemotherapy. It has been estimated that 70% or more of chemotherapy treatments are furnished in physician offices. If Medicare payments are not adequate to cover the costs of this service, physicians will be forced to try to have chemotherapy delivered in some other setting. It is far from clear, however, whether hospital outpatient departments have the capacity or the resources to handle a large inflow of chemotherapy patients. Any significant reduction in office-based chemotherapy could therefore result in a massive disruption in the care of Medicare patients with cancer.

### **Payments for Drug-Related Services**

As I stated earlier, ASCO supports a reduction in the Medicare payments for drugs. Before discussing that aspect, however, I want to speak first about the simultaneous change that must be made to ensure that Medicare cancer patients will still be able to obtain chemotherapy treatment after the drug payments have been reduced. Under the current reimbursement system, the payments for drugs compensate at least in part for the underpayment or lack of payment for the related services, and all parts of the system must therefore be reformed at the same time.

In the 1970s, there were few drug treatments available for cancer and, as I mentioned earlier, those that were available were generally administered to hospital inpatients. The few types of chemotherapy that were first furnished in the office setting were relatively simple, but they established the basis for the low Medicare payment levels for chemotherapy administration services that continue to exist today. There has been no major revision, even though the complexity of chemotherapy furnished in the outpatient setting has increased enormously. This problem was noted by Congress as early as 1987, when 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 are adequate. Unfortunately, this study was never conducted.

In 2000, however, the Health Care Financing Administration, now the Centers for Medicare & Medicaid Services (CMS), reviewed the matter and wrote Congress that “Medicare payments for services related to the provision of chemotherapy drugs . . . are inadequate.”

The inadequacy of the Medicare payment amounts is illustrated by the costs of one of the principal services. Under the physician fee schedule, the current Medicare payment level for the first hour of a chemotherapy infusion (CPT 96410) averages about \$56. The cost of the supplies and equipment used in this procedure are estimated to be about \$29, based on the 1994-95 prices used by CMS for these estimates. The salary and benefits of the oncology certified nurses who furnish chemotherapy are currently estimated by CMS to average about \$35 an hour, and the total nurse time involved in furnishing an hour of infusion is estimated at about two hours. Among other elements, this work includes reviewing the patient's medical history, verifying the drug orders, preparing the drug, educating the patient, assembling the necessary supplies, administering the drug, documenting the procedure, and follow-up phone calls.

Thus, the costs of the supplies, equipment, and nurse time for an infusion by themselves significantly exceed the Medicare payment amount. Moreover, there is nothing in the Medicare payment to cover the other costs of the office, including the administrative staff and the overhead, which CMS, using American Medical Association data, estimates to be about two-thirds of a physician's costs. The Medicare payment amount for chemotherapy services are far less than the costs incurred to furnish the services. ASCO estimates that Medicare pays less than one-fourth of the total costs of the principal chemotherapy procedures.

ASCO believes that this underpayment results at least in part because of the way in which the methodology for the Medicare physician fee schedule sets payment amounts for services that may represent significant expense to a practice but are not directly furnished by the physician.

Chemotherapy is one example. At the time that CMS adopted this methodology in 1998, it characterized its approach as “interim” but the methodology has not yet been revised.

ASCO believes that the payment amounts for services of this kind – those that do not have a physician work component – should be based on information about the costs of providing those services, and not on the current “top-down” methodology that is used in general to set payment amounts. Although it would be desirable to collect new cost data, any restructuring in the near future must depend on information that currently exists or can be promptly developed. Consequently, ASCO recommends use of the data on costs that was initially developed by the Clinical Practice Expert Panels (CPEP) and has subsequently undergone review in the American Medical Association refinement process and analysis by CMS. Medicare should pay the full direct and indirect costs of chemotherapy services as estimated in that process. If the CPEP data are not viewed as acceptable, then there should be a process for acquiring new data, or for analyzing proposed payment amounts, prior to any payment reform being approved by Congress.

There should also be a new type of Medicare payment for services that are related to chemotherapy but are not part of the chemotherapy procedure itself. Oncologists and their professional staffs typically furnish a variety of services to cancer patients for which there is no explicit reimbursement. These services include the extensive support that seriously ill cancer patients frequently require, including social worker services, psychosocial services, and nutrition counseling. Social worker services encompass a variety of services intended to help patients carry out their therapy, such as help with insurance, arranging transportation to treatment, and filling prescriptions. 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. In addition, physicians treating cancer patients perform an extraordinarily high amount of work outside the patient's presence, including family counseling, telephone calls, arranging for entry into clinical trials, and so forth. While other types of physician specialists may provide such services to occasional patients, oncologists and their staffs typically provide these services to the bulk of their entire patient load. If the Medicare payments for the drugs and drug administration are aligned closely with their costs, there will not be sufficient funds available to continue these services, which are so important to the seriously ill cancer patient population. Medicare patients need to continue to receive these services to deal with their disease, and the services should not be cut off to save money.

### **Payments for Drugs**

Finally, let me turn to the Medicare payments for the drugs themselves. The current Medicare payment amount for covered drugs is based on 95% of published average wholesale price (AWP). As is widely known, published AWP overstates, by a varying amount, the prices at which drugs can actually be purchased. This circumstance does not necessarily make AWP useless, however, and AWP is widely used by public and private insurance programs in their reimbursement methods for drugs that are dispensed by pharmacies or administered in physician offices.

In recent years, the difference between AWP and actual prices for some drugs has become very large. This situation typically occurs for multiple-source drugs or drugs with close competitors, where competition forces down the actual price even though the list price, on which AWP is

based, remains high. The large discrepancy between price and reimbursement amount for some drugs is not an appropriate situation.

As part of restructuring the Medicare payment system, ASCO recommends one of two approaches to revising the payments for drugs. First, Medicare could determine the market prices of each drug. Instead of using AWP, the law could require drug wholesalers to report to a Medicare contractor the prices at which they sold each Medicare-covered drug, considering all discounts, and the quantity sold at that price. The contractor could then compile those reports into a picture of the range of market prices for each drug and set a Medicare payment level accordingly.

If this market approach is adopted, ASCO believes that a number of features should be included to ensure that the survey results in an appropriate payment level:

- The price reports should be frequent so that they reflect changing market conditions. ASCO recommends that the wholesalers submit reports every month and that the contractor process the data promptly so that it can be used for reimbursement purposes in the second following month. For example, prices of drugs sold in January would be used to set the payment amounts for March.
- Since there will be a variation in the prices, the Medicare payment level for each drug should be set at an amount that will cover the prices actually paid by the vast majority of physicians. ASCO recommends the 95th percentile. Prices actually paid may vary greatly because physicians in larger groups are able to negotiate lower prices based

on their volume purchases. It would be extremely unfair to pay based on the median price or some similar price because that would systematically discriminate against physicians who are unable to negotiate lower prices. Oncologists who are routinely reimbursed less than what they pay for a drug would be unable to continue furnishing drugs to their patients.

- The payment methodology should be flexible enough to take known manufacturer price increases into account immediately. For example, if data on wholesale prices is collected during January for use in March, but the manufacturer raises the price of a drug by 5% on February 1, that should be taken into account in setting the March payment amounts.
- There should be an add-on amount to reflect certain costs associated with use of the drug. These include costs such as spillage, wastage, the opportunity cost of the capital tied up in drug inventory, procurement and storage costs, and unpaid patient coinsurance (bad debt). Although Medicare Part B does not ordinarily cover bad debt, bad debt here represents an out-of-pocket loss to the physician and should be treated specially. The various components of these extra costs are difficult to estimate, so ASCO recommends a flat 10% add-on to cover them.
- Sometimes physicians will encounter especially high prices for drugs, such as if they have to purchase a drug from a pharmacy in an emergency. The system should always allow a physician to be reimbursed for the actual acquisition cost by submitting documentation as to the purchase price.

- In states that impose a sales or gross receipts tax on physician-administered drugs, Medicare should also cover that amount so as to keep the physician financially whole.

An alternative approach to using a survey of market prices would be to make the published prices used by Medicare more accurate. The main concern expressed about the published prices has been the particularly large differences between the published prices and actual prices for some drugs. The law could be changed to require manufacturers to submit accurate prices to the publishers. This approach would have the advantage of not requiring a government contractor to compile data.

ASCO could support either of these approaches. Our concern is only that the resulting Medicare payment must be adequate to cover the full costs incurred by oncologists. Oncologists pay varying amounts for drugs, with large practices and entities able to obtain volume discounts not available to everyone. The methodology adopted must be adequate to ensure that all oncology practices, regardless of size, obtain full reimbursement of all their drug-related costs.

### **Hospital Outpatient Departments**

The Medicare statute ties payments under the hospital outpatient prospective payment system to AWP by paying for drugs used in cancer therapy based on 95% of AWP for a two to three year transitional period. As the payment methodology for drugs furnished in physician offices is revised, it is important that possible effects on payments for services in hospital outpatient departments be kept in mind. Hospital outpatient departments are an essential part of the

delivery system for cancer care, and Medicare payments must be adequate to support their continued operation.

### **Conclusion**

The Medicare program should be reformed by:

- Extending coverage to all oral anti-cancer drugs so that patients may have access to new targeted oral drugs as well as proven drugs like tamoxifen for breast cancer;
- Reducing payments for drugs to more closely approximate their acquisition and others costs; and
- Simultaneously increasing payments for services related to the provision of chemotherapy to Medicare beneficiaries in order to cover the costs of providing such services.

In undertaking such reform, the Congress should be guided by what will maintain quality cancer care for beneficiaries. We look forward to continued work with the Congress to achieve reform without disrupting patient care for beneficiaries with cancer.