

The New Medicare Bill: Far-Reaching Effects on Cancer Treatment

Abstract

Recent legislation has dramatically changed the Medicare payment methods for drugs and drug administration services. A large net reduction in total payments will take effect in 2005 and is likely to have significant adverse effects on the delivery of care to cancer patients.

Keywords

Medicare, reimbursement, drugs, drug administration

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The Medicare system of reimbursement for oncology and other drugs is undergoing a major change that may have important repercussions on how cancer patients are treated and on the cancer care delivery system in general. This article summarizes those changes.

Payment for Chemotherapy Administered in Physician Offices

Most cancer patients receive chemotherapy in physician offices, rather than in hospitals. Until 2004, the reimbursement system in the office setting under both public programs, such as Medicare, and private insurance programs has been largely based on funding services through payments for the drugs used. Medicare reimbursed at 95% of the published "average wholesale price" ("AWP"), and most private insurance companies paid that percentage of AWP or a higher percentage.

AWPs are benchmark prices published by private compendia, and while they do not reflect actual market prices, they are widely used as a starting point for setting reimbursement amounts. The use of the AWP by Medicare came under much criticism because it can significantly exceed the prices actually paid by physicians. Although in the early 1990s, segments of Congress and the Bush and Clinton administrations simply wanted to cut Medicare payments for drugs, eventually a consensus developed that the drug payments were funding the provision of services and that drug payments could be reduced only if payments for services were increased.

Legislation enacted in December 2003 that became effective January 1, 2004, radically revised the Medicare payment system for drugs and drug-related services furnished in physician offices. The Medicare Prescription Drug Improvement and Modernization Act of 2003 established interim payment methodologies for drugs and drug administration services in 2004. Generally, payments for drugs have been reduced by about 10–15%, while payments for drug administration services have been substantially increased—tripled in some cases. Although the change for drug payments seems small and the change for services very large, the overall net change is close to neutral, which gives some indication of the degree to which financial support for chemotherapy services has depended on drug payments.

Although there is little aggregate fiscal effect from the new legislation in 2004, there will be a substantial overall reduction in 2005 and later years. For 2005, the payments for drug administration services will decline by about 20%. Payments for drugs will be determined by a new method that relies on price information submitted by manufacturers. Medicare

payments will be set at 106% of the manufacturer's average sales price ("ASP"), and ASPs will be determined by including prices in transactions to large buyers such as hospitals, as well as sales to physician offices. The Congressional Budget Office has estimated that this change will result in a large decrease in payments for drugs compared to 2004, but the exact payment amounts will not be known until manufacturers submit their price information.

The new legislation also requires Medicare to attempt to set up a new mechanism, beginning in 2006 at the earliest, by which physicians may elect to obtain drugs from Medicare contractors. Medicare would contract with entities that would furnish drugs to physicians for particular patients, and the contractor would be responsible for billing Medicare and the patient, with the physician having no financial role. This contractor system presents serious financial-risk and operational problems, and it is unclear whether it will be a practical alternative for physicians. The legislation appears to hold the contractors responsible for losses due to denied claims and unused drugs even though they cannot control those risks. The system may be unworkable if physicians must physically segregate each patient's drugs and if they have inadequate flexibility to deal with regimen changes.

Private insurance plans have traditionally followed Medicare's lead in payment methods, and may seek to emulate Medicare's changes. Since each individual private insurer is responsible for fewer patients than Medicare, however, it may be more difficult for them to impose the same kind of drastic reductions as Medicare is implementing.

Payment for Chemotherapy Administered in Hospital Outpatient Departments

The Medicare payment for drugs administered in hospital outpatient departments is completely different from the method used in the physician office setting. In the hospital setting, payment rates for an expensive drug are supposed to be based on the median price paid by hospitals for the drug. There is an exception for new drugs, which are generally paid at 95% of AWP for 2–3 years, during which time data on prices paid by hospitals are to be collected. Payments for drug administration services are based on a method similar to that used to set payment rates in the office setting, except that the payment amounts are based on costs incurred by hospitals, rather than costs incurred by physician offices.

Although the system is intended to pay for drugs based on their median cost to hospitals, the manner in which Medicare estimates that cost has been severely criticized. Medicare has available the aggregate costs and charges of every hospital's pharmacy department, as well as the charges for individual drugs. The Medicare program assumed that the cost to the hospital of any particular drug could be estimated from the hospital's charge for the drug by using the pharmacy department's overall ratio of costs to charges. Since hospitals tend to mark up the charges for expensive drugs by a much smaller percentage than for inexpensive drugs, this approach led to serious underestimations of the prices that hospitals paid for the more expensive drugs. As a result, the Medicare payment amounts for those drugs were often

less than the cost of the drugs, an anomaly that especially affected oncology departments.

To address this situation, the same legislation that revised the payment structure for office-based chemotherapy also revised payments for hospital outpatient department services. Payments for drugs have been generally increased on an interim basis for 2004 and 2005. Beginning in 2006, payments will be based on surveys of hospital acquisition prices that are conducted by the General Accounting Office, a government agency.

New Medicare Outpatient Drug Benefit

Currently, Medicare generally covers only parenteral drugs that are administered in physician offices or hospitals. With only a few exceptions, oral and other self-administered drugs are not covered. One of the principal components of the 2003 Medicare legislation was an expansion of the Medicare benefits package to include partial coverage of outpatient prescription drugs effective in 2006.

The new outpatient prescription drug benefit would be administered by private entities, rather than by the government, as is the case for most current Medicare benefits. Individuals who elect the new benefit would enroll in a Medicare managed care plan that offers the benefit or in a freestanding prescription drug plan offered by a private insurer. These plans would be heavily subsidized by the federal government, but would have more flexibility in administering the new benefit than government programs generally exercise.

The new benefit is not complete coverage for outpatient drugs. First, there is a \$250 annual deductible before the Medicare coverage begins. Then, for expenditures between \$251 and \$2,250, Medicare pays 75% (or the equivalent, as discussed below), and the patient is responsible for the remaining 25%. The Medicare beneficiary is responsible for all drug costs between \$2,251 and \$5,100 in drug expenditures (which detractors of the legislation refer to as the "doughnut hole"), after which the Medicare program would be responsible for 95% of the costs. To obtain this benefit, a Medicare beneficiary would have to pay a premium, which is estimated to be about \$35 per month, initially.

Although the "standard" benefits package will pay 75% of drug costs after the annual deductible is met, drug plans are in reality likely to use formularies and tiered copayment structures, rather than a flat-rate copayment of 25%. This structure, which the new legislation permits, is intended to mimic private insurance plans, which use differential copayments to favor generic drugs and drugs for which the insurance plan has negotiated favorable financial terms with the drug's manufacturer.

As outlined above, the new Medicare benefit provides some coverage for drug expenditures at modest levels but provides its most extensive benefit as a catastrophic coverage plan, ie, when the drug expenditures exceed \$5,100 per year. This may be of particular benefit to cancer patients, whose drug costs can often reach such levels. The new benefit does not override the existing Medicare benefit for drugs adminis-

tered in physician offices and hospitals, which has a 20% coinsurance requirement without any limit. The new legislation does require a study, however, on how the currently covered parenteral drugs could be transitioned into the new benefit structure.

For the period 2004–2005, the legislation requires a “demonstration project” under which Medicare will cover certain oral and self-injected drugs on a temporary basis until the overall outpatient drug benefit becomes effective in 2006. The project is limited to 50,000 patients and \$500 million in expenditures. A large part of these funds is expected to pay for oral anticancer drugs.

Effects of the New Legislation

Unless the legislation is changed, beginning in 2005 there will be severe reductions in Medicare payments to physicians to support chemotherapy services. Private insurance companies may also attempt to adopt Medicare’s payment amounts, which would, of course, exacerbate the problem. A number of effects from these changes can be anticipated.

The site of service may change. If physicians find their financial situation untenable, more patients will be referred to hospitals for chemotherapy. It is not clear whether hospitals have the capacity to receive large numbers of new chemotherapy patients and, if they do not, whether they will expand their facilities to meet the increased demand.

Reduced payments for drugs are likely to affect drug selection. There will probably be stricter adherence to published guidelines for drug therapy. Physician practices that do not have internal protocols for drug use are likely to develop them on an accelerated basis. Practices will be more inclined to limit the authority of their physicians to prescribe drugs for off-label uses unless insurance coverage is assured. There will be more financial analysis of alternative drug regimens and equivalent products to determine the appropriate therapy. Finally, interest in oral drugs is likely to become more intense even if there is a parenteral alternative.

Physician practices will also focus on reducing their costs and expanding the variety of services they offer. Physicians will hold off on expansion of medical oncology capacity until the financial consequences of the legislation are fully under-

stood. Significant staffing changes will likely occur over time. Diversification will take the form of adding services such as radiation, positron emission tomography scanning, and diagnostic imaging. To support such expansion, larger practice groups may be formed.

Preventing financial loss will become a priority. Physicians will be more reluctant to take patients without secondary insurance, and patients with high debt risk will be referred to hospitals for chemotherapy. Within group practices, physicians who order drugs for which coverage is denied are more likely to face financial penalties.

If medical oncology becomes a less rewarding specialty, there may be increased reliance on nurse practitioners and physician assistants, both in the office and hospital settings. Medical schools will need to confront the question of how many medical oncologists should be trained.

Finally, the new legislation will have an adverse impact on clinical trials. Trials in the office setting are likely to decrease as resources are directed toward staffing chemotherapy appropriately, instead of administering studies. Revenue from drug payments has subsidized nurses as data managers, but that era may have passed. Practices will provide fewer patients for trials conducted by academic medical centers, and there will be fewer investigator-initiated trials of new uses of approved drugs.

Conclusion

The Medicare legislation enacted in 2003 will have a profound and largely negative impact on the care of cancer patients. While the new outpatient drug benefit will provide financial assistance with respect to oral cancer drugs, the severe reductions in payments for the currently covered drugs and drug administration services will pose serious problems for office-based physicians and the patients they treat. Far-reaching effects on the cancer care delivery system can be envisioned.

Oncology groups, led by the American Society of Clinical Oncology, are seeking legislation that would remedy the flaws in the 2003 law, but many in Congress are resisting change until they can assess whether the new payment rates will actually affect cancer care delivery.