At the same time that new targeted therapies are making their debuts in cancer clinics—at a cost set by their pharmaceutical manufacturers of often thousands of dollars a dose, and tens of thousands per treatment course—the federal government announced that it plans to slash Medicare reimbursement prices for some common chemotherapy drugs by as much as 81% below current levels.

“It is at least as bad as we thought it could be,” said Deborah Kamin, senior director for policy and clinical affairs at the American Society of Clinical Oncology (ASCO). “The Congressional Budget Office had anticipated [cuts in reimbursement amounts] of $300 million, but this is $500 million. These are big, big cuts.”

With the sampling of proposed reimbursement amounts in hand, private practice oncologists are now trying to “guestimate” how much they may lose starting Jan. 1, 2005, in reimbursements on cancer drugs they give to their Medicare patients. Although fees for chemotherapy services paid by Medicare could balance any loss, the Centers for Medicare & Medicaid Services (CMS) warned that it will cut its 2004 drug administration reimbursements by 29%, said Kamin, although those figures will not be announced until much later this year.

“Given all of this, the ability of community oncologists to even deliver services may be compromised,” she said.

Bid to Freeze Reimbursement Levels

Given that there was some degree of parity in this system, most oncologists took a cautious wait-and-see attitude to the specter of future cuts, but others began to inform their Medicare patients that they may have to go to local hospitals to receive chemotherapy.

### Proposed Changes to Medicare Cancer Drug Payments

In July, the Centers for Medicare & Medicaid Services announced its proposed changes to the payment schedule for physician services and drugs. Several cancer drugs, a few of which are listed below, would be affected by the proposal, which would take effect Jan. 1, 2005.

<table>
<thead>
<tr>
<th>Trade name (generic name)</th>
<th>2004 Pay allowance ($)</th>
<th>Estimated 2005 allowance ($)</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zometa (zoledronic acid)</td>
<td>194.54</td>
<td>202.50</td>
<td>4%</td>
</tr>
<tr>
<td>Taxotere (docetaxel)</td>
<td>301.40</td>
<td>287.59</td>
<td>-5%</td>
</tr>
<tr>
<td>Zoladex (goserelin)</td>
<td>375.99</td>
<td>234.28</td>
<td>-38%</td>
</tr>
<tr>
<td>Camptosar (irinotecan)</td>
<td>130.24</td>
<td>123.86</td>
<td>-5%</td>
</tr>
<tr>
<td>Lupron (leuprolide acetate)</td>
<td>500.58</td>
<td>234.28</td>
<td>-53%</td>
</tr>
<tr>
<td>Taxol (paclitaxel)</td>
<td>138.28</td>
<td>25.84</td>
<td>-81%</td>
</tr>
<tr>
<td>Rituxan (rituximab)</td>
<td>427.28</td>
<td>438.38</td>
<td>3%</td>
</tr>
<tr>
<td>Herceptin (trastuzumab)</td>
<td>52.01</td>
<td>50.84</td>
<td>-2%</td>
</tr>
<tr>
<td>Navelbine (vinorelbine)</td>
<td>76.19</td>
<td>64.67</td>
<td>-15%</td>
</tr>
</tbody>
</table>
ASC0 and other groups asked that 2004 pricing remain fixed through 2006, if need be, while three government-mandated studies on the effect of the MMA on cancer care are completed.

But the cuts just announced, which are the agency’s suggested 2005 reimbursement prices for a handful of commonly used chemotherapy drugs, are anything but a freeze.

On the basis of what CMS calls “very preliminary ASP data,” the agency projected a net reduction in the amount of money that Medicare pays out for oncology drugs and services. Cuts in reimbursement amounts for drugs used to treat cancer and certain lung diseases would save the government $530 million and Medicare beneficiaries $270 million next year, according to CMS administrator Mark McClellan, M.D., Ph.D. Saying he “is going to get more for our money,” McClellan also projected a decline in revenues for cancer specialists that spanned from 2% to 8%.

The rules offered just a small sampling of suggested reductions, and McClellan said that the agency could adjust reimbursements based on input from affected physicians and several reviews that are under way, such as the one by the American Medical Association, before the final rule is published November 1 and goes into effect next January.

The proposed cuts define the ASP for 30 drugs on which Medicare spends the most money annually, and some of the projected savings in chemotherapy drugs mandate that oncologists use generic equivalents, which are cheaper (see box, p. 1268). For example, the reimbursement amount for a unit of Taxol (paclitaxel) will drop 81% to match the cost of a generic competitor. But other cancer drugs, for which there are no generic equivalents, are also affected. Examples are the cost for Lupron, a prostate cancer drug, which has been slashed in half, and Zoladex, which will fall 38%.

Not only will drug reimbursements drop next year, but CMS has said that it intends to roll back the increase in chemotherapy administration fees that it granted in 2004. ASCO President David H. Johnson, M.D., has responded by saying he does not see how a practice can survive taking care of Medicare patients, based both on the proposed cuts and the uncertainty in the whole pricing structure.

“I am concerned that oncology practices will not have all the financial information they need to fully determine how patient care will be provided once the 2005 cuts take effect,” he said.

ASCO supported Medicare’s goal of balancing costs, but now “we fear that patients and their families may be deprived of critical community-based cancer care as a result of these substantial cuts,” Johnson said.

**Oncologists in Private Practice**

Some private oncologists have protested that they are just the middlemen and that it is the drug companies setting the high prices that has been breaking the federal bank. And now only large oncology networks with bargaining power will be able to negotiate an ASP that they can live with, they say. “I am like the small corner grocer who pays the highest prices for my goods. I don’t get the deals that Wal-Mart does,” says Dean Gesme Jr., M.D., of Oncology Associates of Cedar Rapids, Iowa.

Given that 80% of all cancer care in the country is delivered in private oncology clinics and that 40% of that is reimbursed by Medicare, cutbacks in federal reimbursements that do not pay adequately for drugs or services such as finding, stocking, and administering drugs and disposing of wastage, could spell doom for the smallest oncology clinics, said Gesme, who is working with the AMA on its review of reimbursement issues. “Clearly, given what we know, there will be dramatic revenues reductions in oncology practices, and who is to say that private insurance companies won’t then follow Medicare’s example?”

Substantially boosting service fees in 2004 was a welcome change, said Robert Siegel, M.D., of Oncology Associates in Hartford, Conn. “For the first time in years, even decades, we were paid for what we do, not for what we administer, which is the way it should be.”

But if CMS does reduce the 2004-level service fees, as promised, “it will be virtually impossible for us to continue to give outpatient chemotherapy,” Siegel said. “It is immensely frustrating to be stuck in the center of a cost crisis that we did not create but are blamed for.”

**No Political Will**

What is needed is a fresh look at how drug prices are set in the first place, according to Deborah Schrag, M.D., a health outcomes researcher and practicing oncologist at Memorial Sloan-Kettering Cancer Center who wrote a perspectives piece on the subject in the July 22 issue of the *New England Journal of Medicine*.

“It’s ironic that the government is willing to cut the amount that doctors are reimbursed on use of chemotherapy, when it has no political will to look at how to stop drug prices from being set so astronomically high in the first place,” Schrag said.

She specifically looked at drugs used to treat colon cancer and found that while the median survival rate for colon cancer has nearly doubled over the past decade, it has been accompanied by a 340-fold jump in the cost of drugs used to treat the disease.

Most disturbing, Schrag said, is the sticker shock associated with the newly approved targeted therapies Avastin (bevacizumab) and Erbitux (cetuximab), used to treat advanced colon cancer.

Neither of these drugs, which costs $10,000 to $20,000 on top of the price of an 8-week course of chemotherapy, offer much of a survival advantage. If the full course of treatment for stage IV colorectal cancer is calculated, includ-
ing 8 months of frontline therapy and 4 months of targeted therapy, the tab reaches $295,000, she said.

**Difficult Decisions**

These “mind boggling” costs have put oncologists in yet another tough position, Schrag said. “Physicians find themselves in the undesirable position of having to help patients make decisions about whether the potential clinical benefits warrant the financial strain that even co-payments for these medications may create.”

Siegel agrees, saying he feels he must police use of expensive therapies that may offer little benefit, or else he fears “the system will implode. Everyone agrees the costs are too high, yet patients want whatever is out there,” he said. “The federal government is balking at the price of drugs, but it does nothing but sting the physicians.”

Because the federal government, by law, cannot consider the cost effectiveness of a drug, they are leaving it up to the physician to do so, Schrag said. Equally galling, she added, is the fact that Congress has prohibited Medicare and Medicaid, which buy more drugs than any other organizations in the United States, from negotiating discounts with drug companies.

Pressure on the federal pocketbook to fund cancer drugs will only build when Medicare begins to fund use of oral cancer drugs, which will cover drugs that range from tamoxifen to Gleevec and Iressa. Congress agreed to a $500 million “demonstration project” to cover oral and self-administered drugs, which will begin in 2005. Enrollment is limited to 50,000 patients and to 13 cancer drugs in 2005, but will presumably be available to all Medicare cancer patients in 2006.

The high costs of the newest drugs “means that non-Medicare health plans are likely to deny coverage or, alternatively, raise premiums,” Schrag said. Patients will mortgage their homes, their futures, to finance expensive drugs that may offer only modest gains in survival, she added. “The entire Byzantine system of drug development and pricing must be fixed.”

—Renee Twombly