



MEDICARE'S COMPETITIVE ACQUISITION PROGRAM:

Stats Reveal Who's In/Who's Out and Why

By Bryan Cote





Today, physicians are at a crossroads. Not only are they no longer able to withstand reductions in the cost of drugs they administer, but they are also not able to withstand the fluctuations and delays in Medicare reimbursement. For some, CAP has quietly become a smart business decision and a viable alternative to buying-and-billing drugs.

The days of private practice physicians' system of buying-and-billing drugs for their Medicare patients are fading like the Kansas City Royals in summertime. Many practices have figured out that the need to get a grip on their costs is essential to survival.

Built into the landmark Medicare Modernization Act (MMA) of 2003, the CAP had one primary mission: to allow physicians to reduce their financial risk when administering to their Part B patients. MMA allowed physicians to exit the drug purchasing business, and it provided physicians with an alternative to the buy-and-bill system.

Thereby, physicians who enrolled in CAP, would bill the government for drugs administered, and would also hand over drug acquisition, patient co-pay collection, and a host of other responsibilities to a selected vendor chosen by Medicare. That vendor is BioScrip, a specialty pharmacy, selected by Medicare to manage its competitive acquisition program for a three-year period, concluding in 2008. (The insurance company Noridian serves as the designated claims processing group.)

By the Numbers

Under the internal medicine or family practice designation, a large number of multi-specialty practices are enrolled in the CAP. According to Russell Corvese, Principal Administrator for BioScrip Pharmacy Services, "We had almost 300 internal-medicine specialists enrolled in 2006. Many were multi-specialty practices with an oncologist writing the chemotherapy script."

Doctors writing oncology scripts may be benefiting from the CAP, but this has not translated to large enrollment of oncologists. "There are far fewer oncologists enrolled in the CAP than there are physicians writing scripts for oncology meds," said Corvese. According to unofficial December 2006 totals, oncology was near the bottom of enrolled specialists. However, there are signs of momentum, including:

- Total physician enrollment spiked to 2,200 at the end of 2006, up from 1,300 in early December.
- The director of CMS's division of ambulatory services has confirmed that there's been significant talk of opening up a special enrollment period in spring 2007.
- Congress has eliminated some of the program's initial administrative burdens.

Managing Financial Risk

Most medical specialties, including oncology, have reported moderate-to-severe reductions in their Medicare reimbursement for acquiring and administering drugs. Two changes occurred in 2005 that began to turn buy-and-bill on its head and force doctors to take a look at their books. They were:

1. Medicare revised the way it paid physicians for acquiring drugs so that doctors would receive a maximum payment limit based on the drug's average sales price (ASP).

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2. Medicare cut the amount it paid doctors for administering drugs. For instance, in 2003, first hour infusion (code 996410)—the bread and butter of medical oncology—was reimbursed at around \$59, then reimbursement rose to \$217 in 2004, then it fell back to \$177 in 2005. With that in mind, it was easy to see why physicians thought they were making less on infusions and injections in 2005.

An oncologist from Stamford, Conn., Sal Del Prete, MD, said that in 2005, he was paid at roughly 70 percent of the average wholesale price (AWP) of drugs administered in his office setting. This percentage was much lower than in 2004 and 2003 and it forced him to stop doing infusions, cut nursing and tech staff, and reduce his practice office space. As a consequence, Dr. Del Prete felt he had to send letters to his chemotherapy-infusion patients and inform them they would need to get further infusions at Stamford Hospital.

Although many doctors are skeptical about shifting patients to hospitals in mass quantities, the alternative is no picnic. Practices under Medicare's revised drug reimbursement system have to live with unpredictable payment limits called allowables. As of 2005, CMS set its Part B reimbursement for drugs and biologics based on each product's ASP.

Since ASPs can change quarterly, the payment limits are unpredictable, such that the most affordable drug in a given class could be different at every quarter. For example, the ASP for Gemzar® dropped 0.20 percent from the third to the fourth quarter, 2006; Velcade®'s ASP dropped 0.06 percent and Aranesp®'s ASP dipped 1.32 percent. These fluctuating limits are problematic for a host of financial and clinical reasons.

Summit Cancer Care in Savannah, Ga., did a preliminary analysis back in 2005 of Medicare

numbers and identified seven drugs most affected by fluctuating average sales prices.

Drugs included

- Aridea® for bone metastasis
- Gemzar® for pancreatic, breast, lung, and ovarian cancer
- Procrit® a growth factor to build back red blood cells

"We knew we would have to redirect some patients who lacked secondary insurance to area hospitals, but the rural hospital here doesn't even give the support drugs like Procrit," griped Sharon Bromley, Summit Cancer Care's CEO.

Without secondary insurance, patients may not be able to afford their Medicare co-payment and physicians may not be able to take on the risk of unpaid co-payments. According to CMS, this is a primary reason physicians cite for enrolling in the CAP.

"One Medicare rejection puts us in the hole," said Nancy Fairclough, an administrator for a multi-specialty practice in Wilmington, Del. "Initially, our doctors didn't want to enroll, but we're a small practice with just four physicians (one oncologist) and our Medicare reimbursement is too sporadic." She cited the costs of purchasing oncology drugs and the costs of running their practice compared with their Medicare reimbursement as key reasons why they enrolled into the program.

"Most oncology practices are reeling," reported Dawn Holcombe, Director of the Connecticut Oncology Association. "The \$130 under the oncology demonstration of 2005 dipped to \$23 in 2006," and, as more patients were absorbed into Medicare HMO and Medicare Advantage plans, fewer patients were eligible for the demo. The program has now disappeared.

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Rejecting the CAP

Enrollment data to date suggest CAP is more attractive to small practices, especially small-size allergy and rheumatology groups that rely on patients needing one or two injectables compared with oncologists with small-size practices with patients who need multiple injections.

CAP, according to Glenn Balasky, Executive Director for Mid-Ohio Hematology-Oncology in Columbus, Ohio, is unlikely to be the solution of choice for most oncology and urology groups. "There are a lot of other things oncologists would do first," he said. "[CAP is] too inconvenient for patients and chaotic for practices. But I can see where a smaller practice of any specialty would find it attractive." His group, among the largest in the Columbus area, has no plans to enroll.

Neither does practitioner Stewart Sharp, MD, of Hematology-Oncology of Danville, Va. He estimates that the CAP would force him to spend \$100,000 to handle operational and inventory needs simply for enrolling. Henry Fox, MD, an oncologist in Washington D.C., is most concerned about patients with little monetary means going without treatment.

Fox's concern can be illustrated with this example:

Consider a 67-year-old female with advanced colon cancer who is having a dramatic response to chemotherapy. On Day 1, she arrives for treatment with a CAP-enrolled doctor, but there are changes in her toxicity levels compared with the previous treatment. The oncologist needs to change the patient's treatment, but is not sure that the vendor can deliver the necessary medications.

On Day 2, the patient arrives for treatment but is unable to afford her 20 percent coinsurance, a Medicare requirement. Before the Medicare Prescription Drug Improvement

and Modernization Act of 2003, patients who couldn't afford their 20 percent coinsurance could still receive care in most cases. This is not true anymore. Therefore, physicians are split on how to proceed with the patient. Some would send her back to the CAP vendor to resolve the issue; others would direct her to the hospital.

These are valid concerns; though it is possible physicians are confused about the rules under CAP. Prior to enrolling in CAP, some doctors' offices were incorrectly told that patients must submit their Part B drug administration co-pay before BioScrip would ship the drug to the doctor. The truth is that BioScrip will collect the co-pay after CMS reimburses the company. "We won't attempt collection until the claim has been paid, then the patient has 30-45 days to respond from the date [on which] we get reimbursed," said BioScrip's Corvese.

Interestingly, doctors reluctant to join the CAP are not shy about admitting their financial woes. Some would rather stay in a reimbursement slide than avoid the unknown of CAP. For instance:

- D. Frey, MD, an oncologist near Columbus, Ohio, has no plans to enroll at this stage, but says his practice's injectable reimbursement from Medicare Part B in 2005 was about \$100,000 less than in 2004 and cash flow remained a problem through 2006.
- Kuo Tong, MD, an oncologist in California, plans to shift patients to area hospitals to reduce the reimbursement burdens of Medicare. He cited G-CSF and doxorubicin as drugs causing reimbursement trouble.

Enrollment Decisions

On the eve of the most recent CAP enrollment period, October 2006, most oncologists remained in a wait-and-see mode. Eighty-six percent of 110 oncologists **cont. on pg 28 >>**



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surveyed by *Medicare & Reimbursement Advisor Weekly* in September 2006 said they would not enroll in the CAP for 2007; of this number, more than half said their Medicare reimbursement continued to drop and that they were redirecting more patients to hospitals.

For oncology practices that continue to buy-and-bill under Medicare, the trend is to assess more patients on a case-by-case basis. "We might go forward with the treatment and take a loss for two more treatments, but if nine more are needed, we can't afford that," said Karen Pagano, oncology practice manager at Bronstein & Jeffries in Harrisburg, Pa., and a board member with the Oncology Hematology Managers' Society of Pennsylvania. "We look more closely at protocols . . . for example, at Adriamycin with Decadron, with Cytosan, and with Aloxi, rather just one drug's ASP."

"Without the chemo demonstration cushion, we'll have to pay closer attention. This is going to produce a catastrophic domino effect as the hospital will not be able to handle the increased patients," said Pagano, whose multi-specialty group uses a dummy drug charge sheet to assess each patient's treatment costs before the first infusion. "We're all okay with ASP because we belong to group purchasing organizations and utilize some of the indigent drug programs to keep patients in our chair, but that's getting harder."

Signs of Compromise

After months of administrative delays with payments to CAP-enrolled physicians and BioScrip, Congress responded by requiring CMS to institute a key change under the Tax Relief and Healthcare Act of 2006. The program now calls for a post-payment review process to ensure that payments to doctors are made for a drug or biological only if the drug or biological is delivered for administration to a beneficiary.

"We'll be required now to figure out a way to go in after payments are made to physicians and to [BioScrip] and verify that the drug or biologic was administered. This is a major shift," the CMS Director said on condition of anonymity.

Before, a payment to a doctor or to BioScrip could be held up for a kind of pre-payment review, or matching process. This made the program more of a burden than a solution.

Life under the CAP

Every practice is different based on their patient mix, but for oncologists on the fence and for industry interested in understanding what elements of the CAP could enhance its value, here are three program components flying under the radar:

- **Medical necessity:** If enrollees want to administer a drug that's on the list but is not covered by BioScrip, it must go through the medical necessity process with CMS. A Palm Springs, Florida-based oncology practice that asked to remain anonymous was under the impression that before enrolling into CAP, CMS or BioScrip could deny a drug request. "In our experience, BioScrip has helped guide us and in some cases identified alternative therapies on their list that will be covered," said the administrator.
- **New drugs:** BioScrip can apply to have additional drugs available to physicians enrolled in the CAP. BioScrip must make the case that not otherwise classified, or notice of compliance (NOC) drugs add a cost-saving benefit by being covered under the CAP. All physicians enrolled in the CAP report a special Q-code to get reimbursed.
- **Voluntary agreements:** Many practices are concerned that the CAP will force them to hire staff and commit resources that make the program unworkable. BioScrip's

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Corvese said he encourages doctors to consider these customized agreements that can allow a practice to address its specific inventory and administrative nuances.

The Cancer Care Shift

Few agree that CMS will bring back oncology-drug reimbursements to 2003 levels. As a result, alternatives to buy-and-bill, like the CAP, have to work or there will be a steady increase in patients directed to hospitals. But is that in the patients' best interests? "Many hospitals aren't ready to handle this volume," said Faye Satterly, Director of Martha Jefferson Hospital's Cancer Care Center in Charlottesville, Va.

Hospital infusion centers downsized a few years ago as Medicare wanted patients to receive their therapy in the outpatient setting. Physicians responded well and hospitals didn't complain because their ambulatory payment reimbursement was getting cut. Hospitals took their smaller spaces to do transfusions and to do once-a-day antibiotics. Now, they're unprepared from a facility standpoint to manage patients with cancer.

Hospitals are operating on tight margins so many would need to turn to older-generation drugs for infusion therapy. It's a cost-saving measure, but one that comes with consequences as physicians will want to continue to pick the newer-generation drugs. Satterly said many hospitals may have no choice. Some may strongly suggest that the doctor opt for an inexpensive drug. "The older drugs are good, but they're perhaps not as effective," she said. "There's likely to be more side effects."

"We probably won't be that aggressive in suggesting something cheaper because we don't operate that way here," said Satterly, noting the importance of patient care over the dollar. "We may make suggestions—but without force."

One year ago, Dawn Holcombe predicted that oncology practices would be okay financially under Medicare ASP through March 2005, but that cash flow challenges would become more significant as the year went on. She was right. The cancer patient shift to hospitals, which was slow in 2005, has picked up in some regions and hospitals are reacting as many feared they would.

For example, Bridgeport Hospital in Connecticut did not provide treatment for drugs such as Avastin® and other newer-generation products last year. Hospitals, said Holcombe, incurred costs 27 percent higher in handling the drug than in 2005. Costs continue to jump.

To avoid this scenario, CAP may work for some smaller oncology practices in the long-run, but Balasky predicts the following:

- Hospitals will take over chemotherapy services in joint ventures.
- Physicians will remain involved in treatment protocol decisions.
- Practices will add diagnostic imaging (e.g., mobile PET services).
- Practices will add a specialty oral pharmacy option, which brings in more viable margins.

The Private Payer Factor

To counter downward reimbursement pressure for infusion services, group specialty practices are aggressively trying to have a dialogue with local managed care insurers in hopes of sustaining appropriate financial reimbursement for their services. At Mid-Ohio Hematology-Oncology, the group negotiated full current reimbursement for 2006, plus "over 200 percent for administrations," said Balasky.

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January 21 - Research highlighted at the 2007 GI Cancers Symposium showed that adding Avastin® (bevacizumab) to first-line oxaliplatin-based chemo extended progression-free survival in patients with advanced metastatic colorectal cancer. According to researchers, the study was one of the largest ever conducted on metastatic colorectal cancer (ASCO).



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But that is unlikely to hold beyond 2007, because pressure from the East and West Coasts will eventually force groups such as Mid-Ohio to take on lower rates. "From what I hear, other providers, including large groups, are succumbing to pressure, and are having to live with straight Medicare-type rates from the commercial plans," said Balasky.

He believes there may be ways for manufacturers to assist where appropriate, such as:

- Sharing data that Mid-Ohio has collected about how it keeps people out of the hospital
- Highlighting the fact that the younger, non-Medicare cancer population needs access to the best care to help them return to work, and that it is critical for the practice to be compensated appropriately to continue meeting this need

Next Steps

It's evident that the CAP is just one piece of the larger discussion about the best way to deliver cancer care in this country. It is critical to have access to life-extending and supportive medications, but barriers remain. The good news is that the CAP is one way some doctors are able to continue in practice. Financial risk is diminished for some, but for many practices, it's clear they need help understanding their practice costs before deciding about the future of their patients. **BC**

Bryan Cote is editor of *Medicare & Reimbursement Advisor Weekly*, a service which provides first-hand reports and analysis about how Medicare Part B and D, long-term care and managed care reimbursement decisions affect access to drugs and biologics. He authored the report, *The Impact of Cancer Care's Potential Shift to the Hospital Outpatient Setting*, 1st Edition. E-mail Bryan at bcote@hcpro.com for a free trial or more information. Mention *Oncology Business Review*.

CAP: By the numbers (As of December 15, 2006)

3.5	Average size of a physician practice enrolled in the CAP
2,300	Number of enrolled physicians
181*	Number of drugs covered by Medicare through the CAP
1,284	Number of oncology-related administrations
1,830	Number of unique oncology prescriptions
3,844	Total oncology prescriptions
290	Total patients served by oncologists through the CAP

*New drugs can be added to this program through CMS and BioScrip

Source: BioScrip and field reports

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January 25 - Amgen said that, in a trial, its anemia drug, Aranesp®, increased the risk of death when used to treat cancer patients whose anemia was presumably caused by their cancer. Aranesp is approved to treat anemia caused by cancer chemotherapy, but not by the cancer itself (*NY Times*).