

An interview with Mark McClellan, MD, PhD

Overhauling Medicare: the big balancing act

By Cori Vanchieri

As the administrator of the Centers for Medicare & Medicaid Services (CMS), Dr. Mark McClellan is CEO of the largest health insurance organization in the world. He is leading an overhaul of Medicare by implementing the Medicare Modernization Act. Since taking the helm of the CMS in March 2004, he's been faced with the job of convincing oncologists, among others, that change is good.

No stranger to politics, Dr. McClellan knows how to stay on message. His brother, Scott McClellan, is President Bush's spokesperson, and his mother, Carole Keeton Strayhorn, is Texas comptroller. He's been on a leadership track in the Bush administration, first in the White House on the President's Council of Economic Advisers (where he was a senior policy director for health care and related economic issues), then as the FDA commissioner, and now as head of CMS. Dr. McClellan sat down with *Community Oncology* in December to talk about his goals for Medicare's new reimbursement system.

Community Oncology: Starting January 1, 2005, payments for oncology drugs will go down sharply, with prices based on average selling price (ASP) instead of average wholesale price. To balance out the loss, Medicare will begin paying for certain cancer care services in an effort to provide adequate overall funding for cancer treatment. Critics say the new system does not adequately reflect the cost of delivering modern-day cancer

care. The Government Accounting Office (GAO) issued a report on December 1, 2004, saying that Medicare drug payments will decline relative to 2003 but will still exceed oncologists' costs by 6% in 2005 and that chemotherapy administration service fees will be 130% higher in 2005 than in 2003. In other words, oncologists will do just fine under the new plan. Does that give you a green light to go forward with your plan?

Dr. McClellan: Well, it's another independent report. They used their own methods, their own data collection, and they came to some of the same conclusions that we've reached and that other studies have reached—that the payments for the drugs are going to be adequate. Our goal in this whole process was to pay accurately for the drugs and also to pay accurately for drug administration. This is a time when, more than ever before, we're concerned about making sure we're getting the most for the money in the Medicare program. And, at the same time, we also need to encourage high-quality care. The GAO report was another piece of evidence supporting that we're getting there.

But community oncologists have been saying, "This isn't going to be enough for us. The GAO got it wrong because it didn't come out and talk to the physicians in the communities." What do you say to them?

We've been talking to community oncology groups all along. I'm an internist myself and have heard from my

own colleagues in practice. It was input from the community oncologists and organizations like the American Society of Clinical Oncology (ASCO) that led to all of the additional payments we added in for drug administration, all the new codes being added in, and the new demonstration program for paying for the collection and monitoring of information related to patients' quality of life. All of those kinds of additions were a reflection of our ongoing interaction with the practicing oncologist, and we're going to continue that.

Community oncologists say they don't have the buying power to get the low prices reflected in the ASP. They have asked you to create a transition year, running the current system and new reimbursement systems in parallel, to allow for refinements to the new, untested system. Is that option on the table?

One of the things we saw in an ASCO study was that there are a number of small-practice, low-volume groups around the country getting very good prices for their drugs. We need to help make sure that all oncologists are taking advantage of the opportunities out there through drug purchasing arrangements and other programs, to get better prices for their medicines. We tell a lot of our beneficiaries: 'If you just walk into a drug store, you may end up paying a lot more than you need to for high-quality medicine.' There are plenty of tools and plenty of opportunities out there today to get much better deals. We're going to be doing all we can to help the oncologists and the oncology associations get those low prices for all their members.

How?

We have been in contact with ASCO about supporting its efforts to educate members about the best practices for purchasing drugs. There are a number of purchasing organizations that even small practices can work with to get their drugs and to

get some associated services at a lower price. We want to help oncologists find out about them.

What kind of quality control measures will be in place to alert you if oncologists start to see they just cannot get the ASP prices?

We will continue to remain in close touch with the oncology associations to make sure our doctors know about all the new billing opportunities available to them and how they can make the most use of those and to make sure the programs are being implemented effectively. We'll also be collecting data. We'll be doing it ourselves to monitor how our benefi-



Dr. Mark McClellan

ciaries are getting their chemotherapy treatments, and we'll be working with an outside contractor to do an independent analysis and check on the access to ambulatory cancer care. We've been talking about these issues with a lot of the oncology groups to make sure that people are well informed about what they need to do to adjust to the new payment systems. We don't expect substantial disruptions, but we will be monitoring closely.

Community oncologists are saying they're not ready; they don't know how to use these

new codes. How are they going to learn to use them?

We've gotten the codes out and put out our final regulation on schedule and put out a lot of supporting materials in conjunction with it. We've also been working with all the oncology organizations that want to help doctors adjust to the new system as quickly as possible to get the information now. For example, ASCO has on its Web site a very long and detailed list of all the specific new codes, how they should be used, and specific questions that might come up in applying them. And we worked with ASCO on developing that very detailed information on proper billing practices. We've also held an open-door forum for oncologists to participate with us and we're going to be putting out additional materials. We do 'Medlearn Matters,' which are educational updates for physicians on important new issues, and we're going to do one very soon related to billing for adverse events. The information will be there on our Web site. When providers call us or call our carriers, as they do about other billing questions, they'll be able to get assistance.

Critics charge that the new service situation doesn't reflect what community oncologists do. They say, for example, that the complexity of today's chemotherapy cocktails makes nursing intervention much more involved than ever before and that the second hour of chemotherapy will be under-reimbursed in the new system.

We now have codes that recognize the first hour and additional hour and they recognize the first drug and the additional drugs that are used in the more complex chemotherapy cocktails. We worked in a very rapid way with the AMA's system for developing the resource values that go along with these codes and to get them incorporated into our final regulation, so

they are reflected in the payment rates that we have now. Those amounts were adjusted, and these codes were added to reflect exactly that point: Chemotherapy administration is more complex today than it used to be. It does require additional effort to do additional drugs, and we're reflecting that for the first time fully in our payment system.

How do you explain the gap between the people in the community who say the new plan falls short in several areas and what you say, which is that you've considered all of the criticisms and the new plan does what it needs to do?

We have taken a lot of constructive steps to close the gaps, to make sure we are paying appropriately not just for the drugs, but also for the drug administration services. And that is reflected in the close collaboration that we've had with ASCO, for example, in getting out this guidance and letting the oncologists know exactly what they need to do to take advantage of the new payment systems. Between those steps and now, study after study showing the payments are in the right range, we think we're in very good shape, and we're going to monitor closely just to make sure.

Let's talk about the quality-of-life demonstration project. How did you choose to spend \$300 million to study care for nausea, fatigue, and pain?¹

We listened. When you listen to cancer patients and their advocates, when you listen to cancer doctors, these issues are the main concerns. A lot of cancer patients have told us that getting the chemotherapy treatments are important, making sure that they've

¹ See "Washington Update," page 245, in the November/December 2004 issue of *Community Oncology* for a description of this demonstration program and how your clinic can participate in it.

Navigating the CMS Web site

THE LINKS BELOW should help you find details on the Medicare Modernization Act (MMA) and its implementation:

■ <http://www.cms.hhs.gov/opendoor/> The Centers for Medicare & Medicaid Services (CMS) holds a series of conference calls every month called Open Door forums. CMS staff announce upcoming issues of interest to physicians and respond to their questions live.

■ <http://www.cms.hhs.gov/physicians/> On the physician pages of the CMS Web site, oncologists will find resources on the new Medicare codes and other changes, plus a link to *Medlearn Matters*, which contains articles to help physicians understand new Medicare policies.

■ <http://www.cms.hhs.gov/maillinglists/> CMS uses close to 70 "listservs" to send news to various audiences. One is just for physicians;

another covers the MMA.

■ <http://www.cms.hhs.gov/about/regions/professionals.asp>

If you have problems with your contractor—perhaps he or she is nonresponsive or you have questions he or she can't answer—contact your regional CMS office, where you will find CMS employees to help you. A map on this page allows you to click on your state to find your regional office and its contact information.

■ <http://www.cms.hhs.gov/physicians/ccredits/>

If you have a question about whether you can bill two codes together, go to this page of National Correct Coding Edits to find out. Go to your area, then put in one code and see what is not billable with that code.

Other Useful Resources

See this month's attached *Community Oncology* special supplement titled

Oncology Coding Update, a comprehensive list of codes for administering injectibles.

■ <http://www.asco.org/ac/1,1003,12-002776,00.asp>

The Web site of the American Society of Clinical Oncology contains updates, resources, and tools oncologists can use to determine the impact MMA will have on their practices, and an 11-page list of Frequently Asked Questions on the Medicare coding changes.

■ <http://www.communityoncology.org/> The Community Oncology Alliance has been arguing that the MMA is not ready for prime time and should be pilot tested first. Its Web site provides its position papers, links to Congressional representatives, and a link to the Government Accountability Office's report on the potential impact of the MMA on cancer practices.

got access to the latest treatments for potentially prolonging their lives is important, but they also care about the quality of life that they're enjoying in that process. And the important aspects of quality of life that we're measuring here—fatigue, nausea and vomiting, and pain—are issues that matter to patients, that have valid measures already in widespread use, and that can be collected on a routine basis. They are going to help us better understand the kinds of quality outcomes that our patients are experiencing. Again, we intend to work closely with the cancer experts to interpret the data and see about next steps we can take together to make sure that we're not only giving patients access to the latest chemotherapy in ambulatory settings, but we're getting them what they really want, which is the best quality of life possible with a very serious disease.

Part of this is an evaluation of what works and what doesn't?

That's right. And as a first step, we're figuring out just how the cancer patients are doing. There are not good national data for all the different types of diverse Medicare beneficiaries—the elderly, people with disabilities, people from minority groups, people from different communities. We are going to have this for the first time. With measures, we can start identifying problems, and then we can take steps together to work on improving quality. And I intend to keep working with clinical oncology groups to make sure that we're taking all the steps we can to get better care and to do it at the most affordable cost possible.

Do you have a sense of the percentage of oncologists who will participate in this demonstration project?

We've heard very broad expressions of support from cancer patient groups, cancer advocacy groups that want to know this kind of information. They think it's an important next step toward making sure we're doing all we can to get high-quality care and high-quality outcomes for beneficiaries.

Does Medicare cover any of the complementary and alternative medicine approaches that have proven useful for nausea and fatigue, such as acupuncture or mind/body therapies?

Not in the traditional Medicare program. Some of the Medicare Advantage plans are now, in some cases, providing coverage for these additional treatments which may be, for some patients, a cost-effective way to get better outcomes. In

other parts of the Medicare program, we are now doing demonstration programs and pilot programs where instead of paying more for more services, we're paying more for better results. So for chronic illnesses like congestive heart failure, complex diabetes, and chronic lung disease, in 2005, we're going to have some large-scale pilot programs operating where we don't focus specific payment on specific services. Rather, we pay the providers more when they get better results at lower total cost. It will be interesting to see whether there are opportunities to pursue those same kinds of ideas in various areas of cancer care. But cancer has been a little bit behind. In recent years, we've been developing better measures of important outcomes in the Medicare population for these other chronic illnesses and we're just starting to do that with cancer. I'd be very interested to see whether we can find more flexible ways to design payment systems to get better outcomes and save money at the same time. And I think there are a lot of ideas from patient groups and from physicians as to how we can do that.

Medicare will now pay for PET (positron emission tomography) scans for cervical cancer and for studies using PET scans in other cancers. Please talk about the thinking on that.

Well, in the past when it came to new technologies, Medicare had kind of a bifurcated approach: Either we reviewed the evidence and decided it was clear that this treatment was necessary for care, in which case we provide coverage. Or we reviewed the evidence and decided it was either incomplete or non-existent and we would not cover. Now, in that second category, we're taking a new set of steps. If there are some potentially important new technologies where there are good reasons to think they might be beneficial, but the evidence

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is not there yet, we're going to be supporting coverage for these treatments in settings where we can collect better evidence on whether or not they work. So we can have better evidence for the oncologists and their patients to use in making decisions about appropriate therapy. And we can help make sure that Medicare is not only paying for treatments that do some good, but we're also helping to drive forward the level of medical knowledge. Oncology is a field of medicine where there are a lot of new ideas about new approaches, about additional uses of existing therapies that may lead to better outcomes. We want to be doing more to help oncologists to further our level of knowledge about which treatments work or not for our beneficiaries.

How did your tenure as head of the FDA inform your thinking on these Medicare issues?

One of the things I saw at the FDA first hand was the large number of therapies in development. There are entire new sciences that are just starting to have an impact on clinical practice—pharmacogenomics, proteomics, nanotechnology—for delivering treatments to the right place at the right time. But there are very few treatments that are actually approved using these new therapies. One of the things that I think we can do in the Medicare program is help develop better evidence on some of these treatments as they come along and get approved. Medicare is the biggest payer in the world. I think it can also be the biggest supporter of developing better evidence of what really works for seniors and people with disabilities in this country and around the world.

Let's talk about the new medicines, which can be very costly. Some of the community oncologists are saying they won't be able to offer these new drugs now, because

they're not going to be making the kind of money they need to.

Again, the goal of this whole approach is to pay accurately for the drugs and for the drug administration and to take new steps to improve quality of care at the same time. We're improving quality of care by developing better evidence on how our patients are doing and on what some of these new technologies may actually do for them, and we're going to pay appropriately for the treatments and their administration. So for the new colon cancer drugs, for other new treatments coming along, we will have accurate payments and will be doing even more to develop better evidence on when they work best.

How bumpy do you think the road is going to be in the next 12 months?

I think that the thing about our health-care system is that there's always going to be bumps and that's partly a good thing. It's a reflection of the fact that our knowledge is changing rapidly and so the way that we practice medicine needs to change to keep up with it. The way that Medicare pays for services also needs to change to catch up. I think the worst possible approach is not finding smarter ways to pay. When that happens, the solution that people in Congress always turn to is just to cut payments across the board. And that doesn't lead to better access and better quality of care if the cuts are not appropriate. So we've tried to be very careful in working closely with oncologists to try to get changes and payments right so that we can pay accurately, but also so that we can keep up with these new developments in therapy and make sure we're focusing on the right bottom line, which is how we get better care to our patients as quickly as possible.

For a commentary on Dr. McClellan's interview, see "The Medicare fix: off kilter," page 98.