

Q&A

Mark B. McClellan, MD, PhD, on the Progress and Steps that CMS Is Taking to Improve Medicare Part D

CMS Administrator Mark B. McClellan, MD, PhD, recently hosted a conference call to discuss the Medicare Rx Prescription Drug Coverage: “Secretary’s One Month Progress Report on the Medicare Prescription Drug Benefit.”¹ Prepared by Mike Leavitt, Secretary of Health and Human Services, the report summarized the progress seen in the first month of program implementation, as well as some unexpected problems. After presenting his views on the progress and problems encountered during the first 30 days of Medicare Part D, Dr. McClelland fielded several important questions that we feel many of *MPM*’s readers may themselves have.

The Q&A session from Dr. McClelland’s teleconference is provided below.

Joanne Condi, Idaho: In the “Progress Report,” you talk about the competitive marketplace and the price of prescription drugs. Isn’t it true that the only entity contributing is the profession of pharmacy? The cost of drugs from manufacturers has not been reduced for pharmacies. Is anything being done so that the manufacturers share in the costs pharmacies are bearing?

Mark McClennan: It’s a good question. The prices are lower and we’re seeing lower prices in Medicaid. Some of that is because of competition at the pharmacy counter. We’re also seeing discounts from the manufacturers and bigger rebates from the manufacturers that are being passed along in the form of lower costs of the benefit. We have issued a press release based on

new estimates from our independent actuaries, which are showing that the premiums that beneficiaries are actually paying are turning out to be about a third less than what had been predicted before this competitive process started. There was a strong competitive process among plans negotiating lower prices effectively, and costs to the taxpayer in 2006 are going to be 20% lower than expected. That’s because the plans have negotiated lower rebates and because the government doesn’t pay for anything but the actual costs incurred—that being translated into lower tax payer contributions to the cost the Part D benefit and a lower cost to the federal government.

Neil Kurshner, American College of Physicians: Our members are very appreciative of the problems and, particularly, the 60-day extension to the Part D benefit. Regarding the 60-day extension, can you refresh us on how it relates to copayments?

McClennan: The copayment issue is one that should be permanent in the Program. So if you are a dual beneficiary or a lower-income beneficiary, you should be paying lower copayments for your drugs from day 1. For beneficiaries who are not in the lower-income subsidiary category, the same coverage for formulary drugs and off-formulary drugs that are part of an existing therapy would continue. That’s not changing. We’re continuing the same transition policy that was in effect for the first 30 days.

Kurshner: Another problem is that some of our doctors are still having difficulties getting formularies from the plans.

McClennan: We have formulary lists available on the CMS Web site. Another good place for doctors to go to get formularies is Epocrates.com. I haven’t been in practice recently, but when I was, a lot of doctors, including me, used a handheld version of Epocrates. Epocrates has made formulary lists available on-line and provides a pretty powerful set of tools that you don’t even have to subscribe to. Basically, you just fill out a form, without having to pay any money, and you’ll have access to the formularies. These are organized by plan or drug type, depending on

how you want to do your search. For example, if you type in a drug or drug class under a plan, it will tell you which are the preferred drugs for a patient in that plan. It's a tool that anyone with on-line access can use for information on plans in their area. They are especially designed for doctors and other health professionals.

Brenda Wilmoth, Director of Barbour County Senior Center, Inc., Philippi, WV:

Will drug companies' patient assistance programs continue to help clients so that they won't be worse off after Part D than they were before? I had a couple in yesterday that had been paying \$36 a month for the wife's medication because they were getting help through a patient assistance program. Now, with Part D, her costs are going up to \$231 per month and they just can't afford this. Some of the drug companies are already cutting off their patient assistance programs. Is there any way these programs can be continued for awhile to give people a chance to try and work something out?

McClennan: I am very concerned about assistance programs continuing. Just because a drug benefit starts doesn't mean that help should stop. For people who qualify for the lower-income subsidy, the new drug coverage is very comprehensive and may be as close to or as good as the patient assistance program. What I'm most concerned about are the people who have income or asset levels that are higher than would qualify them for the lower income subsidy, but would still be covered by a patient assistance program. Just to make sure that all the drug manufacturers know that they can continue these programs in addition to Part D, we not only issued guidance last fall from the Inspector General and from CMS, we released a White Paper along with a phone call to advocacy groups, charity groups, and the drug manufacturers themselves, which laid out in a summary fashion how they can continue with Part D. To cut to the chase, what's not allowed according to our Inspector General is for the manufacturer to pay for a drug inside of Part D. The reason is the Inspector General is worried that this

will be a type of kickback or something that would add to the cost of the drug benefit. It would be basically taking drugs that the manufacturers were giving away for free or at a much-reduced cost and having the government, in effect, start paying for them. What is allowed is for these assistance programs to continue in addition to Part D. For example,

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suppose that someone is signing up for Part D for their basic medications, like cholesterol drugs or blood pressure medication, but they also need a very expensive drug for cancer, rheumatoid arthritis, or HIV/AIDS. The manufacturer can continue to offer their assistance programs outside of the scope of Part D so the person could get some of their medications on the same assistance programs as before and others that are included in Part D. We are working very hard right now to make sure that every manufacturer knows about this opportunity. If you are interested in following up or working with us, there are materials on the CMS Web site.

We have also been in close consultation with many of the manufacturers to encourage them to follow this route. It's a win for everybody—the manufacturer programs are less burdensome than they used to be because the low-income subsidy is picking up many beneficiaries. For those remaining beneficiaries above the \$150 poverty level or who are over the \$200 maximum level for the coverage, it's a smaller group but one we really want to help. That's what this additional guidance and fact sheet [on the CMS web site] focus on. We hope we can continue to work together so these patient assistance programs continue.

Leslie Freid, Alzheimer's Association: First, I'm thrilled to hear that the transition period has been extended for another 60 days. But the question is: Are you sending the word out to the plans and pharmacies, because as we all know, part of the problem of implementation on January 1st was that the plans and pharmacies never really knew about it?

My second question is that even after the Part D plan began to enroll and people were getting their transition drugs, beneficiaries were not getting letters from the plans telling them that this was a one-shot, 30-day deal and that they needed to either go to their doctor about changing their drug or file for an exception. That letter is really important.

McClennan: That's right. The fact that some plans are not doing that as effectively as we wanted is one reason for the actions that we announced today. We have been discussing this with prescription drug plans over the last several days, and have had meetings with various associations and plans. A formal notification has been released to all plans working with Medicare that was very clear about what the policy means, which is essentially that it is a continuation of the first 30-day policy. This is exactly why we wanted to have some more time—so we could make the transition issues go more smoothly over the next 60 days. It will give the plans more time to send out their letters. We've seen some cases of people switching drugs voluntarily. Some plans have been using approaches like "Pay and Educate," where they pay for the medication, but then they will get the communication process

going with the beneficiary, the pharmacist, and the physician, if necessary. In a number of cases, beneficiaries have found that the alternative drug is cheaper and "since my doctor has said that it may work for me, I'm going to try it out." Over the next 60 days, we want to see a similar process for everyone, and that's why we're providing plenty of time for plans to send out their letters and make sure that plans are following through on their transition process requirement so that we can achieve a smooth transition by the end of March.

Sandy Park, Ohio Medicaid: I want to make sure that the States getting assistance continue to do so, but if we're not on the State Medicaid list, where do I find the template to do so?

McClennan: The template is on our [CMS] Web site. With respect to the State assistance, our reimbursement program for the State is working off a specific checklist or template. As soon as States get that, they can go down the checklist, which we developed working very closely with a group representing State Medicaid Directors and other State officials. As soon as we get that form back, we can check all the boxes and get the reimbursement process started. The duration of the assistance for States really depends on the situation in the State. Based on what we've seen in a lot of States, including Ohio, there are some best practices that they can follow that limit their need to use their own reimbursement system. For example, in Pennsylvania, the State has put in extra effort in helping pharmacists use Medicare tools available and helping us work together and connect people with their coverage. That does create administrative costs for the State. We recognize that, and those administrative costs will be covered as well under this template. We think that, based on what we are seeing in many States, we can get the billing down within the next 2 weeks, but we will continue the reimbursement payment further if that's necessary in your particular State. It is time, though, for us to really roll up our sleeves and work together to get the remaining dual eligibles connected with their coverage. In many States, it is a really small number at this point.

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Paul Peck, Medicare Rights Center:

My first question is: Does [extending the transition coverage through 90 days] mean that, where plans were providing a fill for 30 days, they will now be providing a fill for an additional 60 days, or is this just a time-limited transition that applies to the first 3 months?

McClennan: This [transition coverage] is likely to be implemented by plans in the same way as the first 30-day policy. My best guess is that, in most cases, a beneficiary will get another 30-day fill for their prescription. The plan may then start undertaking some activities to let that beneficiary know about the fact that there are alternative drugs covered under their formulary that they should, with their doctor, at some point before the transition period ends, consider. If they have not had a chance to resolve their issues by March, they'll come back in and get another 30-day prescription.

Peck: My second question has to do with quantity limits. I've gotten a number of calls from people who are on psychotropic drugs, but the plan they have imposes a quantity limit—that is, it allows only as much for a 30-day period. Can people get a transitional supply for that while they are working out an “Exceptions” [process] and, if that's the case, can we let plans know that this is also a potential problem?

McClennan: We will have to look into that issue further. We have heard a few complaints and concerns about that. The ones I've heard about have generally been able to be worked out with the plans. My expectation is that as the wait-times on pharmacy and provider help-lines continue to diminish, and we get these exceptions processes working more smoothly, those issues will be resolvable. That's something we'll keep an eye on. As you know, the plans are required to provide medically necessary treatment—in this case, that includes an adequate number of pills to meet patient needs.

John Keegan, Community Pharmacist, Hazelton, PA: I have 3 questions. The first one has to do with the E-1 transmission. I'm running into situations where the plan has processed the patient's application,

CMS has approved it, and [the beneficiary] has received information back that they are in the plan, but the E-1 does not contain the patient information. That's a problem for us.

The second question, to continue on this transition process, if the transition goes through, they may end up postponing it, although I'm hearing what you say about how the plans might try to start the process of transitioning to formulary drugs. We are not getting notices that this may be an issue. It's just letting the prescription go through so that this transition has been allowed, so that we can alert the patient to speak with their physician in regards to what is on the formulary. Because physicians usually don't know what's on the formulary, generally it's the pharmacist who has to let them know what's in there.

In fact, we're hoping to bill the E-1 system out and make it a more broadly useful benefit tool for the pharmacist to avoid phone calls; but that's a little down the road.

My third question is on the quantity limits. I have a patient who required 15 mg of Lexapro®. It only comes in 10- and 20-mg formulations, so [the prescription] would [have] needed to be 45 Lexapro® 10, so that the patient could take 1½ a day. The quantity limit kicked in, yet the same plan was allowing 20 mg, once a day to go through. [Shouldn't] they should be looking at the total mg dose, not just quantities, when they set up quantity limits?

McClennan: Those are all good questions. Starting out with the E-1, if you've got a beneficiary with either an acknowledgment letter from the plan that has the billing information or a drug card from the plan, or they'll find out that they'll have a drug card with the billing information on it in hand in a few weeks, there's no need to do an E-1 transaction.

You only need to do an E-1 transaction when the beneficiary's billing information can't be located through other means. I do know we had some issues, especially for the non-dual eligible beneficiaries earlier in January, [concerning] the completeness of information coming in from the plans to our E-1 TrOOP facilitator. Just looking at the numbers, we've gotten a lot better, with close to full information on most of the dual eligible beneficiaries and the vast majority of the non-dual eligibles. If you can bill directly because you've got a card or an acknowledgment letter, you don't need to do an E-1 transaction at all. In the cases where the beneficiary doesn't have that card in hand and you can't do the E-1 match because we really haven't ramped up with the plans to reduce their pharmacy wait times, now it should be much easier than it was before to call the plan for that information. The whole point of the E-1 was to avoid the need to make that phone call that, you know, happens more often than it should. Many times people switch into new plans and don't have their billing information with them. In fact, we're hoping to bill the E-1 system out and make it a more broadly useful benefit tool for the pharmacist to avoid phone calls; but that's a little down the road.

On the transition policies, we've heard a lot of good ideas directly from pharmacists about how information coming back from the plans could be much more useful. Soft edits could flag an off-formulary or prior-authorized drug or, 60 days from now, we're going to need address what the formulary drugs are for [a particular] plan. We've seen a strong interest from leaders in the pharmacy community and from the plans to make these transaction issues work much more consistently, practically, and smoothly from the pharmacist's standpoint. As a result, we have pushed for the development of a group that is going to be led by plan and pharmacy representatives to focus, in the short term, on working out more consistency in messaging, more use and adoption of standard exceptions and appeals forms, and more consistency in the business process. You know, plans do want to compete to get prices down and provide effective services, but they

don't want to compete in making pharmacists necessarily learn about different nomenclature and have to guess about what an off-formulary message means in one plan versus what it means in another. That's one area where I'm going to be paying a lot of personal attention, along with my senior staff, in the coming few weeks to make sure that we see more progress in getting real consistency. There have been a lot of concerns that, on the one hand, people like the fact that millions more are getting coverage and that it's coming in at a lower cost

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than expected and with better benefit options, while on the other hand, there is a lot of concern, especially among pharmacists, about the lack of simplicity. They need to deal with a lot of different plans, so there's a shared interest in trying to address these consistency issues in terms of edits and other approaches.

In terms of your question on quantity limits, it would make eminent sense for the plans to cover 45 [Lexapro®] times 10 mg, rather than 30 times 20 mg. My hopes are that this issue will become much easier to address as the plans systematically build them into their edits or are going to be much quicker to address with a phone call to the plans because you're going to have the faster access, which you should expect in dealing with a Medicare plan.

Trevor Miller, Regional Coordinator for a Community Care Rx in the Atlanta, GA, Market: My question today is two-fold. First, in regards to applications submitted through CMS that are either backlogged or being delayed for cross-referencing for dual eligibility in Medicare and Medicaid,

what additional information can be fed to the consumers or additional entities, such as pharmacies, hospitals, and clinics where enrollment is taking place, so that these consumers can be well-assured that they are being taken care of? Because other than at the time of application, they may only receive a simple paper receipt or reminder brochure with an application. There is no reassurance that they are even in the system at this time. [So my second question is:] Is there anything that CMS can do for them?

McClennan: Some of the steps we're taking between Medicare programs and the plans should improve the data handoff. As we set this system up, there's obviously a lot of information that needs to flow for beneficiaries to get their prescriptions filled properly, without any difficulty at the pharmacy counter. Some of that information is coming in from the

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plans to us, other is information coming from the States to us, and more is information coming from us back to the plans, for example, on copay levels and the like. Each of those data handoffs are opportunities for problems to exist, and we've seen cases where specific plans generally weren't aware of the technical requirements for submission, which led to claims being rejected or held up in both our systems and their systems and complete information not being available on all beneficiaries. We have been working closely with a number of technical experts from the drug plans to fill in those gaps and prevent those errors from hap-

I'm impressed by the number of people served and by the number of prescriptions that are going up every day. This wouldn't be happening without you.

pening. So I can safely say those data transactions are being handled more smoothly. They have gone better with some plans than others, depending on the technical capabilities on the plan side, but I think across the board, we're seeing improvement. To make sure that plans don't have to depend on individual transactions getting through, we're also sending out, on a regular basis, files that include complete information from our records on all the enrollees in the plans and their copayment and dual eligibility status. The most recent of these files was sent out on January 30th, and we're going to keep sending those out on a regular basis, particularly to plans that are having difficulty in data handoffs.

Another way to verify complete information from our systems about coverage and copayment levels, plans can also submit eligibility queries, which don't involve the full set of data submission [needed] to do a check on a beneficiary who has just enrolled as to how to we have them listed in terms of dual eligibility status or limited income subsidy copay status. They can know that information even as they are processing an application initially. All these steps together give beneficiaries the process they want.

For those who work in these enrollment activities, it is important to let people know that it takes a little bit of time for their information to be fully loaded into the pharmacy systems and so forth to assure that all of their transactions are going to go smoothly. Typically, after a person signs up, within a week or so, they'll receive an acknowledgment letter from their plan that includes billing information the

pharmacist can use, and within 3 to 4 weeks later, a drug card that also includes their billing information. It's important to tell people to hang on to that letter until they get their card. If they can wait a couple of weeks until they have an acknowledgment letter or drug card in their hand until they go to the pharmacy, they are very likely to have a much smoother transaction at the pharmacy than if they sign up for coverage or change plans at the end of the month and then try to use the coverage soon after that. We are encouraging advocates and others to let people know about this several-week period that it takes to get fully into the system. If you need drugs sooner or if there's a problem, it doesn't mean that you are not going to get your medication. It means you have to go to other systems, such as the E-1 system and the CMS help-lines available to pharmacists.

I want to thank all of you for taking the time to talk today, as we're a month into the biggest change in Medicare in 40 years. Thanks to your efforts, millions of people are getting their prescriptions filled every day. I'm impressed by the number of people served and by the number of prescriptions that are going up every day. This wouldn't be happening without you. I know there continues to be a lot of work out there for many of you dealing with these transition issues. The steps that we have been talking about are the direct result of [CMS] interactions with you.

So thank you very much for your continued leadership and all of your efforts to help everyone take advantage of the new drug coverage. The audio of this call is available on the CMS Web site [at www.cms.hhs.gov/apps/files/8105492.mp3]. You can also go to the Highlights Section [on the Web site] for more information about the announcements we've made today, as well as continuing information and updates on the prescription drug program. MPM

Reference

1. Leavitt M. Medicare Rx Prescription Drug Coverage: "Secretary's One Month Progress Report on the Medicare Prescription Drug Benefit." Available at: <http://www.hhs.gov/medicare.pdf>. Accessed February 15, 2006.

From the Editor

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comes to Medicare reimbursement for physicians. Under the MMA, provider reimbursement, which was expected to decrease according to the Medicare formula, instead increased by 1.5% during 2004 and 2005. Medicare normally updates the conversion factor each year through a complex formula specifically defined by federal statutes. Using this formula, the 2005 conversion factor would have decreased provider reimbursement by 3.3%. However, this cut was averted because of a Congressional mandate in the MMA that the update of the conversion factor for 2005 could not be less than 1.5%. However, this did not correct the problem of decreasing physician reimbursement, but rather delayed those cuts until 2006. Yet, once again, Congress stepped in and substituted a planned 4.4% decrease with a 0% change over 2005 reimbursement rates. So at least during 2006, the cuts that have been planned for the last 3 years have been put on hold. Given the administration's desire to cut \$36 billion from Medicare, it remains unclear how much longer physicians will have to wait until they must accept Medicare reimbursement cuts.

Hopefully, as you read this and future issues of *Medicare Patient Management*, any Medicare-related dizziness will be eased so that you will be in a better position to care for your senior patients. As the baby boomers, who include many of us, reach the age of Medicare eligibility, the numbers of senior patients will double, affecting just about every health care provider who cares for Medicare patients.



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1. The Kaiser Family Foundation. Medicare beneficiaries with creditable prescription drug coverage by type, as of January 13, 2006. Available at: <http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi?action=compare&category=Medicare&subcategory=Medicare+Drug+Benefit&topic=Medicare+Rx+Drug+Coverage>. Accessed February 20, 2006.