

**Newsmaker Luncheon:  
Kaiser Conversations on Health with CMS Administrator Mark  
McClellan  
September 29, 2004**

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**DREW ALTMAN:** I'm Drew Altman. Hi, Everybody. It's good to see you all. Welcome to the Barbara Jordan Conference Center, and welcome to this "Conversations on Health". This is the third in our new series, moderated by Jackie Judd, and as Mark reminded me, we started with Don Allen. Today we have Mark McClellan, so we have a pretty wide range in this "Conversations" series. What we do in these "Conversations on Health" is combine the capabilities of the Barbara Jordan Conference Center and also Kaiser Networks to bring the most important leaders in healthcare, both to a live audience in Washington, DC, but importantly to people in the health policy and healthcare communities across the country who don't have—how should I put it?—equal access to the players and to the events that occur inside the Beltway. So, if you're watching out there and you want to participate in this event, you can send in your e-mail questions. You send them in to [conversations@kff.org](mailto:conversations@kff.org). That's [conversations@kff.org](mailto:conversations@kff.org), and you'll get a free set of steak knives. If you act now, you'll get a complete set of Medicare fact sheets absolutely free. As you might have imagined, following our organization, our purpose here is much more Ryan Lamb than it is Bill O'Reilly, God forbid. And Mark may very much want to make news today, and we welcome him to do that, but we, as we always do, want to go a little bit deeper, and yes, be a little bit wonkier and be a little bit more intellectual, and just spotlight people who are in leadership positions in our government and in national healthcare. I was talking to a student at a

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university the other day, and he actually asked me, "Have you ever met Mark McClellan?" I realized, they see a glimpse, six seconds or whatever it is, Jackie, on the nightly news. So it's an opportunity to spotlight people in a greater depth who really are playing the most significant roles in the healthcare field.

We're in the Barbara Jordan Conference Center. When Barbara Jordan was in office, one of her constituents said, "I heard her on the radio and I thought it was God." Well, Mark McClellan has the resumé from God. He is both, of course, a physician and an economist. He's the former Deputy Assistant Secretary for Treasury, in yes, the Clinton Administration. Of course, he's a member on the Council of Economic Advisors and an advisor to President Bush, former Commissioner of the FDA, and now the CNS Administrator, with appropriate speculation about what might come next, depending on the outcome of the election, subject to confirmation, or course, by his wife Stephanie and his two daughters, whom I assume will have something to say about his continuing in these crazy and most difficult jobs.

I have three special connections to Mark McClellan, he just doesn't know it. One is, he is a product of the Harvard/MIT division on Health Sciences, and he did his PhD in Economics at MIT. I did mine in Political Science at MIT, next door. We shared a doughnut stand with Economics, but that was as close as we were ever allowed to get. Secondly, Mark was an Associate Professor—he still is, technically—an Associate Professor of Medicine at Stanford Medical

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School, which is literally just down the street from our headquarters in [inaudible] Park, so we are geographically proximate, and used to have lattes every morning, and then go surfing. I completely made that up. I know that you can imagine Mark surfing, but you cannot imagine me. Really, more seriously, I also worked as a young person in the Administrator's Office in then, HICFA, in the Carter Administration, and as some of you may remember, was for a time, former President Bush's nominee to run the Healthcare Financing Administration. And so I really do have a deep and personal appreciation for how difficult and serious the challenges are that Mark McClellan faces in this job. And I thought I would just close my little welcome with that point, and the gargantuan job that Mark has, and use this device—this little chart. What I did was pull this off our website—this is brand new on our website—and it just shows the timetable for implementation of the new prescription drug law. I'm using it for effect; I will not present it to you. But you can see, here we are in the difficult regulation writing stage, and then we move through—I will not read them all, but pick one—Deadline for CMS to publish risk adjustment methodology in determining 2006 payment rates. I can assure you, there are six people in the world, or maybe ten who actually understand that issue. And more deadlines, and more deadlines. Here's an interesting date. You see that arrow that I put in, corrupting our website? It turns out there's nothing happening in August of 2005, which might be vacation, or the month they get to focus on the Medicaid program, I don't know. And then of course there

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are more deadlines, and more deadlines. It's actually November 15 when people get to enroll, and then of course, it's January 1 when the new benefit becomes live. Then there are more deadlines—it's not even over then—and then there are more deadlines. And so, at the end, what is mind-boggling is that this is only one challenge that he has. It may be the biggest one at the moment, but it's only one challenge that he has in this job. So with that as an introduction, we're going to begin with a video prepared by Jackie Judd and company, and then the lights will come back up and we'll get started.

**PRESIDENT GEORGE W. BUSH:** First I want to start out with my friend Mark McClellan. He is a doctor and a Ph.D. He's from Texas. He at one time was the head of the FDA.

**MARK McCLELLAN:** Threats from potentially unsafe medications and food that are based on increasingly complex production processes, new infectious diseases, and it's now a regular part of the FDA Commissioner to get classified briefing about potential terrorist threats. Altogether, we have the responsibility for assuring safety in over 20 percent of America's consumer economy. The bottom line's the same whether you're dealing with a vital heart medication or a vitamin pack. We're working hard to create a marketplace with truthful, non-misleading, useful information about the health consequences of products to empower consumers and to encourage better and healthier and more affordable foods, medicines and supplements.

**PRESIDENT GEORGE W. BUSH:** He did such a fine job there,

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that I gave him a tougher job. He is Administrator of the Centers for Medicare and Medicaid Services. His job is to make sure the Medicare system works well.

**MARK McCLELLAN:** It is a fundamental [inaudible] in Medicare that makes it a more personal one. That's how we can best take advantage of the fact that different people have different needs, [inaudible] medicines and the kinds of other health services that they receive and a different perspective on how to get those services. And with more benefits coming in Medicare than ever before we want to do more than ever before to match up people and their preferences with the best benefits and the best medical services for their needs. . . We want to do as much as we can to help patients and their physicians find the least costly way to get the health benefits that prescription drugs provide. All of the cards in the Medicare Discount Card Program provide discounts on all of the top 100 drugs used by seniors that can be included in the drug card program, all of them, all 100. Most of the drug cards, almost three-fourths of the drug cards provide discounts not only on the drugs that you're most likely to need, those top 100 drugs, but also on more than 80 percent of all the drugs that are marketed in the United States that could be covered by the program.

**PRESIDENT GEORGE W. BUSH:** He understands healthcare, and he understands the task.

**JACKIE JUDD:** Welcome.

**MARK McCLELLAN:** Thank you.

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**JACKIE JUDD:** We're going to get to all of those issues and more today, but first I want to start with a very, very critical issue to an audience of Washington's today. Do you continue rooting for your Texas home teams, or do you join us here in Washington with our new team?

**MARK McCLELLAN:** Oh, Jackie, there are some truly sensitive issues that I have to [inaudible] at this time. [Laughter.]

**JACKIE JUDD:** I'll give you a pass, but let's move on to the business of the day. A former colleague at Harvard said of you after President Bush nominated you for your current position, "He believes in markets. He has a way of thinking about the world that is economically driven with costs and incentives of individual choice." Is that accurate, and how does that fit into what you want to do at CMS?

**MARK McCLELLAN:** Well, there's no question that financial incentives, opportunity for choice can have a very positive impact in many areas of our lives. When people can choose less expensive foods, when they can choose less expensive services, they often do it, and that leads to better opportunities for people to get more for their money.

**JACKIE JUDD:** How did you, Mark McClellan, come to that kind of worldview?

**MARK McCLELLAN:** I think it was a combination of experience and training. The experience mainly came in my professional life in medicine, where I'd actually been caring for patients. You get into

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situations—you wonder how you got there—where there's a very ill patient in the hospital, ill, someone with diabetes, other chronic illnesses, who's on dialysis, who has had maybe an amputation—this happens especially in some of our minority populations—and everything I've learned about in medical school was that we should prevent this. But it doesn't seem to be happening, even if we've got coverage in place. A lot of these are Medicare beneficiaries, or people with Medicaid who should be able to get access. They should be able to afford many of the treatments that they're using if these programs are working well. Yet we still see lots and lots of these complications. And what we've seen is a lot of opportunities to change that by giving people better information, by giving them choices, by empowering them to get better care. And too often that still doesn't happen today.

**JACKIE JUDD:** When you were still a practicing physician, what did you conclude about that question? Why wasn't it happening?

**MARK McCLELLAN:** One of the things I used to see was my senior faculty telling me, "Well, it would have been nice if this patient was on prescription medicines. It would have been nice if they would have complied with it, but Medicare doesn't cover the drugs, and the patient didn't come to clinic regularly, and I just get paid for the office visits. We can't afford — yeah, it would make sense to put a program in place where this person has an outreach, and this person calls them up regularly to help them stay on their medicines, but that's not the way the program's set up. There's no

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money for that. On the other hand, we get paid a lot when we admit them to the Emergency Room or when we admit them for a surgical procedure or dialysis," and that's the way the healthcare system works all too often today. The money, the financial incentives make a big difference. It's not everything. Knowledge matters. Informed patients matter. Empowered patients matter a lot, but the financial incentives matter too. And my medical training and economics, that's what economics is really all about. It's not some over-simplified view of the world where an economist thinks that all that matters is pricing and quantities of services. But it is something that can matter a lot, and we'd really like to make the financial incentives work for us so that doctors and health professionals, advocates, people who are working to help patients don't have to feel like they're swimming against the financial tide so much of the time.

**JACKIE JUDD:** Well, last night I heard you say, actually in this very room, speaking to a different group—

**MARK McCLELLAN:** Spending a lot of time at conferences.

**JACKIE JUDD:** We're very happy to have you here as often as you'd like to come. But you said that you wanted to do nothing less than transform healthcare with CMS at the lead, and you went on to lay out a fairly broad strategic plan. It seemed to me that one of the underpinnings for that plan was pay-for-performance. Again, apply that to the Medicare and the Medicaid program, if you can.

**MARK McCLELLAN:** We've seen a lot of experiences of health plans that are outside of Medicare getting some big payoffs when they

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implement some elements of pay-for-performance. And as I said last night, pay-for-performance isn't the be-all and end-all, but when doctors are not being rewarded and are not being encouraged to take steps that improve quality and may even reduce costs, something's wrong with our system. Plans like the Civicare [misspelled?] had tried to implement quality measures, or good, basic medical practices, like regular checkups for diabetics and managing their hemoglobin-A1C levels effectively. They'd had measures in place for a while, and they were tracking these over time, maybe over several years they would get a three or four percent improvement. They would exhort the doctors, and so forth, but nothing would really change. When they started implementing some actual financial incentives tied to the quality measures, they got real improvement, one, two wobbles of 30, 40 percent or more improvement in these known steps that prevent complications and help people live longer and healthier lives.

We're trying to bring the same kind of idea into the Medicare program. We're starting with hospitals. The hospital payments for next year are going to depend on whether they actually report accurate measures of quality in ten different dimensions. We're working a very broad effort to expand that set of quality measures quickly to get more quality improvement, and we're doing the same kind of thing with physician measures and outpatient ambulatory measures, and nursing home measures and other aspects of care as well, so that we can move towards actually rewarding our healthcare

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professionals for doing what they want to do, which is improve patients' outcomes.

**JACKIE JUDD:** And when you talk about performance, is it always about the kind of medicine that's administered, and it's not the actual patient outcomes, which could lead to cherry picking?

**MARK McCLELLAN:** It can be some of both. It's very important, and that's one reason why pay-for-performance measures can't be the be-all, end-all now. We don't have good, validated, reliable measures of quality in all of the aspects of care that people like to get. One of the things that's very important in this process is make sure that we bring all the stake-holders together—health professionals, consumers, perspectives from industry—about what can actually work to provide useful quality measures. But the good news is that in very many areas the studies have been done, the risk adjustment methods are there to get adequate measures of processes of care, and in some cases, outcomes of care. There are important outcomes that should be avoided, outcomes that we really should be aiming for zero events, like post-surgical infections. We can develop quality measures based on that and start rewarding hospitals—instead of paying them more when a patient has more complications and stays longer, let's pay them more when they do the care right the first time.

**JACKIE JUDD:** And do you put this approach inside of traditional Medicare, or is this part of your move towards private plans?

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**MARK McCLELLAN:** I think it's part of all Medicare, even with the reforms that are taking place right now in Medicare to give seniors access to more reliable health plan choices, like Preferred Provider Organizations. In all of our models, and all of our forecasts, most people on the Medicare program are going to stay in traditional Medicare. So we absolutely can't ignore that. Many of the private plans in Medicare for a while have been doing things like providing preventive benefits and drug coverage and disease management services that keep people out of the hospital and keep them healthy, and traditional Medicare has fallen behind. The new drug benefit is a big help in that regard, but we're also taking other steps for bringing these kinds of quality improvement efforts to the traditional Medicare program. We're starting a new chronic care improvement program with 300,000 beneficiaries on a pilot basis next year, and we're going to make that nationwide just as quickly as we can. As I said, we're implementing some of these performance measures for providers in the traditional Medicare program, and we're actually starting to pay based on whether the quality measures are being reported, and I think there's a lot of room to build on that, quickly.

**JACKIE JUDD:** How does this work with Medicaid?

**MARK McCLELLAN:** Many states are also looking at quality measures in their Medicaid programs. The states are the primary administrators of Medicaid in each state, but what we can do to help is look around the country at successful models for bringing better

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value to the taxpayers and beneficiaries in Medicaid programs. For example, states like North Carolina and Washington have recently implemented some major disease-management programs where they are tracking patient outcomes and they've set up incentives for providers that keep diabetics healthy, keep people with asthma and heart failure out of the hospital, and they're working. Their lower costs in North Carolina estimate savings as much as five percent of their overall Medicaid costs for acute care as a result of disease-management services. That's while they're getting better quality at the same time. We've looked at the example in that state, and we're making it easier for other states to implement similar programs by providing some expert consultations and assistance for them.

**JACKIE JUDD:** And not surprisingly, you are getting some pushback from certain quarters, from doctors and others who say it's not a practical approach because they don't have the technology to do the kinds of things that you've been talking about, and they can't control what a patient does, like not showing up for an appointment.

**MARK McCLELLAN:** That's right, but there are a lot of proven, evidence-based steps that we can take that do help patients show up for appointments. That's one of the main factors that we're looking at in selecting programs to participate in our chronic care improvement program. We've got a lot of bidders to participate in this program next year, and many of them have extensive experience with doing exactly that, helping patients understand their disease, understand why certain medicines are important, understand how they

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can best comply with those medicines and helping them take regular steps, like getting into their doctor's office for regular check-ups for monitoring their blood sugar regularly, or taking other necessary steps to stay healthy. There are proven, effective ways to do this, through visiting nurses, through home health agencies, telemedicine assistance, and we need to make those services more widely available in Medicare so we can keep our overall costs down and improve the quality at the same time.

**JACKIE JUDD:** You talked about evidence-based medicine. Last night you said something that would not surprise anyone in this audience, and that is, you said sometimes bad decisions are made because of politics. So when politics and evidence do come in conflict, how do you resolve that?

**MARK McCLELLAN:** I try to resolve it as best I can base on the science. Coming into this job from the FDA was a very good experience in that regard, because the FDA has a very strong tradition of basing their decisions on the medical science. We're trying to bring that same perspective to CMS. CMS has always had it as well. Evidence is a very important determinant of our coverage system, for example. But as part of our quality improvement efforts, we started a new counsel on technology and innovation that is making it even easier to make timely decisions based on the best and latest science. Just yesterday, we announced the proposed new coverage decisions on internal Hardy-Berger defibrillators, those little shock-boxes that can be implanted in a person's chest, and can

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substantially reduce death from the number one cause of death in our beneficiary population, which is sudden death with heart disease. We're making this technology much more available because the scientific evidence now says that it is very helpful in preventing deaths for potentially a large part of our beneficiary population. We're also taking steps to develop further evidence. We're going to set up a registry in conjunction with our new coverage so that we can learn even more about which patients actually benefit when they get this technology, and that in turn is going to help doctors and patients make more informed decisions. I think that by having good information in the hands of doctors and patients, we can do a lot to avoid politics in healthcare and do a lot towards getting more for our money, and getting higher quality care as well.

**JACKIE JUDD:** But you're not immune to politics. You couldn't survive as well as you have in this [inaudible], being immune.

**MARK McCLELLAN:** There's definitely an environment. I have to say I came in here from California three years ago. I spent a year or so here before in the previous administration, and for all that you read about what makes the headlines, certainly the tough political attacks, the shock and so forth—there are a lot of people here in town who are very good at that—but once you get below that, there are a lot of people here on both sides of the aisle, Republicans and Democrats, who really want to get something done, who really want to make our healthcare system better. Even now, right

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now, just a few weeks before a contentious Presidential election, there are a lot of discussions going on about how we can improve the SCHIP program, about how we can get our money-follows-the-person initiative enacted in Medicaid so that we can get more people with disabilities out in the community where they want to be, about how we can potentially work on the Family Opportunity Act. These things are going on right now, even though we're just a few weeks away from the election. You wouldn't know it from reading the headlines, but I've got a lot of faith in this community to actually get beyond politics.

**JACKIE JUDD:** Well, you and Drew had mentioned that you both had lived here earlier when you were in the Clinton Treasury Department. I'm curious about what kind of philosophical shift happened in you that allowed you to move from the Clinton White House to the Bush White House.

**MARK McCLELLAN:** I think it's not so much a philosophical shift in me, it's just that underlying our policy decisions in this country ought to be good evidence and good science. When I was at the Treasury Department, it was headed by Secretary Bob Rubin and the Deputy Secretary was Larry Sommers, who I actually had as a professor back when I was a student in graduate student in Harvard and MIT. He had always been a proponent of trying to bring good science and good ideas into policy making. There it was in the Treasury, but they dealt with the same kind of major economic issues that involved healthcare. Healthcare is a huge part of our economy. Secretary Rubin was again, focused on what's the right policy approach. That's the

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same kind of attitude that I try to keep with me all through my career in public service. And you know what? I think the good ideas end up getting some traction, and there's a lot of common ground between both parties.

**JACKIE JUDD:** I'm wondering, what has been the hardest part? What has been unexpected in your experience since you joined CMS? What was harder than you thought?

**MARK McCLELLAN:** Right now is a very politically contentious time, and coming into the job just before a Presidential election, after some major legislation on a very important issue, an overview legislation on bringing Medicare benefits up to today, with prescription drugs, preventive benefits and the like, I kind of felt like I was stepping into a tough political minefield, which is probably saying something, coming from FDA. One of the things that I have noticed, at FDA our press coverage tended to start with what the agency actually did. Most of the people that cover the agency are consumer reporters, or science reporters. Certainly there are strong views on all sides of actions that the FDA takes, and so all the articles duly print those criticisms. With CMS, it tends to be more politics that gets in the paper first, so when we do a new program like a drug card that can provide thousands of dollars in help right now to low-income seniors, the first couple of paragraphs of the stories aren't always, "Here's what the card does. Here's how you find out about it. Here's how you sign up," but rather the criticisms and what the supporting statements are on one side versus the other,

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exactly how this was done. So, people have to read a little bit further down for what does this actually mean for me, and what can I do to lower my costs now, to get better benefits, to get better healthcare? That's something that's more of a communication challenge than I expected, and we're now doing a lot more work with outside organizations, non-profit groups, non-partisan groups to help make sure that we get the facts out so that people can-

**JACKIE JUDD:** This is on Medicare Reform?

**MARK McCLELLAN:** Yeah, this is on Medicare specifically, but in CMS the issues that we deal with are some sensitive ones, with strong political views on both sides. And again, below the surface, there's a lot of interest in moving things along, finding the best ways to do it. Some of the best ideas we've had about implementing the drug card, about implementing the drug benefit have come from Democrats, have come from people outside the Administration who are publically pretty critical of the whole approach to undertaking these improvements.

**JACKIE JUDD:** Can you give me an example?

**MARK McCLELLAN:** Well, I don't want to name any names. Well, actually I can. We recently announced a new program to do automatic enrollment in the drug card program for a lot of low-income beneficiaries. We had thought earlier that it was going to be very difficult to do this because we didn't think we had the statutory authority. We thought we would have to work through the states, and the states had helped us in enrolling some beneficiaries in the

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prescription drug assistance programs, but they weren't really interested in doing it for this much broader population of low-income beneficiaries. We got to talking to a lot of people outside of the Administration, particularly the Access to Benefits Coalition, which is this non-partisan umbrella organization of more than 90 beneficiary advocacy groups and community organizations ranging from AARP, United Seniors Association, Medicare Rights Center, and those groups collectively gave us some really good input into how we could come up with a way for getting this drug card benefits out to low-income beneficiaries, which includes some groups that overall have been pretty public in their opposition to the law—at least some aspects of the law—but who really want to get help now to people who are struggling, have limited means, and who are struggling in affording their medications. As a result of all of us coming together we were able to announce a new program that is going to get these cards out to about 1.8 million beneficiaries within the next couple of weeks, and that means thousands of dollars in help for a lot of people who are struggling right now because of input from all parts of the political spectrum.

**JACKIE JUDD:** When Medicare Reform was passed, I think that many people presumed that getting people involved would be the easy part, and it hasn't been. I think the goal is 7.5 million people enrolled by the end of this year. You're slightly over half there.

**MARK McCLELLAN:** We're over 4.5 million at this point.

**JACKIE JUDD:** But does it alarm you that it's been much

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more difficult than you expected?

**MARK McCLELLAN:** That depends on whose expectations we're talking about. When we were putting together our outreach plan for the Drug Card, we went back and looked closely at how outreach had worked, and how enrollments had worked for a number of previous health programs, new federal initiatives, like the Children's Health Insurance Plan, or the Medicare savings programs that limited Medicaid benefits to beneficiaries who don't qualify for full Medicaid but have limited income in getting premium help and things like that, and what had been done, what had worked and what had not worked to get those programs off the ground. It was surprising for me when we first started looking at it how long it takes to get any new program launched. For example, the CHIP program, Children's Health Insurance Program, great program, now covering close to six million kids after it's been in place since 1997, in its first year had less than two million enrollees, even though this is a very heavily subsidized health insurance program for low-income children. It took a long time to get up. For the Medicaid savings plans, most of those plans even today, decades plus after their enactment, are still only reaching about half of the people who are eligible for it. So this outreach issue is a huge deal. These are programs that are either heavily subsidized or free, and many beneficiaries who need the most help still aren't taking full advantage of it. That's what led us to do a much more aggressive approach in working with community organizations, in working with expanding our funding for the so-

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called States Health Insurance Assistance Programs, either state level, state government run programs that can provide face-to-face on the ground help in each and every county around the country, to get face-to-face help and inform people about it. That's why we're working a lot more with community organizations, faith-based organizations, trusted members of the community that can get the facts out, not only about the Drug Card program, not only the new drug benefits, but also many of the existing programs that many people aren't taking advantage of. Talking with Jim Farman, who is the head of the Access to Benefits Coalition, he likes to stress that finding help for low-income beneficiaries to them, at least, often feels like finding a needle in a haystack. They have to go through a lot of paperwork—they may not have a good source of information—and what we need to be doing in the federal government is putting a bunch of these needles together, making it easier for people to go to one place, or to one trusted person in their community to get help, and make it easy to sign up for a lot of these important new benefits. I think we're changing the way that we're doing a lot of the outreach for these important federal benefit programs because it is so important and so challenging to educate people and help them take the steps necessary to get help from these kinds of initiatives.

**JACKIE JUDD:** Well, what number do you expect to be at by the end of this year?

**MARK McCLELLAN:** We expect to be—we're still getting 10,000-plus people a day signing up on their own, and at this point

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it's a lot of word-of-mouth. People using the cards, getting a lot of savings on their drugs, telling their friends about it, hearing about it from their pharmacist, things like that. So that's going to continue, plus the 1.8 million whose enrollment is now automatic. With the cards that are being mailed out they just need to make a phone call and answer two questions, and they can start getting thousands in savings too. We expect to be up towards that seven million target number.

**JACKIE JUDD:** Up towards, but not quite at?

**MARK McCLELLAN:** Maybe at. I don't know. We're getting a lot of outside help now in getting these benefits out. The Access to Benefits Coalition has set as their goal getting 5.5 million low-income beneficiaries enrolled in the drug card program by next year. We're working very closely with them to make sure all the low-income beneficiaries who can get full advantage of this program, plus there are millions of higher-income beneficiaries who don't have good drug coverage now who are signing up too, so I think we could well be in the seven million range. Our goal is really, Jackie, to get as many people signed up for this program who can actually benefit from it, and that's why our focus is on getting as many of these outreach efforts and new and innovative approaches of outreach going.

**JACKIE JUDD:** How daunting a task is it going to be to get the six million people on Medicaid switched over to Medicare in a very finite period of time?

**MARK McCLELLAN:** It is one of many big challenges. Drew put

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up that long list of deadlines that we need to meet, and some of the key ones on that list, but by no means all, relate to making sure that low-income beneficiaries get this full and comprehensive drug benefit that's going to cover 95 percent or more of their drug costs starting in 2006. We are not waiting until November of 2005 to sign them up. We've already been working very closely with the Social Security Administration, who for the first time are going to be really doing some active help in enrolling people in a very simple process and getting into this program. We're already doing outreach. The same methods and the same organizations that we're using to let low income beneficiaries know about the Drug Card, we're also letting them know that this new drug benefit is coming in 2006, and the Drug Card has actually been very helpful in helping us identify and get in touch with a lot of low-income beneficiaries that previously haven't had a whole lot of contact with the Medicare program. So that's all in place. We're going to be sending out some additional mailings and some additional contacts next Spring, and our goal is to get a lot of these people, if not most of them, identified and sort of pre-enrolled by next Summer to early Fall so that all we need to do later next year is help them choose a plan or help them facilitate their enrollment in a plan very much as we're doing for the Drug Card. This is an effort that's involving Social Security, states, the same kind of community organizations that have been helping us a lot with the Drug Card.

**JACKIE JUDD:** I want to ask you one more question before I

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open it up to the audience. I'm switching gears here a little bit, but there was one quote I read from you that intrigued me, and I want to know how you apply it now at CMS. It's something you said when you were the FDA Commissioner. "One of the things I've noticed since coming into this job at the FDA is that no matter what I do, I'm going to be criticized, and that frees me up to focus on what I think is right." Is it true? What do you mean? And how does that affect what you [inaudible]?

**MARK McCLELLAN:** What I've found, and you have to do some homework, but if there's a good policy rationale for what you're undertaking, whether it's based on—at FDA it's usually the medical science, or the food science, or the safety issues. At CMS often coverage issues relate to the underlying science, but a lot of our other actions relate to evidence on what kinds of quality improvement programs work, what kind of Medicaid performance [inaudible] work, things like that—That's still absolutely true, and again, I think there's a lot of politics on the surface, but people want to listen and they want to focus on what is actually going to make our healthcare system work better, and if you keep coming back to that in your decisions, everybody might not agree with you—people have strong views about the best future for our healthcare system, and not everybody agrees on that, but—for particular decisions if you focus on the evidence and a good policy rationale for what you're doing, even now, right before an election, it still makes a lot of sense.

**JACKIE JUDD:** Okay, with that we're going to open it up to

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the audience. We do a little move here. It's "Inside the Actors' Studio" moment. We're going to ask you to join us up here. Bring the stool around, and take some questions from our audience. We also had asked our webcasting audience to e-mail in some questions, so I'll start with one of those and—

**MARK McCLELLAN:** So I sit and you stand?

**JACKIE JUDD:** You sit and I stand. You do all the talking. We had one question coming in earlier today about the uninsured, which is a huge issue here. The US is almost 45 million Americans who do not have health insurance or coverage. Do you ever see a universal healthcare in America, and what are the major barriers?

**MARK McCLELLAN:** I think there are different views about how we can get to higher levels of coverage. Certainly President Bush, and the Democrats as well have different kinds of proposals for getting a much broader coverage. So I think what they all have in common is they don't view our healthcare system as one that can be solved with a one-size-fits-all approach. The different approaches out there focus on expanding and strengthening the programs that are working now. For example, we've proposed some additional funding for SCHIP. We've also proposed some new steps for more affordable coverage through employers through a combination of tax credits for smaller employers and programs like health savings accounts for larger employers whose employees are facing higher out-of-pocket costs. I think that one thing that we need to focus on in dealing with the problem of the uninsured is while there are different

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segments, different programs—Medicare, Medicaid and SCHIP, employer coverage, other privately purchased coverage—we need to focus on ways of getting the overall costs of this kind of coverage down. There are a lot of people today, for example in small businesses that may be shifting from job to job, may be part-time, and may not be being offered employer coverage, and they have no place to go except an individual insurance market that may not offer them very good prices. That's why the President supported purchasing groups that help people band together and get a better range of healthcare options, and why he supported association health plans. Other steps that we can take to lower costs and make health insurance much more affordable include things like liability reform, quality improvement, some of the techniques and approaches that we've just been talking about as well as steps like better health information systems to prevent errors and help people get the right care, and get information about cheaper care the first time. One thing that we announce, and you showed it in the video, just a few weeks ago this new website on Medicare at [medicare.gov](http://medicare.gov) that lets people know about lower cost versions of their drug, generic versions of their drug. For many of the most commonly used medicines in this country, there are a lot of drugs out there that work in quite similar ways, and you need to talk to your doctor about it. A lot of people don't even know that for a cholesterol medicine, there are a number available that cost 20, 30, 40 dollars a month less than the prescription they're taking now, and in most people, can provide the same kind of benefits in terms of reducing

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cholesterol levels and reducing risk for heart attack. We can have a lot more discussions about that and a lot more help for patients so they can find a lot less expensive ways to get their care. The solution to our healthcare problem—there's a ton of money in our system now—we need to find much better ways to use it, not just put in more and more funding.

**JACKIE JUDD:** Yes, the question over there. If you could identify yourself—we have a special guest here today—and your affiliation.

**ALLEN ROSENFELD:** Allen Rosenfield. I'm Dean of the [inaudible] School of Public Health at Columbia University. It's nice to see you. Just two quick questions. One, as the now manager of Medicare, would you like to comment on why we could not in this country move to Medicare for all as a solution to the problem of the uninsured? And secondly, within the Medicare law, which obviously you didn't pass, the stipulation is that you are not allowed to negotiate with drug companies on the price of drugs seemed to me to have been a most inappropriate stipulation. We should be able [inaudible] negotiate pricing for drugs that don't have a generic substitute, and I wonder if you'd comment on that?

**MARK McCLELLAN:** Let me take the second one first, because I can go to talk about Medicare more broadly. As I just said, we have got to find ways to get our costs down safely, and price negotiation for drugs is an absolutely critical part of that. We need people banding together and negotiating lower prices for the drugs they

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need. At the same time, we don't want to sacrifice quality when we're doing that, so when we were designing our implementation of the new Medicare law, we looked at what would be the most effective way to get prices down. In our proposed regulation we have a lot of discussion about this issue. In fact, we're seeking comments on what is the maximum stuff we can take to get lower drug prices. And in our analysis--this includes input from independent actuaries--our conclusion is that the approach we're taking, we get prices that are as low if not lower than direct government negotiation, as well as get people a broader range of choices or formularies and coverage that will help them get their drug needs met at a lower cost. There are tons of negotiations for prices that will go on in the Medicare drug benefit. It will happen the way it happens now for most Americans, and that's through prescription benefit managers that have strong incentives, strong economic pressures to get low costs. That's why we're projecting savings of up to 23 percent per person in the Medicare drug benefit from this price negotiation, millions of people banding together just as they do now with private coverage, and they're going to have an opportunity to choose a formulary to get the coverage that they need. Medicare has had some experience through price regulation approaches to drugs. In fact, one of the other sensitive issues that I'm dealing with right now has to do with the prices that we pay for the drugs that fall under Part B of Medicare. These are drugs administered in physicians' offices, and the prices that we're paying right now are far above the best competitive prices

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that PBMs and other competitive organizations are able to get for those drugs. So our track record on this has not been terrific, and I'd much rather see a system in place that can drive prices down right away. And it also gives beneficiaries confidence that they're going to be able to get the drugs that they need. They're not going to be stuck in a one-size-fits-all government formulary. We want comments on this, though. We're looking for other ways to get prices down even more, but according to our analysis, also according to the Congressional Budget Office, this is the best way to get the maximum savings on drug prices while still providing high-quality access to pharmaceuticals.

The broader issue of Medicare for all—there are proposals out there for that. I think, frankly, it's better for people under 65 to build on the employer coverage, the other types of private coverage that are available now that are providing access to innovative services through a broader range of treatments that haven't been covered in Medicare. Remember that until this bill, Medicare didn't provide for a full range of preventive benefits that the recommendations of the US Preventive Services task force. As a doctor, I'd be telling my patients that they should be getting cholesterol screening and Medicare didn't cover it at all. Disease-management programs haven't been in Medicare. We're catching up with that in our fee-for-service program. All those services are going to be available starting in 2006 and beyond—2005 for the preventive benefits—but we're doing a lot of work now just to bring Medicare up

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to date for the people it was intended to cover, for the promise that we made to seniors and people with disabilities. Keeping that promise is going to be pretty tough in the years ahead as we face the baby boom and as costs keep rising. So, I want to make sure that we keep Medicare secure for the people for whom the entitlement was intended first, while we're taking other steps to improve coverage for everyone else. But we'll keep working on this. As Medicare gets more and more up to date, I'm sure this will continue to be a topic of debate. Good question.

**JACKIE JUDD:** If prices don't go down as you expect, would you be open to reconsidering—

**MARK McCLELLAN:** I think these people are going to be paying an awful lot of attention continuously to what kind of prices we're actually getting for drugs in the Medicare program. What's happened with the Drug Card program where there have been a lot of studies done to see just what kind of discounts are there, and there are actual discounts, including a Kaiser study, which found, mostly on brand name drugs, 20 percent or more price savings on retail pharmacies. People are going to be paying a lot of attention to this, and we're going to make it easy to happen. One of the things that's new with the Drug Card and we're going to continue with the drug benefit is making price information transparent. Until now, you probably had no idea what your drugs cost. Your insurance plan paid part of it, maybe the PBM kicked in something. It was very hard to sort out what the drug actually cost. Now with Medicare, for every

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prescription drug that's marketed in the United States, at every pharmacy that's participating in our Drug Card program, and subsequently in the drug benefit, we're going to have that pricing information available so that they can see exactly how well we're doing. I think that's going to promote more price competition to get the prices down, too.

**JACKIE JUDD:** A question up here, if you could just wait for the microphone that's coming your way. Over here. The lady in front.

**JUDY WAXMAN:** Hi. I'm Judy Waxman, National Women's Law Center. Thank you for being here.

**MARK McCLELLAN:** Glad to be here.

**JUDY WAXMAN:** I have a Medicaid question, and that is, the Governor of Tennessee has recently announced that he is applying on behalf of the state for a major proposal to change their Medicaid program. In the Tennessee paper in which this was announced, the CMS spokesperson was quoted as saying, "Oh, we've been talking with the Governor for some time, and it's very close to approval." One of the pieces of that proposal is to ask for a pre-approval to virtually change the state program anyway that the Governor would see fit in the future, whether it affects kids, people with disabilities, seniors' benefits, whatever. And so my question to you really is, do you think that's a good idea, to give a governor pre-approval to change the program anyway he or she sees fit?

**MARK McCLELLAN:** Good question, and being that the first

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part of your statement we just recently got this 1115 waiver proposal in from the Governor. He's been through an extensive process in the state, trying to bring both parties together, Republicans and Democrats through the public process behind the proposal. But it did just get to us recently, and I wouldn't say a decision from us is imminent. We're having a lot of discussions with the state now to clarify some of the details of the proposal and answer questions and things like that. That's kind of where we are on the overall proposal. I'm not going to prejudge, hypothetical, what our decision would be, but I can tell you, if you look back at recent cases where states have come in and asked for basically pre-approval for changing coverage or limiting coverage for things like that—just as a proposal from Washington State, for example—we did not approve that. States have had—I can't think of any exceptions—the states have to come in and check with us first before making any changes in coverage. That's kind of where that stands.

**JUDY WAXMAN:** Thank you.

**JACKIE JUDD:** Over here.

**JONATHAN COHEN:** Hi. I'm Jonathan Cohen from the New Republic. My question is, back when they were debating the Medicare law, one of the findings that the Medicare Payment Advisory Committee came out with was you adjust for the health of the beneficiary. We were already overpaying private plans in the Medicare system. The new law actually pays them even more money on top of that through extra subsidies. I think the question a lot of critics have is, if it's

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costing that much more just to get these plans to stay in, wouldn't it be a better use of that money to offer a more rich drug benefit, or not hit beneficiaries with a 17 percent [inaudible] hike? What is the argument for using that money? If the private plans need that much of an incentive just to stay in, are they really more efficient?

**MARK McCLELLAN:** Let me tell you about the private plan part of this Medicare Advantage part. I just want to come back to the premiums and talk about that to. I've seen some of the premiums on the Medpacs, something like that—

**JACKIE JUDD:** GAO just came out with a report—

**MARK McCLELLAN:** —difference in costs. That's actually a little bit different topic. We can talk about that one, too. The main thing that I think we need to think about for our healthcare system is not, can we save the government money by shifting costs to beneficiaries, or doing something that just keeps government costs a little bit lower. The main thing that we ought to be focused on is how we get the most efficient healthcare system possible. In my view, coming at this from medical practice, an essential part of an efficient healthcare system, that gets the most of the money that we spend, that avoids unnecessary costs are things like, a strong emphasis on preventive care, a strong emphasis on managing diseases, a strong emphasis on coordination of care, and the fact is that the private plans in Medicare are doing a far better job of that. They are able to offer many more benefits than are provided in the traditional Medicare plan for what they get paid, and they're also

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able to buy down cost-sharing, reduce premiums for people in the Medicare Advantage plans. If you look at the people who most benefit from Medicare Advantage being available, people who have limited incomes but not low-enough to qualify for full Medicaid—so they're stuck with paying a lot of costs out-of-pocket on a fixed Social Security check, and they don't have the luxury of some generous wrap-around employer coverage—that's what you have, and we're taking steps to strengthen that, too. But most beneficiaries today don't have that, and we can't count on it. So, for people who are stuck, either paying all of Medicare's co-pays and deductibles and filling in the coverage gaps of their own, or filling in a Medigap premium that in many parts of the country—in New York recently, hearing from a couple that's paying \$350 a month for their Medigap that's going up to \$400 a month, they're looking into a Medicare Advantage plan potentially is a much less costly way to get the healthcare they need. It's a lifesaver. If you look at the numbers, the out-of-pocket costs for beneficiaries in Medicare Advantage plans average more than \$700 less per year. If you think about what we ought to be focusing on, which is total costs adjusted for health status. Actual difference is something like \$50 a month lower in costs for Medicare covered services, another close to \$30 a month lower in costs for services that Medicare doesn't cover—dental, drugs, eyeglasses, wellness programs, things like that—that really adds up, and we need to find solutions for health problems that don't just shift the costs back to the beneficiaries. The fact is, the fee-for-service has a lot going

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for it. It's a program that many people depend on, but it has fallen behind. When it comes to coordinated care, people on the program have not had access to disease management services, nor to preventive benefits, and their healthcare costs are higher as a result. We'll keep working to strengthen fee-for-service, but right now Medicare Advantage is a tremendous help for people with limited means. And that shows up in who actually signs up for Medicare Advantage. The enrollment in Medicare Advantage plans is disproportionately people with incomes below \$30,000, in many cases incomes of \$15,000 or less, living on the Social Security check only, because they can save a lot of money that way. It's the only affordable option they have for their healthcare, and I don't want to take that away.

**JACKIE JUDD:** You had your follow-up. Up here in the front row.

**MARY AGNES KERRY:** Hi. I'm Mary Agnes Kerry with Congressional Quarterly Health Beat. The Administration is planning to spend about a billion dollars on new outreach programs for SCHIP, the States' Children's Health Insurance Program. Why would your programs be more effective than the ones currently out there?

**MARK McCLELLAN:** I'm glad you asked about that, because that's something that's a good example of what we were talking about, the politics a minute ago. Again, beneath the surface, there's still a lot of discussions going on, bipartisan discussions about how we can improve our health programs, and SCHIP is a critical area for that. Now, just to clarify what the Administration has proposed, what

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we'd like to see with some of the additional money available in SCHIP is that it actually go to increasing coverage for children. Right now, there are a lot of SCHIP unspent funds available, all together about \$10 billion. We're projecting to distribute another \$600 million-plus at the end of this year. Out of that \$600 million, we will do it in a way that makes sure that no state faces any shortfall. In addition to that, there's a 1.1 billion of funds that scheduled to expire and revert back to the Treasury and not be used. With \$10 billion in the bank, with the maximum projections about costs of continuing coverage for kids in SCHIP programs now far short of that—5 billion or so left over—we think it would be a good idea to try to make a push to use more of this money to get more eligible kids enrolled in the program. There are more than a million kids who are currently eligible for SCHIP who are not signed up, and who are not getting coverage today. We need to do something about that. The present proposal, and the kind of framework that we like to work with Congress on implementing would put some additional money into outreach efforts—and there are some successful examples of outreach efforts already—and would also put some additional funding into performance grants for states, which would be a new thing for SCHIP, where the states would be reimbursed, made whole for any increase in costs that they might incur from more kids signing up. That's what's making some of the states nervous, I think, about making more of an outreach with CHIP right now. So it's not only outreach programs that are effective. In the states we have to adopt proven effective

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outreach approaches to do this, but it's also additional funding for the additional kids who actually get enrolled in the program. So right now, we're having a lot of discussions with people in both parties about how we can work together to get more kids covered in SCHIP, which is something that we really need to do. Extending the funds is a nice idea, but it would be really nice to actually get more coverage as a result.

**JACKIE JUDD:** Mark, we have a question over on this end.

**GREG SMILEY:** Hi. My name's Greg Smiley, and I do federal affairs with the American Academy of HIV Medicine. We're one of a number of organizations that are concerned about the implementation of prescription drug benefit, and what it would do for our patients, specifically. There are tons of questions, but in talking about the formularies, it looks like some classes will be restricted to two drugs per class. When you're talking about a patient population where they need all of the available antiretrovirals and other medications approved by the FDA because they're not so interchangeable, or because of toxicities or resistance build-up and so forth, there's potentially a threat to their health that has such a restrictive formulary. What can you say to people who might need some ease, that the special population—I'm sure there are tons of other people that might need more of an open formulary.

**MARK McCLELLAN:** Craig, that's a good question. I've been talking to a lot of groups that share that concern. I want to start out by saying that I'm not working in this job as hard as I am, and

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spend all this effort to get here, and I know my staff is not working nights and weekends to end up with a drug benefit that doesn't actually provide access to the medicines that people need. We are going to make sure that people get the treatments that they need, and we're going to do it at the best prices possible. What we're getting comments on right now is exactly the best way to do that. Those comments are coming in a number of ways. We've got the comment deadline for our proposed regulations, yeah, next week. Hope you've been writing. We're going to also issue a guidance a little bit later this year, a proposed guidance for a framework that we're going to use to oversee the prescription drug plan. I think one reason this has come to a head a little bit more, a little bit sooner than I would have expected, given all the steps that we're taking to get effective protections in place is the USP proposal for a formulary classification system, which is something, to remind you, that was included in [inaudible] to ask the United States pharmacopoeia to come up with a model system for drug classes. But the statute recognizes that that's only one element of determining whether or not a drug benefit is providing access to necessary medicines at an affordable price. Formulary classes are one thing, but also what matters is what drugs are actually included in the formulary, and what the prices of those drugs are. You could have a very detailed set of formulary classes—400 or 500, whatever—but if all the drugs that are included are third-tier prices, it's not going to provide very good access to medicines. Similarly, prior authorization

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requirements, utilization review management techniques—even if you got a very detailed classification system that can still get in the way of people getting access to necessary medicines. In our regulation of the drug benefit, we are taking a holistic look at all of these elements. The draft framework that we'll put out, we'll be asking for comments about classification, which USP is doing the model system for, but also about tiering in formularies, prior authorization in formularies, and populating the formularies, as well as other issues like how the PNT committees, the Pharmacy and Therapeutics Committees work, making sure that they're independent and that they follow the best practices, having a good influence on the coverage decisions, and also the acceptance and appeals processes, to make sure that those work in an orderly way, to make sure that people get access to necessary treatments. The law is very clear on this. It says that medically necessary treatments will be covered, and it also says that the drug benefit cannot discriminate against any type of beneficiaries. We make very clear in our regulations that we've interpreted that to mean based on your disease status. If you're a patient who needs AIDS drugs or other costly medicines, it cannot discriminate against you. It must provide you, just as everybody else, access to medically necessary treatments. But we do want to do this in a way that enables the best possible prices, enables that kind of negotiation that we were talking about to take place. It's gotta provide access to the necessary medicines, though.

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So, we're looking forward to the comments that we get on our proposed regulations. We'll be looking for the next round of comments that we get on our proposed guidance, and when the final regulations come out along with our guidance to our drug benefit providers early next year, we expect to have a strong set of protections in place, a strong set of ground rules to make sure that the drug benefits are competing, are getting those high quality drugs at the lowest prices, not based on discriminating against particular types of beneficiaries who happen to need some expensive drugs.

**JACKIE JUDD:** We have time for one more short audience question and answer. Back here.

**BOB:** Advancing Independence, Mark as you know, about the third of those with Medicare coverage and disabilities and chronic conditions, the large percentage of those individuals [inaudible] age 85 and older, another six million went on Medicare after they became disabled while working. The majority are very poor, must also live in our communities, not in institutions, and as you know well, most take not just one or two prescription drugs, but five or more drugs daily. Coordinated care is [inaudible]. My question of you is this: Many of us have deep concerns about how this will all play out for these folks. What are your top three or four concerns in this regard?

**MARK McCLELLAN:** Very good question, Bob, and you stated the question very well. We have to focus in this drug benefit on a very large population of people who need multiple medications, whose frailty or other conditions may make it hard to get those medicines

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and follow a complex set of treatment regimens. We need to reach out to them and make sure they're taking full advantage of these benefits. There are a whole set of issues that come up in dealing with this. One set of issues relates to outreach and education, and empowerment, to make sure that all these beneficiaries know what they can get and take full advantage of it. It's especially true for our many disabled beneficiaries, and our oldest old beneficiaries who have very limited incomes, who are just trying to get by on Social Security, and not much, at that. Those beneficiaries are generally going to qualify for a comprehensive drug benefit, one that will cover 95-plus percent of their drug costs, but we need to get them enrolled. That's why a big part of our efforts right now are focusing on outreach through Social Security, through collaboration with the states to transition their Medicaid beneficiaries over to this program, and through other creative steps like auto-enrollment or facilitated enrollment processes that we're working out right now with the Drug Cards, and also through collaboration with a lot of outside organizations, including yours to help make sure we get the word out effectively, and people have straight forwards steps they can take to take advantage of the new system.

A second set of issues relates to non-discrimination in the drug benefit. As I just answered in the previous question, a major focus of our efforts in the proposed regulations, and when we go to the final regulations, we're going to review all the comments that we have through a very public process just to make sure that we have a

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comprehensive, effective oversight mechanism in place that will on the one hand give people access to the medicines that they need—even if it's multiple medicines, even if it's costly medicines—on the other hand provides the maximum opportunities possible to drive prices down, to negotiate lower prices.

So that's the second big area, and the third is, as we talk a lot in the regulation, coordination of care is really important. We have a lot of discussion in the regulation about medication management therapy programs, something we've been working with a lot of pharmacy groups to try to put in place as part of the drug benefit. Beyond that, as I mentioned earlier, we're trying to do a lot of care coordination more broadly in the traditional Medicare program. There's one area where traditional Medicare is way behind the times. The people in this country who have the most to gain from disease management services and care coordination have had the least access to it because financial incentives just aren't there, just to come back full circle to where we started. We're changing that with the Chronic Care Improvement Pilot programs which we're going to take national as soon as we can. Those are population-based programs, so they cannot survive, they will not get paid unless they improve outcomes and reduce costs for all of our Medicare beneficiaries, which for people with multiple chronic diseases, particularly including the oldest old, and particularly including the disabled beneficiaries. They will not be left behind in this process. They will only get paid, they will only succeed and only continue in

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Medicare if they're serving the full population.

Those are some examples. There are many other issues that come up with this. This is where the money is. This is where our obligation to the public is strongest, and this is where we can make the most difference in the public health. That's why we're paying so much attention to it.

**JACKIE JUDD:** I have one final question that you can answer with a yes or no. It's not about baseball. If there is a second Bush term, do you want to be the Secretary of HHS?

**MARK McCLELLAN:** Can we go back to baseball? Actually all those deadlines that you put up there, I am really focused Jackie, on making this program work, so-

**JACKIE JUDD:** It's not a yes or no, but I'll let you go with that. Thank you so much, very, very much.

**MARK McCLELLAN:** Thank you very much. It's been a pleasure being here with all of you. Thank you.

**JACKIE JUDD:** We appreciate all the time you gave, in this especially busy time for you. We hope you will come back, in whatever capacity that may be.

**MARK McCLELLAN:** Well, I'd be delighted to come back. I appreciate the tough questions, and this kind of dialog is important to help make sure that we get it right. I want to thank all of you for the comments that you've given us on all these really important programs that we're implementing now, and looking forward, we're going to need a lot more public input on the regulations, on the

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guidances that we're putting out, on every step along the way to make sure we get the most benefits to people on Medicare, Medicaid and SCHIP. So thank you for your constructive help on all of this.

**JACKIE JUDD:** Thank you all here and on our webcast, and we hope you join us again for our next Kaiser Conversation on Health. Thanks.

[END RECORDING]