AMERICAN HEALTH QUALITY ASSOCIATION

KEYNOTE ADDRESS

SPEAKER:
DR. MARK MCCLELLAN

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MR. : Now Dr. McClellan has arrived so I would like to introduce the president of the American Health Quality Association and the American Health Quality Foundation, Dr. Dale Bratzler, who is the principle clinical coordinator at the Oklahoma Foundation for Medical Quality.

DR. DALE BRATZLER: Good morning. Thank you, David. On behalf of the board of directors and the membership of the American Health Quality Association, I too would like to welcome all of you to this meeting, and it's really my pleasure this morning to get us started by introducing our first keynote speaker this morning, Dr. Mark McClellan.

Dr. McClellan was just sworn in as the CMS administrator on March 25th of this year after he left the position of commissioner of the Food and Drug Administration where he had been in that service since November of 2002. Previously he had been associate professor of economics at Stanford University and an associate professor of medicine at the Stanford Medical School, a practicing internist, and an active researcher. He's been a research associate with the National Bureau of Economic Research and visiting scholar to the American Enterprise Institute, a member of the National Cancer Policy Board and the National Academy of Sciences, and the list goes on.

Dr. McClellan served in the White House from 2001 to 2002 as a member of the President's Council on Economic Advisors and has served as a senior policy director for health care and related economic issues for the White House. His research studies have addressed measuring and improving the quality of health care, something I think all of us here today are quite interested in. He's done a number of research studies on estimating the effects of medical treatments, technological change in health care, and other issues related to health care quality.

He's twice received the Arrow Award for outstanding research in health economics. He has an extensive training background that includes an M.D. degree from the Harvard MIT division of health sciences and technology, and Ph.D. in economics from MIT. He completed his training in internal medicine at Brigham and Women's Hospital and is board certified in internal medicine. And I believe perhaps this is the first time that Dr. McClellan has got to speak to the QIO community, at least as a group, and on behalf of the American Health Quality Association I want him to know that we really sincerely look forward to working with you closely to improve the quality of health care for America's seniors.

Please join me in welcoming Dr. Mark McClellan.

(Applause.)

DR. MARK MCCLELLAN: Thank you very much for that kind introduction, and it is a real pleasure to be here. You know, I've been in this job for a little bit over a month but my interactions with the QIOs go way back. David Schulke and I used to spend a fair amount of time talking together when I was working in the White House and helping to coordinate some of the administration's healthcare policies, and from that time, and actually previously in my academic career in working on quality issues, I've had a great appreciation for what formerly the pros did and what you all are doing now as QIO.

So it's a special privilege to be able to be here so soon after I started in this job, and also it's such an important time for the QIOs. I said in a lot of my speeches how challenging of a time we face in Medicare and our healthcare system overall today. On the one hand there are more and better medical treatments around than ever before. On the other hand, people are more worried than ever about whether they're actually going to benefit from them because of the problems of the affordability of health care. As costs keep rising people worry that they may not be able to afford it. And every time we'd look we'd see lots of examples of ways in which we could get more out of our healthcare spending.

I think the good news is that thanks to new legislation passed by Congress, and also thanks to ideas that have been developed and in many cases implemented in programs that you all are involved with, we've got better opportunities now than ever before to find ways to get more for what we're spending in health care, and to encourage innovation while at the same time assuring the affordability and the quality of health care as well.

I've had a chance over the last few weeks to get to know the CMS staff and get to appreciate some of their views about most useful and most promising approaches to achieve this goal, health care that's both innovative and affordable, and recurring in those conversations with our staff is the importance of what the QIOs do. You all are a key part of our overall agenda on improving health care in this country.

In talking with the CMS staff, two things come up more often than any others in terms of what our mission really is about. One of those themes is making sure that our payment systems are not only accurate but create good incentives for improving quality of care, and as the largest healthcare payor in the world with $500 billion of spending that we account for in this year, we make sure we're paying effectively – not just accurately but in a way that promotes higher quality care.

But the second thing that comes up repeatedly in the staff is one that even more directly involves the work that you all do. Our staff strongly believes that we have both opportunities, and really, from a public health standpoint, the obligation to help drive quality improvement and patient safety in the United States. As the largest healthcare payor we've got an opportunity to help move the agenda on quality forward. We have an opportunity not only to look at what's working in our very large healthcare programs involving people who have the most to get out of our healthcare system; we have an obligation, I think, to push that effort along. I'm coming to this job from working at the FDA, which people very clearly regard as a public health agency, an agency that's charged with protecting and advancing the health of Americans.

I think CMS is in exactly the same boat. We have an opportunity in this program as well to fulfill a public health mission. CMS is a public health agency and the QIOs are a critical part of achieving this goal.

As I mentioned, I've had a chance to work with QIOs in the past, both in my work in the White House, and prior to that while I was on the faculty at Stanford and I had an opportunity to work with the California QIO on a number of quality measurement and quality improvement projects. So I know that there is a lot that we can do together to achieve this goal of improving public health in this country.

And I thought I'd spend a few minutes today talking, hopefully a little bit informally, about the big picture, how I've thought about some of these quality issues and how I think we might be able to work together, but I wanted to leave plenty of time for questions and discussions. You are a very informed group. You know a lot more about quality and quality improvement than I do, and I want to make sure that that at this point, this early on in my tenure at the agency, I've heard from you about some of the best ways forward. So if it's okay with you, I'm going to spend a few minutes talking about big picture quality perspectives that I have and then hopefully have some time for discussion after that.

The way that I think about quality and the way I think about improving care really comes down to keeping patients well and healthy. And there are – if you think about healthcare this way you can think of three layers in our healthcare system. Most important, and what ought to be the ultimate focus, is patient's health. We need to keep taking action to keep patients well, to keep them out of the hospital when they're – from potentially severe illnesses; to keep them out of our doctors' offices when they can take steps on their own, and with support from health professionals, to do well in the community. If they do need care we need to get them to the right caregiver promptly and return them to being well and being able to take care of themselves as much as possible.

This is something that affects all of our Medicare beneficiaries, and I'm going to talk more about this in a few minutes, but we are really trying to increase our focus on our ultimate and most important customer at this agency, and this is our beneficiaries in Medicare, our beneficiaries in Medicaid, our beneficiaries in S-CHIP, the total 80 million Americans that depend on us for their health care and that we need to try more than ever to focus on keeping them healthy, and there are more tools that we have available to do that than ever before.

The new Medicare law, in fact, if you think about it, really provides an opportunity to reorient the Medicare program much more to prevention. You all know better than I do that we spend an awful lot of our money and time and resources focusing on care when people get sick and on dealing with complications. Secretary Thompson likes to say that 93 percent of the spending in the Medicare program goes to dealing with complications when they occur. Only a very small fraction goes to prevention. And what I've seen is that there is more science than ever before that we can use to help people stay well, to help them manage their diseases if they have chronic illnesses, to help them stay out of the hospital, and, yeah, with modern technology – telemedicine, email, and things like that -- even out of the doctor's office.

The second layer is primary care. Now, we need to take actions to keep patients who do need care in the primary care setting as best we can to avoid complications and more intensive treatments that hopefully will not be necessary with good care management. And as you know, most of our Medicare beneficiaries have at least one chronic illness; they're on medicines to help prevent those illnesses, and many of them are having difficulty affording those medicines or difficulty getting the care that they need and the support that they need to manage their chronic illnesses effectively, and we're starting new programs now – I'm about to testify this afternoon, in fact, to the Ways and Means Committee on our chronic care improvement pilot program for the traditional Medicare program.

Medicare beneficiaries who you'd think would be the ones who are most likely to benefit from assistance and education about their diseases and managing their diseases are actually the least likely people in this country to have access to disease management and care management services. We're hoping to change that as a result of this large-scale pilot program that we have every intention of extending nationwide to beneficiaries to help them get the assistance they need and help their health care providers get the assistance they need in educating people about their illnesses and following good plans of care that can keep them at the primary care level or out of health care offices altogether.

And of course there are lots of cases when specialty and in-patient, more intensive treatments are needed. In those cases we need to do all we can to create a safe environment and to insure and encourage high quality care to give the doctors and the patients the information they need, not only about the technologies they're using, which in too many cases we just don't have good information on how well they work in the senior population and in people with a number of chronic illnesses, as are common in our Medicaid populations. And we need to give them good information about where they can get the best care so that they can make informed choices about where a major operation should take place or the net benefits of elective surgery and the like.

So I think that in all three of these levels – patient layer, primary care layer, and especially in in-patient layer there are opportunities to improve quality, all with the goal of shifting the focus towards keeping people healthy and out of needing intensive medical interventions as much as possible.

Now, medical innovation is helping with all of this. There are a lot of treatments around that were – that make it possible to turn diseases that used to end up in hospitalizations with terminal illnesses into diseases that people can manage on their own outside of a hospital. You all know better than I do that heart attacks – acute myocardial infarctions – today represent a very different medical prognosis than they did as recently as 20-30 years ago. Back then it was an in-patient condition. It was in-patient supportive care condition. You had your event, you went into the hospital, you got supportive care for a long time, and hopefully, if you were lucky, you lived and you managed to have a little bit more time with the diminished quality of life associated with heart failure. When you have an AMI today you should expect to survive it in perfectly good health. You should expect the AMI to be headed off in process as a result of innovative drugs and other interventions like primary angioplasty.

So what that does is provide innovation that moves care back out of the hospital and gets people to a longer, fuller, more productive life. And there is more medical innovation like that coming along. As I said, though, we need to make sure we're using it as effectively as possible. Where we haven't seen as much innovation as I'd like, though, is in providing the support, the environment for care that goes along with using these technologies as effectively as possible. So I think we can do more to encourage innovation by doing more to use the treatments that come along as effectively as possible to encourage use of underused treatments that add value to reduce the use of unnecessary treatments that don't add value, to reduce the rate of errors and risks -- especially in some of these more intensive sites of care, but they can happen everywhere -- to reduce the mortality and morbidity associated with errors, and as a result of all of these steps to get more value for our healthcare spending.

So we need to encourage innovation but we particularly need to encourage innovation when it comes to delivering modern medical care in an effective and integrated way. There are a variety of tools that you all know about that you all are involved in promoting to help operationalize these goals including strategies like disease management, telemedicine, quality reporting, and so on. What I'd like to focus on is some of the particular approaches that we can take to develop better evidence on when each of these strategies work and to develop better support for encouraging their appropriate use in delivering health care effectively.

And I just want to walk through some of these particular areas where I'm spending a lot of time in the agency trying to promote some new approaches. And as I said before, thanks to new laws that have been passed, thanks to better evidence out there, in part due to your work we've got a clear – we've got clear opportunities to move forward in all of these areas than ever before. One way to – or some of the best ways to encourage these improvements in care involve a combination of better incentives and better support to create a better environment for medical practice.

So, just to begin with and in no particular order, some of the big quality improvement activities that we're focusing on are first public information, getting better information to patients about how they can get the most bang for their buck, the highest quality care. You all have been involved in some recent activities in CMS to promote the development of better quality measures in a broad range of settings of care: hospitals, nursing homes, home health facilities, and so forth. These activities, I think, get a lot of attention. For example, the nursing home section of the Medicare compare website –

which provided quality measures and other information on nursing home options available to beneficiaries – up until last week when the drug cards went up was the most popular part of our website on quality measures. Lots of people using this information to try to think about their options for long-term care support. I want to continue to expand the use of these measures to develop, to identify valid measures, to develop them, to encourage their widespread use.

Going along with this are a number of other types of initiatives. Another type of initiative is providing financial incentives to patients, giving them opportunities for saving when they take steps to improve their health and choose more effective care. One approach to doing this is the Medicare Advantage Program that was created by the new Medicare Modernization Act. This includes the private health insurance plans that until recently were known as Medicare Plus Choice plans. If you think about the way that the payments and the competitive structure for these plans have been set up, they're designed to offer – now to offer beneficiaries the opportunity of getting lower co-payments, lower premiums when they choose these plans.

We made an announcement yesterday about the payments for the Medicare Advantage plan for next year and a lot of people have focused on the payments that the government is making. Again, I want to go back to what I stressed at the beginning, which is how do we get an overall efficient and effective healthcare system. If you look at the plans that people sign up for today, the Medicare Advantage plans, and compare them to Medicare fee for service, there are huge differences in the out of pocket costs that patients pay. If you're in a Medicare Advantage plan today according to some of the most recent studies – which we reviewed yesterday in this new report that's up on our Medicare website and I encourage you to take a look at it if you're interested in this area – the out of pocket cost for people in private plans average about 35 to 41 percent lower than the total out of pocket cost in traditional Medicare fee for service plans for beneficiaries that don't have comprehensive employer Medigap plans which are decreasingly available today, as you know.

The reason for these lower out of pocket payments are twofold. First, Medicare Advantage plans are able to offer lower co-payments, lower deductibles than Medicare for many of their services. And second, if you're in a Medicare Advantage plan you generally don't need to buy a Medigap supplemental policy to fill in the gaps. The most popular Medigap policy today is Plan F, and if you compare beneficiaries in Medicare Advantage to beneficiaries with Medicare Plan F, on average the out of pocket spending is $800 less and that's counting the Medigap premiums. It's $800 less in Medicare Advantage than in Medicare Plan F. And so not surprisingly with these kinds of big, and I'd add, growing differences in out of pocket costs, more Medicare beneficiaries, especially with limited incomes, are starting to sign up for the Medicare Advantage plans.

We need to give beneficiaries affordable options like this, not just give them a choice in a plan that might save the government a little bit of money but does so at the expense of shifting a lot of cost to beneficiaries because they're getting less coordinated care and facing a higher out of pocket cost prospect as a result. And if you look at overall healthcare spending – which again is the thing that we ought to care most about if we're really worried about an efficient healthcare system – adding up what the beneficiaries pay and what the government pays to get total cost, the Medicare Advantage plans do better. They do better in coordinating care. Now, that's not to say that we can't have coordinate care in Medicare fee for service. And I talked a minute ago about our chronic care improvement program which is designed to do just that, to create financial incentives and other incentives to get costs down in the traditional Medicare program as well.

And third we need to provide more help to beneficiaries and we are seeing this right now in the Medicare drug card program. A lot of people made a big deal out of the fact that there's an awful lot of information out there for beneficiaries to sort through and that's absolutely the case. Today there are more medicines on the market. We've got a total of about 60,000 different drug products. There are more options available for where you can get these medicines, a total of somewhere on the order of 50,000 neighborhood pharmacies, grocery store pharmacies, chain pharmacies, mail order pharmacies, Internet pharmacies and the like. And that is an awful lot of information for people to sort through to find the best ways to meet their medical needs, their drug costs at – their drug needs at the lowest possible cost.

To help them through that we have set up an unprecedented program through our website but also available through 1-800-MEDICARE where there's an awful lot of complicated information that goes in. Our job is to help individual beneficiaries figure out how they can get the most savings and the most benefit without exerting a whole lot of effort. And so when you call us up to find out about the drug card we ask for just a few specific items of information: your zip code so we know which pharmacies are in your neighborhood and – or maybe most important for your savings; the drugs that you're on and their dosages so we know which cards to focus on in terms of getting lower prices; and your income, if you've got limited income and might qualify for the $600 in direct financial assistance that's now available through the drug card, and that people have low incomes really should be running to sign up for. They get not only the $600 credit but we've negotiated wraparound low prices, basically $5 a prescription, from many of the major drug manufacturers.

So your income – if you think you may qualify for some of these programs – we'll also hook you up with state programs and other manufacturer programs. And if there are a few specific things that you care about in the way that you get your medicines: if there's a specific pharmacy that you like, if you're interested in cards that have low fees or zero fees – there are a lot of drug cards out there now that cost nothing at all – if you've heard about a particular card – you want the pharmacy card or the AARP card or something like that.

Well, you just give us those limited number of pieces of information and Medicare will send you a personalized brochure about what the drug card means for you. It'll tell you specifically about the programs that you qualify for. It'll tell you not only a list of the cards in your area but detailed information on the three or four or five, your choice, cards that offer the best deal for your particular medical needs. And we've got a simply two page enrollment form to use to sign up for the card.

So, what we're trying to do with this effort and we've – there's still some bumps in the road and we want to take further steps to make our price compare program more even better. We've got constructive suggestions from beneficiary advocates and from many beneficiaries themselves on how to do that and our 800 number, to make that work better as well. But what we are trying to do is to take everything out there offered by Medicare, take everything out there that's in our healthcare system and turn it into the specific facts and specific support that individual patients need to get the most out of our modern healthcare system.

And this is a fundamental change in the Medicare program. This is something that we're not – a lot of people are saying well, it's associated with the drug, card it's going to go away. No, that's not true. We have gone from about 400 customer service representatives at our 800 number to, by the end of this week we'll have close to 1,800, a four-fold increase. And I intend to keep it that way. Maybe we've got a little bit of extra staff for this particular program now, but we are going to change this program to make sure that when beneficiaries have questions they've got one place to go to get answers.

And our beneficiary – our customer service representatives and the programs that back it up and our center for beneficiary choices are going to be working more closely with all of you to make sure if there's a beneficiary question about a quality of care problem or something like that we can help them along in the process. That there's one place for them to go to get all the assistance they need and all the facts they need about Medicare, about the services available in their area, about the quality of their hospitals, the quality of their physicians one day, and so on and so forth to make this – to take all the facts out there and turn it into support that beneficiaries can really use to get better care.

So we have massively increased our individual points of contact for beneficiaries to enable us to walk them through all of these services. We are also substantially increasing our grants to the state health insurance assistance plans, the plans run by the states that consist of core staff and an increasing number of volunteers. We're trying to double the volunteers now to get people on the ground who can do face to face counseling and interactions with patients that may not like to just call us up because of language barriers or because of cognitive impairments and other steps. We want to take those steps as well to make sure we're reaching each and every one of our diverse population of beneficiaries and linking them up with the programs and the facts that they can use to get the best possible health care.

Again, getting back to what I said earlier, the patient, the beneficiary, is where we need to start. That's our ultimate customer and that ought to be the focus of all of our efforts to help them get the most out of our healthcare system and get the most out of our benefits. I should add to this in these efforts we're also working with states and with other private assistance programs. So when you call us up to ask about how you can lower your drug costs we not only tell you about the Medicare programs available to do that, we will check to see whether you're eligible for a program in your state or check to see whether you're eligible for other manufacturer discount programs. We will try to make it as simple for you – we're trying to think about this from the beneficiary perspective of how do we help that beneficiary get the most out of our healthcare system.

So this is a fundamental change. It's going to be lasting. We're going to carry over this big expansion in our beneficiary outreach and beneficiary support activities into our implementation of the drug benefit, into our implementation of the other improvements in Medicare benefits coming, preventative benefits and the like, and I hope you all will be able to help this effort along.

Well, I've talked primarily about beneficiaries so far because that is, I think, the right ultimate focus but obviously healthcare providers are a critical part of making sure all of these support systems and all these incentives and all this new information works as well. We need to provide better information to providers. I've already talked about quality measures. That's something that providers can use in working with their patients to get the most effective care possible, but we need to do more than that for providers, from too many of the treatments that are being used in the – by our beneficiaries today, we just don't have good evidence on whether or not they work.

So there's been a lot of interest in such topics as comparative effectiveness studies; there's new support for that in the new Medicare legislation. I think there's more that we can be doing on collecting information related to safety of drugs and other treatments for patients coming from the FDA. I saw a lot of good promising ideas about how the FDA could work with Medicare to monitor more closely potential safety problems in our Medicare and Medicaid population.

Those are all areas where I think it's possible to do a lot more, and this is not by – in this way I want to emphasize that I'm not just talking about spending some new grant funds at AHRQ, important as that is. We've got a meeting coming up with AHRQ in just less than two weeks on how we're planning on going forward with implementing these comparative effectiveness programs, and that meeting's going to focus on a couple of things that are kind of new. One is to make sure we're talking specifically about the most important questions that need to be answered to get more value for our beneficiaries. So which particular kinds of drugs or other medical treatment do we not know as much about as we'd like? We're going to prioritize them. How would you do that?

At FDA we've already got programs in place to address these kinds of questions with other populations. Many of you may be familiar with the pediatric programs at the FDA which every year have a limited amount of funding that they can use to answer the most important unanswered questions about safety and effectiveness of drugs and other treatments in children. So, every year we get some experts together, both inside government and outside perspectives and advocates, and try to come up with a list of what the top 10 questions are. And then we move forward on trying to fund those with support from NIH and others to make sure that we're pushing along the knowledge frontier as effectively as possible. Well, we need to do the same kinds of things for Medicare beneficiaries. Let's find out which – let's identify the most important unanswered questions for helping beneficiaries get more out of our healthcare system, get more value for their money, and then let's take steps to implement that.

Now, the second part of this meeting with AHRQ, which is kicking off this new push, is gong to involve talking about how we can do this even more effectively. So, it's certainly possible now to do large scale clinical studies on treatments that have been improved. Many of you may be familiar with the ALLHAT study which looks at, basically, comparative effectiveness of some alternative ways of treating hypertension and related conditions. That was a great study. It was very important to have it done. It answered some important questions. As always with new medical knowledge it raised some further questions.

That study cost over $100 million to do. And one reason for that is that it takes a lot of time in our current way of organizing health care to identify patients who should be enrolled in a study, to collect information from those patients, you got to go and abstract paper charts, you all are familiar with how much that costs. A typical cost per patient now in a clinical study where – for an approved treatment where you have to do chart abstraction is $7-10,000 per patient. It adds up fast and it takes a long time and it's extra effort.

Well, that's why we're making a big push toward better electronic health records, and hopefully e-prescribing in the new Medicare benefit – the law says we should get to widespread use of e-prescribing by 2009. And Secretary Thompson – and President Bush for that matter, you guys probably heard him talk about this a couple of weeks ago – think we can get to widespread e-prescribing much sooner than that if we take some steps now to identify what's working, to develop and implement some effective standards, and then to provide incentives and provide support in the implementation of the Medicare drug benefit in 2006 to get there.

If we have those kinds of systems in place we can do this kind of comparative effectiveness evaluation, other studies of safety and effectiveness of approved treatments which we desperate need, at a much lower cost and hopefully much faster for our population. And that will help doctors a lot, and healthcare providers a lot in determining what the most effective approaches for care are.

Information's very useful for providers, so are financial incentives. You heard about my background in economics and that's definitely something I want to pay attention to here. We're implementing for the first time, as you all know, in our hospital payment updates for 2005 pay for performance. And we're going to have more to say about this in a press announcement later today, but for the first time hospitals are getting larger payment increases if they provide quality information to us. And based on what I'm hearing from the hospitals this is in part the result of the work that you all have been doing. We're expecting pretty widespread use – pretty widespread reporting of these quality measures, which I think is great.

To collect these quality measures effectively hospitals have to make – or are supported by making investments in information systems – in electronic information systems that help them collect the data. And, more importantly, by getting these measures out there so that people know about them and can factor this into their decisions about where to get their care, we are providing better incentives for the hospitals to improve on these performance measures. And the payment system is related to that. We are starting to pay for performance and I think we can do that more.

We're also trying to pay for results. Another set of provisions in the legislation involves competitive bidding for products like drugs, for durable medical equipment. We'll be implementing those over the next few years, and the idea here is to promote quality and reduce cost by again focusing on paying for performance. Which contractors – which providers of these drugs and DME products, durable medical equipment products, can give us the results that we need at the lowest cost? We're not going to just set a regulated price anymore. We're going to focus on improved performance in our quality standards in these competitive bidding contracts and lower prices at the same time. Paying – again, trying to pay for performance.

With all this to – for all to succeed we need to be providing more and better technical assistance for providers. So there's a lot of work that we're doing on developing standards. There's a lot of work that you all are doing on advice and demonstrations for successful approaches, and those are going to be needed now more than ever with all the changes coming in Medicare and with all of these additional complexities in delivering health care that I've already talked about. So, we need more help and more innovative approaches to providing technical assistance for providers than ever before.

I want to say a couple of other points and then I'll stop and be happy to answer questions or actually just mainly hear from you. In thinking about technical assistance, in thinking about improving quality, as you all know there are a couple of broadly speaking different kinds of approaches that we use, most of what I've already talked about today fall into the category of incentives and support. As you know, there also are problem providers out there. It's not most of the providers, it may only be a small fraction but we do also have responsibility to prevent low quality care through such approaches as audits and inspections and follow up on unsafe patient care and real quality problems with care.

This auditing function – this inspection function is very important, but I have to tell you I am concerned about how we're perceived by providers when on the one hand we're trying to work with them constructively, but on the other hand they know that the QIOs and we also have a capacity and authority and will when necessary inspect them, review fundamental quality problems and the like. And I think that creates a bit of a tension in our ability to work effectively with healthcare providers and I'd like to think about some creative ways to try to address this as well.

In all these steps we are trying to improve our healthcare system, to get more innovation, higher quality at a lower cost. I think it's very important for all of us to live this in our own work as well. So, one of the things that we're dong right now in CMS, aside from taking on all of these new program challenges, is undertaking some administrative reforms. This goes for our own staff. We're starting there. Some of you may have heard, or even read about in the Washington Post today a new union agreement that we have as a result of an impasse (?) panel that resolved some differences between labor and management on how we are working on such issues as performance evaluation.

We are doing the same kinds of changes with our management staff. We're trying to implement these in a way that are supported by the staff and that reflect high quality work, but once again we're moving in the direction of a little bit more pay for performance, so paying attention – even more attention to the evaluations of our managers, not only by their managers but by their staff, paying more attention to the results that we're actually getting, so that we have flexibility in our workplace so we can adapt to changes that we're facing. But we're keeping the focus on the bottom line results of delivering a lot of value for our beneficiaries and for taxpayers. So that's happening inside CMS with both our union and management employees.

It's also happening with our contractors. One of the big provisions in the Medicare law was contractor reform, and this is going to take place over the next few years. It's really supposed to start on a large scale in 2005, 2006 as we move from a system of contracting with individual carriers, fiscal intermediaries to a system of competitive bidding where we are going to work with providers and the other outside customers, stakeholders, that we need to have strong and positive relationships with, as well as beneficiaries, as well as our oversight committees to come up with good performance measures for our contractors to use. And we are going to competitively bid this process.

So, instead of seeing contractors in different states that are there primarily because they were five or 10 or 20 or 30 years ago, you're going to see contractors around and perhaps having somewhat larger scale of operations if they're very successful in providing their services. Accurate payments, effective interactions with providers, effective interactions with beneficiaries, and steps to help improve quality care to the extent we can support that through our contractor and through our payment processes. I think we need to think about how this kind of contracting model and pay for performance applies in everything else that we do, and I think that's something that we should discuss further as QIO activities go forward as well.

So, I guess to wrap up all of these comments I want to emphasize that I am going to be spending personally a lot of time on raising the profile of quality initiatives inside our agency. And that is only going to succeed if we're able to work effectively with all of you who are our best resources out there throughout the country where health care is actually being delivered, our best resources to improving quality and improving safety and getting more for our money – more value for our money in an innovative healthcare system.

So I will look forward to these discussions with you. I'll look forward to answering questions like how do we balance the QIO program integrity activities and policing roles from these other support and improvement functions. I will look forward to working with you on whether there are opportunities to expand what we're doing, and QIO work in Medicare to work with other partners, JAYCO (ph), NCQA, to other healthcare payers who have also the same interest that we do in developing quality measures and implementing quality initiatives effectively. I'll be looking forward to working with you on how we can improve our partnership to get better health care in this country. That partnership starts between the Medicare program and CMS and the QIOs but it needs to extend to the other purchasers involved in our healthcare system, to our provider community that you all work with every day, and most importantly to beneficiaries.

This is a really interesting time to be here and overseeing the Medicare and Medicaid programs and it's especially an interesting time because of all of the innovative work that you all are doing. So, I think we've got better opportunities to build on then ever before. I'm looking forward to working with you.

Thank you all very much.

(Applause.)

MR. : We have just about five minutes or so for a couple of questions if anybody – and I would ask that you move up to one of – to the microphones, please if anybody has any questions or comments for Dr. McClellan.

Q: Good morning. My name is – is this on? Good morning. My name is Sean Hennessy (ph) from the University of Pennsylvania, and I'm just wondering with the new Medicare drug benefit whether those claims are going to be captured centrally within CMS and made available to researchers to do some of the kinds of things that you talked about this morning?

DR. MCCLELLAN: There's obviously a lot of opportunity to learn more about what medicines are working well, about safety problems, about comparative effectiveness if we use the information that is going to be generated through the drug claims for quality improvement purposes. So that's definitely one of our core goals with implementing the drug benefit effectively.

We have some ideas on that that we're going to be sharing as part of our proposed regulation on implementing Title I of the new Medicare Act and that'll be out very soon, in a matter of weeks. I'd expect sometime around early summer thereabouts. Once that is out we'd like to have some further discussions with you all about how we can use the data as effectively as possible. There are some concerns on the one hand about patient confidentiality and about burden on the prescription drug plans that are going to be providing the data so we want to find the most effective way to answer our questions about safety and effectiveness without imposing undue burdens or without comprising patient safety.

And so you're going to see in this proposed regulation a lot of attention – I know there's been a lot of discussion back and forth between you all and the CMS staff already about how we can get the most out of the data in these new programs for improving care. So more of that's coming and I definitely share your interest in finding the best ways to use all this information to improve care.

Q: Sarah Sellers (sp) with the Center for Pharmaceutical Safety. Dr. McClellan, you mentioned that under the new act there may be opportunities to prevent reimbursement for substandard products. Currently under Medicare Part B we are paying for unauthorized compounded drugs, and in a meeting I had last week with physicians on the Hill they believe in many cases that these are authorized generic drugs when, in fact, they're not. They're not manufactured under good manufacturing practices and, in fact, physicians are being faxed prescriptions with boxes to check off and they believe that those drugs are FDA approved dosage forms when, in fact, they're not. I'm wondering if there's anything that we can do now to prevent population exposures to these substandard products?

DR. MCCLELLAN: Well, a very good question. As you know in some case pharmacy compounding does provide access to needed medicine and does it at a lower cost, but the FDA has long had some concerns about whether all of these compounding practices are generally safe and I think shares many of the concerns that you just raised. I don't have any ideas right this minute but we'd certainly be happy to work with you on determining whether there are ways in the short term to address the safety of compounded drugs. And certainly going forward with the Medicare drug benefit we want to make sure that beneficiaries are getting access to high quality products at affordable prices. So this is another issue that's going to come up in our regulation development, in our process for finalizing the regulations. So I appreciate your interest in trying to help us get that right.

Q: You've mentioned, Dr. McClellan, a little bit of tension between what you described as the inspection or policing functions of the QIO program on the one hand and quality improvement on the other. As you know a number of people actually see those as a continuum rather than a dichotomy and you mentioned some creative solutions to how to balance those tensions. I wonder if you could talk a little bit more about the potential universal solutions, not to commit to a specific thing, but if you could describe what you mean when you described that as a tension and ways you could think of resolving –

DR. MCCLELLAN: Well, I don't know that I have all the answers. I think it is a concern though and I know that many of us view – myself included – view these sets of tools as a continuum, that some of the tools generally – in general the collaborative (?) tools are very effective approaches for most providers who genuinely do want to deliver better care. And most circumstances today are a working environment that often doesn't help them do it, it doesn't encourage it, so anything we can do to make that environment more supportive is going to improve quality care. That doesn't always happen, though.

I think the challenge that we face is that, quite frankly, many providers out there don't yet view it in that way. They don't trust us, I think, when we say well, we know you're a good provider and you're trying to do things right and don't worry if you share information with us, if you work closely with us we're not going to use that against you and come in and inspect you and so forth. I think that tension, honestly I think it's really there and I don't know the best answer for addressing it further. I know that many of the QIOs have taken steps to push that continuum along and if you have ideas or if other peoples have ideas on how we can better address it I'd like to hear about it.

We need to have a strong policing function for the providers that are outside of the bounds of good practice and out to make a fast buck at patient expense and are committing fraud and other kinds of serious healthcare problems as well. These are rare. They're not the mainstream but they are out there. I do think, though, that many providers are worried that rightly or wrongly we might lump them into that category, and so they might be a little bit more reluctant than otherwise to work with us than they would be to work with a quality improvement organization that doesn't have the policing function. We need to fulfill both of those responsibilities and I think we just need to think carefully about the most effective way to do it.

So it's not really an answer but it's a challenge.

MR. : Allison (sp) and then we'll take this question and those will be the last two.

Q: Allison Ross-Davies (sp) from Mavpro (ph). You made quite a bit of emphasis in your first of the three levels of keeping patients healthy on self-management –

DR. MCCLELLAN: Yes.

Q: -- and informed patients –

(Audio break. Tape change.)

Q: We've heard a lot in the last few weeks about health literacy or the lack thereof, especially among the elderly and the low income who are more apt to have the chronic diseases that require self-management. I wonder if you'd comment on how you anticipate CMS and potentially the QIO community assisting in solving or at least ameliorating this health literacy problem?

DR. MCCLELLAN: Well, it's a very good question. I don't have all the answers. I've spent a lot of time talking about this issue with Surgeon General Carmona who is a strong believer in trying to take new and innovative approaches to improving health literacy.

One of the most promising sets of approaches is to provide individualized outreach and individualized education to our beneficiaries, and they are getting bombarded with information from lots of places. There's a lot of confusion out there about what works and what doesn't in health care, and I think to the extent we can provide a reliable and personalized – personalized source of information for them, information that they come to feel like they can trust, we can help overcome some of those problems. That's why the expansions that we're undertaking right now in our customer service – basically it's customer service functions – to get the individual beneficiaries are so important.

We have an extremely diverse patient population ranging from very well educated, very high functioning, fairly wealthy retirees with a very active lifestyle and read all the latest scientific information to, as you said, low income beneficiaries with lots of chronic impairments and even cognitive impairments and who are not very well connected to good medical information support networks. For those beneficiaries in particular we need to find some better ways to do outreach.

We've been trying some new steps. Everything from television advertising – which is actually a proven way to reach low income communities – to at least get them to come to us to find out more, to get us in touch with them about some of the new programs that are available, to expanding our SHIP (ph) programs. I think that's a very promising approach. Many of those health insurance assistance programs in the states have volunteers in each and every community. They have special programs targeted to particular ethnic groups, they have people with connections to community organizations, churches, you name it that are great ways to reach some of these otherwise hard to reach beneficiaries.

And I think about our communications outreach in terms of the diversity of our population. Do we have programs in place that are going to reach each and every one of these groups? And the answer right now is not as many as we should but that's changing. Again, we're quadrupling the amount of people that are there to assist beneficiaries when they call us up on the phone. We're doing more than ever to encourage beneficiaries to call us up when they have any questions about their health care or about Medicare and we are trying to do outreach as well at the individual level with these volunteer groups and the like.

And I do think that these are programs that the QIOs can help with as well. I do think, though, that we need to have people who specialize just in helping beneficiaries get the most out of Medicare. That should be their job and beneficiaries should come to know that there's one place they can go to hear about or to find out more about all the programs, all the assistance that we can provide and that other government organizations can potentially provide to help them out.

This is a big challenge and it's absolutely essential to – as you said to promoting self-care and to make sure that patients are well informed about their illnesses, well informed about steps that they can take to prevent illnesses. It's going to be a key part of individualized Medicare going forward.

Q: Hi, John Houghton (ph) from Doxite (ph). You were just talking about personalized outreach of information. Earlier on you had been talking, and the whole community has been talking, about transparency of IT and kind of open communities. And the question specifically is related to the fact that the QIOs have the protected health information umbrella, but because of the reality of some of the privacy concerns can't share Doctor A's information with Doctor B even though it concerns the patient. And I'm just wondering if there are any specific programs in place or places where interested folks can go to try and work on solving that problem?

DR. MCCLELLAN: I – the president just last week named a new health – electronic health coordinator, David Brailer, who is a great guy and we will be working very closely with him in addressing exactly this challenge. And I would like to find some way for Medicare beneficiaries, at their option, to have their information more effectively shared between healthcare providers. Our beneficiaries typically sees seven different doctors in a year. Many of them are spending time part of the year in one part of the country, another part of the year somewhere else or trying to be good shoppers for where to go for elective surgery and the like. All of that means that anything we can do to help the flow of their clinical information get to these other providers effectively and accurately is going to be very helpful.

There's a lot of support for building on so-called local health information infrastructures to do this. David has a very successful effort in this vein in Santa Barbara where patients do overcome that problem of getting their information shared across providers so they can get more efficient and effective care as a result. We need to find ways to do that more nationally and that's going to be one of David's top priorities in his new job, and clearly implementing that is going to be successful or not based on what we do in CMS and what we do for the Medicare program.

Q: Can I get – just as a quick follow up –

DR. MCCLELLAN: Yeah.

Q: -- given that the QIOs represent basically 50 points of distribution from a wholesale warehouse in a central location to more distribution than providers at retail, is there any appetite within CMS to put the QIOs into that function as the neutral intermediary –

DR. MCCLELLAN: I think there's certainly a lot of interest in CMS in determining whether and how well QIOs could perform that function. You're working with us a lot on the docket program and other doctors office based information – systems to promote – or approaches to promote better use of information technology. I don't think we have all the answers right now, but I do think that's a great topic for you all to be thinking about right now. There is going to be a lot of progress in this area over the coming months.

I know David, you probably do too. He's not a guy who likes to wait around to get things done, neither am I. So this will be an area where we're both going to be spending a lot of effort and I do think there is a potentially important role for QIOs there we just have to define what it is and work out why this is the best approach to solving the problem of having patient information that can be securely and appropriately shared to improve quality of care.

Q: Great, thank you.

DR. MCCLELLAN: Thank you all very much. It's been a pleasure to be with you this morning – (inaudible).

(Applause.)

(END)