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Thank you for having me here today. Dr. Nelson, as we both embark on new challenges, you as the President-Elect of the AMA, and me as Administrator of CMS, I look forward to working closely with you and with health professionals around the country in our partnership to improve the health of almost 80 million seniors, persons with disabilities, children, and other vulnerable Americans.

In my time in Washington, most recently at the FDA, I appreciated the constructive perspective and input from the doctors at AMA on many issues. I appreciated your efforts to help make sure that clinical expertise and experience are well represented in our review processes. And your help in finding a way forward on potentially dangerous products like

ephedra and andro that have been on the market without needed regulation for far too long. The perspective of practicing physicians will continue to be vital to me at CMS, because I think this is a critical time for us to be working together to find better solutions for doctors and patients.

It's a critical time for us all to be involved in medicine and in health policy. We have many new opportunities to improve the lives of our patients. New technologies are being applied in every area, ranging from large-scale imaging of brains to micro-imaging of the smallest cellular structures; we have developed new treatments through a clear understanding of the molecular basis of diseases; and new information-technology approaches are helping health professionals and patients get the best medicine at the right time, and take simple but proven steps to prevent illnesses. The potential for more disease prevention and better health is greater today than ever before.

And the opportunities for the future could be even better. At FDA, we are seeing more drugs, biologics, and other innovative products in development than ever.

For all of these reasons, many expect that history will look back on our time as the biomedical century, because it holds the potential for unprecedented opportunities for biomedical science to improve our lives.

But this future is not a sure thing. Millions of Americans are rightly worried that, even if these better treatments come along, they won't benefit, because they can't afford it. Americans are struggling to afford the new drugs and other cures of today – and they are even more concerned about the future.

In government and in our medical practices, we need to find better ways to make health care affordable while also encouraging more medical progress to better health.

The good news is, as a result of better evidence, better ideas, and major new legislation, we have more opportunities to achieve the goals of affordability and better, higher-quality care than ever before. We have new legislation and new cures in development that give us more opportunities than ever to give Americans access to the care they need to lead longer and healthier lives.

And that's why I'm especially pleased to be with you here today, just a few days after being sworn in to head the Centers for Medicare and Medicaid Services at this critical time. I'm honored to have this opportunity to oversee the Medicare and Medicaid programs, because I know from talking to my medical colleagues like you that we need to do even more to work together to take advantage of these new opportunities right now, because Americans simply can't afford for us to wait any longer.

We can do better than treating patients for costly and devastating complications that could have been prevented in the first place. We can do better than having doctors and patients making decisions about costly treatments without good information on whether they really work, and whether there are less expensive alternatives available. We can do better than forcing doctors and patients to spend their time and their money on filling out and keeping track of more and more paperwork, when so many other parts of our economy are using less costly and more efficient electronic information systems. We can do better than making doctors and patients spend years in very costly and unpredictable

litigation when things go wrong. We can do better than failing to give patients an opportunity to save money when they take steps to keep themselves healthy, or to meet their medical needs at a lower cost.

And we can do better than leaving America's seniors on their own and paying the highest prices in the world when it comes to their prescription drugs.

We can do better than just spending more and more, without making our health care system more efficient and more effective – and if we want medical care that provides both affordability and high quality, we must do better.

At CMS, we're committed to using these new opportunities to create a healthcare system in which doctors and patients are working together to make the best possible decisions, where care keeps getting better, and where your most important relationship isn't the one you have with your lawyer or your Medicare and Medicaid regulatory manuals, but continues to be the one you have with your patients.

I want to start that process today by outlining some ways in which we can work together to make healthcare more vibrant and more affordable for all Americans – in Medicare, in Medicaid, in SCHIP, and for all patients who walk into any of your offices.

The clearest area where we have some unique and unprecedented opportunities is in Medicare. Last December, after policymakers had been debating for more than a decade about how to keep Medicare up to date, even after passing and repealing legislation on prescription drugs, President George W. Bush and Congress overcame this long and contentious history of inaction to take some big steps forward toward securing Medicare's promise of modern, affordable care for seniors today and tomorrow. The President signed into law the biggest expansion of Medicare in its history to keep that promise.

While people may differ on some of the provisions, the bill included many elements to improve Medicare that had strong bipartisan support. The fact is, we cannot fulfill Medicare's promise without prescription drug coverage, access to modern preventive care, and access to health care

choices that reflect the diversity of our population – and the new law makes it possible for us to do far more than ever before to fulfill these promises, especially for seniors with limited means.

We absolutely need to keep talking and debating about how to make Medicare even better. But to keep our promise to seniors today and seniors tomorrow, we must make safe medicines more affordable right now, and pave the way for preventing more diseases and their complications in the future.

We need a Medicare program that allows doctors and patients to access innovative care effectively and that changes the focus to preventing disease and avoiding unnecessary costs. And so we're going to use this new legislation to act now, and we need your help. That means using the new Medicare law to help empower doctors and seniors to take charge of healthcare decision-making. It means using the new Medicare law to lower the price of drugs to seniors right now. It means eliminating paperwork that has become too burdensome on doctors, and making Medicare's reimbursement systems fairer.

And finally, taking advantage of the new Medicare law means working with people who may not agree on everything about Medicare, but who are willing to roll up their sleeves and do everything possible under the law to achieve our goal of health care that is affordable and vibrant for our seniors and persons with disabilities.

I intend to make sure that the new Medicare law starts bringing new benefits to you and your patients as soon as possible. First and foremost, that means including affordable prescription drug coverage as part of Medicare, as quickly as possible.

As you know, this new law will provide new, voluntary choices for drug coverage. If seniors don't want subsidized drug coverage, they can keep what they have now. The new voluntary drug benefit is an especially important and overdue option for more than a third of seniors and close to half of all older women with limited, fixed incomes. These seniors and persons with disabilities will generally pay no more than \$5 for a prescription, and in most cases – when they use generic drugs or preferred drugs – they will pay only a buck or two. No premiums, and no deductibles. And for all seniors

who choose to sign up, the drug benefit will pay 75% of the cost of \$2000 in drug spending, after the \$250 deductible, plus the peace of mind of coverage for high drug expenses. And all seniors will get lower prices for all of their drug purchases, because they will be able to band together to use their purchasing clout. They will never again have to pay the highest drug prices in the world when they walk into a drug store on their own, with no help.

They will also get, for the first time, access to modern integrated health insurance plans including PPO plans with drug coverage like that available to Federal employees and many millions of Americans under 65.

These are major additions to Medicare, the biggest expansion in its 38-year history, and that's why later this spring we will be issuing proposed regulations and asking for comments and input from you on how to implement this new law as effectively as possible.

But many health professionals and their patients still don't realize that the new legislation actually starts providing important benefits right away. The Medicare Modernization

Act provides more funding to Medicare Advantage plans, the private health insurance plans in Medicare that already offer some limited drug coverage and preventive benefits and disease management programs that Medicare hasn't covered in the past - to make up for years of updates in Medicare that were behind the cost increases they were facing. The law requires that these additional payments must be passed on to beneficiaries – and this is happening already. More than half of the enrollees in Medicare Advantage plans are seeing better benefits, including more drug coverage, and that almost as many will see reduced premiums or out-of-pocket savings. The average premium may shrink by as much as a third. In addition, most of the plans have used the additional payments to enhance their networks, spending more money to recruit and support physicians and other health providers.

Second, the law gives us the ability right away to start lowering drug spending for all seniors who don't have good coverage. We intend to implement a Medicare-endorsed drug discount card for all seniors by June.

Last week, Secretary Thompson and I announced the card sponsors that will offer Medicare-endorsed discount cards to beneficiaries. These cards will allow seniors with no drug coverage or limited coverage to get some long overdue help. And we intend to implement this card program in a way that will fundamentally improve how Medicare beneficiaries buy their drugs.

We will add transparency to the prescription drug market by making public the price of each drug at each participating pharmacy under each card. Today, seniors comparison-shop to find real bargains in price and quality for many products and services in their daily lives. But they can't do it for drugs, even though the drugs they choose can be some of their most important decisions. Whether or not you have coverage, it can be very hard to figure out where to get the best prices. That will change with our new Medicare Compare tool. This is a website that seniors can use directly, or that they can get help in using through our 1-800-MEDICARE help line 24/7, or that seniors groups and consumer groups and others can use to find the best deal. You plug in your drugs and your zip code, and you can look at the actual final discounted prices you can get on your

drugs through each card at participating area pharmacies. And you can get information on generic alternatives, which as you know are just as safe and effective as the brand-name versions when approved by the FDA but often cost 79% less. And you can also get information on less costly alternative drugs in the same drug class. And you can directly compare the total costs you pay under each card, to help you find the card that's best for you.

With the power to compare prices and services, seniors can choose the Medicare-endorsed card that offers the best prices and services for them. So, if a senior citizen knows their medicines and their health problems, they'll be able to easily compare the different drug discount cards to get the one that includes the best deals on the medications they need. And Medicare will be overseeing the program and working with outside groups, to protect patients from cards that try to "bait and switch" through false promises or that seek to profit through other kinds of fraud. Working with beneficiaries, we will make sure that for a card to succeed, and attract Medicare beneficiaries this year and next and then possibly keep them as drug benefit customers, they need to provide low prices and reliable services.

And there's more help for low-income seniors and people with disabilities. This is very important for your lower-income patients who are struggling with drug costs today. They will be able to receive \$600 to pay for their prescription medicines in both 2004 and again in 2005 through the Medicare-endorsed cards. More than 4 million beneficiaries who need help now are expected to enroll - and with your help, I think many more who are eligible can be brought into this important new program. This means many billions of dollars in prescription drug assistance help, plus lower prices, all starting right away.

And quite frankly, we need your help. Looking back over other new programs started by CMS, it's often taken many months or many years to inform people and get them in. But it's also clear that when health professionals get involved, we can do much better. We intend to make it easy for you to work with your patients to help them take advantage of these new opportunities to lower the cost of their prescription drugs. But we need your help right away. Beneficiaries can sign up for cards in May. And the discounts will begin in June.

Let me be very clear about what needs to happen right away. Your Medicare beneficiaries without good drug coverage need to know that they can sign up for Medicare-endorsed discount cards in May, and the discounts will begin in June. And if your beneficiaries include some of the close to 7 million beneficiaries with an income under 135% of the poverty line – that’s about \$12,569 for an individual and \$16,862 for a couple – then they are eligible for \$600 this year and \$600 next year in transitional assistance with drugs, before their comprehensive drug benefit starts in 2006.

The new Medicare law also expands the number of preventive benefits covered by Medicare, beginning in 2005. For the first time, you can give your new Medicare patients an initial preventive physical and have them covered. This new benefit covers EKGs, and can be used with Medicare—covered screening mammography, pap smears, prostate and colorectal cancer screening, fasting plasma glucose tests, diabetes self-management, bone mass measurement, and other screening tests. And the diabetes and

cardiovascular screening blood tests do not have any deductible or co-payments.

The Medicare Modernization Act also takes needed steps toward spending better and making it easier for doctors to provide the care that patients need. It includes provisions to make it easier for doctors to spend more time with their patients and less time with paperwork. For example, the new Medicare law makes payment reviews less complicated and gives providers additional time to repay overpayments. It also allows providers to correct minor errors or omissions in submitted claims. And the new law provides a safe harbor to providers that rely upon erroneous guidance from the Medicare contractors. And we're not going to allow the collection of interest or penalties in such cases.

We're also ending a practice known as "extrapolation" that Medicare used when auditing physician claims. Under current law, auditors may review as few as 30 claims, and if they find that two or three of those claims have been billed improperly, they may extrapolate that error to thousands of similar claims over a four-year period. Physicians may dispute the finding, but they must fork over fines while they

carry on that fight. That wastes your time, and it's unfair. And we are ending it.

And that's not all. The legislation calls for Medicare to look into new documentation systems to replace current rules. The new law also compels Medicare carriers to respond in writing to providers' inquiries within 45 days in a clear, concise and accurate manner. This provision is designed to curtail the number of instances in which providers either don't receive a response or are given the carrier's policy—only to find out later that the advice contained in the policy is inaccurate. And the law gives us broad new authorities to make Medicare's claims processors compete to provide high-quality, efficient services, to help make sure that all of these billing improvements will be implemented effectively. The new Medicare law also improves access to high-quality care by increasing payments for doctors, instead of the payment cuts that would have taken effect had this law not been passed. A 4.5% expected cut in Medicare pay scheduled to take effect this January 1st was converted instead to a 1.5% raise for both this year and next. This is a big turnaround – a turnaround of a total of 6% compared to

what was going to happen - made possible because of the new law.

The law also offers new, additional payments for doctors practicing in rural areas, where access to care is too often a real problem. The law improves payment for physician effort in rural areas; even though the areas are lower-cost, the physician effort can be just as great for a given procedure in a small town as in downtown Manhattan. The new law will also make it easier for physicians to receive the 10 percent bonus payment for furnishing services in health professional shortage areas by requiring CMS to automatically pay the bonus rather than the physician determining eligibility for them. And the new law creates a new physician scarcity bonus payment program, providing a 5 percent bonus for services furnished to the 20 percent of beneficiaries in the most physician scarce areas.

While these are critical steps for improving quality and access for Medicare beneficiaries in 2004 and 2005, I know from my discussions with the AMA that our job isn't done yet. There remains a lot of concern about the way Medicare reduces payments to physicians and other practitioners

whenever program expenditures for Part B services exceeds a set target – the “Sustainable Growth Rate.” I know that this formula may seem like an unfair approach in an environment where a growing part of the costs that Part B covers has nothing to do with the cost of the doctor’s own services, but are for other things - whether it’s new Part B medicines and tests, or other costs that pile on the costs of providing good medical care, such as a liability system that unfairly taxes good medical care.

As you know, I have long been concerned about making sure that payments to physicians are adequate in Medicare. And I intend to keep working with you, with the rest of the Administration, and with leaders in Congress until we have solved this problem. As Medicare costs keep going up, I think that an essential part of the solution is doing more to address these potentially avoidable costs that pile on to the cost of physicians’ services themselves. To make sure that Medicare is sustainable in terms of delivering on its promise of high-quality care to beneficiaries while keeping its benefits financially secure, we need to do a better job of addressing all of these costs besides physician care that are driving the projected reductions in the physician payment rates.

This is a critical problem that we need to work hard to solve together, so that the future won't be like the past often has been. In the past, when Medicare spending seemed too high, the "tried and true" main approach to reducing costs has been reducing provider payments. I don't want to see that happen again just because we can't find better ways to get more for what we spend in Medicare. I think we can do better, by spending our money more wisely and effectively. And physicians are absolutely essential to making that happen, as I'll discuss further in a minute.

I also want to say something to oncologists and doctors taking care of patients who have cancer. I know that many of you have been concerned about the reduction in Medicare payments for drugs administered in your offices. By far, most of these drugs involve the treatment of cancer. And thanks to the better oncology treatments available today, most cancer patients can and should depend primarily on care that you provide in your offices. So these payments really matter.

Prior to January 1, 2004, Medicare paid either a physician's charge to Medicare or 95 percent of the average wholesale

price – whichever charge turned out to be lower. The General Accounting Office, the HHS Office of Inspector General and others have consistently found that payments for most oncology and other drugs were significantly more than what doctors were actually paying for them. At the same time, however, many have argued that Medicare's payment for the cost of administering these drugs was well below costs.

While the new law reduces payment for these drugs, it also requires an increase in what we pay to administer them. These changes permanently increase Medicare payments to physicians for administering drugs by an average of 110% and were effective January 1, 2004. Medicare's payment for the most common drug administration code, the first hour of infusion, increased by more than \$100 (from \$59 to \$165) or 178 percent. For 2004, total Medicare payments to oncologists are expected to stay at current levels.

We intend to look carefully, as well as to work with groups like ASCO who are also watching carefully, to monitor these payment changes and the changes ahead in 2005 for any potentially significant problems of access to care.

But I want to emphasize that we need to do more than simply paying more and more into a too-costly system. It isn't an affordable solution. We need a better system, one that makes it easier for physicians to provide high-quality care at a lower cost. To make Medicare more affordable and to improve its quality, we need to reduce the costs and burdens of practicing medicine. And the new law gives us an unprecedented set of tools to do just that.

The new Medicare law takes many steps toward getting more for our money. I've described just a few of the important ones – steps to lower drug prices and drug costs, and steps to reduce the paperwork burdens facing physicians. But we need to do more to build on our new opportunities, by going after other important causes of the cost problems we face today. We can't afford to wait.

The Medicare law provides new opportunities to get more from our health care dollars by developing better comparative information on different approaches to managing common health problems, including comparative information about the benefits, risks, and costs of different

drugs. Doctors can use this information to make better choices for their patients. And patients can use this information to have a better dialogue with their doctors -- and save on their own out-of-pocket medical costs.

And so we're taking steps like working to implement electronic prescriptions to help consumers get the best medicine for their own needs – based on a decision by the patient and the doctor that is supported by the latest information on the benefits, risks, and costs of all available treatments – with the prescription filled flawlessly with a less expensive drug and provided with the information a patient needs to use it effectively. Americans deserve no less, and an innovative and affordable health care system should deliver no less. The new Medicare legislation, which includes many provisions to speed up the use of electronic prescribing, gives us a great opportunity to fundamentally improve the way that seniors and all Americans choose and obtain the best drug for their conditions.

Finally, the law includes new provisions to improve the availability of generic drugs and of programs to help patients and doctors manage chronic diseases. We need to find

better ways to make use of the best available information to help your patients with chronic illnesses make the most effective – and that includes cost effective – decisions about the treatments they use. That means making use of safe and effective generic alternatives when they are available, and also making smart choices about drug class substitutions when similar but less expensive drugs can provide equal or superior benefits to a more expensive medication. It means leading the way in preventing complications, by doctors participating in and – even better – by leading new disease management and care management programs.

We also need to build on the new law with further measures. As you know better than I do, in many states around the country, rapidly rising liability insurance premiums – if liability insurance is available at all – are threatening both the quality of care that patients receive today and opportunities to provide better, higher-value care in the future. Our current medical liability system is threatening the public health with problems of access to care, and according to CBO and many independent academic studies, it's also adding billions of dollars each year to the cost of Medicare and Medicaid.

Across the country, from Pennsylvania to Nevada, many hospitals and clinics have had to close emergency rooms and trauma centers and cancel other vital services like obstetrics. Doctors are moving to specialty areas with lower premiums, moving to states with more predictable legal systems, or retiring from active medical practice altogether. I've talked to some of the physicians and the patients affected by these crises in access to care. They are very worried, and understandably so.

The President has proposed some bold national medical liability reforms to deal with this crisis. As with all major health care issues, there are strong and well-financed interests on both sides of this one – so of course slogans and anecdotes and so-called “studies” bought and paid for by special interest groups abound. But one of the things that my work at FDA has made very clear to me is that, on virtually all of the critical public health issues we face, there is empirical evidence that we can use to help guide our thinking on difficult health policy issues.

First, there is direct, peer-reviewed, published evidence that the liability reforms supported by the President work. In

states like California, almost three decades of experience show that they result in significantly lower growth in liability insurance premiums, and much greater stability in the availability of physician care. Moreover, there is peer-reviewed, published evidence that the cost savings to the health care system add up to many billions of dollars that could be used for other valuable health care purposes. This includes billions in liability insurance savings passed on as lower costs of care, and billions more in savings from avoiding “defensive” medical practices that are intended to avoid lawsuits, not make patients healthier. And peer-reviewed, published studies also show that these reforms do not result in harm to patients – reasonable limits on the magnitude of lawsuits do not reduce the ability of the legal system to deter and redress poor medical care. Rather, these reforms add value to the health care system, by allowing us to get the same or better health care at a lower cost.

Second, the present crisis in many states is not the result of the so-called “insurance cycle” or reckless investments by insurance companies. I think it is true that we have been on an “up” part of the cycle. But that doesn’t explain premium

increases of 100% or more in the last couple of years in some states that have not reformed their liability system, compared to much smaller increases in most of the states that have implemented significant reforms. The insurance cycle isn't a phenomenon that occurs in some states but not others, like the current crisis in the liability system. And while insurance companies were not immune from the market downturns of the last few years, strict state regulations and reserve requirements already are in place to prevent "reckless" investment. So physician liability reform is a real opportunity to achieve a higher-value health care system, with greater access to modern medical treatment.

These are some of the things we need to do, and that we have new opportunities to do together, to make sure we can avoid unnecessary costs and make it easier for you to focus on what matters most to doctors most -- the relationship that we have with our patients and the opportunities we have to take advantage of advances in medicine to improve peoples' lives.

So I want you to know that you will be hearing a lot from me to make sure that you have what you need to help your

patients stay well informed about what is coming and how they can get the most out of it.

Adding significant benefits to a very large government program is a major task, and there will be lots of bumps and lots of politics along the way. But the goal is too urgent and the opportunities too great for us to get off track.

Over the years, there's been a lot of talk about rising health care costs, and how we need to do more to help people. I think the progress we've made by working together on so many other pressing issues is proof of what we can accomplish. Thanks to the Medicare legislation and other laws enacted by Congress, thanks to increased attention to FDA's programs to help make safe and innovative drugs more affordable, and thanks to a better evidence base than ever on proven approaches to lowering medical costs while improving quality, we now have better opportunities than ever to make real progress on the challenge of providing more affordable, high-quality medical care.

We owe it to the American people to implement durable solutions that will make today's medical breakthroughs

affordable, and that will bring the benefits of the biomedical revolution to patients as quickly as possible. I firmly believe that the most effective solutions can begin with the people who know the most about how to keep people healthy, and have dedicated their professional lives to doing it. I'm looking forward to working with you to use our new laws and new opportunities to make some fundamental progress in the health of the nation. Let's get going. Thank you very much.