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IMPLEMENTATION OF THE MEDICARE MODERNIZATION ACT: DELIVERING PRESCRIPTION DRUGS TO DUAL ELIGIBLES

HEARING

BEFORE THE

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UNITED STATES SENATE

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IMPLEMENTATION OF THE MEDICARE MODERNIZATION ACT: DELIVERING PRESCRIPTION DRUGS TO DUAL ELIGIBLES

THURSDAY, MARCH 3, 2005

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee convened, pursuant to notice, at 2:48 p.m., in room 628, Dirksen Senate Office Building, Hon. Gordon H. Smith (chairman of the committee) presiding.

Present: Senators Smith and Kohl.

OPENING STATEMENT OF SENATOR GORDON SMITH, CHAIRMAN

The CHAIRMAN. Ladies and gentlemen, we welcome you. We apologize to you for the Senate voting schedule that has delayed our arrival. Hopefully, between my colleague and I, we can proceed with this hearing. If another vote is called, we will sort of "Mutt and Jeff" it between us.

This is an important hearing. I believe it will prove to be quite informative. We are going to hear from a variety of witnesses, all of whom have an expertise that can inform our decisions about the implementation of Medicare modernization, and more specifically, the transition of the so-called dual eligibles from the Medicaid program to the new Medicare drug benefit that is slated to begin on January 1, 2006.

I strongly believe that our ability to successfully transition the 6.3 million Americans who are the poorest and most vulnerable citizens into Medicare drug benefits ultimately will prove the overall success or failure of this new program. That is why I have called this hearing on this day, March 3, and by looking at this program today and evaluating the regulations that have been developed by the Centers for Medicare and Medicaid Services, known as CMS, we have ample time to act, if necessary, to make administrative improvements.

Now, before we get started, I would like to commend the CMS staff for their dedication and outstanding work to develop these policies. I have heard from many constituents, and I believe we will hear from many of our witnesses today, they have done an outstanding job. They have labored for the past year in their effort to meet with a wide array of stakeholders, provide opportunities for public comment, and incorporate many of the comments received into the final product, which was released on January 21.

However, as I have learned throughout my many years as a legislator, no bill or other legislative product is ever perfect. I have yet to vote on a perfect bill. Given time and opportunity, improvements can be made, and that is the focus of today's hearing, to determine if improvements are critical to the successful implementation of the Medicare drug benefit, whether adequate safeguards have been built into the system to protect the poorest and most vulnerable, in fact, to be able to protect these dual eligibles.

I look forward to learning more detail about the process that CMS used to develop its regulations and to come to understand more fully the rationale behind their final decisions.

I also eagerly await the testimony of our second panel, who will offer their insight based on their expertise in serving this population in how best to organize the program. As many people know, this population is very diverse. It includes young disabled children, middle-aged persons with significant medical challenges, and, of course, the elderly poor.

At present, Federal and State combined spending on prescription drugs for dual eligibles totals almost $15 billion. However, to truly get an accurate picture of this population, let us look at who are the dual eligibles. Seventy-seven percent have annual incomes below $10,000, and nearly 25 percent are in nursing homes. Over 50 percent are classified as being in fair to poor health. Most have multiple chronic conditions, and 33 percent have significant limitations on activities of daily living, such as self-care, cooking, and even cleaning.

Therefore, as we begin to shape the Medicare prescription drug program to ensure it is properly serving this high-need population, it is clear to me that additional safeguards will be necessary. The question that I will look to Dr. McClellan and our other witnesses to answer today is whether the regulations, as drafted, get the job done, or whether improvements can and should be made. I also will look to our witnesses to assess the benefit added by each of their recommendations, because while improvements can be made, we also must be reasonable in our expectations.

On January 1, 2006, millions of Americans who previously had nothing will begin receiving prescription drug coverage. In Oregon alone, that means 129,000 people will be helped. While many have differing views of the benefit, there is no question that the relief that will be felt by America's poorest and most needy seniors will certainly be there.

I believe it is time to come together and to get the job done properly and I hope my colleagues feel the same. I look forward to working together with them on this and other components of implementation, and I am confident we will continue to have a constructive dialog within the Aging Committee.

I now turn to my colleague, Senator Kohl of Wisconsin, the ranking member of this committee, for his comments.

OPENING STATEMENT OF SENATOR HERB KOHL

Senator KOHL. I thank you, Mr. Chairman, and we welcome all our witnesses who will be testifying here today.

The new Medicare drug benefit will be a big change for the 6.3 million beneficiaries nationwide, including 110,000 in Wisconsin who are known as dual eligibles. These are seniors and people with disabilities who qualify for both Medicare and Medicaid. They typically have incomes below $10,000 and are considered to be the most vulnerable beneficiaries.

Today, their drugs are paid for)by Medicaid, but as of January 1, 2006, Medicaid will no longer cover them and they must all switch to a new Medicare private drug plan. Now, I did not support the Medicare drug bill for many reasons. While I support adding a real drug benefit to Medicare, the new law, in my judgment, fails to take common sense steps to lower drug prices by allowing Medicare to negotiate for the best prices and allowing less expensive imports to appear in our market. I also felt that instead of setting up a straightforward drug benefit in Medicare, the new law sets up a confusing and inconsistent patchwork of private drug plans.

I believe Congress should still act to fix these problems, but as long as the law is going forward in its current form, then it is critical that when these low-income seniors and people with disabilities are switched to Medicare that we get it right. If we do not, they face disruptions in drug coverage that could result in serious harm to their health.

I appreciate the steps CMS has taken to ensure a smooth transition from Medicaid to Medicare for these people, but several concerns remain and we must address them quickly as the Medicare drug benefit takes effect in only ten short months.

Most dual eligibles do not understand their Medicaid coverage will end and they need to select a private Medicare plan. While CMS plans to automatically enroll them in a plan and give them time to switch plans, many may end up in plans that do not cover medicines that they had under Medicaid and many will be unaware of or confused by their new choices.

In addition, private Medicare drug plans will be able to limit the drugs covered by having closed formularies, and this will cause confusion and could result in elderly and disabled patients not getting the drugs prescribed by their physician.

Also, with one in four dual eligibles living in a nursing home, we must be careful with the transition of these vulnerable patients. They require specialized services through long-term care pharmacies that provide 24-hour service, custom drug packaging, and specialized monitoring. The move from Medicaid to Medicare is going to present many challenges for them, and I am looking forward to hearing from Wendy Gerlach from Milwaukee to help educate us on this issue.

As these vulnerable individuals transition from the Medicaid program they know to the uncertainties of the Medicare drug plans, we run the risk of serious glitches that could disrupt their care. So I am glad we are having this hearing so that we can identify the challenges and solutions now and minimize disruptions in drug coverage for these very vulnerable people.

Again, I thank you, Mr. Chairman, for this hearing and I look forward to hearing from our witnesses.

The CHAIRMAN. Thank you, Senator Kohl.

Our first panel consists of the administrator for the Centers for Medicare and Medicaid Services, Dr. Mark McClellan. Thank you, Mark. It is great to have you here and we look forward to your testimony.

STATEMENT OF MARK McCLELLAN, M.D., PH.D., ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, WASHINGTON, DC

Dr. MCCLELLAN. Thank you, Mr. Chairman and Senator Kohl. I really appreciate this opportunity to discuss how we can use the new Medicare prescription drug benefit to provide the best possible assistance for our dual-eligible beneficiaries, and I want to acknowledge the hard work of my staff at CMS and the constructive input that we have received from so many health professionals, advocates, and other experts on providing care to these most vulnerable beneficiaries in support of our effective implementation of this law.

This is important. The new Medicare drug benefit will provide vital new help with drug costs for all Medicare beneficiaries, however they get their Medicare. But it is especially important for almost a third of our beneficiaries with low incomes, beneficiaries who are living on their Social Security check and who, until the Medicare Modernization Act was passed, were too often having to choose between drugs and other basic necessities. Under the Medicare law, these beneficiaries will have a comprehensive drug benefit that will pay for 95 percent or more of their prescription drug costs. This includes all dual-eligible Medicare beneficiaries, many of whom have faced limits on their coverage as States have struggled to maintain their Medicaid coverage.

Mr. Chairman, the over six million full-benefit dual eligibles will qualify automatically for the comprehensive low-income subsidies in the new Medicare benefit, as you mentioned. Under Medicare, these beneficiaries will have no premiums or deductibles, and copayments of just a few dollars, and those residing in institutions will have no cost sharing at all.

We are working hard to make sure that low-income seniors, including all the dual eligibles, get the comprehensive help that the Medicare benefit is intended to provide. We have been working hard with States, the Social Security Administration, other Federal agencies, and many other partners to meet the challenge of moving the dual eligibles to the new comprehensive Medicare benefit. We are implementing protections to make sure that no dual eligible beneficiaries have any gaps in their drug coverage as they move from Medicaid to Medicare.

We are taking new steps to make sure that the drug benefit works well for beneficiaries, pharmacists, and the health care providers who work with them through an ongoing dialog. Throughout this year, we are going to continue to listen and to collaborate to implement this new benefit effectively, and I appreciate the opportunity to continue that dialog and to identify further steps and issues that we need to address through your hearing here today.

As an example of the work that we are doing now, since the regulations were issued, I am pleased to announce that today, CMS is issuing a request for proposals for a contract to assist us in coordinating benefits and facilitating an accurate accounting of a beneficiary's true out-of-pocket spending in near to real time. This system, which we will be implementing on schedule with the full drug benefit, will enable pharmacies and plans to process a beneficiary's prescription smoothly, even for a beneficiary who shows up at a pharmacy in January 2006 and doesn't have the plan card or doesn't even remember the plan's name.

The system will enable plans to inform beneficiaries when they have reached coverage limits or when they can expect even greater financial relief for catastrophic coverage or from other wrap-around assistance. It will tell them how much they can save by switching to a generic version of their medicine. They will have their claims processed correctly without the need for bringing in receipts or submitting other documentation if they have wrap-around coverage, and they won't even need their drug benefit card.

Mr. Chairman, the transition to the Medicare drug benefit has already started. We are getting data from the States to identify dual eligible beneficiaries and we will begin personal outreach to them through mailings and other contacts this summer and will provide follow-up details in the fall. Early in the fall, about three months before the drug benefit begins, we will let them know what drug plan they have been assigned to if they don't select one themselves by the end of December. We will also notify the plan so that the plan can assist in ensuring a smooth transition.

We will be conducting a major education and outreach effort. Beneficiaries will get help through our 1–800–MEDICARE 24/7 bilingual support line and through local outreach activities involving our regional offices and partners in State health insurance assistance programs, Area Associations on Aging, and many other public and private partners.

I am especially pleased to be working closely with the Access to Benefits Coalition, a coalition of almost 100 beneficiary and patient support organizations who have had very different political views, very different views about the Medicare law itself, but who all have one thing in common. They want to make sure that we are implementing this benefit, this crucial new benefit for low-income seniors, as effectively as possible.

We are also working with pharmacists, physicians, and other health professionals on simple steps they can take to help make sure their patients get the most out of the new drug benefit.

Of course, we deeply appreciate the assistance and support of Members of Congress in reaching your constituents. We have already prepared some basic materials on Medicare's new benefits and they can be used in town hall meetings or in staff interactions with Medicare beneficiaries back home.

Of course, our support for dual-eligible beneficiaries doesn't end with getting them transitioned to a Medicare drug plan on January 1. We are paying close attention to make sure the new drug formularies provide access to medically necessary treatments at the best possible price. The Medicare drug benefit will cover virtually all types of FDA-approved drugs and biologics. It is impor-

tant to note that CMS is going to ensure that when plans develop their formularies, they recognize the special needs of many of our beneficiaries, such as patients with mental illnesses, those with HIV or AIDS, people with disabilities, those living in nursing homes, and other beneficiaries who have been stabilized on certain, very specific and sensitive drug regimens.

CMS regulations also require each plan to submit a transition plan for moving enrollees currently taking a drug that is not on the formulary to a medication that is on the list. This process must address the clinical situations where a beneficiary seeks to fill a prescription that is not on the formulary but isn't aware of what is covered by the plan or isn't aware of the exceptions process. We are going to review these plans as part of our approval process and we are not going to approve any drug plan unless its transition plan is adequate to protect Medicare beneficiaries, all of our beneficiaries.

Under our published guidance on prescription drug plan oversight, we will be looking to see if the transition plans are consistent with widely used best practices, retiree drug coverage, and Medicaid plans today.

CMS has also tightened and streamlined the process for exceptions and appeals for the formularies, and beneficiaries can get help from their doctor or a designated representative in this quicker process.

There also are some special protections in place for beneficiaries who live in long-term care facilities. These beneficiaries as you mentioned, are a large part of our dual eligible population. Every plan must provide coverage to all its enrollees who live in any nursing home in its region, and we will have specific performance and service criteria that pharmacies will need to meet in order to serve nursing home beneficiaries. These criteria will address delivery and packaging and urgent access and those other critical needs that you all have mentioned to guarantee there will be no change in drug safety and no change in drug availability for this fragile population.

In addition to all this, if a dual-eligible beneficiary finds that their plan is not the best fit for them, they may change plans at any time.

On all of these transition issues for dual-eligible beneficiaries, we are working with the States to anticipate possible problems and will work together to deal with the transition challenges as they arise. We have already issued a set of guidance documents. We have specific State-by-State contacts, and we have an active work group that focuses on addressing all of the State issues. This involves representation from the States, CMS, and the Social Security Administration. This group has listed out the issues that the States need to address in handling the transition and it has worked to develop a checklist for the steps that States can take with assistance from CMS to execute the transition effectively. We will keep working together until we get the job done.

Thank you for the opportunity to talk about the transition to this important new benefit, which is going to greatly enhance the quality of life for our beneficiaries in greatest need. I am looking forward to working with you as we continue to reach out to review

and to examine the best ways to provide this critical new help to our most vulnerable beneficiaries on time on January 1, 2006. I am happy to answer any questions that you all may have. Thank you.

The CHAIRMAN. Thank you very much, Doctor.

[The prepared statement of Dr. McClellan follows:]

TESTIMONY OF
MARK McCLELLAN, MD, Ph.D.
ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
BEFORE THE
SENATE SPECIAL COMMITTEE ON AGING
HEARING ON
THE TRANSITION OF FULL-BENEFIT DUAL ELIGIBLE BENEFICIARIES TO THE MEDICARE PRESCRIPTION DRUG BENEFIT

March 3, 2005

Chairman Smith, Senator Kohl, distinguished members of the Committee, thank you for inviting me to discuss the transition of full-benefit dual eligible Medicaid beneficiaries to the new Medicare prescription drug benefit.

Beginning in 2006, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) makes prescription drug coverage available to all 43 million Medicare beneficiaries. This important new benefit will provide beneficiaries with substantial help in paying for their prescription drugs, greatly enhancing their quality of life. The law also gives Medicare the ability, for the first time in the program's 40-year history, to provide additional comprehensive help to those in greatest need – beneficiaries with very high prescription drug costs and people with low incomes. Under the MMA, millions will receive comprehensive prescription drug coverage at little or no cost.

All Medicare beneficiaries will have the opportunity to participate in the new prescription drug benefit, including the approximately six-million low-income beneficiaries who also are enrolled in Medicaid. Known as "full-benefit dual eligibles," these beneficiaries will qualify for Medicare (instead of Medicaid) prescription drug coverage with low or no premiums and co-payments of a few dollars. CMS recognizes the enormity of the transition from Medicaid drug coverage to Medicare and is working diligently to ensure the process for beneficiaries is as quick and efficient as possible. Most importantly, protections are in place to help ensure that no full-benefit dual eligible beneficiary will go without coverage when the new Medicare prescription drug benefit starts on January 1, 2006. This is critically important, especially for beneficiaries with chronic conditions who take a number of prescriptions. In addition, CMS will pay particular attention to the formulary designs of the new drug plans to ensure they are not

discriminatory and they meet the needs of all beneficiaries. CMS will ensure formularies recognize the special needs of beneficiaries, including those with disabilities, mental health illness, HIV/AIDS, and those who live in nursing homes.

Standard Benefit Includes Protection from High Drug Costs

The new Medicare prescription drug benefit will offer protection from high pharmaceutical costs for all beneficiaries, regardless of income. Under the standard drug benefit, Medicare will cover on average 75 percent of a beneficiary's drug expenses up to $2,250, after a $250 deductible. Once a beneficiary's out-of-pocket spending reaches $3,600 in a year, the drug benefit will cover about 95 percent of any additional pharmaceutical expenses, effectively protecting the beneficiary from very high drug costs. There is no cap to the Medicare coverage so beneficiaries will be continuously covered after reaching the out-of-pocket spending limit.

Additional Benefits for Low-Income Beneficiaries

The new drug benefit provides even greater protection for low-income and full-benefit dual eligible beneficiaries through a low-income subsidy. Qualification for the low-income subsidies will vary based on the status of the beneficiary (See Attachment 1).

Full-Benefit Dual Eligible Beneficiaries

Full-benefit dual eligible beneficiaries - those who currently receive full Medicaid benefits - will automatically qualify for the low-income subsidy. For beneficiaries in this category with incomes of 100 percent or less of the Federal Poverty Level (FPL), the Federal government will pay for their premiums up to the benchmark amount, and their entire deductible. The beneficiaries will only be responsible for nominal co-payments of no more than $1 for generic or preferred drugs or $3 for other drugs and, should they select such a plan, any premium amount exceeding the benchmark premium until the out-of-pocket limit is reached. As a result, Medicare will pay on average 98 percent of these beneficiaries' drug costs.

Full-benefit dual eligible beneficiaries with incomes greater than 100 percent of the FPL will not pay premiums up to the benchmark amount or deductibles and will have co-payments of no more than $2 for generic or preferred drugs or $5 for other drugs.

The new law offers even greater protection for the approximately 1.5 million full-benefit dual eligible beneficiaries who reside in institutions. They will pay no premiums, no deductibles, no coinsurance, no co-payments, and will not have to spend their personal needs allowance on prescription drugs.

Medicare Savings Program and Social Security Income Beneficiaries

Low-income Medicare beneficiaries who are enrolled in a Medicare Savings Programs (QMB, SLMB, and QI programs) or who receive Supplemental Security Income (SSI), will automatically qualify for a low-income subsidy. The Federal government will pay for the entire deductible and premiums up to the benchmark amount for beneficiaries enrolled in a Medicare Savings Program. These beneficiaries will have co-payments of $2 generic or preferred drugs or $5 for other drugs until the out-of-pocket limit is reached. If they select a plan with a premium that exceeds the benchmark amount, they will be responsible for the difference. Subsidies vary for SSI recipients depending on whether or not the beneficiary has Medicaid coverage. SSI recipients with Medicaid coverage will have no premiums or deductibles and will have co-payments of no more than $1 for generic or preferred drugs and $3 for other prescriptions until the out-of-pocket limit is reached. SSI recipients without Medicaid coverage will have no premiums or deductibles and will have co-payments of no more than $2 for generic or preferred drugs or $5 for other drugs until the out-of-pocket limit is reached.

Other Low-Income Beneficiaries

Subsidies also are available to other Medicare beneficiaries with incomes less than 150 percent of the FPL. These beneficiaries must apply for the low-income subsidy, which varies based on income. Those with incomes less than 135 percent of the FPL and assets up to $6,000 (or $9,000 for a couple) in 2006 will pay no premium up to the benchmark or deductible and will have cost sharing of up to $2 for generic drugs and preferred drugs $5 other prescriptions up to the out-of-pocket limit of $3,600, after which there will be no cost sharing.

Beneficiaries with incomes less than 135 percent of the FPL with assets between $6,000 and $10,000 ($9,000 and $20,000 for a couple) will have no premiums and a $50 deductible. Cost sharing for such beneficiaries will not exceed 15 percent up to the out-of-pocket limit. There

will be no coverage gap and co-payments will be $2 for generic or preferred drugs and $5 for other drugs after the out-of-pocket limit has been reached. On average, Medicare will pay about 96 percent of the drug costs for beneficiaries with incomes below 135 percent of the FPL.

Subsidies also are available for beneficiaries with incomes greater than 135 percent, but less than 150 percent, of the FPL and assets up to $10,000 ($20,000 for couples) in 2006. Premiums for such beneficiaries will be based on a sliding income scale. The deductible will be $50 and cost sharing will not exceed 15 percent coinsurance for costs up to the out-of-pocket threshold. Once the out-of-pocket threshold has been reached, beneficiaries in this income group will also have co-payments of up to $2 generic and preferred drugs and $5 other drugs. For beneficiaries in this income range, Medicare will cover an average of 85 percent of their drug costs. As mentioned above, beneficiaries who select a prescription drug plans with premiums that exceed the benchmark will be responsible for the difference.

The low-income subsidy available under the MMA will impact a large number of Medicare beneficiaries. In fact, in 2006, 14.4 million individuals will qualify to receive help at one level or another under the subsidy program, including:

- 6.3 million full-benefit dual eligible beneficiaries;
- 5.7 million beneficiaries with income under 135 percent of FPL who meet the lower asset tests (which number includes 2 million Medicare Savings Program beneficiaries); and
- 2.4 million beneficiaries with incomes below 150 percent of FPL who meet the higher asset test.

This means that approximately one-third of the nearly 43 million Medicare beneficiaries will be receiving substantial assistance with their drug costs. The remaining two-thirds also will have significant assistance with their prescription drug costs.

Planning the Transition from Medicaid to Medicare

Mr. Chairman, I understand that some Members of Congress are interested in hearing about the comprehensive plan CMS has put in place for full-benefit dual eligible beneficiaries to move from Medicaid to the new Medicare drug benefit on January 1, 2006. Along with our many partners in making sure that full-benefit dual eligibles get the most out of the new comprehensive Medicare benefit, we are implementing a comprehensive plan to assure there are no gaps in

coverage for these beneficiaries. CMS is currently working with states to establish data exchanges that will identify full-benefit dual eligible beneficiaries whose coverage under Medicaid will end on December 31, 2005. After identifying these beneficiaries, CMS will contact them by mail this summer to inform them that they are deemed eligible for the low-income subsidy. Information will also be available through 1-800 MEDICARE, **www.medicare.gov** and through state Medicaid offices. And this fall, the full-benefit dual eligible beneficiaries will be notified of the plan in which they will be auto-enrolled if they do not choose a plan beforehand.

CMS is engaged in multiple meetings and coordination efforts with the states to ensure a smooth transition process. We are currently drafting a "State Legislators' Checklist" in conjunction with state associations, which includes questions pertaining to the role states have for coordinating with State Pharmacy Assistance Programs (SPAPs), accepting and processing low-income subsidy applications, retiree options, state contributions, state insurance laws and regulations, as well as general education and awareness. The checklist will also provide instruction on how the transition of full-benefit dual eligibles will be handled.

CMS will have multiple opportunities to disseminate the checklist to the states. The National Conference of State Legislatures, Council of State Governors, state committee chairpersons and state legislators will each receive mailings. In addition, CMS Regional Offices will serve as an addition resource for states. CMS also is working with the National Governors' Association to convene meetings with state SPAP representatives and with each state Medicaid director. Monthly conference calls with state Medicaid directors are scheduled to provide an opportunity to work through any issues and ensure as much information as possible is available. Furthermore, the SPAP Workgroup is developing guidance on how to use the SPAP grants effectively and CMS will work with the State Issues Workgroup on further guidance on transition issues.

Working in conjunction with the states and Social Security Administration (SSA). CMS also will conduct expansive outreach activities in the spring of this year (which will be described later in this statement) to educate Medicare beneficiaries about the new prescription drug plan and to

encourage those who do not automatically qualify for the low-income subsidy to apply. To avoid confusion, CMS will notify full-benefit dual eligible beneficiaries, Medicare beneficiaries who receive SSI benefits, and those enrolled in an MSP that they automatically qualify for the subsidy and do not need to apply. To make the enrollment process as simple as possible for beneficiaries not deemed eligible for the low-income subsidy, CMS worked with SSA and many advocacy groups through an extensive public process to develop the application form and process to be used to verify a beneficiary's income and resources to qualify them for the low-income subsidy. SSA and state Medicaid agencies will be responsible for handling the low-income subsidy application process. Beneficiaries may apply online, by phone, mail, or in person, and no financial documents will be required at the time of the application. Information listed on the application will be verified later, and beneficiaries will only be asked for follow-up documentation if the application cannot be verified through data matches.

As I mentioned, in June CMS will notify full-benefit dual eligible beneficiaries that their Medicaid prescription drug coverage is ending and that they have the right to choose a new Medicare prescription drug plan. Full-benefit dual eligible beneficiaries will be automatically enrolled in a plan in the fall of 2005, once the plans become available. Beneficiaries will still have an opportunity to select and enroll in a plan on their own, but if they take no action, their enrollment in the CMS-selected plan will become effective January 1, 2006. This will ensure there is no gap in their prescription drug coverage. For those beneficiaries who do not enroll in a plan, a notification will provide the opportunity for them to choose another plan. When auto-enrolling a beneficiary, CMS will operate under the following set of guidelines to select an appropriate plan.

- Beneficiaries already enrolled in a Medicare Advantage plan will be enrolled in a Medicare Advantage Prescription Drug (MA-PD) plan within the same organization to ensure continuity of care. The specific plan selected within the organization will have the lowest premiums.

- Typically, all other beneficiaries will be auto-enrolled in prescription drug plans selected at random that have premiums that do not exceed the premium subsidy amount.

Auto-enrollment will begin monthly after the new Medicare prescription drug plans become available this fall for full-benefit dual eligible beneficiaries. These beneficiaries may switch to a different plan than the one in which they were auto-enrolled. And full-benefit dual eligible beneficiaries may switch plans at any time from one MA-PD to another, from one PD plan to another, or from traditional Medicare and a PD plan into a MA-PD and vice versa. This process ensures that all full-benefit dual eligible beneficiaries maintain a continuity of care with their prescription drug coverage when Medicaid prescription drug coverage ends, while retaining the right to select a plan that best meets their needs. Full-benefit dual eligible beneficiaries also may switch plans after the program begins January 1, 2006.

CMS will facilitate the enrollment for other low-income beneficiaries who receive the low-income subsidy, whether they apply or are deemed eligible. These beneficiaries will receive a letter notifying them they have until May 15, 2006, the end of the open enrollment period, to select a plan. If the beneficiaries do not select a plan, they will be enrolled in a plan effective June 1, 2006. Once enrolled, beneficiaries will have the opportunity to switch plans during a special enrollment period, which runs until the end of 2006.

Extensive Outreach and Education Planned

CMS is aware that education and outreach to beneficiaries about the new drug benefit is critical to its success. CMS will work with a broad array of partners including the Administration on Aging (AoA), our sister agency at HHS, to educate beneficiaries, their caregivers, and others who can help them make decisions about the new Medicare prescription drug benefit and other new Medicare benefits and options. SSA, other Federal agencies, states, employers, unions, and national and community-based organizations will all participate in this effort. Successfully reaching beneficiaries will provide them with the opportunity to select a plan that meets their needs. Mr. Chairman, CMS would welcome any assistance Members of Congress can provide. Participating in Town Hall meetings and including information in your newsletters would complement CMS' outreach activities.

CMS is working on an integrated and multi-pronged education effort that will include media advertising, simple language fact sheets, detailed publications including the annual "*Medicare &*

You" handbook, direct mail, and community-based grassroots efforts to target specific populations with messages directed to their specific needs, including low-income beneficiaries. CMS has enhanced its partnership with the State Health Insurance Assistance Programs (SHIPs). CMS increased SHIP funding in 2004 and will provide $31.7 million to SHIPs in 2005, reflecting the increased emphasis on one-on-one advice and counseling for Medicare beneficiaries. The SHIPs are among the most effective resources in helping beneficiaries learn about the changes to Medicare and will use the additional funds to equip their local organizations with the tools needed to answer beneficiaries' questions.

Additionally, CMS is supporting non-profit community-based organizations to help educate and assist low-income beneficiaries who may otherwise be hard to reach. CMS is working with the Access to Benefits Coalition (ABC), a coalition of almost 100 beneficiary and patient support organizations to target this hard-to-reach population. CMS is gaining valuable experience working with these organizations on the Medicare-approved drug discount card program that will be useful for outreach and education and providing enrollment assistance, especially with the low-income population.

CMS also is conducting the Regional Education About Choices in Health (REACH) Campaign, a nationally coordinated educational and publicity effort implemented on the local level by CMS' 10 Regional Offices through their partners. The campaign will work with community organizations and ensure that low-income Medicare beneficiaries, including full-benefit dual eligible beneficiaries, who may not have learned about the new benefit and subsidy program because of barriers of location or literacy, know how and where to get their questions answered, receive culturally and linguistically appropriate information, and receive accurate and reliable information tailored to meet community needs.

CMS also will work with providers in the nursing home arena, pharmacies and other health professions to let them know how to further assist beneficiaries who they care for and interact with as well as those who can benefit from this important new Medicare resource. CMS is also working with Medicare Today, a partnership of nearly 100 major health care organizations, including providers, advocacy entities, plans and employers to inform beneficiaries about the

new drug benefit. Medicare Today will be a coast-to-coast grassroots effort utilizing the capacities of its various member organizations.

CMS has identified 21 specific Federal programs that employ 80 different communications resources that can be used to educate Medicare beneficiaries about the new drug benefit. For example, the national network of community aging services providers funded by AoA are an important component of our outreach efforts. As the largest provider of home and community-based care in the country, the 56 state agencies on aging, 655 area agencies on aging and 29,000 community providers interact with seniors, particularly low-income elderly, on a daily basis at meal sites, senior centers and in their homes. Other examples of how other Federal agencies can provide assistance include:

- The Department of Housing and Urban Development provides funding for more than 2,000 service coordinators around the country who interact with seniors on a daily basis. CMS is partnering with HUD and the American Association of Service Coordinators to educate HUD residents about the drug benefit.

- The Department of Agriculture's Rural Housing Service targets elderly, disabled, and low-income rural residents. CMS has begun discussions with them to explore ways that we can coordinate with RHS' work, so that the Medicare beneficiaries they interact with will be made aware of the existence of the drug benefit and how it can help them.

- The Department of Energy's Weatherization Assistance Program also targets low-income Americans, particularly households with elderly residents, disabilities or children. CMS has begun discussions with them as to how we can partner with them to contact Medicare beneficiaries about the drug benefit.

The goal is to leverage the resources of the Federal government in such a way that all departments and agencies that potentially interact with Medicare beneficiaries will provide either education materials themselves, or an avenue through which beneficiaries can learn more. The White House will be working with the Department of Health and Human Services and CMS to advocate this inter-departmental and inter-agency effort.

Protections for Beneficiaries

In addition to ensuring a smooth transition for full-benefit dual eligible beneficiaries, the new Medicare prescription drug benefit includes a number of protections. To ensure that drug plans

provide access to medically necessary treatments for all beneficiaries and do not discriminate against any beneficiaries, these protections include use of appropriate formularies; provisions for beneficiaries who reside in long term care facilities; coverage determination, exceptions, and appeals processes; privacy protections; customer service provisions; and enforcement actions. CMS will rely on widely recognized best practices for existing drug benefits that serve millions of seniors and people with disabilities in order to ensure uninterrupted access for Medicare beneficiaries. In addition, a Medicare Beneficiary Ombudsman will serve as a beneficiary advocate to ensure people with Medicare receive the benefits and right to which they are entitled. The Ombudsman will closely track all issues related to drug benefit access. CMS is nearing the end of its search process to fill the position.

Formularies Address Special Needs

The MMA requires each formulary to include at least two drugs in each approved category and class, unless only one drug is available for a particular category or class. This requirement, however, should be viewed as a minimum and plans are encouraged to include more in their formularies. CMS may require formularies to include more than two drugs per category or class in cases in which additional drugs offer unique and important therapeutic advantages and where their exclusion may substantially discourage beneficiaries with certain diseases from selecting the plan. This will ensure plans and formularies do not discriminate against a particular type of patient.

All plan formularies must be developed and reviewed by a pharmacy and therapeutics committee (P&T). A majority of the committee members must be practicing physicians or pharmacists and at least two members – one practicing physician and one practicing pharmacist – must have expertise in geriatric and disabled care. Plans' benefit management tools, such as prior authorization, will be compared to existing national drug benefit management standards and guidelines to ensure they are used in a clinically appropriate manner. The goal of this process is to make sure beneficiaries have access to medically necessary prescription drugs and to allow plans to design and manage their formularies to provide the most affordable benefit possible.

CMS intends to encourage and approve formularies that provide drug lists and benefit management approaches that are already in widespread use. In addition to determining that the categories, classes and the formulary list are not discriminatory, CMS intends to check the plan design, using clear benchmarks that plans can utilize as a guide in building formularies and structuring their bids.

Mr. Chairman, it is important to note that CMS will ensure when plans develop their formularies the plans recognize the special needs of particular types of beneficiaries, such as mental health patients, those with HIV/AIDS, those living in nursing homes, people with disabilities and other beneficiaries who are stabilized on certain drug regimens. CMS regulations require each plan to submit a transition plan for moving enrollees currently taking a Part D drug that is not on their formulary to a medication that is on the list. The process must address situations where a beneficiary seeks to fill a prescription that is not on a formulary, but is unaware of what is covered by the plan or what is included in the exception process. CMS will review these plans as part of the approval process and a plan will not be approved unless its transition plan is adequate to protect Medicare beneficiaries.

Medicare prescription drug plans must arrange with their pharmacy network to provide notices of beneficiary rights under Medicare coverage determination processes. The beneficiary may always pay in full for any prescription and initiate an exceptions request. If a beneficiary requests an exception, plans must make their decisions within 24 hours for expedited requests or sooner if the patient's health requires it. Should the exceptions request be upheld, the beneficiary may submit the receipt for the purchase and the plan will later reimburse the beneficiary for any plan liability. If the beneficiary cannot afford to purchase the entire prescription, pharmacies typically have procedures for dispensing a few doses of a prescribed drug (for which the beneficiary pays). The Medicare prescription drug plans must comply with the provisions of the Federal notice and guidelines, but they may establish additional contractual procedures with their pharmacy network to address such a situation. CMS currently is investigating what additional guidance may be provided to the prescription drug plans and the pharmacies.

Addressing the Needs of Long-Term Care Residents

CMS is working to make the transition from Medicaid to Medicare smooth for all full benefit dual eligible beneficiaries, and there will be specific protections for beneficiaries who live in long-term care facilities and get their prescriptions from long-term care pharmacies. As a condition of providing the new benefit, every plan must provide coverage to all its enrollees who live in any nursing home in its region. To help facilitate the transition, the Medicare prescription drug plans will be notified as to which of their enrollees live in a long-term care setting. This will help the plans and the facilities prepare for any potential changes to a beneficiary's drug regimen. As you know, Mr. Chairman, simultaneously changing a number of prescriptions could adversely affect the health of the patient. Because a large number of long-term care residents may be auto-enrolled, it is important for the transition process to account for filling the first prescription. Medicare prescription drug plans will need to ensure that long-term care pharmacies in their network work with long-term care facilities before enrollment begins to ensure a smooth transition. Also, plans may need to provide a temporary "fill first" supply order for a limited amount of prescribed medications. CMS expects plans' applications for participation in the Medicare prescription drug program to explain their proposed procedures and timeframes to transition beneficiaries who live in long-term care facilities to the new benefit.

Beneficiaries residing in long-term care facilities are more likely to have prescriptions for multiple medications. Fortunately, the MMA includes a new Medication Therapy Management benefit. As an additional clinical support service that will improve the quality of care delivered, beneficiaries enrolled in a new Medicare prescription drug plan that are considered "at risk" (those with costs exceeding $4,000 annually, those with multiple co-morbidities, and those with taking multiple medications) will receive this service to optimize therapeutic outcomes through improved medication use.

Effective Decision Support through Information Technology in Nursing Homes

CMS also is working to improve the quality of care and delivery of prescription drugs at nursing homes across the country. CMS is changing the culture of nursing homes and helping them to incorporate computer technology into their daily operations by examining nursing home data collection and analysis practices, and through special projects and demonstration programs.

Regarding data collection, CMS sees opportunities to encourage nursing homes to adopt or upgrade their computer systems through the Minimum Data Set, the system in which nursing homes submit their claims data to the states. Once these data are collected, they are analyzed and reported on an electronic data network. These reports, which maintain patient confidentiality, are very useful for improving quality of care, but only nursing homes with access to basic computer systems can access them. CMS is conducting several projects to test how best to incorporate information technology into nursing homes. For example, under the "One-Touch" pilot program, hand-held devices are being tested in several nursing homes. Through these efforts, CMS is working to help nursing homes realize the potential information technology has to improve the quality of care delivered in long-term care settings.

State Savings and Wrap-Around Options

States will realize significant savings under the reforms made by the MMA, even after refunding some of their current Medicaid drug outlays to the Federal government and these savings can be used to provide further protections for Medicaid beneficiaries. Each state will see fiscal relief when all facets of the Medicare reforms are considered. For example, states will pay a declining portion of prescription drug costs for full-benefit dual eligible beneficiaries. In addition, states will receive assistance with their retiree prescription drug costs, further reducing their spending on prescription drugs. CMS also is prepared to assist states in implementing the new law to ensure they save the maximum amount possible. As part of this effort, CMS has established a number of state workgroups to provide detailed guidance on the transition and administrative issues facing the states, such as determining eligibility for the low-income subsidy and moving full-benefit dual eligible beneficiaries to the new Medicare drug benefit.

Under the MMA, states can use their savings to "wraparound" the Medicare program by continuing to cover certain excluded drugs that the Medicare prescription drug benefit will not cover. States also will receive Federal match for those drug costs. Under the law, states that cover excluded drugs for their non full-benefit dual eligible Medicaid population must provide this same coverage to those who are full-benefit dual eligible beneficiaries. This provision of the law is fair and equitable and is in the best interest of full-benefit dual eligible beneficiaries and Medicaid programs. States make reasonable decisions on coverage of these drugs that provide

good health care and are economical to the programs. This decision making process should not be any different for the disabled and elderly than it is for families and children.
States with State Pharmacy Assistance Programs also can wraparound the new Medicare prescription drug benefit with their programs. States that choose to do so will be able to provide the same or better coverage at a lower state cost per beneficiary. And Medicaid programs that cover the excluded drugs or provide a wraparound will receive the Federal match as well.

CMS is currently drafting a letter to state Medicaid Directors to provide them with information regarding the Federal match. The letter reminds the states that Federal match will not be available for Part D drugs in the Medicaid program for dual eligibles participating in the Medicare prescription drug program as of January 1, 2006. In addition, the letter informs the states that one option they may want to consider for Medicaid coverage is allowing dual eligibles to receive an extended supply (e.g., 60 or 90 days) of their prescriptions near the end of this calendar year, provided an extended supply is allowed in their approved state plan. To do so would give beneficiaries access to the medication they need to carry them into the first several weeks of the program without violating the Federal match provisions in the MMA.

The wraparound provisions will further protect beneficiaries. The Medicare prescription drug plans will cover drugs in categories that address serious medical conditions and will not deny coverage simply because a state covers a less expensive alternative. Medicare prescription drug plans also may choose to cover some excluded drugs and in such cases, the state Medicaid program would be secondary to the Medicare prescription drug plan. As you know, states will make contributions on a monthly basis to the Federal government for the cost of providing the drug benefit. This amount will decline over time. Drugs excluded from the new prescription drug program are specifically excluded from the contribution each state makes. As a result, states are not double charged if they cover such drugs for full-benefit dual eligible beneficiaries.

CMS also has made significant strides to minimize the impact of the administrative functions associated with eligibility determinations and enrollment procedures. First, along with the SSA, CMS is encouraging beneficiaries to apply for the low-income subsidy with SSA. Individuals will not even have to leave home to make such applications. We will provide guidance to states

that also encourages them to use the SSA eligibility determination process. In addition, when an individual asks to enroll at a state office, the costs associated with this application will be matched by the Federal government.

CMS has worked to be sure that the process for applying for the low-income subsidy has been as automated as possible to minimize the burden to states in making low-income subsidy eligibility decisions. Furthermore, we have made sure that the process for such determinations through the SSA is available to the states; so that they all have a uniform, electronic method available to them should they choose to use it.

We are working closely with the state issues workgroup to produce useful outreach and education materials packages that the states can use in their interactions with beneficiaries. CMS has also prepared language that states can use to mail to their own constituencies so that they don't have to write their own letters to beneficiaries explaining the functioning of the state entities with regard to the new drug benefit.

Coverage and Appeals Protections

To further protect enrollees, the new prescription drug benefit provides coverage determination provisions, including exceptions, and appeals processes for drugs that are not included on a plan's formulary. In order to best serve enrollees, there are short timeframes and simple procedures for plan decisions on coverage determinations. As a result, enrollees will quickly receive decisions about medically necessary drugs that are not covered by a plan's formulary. Generally, plans must make their decisions in no less than 24 hours for expedited requests. However, the decision may be quicker if the patient's health requires it. A plan must provide an expedited determination when it determines, or the enrollees' prescribing physician indicates, that applying the standard timeframe may seriously jeopardize the life or health of the enrollee or the enrollees' ability to regain maximum function. In addition, plans must notify affected enrollees of any changes to their formularies or cost-sharing levels at least 60 days in advance of the change taking effect. If a plan fails to provide such notice, it must provide affected enrollees with a 60-day supply of the medication in dispute and notice of the change when a refill is

requested. This 60-day notice requirement provides adequate time for enrollees to request an exception and file an appeal, if needed.

Each plan must have a procedure for making timely coverage determinations on standard and expedited requests made by enrollees. An enrollee or his or her appointed representative, such as a family member or physician, may request a coverage determination (which includes an exception) or an appeal. In addition, an enrollee's prescribing physician may request a coverage determination or an expedited redetermination on behalf of an enrollee without being the enrollee's appointed representative. Generally, plans must grant exceptions when they determine that it is medically appropriate to do so. Once an exception is approved, a plan may not require an enrollee to request approval for a refill for the remainder of the plan year so long as the physician continues to prescribe the drug and the drug continues to be safe and effective for treating the enrollee's condition. Should a plan make an unfavorable coverage determination, such as denying an exception request, the enrollee, or his or her appointed representative, may appeal the plan's decision to an external entity.

The appeals process for the new Medicare prescription drug benefit is modeled after the Medicare Advantage appeals process, which includes five levels of appeals. CMS and the prescription drug plans are required to provide a considerable amount of information to enrollees, caregivers, patient advocacy groups, providers, and the general public about the coverage determination and appeals processes. As mentioned previously, CMS will monitor plans and review enrollee complaints to ensure that plans do not engage in discriminatory practices. Enforcement actions will be taken against plans that violate Medicare's requirement.

Mr. Chairman, while the appeals process provides an important protection for enrollees, CMS does not expect it to be used frequently. In addition to comprehensive formularies and oversight to ensure benefits are nondiscriminatory, best practices from existing benefit packages will be used. Appeals are generally uncommon when such benefit packages are in place.

Privacy and Customer Service

Furthermore, the new Medicare prescription drug program guarantees privacy and includes customer service protections. Exchanges of data between agencies for purposes of determining and verifying eligibility are conducted in accordance with applicable law. Moreover, plans are required to maintain beneficiary privacy and confidentiality. Medicare will review complaints and take enforcement action against plans that do not meet the requirements of participating in the drug benefit. Medicare also will provide consistent information through 1-800-MEDICARE call centers, the Internet, and beneficiary assistance groups about drug coverage, beneficiary payments, and ways to save on prescription drug costs.

As you can see, the new Medicare prescription drug program includes a host of extensive protections that are available to all beneficiaries, along with additional options for those with low incomes. These protections will ensure that appropriate medicines are available when needed, especially for those with serious illnesses that require expensive prescription drugs.

Conclusion

Mr. Chairman, thank you for this opportunity to discuss the new Medicare prescription drug benefit and the transition process and protections for full-benefit dual eligible beneficiaries. The new benefit also provides a substantial subsidy for low-income beneficiaries, while maintaining their ability to select a plan that best address their needs. At the same time, CMS and its partners are working to ensure full benefit dual-eligibles do not experience any gaps in their coverage during the transition. I thank the Committee for its time and would welcome any questions you may have.

Attachment 1

For 2006, the premium and cost-sharing amounts for various subsidy eligible groups are as follows:

FPL & Assets	Percentage of Premium Subsidy Amount (1)	Deductible	Copayment up to out-of-pocket limit	Copayment above out-of-pocket limit
Full-benefit dual eligible individual – institutionalized individual	100%*	$0	$0	$0
Full-benefit dual eligible individual – Income at or below 100% FPL (non-institutionalized individual)	100%*	$0	The lesser of: (1) an amount that does not exceed $1-generic/preferred multiple source and $3-other drugs, or (2) the amount charged to other individuals below 135% FPL and with assets that do not exceed $6,000 (individuals) or $9,000 (couples)	$0
Full-benefit dual eligible individual – Income above 100% FPL (non-institutionalized individual)	100%*	$0	An amount that does not exceed $2-generic/preferred multiple source and $5-other drugs	$0
Other low-income beneficiary with income below 135% FPL and with assets that do not exceed $6,000 (individuals) or $9,000 (couples)	100%*	$0	An amount that does not exceed $2-generic/preferred multiple source and $5-other drugs	$0
Other low-income beneficiary with income below 135% FPL and with assets that exceed $6,000 but do not exceed $10,000 (individuals) or with assets that exceed $9,000 but do not exceed $20,000 (couples)	100%*	$50	15% coinsurance	An amount that does not exceed $2-generic/preferred multiple source drug or $5-other drugs
Other low-income beneficiary with income at or above 135% FPL but below 150% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	Sliding scale premium subsidy (100%-0%)	$50	15% coinsurance	An amount that does not exceed $2-generic/preferred multiple source drug or $5-other drugs

(1) Premium subsidy amount as defined in §423.780(b)
*The percentage shown in the table is the greater of the low income benchmark premium amount or the lowest PDP premium for basic coverage in the region.

The CHAIRMAN. On the last recess from which we just returned, I spent a lot of time with different provider groups on this very issue and one of them was the assisted living folks. As you probably know, in the State of Oregon, the State regulates assisted living, to a standard similar to nursing homes; however they are being treated differently than nursing homes in the new drug benefit. I just wonder if you can speak to that. Would you include them if there were certain standards met that would ensure safety and continuity of care for the patients?

Dr. MCCLELLAN. Yes. Assisted living facilities are now providing an important part of long-term care assistance on this now very broad spectrum of long-term care assistance that we have. It is a very effective way of delivering long-term care services, medical services and other support that beneficiaries need to stay in the community. We absolutely envision beneficiaries in these settings being fully supported in meeting their prescription drug needs.

The CHAIRMAN. But aren't dual-eligible beneficiaries currently living in assisted living facilities excluded under the regulations from receiving the same level of coverage as these in nursing homes.

Dr. MCCLELLAN. Well, they are not treated as nursing homes under the regulations, but our regulations focus on beneficiary needs. If there is a plan that discriminates against any class of beneficiaries, including those living in assisted living facilities, we would not approve that plan.

So as with these other aspects of care, what we have tried to do in our regulations is lay out the conditions, the best practices that we think need to be met to serve all of our beneficiaries regardless of setting. If there are any specific concerns about assisted living facilities that you have that you think we haven't fully addressed, we would be delighted to hear from your staff about it. We want to make sure that beneficiaries, regardless of setting, have access to the drugs that they need, and we think we have a good set of guidances in place to do that, but we are going to keep working on this to make sure we get it right.

The CHAIRMAN. It does seem to me that often, the people that are obviously writing the regulations, they are at work and they are healthy and they probably take one or two prescriptions at the most, but the people who are likely to receive these may take a lot more than that. Can you explain the methodology that was used in terms of formulating what would be available to them?

Dr. MCCLELLAN. Well, there have been a comprehensive set of steps and approaches that we have used to make sure that we are using all of our authorities effectively to provide access to medically necessary treatments at the lowest possible cost. This includes everything from how we set up the price negotiation under this drug program, and according to our actuaries and independent Congressional Budget Office the projections are that we are going to get the lowest possible prices for the drugs. An add-on government negotiation wouldn't save any more. To ensure how we are actually overseeing the formularies, to how we are overseeing implementation of exceptions and appeals processes.

So there has been a comprehensive process. As we issued the regulations, we also held a whole series of open-door forums for

public participation on particular topics, provided opportunities for written comment—we got over 7,000 substantive comments on our drug benefit regulation—and held many other meetings with key stakeholder groups. Those activities are still ongoing. We have issued the final regulations, but those activities are still ongoing.

I also want to emphasize that in addition to the regulations, we have tried to be as clear as possible about the standards that we are going to use to oversee the drug benefit, that including standards for the formulary. It includes standards for the so-called P&T committee that helps make sure that the formularies are covering all medically necessary treatments. It includes standards for the use of prescription drug management techniques, like prior authorization.

In all these areas, we are looking for the adoption of best practices. There are good benefits being provided today to these very vulnerable populations and we want to bring in the best practices used in retiree plans or Medicaid plans to the Medicare population that will be served under the new comprehensive benefit. This process is ongoing, but we have taken a lot of steps already to make sure we are doing it effectively.

The CHAIRMAN. Let us say you have got someone currently on Medicaid and they have a full panoply of drugs to choose from, but in transitioning to this Medicare drug benefit program, they have got real complex health needs and let us say the plans that are out there don't cover all of their drugs. Would it be advisable to have a phase-in period, a transition period of six months or so? I think some of our witnesses on the second panel may testify to that effect.

Dr. MCCLELLAN. We have heard some of these ideas about transition periods. Let me start out by just making clear that we intend to implement this law so that the beneficiaries can get access to medically necessary treatments from the start under this new program, and we view that as including effective transition plans for managing their medications.

While it is true that some Medicaid plans provide comprehensive access to a broad range of drugs today, many plans do impose limits already, and, in fact, there are good models out there from Medicaid plans that use preferred drug lists as to how transitions can be managed effectively.

We would require our plans to have effective transition plans in place for managing the benefits. This is going to be particularly important at the start of this program, when many beneficiaries may be on particular drugs, that are not covered on the formularies. For that period in particular, we will have some extra efforts and we are going to be paying extra attention to make sure there is a smooth transition.

There have been ideas about whether the State programs could continue during this period. One option that we have been discussing with a lot of States would involve filling a 90-day prescription in December to allow the beneficiary to continue to have access to their current drugs through the first part of 2006. Now, we have some limits on what we can do. Our authority to pay Federal matching funds for Medicaid drugs that are covered under the Medicare drug benefit ends on December 31. But this is another

step, in addition to the transition plans and the effective use of proven approaches to managing medications, which we will be pursuing as we implement the new drug benefit.

The CHAIRMAN. Thank you, Doctor.

Senator Kohl.

Senator KOHL. Thank you very much, Mr. Chairman.

Dr. McClellan, as you know, for many people, if treatment is interrupted for even just a few days, it could result in hospitalization, disease progression, drug resistance, or even death. So we need to make sure that nobody falls through the cracks during this transition.

Let us assume a senior or a person with a disability walks into their local pharmacy on January 1, 2006, tries to fill a prescription for the drug that they have been taking for years, and they find that it is not covered. How will they know how to proceed, and how long will it take for their case to be resolved, and is there any guarantee that they will be able to get the drug that has worked for them for years?

Dr. MCCLELLAN. Senator, we absolutely want to make sure that they can continue to get access to the drugs that they need. In fact, that is why this drug benefit implementation is so important. I saw in my own medical practice before coming into this job a lot of my patients who didn't have access to drug coverage in Medicare having more complications, more visits to the doctor and more visits to the hospital. So preventing that is what we absolutely want to do with this transition to prevent any gap in coverage for beneficiaries who have coverage now.

There are a number of steps that are going to help make sure that we don't run into that problem of a gap in coverage for full benefit dual-eligible beneficiaries on January 1. First of all, as I mentioned, beneficiaries will find out about the plan they have been assigned to, if they don't choose one on their own in early October, three months before the start date. We will also notify the plan of that assignment so that there can be steps during that period to make sure the beneficiary knows specifically what is coming, what drugs are going to be covered and whether there is any transition needed. There may or may not be, many of these plans will continue to cover drugs that have been proven to be medically effective to make sure there are no problems with coverage.

In addition, as I announced earlier, we are implementing a new program, one that I just announced today, that will make sure that if a beneficiary shows up at a pharmacy on January 1, even if they don't have a drug card, even if they don't know which drug plan they are assigned to, if they know their name, date of birth, just some basic identifying information, we will be able to find them and the pharmacist will be able to tell them in real time what their coverage is and what they have to pay. They will be able to fill that prescription without a gap.

Finally, our drug plans are going to have to have transition plans in place so that if a beneficiary comes in on January 1 needing a medication refill, an effective mechanism is in place to deal with that. We are basing our approach on what has been proven to work already for managing medication transitions, and a usual approach is to provide a one-month supply or some supply of that current

medication while the plan sorts out the appropriate management of that patient with the patient's physician over the next month.

In many cases, there may be a need for a medical exception so that the patient can continue that current medication longer. That is built into our program, too. We absolutely do not want there to be any gap in coverage for our dual-eligible beneficiaries.

Senator KOHL. So you are saying that if an individual shows up at a pharmacy needing a particular specific drug, in no case will they be turned away, that they will be able to get that drug?

Dr. MCCLELLAN. What I am saying, Senator, is that we are going to make sure that our beneficiaries have access to all the medical treatments they need, all the drug treatments they need without a gap. If there is a good reason for a transition—remember that having the formularies and the price negotiation that comes from that is going to help us keep the cost of the drug benefit down and it is also going to help save the beneficiaries some money, too—the plan must have an effective, proven approach in place to make sure that any transition is managed effectively, that the patient gets the drug that they need.

One approach to doing that would be to let the patient know months ahead of time, in October or November, after they know that this person is going to be assigned to the plan, that certain drugs are not on the formulary and to work out a transition ahead of time. If that doesn't happen before January 1 and the patient just shows up in the pharmacy, as you said, the plan has to have an effective, proven approach in place to make sure that patient can be managed effectively. Often, that will include filling the prescription there for some period of time while the coverage issues are sorted out and it is determined whether that patient needs to continue on a specific medication or could do fine with the alternative treatment that is covered on the formulary.

There may be other approaches, too. There are approaches that have been proven to handle these situations effectively in Medicaid plans, in many retiree plans and FEHB plans; Those are the kinds of approaches that we are going to require in the Medicare drug benefit.

Senator KOHL. As you know, Doctor, States will initially save money, since they will no longer have to cover drugs for Medicaid. States are then required to pay back most of those savings to the Federal Government and this claw-back provision, as you know, is based on how much each State spent on prescription drugs in 2003 and is increased by the annual growth of drug spending.

Let us look at a State like Wisconsin. After facing high drug costs through 2003, Wisconsin Medicaid began aggressive cost containment and then saved money. However, their claw-back payment will be based on the higher drug costs that they face in 2003 and it will increase every year as drug spending increases. Conceivably, Wisconsin could owe the Federal Government more in claw-back payments than they would save by no longer having to provide a Medicaid drug benefit.

So what can be done to change this? Shouldn't there be flexibility to make a more accurate determination of a State's payment back to the Federal Government?

Dr. MCCLELLAN. Senator, we absolutely want to make sure that States are saving money, as was intended under the Medicare Modernization Act. There are several reasons that I think even the State of Wisconsin is going to come out ahead. By the way, it has been a real pleasure to work with your State on expanding its Medicaid coverage of prescription drugs. As you know, we approved a Pharmacy Plus program that allowed Medicaid coverage to expand in 2002 and we implemented the steps to make it possible under Medicaid for the State to negotiate those better prices for drugs. It has been a pleasure to work with the States that do that and we are going to keep working with the State of Wisconsin to make sure that the State does get savings as we make this transition in Medicaid.

As you mentioned, there is a pay-back provision for a portion of the cost projected forward from 2003. That fraction starts out at 90 percent and it goes down over time to 75 percent. So there is some room there, even if the State did get some additional savings since 2003, to make sure they still come out ahead.

We have asked every State to make sure we have the most up-to-date data from their own experience to use as we calculate their payments under this program and we will be going over the numbers with each State, including Wisconsin, to make sure that there are benefits for the States.

Our independent actuaries have looked at this again in the context of our final rules and we are projecting a total of over $8 billion in savings for the States over the next 10 years. It is going to come from the savings they will get on a per capita basis for their beneficiaries. It is also going to come from the savings that they will get from Medicare picking up more of the costs for what has been covered under Pharmacy Plus in Wisconsin. It is also going to come from the Federal Government picking up the costs of all the State of Wisconsin's retirees. You have some very good retirement benefits for your State workers in Wisconsin and we are going to be providing subsidies worth about $1,000 per retiree.

If you add all that up, I am confident the State is going to come out ahead, but we want to work closely with the State of Wisconsin and any other State, going over their numbers to make sure we get it right.

Senator KOHL. Thank you, Doctor.

Thank you, Mr. Chairman.

The CHAIRMAN. Thanks, Senator Kohl. I have been advised the next vote is in about five minutes, so we will figure out how to proceed.

But Doctor, a couple follow-ups. Would CMS consider having drug plans cover the current drugs during the transition period, also requiring coverage through the appeals process, for example, in addition, where these plans will not cover the non-formulary drugs?

Dr. MCCLELLAN. We will require the plans to have an appropriate transition program, and again, this is not something that we have to invent anew here. There are programs that have been adopted in State Medicaid plans where they have preferred drug lists and managed transitions and retiree plans and the like. De-

pending on the medication, it may be appropriate for providing some continuation of coverage.

As you know, we have tightened up our appeals timeframe so that for an urgent medical need, an exception to termination must be done within 24 hours. We want to make sure that there is no gap in access to medically necessary treatments.

We will keep considering other ideas about how to implement this effectively, but again, I think if we base our approach on proven effective approaches from the private sector and from effective Medicaid drug benefit plans, that is the best way to go, to use the experiences that are already out there to manage transitions effectively and to deal with appeals and exceptions in a timely way.

The CHAIRMAN. Very good. In a Finance Committee hearing, I asked you when we were discussing the USP standards about specifically covering antidepressants, a class of drugs that treat mental illnesses. Can you give us an update on this issue and explain how this class of drugs is going to be provided to people with mental illnesses?

Dr. MCCLELLAN. Well, mental illnesses is one of the groups of beneficiaries that we are going to be looking at especially closely as we review formularies and the whole structure of the drug benefit to make sure it doesn't discriminate against some of the people who can most benefit from prescription drug coverage.

In addition to the USP process, which had a number of categories for antidepressants in their final guidance—that is one factor that may go into our reviews for the plans that want to use the USP approach—we are also going to be looking at whether a plan is providing coverage for antidepressants in ways that are similar to effective plans that exist today. We will be using comparisons to some of the most popular FEHB plans, which provide access to a broad range of antidepressants. We will also look at comparisons to existing Medicaid plans with their preferred drug lists for their access provisions. And again, for tiering approaches, for the use of other tools, we will be looking at comparisons to best practices in successful plans today.

We will keep in close touch with you. I know this particular area is of great interest to you.

The CHAIRMAN. It is.

Dr. MCCLELLAN. We absolutely intend for the Medicare benefit to be effective for coverage of antidepressants. This is a very common condition, an undertreated condition in our senior population, and it is one that contributes to a lot of reduced quality of life and premature deaths in Medicare beneficiaries and I really want to take that on as we implement the new drug benefit.

The CHAIRMAN. Dr. McClellan, thank you for being our first witness and thanks to you and your staff for the way you take on a very Herculean job. We will turn now to our second panel with our appreciation to you.

Dr. MCCLELLAN. Thank you for your support and we look forward to continuing to work closely with both of you and the committee. Thank you very much.

The CHAIRMAN. Thank you.

The CHAIRMAN. We will now call up our second panel, Dr. Tina Kitchin, medical director of the Oregon Department of Human

Services in Salem, OR; Dr. Carl Clark, CEO, Mental Health Center in Denver, CO; and Wendy Gerlach, the director of Pharmacy Operations from Milwaukee, WI. We welcome you all. We thank you for your time with us and we again apologize to you for the delay in this hearing. Hopefully, it won't be much interrupted with any delay.

Why don't we start with Dr. Kitchin.

STATEMENT OF TINA C. KITCHIN, M.D., MEDICAL DIRECTOR, OREGON DEPARTMENT OF HUMAN SERVICES, SALEM, OR

Dr. KITCHIN. Chairman Smith, members of the committee, I would like to first thank you for giving me this opportunity to testify on this very important matter. I would also like to thank the Congressional members who helped pass this momentous legislation that guarantees access to medications for a very needy population.

I also would like to emphasize that I do believe that CMS has done an incredible job in some very tight timeframes, has done a wonderful, professional job of reaching out to numerous people and has attempted to make this the best possible situation that they can.

However, Oregon continues to have some significant concerns about what this will mean for dual eligibles. The initial choice counseling period, or what people have been calling the transition, I think, is a special concern to us. If you think about this, it is going to be a very complicated process requiring beneficiaries to compare their current medications to brand new formularies, their current pharmacies to networks of pharmacies, potential for enhanced benefits, potential for changes in premiums, et cetera, and it is going to be a very complicated choice process.

However, within the duals, we are dealing with people with dementia, developmental disabilities, significant mental illness, some that are homeless, et cetera. The bottom line is that this population is not going to successfully navigate the Internet and the 1–800 numbers. They are going to require the assistance of others and in a lot of situations, that means that Oregon, as the State Unit on Aging, the State Medicaid Office, and the State Mental Health Authority, is going to have to assist people in some of those very difficult choices.

When you look at the timeframes, I don't know how we are going to do it within the current timeframes. I appreciate the fact that people are going to be auto-enrolled as soon as the plans are available and will be notified of that auto-enrollment. Unfortunately, a random process maximizes their chance that they will be in a plan that won't meet their needs and they will still require being walked through that very complicated process to get to a place where this drug benefit is of assistance to them.

I don't know how Oregon will be able to successfully do that within this timeframe. I think that there are some mechanisms under both regulation and potentially statute that could assist with this. I also remain concerned about the fact that under the current regulations, States are required to set up a parallel low-income subsidy determination system for a newly eligible group, parallel to Social Security. That is going to divert our attention from a very

important process of assisting people to be transitioned into these plans.

The CHAIRMAN. Doctor, did you hear anything from Dr. McClellan that gave you any comfort, or do—the fears you just described, remain just as real?

Dr. KITCHIN. Chairman Smith, I know that they really want to make this as beneficial as possible and as smooth as possible. When we moved the Medicaid eligibles into managed care, mandatory managed care, I know that it took Oregon well over a year of planning plus then a year to roll out the process, and at the same time, it was a very intensive workload and it was very difficult to do. I think those choices are small compared to the choices that beneficiaries are going to be faced with this year.

I also think that the part of the regulations that currently require the plans to have adequate transition plans doesn't give many details or specifics upon what that is going to look like, and I know that working with managed care plans in Oregon, we have plans that go above and beyond what is required of them, but we also have plans where it is a struggle to get them to do the minimal. I am afraid that some of these plans will do the minimal or less, and without the detail in those regulations, that concerns me.

I am also concerned a bit about access to long-term care pharmacy services, including those that are in our home and community-based system. You mentioned the adult foster homes and the group homes. Long-term care pharmacies provide very needed services and these regulations don't protect that access for beneficiaries.

I think my red light is on.

The CHAIRMAN. OK. Thank you very much, Dr. Kitchin.

[The prepared statement of Dr. Kitchin follows:]

Testimony

Presented to the:

Senate Special Committee on Aging

March 3, 2005

Presented by:
Tina C. Kitchin, M.D., Medical Director
Oregon Department of Human Services
Seniors and People with Disabilities

Summary of Testimony
Presented to
Senate Special Committee on Aging
March 3, 2005

By: Dr. Tina Kitchin, Medical Director
Oregon Department of Human Services
Seniors and People with Disabilities

Although the Medicare Modernization Act offers a great opportunity for many Oregonians, Oregon continues to have serious concerns with implementation and recommends the following important changes:

- The current timeframe for the initial enrollment process is too short, increasing the potential for unintended, unsafe and harmful consequences as Medicare/Medicaid dual eligibles transition into the Part D benefit. The timeframe should be extended to allow for a phased-in approach.
- The current regulation that requires Part D plans to have a transition plan for beneficiaries entering their plan needs specific details that will ensure that a fairly small subset of the Medicare/Medicaid population will not be harmed and costs shifted to states.
- People in Home and Community Based Waivered services need the same benefits and protections as those in nursing facilities and other institutions.
- States need to be relieved of the burden of developing a parallel process to the Social Security Administration to determine eligibility for the low-income subsidy.
- Access to necessary services supplied by Long Term Care pharmacies to a variety of facilities and institutions needs to be strengthened.
- States need access to individual specific information on medication supplied to Medicare/Medicaid dual eligible, without cost, in order to ensure quality, coordinated care.

March 3, 2005

Senate Special Committee on Aging:

My name is Tina Kitchin, M.D. I am the Medical Director for the Oregon Department of Human Services, Seniors and People with Disabilities. The Department of Human Services is the designated State Medicaid Agency, the State Unit on Aging, and the State Mental Health Authority. The Department administers five different Home and Community-based waiver programs and has responsibility for regulating all long-term care services in Oregon.

The Medicare Modernization Act offers a great opportunity for Oregonians, but comes with serious concerns. Oregon is very appreciative of the hours of dedication required by members of Congress and their staff to develop and pass this historic legislation. Approximately 129,000 Oregonians who currently have no drug coverage will soon have access to medications that will allow them to live longer, healthier lives. The U.S. Congress has addressed a critical health care issue for seniors and people with disabilities.

The Centers for Medicare and Medicaid staff's dedication and commitment have been impressive. Working within very tight deadlines, they have consistently produced professional, thoughtful products. We would like to thank them for their cooperative and open approach to this entire endeavor. They have sought the States', advocates', and providers' input at all steps. They have carefully weighed the multitude of interests, some of which were competing, and provided considered responses. The final regulations significantly strengthened access to Long Term Care pharmacies, strengthened beneficiary protections in appeals and grievances, and strengthened protections in the formulary design. Nevertheless, although progress and effort have been substantial, Oregon continues to have significant concerns that, without additional important safeguards, some vulnerable Oregonians may suffer serious harm, albeit unintentional.

Initial Enrollment Period.

The initial enrollment period will be a momentous programmatic change that, under the current rules, must occur in a very compressed time frame. Over 500,000 Oregonians will have to choose a plan, taking into account the

formularies, network of pharmacies, premiums and cost sharing, and enhanced benefits. The beneficiary must then compare their current medications to their new formulary, review their new network of pharmacies and make the necessary changes prior to receiving this benefit. Because Oregon does not currently allow pharmacists to make therapeutic substitutions, this will involve physicians having to write new prescriptions. Compounding these challenges is the fact the limited enrollment period overlaps the major winter holidays.

The problems presented by the limited timeframe are even more acute for beneficiaries who are dually Medicare and Medicaid eligible. Although they will be auto-enrolled in the available drug plans as soon as they are available to protect them from total loss of medication coverage, because the auto-enrollment process is completely random, the process will maximize the chances that a beneficiary is enrolled in a plan that does not meet their needs. The average Oregon dual eligible has ten to twelve medications. It is highly unlikely that all beneficiaries will be auto-enrolled in plans where the formulary completely matches their current medication profile and their pharmacy of choice.

Experience with the drug discount cards has highlighted the fact that most Medicare beneficiaries are not comfortable with the Internet and using 1-800 Medicare for enrollment. This is especially true for Medicare/Medicaid beneficiaries. A higher percentage have cognitive impairments, ranging from developmental disabilities and psychiatric illnesses to dementia, which not only make these choices almost impossible, but also make these tools irrelevant. The reality is that many individuals in this population will need the assistance of someone else to make these life-impacting decisions. For those without active family or friends, the responsibility for this assistance is likely to fall on Area Agencies on Aging, State Medicaid offices, Community Mental Health Programs and providers of Home and Community-based waiver services or institutions; all of which have other full time responsibilities.

Although additional funding was provided, CMS is relying on contractors in each state, Senior Health Information Programs (in Oregon called SHIBA, Senior Health Insurance Benefits Assistance), to educate Medicare beneficiaries in their choices and to assist them in the enrollment process. Oregon has a total of two staff for this program in the entire state. Those staff

rely on a network of approximately 200 volunteers to provide the actual assistance. Already the volunteers report having been overwhelmed by the drug discount cards. Hence the state has very strong concerns about the system's ability, during the allotted time frame, to handle the 50,000 Oregon dual Medicare/Medicaid beneficiaries, in addition to the over 500,000 general beneficiary population who may also seek assistance.

The task of ensuring that dual Medicare/Medicaid beneficiaries are successfully transitioned into the Medicare drug benefit within the statutory timeframes becomes a task similar to that facing Sisyphus from Greek mythology. Unfortunately, if this process does not go smoothly, Medicare beneficiaries will be harmed, resulting in unnecessary hospitalizations, visits to emergency rooms, and potentially incarceration and homelessness for those with significant mental illnesses.

In the early 1990s, Oregon successfully transitioned Medicaid eligible individuals who were categorically eligible as aged, blind or disabled into mandatory managed care. The primary lesson Oregon learned from that experience was that in order for a major transition project to go smoothly, it must be rolled out over a period of time; smooth transition cannot occur overnight.

Recommended Solutions:

1. Regulatory. CMS should require the Prescription Drug Plans to cover current medications at current pharmacies for the dual eligibles for at least six months. This will allow those assisting seniors and people with disabilities with enrollment to have the entire fall enrollment period plus an additional six months to ensure that people are in appropriate plans, the prescriptions match their chosen formulary. It will also allow long term care facilities and homes to establish critical business relationships with the appropriate pharmacies.
2. Statutory. A better solution would be to allow a full year for the roll out for individuals who are dually eligible. States would need to draw down federal match during this time, but only until the person is enrolled in a Part D Plan. This would allow states to develop plans and transition different groups over the year into the Medicare

benefit. At any one time, only Medicaid or Medicare would be responsible for the medication costs, never both.

Grandfathering or Transition

Current CMS regulations require the new Part D plans to have a transition plan for beneficiaries entering their plan. This regulation has neither detail nor specifics. In addition, CMS has indicated that they will use current Pharmacy Benefit Managers' transition plans as a standard in evaluating the new Part D plans' transition safeguards.

Oregon is concerned that not all beneficiaries should be forced to transition to new medications. This is a very vulnerable population with many conditions that are not common in general populations. Individuals who are stable on particular antipsychotics may never be safe to transition. If forced to switch medication and they decompensate, there are consequences not only to the individual, but to the community. There are also other drug classes where individuals should not be required to transition off their current medications, such as those difficult-to-control seizures or AIDS, among others.

Recommended Solution:

1. Regulatory. CMS should require that Part D plans allow certain individuals to remain on certain classes of medications without needing to use the appeals process.

Appeals and grievances.

Although CMS tightened and improved the process in the final regulations, the appeals and grievance process remains cumbersome and very difficult for people with cognitive impairments. Many physicians are not willing to participate in an unwieldy process. In addition, unlike current Medicaid requirements, the Medicare Part D plan is not required to supply the medication until the appeal process is completed. Many people in this population do not have the ability to purchase medication on their own, resulting in the lapse of coverage of critical medications for some.

Recommended Solution:

1. Regulation. Part D plans should be required to provide coverage throughout the appeal process. In addition to assuring access to needed medication, this will provide an incentive to the Part D plan for timely resolution.

Home and Community-Based Services

Oregon has an extensive community-based long-term care system for both seniors and people with disabilities, including assisted living facilities, residential care facilities, adult foster homes, and group homes. Many facilities and homes individually order all medications and actually administer medication to the clients. Current regulations exclude individuals living in community facilities from the definition of "institutionalized", although by definition in the basic CMS requirements to obtain a Home and Community-Based waiver, these individuals meet "institutionalized" level of care.

Individuals residing in these community facilities must contribute toward the cost of their services and have very limited resources. By excluding them from the definition of "institutionalized", they will be subject to additional copays for their medication. In addition to having extremely limited funds to cover even those minimal costs, they have no real control over their medications and therefore, the copay does not provide an incentive to become a smart consumer. Moreover, it places the facility in the untenable position of collecting the copay from the resident, in order to get medications.

In addition, it is not clear in the current regulations if individuals residing outside of institutions will have access to Long-Term Care pharmacies. These pharmacies provide needed special medication packaging, Medication Administration Records, and other safeguards necessary to ensure that long-term care facility staff – be they staff of a nursing facility, assisted living facility, foster home or group home, safely administer the medications.

Recommended Solution:

1. Regulation. CMS should include individuals residing in community-based facilities in the definition of institutionalized.

2. Regulation. CMS should also require the Part D plans to allow access to Long-Term Care pharmacies for individuals residing in community-based facilities.

Institutions

Nursing and other facilities face unique challenges. They rely upon Long-Term Care pharmacies for vital services to ensure the safe administration of medications. CMS acknowledged this importance in the final regulations. Oregon is concerned, however, that the definition for "dispensing fee" for those pharmacies does not include all of the necessary services from these pharmacies, such as Medication Administration Records, drug reviews, and emergency drug supplies.

Oregon is also concerned about the definition of "institution" in the final regulations. States are currently working with CMS to understand exactly which Intermediate Care Facilities for the Mentally Retarded (ICF/MRs) and psychiatric hospitals are included in the expanded definition of institution in the final regulations. It is extremely important that those institutions that serve Medicare/Medicaid dual eligibles have both access to Long-Term Care pharmacies and the clients are exempted from copays.

Finally, as drafted, the regulations do not appear to create a process by which institutions will know the Part D plans that their clients have chosen. The enrollment process is centered on the individual beneficiary interacting with CMS and the Part D plan. However, facilities have the responsibility for ordering the medications and administering them. Without the ability for facilities to know the Part D plan that an individual has chosen, they will not know the pharmacy available to them.

Recommended Solution:

1. Regulation. The definition of dispensing fee needs to be revised to include the other necessary costs of safe delivery of medication in these settings or another mechanism developed to ensure that these services are provided and reimbursed by the Part D plans.
2. Regulation. The definition of institution needs to include all Intermediate Care Facilities for the Mentally Retarded (ICF/MRs) and psychiatric hospitals that serve Medicare/Medicaid beneficiaries.

3. A process needs to be developed to inform the facility of the client's choice. This may require regulation to allow sharing of this information.

Coordination of Care

Even with the transfer of the drug benefit to Medicare, state Medicaid agencies will continue to provide health services to dual individuals. To assure optimal health care coordination for those individuals, states, without cost, must have access to information on individual-specific medications supplied to dual Medicare/Medicaid eligibles. Under the current rules, CMS will only require Part D plans to share that type of data if the state also has risk in the costs.

Recommended Solution:

1. States should be permitted to have access to information regarding medications supplied to all Medicare/Medicaid dual eligibles and should not be required to purchase it. It is not clear if this would require statutory authority or regulation.

Low-Income Subsidy Eligibility Determination

Medicare beneficiaries qualify for the low-income subsidy in two ways: (1) being eligible for Medicaid and other programs for which states currently have responsibility for eligibility determination or (2) by meeting new and different income and resource standards delineated in the Medicare Modernization Act. Oregon believes that it fulfills its statutory authority to perform subsidy eligibility determination through its existing eligibility determination responsibilities for Medicaid and other programs.

Although CMS and the Social Security Administration (SSA) are establishing a system that will attempt to direct most of the beneficiaries eligible under the new standards to SSA, the CMS final regulations require states to establish a parallel process if a beneficiary demands that the state process the application. This creates an untenable situation for states who have received no additional funding, beyond the offer to provide federal matching, to support this mandate.

In Oregon, SSA plans to send 264,000 letters to Medicare beneficiaries alerting them of their potential eligibility for the subsidy. It is unknown how many of those individuals actually are eligible. It is also unknown how many will demand that the state, as opposed to SSA, process their application. States must prioritize their already limited resources for the population. This additional workload, the primary burden of which will fall during a critical point in state planning for Part D enrollment, has the potential to totally overwhelm the state's ability to successfully transition those most vulnerable individuals who are dually eligible.

Recommended Solution:

1. Regulatory, potentially Statute. Regulations need to be clear that States only have responsibility for those Medicaid populations for whom they currently perform eligibility determinations.

EPSDT Coordination

Medicaid regulations require the State to provide all medically necessary services for children discovered in Early Periodic Screening, Diagnosis and Treatment (EPSDT) examinations. Although the numbers are small, there are children who are both Medicare and Medicaid eligible. Since the drug benefit for duals is no longer the Medicaid responsibility, states should not be required to comply with the EPSDT requirement without federal participation.

Recommended Solution:

1. Regulation. CMS should revise the EPSDT requirement to clarify that states are not responsible for providing medications for these children.

Excluded Part D Medications

Benzodiazepams and barbiturates are excluded from drug coverage under Part D. Although, this may have made sense decades ago when the misuse of Valium and phenobarbitol was common, it is unclear why this outdated exclusion is being continued in Medicare Part D. This exclusion would impact access to important medications for seizure control, for the anxiety common with dementia, and for some psychiatric medication side effects.

Although these classes of medications will not be considered Part D medications, CMS is allowing Part D plans to include these medications as an enhanced benefit. This creates communication and coordination of benefits issues for states. Oregon will continue to cover these classes of medication. How will we know when individual plans agree to cover the medication?

Recommended Solution:

1. Statutory or Regulation. Remove these classes of medications from the excluded list.

Conclusion

Thank you, members of the Senate Special Committee on Aging, for holding this hearing on these important matters. We understand that everyone is interested in the safe and healthy transition of this vulnerable population to this new benefit. We appreciate the extensive work completed by CMS toward this end and believe that the changes outlined above would provide additional protection for Medicare recipients to ensure their successful enrollment in the Medicare Part D benefit.

The CHAIRMAN. I think there is a vote starting. Would you like to go and vote, and I will—I want you to be here for your constituent.

Senator KOHL. I will be right back.

The CHAIRMAN. OK. Carl Clark, please proceed.

STATEMENT OF CARL CLARK, M.D., CHIEF EXECUTIVE OFFICER, MENTAL HEALTH CENTER OF DENVER, DENVER, CO

Dr. CLARK. Thank you, Chairman Smith. I am Dr. Carl Clark. I am the CEO of the Mental Health Center of Denver. I have been practicing psychiatry for over 20 years and I am an assistant professor at the University of Colorado School of Medicine.

The mental health center that I administer serves thousands of uninsured and indigent people every year, most of which have serious mental illnesses, like schizophrenia and bipolar disorder.

My testimony today reflects the consensus views of the National Council for Community Behavioral Health Care, the American Psychiatric Association, the National Alliance for the Mentally Ill, the National Mental Health Association, the Treatment Effectiveness Now Project, the American Association for Geriatric Psychiatry, and the National Association for State Mental Health Program Directors. Although each of these organizations is strongly committed to the successful implementation of MMA, we are concerned about the required transition of dual eligibles to the new Part D drug benefit and here is why.

MedPAC recently estimated almost 40 percent of the 6.5 million dual eligibles have cognitive impairments and mental illnesses. Dual eligibles are twice as likely as others to have Alzheimer's disease, and thus, many of these people may lack the capacity to manage the automatic enrollment process and ensure that they get the medications that they need.

At MHCD, I am personally responsible for the mental health care of a man who is dually eligible. Because of confidentiality, I will call him Peter. He is in his 50's, late 50's. He was homeless for many years, wandering the streets because of untreated schizophrenia. Through a combination of intensive services and the latest psychotropic medications, we got him off the streets. He is living independently in the community. He has gone back to school and connected with his family. He also has diabetes and coronary artery disease. Mr. Chairman, I can tell you that he has a complicated medication regimen.

Because of the special health care needs of dual eligibles, CMS included the provision in the final MMA rule requiring this population to be automatically enrolled in Part D plans, and the mental health community applauds Dr. McClellan for taking this critically important step. However, even with this, we have concerns.

CMS has stated that dual eligibles randomly assigned to plans that don't reflect their current medications can re-enroll into PDPs that do. Based on my clinical experience, I have serious doubts about this approach.

Let us go back to Peter. Even though he is doing well with his schizophrenia, he still has trouble with his memory and speech and information process and decisionmaking. He is going to need a lot of help to negotiate these plans from our case manager and his

mom, who is in her 80's and actually doesn't even live in Colorado. Coverage gaps for particular medications are going to happen, and what we want to do is really minimize that.

So specifically, this is what we propose. People that are clinically stabilized on antipsychotic medications or other psychotropic medications should maintain access to those same medications regardless of the PDP they are enrolled in. This exception to the plan's formulary or utilization process would be automatically granted without prospective review by the PDP when the attending physician provided written certification that the patient is clinically stable, the medication is medically necessary to maintain the functioning, and the physician would also be required to certify that mandatory switching to an alternative drug formulary would be medically contradicted. Plans should defer to the physicians' medical determination.

The CHAIRMAN. Carl, did you hear Dr. McClellan speak to this sufficiently? Did it allay your fears? You are making the point I was trying to make——

Dr. CLARK. Yes. My fears are not allayed because, like Peter as the example, he has three chronic conditions that need to be treated. If he does not get all the medicines for each one of those conditions, he is at risk for hospitalization, emergency room care, and those sorts of things.

The CHAIRMAN. Are you seeing any of the plans out there that would accommodate someone like Peter?

Dr. CLARK. I say that there are lots of people like Peter that are going to be faced with which plan will cover all my medications.

The CHAIRMAN. Just for the record, your point is there needs to be an override of the plan for people like this——

Dr. CLARK. Exactly.

The CHAIRMAN [continuing]. So that their unusual circumstances can be accommodated.

Dr. CLARK. Exactly. Since this final MMA rule requires plans to have an appropriate transition process for dual eligibles during the initial enrollment period, CMS should employ its review authority to ensure that these key continuity of care principles are followed. Let me note that the agency in its own strategy on formulary reviews noted that formularies should contain the majority of antidepressant and antipsychotic medications, and further stated, when medically necessary, beneficiaries should be permitted to continue utilizing a drug that is providing beneficial outcomes.

So the regulatory approach that we are proposing should combine a robust outreach and an education program designated to educate consumers while helping State agencies, patient and family organizations, and community mental health providers furnish one-to-one counseling that clearly will be required.

What is at stake here is that if CMS fails to adopt a common sense approach, like we have outlined, the clinical consequences are serious. A very large percentage of folks will fail on switched medications and this will result in decompensation, hospitalizations, ER visits, and, of course, always the threat of suicide.

For States, the consequences are tough, also. If people don't successfully navigate the transition to Part D, they can wind up destitute, homeless, State prison, State hospitals. So, Chairman, it is

my goal for my staff and myself, who have worked really hard to get Peter off the streets, that we keep it that way.

[The prepared statement of Dr. Clark follows:]

Introduction

Chairman Smith and members of the committee, my name is Dr. Carl Clark and I am the Chief Executive Officer of the Mental Health Center of Denver. I have been a practicing psychiatrist for over 20 years, and I am also an Assistant Professor at the Department of Psychiatry at the University of Colorado School of Medicine. The mental health center I administer serves thousands of indigent and uninsured people annually, including a very large number of individuals with severe mental illnesses like schizophrenia and bipolar disorder.

I am proud to say that this testimony reflects the consensus views of the National Council for Community Behavioral Healthcare (NCCBH), American Psychiatric Association (APA), the National Alliance for the Mentally Ill (NAMI), the National Mental Health Association (NMHA), and the Treatment Effectiveness Now Project.

Vulnerable Dual Eligibles: A Patient Example

Although each of these organizations is strongly committed to the successful implementation of the Medicare Prescription Drug Modernization Act (MMA), we are concerned about the required transition of persons eligible for both Medicare and Medicaid to the new Part D drug benefit. Here's why. Medpac recently estimated that almost 40% of the 6.5 million dual eligibles have cognitive impairments or mental illnesses. Additionally, dual eligibles are twice as likely to have Alzheimer's disease as other Medicare beneficiaries. Thus, many of these persons may lack the capacity to

manage the automatic enrollment process and ensure their enrollment in a plan that provides seamless coverage for the medications they need.

Let me take a brief moment to put human face on those statistics. At the Mental Health Center of Denver, I am personally responsible for the mental health care of a man who is dually eligible. Due to patient confidentiality, I can't tell you his real name, so let's call him Peter. Peter is in his late 50's, and he was a homeless man who wandered the streets of Denver for many years due to untreated schizophrenia. Through a combination of intensive services and some of the latest psychotropic medications, we were able to get him off the street; he's now living independently in the community, and he's gone back to school. You should know that in addition to his severe mental illness, Peter also has diabetes and coronary artery disease. Mr. Chairman, I won't go into the detail, but suffice it to say that Peter is taking a wide array of medications to control each of these chronic illnesses. His day-to-day medical management is extremely complicated.

MMA Enrollment Challenges

Because of the special health care needs of dual eligibles, the Center for Medicare and Medicaid Services (CMS) included a provision in the final MMA rule requiring that this population be automatically enrolled in Part D plans. The mental health community applauds Dr. McClellan for taking this critically important step.

However, even with these provisions, we remain deeply concerned about MMA implementation. CMS has stated that dual eligibles with severe mental illnesses who are randomly assigned to plans that don't reflect their current medication regimens can re-enroll into PDPs that do. Based upon my years of clinical experience with this population, I have very serious doubts about this approach.

Let's go back to Peter for just a moment. His schizophrenia severely impairs his cognitive functioning including memory, speech, information-processing and decision-making. The odds aren't very good that he will successfully navigate the plans available in the Denver region to find one that meets all his medication needs. In effect, the overloaded case managers at the Mental Health Center of Denver and Peter's family will have to help him. But Peter's mother is 80 years old and doesn't even live in Colorado. And my case managers are struggling to handle their existing responsibilities, much less help thousands of patients find new PDPs.

Patient Protections

The end result could well be significant coverage gaps for particular medications required by some of the most disabled people in our society for weeks or even months after initial MMA implementation. By contrast, CMS has the regulatory authority to adopt a more practical approach to ensure continuity of care for this vulnerable population.

Specifically, we propose a regulatory strategy that permits beneficiaries – clinically stabilized on antipsychotic medications and other psychotropic medications – to maintain access to those same medications regardless of the PDP they are enrolled in. This exception to a plan's formulary or utilization process would be automatically granted – without prospective review by the PDP – when the attending physician provided written certification that the patient is clinically stable and the medication is medically necessary to maintain the patient's functioning. The physician would also be required to certify that mandatory switching to alternative drugs on the formulary would be medically contraindicated; plans should defer to the physician's medical determination.

Since the final MMA rule requires plans to have "an appropriate transitional process" for dual eligibles during the initial enrollment period, CMS should employ its review authority to ensure that these key continuity of care principles are followed. Let me note that the agency – in its own strategy on formulary review – noted that formularies should contain the majority of antidepressant and antipsychotic medications and further stated: "When medically necessary, beneficiaries should be permitted to continue utilizing a drug that is providing beneficial outcomes." Of course, the level of agency review we are seeking would supplement the formulary exceptions process outlined in the final rule. In addition, CMS or PDPs would have to furnish providers with the resources – technical or otherwise – to verify enrollment.

This regulatory approach should be combined with a robust outreach and education program designed to educate consumers while helping state agencies, patient and family organizations, and community mental health providers furnish the one-one-one counseling that will clearly be required.

Denial of Continuity of Care: The Consequences

I want to close by emphasizing what is at stake here. If CMS fails to adopt the common sense continuity of care approached we've outlined, the clinical consequences for the individual are serious indeed. The medical literature indicates that a very large percentage of patients forced to switch medications will fail. Typically, this means rapid de-compensation into psychiatric crisis – usually in matter of days. To stabilize the patient again requires an emergency room admission followed by a lengthy stay in psychiatric hospital. Of course, there is the ever present threat of suicide during this terrifying downward spiral.

The consequences for state governments are also significant. It is distinctly possible that dual eligibles with severe mental illnesses who fail to successfully navigate the transition to the new Part D benefit could end up destitute, homeless or in state prison. Mr. Chairman, my staff and I worked very hard over many months to get Peter off the streets of Denver. Let's make sure he stays in school and lives in the community where he belongs.

The CHAIRMAN. Maybe you don't have a percentage, but there is also a public safety component to this. For some of these in this category of people, if they don't have continuity of care, is there a percentage of them that become dangerous?

Dr. CLARK. Well, I will just give an example.

The CHAIRMAN. To themselves, as well?

Dr. CLARK. Yes. At our center, we take care of about 4,500 people——

The CHAIRMAN. Forty-five hundred?

Dr. CLARK. Forty-five hundred, and most of those folks are in voluntary treatment. But we do have 350 people who are in involuntary treatment because they don't have the insight that they have an illness and they actually do become dangerous to the community. So there is a public safety issue here, also.

The CHAIRMAN. What incidents of suicide might there be if they don't have access, if they fall through the cracks, if there isn't continuity of care? I mean, a lot of these people will become unusually depressed, I suspect, may become a danger to themselves. Do you see that in your practice?

Dr. CLARK. Yes, we do. For folks with major depression, bipolar disorder, schizophrenia, the lifetime incidence of suicide is around 15 percent, and that risk goes up when people are not in treatment or if they are not adherent with their treatment.

Just to make a different kind of point, it sounds like drugs are interchangeable, and it is certainly true that some drugs may have similar efficacy, but for the individual person, that may not be true. For the individual person, side effects, which can be severe, can be very bad on one drug and not another, and that often leads to people saying, "I am not taking this medicine anymore."

THE CHAIRMAN. Wendy, I am not ignoring you. I am just waiting for Senator Kohl. [Laughter.]

I would love to hear your testimony, too, because I know you are going to say many of the same things. Don't do your testimony, but if you would like to chime in on any of what the other two witnesses have had and save your testimony for Senator Kohl, if you have a comment to make on that.

Ms. GERLACH. Thank you. I will.

The CHAIRMAN. Tina, you mentioned that in the last transition that you went through, it took a year. Is that what I understood you to say?

Dr. KITCHIN. Chairman Smith, yes. It took a year of working with the population to help them understand their choices and move into care. It took a good year before that of the planning with everybody around the table.

The CHAIRMAN. I think what I heard Dr. McClellan say is that they are contemplating a 3-month transition period. I was suggesting in my discussion with him a 6-month transition period. That isn't a year, but with a running start that we have before January 1, 2006, can you envision being up to speed?

Dr. KITCHIN. Senator Smith, given the three months before plus an additional six months, I feel—I will sleep at night. I am not sure that without that additional six months, it will go smoothly.

The CHAIRMAN. Can you speak to the authorizations given to nursing homes but not necessarily assisted living facilities?

Dr. KITCHIN. Senator Smith, I would be glad to. As you know, as you are well aware, Oregon uses a very extensive community-based system. CMS in the current regulations has really focused on nursing facilities and their access to long-term care pharmacies, the services, and prevention of those institutionalized people from having to pay copays. However, when you have an extensive community-based system, such as assisted living facilities or Developmental Disability group homes, they also need the access to long-term care pharmacies and they need—it is going to be very difficult for the people who are already paying into their cost of their service to come up with the additional amount of money to pay copays. So they need those additional benefits.

The CHAIRMAN. Is there something that CMS should do to get assisted living facilities some standards so that they can qualify like nursing homes to provide for prescription drugs onsite?

Dr. KITCHIN. Senator Smith, I think that CMS has looked at it from a regulatory point of view, and if instead they looked at it from a beneficiary point of view, I think that their regulations could require that the new drug plans allow access to those services and allow the long-term care pharmacies to actually deliver those services in those varied settings.

The CHAIRMAN. To assisted living facilities?

Dr. KITCHIN. To assisted living facilities and the rest——

The CHAIRMAN. Mark is not here anymore, but I want to, through the record, encourage him to do that. I think that that is very important.

Wendy, do you have any comment on any of this so far?

Ms. GERLACH. I do. In the past, the skilled facilities that we see now are becoming very acute settings. The assisted livings are taking over where the skilled has left off. These people have multiple diseases—diabetes, asthma, high blood pressure. They need to have the specialized services that a long-term care pharmacy can provide to them—specialized packaging which cuts down on medication errors, 24-hour-a-day pharmacy services, a pharmacist who is always available for these assisted livings to call with any questions, emergency deliveries. So I think it is very important that we are able to provide these services as long-term care pharmacies to assisted living.

The CHAIRMAN. Any other comment, Carl?

Dr. CLARK. Oh, I could make a lot of comments. [Laughter.]

The CHAIRMAN. Go ahead. We have got time.

Dr. CLARK. OK. Great. I mean, one of the things about the consequences if somebody is on a medicine that works for them, and I can say right now that in psychiatry in particular, we have some medicines that work better than we have ever had in the past and it is so gratifying to see people actually have a life again and be in the community. Like Peter the example, when he reconnected with his mother after being on the streets for 10 years, that is a tremendous thing to see happen.

The CHAIRMAN. What are those drugs? What are the names of them?

Dr. CLARK. His particular drugs? Well, I am sure some of the drug companies would really enjoy my saying the names—— [Laughter.]

But he is on Zyprexa. He is also on lithium, which is a medicine that has been around for a long time. Then he is on a variety of medicines for his diabetes and his coronary artery disease.

But the point is that if somebody has a disruption in care after they have found something that works, that is difficult and the cost can be enormous. In Colorado—I don't know what the cost is in other States, but our State hospital costs about $95,000 a year for a person. So if we have an influx of people that are hospitalized into the system, there are these kinds of costs that are going to occur.

For me, one of the issues is that PDPs are managing a pharmacy budget, but they are not managing the risk for the other types of care that are going to be provided.

The CHAIRMAN. You are shaking your head, Tina. Do you want to say anything about that?

Dr. KITCHIN. Senator Smith, I agree. One of the ways that managed care works the best is that the plan is at risk if they deny a cheaper service and somebody goes into more expensive service, whereas these new drug plans are only at risk for the cost of the medications.

The CHAIRMAN. Let me just tell you publicly, I mean, we are talking here about a Part D corrections bill, things that we could do legislatively, but I will be honest with you. That is a tall order before this is implemented, because I think the Bush administration and perhaps a majority in Congress, and I think many in the leadership of Congress, want to see what the problems are before we start promoting fixes. So part of the reason for this hearing is to get CMS to do as much as they feel they have latitude to transition this smoothly.

But if they don't, can you already envision things that you would like to see in a Medicare Part D corrections bill? Is there something legislative you think that is really missing at this point?

Dr. KITCHIN. Senator Smith, if I could start, it would depend upon the timeframe of it. Obviously, if this could occur before we start rolling out this new drug benefit, a lengthening of the time that States were eligible for Federal participation, so although at one time never are both Medicaid and Medicare at risk for the drug cost, but that we could slow the phase-in process down.

The second of which is that I think having the minimum of two drugs per class works for several different types of drugs, but there are exceptional drugs, or exceptional conditions where really they need to offer the entire gamut of drugs. Those that are treating AIDS, antipsychotics, antidepressants are one of the classes that really come to mind.

In addition, I think that there should be an ability to grandfather in certain people with certain conditions. It is very dangerous to transition somebody with a significant seizure disorder off of their current medications and the attempt to do that can actually cause a seizure that will end somebody's life, although most seizures don't.

In addition, I think that the current framework is based upon assuming that these Medicare beneficiaries can work through an appeals and a grievance process and I have serious concerns about the people that I know being able to respond and say, "No, this

drug is not covered but I have these rights and I can appeal and I need to get my doctor to do this and I need to go through this process." I think that that is beyond a lot of people's ability that I know in this system.

The CHAIRMAN. OK. I am going to go vote and I am going to turn this hearing over to my colleague. But Carl, I would like to just tell you, I have a particular personal reason to make sure that the mental health component of this is done right, and so if it isn't being done right, I want you to yell at me to make sure we use our influence to get it right, because I think the focus of your practice is truly life and death.

Dr. CLARK. Thank you, Senator Smith. It is also quite personal for me, too.

The CHAIRMAN. Thank you.

Ms. GERLACH. Senator Smith, may I address that question?

The CHAIRMAN. Yes. Sure.

Ms. GERLACH. One of the biggest concerns that I have, if there could be a fix, if there are excluded drugs, such as over-the-counter drugs, benzodiazepines, barbiturates, and drugs for weight management. Those we see as a big concern in the long-term care setting. Benzodiazepines can be given for anxiety, and I will throw this example out.

Somebody in the last days of their life are anxious about what is happening to them. One of the drugs that is given to them is called Atavan or Lorazapan, which is a benzodiazepine. Who wants to be sitting in that room and be denied benzodiazepines or the Lorazapan that can give comfort to your loved one while you are watching them pass away?

The CHAIRMAN. Yes. I understand.

Senator KOHL [presiding]. I thank you, Senator Smith.

I am going to introduce Wendy Gerlach right now for her testimony. She is director of Pharmacy Operations in Wisconsin for Roeschen's Omnicare in Milwaukee. For the last eight years, she has worked at Wisconsin's largest long-term care pharmacy, serving nursing homes, assisted living facilities, and correctional care. We are very fortunate to have you here today to describe the unique challenges long-term care pharmacists will face with this new Medicare drug law. We look forward to your testimony.

STATEMENT OF WENDY GERLACH, DIRECTOR OF PHARMACY OPERATIONS, ROESCHEN'S OMNICARE PHARMACY, MILWAUKEE, WI; ON BEHALF OF THE LONG TERM CARE PHARMACY ALLIANCE

Ms. GERLACH. Thank you, Senator. Chairman Smith, Ranking Member Kohl, and members of the committee it is a privilege to appear before you today and especially before my own Senator. My name is Wendy Gerlach and I am the director of Pharmacy Operations in Wisconsin for Omnicare Pharmacy. Omnicare's experienced staff of pharmacists, nurses, and technicians serve approximately one million patients in 47 States. I am grateful for the opportunity to testify today on behalf of the Long Term Care Pharmacy Alliance, whose members provide pharmacy services to more than 60 percent of the 1.6 million nursing home beds in the United States.

The average resident is approximately 84 years of age, suffers from eight distinct diseases, and consumes nine or more different medications concurrently. The instance of cognitive impairment among these individuals is nearly 75 percent. Nationwide, Medicaid currently provides prescription drug coverage for approximately 70 percent of the nursing home residents. It is important to recognize that these residents are not your typical cash-and-carry customers and the specialized pharmacy services they receive are different from retail pharmacy services.

As I noted, they are typically frail elderly and often cognitively impaired. Their pharmacy needs are quite different from those of the average ambulatory Medicare beneficiary who does not reside in an institutional care setting.

As long-term care pharmacies, we provide a large range of specialized services. These services represent the standards of practice developed to assure patient safety and quality care for nursing home residents.

The primary payer for pharmacy services for nursing home residents is Medicaid, which establishes consistent rules for coverage. While States may impose access restrictions, such as preferred drug lists and prior authorization, Medicaid beneficiaries are entitled to access to all medically necessary drugs.

Given the different structures of current Medicaid and future Medicare drug coverage, we remain concerned about the operational impact of multiple plans in each region competing for Medicare beneficiaries. An average-sized nursing facility of 150 beds could conceivably have residents of two or more plans, all operating under different formularies and exception processes. The resulting confusion could increase the risk of medication errors.

In addition, we are very concerned that the MMA specifically disallows coverage of certain drug classes. The excluded classes include over-the-counter drugs, benzodiazepine, barbiturates, and drugs for weight management. Although State Medicaid programs have the option of continuing coverage of these drugs, it is unclear whether they will. Impeding access to these products will almost certainly result in increased hospitalization and higher cost to the program.

Therefore, we believe dual eligibles must be assured access to these excluded drugs. We recommend that Congress strike the

MMA's prohibition on coverage of these drug classes or ensure the States remain obligated to cover the excluded drugs for this population.

While we applaud CMS's commitment to enrollment, the nursing facility staff and the long-term care pharmacy must be involved for enrollment to be successful. The nursing facility can ensure that its residents know which plans include the long-term care pharmacy in their network of providers. In addition, nursing facilities and long-term care pharmacies must be notified of the plan in which the resident is enrolled so that caregivers understand which plan will be responsible for each resident.

Further, moving medically complex patients from a list of well-tolerated and effective drugs to alternatives required by a plan formulary would pose serious challenges. Imagine a common scenario in which a nursing home resident is on eight different drugs covered by Medicaid and three of those are switched at once and there is an adverse event. It would be difficult, if not impossible, to determine which drug caused the adverse event. We strongly encourage CMS to issue very specific guidelines that plans must follow in this regard.

The preferred option is to require a robust formulary for residents of long-term care facilities consistent with the current Medicaid benefit. In addition, an exception process must exist to allow a pharmacist to override formulary restrictions, subject to retrospective review. This option assures that the patient, at least initially, gets the prescribed drug without delay. A pharmacist would dispense a drug and be assured payment from the plan until the retrospective review could be conducted.

To summarize, we make the following recommendations to CMS and to Congress. First, ensure continued access to medically necessary drugs, either by striking the MMA provision excluding coverage of certain drug classes or by requiring States to maintain current coverage.

Second, facilitate enrollment of nursing home residents by notifying beneficiaries, nursing facilities, and long-term care pharmacies of the plan in which the beneficiaries are enrolled.

Third, create a clear standard for plans that will assure access to medically necessary drugs for nursing home residents and will mitigate the risk of switching multiple medications at once.

We believe CMS is diligently working to ensure that beneficiaries are not jeopardized during the transition to Part D and look forward to working closely with CMS, the Congress, and this committee to identify and work through potential areas of concern.

Again, thank you for the opportunity to provide testimony for this very important hearing.

[The prepared statement of Ms. Gerlach follows:]

Long Term Care Pharmacy Alliance

Testimony of the Long Term Care Pharmacy Alliance to the Senate Special Committee on Aging

Chairman Smith, Ranking Member Senator Kohl, and Members of the Committee, I appreciate this opportunity to testify on behalf of the Long Term Care Pharmacy Alliance regarding the implementation of the new Medicare Part D benefit, and the transition for beneficiaries dually eligible for Medicaid and Medicare. The Long Term Care Pharmacy Alliance (LTCPA) represents the nation's leading providers of pharmacy services to residents of long term care facilities, including nursing facilities, intermediate care facilities and assisted living facilities. LTCPA's members provide these services to over 60 percent of all nursing home residents in the United States.

My name is Wendy Gerlach, and I am the Director of Pharmacy Operations in Wisconsin for a company called Roeschen's Omnicare, a leading provider of pharmaceutical care for seniors. Each and every day, Omnicare's experienced staff of pharmacists serve residents in skilled nursing, assisted living and other healthcare facilities, comprising approximately 1,071,000 beds in 47 states, with one goal in mind: to help ensure the health of the senior population in a cost-effective manner. Wisconsin alone had a total of 403 nursing homes in 2003 serving over 36,000 residents, almost 64 percent of which are currently paid for by Medicaid. Though we don't have specific numbers of dual eligibles in Wisconsin, we do know that almost 92 percent of these nursing home residents are over the age of 65 and therefore the majority of the 64 percent of these residents on Medicaid are likely dually eligible, and will therefore be impacted by this transition from Medicaid to Medicare.* These nursing home residents will experience monumental change in the way they receive prescription drug benefits on January 1, 2006. Despite efforts by Congress and CMS to blunt the impact of this change, we believe there is more to be done to assure that the nation's most vulnerable citizens continue to have access to necessary prescription drugs.

As you may know, there are approximately 1.6 million nursing home residents in the United States. This population is disproportionately old and frail. The average nursing home resident is approximately 84 years of age, suffers, on average, from eight, and sometimes more distinct diseases and consumes approximately nine or more different medications concurrently. In addition, the incidence of cognitive impairment among nursing home residents approaches 75 percent, rendering personal participation in their care relatively meaningless.

Medicaid currently provides prescription drug coverage for approximately 70 percent of nursing home residents. An additional 15 percent of nursing home residents are admitted following a qualifying stay at an acute care hospital, therefore their care including prescription drugs is covered under Medicare Part A. Under the Part A benefit, nursing

* http://dhfs.wisconsin.gov/provider/pdf/03nh&r.pdf

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homes are paid a global payment that includes the cost of prescribed drugs. The remaining 15 percent of nursing home residents pay for their prescription drugs from their own resources or from third-party insurance. These residents typically are spending their resources down to the level at which they will eventually qualify for Medicaid.

It is important to distinguish the special pharmacy services provided to long term care residents from outpatient retail pharmacy services. Long term care residents are not your typical "cash and carry" ambulatory pharmacy customers. Instead, they require pharmacies that can dispense their drugs in special packaging, 24 hours a day, to the nursing facility where a nurse will directly administer the drug to the patient in a safe and effective manner.

Under federal regulations, nursing homes have the primary responsibility for assuring that their residents receive appropriate pharmacy services. Nursing facilities generally comply with this obligation by contracting with specialized long term care pharmacies to provide services that help the facility provide the highest level of pharmacy care at reasonable cost.

The long term care pharmacy industry provides these services, including:

- **Specialized packaging**: The simple fact that nursing home residents are not able to administer their own medications necessitates the development and maintenance of systems that clearly identity the drug; the patient for whom it is prescribed; and the frequency of administration. These systems typically revolve around the concept of the unit-dose packaged medications. Long term care pharmacies package each medication in a system that segregates each dose and accounts for each dose administered. This system has resulted in the lowest rate of dispensing errors in the pharmacy industry.

- **Scheduled Delivery**: Once again, the residents we serve do not come to us, we must go to them. Therefore, each long term care pharmacy provides scheduled routine delivery service to each facility it serves. Generally, these deliveries are made twice each day. The delivery consists of boxes of medicine, compartmentalized for each resident.

- **Emergency Deliveries**: Since residents may be admitted at odd hours and residents may be prescribed treatments in response to a physician's intervention, the pharmacy must be ready to provide prescribed drugs between the scheduled delivery hours. This often necessitates the use of contracted couriers or contracted alternative pharmacies that can respond immediately to necessary medications. It is not unusual for a pharmacy that services 5000 nursing home residents to have more than 700 such emergency deliveries in a 30-day period.

- **Emergency Kits and Interim Supplies**: Pharmacies generally supply nursing facilities with emergency kits of lifesaving drugs in order to respond to medical emergencies. They also supply small amounts of commonly used drugs to provide immediate service to newly-admitted residents.

- **Medication Administration and Treatment Records:** In order to properly document medical treatment ordered by physicians and the administration of prescribed drugs, the pharmacy often supplies documents that facilitate this process.

- **Specialized Therapeutic Monitoring and Intervention:** Under federal regulation, nursing homes are required to have each resident's medications reviewed by a pharmacist for proper identification of unnecessary drugs and potential adverse reactions. Nursing homes generally contract separately for this review, although it is frequently performed by an employee of the dispensing pharmacy.

Currently, the primary payer for pharmacy services for nursing home residents is the state Medicaid program. These programs, although functioning differently from state-to-state, have the advantage of local uniformity. That is, for 70 percent of the residents of any nursing facility, the payer (Medicaid) adheres to a common set of rules for coverage of medically necessary drugs. The importance of this is difficult to overstate. It has been well documented that variation in process is the enemy of quality. In addition, Medicaid operates under the general assumption that, while states may impose access restrictions such as preferred drug lists and prior authorization, the recipient is entitled to access to all medically necessary drugs. Therefore, in practice, we have found that nursing home residents typically get the drugs they need in a timely manner regardless of their preferred status under Medicaid.

We anticipate that the Medicare Modernization Act (MMA) will have a significant impact on long-term care pharmacy services. The philosophical foundation of the MMA is that the combination of market dynamics and consumer choice will result in higher quality at lower cost. This assumption is not unreasonable. The long history of quality improvements resulting from private sector competition is replete with examples of innovation and efficiencies that have advanced the American economy and resulted in better lives for each generation.

The Part D experiment, as applied to the 38 million Medicare beneficiaries who are not residing in long term care facilities, may also succeed in producing similar results. However, the Medicare beneficiaries who will achieve the most robust benefits will likely be those who can avail themselves of the competing choices and make conscious decisions as to the best option that will suit their individual needs. These beneficiaries will most likely have little, if any, cognitive impairment and will generally not be the frailest of the Medicare population. In short, the beneficiaries most likely to benefit the most will be the healthiest and most engaged cohort of the Medicare beneficiary pool.

Congress was generous in expanding low-income subsidies and cost sharing limitations to beneficiaries with incomes below 150 percent of the federal poverty level (FPL), with the most generous subsidies being reserved for beneficiaries below 135 percent of the FPL. Since Medicaid coverage generally begins at about 75 percent of the FPL, these subsidies will encompass a significantly higher percentage of long term care residents than the current 70 percent who currently qualify for full coverage under the Medicaid program. As a result, we expect that more than 80 percent of long term care residents will be exempt from any financial participation in support of the Medicare drug benefit.

Nevertheless, we remain concerned about the operational impact of the transition from the current model, in which Medicaid is the dominant authority in drug benefit delivery to the long term care population, to the new model where multiple prescription drug plans (PDPs) within each region will compete for Medicare beneficiaries. This transition is expected to result in a fragmented decision-making system within the nursing facility. An average-sized nursing facility of 150 beds could conceivably have residents of two or more PDPs, all operating under different formularies and exceptions processes. The resulting confusion could increase the risk of medical errors. The task of managing several formularies and exception processes over small resident populations not only creates administrative complexities, but also potential treatment problems. I hope that my testimony will help Congress and CMS identify potential areas of concern and possible solutions to mitigate this confusion.

Drugs Excluded from the Basic Part D Benefit

We are very concerned that the MMA specifically disallows coverage of certain drug classes in the standard benefit plan of a PDP. These mandatory exclusions include such classes as over-the-counter (OTC) drugs, benzodiazepines (used for the treatment of anxiety disorders), barbiturates (used for the treatment of some seizure disorders) and drugs for weight management. Although state Medicaid programs have the option of continuing coverage of these drugs, there is some uncertainty as to their willingness to do so. Impeding access to these products will almost certainly result in increased hospitalization and higher costs to the program.

Benzodiazepines

Benzodiazepines are a class of psychotropic medication used to treat anxiety, seizure disorders, panic attacks, and insomnia. All benzodiazepine medications marketed in the United States are available in generic form and are relatively inexpensive. Examples include diazepam (Valium), alprazolam (Xanax) and temazepam (Restoril).

No suitable alternative exists for these medications. Treatment of acute anxiety, panic attacks, certain types of seizures and other disorders will be difficult, if not impossible, without these medications. Dual eligible beneficiaries, especially those in long-term care settings may lose access to these medications. Approximately 1.7 million of the 6.4 million dual eligibles are estimated to be taking benzodiazepines. In nursing facilities, 12 percent of residents take benzodiazepines. Without coverage of these medications, physicians may turn to alternative medications that are more costly and/or more toxic, such as atypical antipsychotics and meprobamate (an older medication that is highly sedating and addictive).

Barbiturates

In addition, phenobarbital is a barbiturate widely used for seizures in the elderly. About 2 percent of nursing home residents are estimated to be taking these medications. This drug is currently excluded from coverage by the MMA statute.

Weight Loss

Unintentional weight loss can occur in individuals with cancer, AIDS, or other medical conditions. A number of medications are used to treat weight loss in these populations. Nursing facilities have a publicly reported quality measure on weight loss that tracks their ability to manage this condition in their residents. Without access to medications to treat this condition, nursing facilities and their residents will be adversely impacted when Medicare Part D is implemented.

Over-The-Counter Drugs

Many OTC drugs are a necessary adjunct to maximize the benefit from prescription agents. Iron supplementation is needed with the erythropoetic therapies Procrit® and Aranesp®. Calcium supplementation is necessary with osteoporosis therapies such as Actonel® and Miacalcin.® Acetaminophen is considered first line therapy for the treatment of mild to moderate musculoskeletal pain in the elderly. Stool softeners are necessary to prevent opioid-induced constipation. When OTC medications are a necessary concomitant therapy, there is risk of therapeutic failure when the covered entity is used alone.

The potential loss of this coverage with the implementation of Part D will lead to cost shifting to an already burdened elderly population residing in LTC facilities. When OTC drugs become out-of-pocket costs, Medicare recipients will likely request the physician to prescribe a more expensive covered prescription medication at an additional cost to the program.

Recommendation

Therefore, we recommend that dually eligible beneficiaries be assured access to these excluded drugs. Since full-dual eligibles remain Medicaid beneficiaries, we believe that either states should remain obligated to cover excluded drugs for this population, or that Congress must strike the MMA provision prohibiting PDPs from covering these drug classes.

Enrollment

I know that enrollment is a concern we share with others on the panel who have testified. Medicaid will not be an option for coverage for dually eligible beneficiaries as of January 1, 2006. Though the vast majority of long term care residents will be within the Medicare Part D subsidized population, it is imperative that these beneficiaries are enrolled in a PDP by January 1, 2006. CMS has worked hard to address this issue and has provided continued assurance that these beneficiaries will be automatically enrolled into a PDP, and will of course have the option to enroll in their own choice of PDP, perhaps beginning as early as September of this year.

We applaud CMS' commitment to enrollment, but must emphasize that the nursing facility staff and long term care pharmacy must be involved for enrollment to be successful. The nursing facility can ensure that its residents are aware of the PDPs that include the long-term care pharmacy in its network of providers. In addition, nursing facilities and long-term care pharmacies must be notified somehow of the PDP in which the resident is enrolled so that all concerned caregivers understand which plan will be responsible for each resident.

Otherwise, the facility and pharmacy could be left not knowing what formulary and exceptions process to follow, or what entity to bill.

Transition to Part D Formularies

Many interested parties have expressed concern that moving medically complex patients from a list of well-tolerated and effective drugs to alternatives necessitated by adherence to a plan formulary will present serious challenges. We join in that concern. Imagine a common scenario in which nursing home patient is on 8 different drugs, and 3 of those drugs turn out to not be on the PDP's formulary beginning January 1, 2006. If the nursing facility switches all 3 of the patient's non-formulary drugs at once, and an adverse event occurs, it will be difficult if not impossible to determine which drug caused the adverse event. CMS has recognized this as a priority and has communicated that it will require plans to establish a transition process and that CMS will review this process for reasonableness. We strongly encourage CMS to issue very specific guidelines that PDPs must follow in this regard. LTCPA offers the following recommendations for Congress and the Administration that we believe will help minimize the inherent risk of such a massive transition by maintaining a consistent formulary for long term care residents:

- The preferred option is to require a robust formulary for residents of long term care facilities. This option would be most consistent with the Medicaid benefit currently enjoyed by nursing home residents.
- The next option is to create an exceptions process that allows for a pharmacist to override a formulary restriction, subject to retrospective review. This option assures that the patient, at least initially, gets the prescribed drug without delay. A pharmacist would be allowed to dispense a drug and be assured payment from the PDP until the retrospective review is conducted.

Conclusion

To summarize, LTCPA makes the following recommendations to CMS and to Congress as we work together to make the transition from Medicaid to Medicare Part D as smooth as possible for dually eligible beneficiaries.

1. Maintain access to excluded drugs either by requiring state coverage, or by striking the MMA provision excluding coverage of certain drug classes.

2. Facilitate enrollment of nursing home residents by notifying beneficiaries, nursing facilities and long term care pharmacies of the PDP in which beneficiaries are enrolled.

3. Create a clear standard for PDPs that is available to all interested parties with regard to nursing home residents that will assure access to medically necessary drugs, and will mitigate the risks of switching multiple medications at once.

In closing, we believe CMS is diligently working to assure that beneficiaries are not jeopardized during the transition to a Part D benefit and look forward to working closely

with Congress and CMS to identify and work through potential areas of concern. We thank the Committee for the opportunity to provide testimony for this important hearing and pledge our continued support in your efforts to assure a successful implementation of this program.

Wendy A. Gerlach, R.Ph.

Employment Experience

***Roeschen's Omnicare Pharmacy*, Milwaukee, WI.** **1997-present**

Wisconsin's largest long-term care pharmacy servicing nursing homes, assisted living facilities and correctional care

Director of Pharmacy Operations

Responsible for overall direction, coordination, and evaluation of internal pharmacy operations. Ensures unit is in accordance with state and federal laws and with Omnicare's corporate policies.

- Manages a staff of sixteen pharmacists and six technician managers who supervise all of the employees in the Prepacking, Data Entry, Medical Records, IV, Purchasing, Controlled Drug, and Pharmacy.
- Designated as HIPAA compliance officer by unit president.
- Interview, train, appraise, and discipline pharmacists, technicians, and pharmacy interns
- Oversees educational services that provide newsletters, programs, and in-servicing to facility staff.

***Kroger Company*, Louisville, KY** **1994-1997**

Multi-billion dollar grocery store chain headquartered in Columbus, OH

Pharmacy Co-Manager

Responsible for processing prescriptions, managing and ordering inventory, servicing customers and consulting with medical personnel. Worked with staff of seven.

- Selected for temporary assignments in high volume pharmacies as needed, processing with staff up to 600 prescriptions in 12-hour time frames.
- Exceeded corporate expectations by achieving 98.5% of bi-annual store goal as part of management team.
- Trained pharmacists, pharmacy technicians, interns and co-op students.
- Worked with third-party providers on reimbursements, rejections and drug utilization review.

***Revco, Inc.*, Louisville, KY** **1993-1994**

Regional retail pharmacy chain

Staff Pharmacist

Responsible for processing prescriptions, servicing customers and consulting with medical personnel.

- Processed an average of 100 prescriptions per 12-hour day.
- Counseled customers on use and effects of medications.
- Worked with third-party providers on reimbursements, rejections and drug utilization review.

***Fifth Avenue Pharmacy*, Cedar Rapids, IA** **1992-1993**

Independently owned retail pharmacy which specializes in long-term care and prescription compounding.

Pharmacy Intern

Responsible for compounding prescriptions, receiving telephone orders for long-term care facilities, counseling customers on use and effects of medications and processing prescriptions.

- Acquired knowledge of long-term care pharmacy procedures, including unit dose delivery systems and guidelines regarding long-term care.
- Gained specialized knowledge and experience in the art of prescription compounding.
- Became familiar with Ostomy terminology and supply requirements.

PERSONAL INFORMATION

DOB: 3/28/70
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EDUCATION

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COLLEGE: University of Iowa 1988-1993
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PROFESSIONAL ASSOCIATIONS

American Society of Consultant Pharmacist

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Senator KOHL. Ms. Gerlach, there has been some discussion about creating a transition period where nursing home residents could slowly transition from Medicaid plans which cover their current drugs to the new private Medicare drug plans which may or may not cover all their drugs. In your opinion, how long of a period would you recommend, and what other factors should be considered and included in this transition period?

Ms. GERLACH. Sir, I think that the transition period should be six months to one year. This would allow us to move people slowly to the preferred drug. Maybe we could go by categories so that it is easier for the facilities, the pharmacies, the physicians, so that they know which medications we are supposed to be working on. I just think that we need at least six months to a year to make a smooth transition, to make sure those people that are in those nursing home beds aren't prone to medication errors or go without their medication.

Senator KOHL. So I would take it from your answer and your testimony that you are very, very concerned if this whole process is supposed to commence, period, on the first of January with no transition, that regardless of whatever preparation they think they are making, there will be problems that become insurmountable if this is supposed to occur on the first of January without a transition?

Ms. GERLACH. Yes, sir. We have thousands of residents that we currently serve in Wisconsin and I am very concerned about the transition on January 1, if it is immediate. How hard is it if you have a 150-bed facility and you have 100 people that are dual eligibles now and on January 1, you have all these different medications. Are the nurses going to remember to pull the card? Is a new order going to be written in the chart? It is not only a concern on the pharmacy part, but also the nursing part and the facilities. They are very busy. They are understaffed. We don't want to overwhelm the facility nursing staff, either, which could lead to medication errors on their part.

Senator KOHL. Mr. Clark, do you have an opinion about January 1 and whether or not that should be just the beginning of a transition period?

Dr. CLARK. I think it should just be the beginning. I mean, switching is not an automatic process. It is—when you were out of the room, I talked a little bit about how drugs are not necessarily interchangeable. There is a time period for adjustment. There may be side effects that the person experiences with one drug that they didn't with another and all those things need to be addressed. It is a very short time line to accomplish all this.

My center takes care of 4,400 people. We have 1,400 people that this is going to be an issue for. It is going to be a big burden for case managers and the staff to help people with the transition, select plans, and a variety of things like that. In our group, we have some folks that definitely have cognitive impairments and need help with executive decisions and making decisions.

Senator KOHL. Dr. Kitchin.

Dr. KITCHIN. Senator Kohl, I also would concur that a 6- to 12-month period would be the best. I think that 6 months would be a minimum in which this would happen safely.

Senator KOHL. Do you have any indication that Dr. McClellan understands what you are saying and is coming from the same direction, or are you concerned that they are not interested in this six-month transition? Wendy? Or don't you have a sense of it at this point?

Ms. GERLACH. Sir, I don't have a sense regarding that, but what I would like to say is that we want to work with CMS to make sure that this benefit works smoothly and that the people that we are serving are not in danger. All we want to do, as long as we know the rules, we can work within those rules. But we need to work with the people making the rules to make sure that they benefit the beneficiaries.

Senator KOHL. Mr. Clark, any sense of what CMS is thinking at this moment?

Dr. CLARK. I thought there was one disconnect for me, which is when you asked the question about somebody going to the pharmacy and now their medicine is no longer on the formulary for their plan, what would happen, and the response was that these PDPs needed to be able to have a plan in place to assure a transition. Well, the reality is that the pharmacy plans aren't doing the transition. The providers are doing the transition. So there is a disconnect there for me about how that is actually going to occur.

When CMS says that there are good practices out there about transitioning people from one drug to another, I am glad there are. I think most providers don't know what those are.

Ms. GERLACH. Can I make a brief——

Senator KOHL. Yes, Wendy?

Ms. GERLACH. In the nursing home, it is a three-way communication. It is not just between the physician and the pharmacy. It is between the physician, the nurse at the nursing home, and the pharmacy. So the physician will write an order, he will communicate that to the nursing staff, the nursing staff will communicate it to us. Then if the drug is not covered, we have to backtrack, go back to the nurse so that she will know this is not covered so that she can contact the physician and get it covered so that it will get switched to the correct medication.

It is an administrative nightmare for everyone, and who is going to do the work for the prior authorizations? Who is going to take all the work that is required to submit all that information to the PDPs? That is not answered. There is no clear-cut plan that has been told to us, these are the steps you are going to follow.

Senator KOHL. OK. Dr. Kitchin?

Dr. KITCHIN. Senator Kohl, I think that CMS has been working within very, very tight timeframes. I think they have done a heroic effort to reach out and get input from lots of people. However, I don't think that they have had some of the day-to-day experience of doing these transitions and understand some of the implications.

Senator KOHL. All right. Does anybody else want to make comments about anything that you feel needs to be brought to the table and put under the lights, any issues at all? Wendy, do you want to speak first?

Ms. GERLACH. Yes, I will. There is another concern that we have. What happens to the residents that are switching over from Medicare Part A or coming directly from the hospital and they have

been stabilized on their medications and then they transition into Medicare Part D? Is there going to be a transition period for those residents, also, three months, six months, so that we can switch those people over appropriately and not take them off their medications as soon as they leave the hospital?

Senator KOHL. All right. That is a good question.

Tina, do you have anything else you would like to bring to the table?

Dr. KITCHIN. Senator Kohl, yes, I would like to make a couple more comments that I don't feel I had time to do, one of which is I think that the appeals and the grievance process is still—it has been tightened tremendously, but it is still cumbersome for a lot of people in this population and I think that CMS needs to require that the drug plans cover the medications during the time that the person is going through their appeals or grievance.

I am also concerned about the coordination of benefits requirement. Right now, CMS has said that it doesn't believe that CMS has the authority to share detailed drug information with the States if the State is not also at cost risk for that medication, and yet we will still be providing a significant number of medical services to those dual eligibles and we need to have access to that information without states paying the drug plans for it.

Senator KOHL. All right. What we will do, if you would like, in the absence of Dr. McClellan—I wish he were here right now. I think it would be great to give you a chance to ask him some of these questions and get the answers from him. But if you want us—and we will, I would like very much to present your questions directly to him and get an answer from him so we can get back to you with some of these comments and thoughts that you have had.

Carl, do you want to make any comments yet?

Dr. CLARK. Well, the only comment I would say at the end here is that what is the real cost for failure? I mean, there is certainly the cost to the individual person about getting ill again or having difficulties in that way, but there is a ripple effect. It is not just that person. It is also the families, the providers, everyone is affected by things when they go awry, and I think that is what people are most concerned about, is how do we assure that people who are already doing well on their current medicines have something in place where they continue to do well?

Senator KOHL. No question. It is crucial. We certainly do not want a catastrophe on January 1. That would be a terrible, terrible thing. In fact, there is no sense of a deadline on January 1. As you are pointing out, that should be the beginning of a process. It is not the end, it is the beginning, and there is no need for us to feel that this thing has to be fully in place and operational on January 1. I would like to hope that Dr. McClellan feels that way, but we will find out.

Anything else, guys? Wendy?

Ms. GERLACH. No, sir.

Senator KOHL. No?

Dr. KITCHIN. I would just like to thank you for this opportunity. It has been very good to have this occasion to express our concerns.

Senator KOHL. Thank you. It has been a good hearing and I think it gives us the warnings and tells us that we need to be care-

ful and cautious in how we proceed, so your coming here and testifying has been really important. Thank you so much.

Dr. CLARK. Thank you.

Dr. KITCHIN. Thank you, sir.

Senator KOHL. The committee is adjourned.

[Whereupon, at 4:08 p.m., the committee was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR JAY ROCKEFELLER

I am very pleased that Senators Smith and Kohl are holding this important hearing today. The transition of 6.4 million dual eligibles from Medicaid prescription drug coverage to Medicare Part D represents the largest transition of beneficiaries from one insurance program to another, public or private. It is essential that we in Congress work to ensure as smooth a transition as possible so that no senior or disabled individual experiences a gap in prescription drug coverage.

Medicare beneficiaries who also qualify for full Medicaid are among our nation's most vulnerable citizens. They are disproportionately women and minorities and live alone or in nursing homes. Over half are limited in activities of daily living and, in comparison to other Medicare beneficiaries, they are much likely to have heart disease, pulmonary disease, diabetes, or Alzheimer's. Therefore, it is crucial that we get this transition right the first time.

The Medicare Modernization Act of 2003 (P.L. 108–173) rightfully included Medicare prescription drug coverage for dual eligibles. Medicare's universality is something I fought hard for during the Medicare debate. I strongly believe that low-income seniors and disabled individuals should not be excluded from Medicare benefits because of their income levels. While the Medicare law seems to support the principle of universality, it simultaneously undermines it by treating dual eligibles differently from other Medicare beneficiaries.

The law provides Medicare beneficiaries who are not dually eligible for Medicaid six months to transition to Medicare Part D. Yet, the law only requires a six-week transition period for dual eligibles, from November 15, 2005, to January 1, 2006. Moving a large number of seniors and people with disabilities to an entirely new system for prescription drug coverage is a major undertaking. In its June 2004 report to Congress, the Medicare Payment Advisory Commission (MedPAC) suggested that even large, private employers need at least six months to transition their employees' drug coverage from one pharmacy benefit manager to another. The two large employers that MedPAC studied had 25,000 and 75,000 employees, respectively. The states and the federal government are taking on a far more complex task with 6.4 million dual eligibles.

Dual eligibles require adequate outreach, education, and timing in order to adjust to major changes in our health care delivery system. The Centers for Medicare and Medicaid Services (CMS) has taken several steps to improve the transition of the dual eligibles from Medicaid to Medicare. However, I fear these steps do not go far enough. Automatic enrollment does not guarantee that beneficiaries will know that they have been enrolled in a new Medicare drug plan or know how to access necessary prescription drugs using that drug plan. Once beneficiaries are enrolled, they are likely to experience ongoing confusion about covered drugs, authorized pharmacies, and the Medicare appeals process.

In order to achieve the best possible outcomes for dual eligibles transitioning to Medicare, we should extend the transition period to at least six months. An extended timeframe would give states enough time to carry out comprehensive education and outreach initiatives. It would also give seniors and individuals with disabilities time to explore their options and gradually transition to Medicare Part D.

I have drafted legislation—the Medicare Dual Eligible Coverage Act—which would achieve all of the objectives mentioned above. I plan to introduce this legislation next week, and I urge the Members of this Committee to support it. I thank the distinguished Chairman and Ranking Member for allowing me to submit a statement on this critical issue.

QUESTIONS FROM SENATOR KOHL FOR MARK MCCLELLAN

Question. Today we discussed the challenges with the implementation of the Medicare Part D program for dual eligibles. Dual eligibles are also a significant part of nursing home populations and the President's budget includes a $1.5 billion reduction in Medicare payments to nursing homes. As a result, in real terms the payment would be lower per day than it was in 1998 if the President's budget is enacted.

When rates dropped in 1998, 15 percent of nursing homes in the country went into Chapter 11, and 7 out of the 12 publicly traded companies filed Chapter 11. As a result, Congress increased the rates and stabilized the industry.

In December, you and then Secretary Tommy Thompson held a press conference in which you congratulated the industry for its efforts on improving quality. Can you assure the Committee that as a result of the implementation of the President's budget there will not be a loss of the quality improvements made, a reduction in the nursing home workforce or a disruption in the delivery of nursing home services to either Medicare recipients or dual eligibles?

Answer. We realize that the elimination of the $1.5 billion temporary add-on to the skilled nursing facility (SNF) prospective payment system raises concerns about how the change will impact the quality of care in our nursing homes. First, I want to assure you that quality improvements in nursing home care have been a priority for this Administration and we plan to continue our efforts in this direction.

Second, I want to point out that, while it is true that a number of nursing homes filed for bankruptcy shortly after the introduction of the SNF prospective payment system, the financial problems these companies experienced were not necessarily related to the SNF prospective payment system. In fact, a Government Accountability Office review ("Skilled Nursing Facilities: Medicare Payment Changes Require Provider Adjustments but Maintain Access," GAO/HEHS–00–23, December 1999) of two of the largest publicly held chains (Vencor and Sun Healthcare Group) found that the financial position of both firms suffered from high capital-related costs; substantial, non-recurring expenses and write-offs; and reduced demand for ancillary services related to several other provisions in the Balanced Budget Act of 1997. Vencor's SNF operations remained profitable after the implementation of the SNF prospective payment system. In addition, there were a number of media reports that cited rapid expansion into other lines of business, high capital costs, and inadequate cost controls as other factors influencing the financial status of the SNF industry.

The Department of Health and Human Services' Office of Inspector General (OIG) conducted two studies on beneficiary access under the SNF prospective payment system ("Early Effects of the Prospective Payment System on Access to Skilled Nursing Facilities," OEI–02–99–00400, August 1999; and, "Early Effects of the Prospective Payment System on Access to Skilled Nursing Facilities: Nursing Home Administrators Perspective," OEI–02–99–00401, October 1999). These studies, which surveyed nursing home administrators and hospital discharge planners, found no widespread access problems in placing Medicare beneficiaries in SNFs. The OIG confirmed these preliminary findings in a follow-up study, "Medicare Beneficiary Access to Skilled Nursing Facilities: 2000," OEI–02–00–00330, September 2000, which indicated that almost all discharge planners reported being able to place Medicare beneficiaries in SNFs. Further, Medicare data show a decrease in the average length of hospital stays for beneficiaries prior to a SNF admission, suggesting that the hospital stays are not being prolonged by a delay in SNF placement.

While Congress enacted four add-on payments to the SNF prospective payment system rates, the intent was to establish the adjustments as temporary measures only. In fact, two of the temporary add-on adjustments expired, according to statute, in 2002. At that time, there were also concerns about the negative impact the payment reduction would have on quality. These concerns were not realized, as evidenced by the positive profit margins reported for the SNF industry. In its March 2005 report, the Medicare Payment Advisory Commission estimated that the estimated aggregate 2005 Medicare margin for freestanding SNFs (the majority of SNF providers) is 13 percent.

The remaining two add-on payments (a 20 percent increase for 12 complex medical payment groups plus a 6.7 percent increase for 14 therapy groups, and an across the board 128 percent increase for beneficiaries with AIDS) are scheduled to expire when the Centers for Medicare and Medicaid Services implements refinements to the case-mix classification system. The President's FY 2006 budget request assumes the implementation of case-mix refinements in the coming fiscal year. Any such proposal would be introduced through the rule-making process and would be open for public comment.

Statement for the Record

Robert M. Hayes
President
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March 3, 2005

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Chairman Smith, Senator Kohl, and Members of the Committee,

Thank you for holding a hearing today on a critically important subject – how the Medicare Modernization Act (MMA) will affect the millions of so-called "dual eligibles," Medicare's most vulnerable, poorest, and sickest individuals, who are enrolled in both Medicare and Medicaid. The nearly six-and-a-half million "dual eligibles" have the unfortunate distinction of being at greatest risk of being harmed by the MMA. Under the law, they will lose Medicaid drug coverage and replace it with Medicare coverage literally overnight on January 1, 2006. There is no margin for error, and if the transition does not go perfectly, dual eligibles will have nothing to fall back on to get the medicines they need.

In our view, it is essential that the federal government act swiftly to ensure that it does not violate the most fundamental principal of health care: do no harm. We look to Congress to ensure that their transition to Medicare drug coverage is smooth and assures that they can get the drugs they need when they need them.

In addition to trading Medicaid drug coverage for Medicare coverage, "dual eligibles" are singled out for another special distinction in the MMA scheme: they are the only group guaranteed to be enrolled in Part D plans on the very first day that Medicare drug coverage begins. The rest of Medicare's 35 million beneficiaries will be able to wait a few months to see how the Part D plans are working before they must decide whether to enroll. If dual eligibles' transition experience is rocky, it could bode very badly for the success of the entire Part D benefit.

But the prospects for a smooth transition are dim. Despite CMS's best efforts to add a few weeks to the transition timetable, there is simply not adequate time to ensure that the frailest people on Medicare will be able to access needed medications when Medicaid drug coverage ends on January 1, 2006. If there are gaps in drug treatment, there will be unnecessary hospitalizations, disease progression, drug resistance, and deaths. The stakes for this transition are very high.

There are so many ways that many of America's most vulnerable men and women can fall through the cracks of this transition. They could move during the transition period and not receive their Part D card on time; they could receive it and toss it, or misplace it, as we have all done; they could remember to bring it with them to the pharmacy on January 1 but not realize that their old pharmacy is not in their new network; or they could make it to the right place with the right card only to learn that their plan doesn't cover the right drug for them. The potential for problems is endless; the time to resolve them is extremely short.

The attached analysis, *MMA and Dual Eligibles: A Transition in Crisis,* was developed by a small working group led by the Medicare Rights Center, a national consumer service organization. It provides greater detail on the nature of the challenge posed by the dual eligible transition under the MMA. And it proposes a way for Congress to buy more time for the critical education and outreach activities needed to ensure that "dual eligibles" have access to the drugs they need on January 1, 2006 and thereafter. In short, Medicaid should be permitted to continue for a targeted transition period as backup coverage to new Part D plans.

This way, the neediest and frailest men and women with Medicare can ease into a complex new program with a familiar safety net, Medicaid, for the first few months of the program.

MMA and Dual Eligibles: A Transition in Crisis

March 2005

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Acknowledgements

This analysis was prepared by a small working group coordinated by the Medicare Rights Center. Contributors include Andrea Cohen, Karen Davenport and Kim Glaun of the Medicare Rights Center, Patricia Nemore of the Center for Medicare Advocacy, and Jeff Crowley of the Health Policy Institute, Georgetown University.

Medicare Rights Center

Medicare Rights Center (MRC) is the nation's largest independent source of health care information and assistance for people with Medicare. Founded in 1989, MRC helps older adults and people with disabilities get high-quality, affordable health care. MRC provides telephone hotline services to individuals who need answers to Medicare questions or help securing coverage and getting the health care they need. MRC brings the consumer voice to the national debate on Medicare reform.

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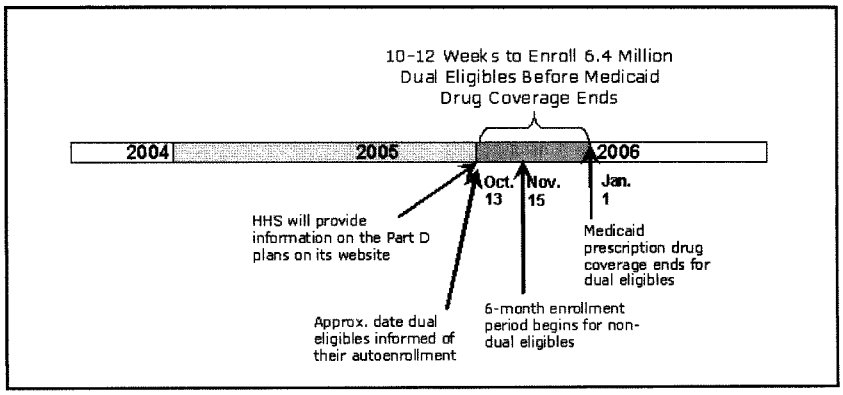
Overview: The Medicare Modernization Act (MMA) eliminates Medicaid drug coverage for 6.4 million dual eligibles (those enrolled in both Medicare and Medicaid) and moves them into Medicare drug coverage on January 1, 2006. Because Medicaid coverage ends on the first day that Medicare coverage is effective, the transition leaves literally no margin for computer error, system failures, postal delays, or inevitable disruptions and confusion involved in moving millions of the frailest older and disabled adults out of one program and into a very different one.

- Under the current timetable, millions of dual eligibles could experience gaps in treatment during the first months of the Medicare prescription drug benefit. Such gaps would have catastrophic consequences, including increased hospitalizations, disruptive behaviors, disease progression, drug resistance, and premature death, and result in a failed rollout of the MMA for the first group required to enroll in Part D.

- In final rules implementing the MMA, CMS recognized special concern for dual eligibles. But the CMS approach – adding a few more weeks on the front end of the enrollment timetable – is inadequate. While helpful, it will not avert a transition crisis.

- Avoiding a crisis will require enough time to implement a comprehensive education and transition plan involving states, CMS, health advocates, providers and drug plans. The plan must include a limited period in which Medicaid serves as back-up drug coverage for dual eligibles.

Timeline for Dual Eligibles' Loss of Medicaid Drug Coverage and Transition to Part D



Key Transition Challenges For Dual Eligibles:

1. Data/System Barriers: Full coverage for dual eligibles on January 1, 2006 will require perfect data and perfect data transfers between states, CMS, and multiple drug plans. CMS must:

Example: Ms. R

Ms. R is 33 years old and has severe physical disablities. She is well aware of the changes in Medicaid drug coverage and has been informed that she will be automatically assigned to an appropriate plan in time to refill her prescriptions in January, 2006. On December 15, she still hasn't received a new Part D card. She calls her state Medicaid office and is told not to worry, she will be assigned to a plan and cards will be sent at the end of the week. On January 5, she still hasn't received a card and her prescriptions are running out. She calls again and is told that they don't have a record of her as a dual eligible, and therefore haven't assigned her to a plan. She will have to go to the Medicaid office with her card to straighten it out. She arranges a ride and goes to the office the next day, where she waits in line for 5 painful hours. At the end of the day, she is told that she must wait for her new plan to process her enrollment and to send her a Part D plan card before she can fill her prescriptions.

- obtain and maintain complete, up-to-date names and addresses of dual eligibles from 51 Medicaid programs;
- match the 6.4 million individuals with appropriate plans in their regions;
- ensure that all assignments are accurately communicated to the plans and to beneficiaries;
- accommodate changes within the 10-12 week period from individuals who move or change their mailing address, whose Medicaid eligibility varies month-to-month, and those who elect to switch plans during the enrollment period.

2. Education and Access Barriers: The biggest challenge to autoenrollment is educating dual eligibles how to navigate a complex new world of competing plans, formularies, and pharmacy networks. In order for dual eligibles to fill prescriptions using their new Medicare coverage, CMS will have to ensure that by January 1, 2006, each dual eligible knows and understands:

- her Medicaid card will not work at a drugstore anymore,
- which Part D plan she is assigned to;
- which pharmacies she can use to fill prescriptions;
- which of her drugs are on the new plan formulary;
- what to do if a drug she takes is not on the plan formulary;
- what her copayments will be at the pharmacy (and that she must pay or not get her drugs).

Example: Mr. H

Mr. H is 75 years old, lives on his small Social Security check in a small town in Eastern Montana, and takes medication to control his high blood pressure and diabetes. He learns that he has been automatically enrolled in a Part D plan when he receives a Part D plan card in December 2005. In late January, he brings the card with him when a neighbor drives him to the nearby pharmacy he has used for 40 years to refill his prescriptions. His pharmacist tells him that the pharmacy is not part of his new plan's network and he can't use his Medicaid card to buy his drugs any longer. Several days after that, he confides in his son that he has run out of his medications and doesn't know where to turn. His son calls 1-800-Medicare and determines which pharmacy his father can use. Because the pharmacy is 15 miles away in the next town, he must wait until the weekend to refill his prescription when his son can drive him there. By the time his prescriptions are refilled, he has been off his medication for 6 days and is at high risk for complications.

Experience with the discount card shows that the most aggressive outreach and education campaign cannot effectively reach this vulnerable population in such a short time.[1] According to a recent report from the Kaiser Family Foundation, "[t]he experience of states that have successfully enrolled dual eligibles [into managed care] is that this is a very challenging population to contact and engage."[2] **Even if 80 percent of dual eligibles can be educated about program changes during the ten to twelve week transition period, more than one million of the frailest Medicare beneficiaries will lack access to needed medications on January 1, 2006.**

Example: Mr. P

Mr. P is 84 years old, living alone, with early stage Alzheimer's disease and glaucoma. He receives a new drug card in the mail in November 2005, but he throws it out, thinking that it is an unsolicited credit card. On January 4, 2006, he walks to his corner pharmacy and presents his Medicaid card. The pharmacist tells him that he can't accept it anymore, and asks Mr. P if he has a new card. Mr. P is angry, because his Medicaid card has always worked before. The pharmacist has no way to determine what plan Mr. P is enrolled in or where to refer him. He suggests that Mr. P call 1-800-Medicare, and Mr. P goes home empty-handed. Mr. P can't remember the number when he gets home. He doesn't refill his prescriptions until his daughter takes him to the doctor in March, where she discovers that he has been off his medications for two months and his eyesight has deteriorated significantly.

3. Health System/Infrastructure Barriers: Changing procedures for millions of individuals on one day can be expected to result in short-term disruptions to the entire care delivery system:

Example: Ms. B

Ms. B has schizophrenia and a dependent personality disorder and takes 8 prescription drugs per month, including an atypical antipsychotic called Risperdal. She receives a new Part D plan card in the mail in November 2005. When she brings the card to her pharmacy to refill her prescriptions on January 10, 2006, her pharmacist tells her that three of her prescriptions, including Risperdal, are not on the new plan's formulary. Ms. B is frightened and confused. The pharmacist suggests that she call her physician. Ms. B's doctor has been seeing patients like Ms. B to address new formulary restrictions round-the-clock since January 1. His receptionist tells Ms. B that her doctor's first available appointment is in three days. Ms. B runs out of Risperdal while waiting for her appointment, and on January 12 she is hospitalized after a suicide attempt.

- Part D plans must prepare for hundreds of thousands of coverage requests and appeals;
- pharmacist workload will increase dramatically, as confused dual eligibles seek personal assistance from front-line providers to explain the new benefit;[3]
- the risk of medication errors at pharmacies will increase;[4]
- physician workloads will spike, as physicians will have to review new formularies, provide new prescriptions, and help patients appeal so current medications can be continued.

Under the existing MMA timeframe, CMS will have **ten to twelve weeks** to accomplish transition tasks that the Medicare Payment Advisory Commission (MedPAC) suggests require at least **six months.**[5]

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[1] For example, CMS officials confirmed that of the 1.1 million people enrolled in Medicare Savings Program who received Medicare discount cards in the mail with a $600 credit attached, less than 6% had actually used their cards 8 weeks after they were mailed.

[2] Kaiser Commission on Medicaid and the Uninsured, The New Medicare Prescription Drug Law: Issues for Enrolling Dual Eligibles into Drug Plans, (Jensen, R.), January 2005.

[3] 30% of seniors are likely to turn to a pharmacist, and 38% to a doctor, for help navigating the new Medicare benefit. Kaiser Family Foundation, *Health Poll Report Survey: Selected Findings on the Medicare Drug Law*, 2005.

[4] Phillips, D., Jarvinen, J., and Phillips, R, "A Spike in Fatal Medication Errors at the Beginning of Each Month," Pharmacotherapy 2005: 25(1).

[5] Medicare Payment Advisory Commission (MedPAC), Report to the Congress: New Approaches in Medicare, Ch. 1, June, 2004.

Characteristics of Dual Eligibles

The characteristics of the dual eligible population will complicate transition efforts and make it particularly difficult for dual eligibles to navigate the Part D transition. Dual eligibles are/have:[6]

- **Sick.** More than 50 percent are limited in activities of daily living, and they have higher rates of Alzheimers disease, diabetes, pulmonary disease and stroke than other people with Medicare.
- **Cognitive impairements.** Nearly 4 in 10 have a mental or cognitive impairment. That means that 2.5 million dual eligibles may not be able to navigate program changes even if education and communication efforts are appropriate for an elderly population.
- **Underserved.** More than 40 percent of dual eligibles are racial/ethnic minorities, and dual eligibles are more likely to live in rural areas than other Medicare beneficiaries.
- **Dependence on Prescription Drugs.** Dual eligibles are expected to fill 20 million prescriptions in January 2006.
- **Institutionalized.** One in four dual eligibles lives in a nursing home or other long-term care facility.
- **Poor.** More than 60 percent live below the poverty level.

Example: Mrs. L

Mrs. L is a 94 year-old widow living in a nursing home. She is randomly assigned to a Part D plan that does not have a contract with the long-term care pharmacy that services her nursing home. Her roommate is automatically assigned to a different Part D plan, and her neighbors down the hall have chosen a third Part D plan to enroll in. The nursing home social worker has set aside two hours every day to develop a chart indicating the plans that residents are assigned to, the plan rules and formularies, the pharmacies in the networks, and which of the pharmacies delivers 24 hours a day and keeps intravenous versions of certain medications in stock. On January 5, before the social worker had completed her chart, Mrs. L begins showing signs of a low-grade pneumonia. The doctor prescribes antibiotics before he leaves the facility that night. The nurse on duty spends several hours juggling her workload while determining which pharmacies in Mrs. L's plan stock the IV solution. Mrs. L's condition deteriorates while she waits for the medication, and at midnight the nurse calls for an ambulance to take Mrs. L to the hospital.

Potential Solutions

To ensure the successful implementation of the MMA and the safe and smooth transition of dual eligibles, Congress should extend the availability of Medicaid as backup drug coverage during a reasonable transition period to Part D. The backup coverage would be used for: (1) dual eligibles not enrolled in a Part D plan on January 1, 2006; (2) dual eligibles who have not received notice of their plan assignment or do not yet know how to obtain medications using their Part D plan; and (3) dual eligibles who must be evaluated and for, and stabilized on, new drug regimens to comply with their Part D plan formularies.

[6] Id., Ch. 3. The statistics cited in the MedPAC report apply to full dual eligibles and those enrolled in the Medicare Savings Programs.

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