

TESTIMONY OF
MARK B. MCCLELLAN, MD, PH.D.
ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
BEFORE THE
SENATE SPECIAL COMMITTEE ON AGING
HEARING ON
IMPLEMENTATION OF THE
NEW MEDICARE PRESCRIPTION DRUG BENEFIT

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**Testimony of
Mark B. McClellan, MD, Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Before the Senate Special Committee on Aging
Hearing on Implementation of the New Medicare Prescription Drug Benefit
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Chairman Smith, Senator Kohl, distinguished members of the Committee, thank you for inviting me to discuss the implementation of the new Medicare prescription drug benefit. While millions of people with Medicare are now using their new drug coverage effectively, I also want to focus on the work we are doing around the clock to make sure every beneficiary gets the full benefit of their drug coverage.

New Medicare Prescription Drug Benefit Delivers Drugs and Savings to Millions

Prescription drugs are a critical component of 21st Century medicine, but until recently the Medicare program had never included an outpatient prescription drug benefit. Now, Medicare's new prescription drug benefit provides seniors and people with disabilities with comprehensive prescription drug coverage, the most significant improvement to senior health care in 40 years. Millions of seniors and people with disabilities are already using this benefit to save money, stay healthy, and gain peace of mind.

Since the new prescription drug benefit began January 1, 2006, enrollment is off to a strong start. As of mid-January, nearly 24 million people with Medicare now have prescription drug coverage and tens of thousands are enrolling every day. Pharmacists across the nation are filling a million prescriptions each day for people with Medicare. Nationwide, pharmacists are processing more than 40,000 Medicare prescriptions an hour during peak hours as hundreds of thousands of people with Medicare are now getting help with their drug costs each day. In the first 10 days, over three million prescriptions were dispensed to Medicare beneficiaries in nursing homes. And pharmacists across the country are reporting to CMS that people who did not have good coverage previously are now no longer struggling with their drug costs. For example, one pharmacist told us how, for the first time, he didn't have to advise one of his patients with Medicaid about which prescription he couldn't fill completely because of the coverage limits.

And many reports from people who are getting their drugs under the new prescription drug benefit are very positive. One man wrote, “My drug bill went from \$154.28 per month to \$34 for the same drugs. That is a 78% savings! I chose a program that had no deductible so I would not have to wait to spend \$250. After paying the monthly fee of \$39.50, my savings per month is 52.7%. Tell me I didn't get a good deal...”¹

Enrollment Status Update

Figure 1 shows the significant increases in enrollment from about 15 million people with drug coverage on December 21, 2005, just a week and a half prior to the onset of the prescription drug benefit to 24 million on January 14, 2006, two weeks after the benefit debuted.

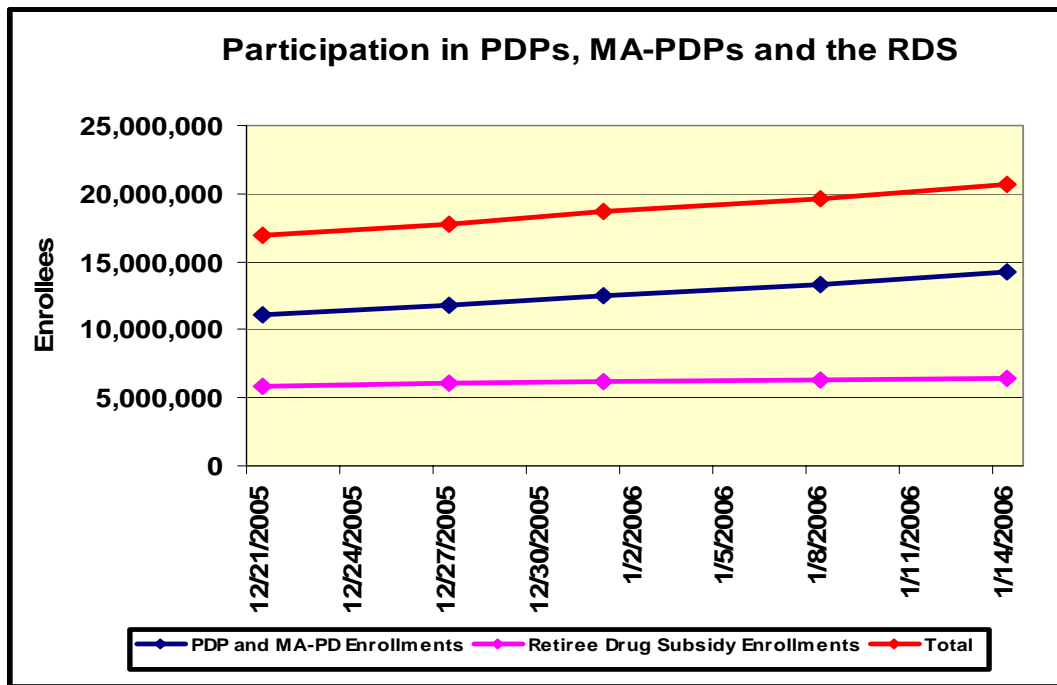


Figure 1: Enrollment in Medicare Prescription Drug Benefit, Medicare Advantage-PDPs, and the Retiree Drug Subsidy.^{2, 3, 4}

1 *Wall Street Journal*, January 11, 2006, <http://online.wsj.com/article/SB113684922094842048-search.html?KEYWORDS=medicare&COLLECTION=wsjie/6month>.

2 MA-PDP enrollments are under-reported as plans update CMS records concerning the movement of beneficiaries from MA to MA-PD plans.

3 Retiree Drug Subsidy enrollment numbers between 12/27/05 and 1/8/06 are estimates.

4 Total enrollment does not include FEHB or TRICARE covered Medicare beneficiaries.

In the last 30 days more than 2.6 million people have signed up for the new stand-alone prescription drug coverage. This number is on top of the 1 million who enrolled in stand-alone plans in the first 30 days of the initial enrollment period. An additional 4.5 million individuals, including 600,000 people who qualify for Medicare and also for full benefits under Medicaid, i.e., full benefit dual eligible individuals, are enrolled in a Medicare Advantage plan. Overall, about 6.2 million full benefit dual eligible individuals, including those enrolled in a Medicare Advantage plan, have transitioned to Medicare prescription drug coverage. In addition, Medicare's retiree drug subsidy will reimburse a portion of drug costs incurred by at least 6.4 million retirees for 2006. Also, an estimated 1 million retirees are in employer- or union-sponsored coverage that incorporates or supplements Medicare's coverage. Another estimated 500,000 retirees are continuing in other employer or union coverage. An additional 3.1 million Medicare eligible retirees are receiving their coverage through TRICARE for Life or a Federal Employee Health Benefit Plan.

CMS Works to Resolve Start-up Challenges

We are fully focused on resolving the difficulties that some beneficiaries have faced in using their coverage initially, particularly a group of people with both Medicare and Medicaid. Adding a benefit as significant as the new Medicare prescription drug program, involves some start-up challenges. CMS recognizes the enormity of this transition and has been working intensively for many months with partners in and out of government, including States, plans, pharmacists, advocates, and other key partners to ensure the transition process is as smooth as possible for people with Medicare and all of our partners. We have improved our data system, particularly helping the dual eligible population, have strengthened our 1-800-MEDICARE call centers, instructed plans on ways to better serve both beneficiaries and pharmacists, and have dedicated greater CMS resources to addressing pharmacists' needs and enrollee concerns.

Despite these efforts, we are very concerned that some people with Medicare have had difficulty in using their drug coverage for the first time. These problems generally do not occur for people who enrolled far enough ahead of using their coverage to get their drug benefit card, and many of these initial problems have been straightforward to resolve. For

example, one woman stated on January 10, 2006 that she did not immediately receive her plan card although her husband received his from the same plan after enrolling at the same time. When she contacted the plan, the problem was quickly resolved. After getting her prescriptions filled, she reported, “I normally spend \$538 for a three-month supply of my drugs. But this time it cost only \$278. And these weren't even generic drugs.”⁵ After people use the system once, these initial problems that some beneficiaries have faced with using their coverage generally do not recur.

We have been most concerned about helping beneficiaries who are eligible for Medicare and Medicaid to use their new benefit. While the vast majority of the more than 6 million dual eligible individuals have already begun to use their drug coverage, certain of these dual eligible individuals have had initial difficulties. In particular, a fraction of a potential universe of a few hundred thousand dual eligible beneficiaries who switched plans, particularly near the end of the year, did not have complete information available on their coverage with their new plan in early January. In addition, information transfers among states, CMS, and plans did not occur perfectly for all beneficiaries. This group is an extremely important population and CMS is committed to ensuring they receive their needed prescription drugs. Many steps are now in place to ensure this happens. In addition some states have taken steps to further support the CMS systems.

One major contributing factor to CMS’ challenge is that the onset of the benefit affected many millions of people with Medicare simultaneously at the beginning of January, including millions of people who enrolled or switched plans near the end of December. In addition, CMS worked with numerous partners leading up to the start of the drug benefit to educate beneficiaries and their caregivers about the Medicare prescription drug benefit. We, along with the plans, pharmacists, States, and hundreds of other partners, helped people understand how to make decisions about their prescription drug coverage based on cost, coverage and convenience.

⁵ *TheStreet.com*, Jan 10, 2006. <http://www.thestreet.com/funds/retirement/10260920.html>

As a result of our successful outreach efforts, we experienced a substantial surge in enrollment at the end of the year and many dual eligible individuals electing to change plans close to December 31, 2005. As shown in Figure 2, both visitors to the prescription drug plan on-line enrollment center and enrollments rose steadily throughout December and peaked at the end of the month with over 100,000 enrollments on both December 29 and 30, 2005. CMS continues to see tens of thousands of new enrollments daily.

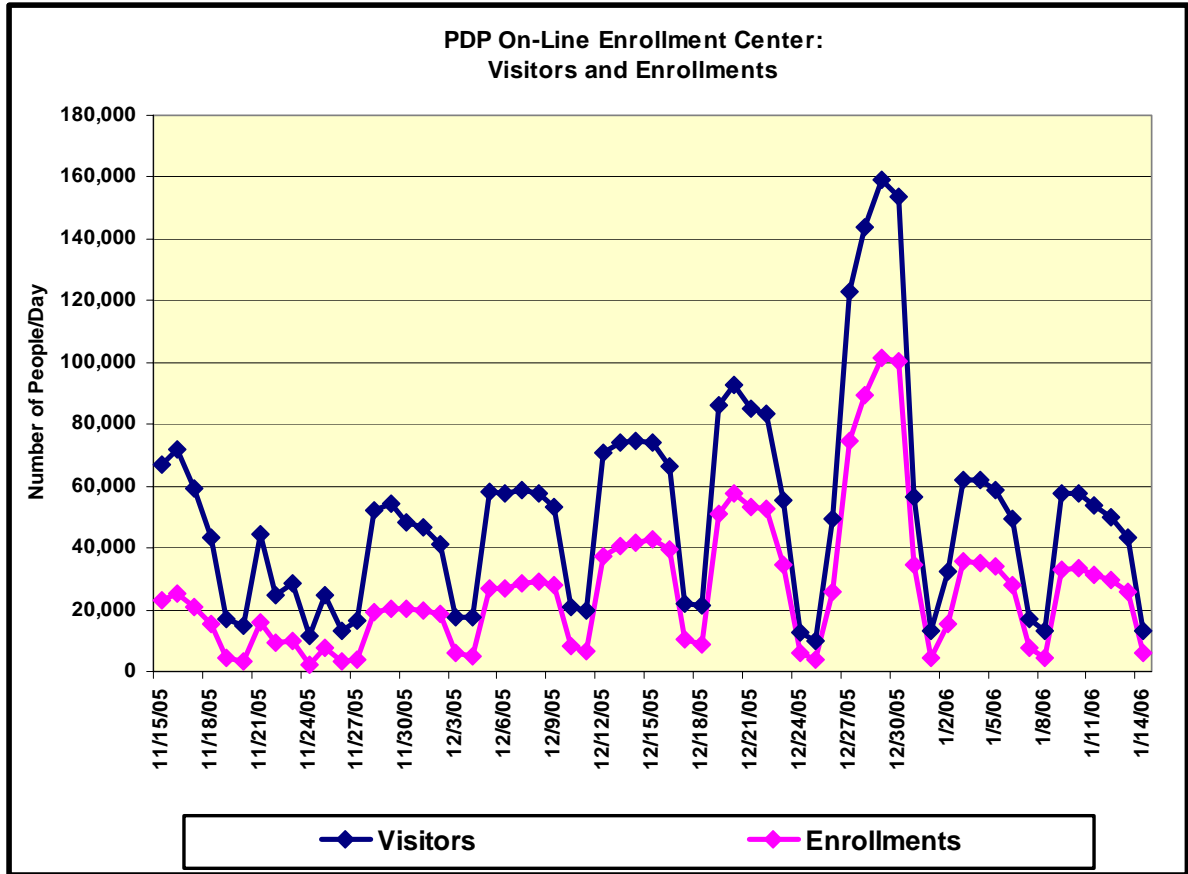


Figure 2: Prescription Drug Plan On-Line Visitors and Enrollments⁶

With the initial implementation of the drug benefit, our start up challenges fall into several key categories including new systems and data transactions issues, customer service, pharmacy support, and State issues. We have worked closely with the plans and our other partners to reconcile specific plan and enrollment information for dual eligible individuals who did not have complete information available with their plan. We are reviewing systems;

⁶ Cyclical weekly low points are Saturdays and Sundays

continuing pharmacist support, education and outreach; conducting casework around the country; and helping dual eligible individuals and long-term care residents. CMS is committed to making sure that every person with Medicare gets the medications he/she needs. We are seeing improvements on a daily basis as more people with Medicare receive their enrollment confirmations and their personal information is available in the database systems, which allows them to easily fill their prescriptions.

CMS Plans for Implementation of Drug Coverage on January 1, 2006 for Individuals Eligible for Both Medicare and Medicaid

After passage of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) in December 2003, CMS began planning for implementation of the Medicare prescription drug benefit. It has been a process involving many steps and partners to get to where we are today. A major focus of this preparation was to provide for the transition of millions of dual eligible individuals who are required to get their prescription drugs through a Medicare drug plan beginning January 1, 2006. Previously, state Medicaid programs provided prescription drug coverage to the dual eligible population.

CMS Worked With States

Since both CMS and the States are responsible for administering benefits for the dual eligible individuals, CMS is committed to working with States on an ongoing and collaborative basis. Both CMS and the States are working to ensure the start up challenges for current dual eligible individuals are addressed. This effort has required an unprecedented level of collaboration between the States and Federal government. This work commenced in August 2004 through the State Issues Workgroup, which included representatives from State Medicaid Agencies, the Social Security Administration, and CMS.

CMS also has worked with States through various workgroups to assure that States report and CMS knows of every dual eligible beneficiary in the country undergoing this transition from Medicaid to Medicare drug coverage. In addition the CMS and State workgroups collaborated to

- develop an efficient and effective low-income application process for individuals who are not dual eligible;
- train, educate, and conduct outreach in a coordinated fashion;
- assure a successful process is in place to auto-enroll every dual eligible beneficiary who does not join a Medicare prescription drug plan on his or her own;
- develop strategies for transitioning dual eligible individuals from Medicaid to Medicare while also assuring coordination of care; and
- assure that the calculation of the phase down State contribution is accurate.

In addition to the ongoing efforts of the State Issues Workgroup, CMS engaged the States in a series of summits, conference calls, and workshops to discuss and address implementation issues associated with the MMA. These gatherings include monthly all-State conference calls; State Pharmacy Assistance Program (SPAP) Workgroup conference calls; and conferences hosted by organizations representing the States including the National Governors Association, National Conference of State Legislatures, and Council of State Governments.

In addition, CMS provided States with:

- enrollment information for full-benefit dual eligible individuals including their assigned plans;
- comparative information on the specific Medicare prescription drug plans including formularies and pharmacy networks that are serving each state; and
- targeted educational and outreach materials.

Finally, CMS has worked diligently with States to ensure that they appropriately identify their full benefit dual eligible individuals. CMS validated the information that States reported to minimize reporting errors, mistakes, and omissions that may affect the identification of the States' dual eligible residents. These validation data matches showed match rates of over 99% for all States, according to an independent evaluation completed in the fall of 2005.

CMS Automatically Enrolled Dual Eligible Individuals into Plans

To ensure that there was no lapse in prescription drug coverage for full benefit dual eligible individuals, CMS worked diligently to make sure they were enrolled in a Medicare prescription drug plan before January 1, 2006. In November 2005, any individual who was a dual eligible for even one month, beginning in March 2005, was automatically enrolled in a plan. CMS understood that the dual eligible population is typically the hardest to reach and preparation was necessary. To that end, CMS sent letters in May to all dual eligible individuals to inform them of their upcoming auto-enrollment into a prescription drug plan. Then, in the fall, CMS sent these individuals a letter that informed them of their new plan and the option to choose another plan if they were not satisfied with the auto assignment. In addition to the letters, individuals can call 1-800-MEDICARE to find out the plan in which they have been auto-enrolled.

Also, while other individuals generally have the opportunity to change plans only at the end of the calendar year, dual eligible individuals have the opportunity to change plans at any time. This flexibility ensures continuity of care when Medicaid prescription drug coverage ends, while also allowing them to select a plan that best meets their needs.

CMS also has worked with States to identify and auto-enroll individuals who are about to become full-benefit dual eligible prior to the end of their Medicaid drug coverage to ensure a seamless transition on an on-going basis. This includes those Medicaid individuals who will age into Medicare or who will reach the end of the 24-month Medicare disability waiting period.

CMS Developed New and Enhanced Information Technology Systems for the Prescription Drug Benefit

Information technology (IT) systems played a crucial role in ensuring the prescription drug benefit could be implemented January 1, 2006. Planning for the information technology to support the implementation of the Medicare prescription drug benefit began in 2004 with CMS identifying the key functions affected by the new law and beginning development of a large-scale, integrated computer system. CMS ensured that more than one dozen critical

systems development efforts were implemented in time to meet MMA-legislated deadlines. In conjunction with its business partners, CMS developed innovative solutions and leveraged existing business and systems relationships, such as using the existing pharmacy transaction processing network, to assist with the coordination of the various prescription drug benefit plans covering people with Medicare.

Staff created and modified a variety of complex, integrated systems that currently interact with the private and public sectors to implement the new benefits. These IT systems support the key critical business processes that CMS uses to manage the Medicare Advantage and prescription drug benefit programs. The integrated system provides CMS with the ability, among other things, to enroll people with Medicare into prescription drug plans, make payments to plans, and ensure that beneficiaries receive their drug coverage. The integrated information technology system also allows CMS to pay the Retiree Drug Subsidy to approved plan sponsors and track True-Out-of-Pocket Expenses (TrOOP) for people with Medicare. In addition, the updated systems ensure the correct premium amount is either paid directly to the plan or provided to the Social Security Administration to withhold from a beneficiary's Social Security check. Through contracts with telecommunications clearinghouses that currently service the majority of retail pharmacies, the pharmacies will be able to perform real-time eligibility determinations and will be able to route claims to primary, and if applicable, secondary plans for proper adjudication to accurately coordinate benefits. The new and modified systems also were designed to ensure only authorized individuals have access to Medicare information.

CMS worked closely with industry experts to implement nine system modules. Implementation included application development and integration efforts, system engineering activities, and validation and testing. In order to meet the deadlines, CMS worked creatively and collaboratively to compress what would ordinarily be an 18 to 24-month systems development process. CMS ensured that the necessary computer and network capacity and capabilities were in place as the CMS IT applications came online.

These enhancements included

- providing capabilities for more than 400 new CMS business partners to connect to CMS systems over the Internet,
- providing advanced technology for secure file transfers, and
- implementing a new user id/password management system.

CMS implemented backup and parallel support systems to minimize any vulnerabilities, and also oversaw the implementation of a secure, Internet-based computing environment in the CMS data center. If these systems had not come online on schedule, CMS would not be able to enroll beneficiaries or pay the health plans that are administering the new benefit. CMS set new standards for documenting requirements, program management, managing change, testing systems, and documenting and ensuring that system development life cycle reviews were undertaken.

Extensive Plan Formulary Requirements Provide Access to Needed Prescription Drugs

CMS developed a set of checks and oversight activities to ensure that prescription drug plans offer a comprehensive benefit that reflects best practices in the pharmacy industry, as well as current treatment standards. Plan formularies must recognize the special needs of particular types of people with Medicare, such as individuals with mental health issues, individuals with HIV/AIDS, individuals living in nursing homes, people with disabilities, and others who are stabilized on certain drug regimens. CMS has reviewed plan formularies and benefit structures to verify that they are in compliance with the following critical requirements. A plan's formulary must cover multiple drugs in each class with a minimum statutory requirement of at least two drugs in each approved category and class (unless only one drug is available for a particular category or class). Furthermore, CMS requires that each plan's formulary include all or substantially all drugs in each of the following key categories: antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and antiretrovirals for treating HIV/AIDS.

In addition, each Medicare prescription drug plan's formulary was developed and reviewed by the plan's pharmacy and therapeutics committee. Each formulary must be consistent with

widely used industry best practices. Furthermore, CMS compared the prescription drug plans' use of benefit management tools to the way these tools are used in existing drug plans to ensure they are being applied in a clinically appropriate fashion. Prescription drug plan formularies typically include upwards of 80 percent of the 100 most commonly used drugs.

CMS has developed exceptions procedures designed to ensure that enrollees receive prompt decisions regarding whether medications are medically necessary. For example, if the enrollee is requesting coverage of a non-formulary drug, the drug may be covered if the prescribing physician determines that all of the drugs on the formulary would not be as effective as the non-formulary drug or would have adverse effects for the enrollee, or both. The plan would have to review the physician's determination and must make its decision as expeditiously as the enrollee's health condition requires after it receives the request, but no later than 24 hours for an expedited coverage determination or 72 hours for a standard coverage determination.

CMS Required Plans to Have a Transition Process for Dual Eligible Individuals

CMS required each Medicare prescription drug plan to establish an appropriate transition plan for all new enrollees with Medicaid. All of the transition plans now include a minimum 30-day one-time fill of any prescription drug excluded from the plan's formulary in order to accommodate situations in which a non-formulary prescription has previously been filled at a participating pharmacy. Each transition plan identifies the plan sponsor's method of educating both people with Medicare and providers to ensure a safe and complete accommodation of an individual's medical needs with the plan's formulary. Additionally, CMS recommends that transition plans address unanticipated enrollee transitions when individuals need to change treatment settings due to a change in their level of care.

CMS Worked With Plans to Ensure a Smooth Transition in Long Term Care Facilities

CMS is committed to ensuring that people with Medicare in long-term care (LTC) facilities continue to receive the medications and pharmacy services they need under the new Medicare prescription drug coverage without interruption.

There are 1.6 million people with Medicare who are residents in 15,800 nursing homes throughout the nation. The majority of nursing home residents are dual eligible individuals. Almost half of all nursing home residents have some or all of their stays covered under Medicare Part A. Individuals in LTC facilities represent a unique and vulnerable population because they have cognitive and/or functional impairments. This population typically has multiple co-morbidities, the highest utilization of drugs, with an average of nine medications per day, and the highest spending for prescription drugs compared to other people with Medicare.

In March 2005, CMS issued guidance for the implementation of CMS requirements regarding pharmacies that provide products and services to individuals in LTC facilities. This guidance addressed pharmacy performance and service criteria, convenient access standards, formulary considerations, and other beneficiary protections that prescription drug plans should consider as they develop their prescription drug benefit offerings for people with Medicare in LTC facilities.

Auto-enrollment of Individuals in LTC

Cognitively impaired individuals represent a particularly difficult group to educate about their enrollment options. Much of this population, specifically dual eligible individuals, was auto-enrolled into the new prescription drug benefit. CMS encouraged nursing homes to determine into which plans their residents were auto-enrolled prior to January 1, 2006. As part of this initiative, CMS established dedicated call lines and overnight mail options to allow nursing homes to fax and mail beneficiary information to CMS customer service representatives (CSRs). This strategy enabled CMS to help nursing homes identify the plans for more than 500,000 residents. Pharmacists used the electronic eligibility and enrollment verification (E1) system to identify the remainder. By notifying plans that their enrollees reside in nursing homes, CMS is ensuring nursing home residents have access to Medicare drug coverage for no premiums and no copays.

Performance and Service Criteria for Pharmacies Providing LTC Service

To address the unique and diverse needs of people with Medicare in LTC, CMS developed minimum performance and service criteria for pharmacies providing LTC service, based on widely used best practices in the market today and with input from external stakeholders.

These criteria address:

- Comprehensive inventory and inventory capacity
- Pharmacy operations and prescription orders
- Special packaging of medicines
- IV medications
- Compounding and alternative forms of drug composition
- Pharmacist on-call service
- Delivery service
- Emergency boxes
- Emergency log books
- Miscellaneous reports, forms and prescription ordering supplies

For example, network LTC pharmacies (NLTCPs) must have the capacity to provide specific drugs in unit of use packaging, bingo cards, cassettes, unit dose or other special packaging commonly required by LTC facilities. NLTCPs must have access to or arrangements with a vendor to furnish supplies and equipment including but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging required by the LTC setting. Additionally, NLTCPs must provide on-call, 24 hour a day, 7 day a week service with a qualified pharmacist available for handling calls after hours and must have medication dispensing capability available for emergencies, holidays and after hours of normal operations.

Prescription Drug Plan Formularies for LTC residents

In the long term care setting, the Medicare prescription drug plan formularies are in general more robust than State preferred drug lists or commercial formularies. Plans must accommodate within a single formulary structure the needs of long term care residents by providing coverage for all medically necessary medications at all levels of care. Coverage of

all medically necessary medications may include, but is not limited to, alternative dosage forms such as liquids that can be administered through feeding tubes, intravenous medications, or intramuscular injections.

CMS recommended nursing homes include a 90 to 180 day transition period. The vast majority of plans are providing 90 day transition periods with many offering the option of extending to 180 days. However, the LTC emergency first fill policy is unique to this setting and continues throughout the entire year for any off-formulary prescription written. In addition, plans are required to cover drugs as written during the 7 to 14 days allowed for initial exceptions and appeals process.

CMS Provides Education Regarding LTC Pharmacy Requirements

Prior to the implementation of the Medicare prescription drug benefit, CMS conducted extensive outreach and education to ensure LTC facilities, pharmacies and other stakeholders were informed about requirements for delivering services under the benefit. CMS established a working group consisting of representatives from the American Health Care Association, American Association of Homes and Services for the Aging, American Medical Directors Association, the Alliance for Quality Nursing Home Care, Long Term Care Pharmacy Alliance, National Center for Assisted Living, Assisted Living Federation of America, National Association of State Mental Health Program Directors, and the National Association of State Directors of Developmental Disabilities Services that assisted CMS over an eight month period in 2005.

CMS also provided and continues to provide instruction through trade association newsletters, fiscal intermediary newsletters and conferences. In addition, CMS developed electronic messages that are shown to facilities each time they enter data on the Minimum Data Set (MDS) - part of the federally mandated process that provides a comprehensive clinical assessment of all residents in Medicare and Medicaid certified nursing homes. Education included, for example, a three pronged approach for ensuring that nursing home residents who spend down the Medicare simultaneously apply for Medicaid and the low income subsidy and enroll in a PDP to maximize their prescription drug benefits. This

outreach also included numerous Open Door Forums, in which all stakeholders were invited to participate so CMS could share the outcomes of critical policy and procedural decisions and to solicit feedback on areas of concern.

CMS Educated and Coordinated Outreach Efforts for Pharmacies

Partnerships: CMS worked extensively with pharmacy industry leaders to educate and motivate the pharmacist community about the new Medicare prescription drug benefit. Specifically, we partnered with chain and independent pharmacies in an education and outreach program for the low-income subsidy, which reached over 30,000 stores. CMS participated in 24 town hall events hosted by the National Community Pharmacists Association (NCPA). These events provided a prescription drug benefit overview to independent pharmacists and a question and answer session following each event. In total, over 6,500 pharmacists participated in this program.

Direct Communications: CMS made extensive efforts to directly reach pharmacists in preparation for January 1, 2006. CMS created the Medicare Rx Update as a periodic update to pharmacists to ensure they are well informed about the details of the Medicare prescription drug benefit implementation. CMS distributed the Rx Updates through the internet to directly reach practicing pharmacists with highlights and clarifications about implementation issues. Since its inception in May 2005, CMS has sent 25 Rx Updates to the pharmacy community addressing topics including the pharmacists' role with the low income subsidy, marketing guidelines, the prescription drug plan compare tool, and the true-out-of-pocket (TrOOP) facilitator. With thousands of subscribers and because State and national organizations distribute the Update as well, these bulletins have gone a long way toward educating the pharmacy community about the procedures related to the new benefit.

CMS also created and maintains a website (<http://www.cms.hhs.gov/Pharmacy/>) specifically for pharmacists. In addition to the Medicare Rx Updates, the pharmacist website contains informative prescription drug benefit guidance, links to training materials, information for special practice pharmacies, and more.

CMS' pharmacist outreach team, which includes our regional pharmacists, has conducted the most targeted personal outreach. CMS' central office pharmacy team, which includes 21 pharmacists, as well as the pharmacists and staff from CMS' 10 regional offices, have traveled the country educating pharmacists in all practice settings about the new benefit. The pharmacists have presented at hundreds of events and gatherings reaching tens of thousands of pharmacists.

Furthermore, CMS created a forum known as the Pharmacy Information Exchange, a periodic open phone town hall style meeting. Hundreds of pharmacists attended calls hosted by CMS' pharmacists. These calls have enabled CMS to present on hot topics, answer many questions and identify new issues from the community. Finally, CMS has developed two pharmacist-specific continuing education programs that were distributed through the on-line arm of Drug Topics, the magazine dedicated to the profession of pharmacy, and through Kansas University, respectively.

Plans to Address Pharmacy Operational Issues: Finally, as January 1, 2006 approached, CMS finalized a comprehensive plan for further pharmacist training, including materials targeted to explain technical details of the TrOOP facilitation process, Medicare Part B versus Part D coverage, out-of-network policies for Hurricane Katrina evacuees, the point-of-sale facilitated enrollment process for dual eligible individuals, and more. CMS is working directly with a wide range of pharmacy organizations, identifying operational questions for pharmacists and developing dynamic action plans on how to anticipate problems and, to the extent that we can, address them in advance. In preparation for the first days of the benefit, CMS engaged the pharmacy community in a virtual "war room" so that the Agency could work directly with the industry to provide direct assistance for any issues that arose in the early days of implementation.

CMS Worked With Physicians

An important part of CMS' outreach and education effort included the physician community. Throughout 2005, CMS medical officers spoke to 24 physician specialty groups about the new Medicare prescription drug benefit, transition policies and formulary exceptions and appeals. CMS has held weekly telephone question and answer calls for physicians, other

prescribers, and their office staff in anticipation of the new drug benefit. The first call had 1,300 callers and is averaging about 500 callers a week now. CMS has had a similar call for mental health providers and a call focused specifically on distinguishing between coverage for Part B and Part D prescription drugs. In addition, CMS participates in the AMA workgroup, which has been meeting since November to discuss physician issues and suggest improvements and refinements.

Point-of-Sale System Facilitates Enrollment

CMS is making its best effort to identify and auto-enroll dual eligible individuals prior to the effective date of their Medicare Part D prescription drug coverage eligibility. However, it is possible that some individuals may go to pharmacies before they have been auto-enrolled in a prescription drug plan. For this reason, in anticipation of the shift from the Medicaid to the Medicare program of dual eligible individuals' drug benefits, CMS has developed a process for a point-of-sale interaction to ensure these individuals experience no gap in coverage. CMS contracted with WellPoint, a national prescription drug plan to provide prescriptions and enrollment at the pharmacy point-of-sale (POS). The relationship with WellPoint is specifically designed to ensure that pharmacists can fill prescriptions and bill WellPoint for full benefit dual eligible individuals who had not been previously enrolled in a new Medicare prescription drug plan.

Beneficiaries, who present at a pharmacy with evidence of both Medicaid and Medicare eligibility, but without current enrollment in a prescription drug plan, can leave the pharmacy with a filled prescription and the claim for their medication submitted to a single account for payment. A CMS contractor will immediately follow up to validate eligibility and facilitate enrollment of the full-benefit dual eligible individual into a prescription drug plan. As of early January, over 10,000 dual eligible individuals have received their prescriptions through the Wellpoint point-of-sale system. Many of the individuals who received prescriptions through Wellpoint are members of others plans.

CMS has provided information on the WellPoint system to pharmacy associations, plans, and individual pharmacies. This information describes how the process of POS-facilitated

enrollment starts at the pharmacy with the pharmacist verifying dual eligibility and billing a special Wellpoint account in order to ensure that the individual with Medicare receives the prescription.

CMS Takes Action to Ensure Timely Receipt of Prescription Drugs after Start of Benefit

Despite the best efforts of everyone involved in the new program, there is a group that potentially included a few hundred thousand dually eligible individuals who had difficulty when they initially used their drug coverage. These individuals were described previously. In addition, CMS has taken steps to address other issues that have arisen with the implementation of the drug benefit.

CMS Works to Ensure Emergency Fills for Dual Eligible Individuals

CMS is working to ensure that dual eligible individuals who need emergency fills of their prescriptions receive them in a timely fashion. If any dual eligible individual needs prescriptions immediately, and other mechanisms have not worked, CMS can help them get the medicines they need. Many pharmacies are filling prescriptions for dual eligible individuals that present at the pharmacy counter when enrollment and billing information cannot be confirmed. If the individual is in an urgent situation, he or she should call 1-800-MEDICARE (1-800-633-4227) or the pharmacist can call the pharmacy helpline and tell the CMS customer service representative that a person with Medicare has an urgent situation. As described below, CMS casework staff will be alerted and help the person obtain his/her medication.

CMS Educates People with Medicare About the Timing of Selecting a Plan

CMS has informed people with Medicare about the need to allow some time between the date of enrollment and when they first attempt to fill a prescription. This provides CMS and the plans with enough time to see to it that the data systems are accurately updated in order to properly handle the filling of a prescription. Such is generally the case anytime someone enrolls in a new health insurance plan or makes changes to it, and we want people with Medicare to be aware of this situation.

Generally, if an individual newly enrolls in a plan, or switches to a different plan by the 15th of the month, their information should be available at the pharmacy by the beginning of the next month. So we have begun encouraging people with Medicare to enroll at least a few weeks before they expect to need to use their drug coverage, and to be prepared to wait several weeks to be fully entered into the system.

We are developing model language for plans to use to inform their enrollees of these facts, and will also provide those who enroll through our 1-800-MEDICARE call centers and our internet-based Plan Finder tool with a similar notice. Enrollees will also be informed that while waiting for the data systems to be appropriately modified, they may, if need be, use the acknowledgement letter sent to them by the plan when they go to the pharmacy to fill their prescriptions.

CMS Supports Ongoing Success of IT Systems

To continually improve the IT systems and CMS services to the beneficiaries, plans, and pharmacies, CMS continues to work closely with the plans via system-level conference calls that occur three times a week, in addition to the twice-daily production calls that synchronize the complex operations of all systems. Also, the Agency pulled together critical resources to:

- evaluate the performance of systems,
- identify issues with the plans and pharmacies, and
- develop and implement corrective actions.

Based on these evaluations, CMS has identified, in priority order, key performance and operations issues. The resolution and implementation of the solutions is underway.

CMS has taken steps to ensure plans have the means to cross-check CMS data with plan data for improved accuracy and completeness to ensure that dual eligible individuals can be appropriately identified when they present at the pharmacy counter. On January 12, 2006 and again on January 18, 2006, CMS sent files to each plan with information about its dual eligible enrollees along with instructions on how to process these files. As these data are processed by plans, this process is substantially reducing the workload of the pharmacists and

assisting the vast majority of dual eligible individuals in getting their drugs. Providing this information enables pharmacists to identify plans in which dual eligible individuals are enrolled and ensure that correct and appropriate co-payments are charged to the individual with Medicare. Furthermore, on January 30, 2006, CMS sent an additional file of low income subsidy eligible individuals, this time using an enrollment effective date of February 1, 2006. This file should provide an additional source of information for many of the plan changes that have taken place in the past couple of weeks and help plans prepare for enrollments that are effective beginning in February.

CMS also has been working with specific plans to resolve their unique issues surrounding sending and receiving data files from CMS. As a result of these efforts, dual eligible beneficiaries who had been having difficulty with correct co-payments and eligibility are now getting their prescriptions filled correctly.

To ensure CMS' performance evaluation system and corrective actions are effective, CMS contracted with Electronic Data Systems (EDS) as an independent reviewer to help resolve specific data translation issues with the plans, States, and pharmacies.

CMS Improves 1-800 MEDICARE Call Center to Reduce Wait Times

CMS' 1-800 MEDICARE Call Center has customer service representatives (CSRs) available to answer Medicare questions 24 hours a day, seven days a week. As shown in Figure 3, call volume to 1-800-MEDICARE peaked around 400,000 calls when enrollment began on November 15, 2005 and again in early to mid-January.

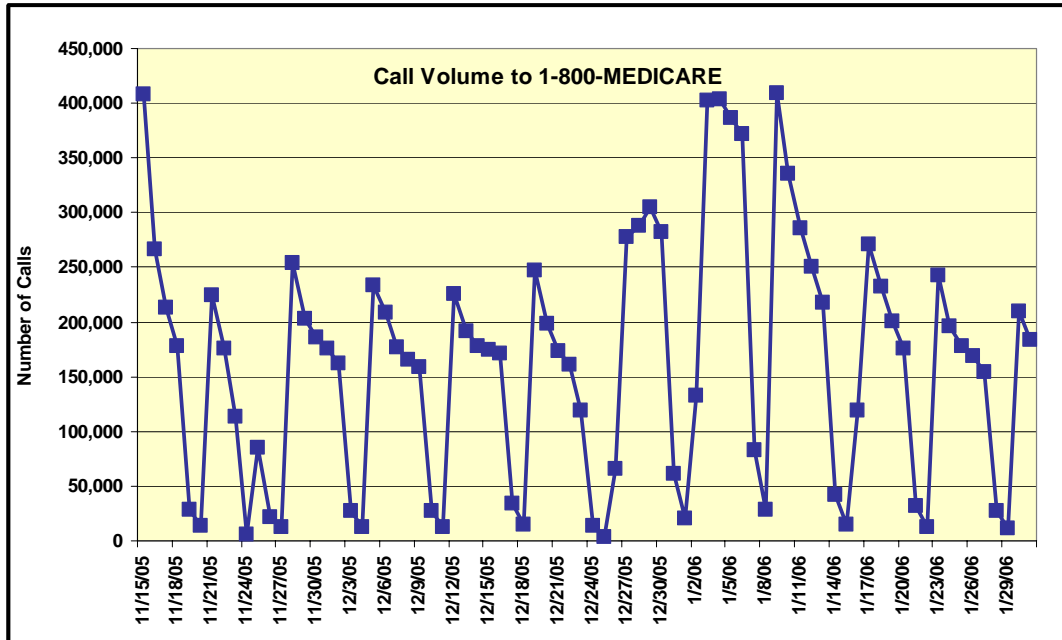


Figure 3: Call Volume to 1-800-Medicare

On average, callers have experienced wait times of less than two minutes from mid-November to mid-January, with longer waits sometimes occurring during peak call periods.

CMS has increased the number of CSRs from 3,000 in June of 2004 to as many as 7,800 to handle beneficiary calls. We have also acquired additional infrastructure including telephone lines, workstations, and seats at call center sites. We have upgraded our CSR scripts by reducing redundant information, indexing scripts for quick access, and including probing questions to help the CSRs better identify the caller’s concerns.

CMS has implemented a major enhancement through the use of Smart Scripts, which provide the CSRs with an easily followed path of responses to the most frequently asked questions. Smart Scripts are a new type of script that have hyperlinks built into the body of the text that when activated will take the CSR directly to related information about that subject. In addition, we have CSRs participate in the content workgroups for the actual development of scripts and job aides. CMS also has implemented a CSR feedback system and streamlined our approval process for updating the scripts in a timely manner to respond to the changing needs of our customers or to incorporate policy updates.

CMS hired and trained additional staff to exclusively use the Prescription Drug Plan Finder (PDP) tool to handle only PDP calls. All CSRs receive one week of classroom training followed by two or three additional days of practice calls, simulation, quality monitoring and follow-up coaching to ensure peak performance. CSR certification with a written examination and test calls is required prior to taking live calls. Calls are being handled on an in-bound basis and steps CMS has taken to strengthen the call centers' capabilities and reduce wait times have made it possible to address beneficiaries' concerns as they arise.

Customer satisfaction surveys indicate that the bulk of callers who interact with our CSRs, 84 percent, are satisfied with their experience. They are particularly pleased with how courteous and patient the CSRs are (rated at 97 and 95 percent, respectively). These responses came not only from people with Medicare, but also friends or relatives calling on their behalf, who made up 48 percent of callers during December, 2005.

CMS' Medicare website, www.medicare.gov, has also been a source of useful information for people with Medicare. Since the first of the year, our frequently asked questions have been accessed more than 530,000 times. CMS has also responded to over 5,300 e-mails received through the site, with 93 percent of them being resolved satisfactorily in the first response.

CMS Works with Plans to Improve Their Customer Service

In addition to this significant strengthening of our 1-800-MEDICARE capabilities, we have issued guidance to the plans, instructing them to increase the numbers of CSRs in their own call centers and improve their abilities to immediately resolve enrollee concerns. Plans have responded and reported significant increases in the number of CSRs in their call centers.

We have also informed plans that they must comply with their transition policies so that enrollees who require a specific medications are able to obtain coverage for a one-time supply of those drugs, while they work with their physician and plan to select a new drug in the same therapeutic class, or appeal for coverage of their existing prescription. Further,

plans have been required to inform their CSRs about their transition policies and empower them to permit a pharmacy to dispense these drugs.

CMS Takes Steps to Identify Areas of Concern

To address the need to capture and track complaints, CMS developed the Complaints Tracking Module (CTM). The CTM is a central repository for complaints that come in to CMS' Central Office, and ten Regional offices and the Medicare Rx Integrity Contractors through 1-800-MEDICARE or CMS directly. The CTM is designed to capture complaints from beneficiaries, providers, or plans about prescription drug plans, pharmacies, subcontractors, and providers. Because it is a web-enabled system, CTM can be accessed from off-site locations. This allows for regional and off-site staff to quickly enter information into the system. Since complaints may need to be escalated or referred across components, referral capabilities exist for this type of transfer. This provides for an efficient exchange of information, which allows for a quicker resolution and accountability, as each complaint is assigned to only one individual at a time.

CMS began development of the CTM in the Fall of 2005 and refined the system in response to input from various stakeholders. The design of CTM format and content were driven from previous experience with the Drug Card, intra-agency components, and insights from the Pharmacy Benefit Management (PBM) Industry. CMS launched the CTM into production on October 3, 2005. Since this time, the CTM has been fully tested to accept large numbers of daily transactions simultaneously from many users across the Agency. CMS began tracking complaints in January and although this process is still in the early stages, we have seen a general decline in complaints.

CMS Provides Caseworkers for One-on-One Counseling

While millions of prescriptions are being filled for people with Medicare, CMS is very concerned about those individuals who are encountering difficulties at the pharmacy counter. This is certainly distressing for those individuals and their caregivers.

CMS has established a system to help resolve urgent issues on a case-by-case basis. CMS has hundreds of trained caseworkers who are working as rapidly as possible with individuals with Medicare and plans to resolve urgent issues to help ensure that people with Medicare get their prescriptions filled. CMS urges people with Medicare or their family members who are having difficulties to call 1-800-MEDICARE, and if necessary, their case will be forwarded to our caseworkers. Urgent cases have high priority for rapid resolution.

While the number of individual cases is small in comparison to the millions of prescriptions and individuals who are successfully receiving their prescriptions, CMS is committed to ensuring that every individual receives their needed medicines, are properly identified, and are charged the appropriate co-pays in the future.

CMS Provides Dedicated Support to Pharmacists

CMS has provided a number of ways for pharmacists to obtain help in filling prescriptions for plan enrollees. If the enrollee does not have a card, pharmacists can use our eligibility system (the E1 system) to obtain information needed to fill the prescription. Pharmacists can also call plans directly, on lines dedicated for pharmacists. They can contact Medicare's own CSRs if need be, and CMS also has specially trained case workers in our regional offices who can intervene in special cases to make sure that enrollees get the medications they need.

CMS has significantly increased the capacity of the toll-free pharmacy support phone lines to help resolve issues pharmacists encounter in dispensing medications to those newly enrolled in the Medicare prescription drug plans. CMS has increased its call handling capacity at the pharmacist help line 30 fold and the line is now available 24 hours a day. We have increased the CSR staffing to support this initiative from 150 CSRs to about 4,500. The increased capacity has reduced the wait time to less than a minute for pharmacists who want to use this mode of communication for eligibility and enrollment determination.

CMS Responds to Early Technical Problems with the Eligibility and Enrollment Query System for Pharmacists

During the first week of the Medicare prescription drug program, CMS experienced some delays in response time with the new computer tool provided to pharmacists for real time enrollment and eligibility look-up. Working with our contractor, CMS has improved response time to less than one second with no delays. CMS continues to load data into this system from information obtained on individuals' recent enrollment or plan switching activity, which will help pharmacists obtain complete enrollment and billing information on more individuals when they use the E1 system at the pharmacy counter. As shown in Figure 4, CMS is seeing an overall decline in the number of times pharmacists must utilize the E1 system from a high of 1.47 million to about a half million in recent days. This reflects a more efficient and effective use of the system after CMS issued a tip sheet in early January on how best to use the system. In addition, more individuals have received appropriate plan identification information, so the need for the E1 system has declined.

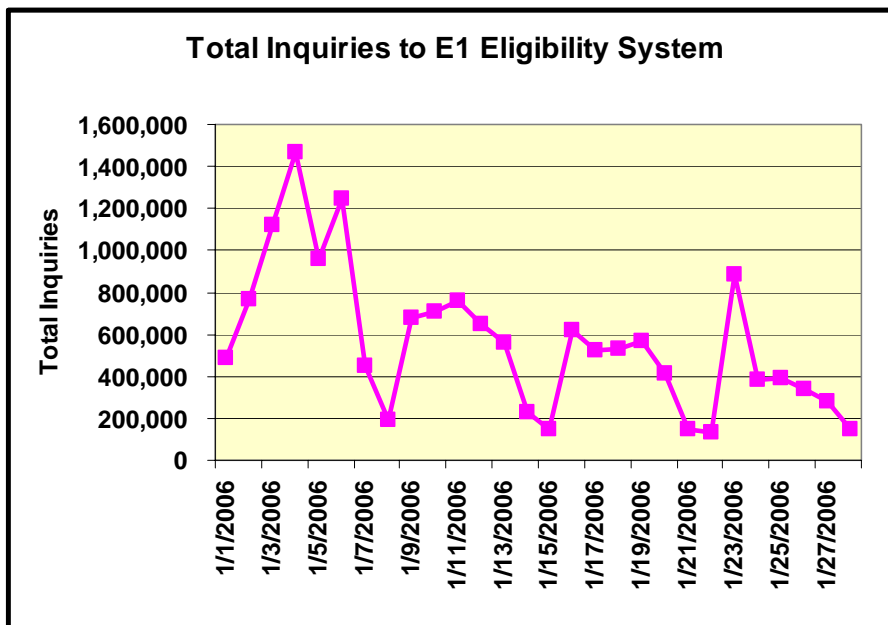


Figure 4: Total Inquiries to E1 Eligibility System

In addition, pharmacists are reporting that they are experiencing improvements in their ability to query and obtain information from the E1 eligibility transaction system. One pharmacist noted on January 11, 2006, "I wanted to take the opportunity to tell you that our

434 pharmacies have found the (E1) system very helpful and we have seen the system's 'integrity' improve significantly from January 2, 2006 to today.”⁷

CMS Addresses Issues Between Plans and Pharmacies

In addition, CMS and the Medicare health plans are working to address a number of issues that will improve the efficiency of the process at the pharmacy counter and assure that all people with Medicare get the medications they need. Among the steps CMS has facilitated are: a) increasing the capacity of plan help lines; b) providing direct plan-to-pharmacist technical support; and c) streamlining the data submission and reporting procedures from plans to CMS. Additionally, on January 6, 2006, CMS sent a second letter to plans on enforcement of their own transition plans by educating their customer service representatives (CSRs) and ensuring that their data systems have the appropriate information to implement their transition plans. CMS sent two additional letters to the plans on January 13, 2006 providing further clarification on formulary transition policies and expedited processes on cost sharing for dual eligible individuals. Specifically, CMS required plans to make override information readily available to pharmacists, which will allow the correct co-payment to be charged. Should the plans' pharmacist assistance line be inaccessible, CMS can provide assistance through Medicare's 1-866 designated pharmacist help-line. CMS also specified that steps have been taken to ensure that pharmacists can override inappropriate claim denials. For example, plans must have expedited procedures for pharmacists to obtain authorization to override any improper claim denial, in accordance with their transition policy, in case a beneficiary's prescribed medications are not on the plan's formulary. In all of these areas, health plans had already responded by taking these and other steps to assist beneficiaries. The CMS actions help ensure that all plans provide effective service.

CMS also has regular one-on-one calls with the plans to identify issues and solutions. CMS is in constant communication with the plans pertaining to issues as they arise, and the Agency has developed a collaborative process whereby CMS organizes calls with plans and their pharmacists to resolve problems as quickly as possible.

⁷ Winn-Dixie Pharmacist email January 11, 2006

CMS Continues Extensive Outreach to Pharmacists

Since implementation of the benefit, CMS has continued its extensive outreach to pharmacists. We have continued discussions with pharmacy organizations both centrally and regionally, as well as our direct contact with both independent and chain pharmacies. Additionally, CMS hosted a technical support teleconference for pharmacists across the country January 5, 2006 and also hosted a national open door forum for pharmacists January 10, 2006 to answer questions. The first was to directly address the point of sale enrollment process. The second call addressed many implementation issues and included a lengthy question and answer session. We have also sent four Medicare Rx Update communications since December 30, 2005. CMS has identified frequently asked questions regarding the point of sale facilitated enrollment system, plan transition policies, plan contact information, "What If" scenarios for pharmacists, tips for using the E1 system and much more. Specific examples of outreach that CMS has performed in relation to January 1, 2006 issues include:

- Daily calls with pharmacists and pharmacy executives all over the country. These calls help identify trends and workable solutions to numerous issues associated with implementation as well as facilitating outreach to thousands of pharmacists.
- Over 1,000 emails and calls in direct response to specific issues presented to the pharmacist since January 1.

In addition, CMS is holding weekly conferences with pharmacy associations that help CMS distribute information and educate pharmacists to ensure they have the most complete and up-to-date information possible. Also, CMS is communicating on a daily basis with both chain and independent pharmacies. Pharmacists in CMS' ten regional offices are working directly with local pharmacies, pharmacists, and pharmacy associations to identify troubling trends and specific problems. CMS is working closely with the National Association of Chain Drug Stores (NACDS), the National Community Pharmacist Association (NCPA), the American Pharmacists Association (APhA), the National Council of State Pharmacy Association Executives (NCSPA), the American Society for the Automation of Pharmacy (ASAP) and other groups to help communicate with and educate their membership.

CMS Continues Outreach with Physicians

On January 1 CMS placed an announcement on the welcome page to our Physicians Regulatory Issues Team (PRIT) website with advice for providers and an invitation for them to call or email CMS with issues or concerns about the Medicare prescription drug benefit. We have received and responded to almost 200 emails from providers.

In addition, CMS sent a letter to physicians outlining specific sources of help and information including the following.

- A web-based formulary finder linked to all plan formularies.
- Information about Epocrates, an electronic handheld and web-based drug and formulary reference for physicians, that is providing plan formulary information including both tier and step therapy information and is updated constantly.
- An exceptions and appeals contact list for each prescription drug plan so physicians can help a patient by filing a prior authorization for a medication or appeal a medication's tier.
- Information about coverage determinations, exceptions, appeals, and expedited requests.
- A universal, faxable form created by a coalition of medical societies and advocacy groups for pharmacists and physicians to use in the event a patient's prescription is not on a formulary or on a higher tier. This optional form provides a straightforward way for the pharmacist to communicate with a physician's office.
- A chart to determine if the drug a physician prescribed is a Part B or Part D drug.
- Information about the CMS web-based email and weekly conference calls where physicians can get direct help with their concerns.

CMS Continues Collaboration with States

To ensure ongoing coordination with the States after the prescription drug benefit began, CMS is hosting conference calls with the State Medicaid Directors about Medicare prescription drug plan implementation challenges and solutions several times each week. Additionally, calls continue with States and plans, pharmacists, and CMS staff. CMS

regional offices are making regular calls to the State Medicaid Directors and their staff with updates and to address specific problems.

CMS Establishes Reimbursement Plan for States that Cover the Cost of Dual Eligible Individuals

CMS is working with the States to ensure all dual eligible individuals are able to leave the pharmacy with the drugs they need. In addition, pharmacies need to continue to work with the plans to sort out start-up issues as quickly as possible. However, some States are reporting that dual eligible individuals have been charged the wrong cost sharing amounts when they have gone to the pharmacy and some have left the pharmacy without their drugs.

Certain States have taken steps to help their dual eligible individuals by using their State system of reimbursement to pharmacies. These States are now paying for dual eligible beneficiaries' prescriptions that should be paid for by the prescription drug plans, and, if States have stepped in they will be reimbursed.

On January 25 we announced a demonstration project to reimburse States for their expenses related to the Medicare prescription drug program. CMS will work to ensure that prescription drug plans to reimburse States for the dual eligible individuals up to the amount they would otherwise have paid for the duals' drug costs. Through this demonstration project, the federal government will reimburse States for any differential between the plan reimbursement and the state payment, as well as for certain administrative costs for paying the State claims and facilitating the correct enrollment of dual eligible individuals into a prescription drug plan. States will work with CMS to help obtain accurate beneficiary information on drug spending. They will also use payment approaches that support pharmacists' efforts to primarily bill the Medicare prescription drug plans and ensure the use of the Medicare point-of-sale billing before relying on State payment such that states serve as a payer of last resort. States that follow these recommendations have had only limited claims made against their Medicaid systems. The demonstration requires States to make significant progress toward turning off their State reimbursement systems and return to the

Medicare prescription drug system by February 15, 2006 with the Secretary having discretion to extend the demonstration for a limited period thereafter if necessary.

With input through a State workgroup, CMS developed a template to apply for this demonstration for use by those States that re-instituted some coverage through their Medicaid system for dual eligible individuals. The template is expected to be available shortly and will be posted on the CMS Website.

In addition to providing reimbursement to the States, the demonstration will include timely data sharing and claims identification features. States that participate should provide timely summary information on claims incurred, including summary amount and beneficiary identification information, to facilitate reconciliation and beneficiary transition to prescription drug plans. States should also work with CMS to provide valid data on any set of beneficiaries who may not have been included properly in the State's previous dual eligible files. Also, States should separate claims for the transition period from claims the States would have otherwise paid through a separate State program. In some States, the State has elected to pay all cost sharing, for example, on behalf of some individuals who would otherwise have paid a copayment.

Under the demonstration, plans, and then Medicare, would reimburse State paid claims previously incurred and up to and through the anticipated end date of this demonstration of February 15, 2006. CMS will continue to work closely with the States, as we have been, to resolve temporary transition issues and make sure people with Medicare can get the new prescription drug coverage if they want it.

CMS Continues to Work Hard to Ensure the Most Important New Benefit in 40 Years Delivers Drugs to People with Medicare

Mr. Chairman, thank you for this opportunity to discuss the new Medicare prescription drug benefit and the transition process and protections for people with Medicare. Transition is never without challenges. CMS is taking many steps with systems, plans, pharmacists, States, and other partners to quickly resolve the implementation challenges that have arisen

in the first weeks of this beneficial new program, and we appreciate your collaborative efforts to address them. As the *New York Times* noted in 1966 when Medicare debuted, “This great new experiment must be given ample time to get over its growing pains.”⁸ CMS is confident that we too will overcome our “growing pains” as we continue to address the challenges set before us implementing the new Medicare prescription drug benefit. I would be happy to answer your questions.

⁸ *New York Times*, "Medicare's Beginning," pg. 34, July 1, 1966