



# MEDICARE Modernization Act + FINAL REGULATIONS

**O**n January 21, 2005 the Centers for Medicare and Medicaid Services (CMS) released the final regulations implementing the Medicare Modernization Act (MMA). The final regulations provide substantial insight into how the program will be implemented. This document summarizes the regulations.

**OVERALL,** it appears CMS has established specific standards for prescription drug plans (PDPs) that will serve beneficiaries in long-term care (LTC) settings. However, concerns remain over multiple formularies in nursing homes and difficult provisions for access to non-formulary drugs.

**BACKGROUND:** The MMA was passed and signed into law on December 8, 2003. CMS had been working to implement this law and the final regulations have been a major milestone in achieving the goal.

The MMA was passed in response to an increasing awareness that the benefit structure of Medicare had not kept pace with the changes in health care over the past 30 years. Among the most obvious deficiencies was the

lack of a prescription drug benefit. The MMA's focus was to deliver a prescription drug benefit using competition and consumer choice as foundations on which to create a solution that was responsive to beneficiary needs while helping to hold down costs.

PharMerica's advocacy efforts during consideration of the MMA were focused on assuring appropriate access to prescription drugs for the 1.5 million beneficiaries in nursing homes, most of whom had relied upon Medicaid for their drug benefits.

# How the Program Will Work:

What can Medicare beneficiaries in long-term care settings expect concerning prescription drugs?

**Benefit Delivery:** As of January 1, 2006, Medicare LTC residents no longer receive Medicaid coverage for their prescription drugs. Instead, they receive drug benefits through one of two sources: a managed care plan with a drug benefit (officially referred to as Medicare Advantage, or MA-PD); or through a fee-for-service alternative known as a prescription drug plan (PDP). These PDPs are risk-based insurance plans that have established benefit plans and premium and cost-sharing methodologies and have made them available to LTC residents. Most LTC residents (approximately 70 percent) are generally dually eligible for Medicare and Medicaid. LTC residents below 150 percent of the federal poverty level are eligible for federal subsidy payments to make the benefit more affordable. Since State Medicaid programs typically have not provided full coverage for people above 75 percent of the federal poverty level, many more people have financial help in covering their drug costs.

**How The PDPs Work:** As noted earlier, the PDPs are insurance plans that have created a prescription drug benefit and offered it to Medicare beneficiaries in a specific region of the country. CMS has established 34 specific regions; most of them single states, based on the number of Medicare beneficiaries and similar projected prescription drug costs. The PDPs build benefit plans that include the following:

**FORMULARIES:** These are lists of drugs that the PDP will include in its benefits package. CMS has determined that plans must not create formularies that will discriminate against persons with specific diseases and will review plan formularies to prevent discrimination. In addition, plans will be required to provide procedures to review requests for drugs not included on the plan formularies. Formularies are reviewed and approved on a yearly basis.

**PREMIUMS AND COST SHARING INFORMATION:** Plans will need to be able to determine what the monthly insurance premium will be and how the cost sharing will work. For example, some plans may choose relatively limited formulary provisions and relatively low premiums. Other plans may include more drugs and require higher premiums and additional cost sharing. Again, CMS will review these details before plans are approved on a yearly basis.

**PHARMACY NETWORKS:** According to the provisions of the MMA, a PDP must demonstrate that beneficiaries can access their prescription drugs conveniently. There are established standards for proximity to retail locations, and CMS has indicated that a plan must have sufficient relationships with pharmacies that serve LTC residents to provide access for nursing home residents.

Once CMS approves a PDP for the following plan year (beginning October 15th of each year) the plan is then marketed to all Medicare beneficiaries within the region. The Annual Enrollment Period (AEP) runs from November 15 to December 31, every year. All residents in a long term care facility also have a Special Enrollment Period (SEP) which is for anyone who resides in, or is entering or leaving a long term care facility.

## How The New Plan Will Differ From The Current Program:

Approximately 70 percent of nursing home residents received prescription drug benefits through the Medicaid program prior to January 1, 2006. Medicaid programs typically had made all necessary drugs available to their beneficiaries, even though barriers such as prior authorization were increasingly common.

Under Medicare Part D, Medicare beneficiaries will obtain their drugs through an intermediary - the PDP. Unlike Medicaid, the PDP has the ability to create a restrictive formulary and has more power to enforce compliance with the formulary. Whereas one program (Medicaid) has coverage responsibility for about 70 percent of the nursing home residents, the new program may have several PDPs within each region. This may establish several different sets of access and formulary standards within the nursing home population.

Low income residents will receive government assistance in paying for their drugs, premiums and cost sharing. This assistance will apply, in varying degrees, to residents under 150 percent of the federal poverty level.

Nursing home residents dually eligible for Medicaid and Medicare or Low Income Subsidy (LIS) beneficiaries will not be required to pay any of the costs themselves.

Medicare beneficiaries in LTC facilities will be allowed to change PDPs upon entering a facility if a different PDP has a more appropriate plan for their condition.



## LTC Pharmacy Relationship:

**WITH PDPs:** CMS has laid out a plan that will require PDPs, in their application, to demonstrate that they have sufficient number of contracts with LTC pharmacies to provide convenient access for residents of LTC facilities.

CMS has provided guidance concerning the specific services required for LTC residents. Examples of these special services include special packaging, routine and emergency delivery and emergency supplies of medication. PDPs will be required to assure that the pharmacies they contract with are able to provide these services.

**WITH NURSING HOMES:** CMS states that they intend for nursing homes to be able to continue the standard practice of contracting with a single pharmacy provider. PharmMerica provides assistance to their nursing home customers in identifying broad formulary coverage PDPs.

## How Beneficiaries Are Enrolled

**In PDPs:** Since the majority of LTC residents are either fully eligible for both Medicaid and Medicare (dual eligibles) or will be beneficiaries of the federal subsidy for people below 150 percent of the federal poverty level, Medicare will take steps to assure that they are covered by a Medicare plan as they become eligible.

For subsidy populations with incomes and assets above the level that qualifies for dual eligible status, CMS facilitates enrollment. This facilitation will involve special outreach efforts aimed at encouraging them to enroll in a plan.

Beneficiaries with incomes above the subsidy level (150% of FPL) will have from November 15 through December 15 of each year to choose a PDP or MA-PD without any involuntary or auto-enrollment.

## How LTC Residents Will Access Non-Formulary Drugs:

Since PDPs are allowed to maintain restrictive formularies, there will be occasions when the prescribed drug for an LTC resident will not be readily available from the PDP.

CMS has made provisions for this in their final regulations. Among the more important provisions is the ability of the resident to designate a representative to act on their behalf with the PDP to access exceptions to the plan formulary. The list of individuals that can perform this function includes a pharmacist, physician, family member or other appointed representative.

Although the rules on this subject are fairly complex, the regulation calls for two types of appeals: a standard appeal (non-urgent), and an expedited appeal. Since nursing home regulations generally require drugs to be available within a fairly short time frame, we expect the majority of requests for exceptions to fall under the expedited category. However, the PDP has the ability to determine which requests will receive expedited review.

If the PDP grants an expedited review, the plan has 24 hours to notify the enrollee of its determination. If the request for expedited review is denied, the plan has 72 hours to respond.

There are additional conditions and regulations surrounding requests for review and appeals in the final regulations.



## How CMS Allows For An Orderly Transition From Medicaid to

**Medicare:** Beginning in 2006, beneficiaries who will be covered by Medicaid are covered by Medicare D. This often necessitates a transition between the Medicaid formulary and the PDP formulary. CMS has provided further guidance on this issue, but has noted in its final regulation that plans will be required to spell out their transition policies when they apply for approval to CMS.

## How CMS Treats The MMA Provisions Regarding Medication Therapy Management (MTM)

**Programs:** One of the provisions of the MMA is the requirement for PDPs to have medication therapy management programs in place in order to manage beneficiaries with chronic conditions that consume a large number of prescriptions and result in high costs. Although CMS was not comprehensive in the final regulation on this topic, it did suggest that services provided by LTC pharmacies that were not included in the definition of dispensing fee could be included under the plan's MTM program.

CMS will require the PDP to have an MTM plan in place, but will not spell out the exact requirements in regulation.

**Quality Standards:** CMS refers to pharmacy quality standards that are part of OBRA '90. These standards required states to adopt laws and regulations that required point-of-service counseling for Medicaid beneficiaries. Most states adopted these standards and expanded them to the general population. CMS will not create additional requirements in this regulation.

The regulation does require plans to maintain prospective and concurrent drug utilization review programs and encourages the adoption of electronic prescribing and the use of bar codes.

**Risk Adjustment:** In order to provide resources to PDPs, and not discourage them from enrolling high-cost beneficiaries, CMS will provide risk adjustment payments to PDPs that account for the higher cost of serving institutionalized and low-income individuals.

**IMPORTANT DEFINITIONS:** CMS provides definitions for some important topics in the final regulation.

**LONG-TERM CARE FACILITY:** Includes skilled nursing facilities, intermediate care facilities and "any medical institution or facility for which payment is made for institutionalized individuals under Medicare."

**LONG-TERM CARE PHARMACY:** A pharmacy owned by, or under contract with, a long-term care facility to provide prescription drugs to the facility's residents.



866.577.3784  
pharmerica.com  
info@pharmerica.com