The Long Term Care Pharmacy Alliance Welcomes
Medicare Modernization Act Final Regulations

On January 21, 2005 the Centers for Medicare and Medicaid Services (CMS) released the final regulations implementing the Medicare Modernization Act (MMA). LTCPA congratulates CMS on issuing the regulations—the most recent in a number of agency accomplishments—under short deadlines since the MMA's enactment in December 2003. LTCPA also welcomes the regulations, which lay the framework for the mechanics of the new prescription drug benefit's implementation. The Alliance looks forward to continuing to work closely with CMS in formulating the additional regulatory guidance documents that will be issued, bringing even greater clarity and functionality to the implementation of the new benefit on January 1, 2006.

Summary of the Regulations: The final regulations provide substantial insight into how the Medicare prescription drug program will be implemented. Through the regulations, and several additional guidance documents from CMS to be issued in the coming weeks, we have a more complete picture of how this program will implemented among long term care residents.

Overall, CMS has appropriately created the fundamental building blocks upon which to create necessary, specific standards for prescription drug plans (PDPs) that will serve beneficiaries in long term care (LTC) settings. While we remain concerned about the potential difficulties in managing multiple formularies in nursing homes and about the need for timely access to non-formulary drugs, we are committed to working with CMS on these important issues to ensure that nursing home residents have access to all medically necessary medications and that quality of care is not compromised.

Background: On December 8, 2003, President Bush signed the MMA into law. Since that time, CMS has been working to implement this law. The final regulations are a major milestone in achieving that goal.

The MMA was passed in response to Congress' 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 goal is 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.

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

1025 Connecticut Ave., NW, Suite 1000 Washington, DC 20036
Phone: (202) 327-5478 Fax: (202) 327-5479 www.ltcpa.org

How the Program Will Work: The final regulations establish a basic framework for how Medicare beneficiaries in long term care settings can expect to receive prescription drugs.

- **Benefit Delivery**: Beginning January 1, 2006, all Medicare-eligible LTC residents can receive prescription drug coverage through the new Part D benefit. Those Medicare-eligible residents who also qualify for the Medicaid program will, for the most part, be shifted into the new Medicare program. The Part D program will provide drug benefits through one of two sources: (1) a managed care plan with a drug benefit (i.e., Medicare Advantage, or PA-PD); or (2) through a fee-for-service alternative known as prescription drug plan (PDP). PDPs are risked-based insurance plans that will establish benefit plans, premiums and cost sharing programs for all Medicare beneficiaries, including long term care residents.

- Most LTC residents (approximately 70 percent) are dually eligible for Medicare and Medicaid. These residents will receive virtually all their drug benefits through the Part D program, without any out-of-pocket costs. LTC residents below 150 percent of the federal poverty level (FPL) will be eligible for significant federal subsidy payments to make the new benefit more affordable. Since State Medicaid programs typically do not provide full coverage for people above 75 percent of the FPL, we anticipate many more people will have financial help in covering their drug costs.

- **How the PDPs work**: Participating plans provide a prescription drug benefit, offered to all Medicare beneficiaries in one of 34 specified regions across the country. The 34 specific regions, most of them single states, were based on the number of Medicare beneficiaries and similar projected prescription drug costs. The PDPs will be expected to build benefit plans that include the following:

    - ***Premiums and Cost Sharing Information***: PDP plans must fix their monthly insurance premium and specify to beneficiaries how 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. PDPs may develop and market more than one benefit plan. They can develop an enhanced benefit plan that includes additional benefits at additional cost, although subsidy populations will not generally have access to these benefit plans.
    - ***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 beneficiaries to provide access for nursing home residents. The specific services that plans will be

required to contract for, with LTC pharmacies, will be clarified in future guidance.

- ***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.

Once CMS approves a PDP, the plan will then be able to market its plan to all Medicare beneficiaries within the region. The initial enrollment period for 2006 runs from November 15, 2005 to May 15, 2006. However, since Medicaid drug coverage will not be available for current Medicaid beneficiaries who also qualify for Medicare, initial enrollment will begin earlier.

- **How the new plan will differ from the current program:** Approximately 70 percent of nursing home residents currently receive prescription drug benefits through the Medicaid program. Medicaid programs typically make all necessary drugs available to their beneficiaries, even though access barriers such as prior authorization are increasingly common.

  Under the new plan, Medicare beneficiaries will obtain their drugs through a new 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 today, about 70 percent of the nursing home residents obtain drug coverage from once source (Medicaid), the new program may have several PDPs within each region, each with different access and formulary standards within the nursing home populations in a given region

  Low income residents will continue to 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 will not be required to pay any of the costs themselves. However, cost sharing will be required for non-full-benefit dual eligibles, as it is today.

  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. This process will not be automatic, but must be initiated by the enrollee or their legal representative.

- **Long term care pharmacies' relationships 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 will soon be providing guidance defining the specific services required for LTC residents. Examples of these special services include special packaging, routine and emergency delivery (including 24-hour availability) and emergency supplies of medication. PDPs will be required to assure that the pharmacies they contract with are able to provide these services. Only those pharmacies providing these services will qualify as "long term care pharmacies".

- **LTC pharmacies' relationship with nursing homes**: CMS intends that nursing homes be able to maintain the standard practice of contracting with a single pharmacy provider. CMS believes, however, that the pharmacy will have a special incentive to contract with as many PDPs as possible, since routine out-of-network access will not be allowed. However, CMS has made a provision that LTC residents will have access to a special enrollment period that allows changing PDPs when a beneficiary is in an LTC facility. This applies to all dual eligibles as well.

- **How beneficiaries will be 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 on January 1, 2006.

  For full-benefit dual eligibles, Medicare will probably begin enrollment outreach in the fall of 2005, with involuntary enrollment for those beneficiaries who do not enroll on their own by the end of 2005. CMS has indicated that the auto-enrollment process will enroll current members of an MA plan into the MA-PD plan offered by their carrier. All other dual eligibles will be enrolled in a PDP with premium plans at or below the subsidy costs for these beneficiaries.

  For subsidy populations with incomes and assets above the level that qualifies for dual eligible status, CMS will facilitate enrollment through a special outreach effort aimed at encouraging them to join a plan.

  Beneficiaries with incomes above the subsidy level (150 percent of FPL) will have from November 15, 2005 through May 15, 2006 to choose a PDP or MA-PD plan without any involuntary or auto-enrollment. If they choose not to enroll they will remain responsible for their own medication costs.

- **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, including a pharmacist, to appeal on their behalf with the PDP for access to exceptions to the plan formulary.

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 long term care exceptions requests will likely be expedited. The regulation is explicit that a plan must have a procedure in place to provide expedited appeals when using the standard appeal may "seriously jeopardize the enrollee's life, health, or ability to regain maximum function.."

Plans must determine whether to grant requests for expedited appeals as expeditiously as the enrollee's condition requires, but not more that 24 hours after they receive the request. Expedited appeals requests will not be required when the drug has already been dispensed.

For standard appeals (non-urgent) the plan has 72 hours to respond to the resident concerning their determination. Requests for expedited appeals that have been denied must also be responded to within 72 hours.

Since the regulations governing the nursing home's responsibilities are not affected by this regulation, we would like some clarification concerning who is responsible for paying for a prescribed drug for which the PDP will not pay.

- **How CMS will allow for an orderly transition from Medicaid to Medicare:** Beginning in 2006, beneficiaries currently covered by Medicaid will be covered by Medicare. This will necessitate a transition between the Medicaid formulary and the PDP formulary. CMS will provide 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 will treat the MMA provisions regarding medication therapy management (MTM) programs**: The MMA requires PDPs to provide medication therapy management programs in place in order to manage beneficiaries with chronic conditions requiring a large number of prescriptions and result in high costs. Although the final regulation does not fully address the topic, CMS has suggested that services provided by LTC pharmacies beyond medication delivery could be included under the plan's MTM program. Thus, while CMS will require the PDP to have an MTM plan in pace, the agency has not spelled out the exact requirements in the final regulations.

- **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 PDP plans to maintain prospective and concurrent drug utilization review programs and encourages the adoption of electronic prescribing and the use of bar codes. We anticipate that PDPs will employ long term care pharmacies for this purpose.

- **Important Definitions**: CMS provides definitions for the following terms in the final regulation.
  - ***Long term care facility***: Include skilled nursing facilities, intermediate care facilities and "any medical institution or facility for which payment is made for institutionalized individuals under Medicaid"
  - ***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.

- **Risk Adjustment**: In order to encourage PDPs to enroll high cost beneficiaries, CMS will provide risk adjustment payments to PDPs that account for the higher cost of serving institutionalized and low-income individuals.