A Strategy for Transitioning Dual Eligibles from Medicaid to Medicare Prescription Drug Coverage – May 2, 2005

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, including the approximately 6 million low-income beneficiaries who also are enrolled in Medicaid. Known as "full-benefit dual eligibles," these beneficiaries will now qualify for Medicare prescription drug coverage with low or no premiums and co-payments of a few dollars. This coverage will begin on January 1, 2006.

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. 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 who take a number of prescriptions to manage their one or more chronic conditions.

CMS is committed to accomplishing the following objectives to ensure a safe and appropriate transition of full-benefit dual eligibles to the Medicare prescription drug program.

1. Providing Comprehensive Coverage
2. Ensuring Continuity of Coverage
3. Working with States
4. Establishing Appropriate Safeguards
5. Protecting Special Populations
6. Reaching People with Medicare: Outreach and Education

Providing Comprehensive Coverage

Full-benefit dual eligible beneficiaries automatically qualify for assistance with their Medicare prescription drug plan costs and do not need to file an application for the low-income subsidy. Certain other groups are also eligible for this assistance including Medicare beneficiaries who are recipients of Supplemental Security Income (SSI) and participants in Medicare Savings Programs as Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs), and Qualifying Individuals (QIs). Other beneficiaries with low incomes and limited assets (including savings and stocks but not counting one's home) who do not fall into one of the automatic subsidy eligibility groups will need to apply for this extra help. In May 2005, CMS will begin mailing notices to dual eligibles informing them that Medicare will begin providing prescription drug coverage through Medicare prescription drug plans and that they qualify for extra help paying their Medicare prescription drug plan premium, deductible and cost-sharing. The notice will also explain that additional information will be available in October 2005 about the specific Medicare prescription drug plans in their area.

For all full-benefit dual eligible beneficiaries, the Federal government will pay for their prescription drug plan premiums up to the benchmark amount, and their entire deductible

(Appendix A). Beneficiaries will only be responsible for $0 to $5 copayments per prescription according to the following rules:

- If a beneficiary has income above 100% of the Federal Poverty Level (FPL), he or she will pay up to $2 for generic or preferred drugs and $5 for other drugs.
- If a beneficiary has income at or below 100% FPL, he or she will pay up to $1 for generic or preferred drugs and $3 for other drugs.
- If a beneficiary is residing in an institution such as a nursing home or intermediate care facility for people with mental retardation (ICF/MR), he or she will have $0 copayments.

Full-benefit dual eligible beneficiaries will be responsible for copayments up to the out-of-pocket limit, after which they will have no copayments for their prescription drugs.

Ensuring Continuity of Coverage

Full-benefit dual eligibles will have the opportunity to join a Medicare prescription drug plan in their area once enrollment begins on November 15, 2005. However, if they take no action on their own, CMS will enroll them in a Medicare prescription drug plan effective January 1, 2006 to ensure there is no lapse in prescription drug coverage. Depending on the type of coverage a beneficiary has for his or her Medicare Part A and/or Part B benefits, CMS will enroll him or her according to a set of guidelines (Appendix B) that minimizes disruption of their current care delivery. In certain cases where a dual eligible is enrolled in a Medicare health plan, the plan will notify him or her that she or he will be enrolled in the health plan's prescription drug coverage through the plan renewal process at the end of 2005. Full-benefit dual eligibles will have the opportunity to switch plans at any time. This way, they have continuity of care when their Medicaid prescription drug coverage ends, while also retaining the right to select a plan that best meets their needs.

<u>Enrollment and Eligibility Process in 2005</u>

- States will identify dual eligible beneficiaries by submitting a monthly file to CMS of people in their State who have Medicaid and Medicare.
- In May, CMS will mail a letter notifying full-benefit dual eligible beneficiaries that they automatically qualify for the low-income subsidy and do not need to apply.
- In October, CMS will mail a letter to these beneficiaries identifying the plan in which Medicare will enroll them, effective January 1, 2006, if they do not choose a plan on their own by December 31, 2005.
- In October, at the same time CMS is notifying beneficiaries of the plan they will be enrolled in, CMS will notify Medicare prescription drug plans of the full-benefit dual eligible beneficiaries assigned to their plan.
- Medicare prescription drug plans will mail enrollment materials to the beneficiaries assigned to their plan that includes the list of covered drugs and pharmacy network.
- The beneficiary will then have the opportunity to review the plan materials available to him or her to make an informed choice of a drug plan.

- If the beneficiary does not make a choice, CMS will enroll him or her in a Medicare prescription drug plan with an effective date of January 1, 2006.
- Full-benefit dual eligible beneficiaries will have the opportunity to switch plans at any time.

CMS is working diligently with States to ensure that they appropriately identify their full-benefit dual eligibles. CMS will validate the information that States report to minimize reporting errors, mistakes, and omissions that may affect the identification of the States' dual eligible residents. In the event that these safeguards fail, CMS is also working on a way to ensure that any full-benefit dual eligible omitted from our process are able to receive Medicare prescription drug coverage when it begins in January 2006.

Working with States

CMS is committed to working with States on an ongoing and collaborative basis to ensure a smooth transition for their dual eligible residents. This work officially commenced in August 2004, when CMS convened the first meeting of the State Issues Workgroup with representatives of State Medicaid Agencies, the Social Security Administration (SSA), and CMS. The Workgroup tasked itself with identifying potential solutions for outstanding policy issues affecting the states; providing recommendations for data exchanges and systems processes required for successful implementation; and developing a protocol for working with SSA on training and outreach on the low-income subsidy. The Workgroup has a shared concern for the dual eligible population and common purpose to make the transition as transparent as possible to the beneficiary. Many of the subcommittees are working directly or indirectly on issues affecting the dual eligible population:

- Identification—To assure that States report and CMS knows of every dual eligible beneficiary in the country undergoing this transition.
- SSA Interaction—To develop an efficient and effective low-income application process and train, educate, and conduct outreach in a coordinated fashion.
- Enrollment—To 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.
- Transitions—To develop strategies for transitioning dual eligible beneficiaries from Medicaid to Medicare while also assuring coordination of care.
- Phase-down State Contribution—To assure that the calculation of the phasedown state contribution is accurate.

In addition to the ongoing efforts of the State Issues Workgroup, CMS has engaged the states in a series of meetings, conference calls, and workshops to discuss the implementation of the MMA. These engagements include monthly all-state conference calls; state pharmaceutical assistance program (SPAP) workgroup conference calls; conferences hosted by the organizations representing the states including the National Governors Association, National Conference of State Legislatures and Council of State Governments; and face-to-face meetings with states that are coordinated and facilitated by CMS's regional office staff who have close working relationships with states in their respective regions. These interactions allow CMS to share the

most up-to-date information on our implementation efforts, and more importantly, gives CMS the opportunity to listen to States' questions and concerns.

CMS is encouraging States to develop a plan for transitioning their dual eligible residents. A State may design a plan for their entire dual eligible population or specific subpopulations such as residents of long-term care facilities or people with sensitive medication needs, complex diseases or cognitive impairment. Among the tactics a State could employ under this plan are the following:

- Establish policies and procedures to assure the accuracy and validity of the enrollment information reported to CMS on dual eligible beneficiaries in the State.
- Develop a communications plan to:
  1) Help dual eligibles understand the features of the Medicare prescription drug program that may not currently be in place or apparent to them under their state's Medicaid program.
  2) Inform Medicaid providers about upcoming changes in drug coverage to enable them to arrange for appropriate switches of medications or exception requests, if necessary.
  3) Contact, inform and develop partnerships with sister state agencies, employers, community-based organizations and other entities to establish information exchange networks.
- Provide counseling and support to ensure that dual eligibles make an informed choice.
- Develop business relationships and exchange relevant information with plans to promote coordination of care in a manner that is consistent and compliant with Federal privacy and other applicable laws.

To assist the States further, CMS will be providing them with access to the following tools and resources as soon as they are available:

- Enrollment information for full-benefit dual eligibles including their assigned plans.
- Comparative information on Medicare prescription drug plans including formularies and pharmacy networks.
- Targeted educational and outreach materials.

As an additional precautionary measure, CMS is also providing States with two options to minimize unexpected disruptions in a full-benefit dual eligible beneficiary's treatment toward the end of 2005. CMS is issuing a State Medicaid Director letter clarifying that it is permissible for a state to allow beneficiaries, including full-benefit dual eligible beneficiaries, to receive an early refill or an extended supply (30-90 days) of their prescriptions near the end of this calendar year and receive federal matching funds, Federal Financial Participation (FFP). CMS is also planning to issue a State Medicaid Director letter clarifying that after January 1, 2006, States may continue to cover and claim FFP for certain drugs that are not covered under the Medicare prescription drug program. This list of drugs includes benzodiazepines and barbiturates, which are used in the treatment of many mental health diseases.

Establishing Appropriate Safeguards: Formularies, Transition Plans, and Appeals and Exceptions

Formularies

CMS has 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. As they develop their formularies, plans will need to 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. We will review these formularies and benefit structures to verify that plans are in compliance with the following requirements:

- Multiple drugs in each class: The minimum statutory requirement is that a formulary must include at least two drugs in each approved category and class (unless only one drug is available for a particular category or class), regardless of the drug classification system that is utilized. We view this requirement as a floor rather than an absolute standard. CMS may require more than two drugs per category or class in cases where additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and where their absence from the plan formulary may substantially discourage enrollment in the plan by beneficiaries with certain diseases.

- Pharmacy and therapeutic committees (P&T): A Medicare prescription drug plan's formulary must be developed and reviewed by a P&T committee. CMS will require that plans assure the implementation and use of a P&T committee consistent with widely used industry best practices. Our oversight will assure that plan formularies are designed to provide appropriate, up-to-date access for beneficiaries and give plans the flexibility to offer benefit designs that provide affordable access to medically necessary drugs. A majority of the P&T committee members must be physicians, pharmacists or both.

- Review of Drug Classification System and Drug Lists: CMS will evaluate formulary classification systems as well as the actual list of drugs included in the formulary, using existing widely used classification systems and drug plans as checks.

- Benefit Management Tools: CMS will compare the prescription drug plans' use of benefit management tools, like prior authorization, to the way these tools are used in existing drug plans, to ensure that they are being applied in a clinically appropriate fashion.

For more detailed information, please see Appendix C for the CMS document, "CMS Strategy for Affordable Access to Comprehensive Drug Coverage," which describes the framework for CMS review of Medicare prescription drug plan formularies.

Transition Guidance

CMS is requiring Medicare prescription drug plans to establish an appropriate transition process for new enrollees including full-benefit dual eligibles who are transitioning to the Medicare benefit from other prescription drug coverage. CMS believes that a requirement for an appropriate transition process balances the protection of certain vulnerable populations with the flexibility necessary for Medicare prescription drugs plans to develop a benefit design that promotes beneficiary choice and affordable access to medically necessary drugs. While we are ensuring that there is no lapse in coverage for full-benefit dual eligibles, we recognize that this population may be unaware of their changing coverage in spite of our best collective education and outreach efforts. As a result, this transition process will need to address the plan sponsor's method of educating both beneficiaries and providers to ensure a safe accommodation of an individual's medical needs with the plan's formulary. We believe some period of adjustment may be necessary to introduce the new formulary requirements, and set forth our expectations of what constitutes a reasonable transition timeframe. We also recommend that the transition process address unplanned transitions as individuals change treatment settings due to a change in the level of care. We will review the plan's transition process as part of the formulary and plan benefit design review.

For more detailed information, please see Appendix D for the CMS document, "Information for Part D Sponsors on Requirements for a Transition Process," which sets standards for Medicare prescription drug plans as they develop transition policies for beneficiaries who currently have other types of prescription drug coverage.

Coverage Determinations, Appeals & Exceptions

CMS has also developed appeals procedures which ensure that enrollees quickly receive decisions regarding medically necessary medications. Because most enrollees will receive information about the amount of cost-sharing for a requested drug at pharmacy counters, CMS is requiring plans to arrange with their network pharmacies to distribute or post notices that instruct enrollees to contact their Medicare prescription drug plans to obtain a coverage determination or to request an exception to the plan's formulary if they disagree with the information provided by their pharmacists. If an enrollee would like to receive a requested drug before a decision on a coverage determination or appeal has been made, he or she may choose to pay for the prescription and then request a written coverage determination or an exception from the plan. If an enrollee requests a coverage determination or exception, the plan 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. If an enrollee has already purchased a drug and, for example, an off-formulary exceptions request is later approved by the plan, the enrollee should submit the receipt for the purchase to the plan to obtain reimbursement. If an enrollee cannot afford to purchase the entire prescription before requesting an exception from the plan, pharmacies typically have procedures for dispensing a few doses of a prescribed drug (for which the beneficiary may have to pay). Medicare prescription drug plans must comply with the provisions related to making arrangements for their network pharmacies to distribute or post the notice that instructs enrollees to contact their plans to obtain a coverage determination or an exception. Medicare prescription

drug plans may also establish additional contractual arrangements with their network pharmacies to address situations where an enrollee has an immediate need for a non-formulary drug. Additional guidance is provided in the CMS document "Information for Part D Sponsors on Requirements for a Transition Process" (see also Appendix D).

Protecting Special Populations: Dual Eligible Residents of Long-Term Care Facilities

CMS has established 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. Because a large number of long-term care residents are full-benefit dual eligibles, it is important for the transition process that plans employ to account for any issues associated with filling the first prescription of a non-formulary drug. 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 that are not a plan's formulary while the enrollee is transitioned to an appropriate therapeutically equivalent drug or obtains formulary exception for that drug (if medically necessary). 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.

For more information, see Appendix E for the March 16, 2005 document "Long Term Care Guidance," which is designed to assist Medicare prescription drug plans in formulating policies for serving beneficiaries who reside in long term care facilities.

Reaching People with Medicare: Outreach and Education

CMS is developing an integrated and multi-pronged education effort that will include media advertising, plain language fact sheets, tip sheets, posters, 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.

Message

Our message specifically targeted to full-benefit dual eligible beneficiaries will convey the following information:

- On January 1, 2006, Medicare will begin providing prescription drug coverage through Medicare prescription drug plans.

- If you currently get prescription drug coverage from Medicaid, this coverage will end on December 31, 2005. Some state Medicaid programs may cover those prescriptions that won't be covered under Medicare prescription drug coverage.
- You qualify for extra help from Medicare with your prescription drug plan costs.
- Starting in fall 2005, you should compare drug plans to find a plan that meets your needs.
- People with Medicaid and Medicare need to enroll in a Medicare prescription drug plan by December 31, 2005, or Medicare will enroll you in a plan automatically (you can change this plan later at any time, for any reason).
- Information about Medicare prescription drug coverage is available by calling Medicare at 1-800-MEDICARE or by visiting www.medicare.gov on the web.

National and Local Activities

CMS is committed to working hand-in-hand with other Federal agencies, states, employers, unions, and national and community-based organizations to educate people with Medicare, their caregivers, and others who can help them make decisions about the new Medicare prescription drug coverage and other new Medicare benefits and options. Included in the activities planned to date, CMS is:

- Increasing State Health Insurance Assistance Programs (SHIPs) funding, 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.
- Identifying key stakeholders for this population, and enlisting their help in reaching the beneficiaries.
- Providing non-profit community-based organizations with the training and materials they need to help educate and assist low-income beneficiaries who may otherwise be hard to reach.
- Coordinating with 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 low-income subsidy because of barriers of location, language 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.
- Working with providers in nursing homes, 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. Specifically, working with LTC Associations to provide language for the nursing home administrators to use when contacting the family/caregiver of the beneficiary.
- 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.

- 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.

In addition, CMS has identified many specific Federal programs that employ numerous different communications resources that can be used to educate Medicare beneficiaries about the new drug benefit. Examples of how CMS is working with other Federal agencies to provide assistance include:

- CMS has partnered with the national network of community aging services providers funded by Administration on Aging (AoA) as 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.
- The Department of Housing and Urban Development (HUD) 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 (RHS) targets elderly, disabled, and low-income rural residents. CMS has begun discussions with RHS to explore ways that we can coordinate with their work, so that the people with Medicare 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.

Direct Beneficiary Mailings and Notices

CMS and states will send multiple notices to full-benefit dual eligibles about the upcoming changes in their prescription drug coverage.

CMS Notices: In May 2005, CMS will send a notice explaining Medicare prescription drug coverage and informing recipients of their automatic eligibility for the low-income subsidy. In October, CMS will mail a letter to dual eligibles notifying them of the plan into which they will be enrolled if they do not choose a plan by December 31, 2005. This letter will also contain information explaining that their Medicaid prescription drug coverage is ending.

State Notices**:** States are required to notify their beneficiaries alerting them of the upcoming changes in their Medicaid prescription drug coverage. CMS worked with States to develop

model language for States to send to dual eligible beneficiaries to ensure the beneficiaries receive consistent, repeated information and messages.

Provider Outreach

CMS is undertaking a variety of educational efforts to assist providers, beneficiaries and their advocates in understanding this new coverage. In this effort, we recognize and value the role that health care providers, including physicians, pharmacists, nurses and other health care professionals and staff who work with them, have in health care decision-making. We are therefore working to ensure that the provider communities are not only informed about Medicare prescription drug coverage, but are also prepared to refer Medicare beneficiaries to appropriate resources. As such, we intend to utilize a number of dissemination mechanisms to share information to the Medicare provider community, including the following:

- Creating a series of national Medlearn Matters articles that are coordinated and consistent with educational materials for people with Medicare.

- Posting materials on the new Medlearn web page dedicated to provider information on drug coverage, http://www.cms.hhs.gov/medlearn/drugcoverage.asp on the web.

- Sending notices through provider and CMS-sponsored email listservs.

- Including text messages on paper versions of the remittance advice providers billing for Part B services receive each time they submit a claim.

- Partnering with national provider associations.
  We routinely partner with associations that represent providers who have ongoing interest and need for information related to the Medicare program. Our provider and pharmacy association partners play a crucial role in disseminating educational materials to their membership. Regular communication with these partners provides a dissemination method as well as feedback from Medicare providers.

- Sponsoring an exhibit program at national provider conferences and meetings.
  The CMS Exhibit Program provides a unique opportunity for CMS staff to interact with Medicare providers attending national association conferences and meetings. National educational materials are distributed at the CMS Exhibit Booth during the conferences and meetings by CMS staff. We will provide hard copy educational materials, marketing items, and e-product links at national provider and pharmacy association meetings and conferences throughout 2005 and 2006.

- Hosting Open Door Forums (ODFs).
  ODFs are informational events that promote a two-way discussion between CMS senior level officials and the public, including the provider community.

- Capitalizing on earned media.
  CMS will solicit free advertising (e.g., publication of the Medlearn Matters Special Edition series) in popular provider publications or on provider-focused websites (e.g., WebMD).

- Working with our regional office staff who engages in outreach and education to the state and local provider communities.

- Working with our Medicare fee-for-service contractors.
  Our fee-for-service contractors conduct in-person educational seminars, publish materials in bulletins, post information on their websites, send notices through their email listservs, and perform other outreach activities targeted to each contractor's provider constituency.

Timeline of Dual Eligible Activities

2005

March – June *Awareness Phase for the Medicare Prescription Drug Benefit*

March

- 16th - CMS issues transition guidance for Medicare prescription drug plan sponsors (Appendix D)
- States submit first test enrollment files

April

- 30th - Low Income Fact Sheet available through www.medicare.gov

May

- Mid-May - CMS mails a notice to full-benefit dual eligible beneficiaries in 44 States and the District of Columbia notifying them that they automatically qualify for the low-income subsidy and don't need to apply.

June

- Early June - CMS mails a notice to full-benefit dual eligible beneficiaries in 6 States (IL, FL, SC, WI, VT, and MD) notifying them that they automatically qualify for the low-income subsidy and don't need to apply.

October – December *Enrollment Phase of Outreach and Education Campaign*

October

- *Medicare & You* handbook mailed to all beneficiaries, with drug plan information.
- Mid-October - CMS assigns full-benefit dual eligibles to prescription drug plans and notifies them of the plan assignment.
- Mid-October - CMS notifies plans of full-benefit dual eligible enrollees.
- Mid-October - CMS notifies States of the plan assignments of their full-benefit dual eligible residents.
- Mid-October - Full-benefit dual eligibles begin reviewing their prescription drug plan options and deciding if they want to opt out of their assigned plan.

November

- 1st - Begin routine monthly auto-enrollment and notification for new full-benefit dual eligibles.
- 15th - Enrollment period begins if the dual eligible wants to opt-out of their assigned plan.

December

- 31st - Full-benefit dual eligibles must opt-out of their assigned plan by this date or they will be auto-enrolled.
- 31st – Medicaid drug coverage ends for full-benefit dual eligibles.

2006

January –May *Urgency Message Phase*

January

- 1st - Medicare prescription drug coverage begins.
- 1st - Prescription drug coverage by auto-enrolled plan effective for full-benefit dual eligibles

Appendix A

Assistance for Full-Benefit Dual Eligibles in 2006

Category of Dual Eligible	Percentage of Premium Assistance (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 $7,500 (individuals) or $12,000 (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

(1) Premium assistance is defined as the premium subsidy amount in 42 CFR §423.780(b).
* The percentage shown in the table is the greater of the low-income benchmark premium amount or the lowest prescription drug plan premium for basic coverage in the region.
** The asset amounts assume an individual or a couple has funds set aside for burial or funeral expenses. The exclusion amount is $1,500 for an individual and $3,000 for a couple. If no such funds are set aside, then the asset amounts are not to exceed $6,000 (individuals) or $9,000 (couples).

Appendix B

The Nuts and Bolts of the Auto-Enrollment of Full-Benefit Dual Eligible Beneficiaries

Who are the full-benefit dual eligibles?	People with Medicare and • Comprehensive Medicaid benefits; or • Some Medicare Savings Programs: ➢ QMB-**plus** (full Medicaid **plus** payment for Medicare Part A and Part B premiums, coinsurance, and deductibles) ➢ SLMB-**plus** (full Medicaid **plus** payment for Medicare Part B premium)
When will auto-enrollment start?	Auto-enrollment of full-benefit dual eligibles will start in the fall of 2005. These beneficiaries lose Medicaid prescription drug coverage 12/31/05, so auto-enrollment must be started in time to be effective 1/1/06.
How will auto-enrollment work for the initial round?	First round in 2005: August – CMS identifies the initial pool of existing full-benefit dual eligibles (based on state data submitted the end of July). Mid-September – CMS finalizes contracts with Part D plans. Mid-September – CMS creates auto-enrollment transactions with effective date of 1/1/06 (to ensure no coverage gap after Medicaid ends 12/31/05). If the beneficiary chooses another plan before the auto-enrollment effective date, the beneficiary's choice will prevail. Mid-October – CMS notifies beneficiaries, plans, and state Medicaid agencies of plans into which beneficiary will be auto-enrolled if they do not choose on their own. November 15 – Enrollment period begins if the dual eligible wants to opt-out of their assigned plan. December 31 – Full-benefit dual eligible beneficiaries must opt-out of their assigned plan by this date or they will be auto-enrolled. January 1, 2006 – Auto-enrollment takes effect (if person has not chosen another plan). Full-benefit dual eligibles may still change plans at any time after auto-enrollment is effective.
How will full-benefit dual eligibles get	Full-benefit dual eligible beneficiaries will be enrolled based on where they currently get their Part A and/or Part B benefits, and the amount of the prescription drug plan's premium. PACE enrollees will

their Medicare prescription drug coverage?	automatically get their Medicare prescription drug coverage through their PACE organization. MA plan → MA-PD in same MA organization with the lowest Part D premium MA-Private Fee-for-Service (PFFS) with Part D → Same PFFS for Part D Cost plan with Part D optional supplemental benefit → Same cost plan for Part D Original Medicare → PDP* PFFS with no Part D → PDP* Cost plan with no Part D → PDP* MSA → PDP* * If there is more than one PDP with a beneficiary premium at or below low-income premium subsidy amount, beneficiaries will be auto-enrolled on random basis among available plans.
How will full-benefit dual eligibles know what plan they will be enrolled in?	CMS will send a letter to full-benefit dual eligibles that provides: • An explanation of how to choose a Medicare prescription drug plan. • The name of the Medicare prescription drug plan that Medicare will enroll them in if they don't choose a plan by 12/31/05. We will also include that plan's toll free member services number and website. • A reminder that their Medicaid drug coverage ends 12/31/05; they qualify for extra help with their drug plan costs; and they can change plans at anytime. • An explanation of their right to affirmatively decline Part D. • The 1-800-MEDICARE number for questions.
How often can a beneficiary change plans?	Full-benefit dual eligibles have a permanent Special Enrollment Period granted by statute. As long as the beneficiary remains a full-benefit dual eligible, the beneficiary can change Part D plans at anytime. The Special Enrollment Period allows full-benefit dual eligibles to switch from one MA-PD plan to another, from one Prescription Drug Plan to another, or from Original Medicare and a Prescription Drug Plan into an MA-PD plan and vice versa.

When will the on-going monthly auto-enrollment process start for new beneficiaries?	Estimated to be October 2005, and monthly thereafter.

MEDICARE MODERNIZATION ACT FINAL GUIDELINES -- FORMULARIES
CMS Strategy for Affordable Access to Comprehensive Drug Coverage
Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures

1. Purpose of the Guidance

This paper is final guidance on how CMS will review Medicare prescription drug benefit plans to assure that beneficiaries receive clinically appropriate medications at the lowest possible cost. Two key requirements in the Medicare Modernization Act (MMA) are to assure that drug plans provide access to medically necessary treatments for all and do not discriminate against any particular types of beneficiaries, and to encourage and support the use of approaches to drug benefit management that are proven and in widespread use in prescription drug plans today. The goal is for plans to provide high-quality cost-effective drug benefits by negotiating the best possible prices and using effective drug utilization management techniques. This goal can be achieved through a CMS drug benefit review strategy that facilitates appropriate beneficiary access to all medically necessary Part D covered drugs along with plan flexibility to develop efficient benefit designs, thus bringing drug benefit strategies that are already providing effective coverage to millions of seniors and people with a disability to the Medicare population. Our formulary review process focuses on three areas:

1. Pharmacy and Therapeutics (P&T) committees. CMS will require P&T committees to rely on widely-used best practices, reinforced by MMA standards. CMS oversight of these processes will assure that plan formularies are designed to provide appropriate, up-to-date access for beneficiaries and give plans the flexibility to offer benefit designs that provide affordable access to medically necessary drugs.

2. Formulary lists. CMS' review of plan formularies will look to best practices in existing drug benefits serving millions of seniors and people with disabilities to ensure appropriate access for Medicare beneficiaries. CMS will evaluate formulary classification systems as well as the actual list of drugs included in the formulary, using existing widely used classification systems and drug plans as checks.

3. Benefit management tools. CMS will compare plans' use of benefit management tools, like prior authorization, to the way these tools are used in existing drug plans, to ensure that they are being applied in a clinically appropriate fashion. We have protected beneficiary rights by putting appropriate appeals and exceptions standards in the final regulations and by reviewing processes that plans use to provide timely access. In developing this approach, CMS has looked to existing national drug benefit management standards and guidelines that underlie drug plans that are currently providing effective coverage, as well as a variety of examples of such drug plans.

CMS has developed the final rule for the new Medicare drug benefit based on extensive public comments on how best to provide access to up-to-date medical treatments for all beneficiaries at the lowest possible cost. This paper sets forth the approach that will be used in conjunction with the final regulation to promote transparency, predictability, and effective implementation of the law in conjunction with our final rule.

2. Background

The addition of a prescription drug benefit to Medicare as a result of the MMA represents a landmark change to the Medicare program, a change that will significantly improve the healthcare coverage available to millions of Medicare beneficiaries. In the final regulation, we have included policies, such as formulary requirements and exceptions and appeals processes, to assure that beneficiaries have access to covered drugs that are medically necessary for their condition while enabling plans to design and manage their formularies to provide the most affordable benefit possible. We are also adjusting the payments to drug plans based on the expected costs of their enrollees, as well as implementing many other steps to limit the financial risk facing drug plans. Together, our goal is to provide a foundation for fair competition to offer high-quality coverage at the lowest cost to all types of Medicare beneficiaries, and to reward plans that focus on this critical policy goal.

The MMA is designed to encourage prescription drug plans and Medicare Advantage prescription drug plans that meet the law's requirements to offer comprehensive prescription drug plan options for Medicare beneficiaries by providing flexibility for plan design and management. This flexibility is modeled after the way most Americans, including millions of seniors and people with disabilities, receive drug benefits today through federal and private-sector retiree coverage, as well as State Medicaid programs. How much beneficiaries save depends on how a plan's formulary is structured and the benefit is operated. The goal of this program, however, is not to save money on prescription drug costs at the expense of appropriate medical care. Appropriate medical care would not be possible if plans actively sought to discourage enrollment by beneficiaries with high, expected drug costs.

Consequently, CMS seeks to implement a strategy to ensure that formularies and utilization management tools are consistent with effective practices in drug benefit management today, in conjunction with many other steps we are implementing to appropriately compensate plans for covering beneficiaries with relatively high expected drug costs. CMS oversight will ensure that Part D plans operate in accordance with this strategy. We will compare proposed Part D formularies using current best practices for developing and maintaining a formulary's drug categories and classes, and will support the use of USP model categories and classes for plans that choose to use them (plans are not required to do so). However, because drug classes alone, whether detailed or general, are not sufficient to determine whether beneficiaries have adequate access, we also will review the drug plans' formularies and benefits to identify discriminating practices. Under Section 1860D-11(e)(2)(D) of the Social Security Act, a plan design will be approved only if "the Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." Thus, even if CMS concludes

that a plan's therapeutic categories and classes are robust, our review may find the plan design violates this statutory provision if some other aspect of the plan's benefit design is problematic.

CMS intends to encourage and approve formularies and benefit management approaches that are already in widespread use to provide drug coverage to millions of seniors and people with disabilities today. We will consider the structure and use of an organization's P&T committee, as well as the structure of the formulary and the policies and procedures for providing access to both formulary and non-formulary drugs. Since drug utilization management activities are as important as the list of drugs in the formulary in providing access to high quality pharmaceutical care for all categories of beneficiaries, we will use checks based on commonly-used best practices to review those policies and procedures to ensure beneficiary access to Part D covered prescription drugs that are medically necessary for their course of treatment. Approved formularies for Part D contractors will be available for beneficiaries in time for them to consider their options prior to enrollment. We anticipate that drug plans that follow commonly used best practices will have little difficulty with these checks.

3. Guiding Principles for CMS Formulary and Benefit Review Strategy

A formulary is more than a list of approved medications. A formulary must consist of drugs that will provide patients with a clinically appropriate medication for the course of treatment established by the physician. Consistent with industry standards/practices, the formulary is supported by a system of care management tools to consistently provide patients with access to medications that have been demonstrated to be safe, effective, and affordable, while maintaining and improving quality patient care. To ensure that Medicare prescription drug plans are following best practices, the CMS formulary review will follow four important principles.

Principle #1 – Rely on Existing Best Practices: CMS' review will rely on widely recognized best practices for existing drug benefits serving millions of seniors and people with disabilities, to ensure appropriate access for Medicare beneficiaries.

Principle #2 -- Provide Access to Medically Necessary Drugs: We will require that drug plans provide access to Part D drugs determined to be medically necessary.

Principle #3 -- Flexibility: CMS will allow plans to be flexible in their benefit designs to promote real beneficiary choice while protecting beneficiaries from discrimination.

Principle #4 – Administrative Efficiency: CMS will develop a streamlined process to conduct effective reviews of plan offerings within a compressed period of time.

4. Strategic Approach

A. P & T Committee Review

We believe that current best practices for P&T committees should be applied when developing and administering P&T committees for the Medicare drug benefit. Incorporating best practice philosophies, along with inclusion of the MMA requirements, allows for a drug benefit that is clinically robust.

Rationale

CMS oversight of the P&T committee process is an important requirement of the MMA to ensure plans offer a comprehensive drug benefits. Operated under appropriate guiding principles, a P&T committee is a forum for an evidence-based formulary review process that establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are medically appropriate and cost-effective. P&T committees must meet best practices consistent with those contained in several widely accepted guidelines for P&T management. CMS standards and guidelines for the P&T activities will help ensure that formulary decisions are based on scientific and economic considerations that achieve appropriate, safe and cost effective drug therapy, and that the P&T committee has a key role in defining policies for utilization management activities such as access to non-formulary drugs, prior authorization, step therapy, quantity limitations, generic substitution, and therapeutic interchange protocols to assure that products and therapies, such that these tools are used to drive medically appropriate and cost-effective access to Part D covered drugs. The P&T committee will also be expected to analyze and recommend, where appropriate, regional variations of national best practices.

These standards will be clearly articulated in the plan applications and our contracts with Medicare prescription drug plans. They will also be integrated into the CMS management and oversight of Part D plans after January 2006, to assure that the P&T rules are maintained and followed.

Approach

CMS will require that plans assure the implementation and use of a P&T committee consistent with the pharmacy benefit management principles outlined and expressed by the American Society of Health System Pharmacists (ASHP Statement on the Pharmacy and Therapeutics Committee, Am J Hosp Pharm. 1992, *http://www.ashp.org/bestpractices/formulary-mgmt/Form_St_PTComm.pdf*), or the Principles of a Sound Drug Formulary System October 2000, *www.amcp.org* , a consensus document endorsed by the Academy of Managed Care Pharmacy, American Association of Retired Persons, the Alliance of Community Health Plans, the American Medical Association, the American Society of Health-System Pharmacists, the Department of Veteran Affairs, the National Business Coalition on Health, and the U.S. Pharmacopeia.

The requirements listed below are represented as 'BP' for best practice (or Industry Standard Practice) where they have been drawn from commercial best practices consistent with these nationally recognized P&T guidelines, and are represented as 'MMA' where the requirements support the unique provisions of the MMA.

Membership

- P&T committee members must represent various clinical specialties that adequately represent the needs of plans beneficiaries (i.e., include representation of "high volume specialists" in the standard terminology of the industry). (BP)
- A majority of the P&T committee members must be practicing physicians, practicing pharmacists or both. (BP)
- At least one P&T committee practicing pharmacist and one practicing physician must be experts in the care of elderly or disabled persons. (MMA)
- At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the plan and pharmaceutical manufacturers. (MMA)

Conflict of Interest

- P&T committee members should sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions. (BP)

Meeting Administration

- P&T committee should meet on a regular basis, and not less frequently than on a quarterly basis. (BP)
- P&T committee decisions regarding formulary development or revision must be documented in writing. (BP)

Formulary Management

- P&T committee must review for clinical appropriateness, the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, generic substitutions and other drug utilization activities that affect access. (BP)
- Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe and cost effective drug therapy. (BP)
- The P&T committees will be required to establish and document procedures to assure appropriate drug review and inclusion. (BP)
- Clinical decisions by the P&T committee should be based on scientific evidence and standards of practice, including peer reviewed medical literature, well-established clinical practice guidelines and pharmacoeconomic studies as well as other sources of appropriate information. (BP)
- Drugs' therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs and placing them into formulary tiers. (MMA)
- The P&T committee will make a reasonable effort to review a new chemical entity within 90 days, and will make a decision on each new chemical entity within 180

days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. These timeframes also include the review of products for which new FDA indications have been approved. We set this timeframe in response to public comment on our proposed guidance, but note that plans must make access to new drugs available to enrollees when medically appropriate via exceptions processes even before this deadline. (BP)

- P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis. (MMA)
- Formulary therapeutic categories and classes may be changed only at the beginning of each plan year or when new drugs or new drug therapeutic uses appear. (MMA)

Formulary Exceptions

- P&T committees must review for clinical appropriateness protocols and procedures for the timely use of and access to both formulary and non-formulary drug products. A non-formulary drug may be needed, for example, when the formulary drug would cause adverse effects or would not be as effective or both, based on scientific evidence or medical necessity. (BP)

B. Formulary List Review

Rationale

The formulary list review will incorporate best practices from the private sector, Medicaid and FEHB formularies. The MMA requires CMS to review Part D formularies to ensure that beneficiaries have access to a broad range of medically appropriate drugs to treat all disease states and to ensure that the formulary design does not discriminate or substantially discourage enrollment by certain groups. We expect that the kinds of formularies in widespread use today, which provide high-quality drug coverage to millions of Medicare beneficiaries, would receive a straightforward approval under this approach with modifications to account for specific features of Medicare's benefit structure, (i.e., including home infusion products that may not be covered under a pharmacy benefit in commercial benefit designs). Plans may also have to make modifications to existing commonly used formularies to allow for coverage of commonly-used vaccines and diabetic supplies as outlined in the MMA. Below we provide a series of checks that CMS will use to confirm that plan formularies will provide the kind of effective, non-discriminatory access available in drug benefit plans today.

Approach

We encourage plans to submit formularies similar to those in widespread use today. We will check the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, to satisfy the MMA requirement that a plan's categorization system does not discourage enrollment to any group of beneficiaries. We also will consider the specific drugs, tiering and utilization management strategies employed in each formulary. CMS will identify outliers from common benefit management practices for further evaluation. Plans may be asked to provide written clinical justification for unusual benefit features that are deemed as outliers.

Review of Categories and Classes

We will review all classification systems to assure that plans provide an appropriate breadth of categories and classes that cover all disease states. CMS will not consider a classification system in isolation from the subsequent steps in our formulary review; a classification system with a smaller number of classes may be acceptable if it nonetheless provides preferred access to a relatively broad range of widely used medicines.

As described in the MMA, plans that utilize a classification system that is consistent with the USP classification system, available at *http://www.usp.org/pdf/drugInformation/mmg/finalModelGuidelines2004-12-31.pdf*, will satisfy a safe harbor and thus CMS will approve their formulary classification system. For plans that choose to adopt an alternative to USP's classification structure, CMS will check the plan's proposed classification system to determine if it is similar to USP or other commonly used classification systems, such as the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification, information available at *www.ashp.org/ahfs*.

The minimum statutory requirement is that a formulary must include at least two drugs in each approved category and class (unless only one drug is available for a particular category or class), regardless of the classification system that is utilized. We view this requirement as a floor rather than an absolute standard. CMS may require more than two drugs per category or class in cases where additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the plan formulary may substantially discourage enrollment in the plan by beneficiaries with certain disease states.

Even though a formulary may pass the classification review and have a safe harbor for its categories and classes, it still must undergo the drug list review and benefit management tools review in order to analyze the depth and breadth of drugs and their restrictions.

Drug List Review

Regardless of the classification system chosen, CMS will review and approve drug lists that are consistent with best practice formularies currently in widespread use today. The following paragraphs describe the multiple checks that will be utilized as part of the drug list review.

1. CMS will review formularies for at least one drug in each of the *Formulary Key Drug Types* identified by USP as Attachment B in comments provided to CMS on the draft formulary guidance, available at: *http://www.usp.org/pdf/drugInformation/mmg/attachmentstoUSPComments2004-12-30.pdf*. Best practice formularies commonly include at least one drug in each of the *Formulary Key Drug Types* as a minimum on their formulary. Plans may present a reasonable clinical justification for formularies that do not contain at least one drug for each of the USP *Formulary Key Drug Types*.

2. CMS will review tier placement to provide an assurance that the formulary does not discourage enrollment of certain beneficiaries. When developing their formulary tier structure, plans should utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any and all subsequent tiers within the formulary structure will be higher cost-sharing tiers in ascending order. For example, drugs in Tier 3 will have a higher cost-share for beneficiaries than drugs in Tier 2. Best practices in existing formularies and Medicaid preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary. The CMS review will focus on identifying drug categories that may discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.

3. CMS will analyze formularies to determine whether appropriate access is afforded to drugs addressed in the following widely accepted national treatment guidelines which are indicative of general best practice: asthma, diabetes, chronic stable angina, atrial fibrillation, heart failure, thrombosis, lipid disorders, hypertension, chronic obstructive pulmonary disease, dementia, depression, bipolar disorder, schizophrenia, benign prostatic hyperplasia, osteoporosis, migraine, gastroesophageal reflux disease, epilepsy, Parkinson's disease, end stage renal disease, hepatitis, tuberculosis, community acquired pneumonia, rheumatoid arthritis, multiple sclerosis and HIV. This list of conditions does not represent an exhaustive list, but merely serves as another check in the review process. Drugs or drug classes included within these widely accepted guidelines will not place undue burden on plans since these drugs are usually placed in favorable positions on commonly used, best practice formularies.

4. CMS will use Medicare risk adjustment data to check proposed formularies to determine whether the formularies include drugs that are most commonly used by the Medicare population and are reflected across the Drug Hierarchical Condition Categories (DHCC) used to determine Medicare risk adjustment. These DHCCs are representative of more than 5,000 ICD-9 diagnostic codes. For each DHCC, both the inclusion of the drug and its tier position will be checked against other Part D formularies and commonly used drugs in the overall Medicare population, to avoid drug selection and cost-sharing that discriminate against specific disease groups.

5. CMS' expectations are that best practice formularies contain a majority of drugs within the following classes: antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants, and antineoplastics. Following common best practices, CMS will check to see that beneficiaries who are being treated with these classes of medications have uninterrupted access to all drugs in that class via formulary inclusion, utilization management tools, or exceptions processes. When medically necessary, beneficiaries should be permitted to continue utilizing a drug that is providing clinically beneficial outcomes. In cases where practices may deviate from the above, plans must provide clinical documentation to justify their decisions.

6. CMS will analyze the availability and tier position of the most commonly prescribed drug classes for the Medicare population in terms of cost and utilization (Appendix A). This list is derived from the Medicare Current Beneficiary Survey (MCBS) data from 2002. CMS understands that plans will not provide identical coverage of these drug classes, and our review will focus on assuring that plans present a balanced formulary. These drug classes will cover common diseases and conditions, and will allow us to ensure that plans are covering the most widely used medications, or therapeutically similar medications, for the most common conditions.

All formularies will be evaluated using the criteria outlined above. Outliers for each area of review will be further evaluated by CMS to determine if the outlier is deemed potentially discriminatory. Examples of this may include a lack of appropriate drug classes to treat certain diseases, a lack of sufficient drugs in a therapeutic class, inappropriate tier placement that would discriminate against a group of beneficiaries, or missing drugs that would cause discrimination. If any of the outliers appear to create problems of access, plans will have the opportunity to present reasonable clinical justifications.

Long Term Care Accessibility

Part D plans will be required to provide medically necessary prescription drug treatments to LTC facility residents. Well in advance of the application deadline, CMS will provide additional LTC guidance that will reflect standard practices in LTC pharmacies.

C. Review of Benefit Management Tools that Affect Access

Rationale

CMS will review plans' use of utilization management tools, including prior authorization, step therapy, quantity limitations, and generic substitution to ensure that beneficiaries are given appropriate access to drugs in a timely manner. We will also review plans' drug utilization review procedures and appeals, exceptions and grievances processes. Our review will focus on ensuring that these plan systems reflect best practices that are commonly utilized in the private sector, Medicaid and FEHB plans.

Approach

Prior Authorization, Step Therapy, Quantity Limitations, Generic Substitution

CMS will look to existing best practices to check that plans' use of these utilization management tools is consistent with such practices. We will look to current industry standards as well as appropriate guidelines that might be found from expert organizations such as NCQA, AMCP, and NAIC, and to the use of such standards in existing drug plans that are widely used by seniors and people with disabilities. CMS will assure that

plans' use of such tools is consistent with best practices. CMS will also compare formularies amongst the applicants to analyze the comparative use of practices such as prior authorization, step therapy, and quantity limits. Our expectation is that these techniques will be used in Part D formularies consistently with the way they are applied in existing formulary systems, both in terms of the situations in which they are used and the timeliness of the processes. In cases where a plan may fall outside of best practices, the plan will be asked to provide a reasonable justification for their practices.

Drug Utilization Review (DUR)

CMS will review plans' DUR practices to confirm that they meet industry best practices in terms of access to drugs and quality oversight. We will expect plans' use of tools and techniques currently in place in their commercial coverage business. These processes may include concurrent review as well as prospective and/or retrospective utilization review. These reviews will be expected to assure appropriate access to medically necessary therapies as well as guard against inappropriate or dangerous utilization of prescription medications.

Appeals, Exceptions and Grievances

The standards for handling appeals, exceptions, and grievances are specific and are contained in the final rule. We believe the final rule reflects current best practices around appeal and grievance timeframes. We are developing notice requirements to ensure that beneficiaries understand their rights in this area. We also expect to require standardized reporting from Part D plans on denial, reconsideration and appeals, and exceptions processing, and we will use these data in our management and oversight activities. We expect plans to make appropriate use of the data for internal quality initiatives, such as those directed at managing excessive rates of overturned utilization management decisions. Part D plan sponsors that provide prescription drug benefits for Part D drugs and manage this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination.

5. Formulary Submission Requirements

In support of the Medicare Modernization Act (MMA), CMS is establishing a systems interface within the Health Plan Management System (HPMS) to enable MA-PD plans and PDPs to submit their formularies electronically. This functionality will provide for the upload and receipt of the formulary file, exceptions and notes file, prior authorization supplemental data and step therapy supplemental data, as defined by CMS. It will also allow CMS to provide more timely, systematic, and consistent feedback to plans regarding their formulary practices.

Using the HPMS formulary upload module, the user will submit one or more formulary files for the MA-PDs or PDPs offered under a contract. This submission must occur prior to April 18, 2005 at 5:00pm EDT. Detailed technical user instructions will be forthcoming. The general

process that the user will complete in order to submit their plan's drug formulary information includes the following steps:

- General formulary-level data entry in a designated HPMS web page
    - Plan will be required to complete data entry in an HPMS web interface for information such as Plan name , formulary name, classification structure used, etc.

- Attachment of an NDC-level Formulary file in a flat file text format
    - Plan will attach their Formulary file submission. The Formulary file will be created as a flat file in ASCII format by the MA-PD or PDP outside of the HPMS prior to submission. The file must be created using National Drug Codes (NDCs) as a proxy for drug name. Appendix B illustrates the required data fields for each NDC record in the Formulary file.

- If relevant, attachment of a Step Therapy Algorithm file in MS-Word format
    - During the general formulary-level data entry process, the user will be asked if the NDCs in the formulary submission are associated with one or more Step Therapy management programs. If the drugs in the formulary submission are associated with Step Therapy management programs, then the user is required to submit an attachment that provides the detailed algorithms for all Step Therapy management programs in the formulary. The Step Therapy Management Algorithm file should be submitted in HPMS as a Word file. The user should submit only one Step Therapy Management Algorithm file attachment per formulary file submission.

- If relevant, attachment of a Prior Authorization Criteria file in MS-Word format
    - During the general formulary-level data entry process, the user will be asked if the NDCs in the formulary submission are subject to prior authorization. If the drugs in the formulary submission are associated with prior authorization, then the user is required to submit an attachment that provides the detailed criteria for all prior authorization programs. The Prior Authorization Criteria file should be submitted in HPMS as a Word file. The user should submit only one Prior Authorization Criteria file attachment per formulary file submission.

- If relevant, attachment of an Exceptions and Formulary Notes file in MS-Word format
    - The user will have the ability to attach a Word file that provides additional details about any exceptions associated with the Formulary file. For example, when a particular dosage form or strength has restrictions, such as prior authorization or unique quantity limits, then the user should note these exceptions in a Word attachment (e.g. Imitrex injection vs. tablets). Plan must also include in the notes section, an explanation of its entire exceptions process.

Information concerning formularies will be made publicly available at some point prior to the beneficiary enrollment period. Applicants can always seek to protect their information under the Freedom of Information Act and label truly proprietary information "confidential" or "proprietary." When information is so labeled, the Applicant is required to explain the

applicability of the FOIA exemption they are claiming. When there is a request for information that is designated by the Applicant as confidential or that could reasonably be considered exempt under Exemption 4, CMS is required by its FOIA regulation at 45 C.F.R. §5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. To determine whether the Applicant's information is protected by Exemption 4, the Applicant must show that— (1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value. Consistent with our approach under the Medicare Advantage program, we would not release information under the Medicare Part D program that would be considered proprietary in nature.

6. Formulary Maintenance Requirements

Under the MMA, plans may only change therapeutic categories and classes at the beginning of each plan year unless new drugs or new therapeutic uses appear. However, plans must submit changes to the formulary (additions, deletions or tier changes) as they occur. CMS will accept changes to formulary drugs on a regular basis, within 30 days after a P&T committee makes decisions. Plans shall submit any formulary drug list changes between the 1st day and the 7th day of each month, beginning November 1, 2005. These submitted changes will be reviewed by CMS to ensure that formularies remain nondiscriminatory and meet other minimum standards. The effective dates of submitted formulary changes are subject to the time periods outlined in the final rule.

Appendix A

Top Drug Classes by Cost and Utilization

Top Drug Classes by Cost and Utilization	
ACE inhibitors	Nitrates
Alpha blockers	Non-sedating antihistamines
Angiotensin receptor blockers	Opioids
Anticoagulants	Opioid / analgesic
Antigout	Platelet aggregation inhibitors
Atypical antipsychotics	Potassium
Beta-blockers	Potassium sparing diuretic / thiazide diuretic
Biguanides	Ophthalmic prostaglandins
Bisphosphonates	Proton pump inhibitors
Calcium channel blockers	Quinolones
Calcium channel blocker / ACE inhibitor	Sedatives
Cardiac inotropes	Selective estrogen receptor modifier
Cholinesterase inhibitors	Short-acting beta agonists
Corticosteroids	SSRIs
Cox-2 inhibitors	Statins
Estrogen replacement	Sulfonylureas
GABA Agents	Thiazide diuretics
Leukotriene modifiers	Thiazolidinediones
Long-acting beta agonist / inhaled corticosteroid	Thyroid replacement
Loop diuretics	Tricyclic antidepressants

Appendix B

Draft Formulary File Record Layout

Required File Format = ASCII File

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
NDC	CHAR NOT NULL	11	11-Digit National Drug Code	00000333800
Tier_Level_Value	CHAR NOT NULL	2	Defines the Cost Share Tier Level Value Associated with the NDC. Assumption is that the NDC is assigned to one tier value. These values are consistent with the selection of value options available to data entry users in the Plan Benefit Package software. If no Tier Level Value applies, enter '1' as the value for this field.	1 = Tier Level 1 2 = Tier Level 2 3 = Tier Level 3 4 = Tier Level 4 5 = Tier Level 5 6 = Tier Level 6 7 = Tier Level 7 8 = Tier Level 8 9 = Tier Level 9 10 = Tier Level 10
Drug_Type_Label_Value	CHAR NOT NULL	1	Define the Drug Type Label Value for the NDC. Enter the label value for the Drug Type from the defined list of labels in the instructions. If Drug Type Label Value 6 = "Other" is used, then the user must describe the "Other" label description in the Drug_Type_Label_Value_Other field.	1 = Generic 2 = Preferred Brand 3 = Non-Preferred Brand 4 = Non-Formulary 5 = Specialty 6 = Other
Drug_Type_Label_Value_Other	CHAR NULL	50	Describe the "Other" label description. If "Other" does not apply, leave this field blank.	Orphan
Quantity_Limit_Amount_YN	CHAR NOT NULL	1	Does the NDC have a quantity limit other than a 30-day or 34-day limit?	1 = Yes 0 = No

Quantity_Limit_Amount	NUM NULL	3	If Yes to Quantity_Limit_Amount_YN, enter the quantity limit unit amount. The units for this amount may be defined as number of pills, number of injections, etc. If a limit other than 30 or 34 days does not apply, leave this field blank.	9
Quantity_Limit_Days	NUM NULL	3	Enter the days associated with the quantity limit. If a limit other than 30 or 34 days does not apply, leave this field blank.	60 (e.g., 9 pills every 60 days) (e.g., 9 injections every 60 days)
Prior_Authorization_YN	CHAR NOT NULL	1	Is prior authorization required for the NDC?	1 = Yes 0 = No
Therapeutic_Category_Name	CHAR NULL	100	If the Category/Class Database Source is indicated as "OTHER" in the HPMS Data Entry Web Interface (i.e., neither USP nor AHFS is used by the plan), then the user should enter the Therapeutic Category Name for each NDC in the file. If the drug is based on either USP or AHFS Therapeutic Category Classes, then leave this field blank.	Analgesics
Therapeutic_Class_Name	CHAR NULL	100	If the Category/Class Database Source is indicated as "OTHER" in the HPMS Data Entry Web Interface (i.e., neither USP nor AHFS is used by the plan), then the user should enter the Pharmacological Class Name for each NDC in the file. If the drug is based on either USP or AHFS Pharmacological Classes, then leave this field blank.	Opioid Analgesics
Formulary_Key_Drug_Type_Name	CHAR NULL	100	*OPTIONAL*: If the Category/Class Database Source is indicated as "OTHER"	Opioid Analgesics, long-acting

			in the HPMS Data Entry Web Interface (i.e., neither USP nor AHFS is used by the plan), then the user has the option to enter the Formulary Key Drug Type (subdivision) Name for each NDC in the file. If the drug is based on either USP or AHFS, then leave this field blank.	
Step_Therapy_Type_Group_Num	NUM NULL	1	Number of step therapy drug treatment groups, in which the NDC is included. If Step Therapy does not apply to this drug, then leave this field blank.	3
Step_Therapy_Type_Group_Desc_X	CHAR NULL	100	Description of step therapy drug treatment group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Type_Group_Num If Step Therapy does not apply to this drug, then leave this field blank.	Step_Therapy_Type_Group_Desc_1 = "CH Therapy" Step_Therapy_Type_Group_Desc_2 = "An Therapy" Step_Therapy_Type_Group_Desc_3 = "CV Therapy"
Step_Therapy_Type_Group_Step_X	CHAR NULL	3	Step number within the sequence for the Step Therapy Group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Type_Group_Num AND in the same order as Step_Therapy_Type_Group_Desc_X If Step Therapy does not apply to this drug, then leave this field blank.	Step_Therapy_Type_Group_Step_1 = 4 (e Step 4 of 6) Step_Therapy_Type_Group_Step_2 = 1 (e. Step 1 of 3) Step_Therapy_Type_Group_Step_3 = 5 (e. Step 5 of 5)

Information for Part D Sponsors on Requirements for a Transition Process
March 16, 2005

Overview

CMS review of plan formularies will ensure that plans offer a comprehensive array of drugs that reflects best practices in the pharmacy industry as well as current treatment standards. We expect plan formularies and plan benefit designs to include the full range of treatment options and at the same time reflect drug benefit management tools that are proven and in widespread use in prescription drug plans today. Our goal is to ensure beneficiaries receive clinically appropriate medications at the lowest possible cost. In reaching this goal, we also need to acknowledge the specific needs of individuals with certain medical conditions who are already stabilized on certain drug regimens (for example, enrollees with HIV/AIDS, mental illness, and those with other cognitive disorders). In addition, it is important to recognize the needs of full-benefit dual eligibles who may be auto-enrolled in a prescription drug plan and who, despite education and outreach efforts on the changing nature of their drug coverage under the new Medicare drug benefit, may be unaware of the impact of the prescription drug plan's formulary or utilization management practices on their existing drug coverage.

To address the needs of individuals who are stabilized on certain drug regimens, Part D plans are required to establish an appropriate transition process for new enrollees who are transitioning to Part D from other prescription drug coverage, and whose current drug therapies may not be included in their Part D plan's formulary. This transition process will need to address the plan sponsor's method of educating both beneficiaries and providers to ensure a safe accommodation of an individual's medical needs with the plan's formulary. We believe some period of adjustment may be necessary to introduce the new formulary requirements, and set forth our expectations of what constitutes a reasonable transition timeframe. As we indicate later in this paper, we also recommend the transition process address unplanned transitions as individuals change treatment settings due to changes in level of care.

We will review the plan's transition process as part of the formulary and plan benefit design review. As we indicate in the preamble to our final rule for the Medicare prescription drug benefit, we believe that a requirement for an appropriate transition process for new enrollees balances the protection of certain vulnerable populations with flexibility necessary for Part D plans to develop a benefit design that promotes beneficiary choice and affordable access to medically necessary drugs.

I. General Transition Process for New Enrollees

The issue of transition is important with respect to (1) the initial transition of beneficiaries to the Medicare prescription drug benefit on January 1, 2006, (2) the transition of new enrollees after the initial implementation of the program, and (3) the transition of individuals who switch from one plan to another after implementation of the benefit. Our intent when evaluating a transition process is to ensure that beneficiaries will transition smoothly to drugs on the formulary while providing potential plan sponsors with maximum flexibility in order to manage their prescription drug benefit offerings. To that end, we encourage plan sponsors to consider a variety of

strategies and communication methods to address the needs of vulnerable groups such as individuals with chronic conditions and Medicare/Medicaid full-benefit dual eligibles.

P& T Role

At a minimum, we expect that a transition process would address procedures for medical review of non-formulary drug requests and, when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. We would expect that a plan's pharmacy and therapeutics (P&T) committee will review and provide recommendations regarding the procedures for medical review of non-formulary drug requests and we will look to the transition process for assurances and clarification of the P&T committee role. P&T committee involvement will help ensure that transition decisions appropriately address situations involving enrollees stabilized on drugs that are not on the plan's formulary and which are known to have risks associated with any changes in the prescribed regimen. If the prescribed drugs are on the plan's formulary but require step-therapy or prior authorization to access the drug, P&T committee involvement should ensure that procedures limiting access are appropriate in situations in which a new enrollee is already stabilized on a drug or has already tried the lower step agents.

Temporary One-time Supply Fills Recommended

The transition process should also address situations where an individual first presents at a participating pharmacy with a prescription for a drug that is not on the formulary, unaware of what is covered by the plan or what is included in the plan's exception process to provide access to Part D drugs that are not covered. This may be particularly true for full-benefit dual eligible beneficiaries who are auto-enrolled in a plan and who did not make an affirmative choice based on review of a plan's benefit relative to their existing medication needs. We expect that plan sponsors would consider processes such as the filling of a temporary one-time transition supply in order to accommodate the immediate need of the beneficiary and to allow the plan and/or the enrollee time to work out with the prescriber an appropriate switch to another medication or the completion of an exception request to maintain coverage of an existing drug based on reasons of medical necessity. Such practices exist in the industry today and may represent the most efficient method of triaging requests for filling initial prescriptions of non-formulary drugs for large numbers of new enrollees who, despite education efforts to make beneficiaries aware of the plan's benefit, may not be aware of all the drugs listed on the plan's formulary.

Transition Timeframes

Plan sponsors have discretion in deciding the appropriate time frame for a one-time transition supply. Such time frames need not necessarily be uniform and may vary based on the drug in question, the unique needs of an individual, and an individual's setting (e.g., a long term care setting). However, the transition process should sufficiently document the range and circumstances which impact decisions regarding the temporary supply time period. As a general indicator, we believe that a temporary "first fill" supply of 30 days may be reasonable for new enrollees who first present at a pharmacy with a prescription for a drug not on the formulary so that the plan and/or enrollees may contact the provider to work out appropriate therapeutic

substitutions or to allow the enrollee and the provider time to request exceptions for continued access to Part D drugs not on the plan's formulary. We expect that the use of this method will reflect more than simply a one-time delay, but rather will involve action on the part of the plan and the enrollee to contact the provider to identify appropriate drug substitutions. We further expect sponsors to have systems capability to effectuate temporary supply policies.

Other Transition Methods

Where the use of a temporary "first fill" supply method is not utilized, we expect the sponsor's transition process to describe in sufficient detail how it will ensure new enrollees stabilized on drugs that are not on the plan's formulary and which are known to have risks associated with any changes in the prescribed regimen will continue to have access to medically necessary drugs without adverse health consequences. For example, the plan may have procedures in place to contact enrollees in advance of the initial effective date of their coverage in order to identify needs and to work out substitutions or exception requests with the enrollee and the enrollee's provider who is responsible for prescribing his or her current medications. Since we anticipate that there is a potential for a high volume of beneficiaries, and providers on their behalf, needing to file exceptions or needing alternative prescriptions on a short-turnaround basis after inception of the new Medicare drug benefit on January 1, 2006, this method may not be realistic for some plans during the initial transition to Part D. This is particularly true for large plans with a high number of full-benefit dual eligible individuals auto-enrolled into their plan who may be hard to reach and unaware of the plan's formulary restrictions. Plan sponsors who rely on this method for transition will need to provide an adequate plan for contacting enrollees and their providers, particularly with respect to the period prior to January 1, 2006.

II. Residents of Long Term Care Facilities

It is important that the transition process take into account the unique needs of residents of long term care (LTC) facilities who enroll in a new Part D plan. Given that a large proportion of residents may be dually eligible for both Medicare and full Medicaid benefits, and could be auto-enrolled into the plan without making an affirmative selection based on the individual's existing treatment needs, it is critical that the transition process address access to medications at the filling of the first prescription. Plan sponsors will need to ensure that LTC pharmacies in the plan's network that have relationships with LTC facilities work with those facilities prior to the effective date of enrollment to ensure a seamless transition of the facility's residents.

Again, plan sponsors may need to provide a temporary "first fill" supply order for a limited quantity of medication prescribed by the attending physician until an appropriate liaison between the facility, the attending physician, and the plan's LTC pharmacy on behalf of the resident can be achieved. Residents of LTC facilities are more likely to be receiving multiple medications for which simultaneous changes could significantly impact the condition of the enrollee. Therefore, plan sponsors may need to identify instances such as polypharmacy circumstances that necessitate a longer transition period in order to appropriately effectuate substitutions to therapeutic alternatives. For example, a transition period of 90 to 180 days might be appropriate for residents of nursing facilities on multiple medications who require some changes to their medication regimen in order to accommodate plan formularies. We expect the plan's transition

process will highlight procedures and time frames to ensure a seamless transition for enrollees who are LTC facility residents.

III. Current Enrollee Transitions and Exceptions and Appeals

In addition to circumstances impacting new enrollees who may enter a plan with a medication list that contains non-formulary drugs, other circumstances exists where unplanned transitions for current enrollees could arise and where prescribed drug regimens may not reflect plan formularies. These circumstances usually involve level of care changes in which a beneficiary is changing from one treatment setting to another. For example, beneficiaries who enter LTC facilities from hospitals are sometimes accompanied by a discharge list of medications from the hospital formulary, with very short term planning taken into account (often under 8 hrs). Similar situations may exist for beneficiaries who are discharged from a hospital to a home; for beneficiaries who end their skilled nursing facility Medicare Part A stay (where payments include all pharmacy charges) and who need to revert back to their Part D plan formulary; for beneficiaries who give up Hospice Status to revert back to standard Medicare Part A and B benefits; and for beneficiaries who are discharged from Chronic Psychiatric Hospitals with medication regimens that are highly individualized.

For these unplanned transitions, beneficiaries and providers need to utilize the plan's exceptions and appeals processes. In the final rule, we streamline the grievance, coverage determination, and appeals process requirements in order to ensure that beneficiaries receive quick determinations regarding the medications they need. In all cases, we make it clear that a Part D plan sponsor is required to make coverage determinations and redeterminations as expeditiously as the enrollee's health condition requires. Even with these protections, there may exist some period of time in which beneficiaries have a temporary gap in coverage while an exception or appeal is undertaken.

We recommend that plan sponsors consider as part of their exceptions processes a transition method for current enrollees with immediate needs for non-formulary Part D drugs. For example, we encourage plans to adopt a one-time temporary or emergency supply process as a method for ensuring that enrollees do not have a coverage gap while proceeding through the plan's exceptions process. This is a particularly important consideration for current enrollees who change treatment settings due to the level of care situations described above. We recommend that plan sponsors consider such procedures and include them in the transition plan for new enrollees.

IV. Public Notice of Transition Process

As a general matter, we believe plan sponsors must make transition processes available to beneficiaries in a manner similar to information provided on formularies and benefit design. It is likely that individuals will base their decision on which prescription drug best meets their needs on a variety of factors. Matching their current medication list with a Part D plan's formulary may only be one factor in the decision making process. Other factors, such as cost issues and inclusion of the retail pharmacy that they are most familiar with in the plan's network, may bear more weight in the final decision making process. Having information about a plan's transition

process may reassure beneficiaries that there will be plan procedures in place to assist them switching to therapeutic alternative medications where appropriate. It will also serve a dual purpose in educating advocates and other interested third parties about plan transition process; for example, state Medicaid agencies with regard to full-benefit dual eligibles auto-enrolled into prescription drug plans.

Long Term Care Guidance
March 16, 2005

This document is provided as guidance to assist Medicare Part D plans in formulating policies for the implementation of CMS requirements regarding pharmacies providing products and services to Long Term Care (LTC) facilities. This guidance is organized to address pharmacy performance and service criteria, convenient access standards, formulary considerations, and other beneficiary protections that Part D plans should consider as they develop their prescription drug benefit offerings for institutionalized LTC Medicare beneficiaries. As defined by the final regulation for the Medicare drug benefit, LTC facilities include skilled nursing facilities as defined under Title XVIII of the Social Security Act (the Act), or a medical institution or nursing facility for which Medicaid makes payment throughout a month as defined under Title XIX of the Act.

I. LTC Pharmacy Performance and Service Criteria

Part D plans will be required to offer a contract to any pharmacy willing to participate in its LTC pharmacy network so long as the pharmacy is capable of meeting certain minimum performance and service criteria (and relevant State laws governing the practice of pharmacy in the LTC setting) and any other standard terms and conditions established by the plan for its network pharmacies.

CMS has developed the following minimum performance and service criteria for pharmacies providing LTC service, based on widely used best practices in the market today and with input from various CMS divisions and external stakeholders. We expect that these performance and service criteria will be incorporated into an addendum to a Plan's standard network contract for those pharmacies that would like to be designated LTC network pharmacies.

Performance and Service Criteria for Network LTC pharmacies (NLTCPs)

1. *Comprehensive Inventory and Inventory Capacity* -- NLTCPs must provide a comprehensive inventory of Plan formulary drugs commonly used in the long term care setting. In addition, NLTCPs must provide a secured area for physical storage of drugs, with necessary added security as required by federal and state law for controlled substances. This is not to be interpreted that the pharmacy will have inventory or security measures outside of the normal business setting.

2. *Pharmacy Operations and Prescription Orders* -- NLTCPs must provide services of a dispensing pharmacist to meet the requirements of pharmacy practice for dispensing prescription drugs to LTC residents, including but not limited to the performance of drug utilization review (DUR). In addition, the NLTCP pharmacist must conduct DUR to routinely screen for allergies and drug interactions, to identify potential adverse drug reactions, to identify inappropriate drug usage in the LTC population, and to promote cost effective therapy in the LTC setting. The NLTCP must also be equipped with pharmacy software and systems sufficient to meet the needs of prescription drug ordering

and distribution to an LTC facility. Further, the NLTCP must provide written copies of the NLTCP's pharmacy procedures manual and said manual must be available at each LTC facility nurses' unit. NLTCPs are also required to provide ongoing in-service training to assure that LTC facility staff are proficient in the NLTCP's processes for ordering and receiving of medications. NLTCP must be responsible for return and/or disposal of unused medications following discontinuance, transfer, discharge, or death as permitted by State Boards of Pharmacy. Controlled substances and out of date substances must be disposed of within State and Federal guidelines.

3. *Special Packaging* -- 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.

4. *IV Medications* -- NLTCPs must have the capacity to provide IV medications to the LTC resident as ordered by a qualified medical professional. NLTCPs must have access to specialized facilities for the preparation of IV prescriptions (clean room). Additionally, NLTCPs must have access to or arrangements with a vendor to furnish special equipment and supplies as well as IV trained pharmacists and technicians as required to safely provide IV medications.

5. *Compounding /Alternative Forms of Drug Composition* -- NLTCPs must be capable of providing specialized drug delivery formulations as required for some LTC residents. Specifically, residents unable to swallow or ingest medications through normal routes may require tablets split or crushed or provided in suspensions or gel forms, to facilitate effective drug delivery.

6. *Pharmacist On-call Service* -- NLTCP must provide on-call, 24 hours a day, 7 days a week service with a qualified pharmacist available for handling calls after hours and to provide medication dispensing available for emergencies, holidays and after hours of normal operations.

7. *Delivery Service* -- NLTCP must provide for delivery of medications to the LTC facility up to seven days each week (up to three times per day) and in-between regularly scheduled visits. Emergency delivery service must be available 24 hours a day, 7 days a week. Specific delivery arrangements will be determined through an agreement between the NLTCP and the LTC facility. NLTCPs must provide safe and secure exchange systems for delivery of medication to the LTC facility. In addition, NLTCP must provide medication cassettes, or other standard delivery systems, that may be exchanged on a routine basis for automatic restocking. The NLTCP delivery of medication to carts is a part of routine "dispensing".

8. *Emergency Boxes* -- NLTCPs must provide "emergency" supply of medications as required by the facility in compliance with State requirements.

9. *Emergency Log Books* -- NLTCP must provide a system for logging and charging medication used from emergency/first dose stock. Further, the pharmacy must maintain a comprehensive record of a resident's medication order and drug administration.

10. *Miscellaneous Reports, Forms and Prescription Ordering Supplies* -- NLTCP must provide reports, forms and prescription ordering supplies necessary for the delivery of quality pharmacy care in the LTC setting. Such reports, forms and prescription ordering supplies may include, but will not necessarily be limited to, provider order forms, monthly management reports to assist the LTC facility in managing orders, medication administration records, treatment administration records, interim order forms for new prescription orders, and boxes/folders for order storage and reconciliation in the facility.

The CMS performance and service criteria are not intended to be exclusive or exhaustive. Rather, they are intended to be minimum requirements for becoming a network LTC pharmacy. While payment terms for LTC pharmaceutical and dispensing services are subject to negotiations between the Plan and its network LTC pharmacies, we note that payment to LTC pharmacies under Part D may only cover drug ingredient costs and dispensing fees as defined in the final regulations at 42 CFR § 423.100. The elements above, not including the cost of drugs, would all be legitimate costs to reflect in the dispensing fee. Specialized services provided in the administration of drugs after they are dispensed and delivered from the LTC pharmacy are specifically not covered by the Part D benefit.

II. Convenient Access

As stated earlier, Part D plans will be required to offer a contract to any pharmacy willing to participate in its LTC pharmacy network so long as the pharmacy is capable of meeting certain minimum performance and service criteria (and relevant State laws governing the practice of pharmacy in the LTC setting) and any other standard terms and conditions established by the plan for its network pharmacies. Once a Part D plan has negotiated an agreement with an LTC pharmacy, the LTC pharmacy becomes a network provider and is eligible to serve the plan's enrollees who reside in LTC facilities.

We expect that each LTC facility will select one or possibly more than one eligible NLTCP to provide Medicare drug benefits to its residents. A facility can continue to contract exclusively if it chooses, however, the features to promote competition described above will likely give each facility access to a broader range of potential LTC pharmacies than is the case today. CMS will continue to assist LTC facilities in making informed choices for LTC pharmacy services and finding the best fit for their operational needs. On a voluntary basis, pharmacies that are interested in participating in LTC network contracting under the CMS stated performance and service criteria may be listed on the CMS website. CMS expects to provide pricing and access information to beneficiaries and their representatives as soon as it is available.

Part D plans must demonstrate that they have a network of participating LTC pharmacies that provide convenient access to LTC pharmacies for LTC residents who are Part D enrollees. There

are essentially 4 action steps that a Part D applicant plan sponsor must complete in order to assure CMS that it will provide convenient access for its enrollees to NLTCPs. They include:

1. *Workplan* – An applicant must provide a work plan in its March 23, 2005 application that describes its strategic approach and milestones toward the completion of LTC contracting by July 15, 2005. Part D applicants must work aggressively to complete their LTC pharmacy contracting so that they can provide convenient access to NLTCPs for their enrollees, and they will also need as much time as CMS can reasonably allow them in 2005 to do this. With that in mind, CMS will evaluate and provide feedback if necessary on this work plan. We will look for elements that concern:
    a. Identifying NLTCPs and conducting outreach;
    b. Offering the contract along with arrangements for discussion / negotiation, and approximate timeframe for coming to closure;
    c. Tracking progress; and
    d. Assessing progress to modify approach as necessary

    NOTE: CMS provided in February 2005, a file of all the LTC facilities, their locations and bed capacity to assist plans in their strategic planning and contract negotiations with LTC pharmacies.

2. *Performance and Service Criteria* – An applicant must ensure that its NLTCP contracts include the performance and service criteria drafted by CMS and presented in Section I of this paper. When the applications arrive, CMS will examine the plan's NLTCP contracts to determine if such criteria is included. These criteria are essential to providing appropriate pharmacy service to institutionalized beneficiaries.

3. *Contract With Any Willing Provider* – An applicant must attest that it will provide contracts to any willing pharmacy that meets the standard terms and conditions of the network contract and the performance and service criteria stated in Section I of this guidance.

4. *Convenient Access Requirements* –An applicant must attest that it will ensure that all of its future Part D enrollees who are institutionalized can routinely receive their Part D benefits through the plan's network of pharmacies. In other words, the plan may not rely on the out-of-network benefit to meet the convenient access standard. We would expect that the plan would seek to enter into a network contract with a pharmacy serving the LTC facility as soon as practicable.

    In addition, by August 1, 2005, the plan must provide a list of NLTCPs. As part of this listing, the plan must describe how these pharmacies will adequately provide the Part D benefit to all the plan's future enrollees who are institutionalized.

    In performance years CMS will look at enrollment and disenrollment rates for institutionalized beneficiaries by plan, as well as complaints data and utilization data for patterns that suggest inadequate access. We will also use MDS data and enrollment files to identify institutionalized beneficiaries and link them to LTC pharmacies in a plan's

network to determine whether there is enough LTC pharmacy network capacity by plan to assure the plan's institutionalized enrollees have access to their Part D benefit.

III. Formulary

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. The use of a special long term care formulary violates the requirement that plans offer a uniform benefit because LTC beneficiaries may not have access to the same drugs available to other beneficiaries, or vice versa. 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. Access to necessary medications for long term care residents may be provided through formulary inclusion, utilization management tools, or exceptions processes. Appropriate access to long term care medications should be provided in such a way as to not substantially discourage enrollment by certain part D eligible individuals.

Part D plans are required to establish an appropriate transition process for new enrollees who are transitioning to Part D from other prescription drug coverage, and whose current drug therapies may not be included in their Part D plan's formulary. Elements of what constitutes an acceptable transition process are described in separate guidance.

CMS recommends that Part D plans develop and implement a policy and procedures that ensure the beneficiary's drug history is known to the Part D plan when there has been a change in the beneficiary's LTC pharmacy provider.

IV. Exceptions and Appeals

In the final rule, we streamline the grievance, coverage determination, and appeals processes, which will ensure that long term care residents receive quick determinations regarding the medications they need. As part of these requirements, we expect Part D plan sponsors to consider the special circumstances that are applicable to enrollees who are residents of LTC facilities when making medical necessity coverage determinations based on an enrollee's health condition. These special circumstances may include, but are not limited to, the interrelationship between the LTC facility, the attending physician, and the LTC pharmacy, as well as applicable laws and regulations governing the operation of, and care furnished by, an LTC facility.

Each Part D plan sponsor must have procedures in place for addressing the needs of Part D enrollees who reside in LTC facilities, with particular attention to situations where there is a disparity between the Part D requirements and the Medicare Conditions of Participation (COP) for LTC facilities. Part D sponsors must clearly articulate the financial responsibility of the plan in such situations. In circumstances where current enrollees have an immediate need for a non-formulary Part D drug, we recommend that plan sponsors consider a one-time temporary or emergency supply process as a method of ensuring that such enrollees do not have a coverage gap while processing an exception or appeal request.

Since an enrollee in a long term care (LTC) facility may have cognitive, mental or physical impairments that may preclude the enrollee's ability to participate in the coverage determination and appeals processes, it is important to note that the regulations allow an appointed representative to act on the enrollee's behalf. An appointed representative can be any individual (or entity) chosen by an enrollee or authorized under State or other applicable law to act on his or her behalf in obtaining a coverage determination or with any level of the appeals process. For instance, an enrollee may choose an agent of the LTC facility, such as a registered nurse or case manager, to act as his or her appointed representative.