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The Medicare Modernization Act:
Formulary Issues and Access to Drugs

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On January 1, 2006, Medicare beneficiaries will have access to a new prescription drug benefit. The new benefit is part of a sweeping package of reforms in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), signed by President Bush on December 9, 2003. In addition to creating an historic, new drug benefit, the new law changes market dynamics by creating private, at-risk plans and shifting the costs of dual eligibles from the Medicaid program to Medicare.

This article provides an overview of the new Medicare Prescription Drug benefit and highlights issues that affect beneficiary access to prescription drugs.

Part I
Medicare Prescription Drug Benefit Basic Design Features

Understanding the impact of the new Medicare prescription drug benefit begins with a understanding of the benefit structure. Effective January 1, 2006, the Medicare prescription drug benefit will be offered either through new, regional, stand-alone Prescription Drug Plans (PDPS) or regional Medicare managed care plans, now called Medicare Advantage Prescription Drug Plans (MA-PDs). Local Medicare Advantage (MA) plans also must offer the new drug benefit beginning January 1, 2006.[1]

The MMA favors a market-based approach to price and quality regulation. To promote competition, the Secretary must approve all plans that meet the required elements of plan sponsorship established by law. There is no limit to the number of plans that the Secretary can approve. The Secretary is also prohibited from interfering with the pricing negotiations between drug manufacturers, pharmacies and the drug plan sponsors, and cannot require plan sponsors to adopt a particular formulary or institute a specific pricing structure for the reimbursement of covered Part D drugs.

All approved prescription drug plans must provide beneficiaries with access to negotiated prices, and beneficiaries are guaranteed a choice of at least two qualifying plans in the area in which they live. Negotiated prices must take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fee. The prices negotiated by a PDP or MA-PD are exempt from consideration for purposes of establishing the Medicaid best price.

For standard or basic coverage, most beneficiaries will pay a monthly premium, estimated to be $35 per month in 2006, and an annual deductible of $250 and 25 percent co-insurance for costs above the annual deductible, up to the initial coverage limit which is $2,250 in 2006. Once the

	Beneficiary Out of Pocket Costs	Beneficiary Cost Sharing Percentage	Plan Payment	Plan Payment Percentage
Annual Deductible	$250	100 percent	$0	0 percent
Initial Benefit	$500	25 percent	$1500	75 percent
$2250 Coverage Limit	$750		$1500	
Doughnut Hole	$2,850	100 percent	$0	0 percent
OOP Limit	$3600			
Catastrophic Coverage	> of 5% or $2 for generic or preferred drug/$5 for other branded drug.	----------	----------	95 percent

MMA Prescription Drug Benefit—Basic Benefit (Figure 1)

[1] In order to encourage the development of regional plans, there is a moratorium both on new local plans and the expansion of existing plans for two years beginning December 31, 2005.

initial coverage limit is reached, the enrollee must pay all drug costs until they have spent $3,600 in out of pocket expenses. This is the so-called "doughnut hole." After a beneficiary has spent $3,600 in total out of pocket expenses, catastrophic coverage begins and Medicare will pick up 95% of future costs. Plans must offer at least the standard or basic coverage, and under certain circumstances, can offer different coverage that is actuarially equivalent or enhanced coverage that provides benefits that exceed the actuarial value of the standard or basic coverage.

For low income beneficiaries, the Medicare prescription drug benefit provides significant subsidies. Dual eligible individuals who receive both Medicare and Medicaid, and those with incomes below 135 percent of poverty who meet the Supplemental Security Income (SSI) resource test, pay no premium and no deductibles. With respect to co-payments, full benefit dual eligibles in nursing homes pay none, while community dwelling duals and other beneficiaries with incomes below 100% of poverty pay $1 for generic drugs and $3 for all others. For those with incomes below 135 percent of poverty, co-pays may not exceed $2 for generic drugs and $5 for other drugs up to the out of pocket limit. Individuals with incomes between 135 percent and 150 percent of poverty who do not exceed the SSI resource limit, will pay premium amounts on a sliding scale, a $50 deductible and 15 percent co-insurance until they reach the out of pocket limit. Beneficiaries who are eligible for either the full or partial subsidy also have no "doughnut hole."

With the important exception of dual eligibles, enrollment in a stand alone PDP or Medicare Advantage plan that offers Part D benefits is entirely voluntary. For beneficiaries who are first eligible to enroll as of January 31, 2006, the initial enrollment period will begin on November 15, 2005 and continue until May 15, 2006. For individuals first eligible to enroll in February 2006, the initial enrollment period begins on November 15, 2005 but is extended through May 31, 2006. For those eligible to enroll on or after March 2006, the initial enrollment period is the same as the initial enrollment period for Medicare Part B—three months before becoming eligible, the month of eligibility and three months following eligibility. Thereafter, much like the Federal Employee Health Benefit Program, there will be an annual, coordinated election period. For 2006, the annual coordinated election period will begin on November 15, 2005 and will end on May 15, 2006 to coincide with the end of the initial enrollment period. Thereafter, the annual coordinated election period will begin on November 15 and end on December 31.

Eligible as of:	January 31, 2006	February 1, 2006	March 1, 2006
	November 15, 2005 – May 15, 2005	November 15, 2005 – May 31, 2006	Month of eligibility, plus three months before and after

MMA Initial Enrollment Periods (Figure 2)

Once a beneficiary has elected a plan, most beneficiaries will be locked into the plan until the next open enrollment period unless they are entitled to a special enrollment period. Special enrollment periods (SEP) are only allowed under specified circumstances, including the following: the beneficiary has involuntarily lost credible prescription drug coverage; there have been errors in enrollment, the individual is a full-benefit dual eligible; the individual discontinues enrollment in a Medicare Advantage plan with Part D coverage during the first year of eligibility, or the eligible individual meets an exceptional circumstance defined by the Secretary.

CMS intends to establish (through guidance) an SEP for low-income subsidy eligible individuals whose enrollment into Part D plans will be facilitated by CMS, individuals in long term care facilities, individuals enrolled in, or desiring to enroll, in PACE and individuals enrolled in employer group health plans.

To encourage enrollment of healthier seniors and minimize adverse selection, Part D eligible individuals who wait until after their initial enrollment period and fail to maintain continuous creditable prescription drug coverage during the period of non-enrollment face up to a 12 percent premium penalty when they do enroll. All beneficiaries are subject to the late enrollment premium penalty. However, full benefit dual eligibles and subsidy eligible individuals are only responsible for 20 percent of the penalty amount for the first 60 months during which the penalty is imposed.

Part II
Drug Coverage and Formulary Design Issues

All prescription drugs, except those specifically excluded, may be covered. Drugs that are specifically excluded include all drugs for which payment is available under Medicare Part A or Part B. In addition, Congress excluded all drugs that, under current Medicaid rules, may be excluded from Medicaid coverage at State option. Drugs excluded from coverage under the Medicare Care Part D are listed in the Figure 3.

Beyond the list of excluded drugs, the MMA gives health insurers, pharmacy benefit managers and other entities that

Drugs Excluded From Part D Coverage

1. Over the counter drugs
2. Weight gain and weight loss drugs
3. Fertility drugs and cosmetic drugs
4. Drugs to relieve cold and cough symptoms
5. Vitamins and minerals except prenatal vitamins and fluoride
6. Outpatient drugs for which associated tests or monitoring must be purchased exclusively from the manufacturer
7. Barbiturates and benzodiazepines

Excluded Drugs (Figure 3)

want to be approved as drug plan sponsors broad discretion to design the drug benefit to be offered. This discretion extends to what drugs will be covered, as well as what utilization management tools will be used. Thus, while all plans will be providing actuarially equivalent basic or enhanced coverage, there is likely to be a great deal of variation with respect to the actual drugs that are available within each plan.

When choosing a prescription drug plan, an eligible Medicare beneficiary will need to look carefully at whether a plan's formulary includes the drugs that they take. When drugs are not covered by a plan's formulary, enrollees are responsible for the full cost. Moreover, enrollees' out of pocket costs for drugs that are not covered by a plan's formulary, are not considered "incurred" costs and therefore, do not count toward the enrollee's true out of pocket (TrOOP) cost threshold. As reaching the out of pocket cost threshold is the trigger for catastrophic coverage, it will be especially important for beneficiaries with high drug costs to carefully review plan formularies to ensure that their drugs are included before enrolling in a plan.

Basic Rules for Formulary Benefit Design and Management

While formularies are not required, if one is used, it must comply with certain statutory and regulatory standards and be approved by CMS as part of the sponsor application process. Specifically, all formularies under Part D must be developed by a Pharmacy and Therapeutics (P&T) Committee. The benefit design, including the plan's utilization management program, must not substantially discourage enrollment of certain part D individuals. Furthermore, each therapeutic category or class within the formulary must include at least two drugs that are not therapeutically equivalent or bioequivalent, with different strengths and dosage forms available for each of those drugs, unless there is only one drug in the category or class or one drug is clinically superior. Finally, formularies must include adequate coverage of the types of drugs most commonly needed by Part D enrollees as recognized by national treatment guidelines.

The statute and regulations also impose certain restrictions on when, and under what circumstances, a plan sponsor can change its formulary. Specifically, a formulary's therapeutic categories and classes cannot be changed except at the beginning of each plan year or with CMS' permission, at any time, to account for new therapeutic uses and newly approved drugs. Plans must also give 60 days notice prior to removing a drug or changing its preferred or tiered cost-sharing status. Notice must be given to CMS, State Pharmaceutical Assistance Programs and other programs providing prescription drug coverage, authorized subscribers, network pharmacies and pharmacists. When removing a drug from a formulary or changing its preferred or tiered cost-sharing status, the plan must give direct written notice to affected enrollees at least 60 days prior to the effective date of the change or, provide each enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed. Plans are also prohibited from removing any drug from its formulary or making any change in its preferred or tiered cost sharing status between the annual coordinated election period and 60 days after the beginning of the contract year.

Plan sponsors also must have policies and procedures to educate and inform health care providers and enrollees concerning its formulary and must have grievance and appeal procedures and an approved exceptions process.

How Will CMS Determine if a Formulary Provides an Adequate Benefit?

CMS intends to review all plan formularies to determine whether they are adequate to assure that beneficiaries receive clinically appropriate medications at the lowest price. The formulary review process is designed to promote plan flexibility while providing some measure of assurance that formularies will provide adequate coverage of drugs needed by Medicare beneficiaries. It will be governed by the four principles identified in the Figure 4 and will focus on three areas: Pharmacy and Therapeutics (P& T) Committees; Formulary lists; and Benefit Management Tools. Each of these areas is explained in greater detail below.

Pharmacy and Therapeutics Committee

The statute and regulations require that if a plan uses a formulary, it must be developed and reviewed by a Pharmacy and Therapeutics Committee. The P&T Committee must include a majority of members who are practicing physicians and/or practicing pharmacists and at least one practicing physician and at least one practicing pharmacist must be independent and free of conflict relative to the plan, the plan sponsor and pharmaceutical manufac-

CMS' Four Principles for Formulary Review

Principle #1 – Relying 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: CMS 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.

CMS Principles of Formulary Review (Figure 4)

turers. Additionally, at least one practicing physician and one practicing pharmacist must have expertise regarding the care of elderly or disabled individuals.

The regulations provide that P&T Committees must:

- Base decisions on scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information.
- Consider whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.
- Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.
- Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually consistent with written policy guidelines and other CMS instructions.
- Document in writing its decisions regarding formulary development and revision and utilization management activities.
- Meet other requirements consistent with written policy guidelines and other CMS instructions.

CMS' final guidance on how it plans to review Medicare prescription drug benefit plans states that P&T Committees must meet best practices consistent with those contained in several widely-accepted guidelines for P&T management. Specifically, CMS will require that plans assure the implementation and use of a P&T committee consistent with the pharmacy benefit management principles of the American Society of Health System Pharmacies (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 guidance also lists "best practices" that largely track the requirements of the regulation.

Formulary List Review

Formularies must be submitted to CMS for review and approval as part of the plan's application. CMS will begin accepting formularies for review as of March 28, 2005 and they must be submitted to CMS no later than April 18, 2005.

CMS's statutory authority to review and approve formularies derives from its authority to disapprove of any plan if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. Additionally, CMS, by regulation, is requiring plans to demonstrate that plan formularies include adequate coverage of the types of drugs commonly needed by Part D enrollees, as recognized by national treatment guidelines.

CMS' formulary review will encompass a review of the formulary's category and classes in conjunction with the drugs that populate the formulary. Pursuant to the statute, CMS contracted with the U.S. Pharmacopeia (USP) for a model classification system that will serve as a safe harbor. The model classification system was developed with public input from a broad array of interests groups who were sharply divided on whether the proposed classification identified too many categories and classes of drugs or whether the classification system was too restrictive. The final guideline contains 143 categories and classes of drugs. The USP Model Formulary Guideline is also available at http://www.usp.org/pdf/drugInformation/mmg/finalModelGuidelines2004-12-31.pdf.

A part D sponsor who submits a formulary that utilizes a classification system that is consistent with the USP model guideline will satisfy a safe harbor and thus, CMS will approve its formulary classification system. However, as noted below, meeting the safe harbor with respect to formulary drug classes and categories is only a first step toward approval. 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 system, available at www.ashp.org/ahfs.

USP Formulary Key Drug Types

Significantly, while many interest groups commented that the final USP Guideline was too granular and would not provide plans with sufficient flexibility and control needed to effectively control costs, the USP itself concluded that reliance on the USP Model Classification alone is not sufficient to ensure that a plan's formulary is non-discriminatory. In a letter to CMS Administrator, Mark B. McClellan, USP wrote:

> "The Expert Committee recognized that while the Model Guidelines are an important tool in ensuring that the design and structure of a plan's formulary are non-discriminatory, they are only the first step of a comprehensive formulary review process that will be undertaken by CMS. Therefore, in addition to developing the Model Guidelines as set forth under the MMA, the expert Committee also created a separate list of Formulary Key Drug Types to assist CMS in the Formulary review process."[2]

USP's Key Drug Types are not intended to be part of the statutory safe harbor, Rather, USP created them to provide additional information to CMS regarding drug types that the Expert Committee believed CMS should look for in plan formularies to ensure that regardless of the formulary structure used, beneficiaries will have access to the medications they need. USP recommended that CMS check for at least one item in each of the USP Formulary Key Drug Types—and request justification if a formulary excludes any of these items. In that way, USP believed that CMS could easily determine whether a formulary is comprehensive and will not substantially discourage enrollment of eligible beneficiaries, as required by law.

CMS accepted USP's recommendation. Thus, while the Formulary Key Drug Types are not part of the statutory safe harbor, they are an integral part of the drug list review. Furthermore, CMS has been clear that it views the minimum statutory requirement of at least two drugs in each approved category and class, as a floor. Thus CMS may require more than two drugs per category or class 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.

The Formulary Key Drug Types is available at http://www.usp.org/pdf/drugInformation/mmg/attachmentstoUSPComments2004-12-30.pdf.

Drug List Review

Regardless of the classification system used, CMS will review and approve drug lists for consistency will best practice formularies currently in widespread use today. CMS will undertake the following six checks. Outliers for each area will be further evaluated to determine if the formulary is potentially discriminatory.

1. Does the formulary contain at least one drug in each of the USP Formulary Key Drug Types? If not, plans may present a reasonable clinical justification.

2. Does the tier placement of drugs on the formulary discourage enrollment of certain beneficiaries?

3. Does the formulary provide appropriate access to drugs addressed in widely accepted national treatment guidelines which are indicative of best practice for: 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? CMS says that 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. Does the formulary include drugs most commonly used by the Medicare population as reflected across the Drug Hierarchical Condition Categories (DHCC) used to determine Medicare risk adjustment? 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. Does the formulary contain a majority of drugs within the following classes: antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants and antineoplastics? CMS will check to see that beneficiaries who are being treated with these classes of medication have uninterrupted access to all drugs in that class via formulary inclusion, utilization management tools or exceptions processes. Further when medically necessary, beneficiaries should be permitted to continue utilizing a drug that is providing clinically beneficial outcomes.

6. Using the Medicare Current Beneficiary Survey data from 2002, CMS will analyze the availability and tier position for the most commonly prescribed drug classes for the Medicare population in terms of cost and utilization.

[2] Letter to Mark B. McClellan, Administrator, CMS, from USP, dated December 30, 2004, available at http://www.usp.org/pdf/drugInformation/mmg/commentstotheGuidance2004-12-30.pdf.

Review of Benefit Management Tools Affecting Access

CMS will review plans' use of utilization management tools, including prior authorization, step therapy, quantity limitations, and generic substitution to ensure beneficiaries are given access to drugs in a timely manner. CMS will look to current industry standards as well as appropriate guidelines from expert organizations such as NCQA, AMCP ans NAIC, and to the use of such standards in existing drug plans that are widely used by seniors and people with disabilities. CMS also intends to analyze whether each applicants' utilization management tools are used consistently with the way they are applied in existing formulary systems.

Drug Utilization Review (DUR)

CMS intends to review DUR practices to confirm that they meet industry best practices for drug access and quality oversight. These practices 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 and Exceptions

All drug plans that use formularies must have an exceptions process to enable enrollees to request access to off-formulary drugs, and if the plan uses a tiered formulary, to allow enrollees to request access to medically necessary, non-preferred drugs or to address situations where the formulary's tiering structure has changed during the year and an enrollee is using a drug affected by the change.

An enrollee or the enrollee's physician may file a request for an exception. All exceptions requests must be accompanied by the prescribing physician's oral or written statement supporting the request. For tiering exceptions, the physician's statement must establish that the preferred drug would not be as effective as the requested drug, would have adverse effects for the enrollee or both.

To request coverage of an off-formulary drug, the physician's supporting statement must demonstrate that the requested drug is medically necessary because all of the covered Part D drugs on any tier of the plan's formulary for treatment of the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects or both. If the enrollee is requesting an exception to a drug required because of step therapy protocols, the physician's statement must establish that the required drug has been ineffective to treat the enrollee's disease or medical condition, has caused or is likely to cause an adverse reaction or harm to the enrollee or, based on both sound clinical evidence and medical and scientific evidence and the know relevant physical or mental characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. If the enrollee is requesting an exception to a dose restriction, similarly, the physician's supporting statement must establish that such a does restriction has been ineffective in the treatment of the enrollee's condition, or is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

A plan sponsor's decision to deny an exceptions request is a coverage determination that is appealable. The first level of appeal is a request for reconsideration by the plan, followed by a request for reconsideration by an Independent Review Entity (IRE). If a plan approves a request for an expedited reconsideration, the plan must give the enrollee notice of its decision as expeditiously as the enrollee's heath condition requires but not later than 72 hours. In all other cases, the plan must respond as expeditiously as the enrollee's health condition requires but no later than 7 calendar days from the date the plan receives the request. Similarly, the IRE must process expedited request within 72 hours and standard requests within 7 days. Following the IRE level of review, the enrollee may further appeal an exceptions request to an ALJ, provided the amount in controversy exceeds a threshold set annually by the Secretary. If dissatisfied with the ALJ ruling, the enrollee may further appeal to the Medicare Appeals Council and may further seek judicial review, provided that the amount in controversy exceeds the threshold established by the Secretary.

Besides exceptions, other actions that are considered coverage determinations, and therefore appealable, include: a decision not to provide or pay for a Part D drug, failure to provide a coverage determination in a timely manner when a delay would adversely affect the health of the enrollee, and a decision on the amount of cost sharing for a drug.

CMS expects to require standardized reporting from Part D plans on denial, reconsideration and appeals and exceptions processing and will be using these data in its management and oversight activities. CMS also expects plans to make appropriate use of the date for internal quality initiatives.

Long Term Care Drug Accessibility

Assuring access to drugs for nursing home residents is of particular interest to CMS. The average nursing home resident has 8.07 routine medication order, while 41 percent receive nine or more medications per day.[3] Today, Medicaid pays for the vast majority of prescription drugs in nursing homes. However, Medicaid payments for prescription drugs for dual eligibles will cease effective January 1, 2006. Instead, eligible Medicare beneficiaries who are residing in nursing homes will be expected to enroll in a new Medicare drug plan (or be automatically enrolled), and the new plans are expected to contract with long term care pharmacies.

While nursing home residents with chronic and disabling condition take more drugs, the drugs they take (and need) are different than the drugs typically used by the general population and those served by commercial health plans. Not only are the drugs typically used by nursing home residents different than the general population, geriatricians and other professionals who specialize in treated the elderly must have access to a variety of drugs and dosage forms within each class. This is because there are many changes in the aging body that affect drug action and many differ-

[3] See D.E. Tobias and M. Sey, General and Psychotherapeutic Medication Use in 328 Nursing Facilities:A Year 200 National Survey, 16 Consult. Pharm. 54 (2001).

ences among the elderly with regard to acuity levels, comorbidities, symptoms and tolerances.

Accordingly, in recognition of these specialized needs, CMS has stated in guidance issued on March 17, 2005, that Part D plans must accommodate within a single formulary structure the needs of long term care residents by providing coverage for all medically necessary medications at all levels of care. Coverage of all medically necessary medications may include, but is not limited to, alternative dosage forms such as liquids, etc., and may be provided through formulary inclusion, utilization management tools, or exceptions processes.

When considering an exception request or appeal, CMS' guidance suggests that Part D plan sponsors should consider LTC residents' special circumstances including 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 plan also must have procedures in place for addressing the needs of Part D enrollees in LTC facilities, with particular attention to situations where there is a disparity between the Part D requirements and Medicare Conditions of Participation for LTC facilities. If a resident has an immediate need for a non-formulary drug, CMS is recommending that plan sponsors consider a one-time temporary or emergency supply process to ensure that enrollees do not have a coverage gap while processing an exception or appeal request. The guidance states that enrollees may choose a representative of the facility, such as an RN or case manager, to act as his or her appointed representative for purposes of prosecuting appeals and exceptions.

Treatment of Dual Eligibles

According to CMS, in 2002, there were approximately seven million individuals who were eligible for Medicare and Medicaid at some point in the year. Today, CMS estimates there are approximately 6.4 million dual eligibles at any one time. Dual eligibles are by definition poorer than other Medicare beneficiaries. Seventy-seven percent of dual eligibles have annual incomes below $10,000. They also tend to be sicker and have a greater prevalence of chronic illness than other beneficiaries. For example, 24 percent have diabetes, 20 percent have pulmonary disease, 15 percent have had a stroke and 12 percent have Alzheimer's disease. Over one-third of dual eligibles are under age 65 and have serious physical and mental disabilities.

Dual eligibles represent about 17 percent of the Medicare population, yet they represent 30 percent of Medicare expenditures. In the Medicaid program, dual eligibles also represent about 17 percent of beneficiaries, but represent 35 percent of total Medicaid expenditures.

Although less than one-quarter of dual eligibles live in nursing homes, outside of nursing homes, data on how and where dual eligibles receive care is somewhat elusive. According to CMS, there is currently no comprehensive, fully reliable CMS system that monitors the dual eligible population. Review of information from various sources suggests that most dual eligibles straddle both programs, accessing care on a fee for service basis, with little or no care coordination. Enrollment in managed care, to the extent it is measurable, varies by state. A 2003 study of dual eligibles in managed care found that nationwide, less than seven percent of dual eligible beneficiaries were enrolled in Medicare HMOs, while data on Medicaid managed care simply proved elusive. A very small number of dual eligibles receive integrated care through the PACE program or through Medicare Social HMOs. Fours states, Minnesota, Wisconsin, New York and Massachusetts, provide coordinated care to duals through special demonstrations that combine both Medicaid and Medicare funding streams, while several other states have integrated Medicaid acute and long term care services to provide coordinated care to dual eligibles. To the extent that other dual eligibles are receiving coordinated care, it is largely through Medicaid managed care and behavioral health plans, waivers and demonstrations.

The Transition to Medicare Part D

Currently, dual eligibles receive prescription drug coverage through the Medicaid program. In 2002, total Medicaid spending for prescription drugs for dual eligibles equaled 48 percent of total Medicaid drug spending, with average prescription drug costs per dual reaching more than $1,000 annually. However, under the MMA, Medicaid coverage for prescription drug cover for duals ends on January 1, 2006, the effective date of the new drug benefit. In place of Medicaid prescription drug coverage, dual eligibles will have the opportunity to join a new Medicare prescription drug plan. The initial enrollment period begins on November 15, 2005 and continues until May 15, 2006. If a dual eligible beneficiary has not made a choice, the law provides that the Secretary shall automatically enroll that beneficiary into a Part D plan that has a monthly benefit premium that does not exceed the premium assistance available to low income beneficiaries under Part D. If more than one plan is available, the Secretary is authorized to enroll them in a plan on a random basis.

Although dual eligibles will have little or no cost sharing obligations under the new Part D drug benefit, the transition of duals from state Medicaid prescription drug coverage to coverage under part D is fraught with challenges and potential pitfalls. The first challenge will be ensuring that dual eligibles are targeted to receive the information and assistance needed to make informed choices about drug plans. As the most impoverished group of beneficiaries with some of the highest rates of serious impairment, including cognitive disability, it is very unlikely that internet or even mailings will be effective means for disseminating information and education beneficiaries about their choices. Case studies of dual eligibles in managed care arrangements found that despite investment of printed materials, web-based materials and member services, plans reported many problems with dual eligible beneficiaries understanding coverage and the specific requirements for enrolling in the plan. The complexity of the new drug benefit is likely to further compound the problem of voluntarily enrolling duals in the new Part D plans.

Second, in order to ensure that there is

no gap in coverage between January 1, 2006, when Medicaid payments end, and the end of the initial enrollment period, CMS has launched an ambitious effort to ensure enrollment of all 6.4 million dual eligibles into Part D plans between November 15, 2005 and January 1, 2006, a period of six weeks. Specifically, CMS intends to begin the auto-enrollment process as soon as Part D plans with premiums at or below the low-income premium subsidy amount are know prior to January 1, 2006.

Once enrolled in a Medicare drug plan, dual eligibles may find that the drugs they take are not covered by the new plan's formulary. To address this concern, CMS is requiring plans to have processes in place to transition current enrollees from their old coverage to their new Part plan coverage. On March 17, 2005, CMS issued guidance that set forth minimum requirements for transition plans. Specifically, CMS expects that each plan sponsor's transition plan will include 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. CMS expects P&T committees to be involved in developing the procedures for medical review. Further, CMS is recommending that plans consider a process for filling a temporary one-time transition supply in order to accommodate the immediate needs of a beneficiary who first presents at a participating pharmacy with a prescription for a drug 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 non-formulary drugs. According to CMS, such practice will address the beneficiary's immediate need and provide time to work out with the prescriber an appropriate switch to another medication or the completion of an exception request. As a general indicator, CMS believes that a temporary "first fill" supply of 30 days may be reasonable for a new enrollee.

If the temporary "first-fill" method is not used, CMS expects the sponsor to describe in detail how it will ensure new enrollees who are stabilized on non-formulary drugs will have access to medically necessary drugs without adverse health consequences. CMS anticipates a potential for a high volume of beneficiaries and providers on their behalf needing to file exceptions or needing alternative prescriptions on a short turn-around basis after inception of the benefit on January 1, 2006.

Regarding the transition of LTC residents, CMS is informing plan sponsors that they should work with LTC facilities prior to the effective date of enrollment to ensure a seamless transition of the facility's residents. Plans may need to supply a temporary first fill supply order until an appropriate liaison between the facility, the attending physician, and the plan's LTC pharmacy can be achieved. CMS recognizes that LTC residents are likely to be receiving multiple medications for which simultaneous changes could significantly impact the condition of the enrollee. Thus, CMS suggests that a transition period of 90 to 180 days might be appropriate for residents of nursing facilities who require some changes to their medication regimen in order to accommodate plan formularies.

For unplanned transitions, such as when a resident changes level of care, CMS states that beneficiaries and providers need to utilize the plan's exception and appeals process but encourages plans to adopt the one-time emergency supply process to ensure that enrollees do not have a coverage gap while proceeding through the plan's exception process.

Finally, CMS has informed plan sponsors that they must make the transition processes available to beneficiaries in a manner that is similar to information provided on formularies and benefit design.

Conclusions

While CMS has evidenced a strong interest in ensuring that the new drug plans offer a robust benefit that meets the needs of Medicare beneficiaries, it remains to be seen whether CMS' formulary review process will result in Part D formularies that are more comprehensive than those generally seen in private commercial markets. Controlling access to drugs through formulary management is a key cost control mechanism for health plans and pharmacy benefit managers. Prospective Part D Sponsors have had limited time to make conforming formulary changes, and some insurers may resist broadening their formularies to include additional drugs or placing expensive drugs on formulary tiers with the lowest cost-sharing.

For dual eligibles, including nursing home residents, and other Medicare beneficiaries with serious disability or chronic illness, the transition to Part D coverage is likely to be perilous. Even CMS has admitted that there will be a high volume of beneficiaries who will be switched into plans with formularies that may not cover all of their medically necessary drugs. While CMS is urging plan sponsors to provide for emergency, one-time supplies of non-formulary drugs, it is unlikely that such stop gaps will be sufficient to ensure appropriate, clinically supervised transitions for the millions of beneficiaries who will be compelled to navigate the transition to Part D.

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