California HealthCare Foundation

The Medicare Drug Benefit:
Implications for Chronic Disease Care

ISSUE BRIEF

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Introduction

Most of California's 4.3 million Medicare beneficiaries will experience major changes in coverage for prescription medications following implementation of the new Medicare prescription drug benefit. They will also have to cope with significant differences in the way they obtain those drugs. The new benefit will be administered by private drug plans which will be permitted to employ utilization management tools to control program spending and help ensure appropriate clinical treatment. Such tools include restricted formularies, tiered cost-sharing, and prior-authorization requirements. Many of California's Medicare beneficiaries, including the 1.1 million who are eligible for both Medicare and Medi-Cal, may be subject to these utilization management devices for the first time. Beneficiaries with chronic conditions, many of whom are "dual eligibles," will be particularly affected by the changes.

Lawmakers and program officials in the federal government and in California, as well as consumer advocates, should pay particular attention to the impact of the new Medicare prescription benefit on patients with chronic conditions in order to ensure that their treatment regimens are not disrupted and that their care, and thus their health, does not deteriorate. For example, the Medicare prescription drug benefit does not guarantee that beneficiaries with diabetes or mental illness will have access to all recommended medications. And dual-eligible beneficiaries and Medicare beneficiaries with HIV/AIDS may have higher cost-sharing responsibilities under the new benefit, raising questions about affordability and medication compliance. Deteriorating drug care for dual eligibles also has significant fiscal implications for the state: the cost of other forms of expensive patient care in lieu of effective drug therapy would in large part be borne by the state's Medi-Cal program.

Through regulations and guidance documents, the Centers for Medicare and Medicaid Services (CMS) has taken several important steps to limit the impact of drug plans' utilization management tools on beneficiaries with chronic conditions. Nonetheless, federal and state officials and other stakeholders should remain vigilant in monitoring how beneficiaries with chronic conditions fare after enrolling in the benefit. In particular:

- CMS has issued most of its oversight directives regarding drug plans' utilization management tools through agency guidance documents rather than enforceable regulations. CMS should monitor the experiences of beneficiaries with chronic conditions to ensure that drug plans follow CMS guidance, and modify that guidance as necessary to protect chronic care beneficiaries.
- California officials should assist dual eligibles with chronic conditions to enroll in prescription drug plans that provide appropriate access to all the medications they require, and inform them of their continuing right to switch drug plans on a monthly basis if they are auto-enrolled in a drug plan that provides inappropriate access. State officials should

also monitor the impact of the new benefit on dual-eligible beneficiaries with chronic conditions and consider steps to fill gaps in coverage for this population.

- Beneficiary advocacy organizations should assist beneficiaries with chronic conditions in selecting a drug plan that is most appropriate for their particular condition. Advocates should ensure that these beneficiaries understand that some drug plans may not provide access to needed medications and that utilization management restrictions may impede their current treatment regimens.

Background

On November 15, 2005, Medicare beneficiaries may begin enrolling in the new Medicare Part D prescription drug benefit for coverage that will start on January 1, 2006. In California, 4.3 million Medicare beneficiaries will be eligible for the new coverage. Approximately 3.4 million (78 percent) have existing drug coverage through four primary sources: an employer; California's Medicaid program, Medi-Cal; a medigap Medicare supplemental plan; or a Medicare Advantage (MA) plan. The remaining 933,000 (22 percent) have no prescription drug coverage.[1]

The benefit will be administered by private insurance companies and other organizations under contract with CMS, the federal agency which oversees the new Medicare drug benefit. Beneficiaries may choose to receive drug coverage through a stand-alone prescription drug plan (PDP) or through a Medicare Advantage plan (MA-PDP), which also covers all other Medicare benefits. In order to manage the benefit's costs, CMS has granted prescription drug plans broad discretion in designing plan structures, permitting not only the establishment of formularies but also such utilization management tools as tiered cost-sharing and prior authorization for higher-cost drugs. In addition, beneficiaries will be responsible for a range of out-of-pocket costs, depending on their financial status and drug usage. While these tools are commonly employed by private plans, and to some extent Medi-Cal, this is the first time they will be extensively applied to Medicare beneficiaries.

Such issues do not diminish the fact that the new benefit will provide much needed assistance with the costs of prescriptions for the majority of Medicare beneficiaries. The extent of that assistance will depend on beneficiaries' current drug coverage and on their eligibility for low-income assistance with the new benefit's associated costs. Approximately two-thirds of Medicare beneficiaries will pay less under the new benefit, with their average out-of pocket spending decreasing by $919 annually.[2] Further, many Medicare beneficiaries who today have only limited drug coverage (because of annual benefit caps, for example), will gain greater access to prescription drugs. However, beneficiaries who currently enjoy generous drug coverage — such as Medi-Cal or comprehensive employer-sponsored coverage — may face greater restrictions to prescription drugs or higher out-of-pocket costs under the Medicare prescription drug benefit.

For Medicare beneficiaries with chronic conditions, many of whom take multiple medications on a long-term basis, utilization management is likely to pose particular challenges — with potentially serious health consequences. These management practices may lead to higher state expenditures because a high proportion of the population with chronic conditions is dependent on Medi-Cal coverage for medical services or at risk to become so. These include such expensive services as hospitalizations and surgeries associated with the deterioration of their condition due to non-adherence or drug side effects. For these reasons, it is crucial for federal and state policy makers and patient advocacy organizations to take steps to mitigate such problems

in implementing the new Medicare prescription drug benefit.

This issue brief examines the impact of several key elements of the Medicare prescription drug benefit on beneficiaries with chronic conditions, paying particular attention to California's 1.1 million dual-eligible beneficiaries. It is illustrated with examples of three specific chronic conditions dependent on prescription drug therapy — diabetes, mental illness, and HIV/AIDS. The first two sections of the brief describe the potential impact on beneficiaries of formulary design, cost-sharing, and other pharmacy utilization management tools. The following section describes how planned outreach efforts and Medicare quality initiatives may mitigate some transitional problems, potentially increasing access to drug coverage and even improving quality of care. The final section presents recommendations to federal and state officials and Medicare consumer advocates on how to address the challenges the Medicare drug benefit may pose for beneficiaries with chronic conditions.

Overview

Approximately 87 percent of Medicare beneficiaries and 89 percent of dual eligibles have at least one chronic condition. But non-dual-eligible Medicare beneficiaries with chronic conditions have higher out-of-pocket spending on general medical care than other insured individuals with chronic conditions — an average of $1,487 annually, compared to $710 for those with other government insurance, $435 for those with private coverage, and $183 for those covered by Medicaid.[3] One major reason that Medicare beneficiaries with chronic conditions have higher out-of-pocket costs has been the lack of a prescription drug benefit in Medicare. Drug therapy is the primary clinical management tool for many chronic conditions, so individuals with chronic conditions tend to fill many prescriptions. This is particularly true for people with multiple conditions: beneficiaries with three or more conditions average between 25 and 53 prescriptions per year.[4] The Medicare prescription drug benefit will reduce beneficiaries' out-of-pocket costs and, for some, increase access to drugs.

Having Medicare prescription drug coverage, however, does not guarantee access to specific drugs. The new benefit grants private drug plans broad discretion in designing plan structures to manage beneficiary drug access. As a result, coverage for some drugs will be restricted. Despite recommendations from various stakeholder groups, CMS has declined to issue regulations requiring prescription drug plans to cover certain medications for Medicare beneficiaries with chronic conditions. Instead, CMS has indicated that it will attend to access issues through the vigilant review of drug plans' formularies, issuing guidance documents to explain CMS's formulary review process, establishing and enforcing time frames for appeals and grievances, and creating drug plan "quality requirements." However, this dependence on CMS guidance instead of firm formulary requirements leaves open the possibility that some beneficiaries with chronic conditions may not receive access to all of the drugs they need to manage their conditions.

Pharmacy Management Tools and Their Implications

Formularies, which are lists of preferred drugs covered by the drug plan, are used by nearly all health plans in the private sector today.[5] The development of these formularies is typically based on clinical efficacy and relative costs of therapeutically equivalent drugs. Although not required to do so, each Medicare prescription drug plan will likely establish its own individual formulary to control program costs. Prescription drug plans may also use other utilization management tools, including placing drugs in different cost-sharing tiers, requiring step therapy and generic

Definitions of Utilization Management Tools

Formulary. A list of drugs developed by the plan that limits the number of covered drugs within a therapeutic class by identifying the most cost-effective, clinically appropriate medications.

Generic-only Tiers. A tiered cost-sharing structure in which only generic drugs are available at the lowest-cost tier.

Generic Substitution. Requiring that a pharmacist dispense a generic drug for a brand name prescription when a generic is available.

Preferred Drug List (PDL). Similar to a formulary, a list of drugs developed by Medi-Cal (or other state Medicaid program) that limits the number of drugs available without prior authorization within a therapeutic class.

Step Therapy. Requiring that a lower-cost, therapeutic equivalent drug be dispensed and prove ineffective before a higher cost drug may be covered.

Supply Limits. Permitting plans to limit the number of drugs that may be dispensed per filled prescription.

Therapeutic Substitution. Dispensing a therapeutic equivalent drug without the prior authorization of the prescriber.

Tiered Co-pays. Permitting plans to charge different cost-sharing amounts for drugs that are therapeutically equivalent.

substitution, and placing prior-authorization restrictions on certain drugs (see box). While these utilization management tools have been commonly employed in private sector plans, limited research has been conducted regarding their impact on the Medicare population, who are more likely to have chronic conditions than the working-age population.

Formulary Requirements and Guidance

CMS has stated its intention to balance two goals: ensure that drug plan formularies provide access to a broad range of medically appropriate drugs to treat all conditions; and provide drug plans with sufficient flexibility to limit access and negotiate lower prices to hold down costs. To do so, CMS has established some limited formal requirements and also created guidelines for prescription drug plans regarding the development of their formularies. Before a drug plan can be awarded a contract and enroll Medicare beneficiaries, CMS must review and approve its proposed formulary.

Through legislation establishing the prescription drug benefit and its implementing regulations, CMS requires drug plans to:

- Create formularies based upon the clinical recommendations of a pharmacy and therapeutics committee;
- Provide coverage for at least two drugs within each therapeutic category and class of covered Medicare drugs;[6] and
- Ensure that the formulary design does not substantially discourage certain beneficiaries from enrolling.[7]

Through sub-regulatory documents, CMS has outlined a number of additional formulary guidelines and checks the agency will employ to evaluate whether a drug plan's formulary design is nondiscriminatory, meaning that it does not discourage enrollment by beneficiaries with certain conditions. (See the box on the following page.) CMS has the discretion to reject drug plans from participating in the Medicare prescription drug benefit if they do not meet issued guidelines. However, because guidelines are not enforceable by law, CMS also has the option of approving drug plans that fail to meet those guidelines. Moreover, CMS has the authority to change guidance provisions at any time. These caveats notwithstanding, some of the important guidelines for drug plans in 2006 include:

- Drug plans should provide coverage for certain additional drugs beyond the two-drugs-per-therapeutic-class requirement. CMS added this guidance on the recommendation of United States Pharmacopeia[8] for particular therapeutic

Requirements vs. Guidance

Federal requirements for plan participation in the Medicare drug benefit are enforceable by law; they are rules included either in the statute passed by Congress or in CMS-issued formal regulations. Drug plans will be subject to only a few such requirements when establishing their formularies. First, they must provide coverage for at least two drugs in each therapeutic class. Second, they must base their formulary decisions on the recommendations of a pharmacy and therapeutic (P&T) committee; this is a group composed of physicians, pharmacists and other health professionals who evaluate the clinical use of drugs, develop policy for managing drug use and drug administration, and manage a plan's formulary system. Finally, plans must ensure the formulary design does not substantially discourage certain beneficiaries from enrolling.

CMS has also issued many guidance documents for drug plans. CMS guidance, however, is not enforceable by law. Moreover, CMS can change its guidance at any time without public input. CMS has stated that its current formulary guidelines should only be considered in effect for 2006, and it may issue new guidance for 2007.

classes where more than two drugs may be medically necessary.

- Drug plans should provide coverage for "all or substantially all" drugs within six specific drug classes for individuals with chronic conditions.[9] These classes include:

  Antidepressants. Drugs used to prevent or treat clinical depression;

  Antipsychotics. Drugs used to treat psychotic conditions such as schizophrenia;

  Anticonvulsants. Drugs used to prevent seizures;

  Antiretrovirals. Drugs used against certain types of virus, such as HIV;

  Immunosuppressants. Drugs used to inhibit the body's immune system, many used in the treatment of cancer; and

  Antineoplastics. Drugs to inhibit or prevent the growth or development of malignant cells, used in chemotherapy.

  For all but antiretrovirals, however, CMS guidance permits drug plans to use utilization management tools, such as tiered cost-sharing and prior authorization, to limit use of these drugs.[10]

- Drug plans should establish standardized reporting regarding approval rates of appeals for coverage of drugs not included on the formulary.
- Drug plans should use appeals data for internal quality initiatives, such as placing drugs on the formulary that have high rates of approved appeals.

CMS has indicated that it will oversee the policies and actions of drug plans in several ways, including:

- Monitoring and evaluating drug plans' tiered cost sharing structures and other utilization management tools, particularly for the top 40 drug classes most commonly prescribed and costly for the Medicare population. (See Appendix Table A.)[11] This list contains many critical classes of drugs used to treat a number of chronic conditions.
- Analyzing formularies to determine whether appropriate access is granted to drugs included in widely accepted national treatment guidelines for a number of chronic conditions, such as diabetes, dementia, depression, bipolar disorder, schizophrenia, and HIV (see Appendix Table B).
- Monitoring appeals data to ensure that drug plans are using this information to improve quality of care.

While CMS has reviewed and approved drug plans' formularies for the first year of the Medicare drug benefit, drug plans are permitted to change their formulary lists on a monthly basis beginning in March 2006. A prescription drug plan must seek CMS approval before removing a drug from its

formulary or changing its cost-sharing tier status, providing at least 60 days prior notice to CMS, other entities supplementing the drug plans' benefit, prescribers, pharmacists, and enrollees currently taking an affected drug. The notification must be written and contain the drug's name, the action being taking, the reason for the action, alternative drugs, and instructions for the enrollee to seek a determination that would enable continued coverage of the affected drug. Drug plans do not have to give prior notice for drugs that are removed from the market, either by the Food and Drug Administration or the manufacturer.

Potential Implications for Beneficiaries with Chronic Conditions

Beneficiaries may face restrictions in access to certain medications. CMS's formal guidance does not guarantee open access to all drugs important for managing chronic conditions. Drug plans will retain a great deal of flexibility in their design of CMS-approvable formularies and other utilization management mechanisms. For example, drug plans which include several drugs in a therapeutic class are permitted to divide the class into cost-sharing tiers. The preferred tier with the lowest co-payments might only include generic drugs, while the highest tier might be for brand name drugs with co-payments as high as 80 to 100 percent of the drug's negotiated price. (Dual eligibles and beneficiaries who qualify for the 135 percent FPL subsidy would not be subject to the same tier structure; they would incur co-payments of $1 to $5 depending on whether the drug was generic or brand-name.) Such tier-based cost sharing would meet CMS formulary requirements even though the beneficiary is responsible for all or almost all the cost of the high-tier drug. If Medicare drug plans have restrictive formularies and the physician and patient are not willing or able to navigate prior authorization, the appeals processes, or other barriers to continuation of their current drug therapy, some beneficiaries with chronic conditions may be required to give up their carefully calibrated, effective drug regimens and start over with lower cost medications.

Beneficiaries may have to switch drug plans or pay out of pocket if plans make mid-year formulary changes. Medicare drug plans are permitted to change their formularies at any time (with required notice). Following such a change, beneficiaries with chronic conditions who selected a drug plan based upon its formulary may find that the drug plan no longer serves their needs. Such beneficiaries will either have to adjust to the formulary change, seek coverage of the non-formulary drug through the drug plan's exceptions and appeals processes, pay out of pocket for the drug, or change drug plans when permitted to do so. In response to this concern, CMS will permit dual-eligible beneficiaries and certain other low-income beneficiaries, plus all beneficiaries residing in nursing facilities, to switch drug plans on a monthly basis. Other beneficiaries may only change drug plans during the yearly open enrollment period between November 15th and December 31st.

Seeking an exception or pursuing an appeal is not likely to be a simple procedure, however. And switching drug plans requires navigating the terms and conditions of other available drug plans. Individuals with mental conditions or cognitive difficulties, in particular, may have difficulty understanding formulary changes and the steps needed to respond to them.

Beneficiaries with some chronic conditions may face barriers to effective treatment of co-morbidities. Patients living with chronic conditions typically suffer from additional conditions or side effects from their medications. This makes it important that they have access to all drugs used to treat commonly associated co-morbidities, in addition to the protected drug classes identified in CMS guidance documents. However, many drugs associated with the treatment of common co-morbidities for chronic conditions are

not included in the CMS guidance documents for drug plan formularies (Table 1).

Beneficiaries may experience more side effects and reduced adherence rates. Several important drug classes used to manage the side effects of many chronic disease medications are statutorily excluded from Medicare coverage. Examples include certain drugs used to treat weight loss or weight gain, barbiturates, benzodiazepines, and vitamins. While many of these drug classes do not directly address chronic conditions, they are often prescribed to improve drug therapy adherence rates by mitigating negative side effects of some commonly used drugs. Medi-Cal recently announced that it will continue coverage of benzodiazepines and other Medicare-excluded drugs for dual-eligible beneficiaries. However, this issue remains critical for non-dual-eligible individuals who will not have coverage for these drugs under Medicare.

Beneficiaries may have difficulty accessing drugs for off-label uses. Each drug label has a list of conditions for the treatment of which the drug has been officially approved. However, providers often lawfully and effectively prescribe drugs to treat conditions that are not listed on the FDA-approved drug label. For example, some providers prescribe drugs to treat HIV/AIDS even though the label on the drug only indicates cancer treatment. Because drug plans are not required to cover drugs prescribed for any off-label indication (with some exceptions[14]), patients may have more difficulty obtaining these drugs through drug plans' prior-authorization or appeals processes.

Beneficiaries seeking off-formulary drugs may find navigating drug plans' exceptions and appeal processes time-consuming and complicated. If a drug is not covered on a drug plan's formulary, a beneficiary can request that the drug plan consider whether the patient has an exceptional need for it. If an exception is denied, the beneficiary may further

Table 1. Common Co-Morbidities and Protections for Selected Conditions

	Protected	Some Protection	No Protections
DEFINITIONS	CMS expects drug plans to provide coverage for "all or substantially all" drugs within six specific drug classes for individuals with chronic conditions. Drug plans may still use utilization management tools for these classes, however.	CMS expects drug plans to review drug formularies to ensure adequate access is afforded to drugs prescribed to treat these listed conditions.	No protection specified by CMS for the treatment of these conditions.
Diabetes	None	• High Cholesterol • Hypertension • Heart Disease • Visual Impairment • Stroke • End-State Renal Disease (ESRD)	• Lower Extremity Conditions
Mental Illness	• AIDS	• Chronic Obstructive Pulmonary Disease (COPD) • Hypertension • Arthritis • Respiratory Infections	• Obesity • Alcohol Abuse/Misuse
HIV/AIDS	• Mental Illness	• Pneumonia • Neurocognitive Disorders • Hepatitis C • Hypertension • Diabetes	• Substance Abuse

Potential Consequences of Utilization Management Tools on Beneficiaries with Chronic Conditions

The difficulties presented to individuals with chronic conditions by Medicare coverage restrictions, formularies, and other utilization management tools available to prescription drug plans may be demonstrated through specific examples, using the three chronic conditions discussed throughout this brief — diabetes, mental illness, and HIV/AIDS.

Diabetes. Even if a drug plan follows CMS's guidelines by providing coverage for all five oral agents commonly prescribed to people with diabetes, it may still impose prior-authorization restrictions on these drugs, or require high cost-sharing or step therapy. However, access to each type of oral hypoglycemic is generally vital for proper disease management. People with diabetes often take several oral agents because each performs a physiological function for different organs. Providers typically start diabetic patients on one oral agent and continue to prescribe additional oral agents before beginning insulin. Any step therapy policy or dosage limitation that restricts a diabetic patient to a small number of drugs within a therapeutic class may interfere with a patient's treatments.

Mental Illness. Drugs used to treat mental conditions (including "atypicals") have been shown to have significantly different clinical effects, side effects, and adverse events in different individuals. Physicians have to carefully tailor drug regimens to each individual, taking into account treatment history, likely side effects, other prescribed medications, and associated co-morbidities. It can take six to twelve weeks to determine if a drug is effective, and during that time individuals with mental illness may face hazardous drug interactions, harmful relapses in symptoms, lowered adherence rates, and increased suffering. Often, it takes physicians years to find the right combination of drugs to effectively treat a patient. Studies have shown that the overall financial costs of limiting access or forcing drug-switching for individuals with mental illness greatly exceed program cost savings.[12] The cost to the beneficiary and to society as a whole is more difficult to quantify but no less real.

The Medicare prohibition against coverage of certain specific drugs also raises the possibility of dangerous consequences for certain individuals with chronic conditions. Mental health advocates and providers are especially concerned about the lack of Medicare coverage for benzodiazepines, commonly prescribed to treat anxiety disorders and used in combination with mood stabilizers. Benzodiazepines are also widely used to treat insomnia, muscle spasms, and seizures. Withdrawal for those with anxiety and sleep disorders will be difficult. And for many people with epilepsy, only benzodiazepines are effective in arresting seizures; without them, patients could suffer brain damage or death if they do not get to the hospital in time.[13]

HIV/AIDS. People with HIV/AIDS are typically prescribed many other drugs for co-morbid conditions, such as antibiotics for bacterial infections and statins for high cholesterol. Side effects from drugs prescribed for co-morbid conditions can complicate primary HIV/AIDS treatment, meaning that physicians may need considerable flexibility when designing a patient's drug regimen. While current CMS guidance specifies that prescription drug plans must cover all HIV/AIDS-specific drugs, patients may not have access to drugs used to treat co-morbidities. Thus, restrictive formularies may lead to patients using a combination of drugs that could interfere with each other or cause even more side effects.

appeal to an independent review; the federal Department of Health and Human Services; and finally. the courts. At each stage, a beneficiary pursuing a coverage appeal must actively submit the previous decision for review. Each step in the review process may take from 72 hours to 7 days (although an initial appeal must be reviewed within 24 hours if a physician requests an expedited decision on the grounds that a longer delay would seriously jeopardize the beneficiary's health or ability to function). Dual-eligible individuals currently face a much less rigorous Medi-Cal prior-authorization and appeals process when seeking coverage for a drug not listed on the Medi-Cal preferred drug list (PDL). Dual-eligible beneficiaries with chronic conditions, especially those with mental illness, may find the switch to a new appeals process makes it extremely difficult to obtain medically necessary drugs.

Formulary Issues Associated with Dual-Eligible Beneficiaries

Dual eligibles — those eligible for both Medicare and Medi-Cal — will transition from Medi-Cal to private Medicare drug plans to receive drug coverage. Medicare drug plans' formularies and utilization management tools may result in considerable gaps in coverage for many beneficiaries with chronic conditions. These gaps may be particularly difficult for dual eligibles to manage, since under previous Medi-Cal coverage these beneficiaries have had wide access to medications.

CMS requires drug plans to establish an appropriate transition process for new enrollees who are switching from other prescription drug coverage such as Medi-Cal, and whose current drug therapies may not be included in their Medicare drug plan's formulary. However, CMS has not established any specific requirements regarding this transition process, and it is unclear whether protections in the process will be adequate to prevent adverse events for beneficiaries with chronic conditions. Below are two tables that compare some of the potential changes in utilization management tools and in drugs covered under Medicare for dual-eligible individuals in Medi-Cal fee-for-service (FFS). Some dual-eligible individuals who receive benefits through a Medi-Cal managed care plan already face private sector tools similar to those likely to be used by Medicare drug plans. However, the vast majority of dual eligibles are enrolled in Medi-Cal FFS, and these beneficiaries will be facing significant utilization management restrictions they have not experienced under Medi-Cal.

Table 2. Changes in Utilization Management Tools from Medi-Cal to the Medicare Drug Benefit

DRUG PLAN TOOL	Current FFS Medi-Cal Coverage	Coverage Under Medicare Drug Benefit
Formulary	Open, but access may be restricted by state PDL.	Drug plans may offer closed formularies.
Prior Authorization	Used for select drugs.	Permitted for all but HIV/AIDS drugs.
Step Therapy	Used for select drugs.	Permitted
Generic-only Tiers	No	Permitted
Therapeutic Substitution	No, but state law permits generic substitution.	Permitted
Supply Limits	Yes	Permitted
Tiered Cost Sharing	No	Permitted

Table 3, focusing on treatment of diabetes, mental conditions, and HIV/AIDS, describes how drug coverage could change for key formulary classes for dual-eligible individuals in Medi-Cal FFS after transitioning to the Medicare drug benefit. While coverage comparisons are difficult given that specific Medicare drug plan formularies are still unknown, in general Medicare drug plan coverage for key classes used to treat these three chronic conditions will be narrower than Medi-Cal's relatively generous current coverage.

Table 3. Changes in Drug Coverage for Specific Chronic Conditions*

	Key Formulary Classes	FFS Medi-Cal Coverage†	Medicare Benefit‡	Coverage Comparison
Diabetes	Oral agents and insulin	Prior authorization required for only one of the oral agents.	Drug plans must cover five different types of oral agents and four different types of insulin.	Under Medicare, some oral agents may not be covered or may require prior authorization.
Mental Health	Anti-psychotics and anti-depressants	Prior authorization required for a few antidepressants but not for atypicals.	All or substantially all drugs must be covered on the formulary but they may be subject to prior authorization or other utilization management tools.	Under Medicare, drugs may require prior authorization or other utilization management tools resulting in drug switching.
HIV/AIDS	Antiretrovirals	Prior authorization required for one antiretroviral (Fuzeon)	All drugs must be covered on the formulary; drug plans cannot impose prior authorization on this class except for individuals beginning Fuzeon after January 1, 2006.	Coverage should be similar for dual eligibles, except for higher cost sharing.

*Comparison does not address drugs for co-morbidities or side-effect management.

†This analysis does not address whether there are dosage or form limitations.

‡Coverage Requirements by CMS Guidance, issued January 22, 2005.

Cost Sharing

All Medicare beneficiaries who enroll in the Medicare drug benefit will be subject to at least some cost-sharing requirements. Cost sharing is a widely used tool in health insurance programs as a strategy to control utilization and manage costs. For most beneficiaries with little or no drug coverage, out-of-pocket costs will be lower under the new drug benefit. However, beneficiaries currently receiving assistance with their drug costs through Medi-Cal or some employer-sponsored coverage may experience an increase in out-of-pocket costs, depending on their income, drug use, and the particular Medicare drug plan in which they enroll.

CMS Requirements

Under the Medicare prescription drug benefit, beneficiaries are responsible for a range of out-of-pocket costs, depending on their incomes and assets (Table 4). Prescription drug plans will be required to offer a minimum "standard benefit" to all beneficiaries, while Medicare offers subsidies for lower-income beneficiaries, including dual eligibles. All beneficiaries will have some out-of-pocket costs, the amounts depending on their drug usage and their financial status. Beneficiaries who do not qualify for low-income assistance will have the most significant cost sharing, especially those with total annual drug spending of $2,250 to $5,100, which places them within the benefit's so-called "doughnut hole" coverage gap.

It is important to note that a prescription drug plan may alter the standard prescription drug package, providing it offers at least one package with an actuarially equivalent benefit. For example, drug plans could increase cost sharing and narrow the coverage gap, or they could base cost sharing on a tiered benefit design rather than a set percentage coinsurance amount, either of which would change the standard benefit cost-sharing structure.

Implications for Beneficiaries with Chronic Conditions

The Medicare prescription drug benefit's relatively high cost-sharing requirements may discourage medication adherence. Increased patient cost sharing for drugs has been found to decrease the appropriate use of medications and lead to non-compliance with prescribed treatments.[15] The risk is particularly high for patients with chronic conditions because many are on multiple medications which burden them with cost-sharing responsibilities. If a patient stops taking a medication or even misses a few doses, there can be harmful short- and long-term consequences.

Of particular concern are mental health patients for whom daily compliance with a drug regimen is essen-

Table 4. Out-of-Pocket Costs Under the Medicare Drug Benefit

BENEFIT	Monthly Premium	Annual Deductible	Co-pay (generic/brand)	Co-pay After Catastrophic Limit*	Coverage Gap amount not covered
Dual Eligibles	None	None	$1 / $3	None	None
Income under $12,920 ($17,321 couple) and meets asset test	None	None	$2 / $5	None	None
Income of $12,920 ($17,321) to $14,355 ($19,245) and meets asset test	25–75% of full premium depending on income	$50	15% of drug cost as negotiated by the plan	$2 / $5	None
Standard Benefit†	$23	$250	25% of drug cost	5% of drug cost	$2,250 to $5,100

*Catastrophic limit was $5,100 in 2006.

†Drug plans can vary the cost sharing under the standard benefit; the premium cost of $23 per month is based on the average of plans' bids for 2006 in California, as announced by CMS on August 9, 2006.

tial to both their own well-being and the ability to function in society. Missing even one dose of a prescription drug can result in a loss of drug effectiveness and a psychotic episode or other distress. These not only have a negative effect on the patient's health, but can also have serious and costly implications for society, such as violent behavior, hospitalization or other institutionalization, or medical treatment to stabilize the patient's condition.

Table 5 illustrates the potential out-of-pocket costs for individuals taking five prescriptions per month, comparing the amount they may pay under the Medicare drug benefit compared to what they currently pay and the relation of those costs to their total annual income. Beneficiaries with lower incomes will face relatively high out-of-pocket costs in proportion to their income — even those who receive the low-income subsidy. Low-income beneficiaries who receive none of the subsidies will face high relative cost-sharing obligations (in this example, over 16 percent of their annual income for beneficiaries at 150 percent of the Federal Poverty Level (FPL)). In comparison, a study found that privately insured adults with incomes over 200 percent of the FPL (now about $32,180 for a family of three) spent a total of 0.7 percent of their family incomes on out-of- pocket medical costs in 2002.[16]

While this chart uses the average cost for a prescription drug in California, it is important to note that many of the medications that treat the most complex chronic conditions are much more expensive, with some costing hundreds, even thousands, of dollars for a 30-day supply. AIDS patients can be on 3 to 4 AIDS drugs at a time, take as many as 25 pills per day, and have annual drug costs of about $15,000.[17] Thus, beneficiaries with HIV/AIDS and cancer may spend significantly more on their drugs (and a much larger share of their income) than this table depicts.

The Medicare drug benefit will require higher cost-sharing than California's AIDS Drugs Assistance Program (ADAP), even for beneficiaries who qualify for low-income assistance. California's ADAP program provides assistance to approximately 28,000 HIV/AIDS patients[18] who are uninsured or underinsured. Individuals with incomes up to 400 percent of FPL ($37,240 in 2005) receive ADAP formulary drugs for free, and those with $37,240 to $50,000 in annual income are subject to a small co-pay. California beneficiaries do not pay any premiums for this benefit. Additionally, California's ADAP may assist with

Table 5. Potential Out-of-Pocket Costs for Beneficiaries with Chronic Conditions Filling Five Prescriptions Monthly

MEDICARE DRUG BENEFIT	Current Beneficiary Payment	FPL	Beneficiary Payment Under Part D	Rx Spending as Share of Income
Dual Eligibles	$60	50% 70%	$180 $180	3.8% 2.7%
Income under $12,920 ($17,321 couple) and meets asset test	Varies by current drug coverage. If no drug coverage, $3,546.	80% 100% 120%	$300 $300 $300	3.9% 3.1% 2.6%
Income of $12,920 ($17,321) to $14,355 ($19,245) and meets asset test	Varies by current drug coverage.	140% 145% 149%	$643 $712 $781	4.8% 5.1% 5.5%
Standard Benefit	Varies by current drug coverage.	150% 200% 300%	$2,322 $2,322 $2,322	16.2% 12.1% 8.1%

Note: This table assumes five brand-name prescriptions per month (60 per year). The average price of a prescription drug in California is $59,[19] for total annual spending of $3,546. The premium cost is $23 per month, based on the average of plans' bids for 2006 in California as announced by CMS on August 9, 2006.

deductible or cost-sharing obligations for individuals who have other coverage. The program estimates that approximately 20 percent of its beneficiaries will be eligible for the Medicare prescription drug benefit.

California's ADAP will provide some wrap-around benefits to eligible HIV/AIDS patients who enroll in the Medicare prescription drug benefit. Clients eligible for Medicare will be required to enroll in and use a Medicare prescription drug plan. ADAP will provide them with assistance in meeting the deductible and other cost-sharing responsibilities, although the program will not pay the drug plan's premiums. This coordination will permit ADAP to alleviate much of Medicare's associated cost-sharing responsibilities and provide coverage for Medicare non-covered drugs that are on the ADAP formulary. However, unlike other sources of coverage, contributions from California's ADAP will not count towards the True Out-of-Pocket (TrOOP) threshold to qualify for greater cost-sharing assistance, thereby mitigating the financial benefit of the wrap-around coverage. Given this different treatment for ADAP contributions, for persons with income above 150 percent FPL the program will likely pay the entire cost of drugs covered under its formulary after these clients reach the coverage gap.

Cost Sharing Changes for Dual-Eligible Beneficiaries

Dual eligibles will face increased cost sharing under the Medicare drug benefit. Dual eligibles currently pay $1 for every prescription under Medi-Cal coverage; under the Medicare drug benefit they will pay $3 for brand name drugs and $1 for generic drugs. In addition, under Medi-Cal a beneficiary cannot be denied a drug for failure or inability to pay. Under the new Medicare drug benefit, pharmacists may refuse to provide a drug to an individual who refuses or cannot pay the co-pay. However, pharmacists are permitted to waive the co-pay if they choose, provided that they do not advertise this policy. Also, California's ADAP can cover the cost of these co-pays for HIV-positive dual eligibles.

CMS Mitigation Efforts

CMS recognizes that the new Medicare drug benefit will present difficulties for some beneficiaries, particularly those with chronic conditions, due to the constraints of drug plan formularies and other utilization management tools. As a result, CMS is implementing an extensive outreach program to ease the transition, along with several quality and care management programs for certain categories of beneficiaries. CMS will also automatically enroll dual-eligible beneficiaries and some other low-income beneficiaries to ensure that they do not experience a break in prescription drug coverage. However, these efforts alone may not be sufficient to fully prepare those with chronic conditions for their new coverage, and the extent to which CMS's quality and care management programs can assure high quality care for beneficiaries with chronic conditions is unclear.

CMS Outreach Efforts

Comprehensive outreach efforts are essential to ensure that beneficiaries understand the new program, particularly those currently without drug coverage and dual eligibles who must enroll in the Medicare drug benefit to continue receiving coverage. CMS plans to spend $350 million on outreach and education during 2005 and 2006, encouraging all Medicare beneficiaries to enroll in the new drug benefit. CMS activities include partnering with other federal and state agencies to conduct outreach and enrollment, mailing all Medicare beneficiaries detailed explanations of the Medicare drug benefit and the list of available plan choices in the *Medicare & You* handbook, sending outreach and enrollment materials to providers, pharmacists, and other organizations that interact with Medicare beneficiaries, and a multi-media advertising campaign.

Quality and Care Management Provisions

The Medicare prescription drug benefit's authorizing legislation requires all drug plans to develop quality monitoring and enhancement programs to provide

chronic-care beneficiaries with timely and unhindered access to needed medications, while limiting adverse health events and steering beneficiaries to the most effective therapies. This requirement was established to improve beneficiary health and outcomes while controlling costs, and ensure that drug plans view an individual's care holistically by examining both the drug and medical elements. Drug plans have immense flexibility to design these programs, so it is difficult in advance to evaluate what their impact will be on quality of care under the Medicare drug benefit. Nonetheless, these quality programs have the potential to help protect individuals with chronic conditions from adverse effects of the drug plans' utilization management strategies.

The Medicare prescription drug benefit requires drug plans to implement three types of quality improvement programs related to managing prescription drugs.

- ***Medication Therapy Management Programs (MTMPs)*** will target beneficiaries with chronic conditions who take multiple Part D medications likely to cost more than $4,000 annually. Pharmacists or other qualified providers will administer the MTMPs, which are designed to ensure the appropriate use of prescription drugs, improve outcomes, and reduce adverse drug interactions. CMS is granting Medicare drug plans great leeway in developing these programs, which CMS will consider for approval during its formulary review. Drug plans may develop MTMP services tailored to certain chronic conditions.
- ***Utilization Management Programs*** will establish incentives for pharmacists and prescribing physicians to reduce costs; systems to prevent drug over-utilization and under-utilization; and procedures to report the drug plan's performance to CMS.
- ***Quality Assurance (QA) Programs*** will focus on preventing adverse drug events and promoting appropriate drug use for all covered beneficiaries. Medicare drugs plans must establish QA programs that comply with minimum state standards for formulary practice; conduct retrospective drug utilization reviews to identify patterns of medically unnecessary care; establish internal medication error identification and reduction systems; report on the drug plans' quality assurance measures and systems to CMS; and set up real-time utilization reviews to be performed before dispensing each prescription to the patient.

In addition, the MMA has expanded the role of Quality Improvement Organizations (QIOs) to include quality improvement assistance for Medicare drug plans. QIOs are Medicare contractors that work with providers to improve quality, respond to beneficiary complaints, and ensure efficiency in the Medicare program. QIOs assist local providers to improve the quality of care delivered to Medicare beneficiaries by raising their performance on outcome and process measures. QIOs will be charged with encouraging Medicare drug plans to use evidence-based prescribing, develop programs to decrease adverse drug reactions, and assist with their MTMP programs.

The MMA also authorized Special Needs Plans (SNPs) which are coordinated care plans that exclusively, or disproportionately, enroll special needs individuals. These plans may offer comprehensive care services targeting the dual-eligible population, institutionalized beneficiaries, or individuals with specific chronic conditions. The number of SNPs that will participate in the Medicare drug benefit is not publicly known at this time; however, CMS officials have stated they expect strong interest in this program.

Policy Recommendations

CMS has the central responsibility to oversee drug plans and to ensure that beneficiaries receive the full coverage offered by the Medicare law. But it will also fall to California state officials — with the assistance of consumer advocacy organizations — to assist beneficiaries in navigating the system, monitor drug plan activity, and press CMS to resolve issues if the agency fails to address the concerns of the state and its beneficiaries. This state role will be critical because poor drug coverage for beneficiaries with chronic conditions could result in harmful health consequences, which in turn could increase costs to the state for long-term care services and swell the number of people qualifying for Medi-Cal coverage.

This section identifies efforts which ought to be considered by CMS, state officials, and consumer advocacy organizations to monitor prescription drug plans' activities; see that beneficiaries smoothly and appropriately make the transition to the new drug benefit; and ensure that beneficiaries — particularly those with chronic conditions — receive the full coverage contemplated for them by the benefit's enabling legislation and CMS formal regulations and guidance documents. The authors recognize that federal and state government agencies and consumer advocacy organizations will have already embarked on some of the recommendations included here. Nonetheless, it is both useful and important to present a comprehensive template for addressing the wide range of anticipated issues associated with the introduction of the new prescription drug benefit in California.

Federal Officials

The crucial tasks for CMS, which state officials must monitor and supplement, are to:

- ***Enforce and expand guidelines so that their protections are effective.*** CMS must ensure that drug plans establish comprehensive formularies that do not discriminate against beneficiaries with chronic conditions. CMS must also monitor drug plan changes to ensure that over time plans' formularies do not become so restrictive that they compromise care. CMS should consider requiring drug plans to provide an emergency supply of drugs, at least for beneficiaries currently taking medications, while the plans consider appeals of coverage decisions. Finally, CMS should closely evaluate and monitor quality initiatives and make sure that drug plans are able to identify and address quality of care concerns.
- ***Require drug plans to share drug utilization data with states.*** Drug plans will accrue information about dual eligibles' drug usage and regimens. States need this information to coordinate care for beneficiaries, to monitor dual eligibles' care as they transition to Medicare drug coverage, and to ensure that drug plans are not using utilization management strategies that shift costs to the state by increasing patient use of other services (such as long-term care) in place of drugs. CMS needs not merely to recommend but to require that drug plans provide these data to the states.
- ***Ensure that detailed drug plan information is widely available and comprehensible to beneficiaries, advocacy organizations, researchers, and states.*** Information needs to be as accessible as possible for beneficiaries making health care decisions, as well as the many organizations that will be involved in educating beneficiaries and evaluating drug plan offerings and performance.

State Officials

California state officials from the Departments of Health Services, Aging, Developmental Services, Mental Health, and Managed Health Care should play an active role in helping to ensure that California beneficiaries with chronic conditions successfully

navigate the new Medicare drug benefit. With regard to funding for these efforts, at present only the Department of Aging's Health Insurance Counseling and Assistance Program (HICAP) has received federal funding to assist with enrollment functions. California can use Medicaid funding for outreach and counseling services, but only for dual eligibles.

Within this context, California officials may be able to do the following:

- ***Ensure that outreach, education, and enrollment activities performed by agency staff incorporate specific strategies to communicate with beneficiaries who have chronic conditions.*** Outreach for these beneficiaries will need to be tailored to their specific conditions and unique concerns. Educational materials and contact will need to come from trusted sources, such as beneficiary advocacy or disease organizations, and should incorporate information about drug plan formularies and cost sharing. State officials should consider partnering with consumer advocacy and disease organizations in order to make use of their expertise regarding patients with specific chronic conditions and their established trust within these populations.
- ***Ensure that agency staff informs dual-eligible beneficiaries of their right to switch drug plans on a monthly basis if their plan fails to serve their chronic care or other needs.*** Some drug plans may offer better coverage for certain dual eligibles than the plan in which they are auto-enrolled or choose initially.
- ***Seek congressional, CMS regulatory, or state regulatory changes to require California-participating drug plans to systematically provide necessary information and to make sure CMS monitors drug plan activity.*** If CMS fails to require drug plans to provide detailed information about plan offerings, appeals processes, formulary changes, and drug utilization data, or to otherwise sufficiently protect beneficiaries, the state may need to pursue legislative or regulatory changes.
- ***Consider providing coverage of drugs that are commonly left out of Medicare drug plan formularies.*** The exclusion of these drugs may have adverse consequences on patient health and increase overall health care costs. California would need to use state-only funds to support this type of initiative. Some other states, including Connecticut, Maine, and New Jersey, will provide additional coverage for some of these medications. California will continue to cover drugs excluded from Part D for its dual-eligible beneficiaries, but not for other Medicare beneficiaries. The state is not planning to cover an extended supply of Medicare-uncovered drugs for dual eligibles transitioning to Medicare. North Dakota is one of the few states currently planning to do so.
- ***Review Medi-Cal disease management strategies on a regular basis and ensure that they are coordinated with the Medicare prescription drug benefit.*** Strategies and programs to reduce health care costs for dual-eligible beneficiaries will need to reflect the fact that prescription drug spending will be controlled to a large extent by private, third-party entities.
- ***Monitor the impact of the Medicare prescription drug benefit on Medi-Cal dual-eligible beneficiaries with chronic conditions.*** It is not possible to begin calculating the precise impact of the new drug benefit until drug plan formularies are made public. Also, drug plans can modify their formularies over time. For both these reasons, state agencies should monitor drug plan activities to ensure that:

- Approved drug plans continue to follow CMS guidance, including whether non-standard packages provide coverage as comprehensive as those that follow CMS guidelines establishing minimum standards;
- The prior authorization mechanism, the appeals process, and tiered cost-sharing do not hinder beneficiary access to drugs;
- Quality initiatives focus on quality of all health care services, not just prescription drugs;
- Outreach and education efforts actually get to those with chronic conditions, particularly dual eligibles who are losing some drug coverage in the transition to the Medicare benefit; and
- Changes in drug utilization by dual eligibles, as well as related changes in utilization of other services (e.g., nursing facility care, hospitalizations), are appropriate.

Consumer Advocacy Organizations

Consumer advocacy groups will need to be vigilant in monitoring CMS and state agency activities to educate beneficiaries, and in determining whether CMS is evaluating drug plans and effectively preventing discrimination against beneficiaries with chronic conditions.

Beneficiary advocates might:

- ***Assist chronic care beneficiaries to select a drug plan that is most appropriate to their needs.*** This could include developing a decision-support tool that would incorporate drug plan formularies, cost-sharing structures and other utilization management tools, and plan quality programs aimed at specific chronic conditions.
- ***Monitor drug plan offerings and beneficiary access to needed medications.*** Advocacy groups will want to evaluate coverage options among the drug plans and the level of access to prescription drugs they provide to beneficiaries, and to do so over time as plans modify their formularies and other utilization management tools.
- ***Continue to educate beneficiaries about the drug benefit.*** Advocacy groups have greater freedom to provide targeted information to beneficiaries than do CMS, pharmacists, states and other regulated entities, which have greater restrictions on the type of advice they can give beneficiaries about enrolling in particular drug plans.

Conclusion

While the new Medicare drug benefit will help make prescription drugs less expensive for most Medicare beneficiaries, it is actually likely to increase out-of-pocket costs for those also enrolled in Medi-Cal. And for all beneficiaries, the new benefit significantly alters the manner by which they obtain prescription drugs. Private drug plans that administer the benefit will be permitted to employ private-sector utilization management tools, something most Medicare beneficiaries have not previously had to negotiate. California's policy makers must monitor the application of these tools, especially for beneficiaries who have chronic conditions. Policy makers must ensure that these tools do not create unintended barriers to prescription drug access and drug regimen compliance — central components of chronic condition management. Policy makers and beneficiary advocates should also view the Medicare prescription drug benefit as an opportunity to improve chronic care. More Medicare beneficiaries will have access to prescription drug benefits, and drug plans will be required to implement new health care quality initiatives. However, California stakeholders should make special efforts to ensure that CMS guidelines are enforced and continually monitor beneficiary access so that modifications can be made to improve chronic care management over time.

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For more background on the Medicare drug benefit and its implications for California — including other issue briefs in this series — visit the California HeathCare Foundation's Web site at **www.chcf.org/topics/healthinsurance/drugbenefit**.

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Appendix

Table A. Top 40 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 blockers/ ACE inhibitor	Sedatives
Cardiac inotropes modifier	Selective estrogen receptor
Cholinesterase inhibitors	Short-acting beat 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 antidpressants

Table B. List of 26 Conditions' National Treatment Guidelines CMS Plans to Review

Asthma	HIV
Atrial fibrillation	Heart failure
Benign Prostatic hyperplasia	Hepatitis
Bipolar disorder	Hypertension
Chronic obstructive pulmonary disease	Lipid disorders
Chronic stable angina	Migraine
Community acquired pneumonia	Multiple sclerosis
Dementia	Osteoporosis
Depression	Parkinson's disease
Diabetes	Rheumatoid arthritis
End stage renal disease	Schizophrenia
Epilepsy	Thrombosis
Gastroesophageal reflux disease	Tuberculosis

ENDNOTES

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3. Partnership for Solutions, *Chronic Conditions: Making the Case for Ongoing Care,* September 2004 Update.

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11. Top 40 drug classes listed in Appendix A. "Medicare Modernization Act Final Guidelines — Formularies; CMS Strategy for Affordable Access to Comprehensive Drug Coverage; Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures," January 24, 2005, www.cms.hhs.gov/pdps/FormularyGuidance.pdf.

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