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The New Medicare Prescription Drug Law: Issues for Dual Eligibles with Disabilities and Serious Conditions

EXECUTIVE SUMMARY

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare prescription drug law)[1] creates a new opportunity for Medicare beneficiaries, most of whom do not currently have prescription drug coverage, to purchase drug coverage through Medicare Part D plans starting in January 2006. Over 6 million dual eligibles (i.e., low-income elderly beneficiaries and persons with disabilities who are enrolled in both Medicare and Medicaid) currently receive coverage for prescription drugs through the Medicaid program, but they, too, will need to obtain Medicare drug coverage through a private Part D plan; Medicaid prescription drug benefits for dual eligibles will end when the new prescription drug coverage program begins.

A critical test of the new Medicare drug coverage program will be whether or not dual eligibles are able to have their extensive, complex, and varying needs met through this new program—and how coverage through Medicare Part D compares to the Medicaid benefit it will replace. To meet the needs of people with severe disabilities, Medicare prescription drug plans will have to build the capacity to respond to a wide range of conditions including physical impairments and limitations such as blindness and spinal cord injury; severe mental or emotional conditions; and other serious and disabling conditions including cancer, cerebral palsy, cystic fibrosis, Down's syndrome, mental retardation, Parkinson's disease, multiple sclerosis, autism, and HIV/AIDS. To assure access to services for people with disabilities, it is important that plans not be permitted to avoid persons with high cost conditions or create restrictive formularies that limit drug spending that would not meet the prescription drug needs of those with serious conditions and disabilities.

This brief examines four key questions that emerge related to how dual eligibles will fare under the Medicare Part D plans. Policymakers will need to monitor these issues during the implementation process. Opportunities to address some of these issues will arise through the regulatory process, although some issues will likely require legislative action. Interspersed throughout the paper are short stories of dual eligibles from across the country who depend on prescription drug coverage to maintain their health and functioning. These personal stories help present a picture of the diverse needs of this population and highlights some of the potential issues they will face under the Medicare Part D plans.

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Will dual eligibles be able to get the drugs they need?

Medicare prescription drug plans will need to be able to respond to the range and severity of disabilities and conditions that dual eligibles face including physical impairments, acute and chronic conditions, and serious mental health problems. Some dual eligibles with disabilities require few prescription drugs, whereas others rely on them extensively. Even within groups of people with similar conditions, the use of pharmaceuticals—and the cost—can vary dramatically.

To meet the needs of the dual eligible population, an effective prescription drug benefit must be comprehensive, allowing qualified providers to prescribe the full range of available prescription drugs. If prescription drug plans narrow the scope of coverage, some Medicare beneficiaries may be unable to access the prescription medications that they need.

- The closed formularies permitted under the Medicare prescription drug law could potentially restrict access to medications.
- The Medicare prescription drug law permits prescription drug plans to deny coverage for off-label uses of medications that are currently covered by Medicaid.
- Under Part D, dual eligibles who have been unresponsive to previously available medications could be affected by not having access to drugs that are newly approved.

Will drug coverage be affordable?

Dual eligibles have extremely low-incomes and their meager resources are rapidly consumed by rent, food and other basic necessities. Out-of-pocket costs for prescription drugs can quickly become prohibitive for people of such limited means. In recognition of these constraints, the Medicare prescription drug law contains significant cost-sharing subsidies for dual eligibles and other low-income beneficiaries. However, even with these protections, dual eligibles may experience financial barriers that impede access to appropriate drug coverage.

- Dual eligibles may not have access to the full range of prescription drug plans in their area if they are unable to pay premium costs for selecting a plan with above average costs.
- Small cost-sharing levels on individual drugs may add up to an unaffordable amount for dual eligibles if multiple drugs are needed.
- The potential that drugs could be withheld if beneficiaries are unable to pay cost-sharing could lead to interruptions in treatment regimens.

Will dual eligibles have adequate information to make an informed selection of private plan options?

Dual eligibles will need to identify and enroll in a private Part D prescription drug plan that meets their needs. While the Medicare prescription drug law provides that once enrolled, enrollees will receive information, including responses to individual beneficiary questions, these requirements do not apply to prospective enrollees. This means that individuals with disabilities or chronic conditions who are trying to assess whether specific drugs are covered—or the level of cost-sharing they will be required to pay—may not be able to receive this information until after they have enrolled in a plan.

- Dual eligibles with disabilities need to be able to determine if specific drugs that they need are covered before enrolling in a prescription drug plan. At public forums with various stakeholders, CMS officials have indicated that the regulations will ensure that individuals are able to determine prior to enrollment whether or not a prescription drug plan covers specific drugs and the level of cost-sharing to be charged, but how this will happen has not been specified.

Will the Medicare Part D benefit provide a workable system for challenging plan decisions and resolving drug coverage disputes?

A health benefits program must have an effective and accessible dispute resolution system in place. This is especially important when private, for-profit entities deliver benefits—as both cost containment for the overall program and profit for the prescription drug plan hinge on limits in coverage. The Medicare prescription drug law includes several consumer protections intended to help ensure that individuals can challenge drug plan denials. However, the appeals system may not work effectively for dual eligibles because of their low incomes, their extensive reliance on prescription drugs, and their need to prevent any interruptions in treatment.

- Part D allows for dollar thresholds for appeal rights that could leave low-income dual eligibles without access to drugs they cannot afford and no right to appeal.
- The legislation prohibits physicians from appealing on behalf of their patients, potentially restricting access to the appeals process.
- If non-formulary drugs are excluded from the exceptions process, it would minimize the value of this important consumer protection. CMS has stated that non-formulary drugs are eligible for the exception process; regulations should clarify this issue.
- The absence of provisions for dispensing an emergency supply of drugs, pending an appeal resolution, could be especially problematic.

Conclusion

While it is impossible to predict definitively how effectively the private market will respond to meet the diverse needs of Medicare beneficiaries, prescription drug coverage will change for millions of low-income dual eligibles with uncertain implications

for access. Interruptions and barriers to prescription drugs can be especially problematic for dual eligibles suffering from serious and debilitating conditions, including HIV/AIDS, epilepsy, and severe mental illness, among others.

Policymakers could address the gaps in protection between the existing Medicaid benefit and the new Medicare prescription drug coverage option in at least two ways. They could respond to the specific issues identified here through legislative and regulatory changes. Alternatively, they could permit Medicaid programs to provide wrap around coverage for dual eligibles, an option that is currently prohibited. Some policymakers may prefer to allow Medicare Part D to be implemented and monitored before making any changes in the law. However, given the potential that the dual eligible population could be adversely affected by the current legislation, it may be prudent to give serious consideration to the issues highlighted in this brief as the new benefit is being implemented.

INTRODUCTION

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare prescription drug law)[2] creates a new opportunity for Medicare beneficiaries to purchase prescription drug coverage through Medicare Part D plans starting in January 2006 (Medicare Part D). However, for over 6 million dual eligibles (i.e., low-income elderly and persons with disabilities who are enrolled in both Medicare and Medicaid) Medicaid prescription drug coverage will end when the new prescription drug coverage program begins and their drug coverage shifts from Medicaid to private Medicare Part D plans.

Dual eligibles have poorer health status and more extensive prescription drug needs than most other Medicare beneficiaries. Dual eligibles have a wide range of physical and mental health needs and access to the most current medications is often of paramount importance to maintain their health and functioning. Coverage of medically necessary drugs is particularly critical because most dual eligibles are quite poor, and thus, unable to pay out-of-pocket for non-covered drugs.

Dual eligibles will not have the choice to retain their Medicaid prescription drug coverage instead of signing up for a Medicare Part D plan, regardless of the limitations of Part D plans. Assuring that Part D plans do not avoid persons with high cost conditions or limit drug spending by developing restrictive formularies will be essential given that dual eligibles will be dependent on the adequacy of this coverage. A key issue in implementation of Medicare Part D is whether dual eligibles are able to have their extensive, complex, and varying needs met through this new program and how this coverage compares to the Medicaid drug benefit. This brief focuses on four questions and discusses the key issues in Medicare drug coverage:

- Will dual eligibles have access to the prescription drugs they need, including access to newly approved drugs?
- Will drug coverage be affordable?
- Will dual eligibles have adequate information to make an informed selection of private plan options?
- Will the Medicare Part D benefit provide a workable system for resolving drug coverage disputes?

Interspersed throughout the paper are short stories of dual eligibles from across the country who depend on prescription drug coverage to maintain their health and functioning. These personal stories help present a picture of the diverse needs of this population and highlights some of the potential issues they will face under the Medicare Part D plans.

Because drug purchasing in institutions and the financial requirements for institutionalized individuals are different than for persons residing in the community, the implementation of the law raises an additional set of issues that are not examined in this paper.[3]

Background

Dual eligibles currently receive prescription drugs through Medicaid

Prescription drug coverage is an optional benefit under Medicaid; however, it is a benefit every state has elected to cover. Historically, the Medicaid prescription drug benefit has been closely tailored to the poor and generally sicker population it serves, providing beneficiaries with a range of drugs that they need with little or no co-payment.[4] Medicaid covers a wide array of prescription drugs and allows only nominal cost-sharing. Under federal law, states that elect to provide prescription drugs in their Medicaid programs must cover all FDA-approved drugs from every manufacturer that has entered into an agreement with the Secretary of Health and Human Services to pay rebates to states for the products they purchase. Medicaid programs are permitted to have formularies or preferred drug lists (PDLs). Medicaid formularies are considered "open" because beneficiaries can access non-formulary drugs through a prior authorization process. States can also charge a "nominal" co-payment, defined in statute as 50 cents to $3.00. However, providers are not allowed to deny access to prescription drugs to beneficiaries who are unable to make a co-payment (see Appendix A).

The fiscal problems and rising prescription drug costs that all states have faced over the last several years have prompted them to increase their use of strategies to limit drug spending growth in their Medicaid programs.[5] States have developed PDLs, expanded their use of prior authorization, and increased beneficiary co-payments within the limitations established by federal law. Some states have also imposed limits on the number of prescriptions that Medicaid beneficiaries can fill each month. As a result of this activity, there is considerable variation in the generosity of the Medicaid prescription drug benefit across the states. This variation, and the potential variation in the scope of coverage provided by private Medicare drug plans make it difficult to generalize the impact of the shift to Medicare drug coverage on dual eligibles' access to drugs.

The Medicare Prescription Drug Law will change drug coverage for dual eligibles

Enacted December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 creates a new drug benefit as Part D of Medicare. Beginning in January 2006, Medicare will pay for outpatient prescription drugs through private plans. Beneficiaries can remain in the traditional FFS program, enrolling separately in private prescription drug plans (PDPs), or they can enroll in integrated Medicare Advantage (MA) plans for all Medicare-covered benefits, including drugs.

The Medicare prescription drug law has many components. Under the law, private plans have broad discretion in designing the insurance benefit and will be able to operate closed formularies. Most Medicare beneficiaries will be responsible for a monthly premium, an annual deductible, and cost-sharing, however, the legislation establishes a low-income subsidy program that will offer substantial assistance with cost-sharing to dual eligibles with disabilities and other low-income individuals. The law guarantees that beneficiaries will have a choice of at least two private plans from which to purchase coverage. If two or more risk-bearing plans are not available, Medicare will contract with a "fallback" plan to serve more beneficiaries in that area. The law also includes provisions that require prescription drug plans to provide specific information to plan enrollees. This includes information about access to specific drugs, how a formulary works, cost-sharing requirements, and information about medication therapy management programs. The law also includes several consumer protections, such as an appeals process, intended to ensure access to needed drugs.

The Medicare prescription drug law places prescription drug plans at-risk for limiting drug costs, giving drug plans incentives to limit spending associated with predictable high cost conditions. As a result, plans may seek to avoid persons with high cost conditions or limit drug spending by developing restrictive formularies. In other contexts, such as state Medicaid programs, these considerations are balanced either by the need to avoid increasing costs such as inpatient utilization or through the patient protections required by Medicaid law.

Will dual eligibles have access to the prescription drugs they need?

Dual eligibles include people with disabilities and other serious conditions who need a wide variety of prescription drugs. Medicare and other programs serving dual eligibles must be able to respond to a range of disabilities and conditions, including physical impairments and limitations like blindness and spinal cord injury, debilitating psychiatric conditions, and other serious and disabling conditions such as cancer, cerebral palsy, cystic fibrosis, Down syndrome, mental retardation, Parkinson's disease, multiple sclerosis, autism, and HIV/AIDS. Some dual eligibles with disabilities do not have especially high prescription drug utilization, whereas others rely on drugs extensively. Even within groups of people with similar conditions, the use of pharmaceuticals—and the cost—can vary dramatically. For certain types of conditions, including HIV/AIDS and mental health disorders, many of the drugs that are the most effective are among the most expensive on the market.

To meet the needs of the dual eligible population, an effective prescription drug benefit should be comprehensive, allowing qualified providers to prescribe the full range of available prescription drugs. Too much discretion by prescription drug plans to narrow the scope of coverage could mean some Medicare beneficiaries are unable to access all of the prescription medications that they need. Under the structure of the Medicare prescription drug law, prescription drug-only plans could have incentives to limit their costs and any increased hospital expenses or other increased expenses associated with poorer health outcomes will be borne by Medicare. Additionally, there is potential

for certain drugs to be excluded from Medicare prescription drug plan formularies because they (or particular uses for drugs) are not commonly needed by people without disabilities or chronic conditions.

Medicare Prescription Drug Coverage

The Medicare prescription drug law provides for prescription drug plans (stand alone drug plans and Medicare Advantage plans) to cover "Part D drugs". Part D drugs are defined as drugs that require a prescription and meet the requirements for an outpatient prescription drug, biological, or insulin under the Medicaid program.[6] There are two categories of drugs, however, that are not considered Part D drugs: drugs covered by Medicare Parts A and B[7] and Medicaid "excludable" drugs[8] (except for smoking cessation drugs).

Medicare Formulary Requirements

The Medicare prescription drug law permits prescription drug plans to operate "closed" formularies. A formulary is a list of drugs for which a prescription drug plan will provide coverage. Medicare prescription drug plans are considered "closed" because a private prescription drug plan can limit drug coverage to only those drugs on its formulary, without regard to the medical needs of the individual. If a prescription drug plan elects to use a formulary, then it must meet the following requirements:

- Formularies must be developed by a Pharmacy and Therapeutic (P&T) Committee with a majority of members that are practicing physicians or pharmacists. The P&T Committee must have at least one practicing physician and one practicing pharmacist who are independent from the prescription drug plan and have expertise in the care of the elderly or people with disabilities.[9]
- In developing and reviewing the formulary, the P&T Committee must base its decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on other information that the Committee deems appropriate. The P&T Committee must also consider whether including a drug on the formulary has therapeutic advantages in terms of safety and efficacy.[10]
- The formulary must include drugs within each therapeutic category and class of covered drugs, although not necessarily all drugs within such categories and classes. The law's reference to drug(s) is construed to mean that prescription drug plans must cover at least two drugs in every class, although plans are able to define for themselves what is a class.[11]
- Except to take into account new drugs and new therapeutic uses of drugs, a prescription drug plan can only change the therapeutic categories and classes at the beginning of each plan year.
- Although plans can change the drugs included or excluded from their formulary at any time, before removing a drug from the formulary, the plan must provide

notice to their enrollees through posting the formulary change on the Internet or providing the formulary to enrollees, upon request.

The law establishes a requirement for the Secretary of Health and Human Services to ask the United States Pharmacopeia to develop a list of model guidelines for plans to use in defining therapeutic categories and classes. These guidelines, once they become available, may lead to standardization of formulary classifications across plans, although plans will not be bound to them.

Prescription drug plans are required to operate a drug utilization management program to reduce costs when medically appropriate and to control fraud, waste, and abuse.[12] This program must include a medication therapy management program for targeted beneficiaries, including persons who have multiple chronic diseases or who are taking multiple drugs. These programs will be implemented by pharmacists and are intended to ensure that drugs are used appropriately and therapeutic outcomes are optimized.

Issues for Dual Eligibles

The increasing cost of prescription drugs and the need for both Medicare and Medicaid to control costs make formularies a primary strategy to reduce the dispensing of unnecessary, unsafe, or high cost drugs (when appropriate and effective lower cost alternatives exist). Nonetheless, the potential for Medicare prescription drug plans to limit access to needed drugs raises a number of concerns:

- **The closed formularies permitted under the Medicare prescription drug law could potentially restrict access to needed medications.**

Closed formularies could create substantial risks for dual eligibles with disabilities. While any Medicare beneficiary could have difficulty accessing drugs they need that are not on plan formularies, dual eligibles are at particular risk because their low incomes limit their capacity to purchase non-formulary drugs on their own.

A Dual Eligible Co-Infected with HIV and Hepatitis C Illustrates the Need for Access to All Drugs in a Therapeutic Class

Dan Cusick, age 45, a dual eligible from San Francisco, California has been living with HIV for more than two decades—one of a relatively small group of people who managed to live with HIV for an exceptionally long time even before effective antiretroviral treatments became available in the mid-1990s.

Dan has been living with HIV since 1981. In 1991, he was diagnosed with Hepatitis C virus (HCV), one of the most severe forms of Hepatitis that causes progressive degeneration of the liver. It was at this time that he met the standard for disability and began receiving Medicaid; and then, after the waiting period, Medicare. In 1995, Dan was diagnosed with Progressive Multifocal Leukoencephalopathy (PML). This is a rare AIDS-related condition of the brain that causes lesions and is generally observed only in people with advanced AIDS. At the time, there were no effective treatments and PML was believed to be fatal. Dan was lucky that his diagnosis came at a point in time when scientists were testing the first round of new anti-HIV drugs that have transformed the treatment of HIV leading to amazing declines in HIV mortality. He was one of the first individuals to receive a drug regimen of highly active antiretroviral therapy, and he has been relatively stable on his medications since 1995.

Starting in 1995, Dan was on a drug regimen that included 3 anti-HIV drugs: Indinavir, Lamivudine, and Zidovudine, as well as Acyclovir to treat his PML. Under the Medicare prescription drug law, it will be up to individual prescription drug plans to decide whether his three HIV drugs would be considered to be in the same class, and whether to cover only two (or all) of the anti-HIV medications, of which there are currently 20. If there ever comes a time when he cannot take any of the HIV medications and a new drug is approved, he would not be able to count on having access to the drug (security that he currently has through Medicaid), because each prescription drug plan can decide whether or not to cover new drugs.

Even if Dan selected a Medicare prescription drug plan that covers all of his current medications, he could not feel secure that his drug needs will be met. In January 2003, he and his physician decided to treat his Hepatitis C infection with a drug called Ribavirin. Because this medication cannot be taken with Zidovudine, his physician felt it was necessary to switch to a completely new regimen, changing more than just one drug—to prevent the development of resistance. He now takes Abacavir, Lamivudine, and Nelfinavir to treat HIV, he continues to take Acyclovir to treat PML, and he is about to start taking Ribavirin, to treat Hepatitis C. His doctor also added an anticonvulsant, Levetiracetam to treat seizures associated with PML.

Dan is fortunate in that he continues to feel healthy and he is able to continue to adhere to his current treatment regimen. Due to the high cost of his medications, which cost about $3,000 a month for the HIV medications alone and with the levetiracetam costing about $800/month, he hopes that he will be able to find a Medicare prescription drug plan that is as comprehensive as Medicaid.

- Dual eligibles who have been unable to successfully treat their health conditions could be affected by not having access to drugs that are newly approved.

This could be especially problematic in the case of persons who have failed on all currently available treatments. For persons with multiple sclerosis, Parkinson's disease, Alzheimer's disease, HIV/AIDS, and other progressively disabling conditions, access to the latest medications is important because they can prevent further disability and help the individual stay alive.

A Dual Eligible with Alzheimer's Disease Illustrates the Need for Prompt and Reliable Access to Newly Developed Drugs

Lucille Jenkins, 81, of Frankfort, Kentucky who is legally blind, was diagnosed with Alzheimer's Disease about four years ago. Her daughter, Teresa Bailley recalls noticing increased signs of dementia. She says, "I had spoken to my Mother two hours earlier when I received a phone call from her—and she was screaming at me for not talking to her for two weeks." Teresa has worked as a nurse for twenty years so she has experience interacting with people with dementia and she found that her Mother exhibited many of the classic symptoms.

In April 2001, Lucille wanted to move to a place where she could be less isolated, so Teresa helped her move into an apartment in a community for seniors. This worked well for a time, but she needed increasing levels of support with controlling her medications and taking care of herself. Days were often fine, but the symptoms of dementia were often severe at night. She would frequently have hallucinations, and she often called 911. In August 2002, Teresa's concerns for her Mother's well-being became so intense that she decided that her Mother should be moved into a nursing home. Until this time, Lucille relied on Medicare, and she was a qualified Medicare beneficiary (QMB), which meant that she was able to rely on Medicaid to pay her Medicare premiums and cost-sharing. When she moved into the nursing home, however, her low-income in relation to the cost of nursing care meant that she needed to enroll in regular Medicaid. As someone who worked on an assembly line for 38 years to support her family, enrolling in Medicaid was hard on Lucille's pride, but it was her only option for receiving the level of services that she needs.

Lucille currently takes four prescription medications: Clopidogrel (stroke/heart attack prevention), Galantamine (Alzheimer's Disease), Lorazepam (anti-anxiety), and Olanzapine (antipsychotic). She also takes occuvite vitamins to protect the health of her eyes, as well as potassium. She does not currently take Donepezil (Brand name = Aricept). This is one of the most commonly prescribed Alzheimer's drugs and the one that is believed to be most effective, especially for early-stage Alzheimer's Disease. Lucille took Donepezil for six months, but unfortunately, she saw no observable effect from the medication.

There are at least 20 drugs in development to treat Alzheimer's Disease. While she receives drug coverage through Medicaid, Lucille has protections to ensure that she will receive all new Alzheimer's treatments that are medically necessary. Access to new medications will be much less certain under the Medicare prescription drug law because prescription drug plans only need to update their formularies once per year, and even then, there is no guarantee that prescription drug plan formularies will cover new drugs even if they are an individual's best hope of preventing or delaying Alzheimer's Disease progression.

- **The Medicare prescription drug law permits prescription drug plans to deny coverage for off-label uses of medications, potentially denying access to valuable treatments.**

The Medicare prescription drug law does not require prescription drug plans to dispense any drug on a formulary for any use whenever a qualified physician prescribes a medication. In early 2004, major media news reports indicated that the Centers for Medicare and Medicaid Services (CMS) was beginning to scrutinize the use of prescription drugs for off-label uses, activity that is expected to increased when the Medicare prescription drug law is implemented.[13] Off-label prescribing is a practice where a physician prescribes a prescription medication for a use that is not an indication that was approved by the Food and Drug Administration (FDA). CMS policy is intended to respond to abuses brought about by growth in off-label prescribing and marketing

abuses by drug companies, as well as to require evidence of the clinical benefits of an off-label use.

Off-label prescribing is common in American medicine, and many uses for prescription drugs, while not FDA approved, are therapeutically important. The costs associated with generating data on the clinical benefits of each use for a drug mean that manufacturers may not pursue approval for all possible drug indications. Persons with rare conditions and children have been especially likely to take drugs for non-FDA approved uses because studies have not been conducted to evaluate drug efficacy or safety in those cases. Moreover, for conditions where the standards of clinical practice are evolving rapidly, evidence of the clinical benefits of new uses of drugs is frequently not available in the "real time" needed to treat individuals with life threatening conditions—and new uses have been identified through medical practice.

Will drug coverage be affordable for dual eligibles?

Since people with disabilities and the elderly generally must have very low incomes and minimal assets to qualify for Medicaid, dual eligibles are much poorer than other Medicare beneficiaries. They also tend to have far more extensive health care needs than other Medicare beneficiaries. This poses a challenge to policymakers establishing cost-sharing – they must strive to find the right balance between utilization and cost control and creating undue barriers to access to care. Levels and types of cost-sharing that are appropriate for higher income individuals may create substantial barriers to access to drugs for low-income populations like dual eligibles.

Researchers have consistently found that cost-sharing for health services, even when nominal, disproportionately impacts low-income people.[14] One study found that elderly and disabled Medicaid beneficiaries residing in states with co-payments for drugs between $0.50 and $3.00 had lower rates of prescription drug use than their counterparts in states without co-payments for drugs. After controlling for demographic and state policy differences, they found that the disparity was due primarily to a reduced likelihood of filling any prescription, and that the disparity was greatest for beneficiaries in fair or poor health.[15] Additional studies support these findings, suggesting differences in effects by therapeutic category[16], and link newly imposed or increased cost-sharing to increases in serious adverse effects.[17]

Medicare Prescription Drug Coverage

For most Medicare beneficiaries, the Medicare prescription drug law specifies that individuals must pay a monthly premium, an annual deductible, and cost-sharing of 25% of drug costs during the initial coverage period. This is followed by a period where no coverage is provided until individuals reach a catastrophic coverage period, where all but 5% of drug costs are covered.[18]

Dual eligibles and other low-income Medicare beneficiaries are largely protected from these costs. Federal subsidies to private prescription drug plans ensure that:[19]

- Dual eligibles will not pay a premium for enrollment in a prescription drug plan, as long as the premium cost is the same or lower than the cost for an average cost plan in their area for basic coverage.[20, 21] If dual eligibles believe a higher cost plan is needed to meet their individual needs, they can enroll in the plan, but they are responsible for premium costs above the amount of the average cost plan.
- Dual eligibles will not pay a deductible.
- Dual eligibles will receive full coverage when higher income Medicare beneficiaries are in the coverage gap, commonly referred to as the "doughnut hole."
- As with Medicaid, dual eligibles residing in institutions will not pay any cost-sharing. Dual eligibles with incomes below the poverty level will pay cost-sharing of $1/prescription for preferred drugs and $3/prescription for non-preferred drugs in 2006. Dual eligibles with incomes above the poverty level will pay cost-sharing of $2/prescription for preferred drugs and $5/prescription for non-preferred drugs in 2006.
- For drug coverage above the coverage gap (catastrophic coverage), dual eligibles will pay no cost-sharing.

Issues for Dual Eligibles

The Medicare prescription drug law contains significant cost-sharing subsidies for dual eligibles and other low-income beneficiaries. Despite the cost-sharing subsidies, dual eligibles may still experience financial barriers to affordable drug coverage:

- **Dual eligibles may not have meaningful access to the full range of prescription drug plans in their area.**

The Medicare prescription drug law is predicated on creating meaningful consumer choices among competing prescription drug plans. While the law guarantees beneficiaries a choice of at least two coverage options, the choices available to dual eligibles with disabilities could be greatly diminished if they are unable to pay premium costs for selecting a plan with above average costs.

- **Cost-sharing for dual eligibles may be unaffordable for low-income persons with extensive drug needs.**

With comparatively low cost-sharing of $1 or $3 per prescription for dual eligibles below the poverty level and $2 or $5 per prescription for those above the poverty level, it may be hard for some policymakers to understand the potential barriers to drug access cost-sharing can impose. However, for people whose monthly income already may be too low to adequately cover their other mandatory expenses, such as rent, food, and other basic necessities, cost-sharing can become an insurmountable burden. Many dual eligibles with disabilities rely on several prescription drugs on an on-going basis. For this group, cost-sharing obligations could easily exceed $25-30 per month, a burden that could lead them to go without needed medications.

- **Withholding drugs for inability to pay cost-sharing could lead to treatment interruptions.**

While the cost-sharing standards in the Medicare prescription drug law are in the same range as permissible "nominal" standards for Medicaid, the absence of the Medicaid provision that ensures that low-income beneficiaries can receive their medications even if they cannot pay their cost-sharing raises serious concerns.

The cost to the Medicare program and to individuals could be substantial if gaps in access to medications led to increased hospitalizations or disease progression. For conditions such as HIV/AIDS, drug resistance is one adverse effect of treatment interruptions – even one-time and short-term interruptions could lead to the development of resistance. For a broad range of other conditions, treatment interruptions can lead to increased pain and distress with consequences including the development of seizures, lessening of functional capacity, and acute episodes of mental illness.

A Dual Eligible with Major Depression Illustrates That Even Low Cost-Sharing Can Present Barriers to Drug Access

Jill Zwick, a dual eligible from Long Branch, New Jersey has been dealing with various mental health problems since she was a teenager. Jill, age 38, has been receiving Medicaid since 1992 and Medicare since 1994. Jill is under treatment for major depression and an eating disorder.

Jill likes to work, and she does so intermittently, but she explains that she also has a personality disorder that leads to her losing jobs. The only income she can count on is Social Security Disability Insurance (SSDI). [In December 2003, the average SSDI payment for disabled workers was $862 per month.] For a period of time, she was working and her earned income combined with her SSDI caused her to lose Medicaid coverage. During this period she was able to receive prescription drug coverage through a state operated program that charged co-payments of $5 per prescription. She explains that this may not sound like much, but it was a barrier that sometimes meant she could not afford to get her medications. She has also gone through personal bankruptcy that was associated, in part, with paying for medical expenses.

While Jill has consistently maintained access to Medicare, she regained Medicaid eligibility through a Ticket to Work program which allows people to return to work and continue to receive Medicaid. Because of the cost of her medications, she says she would do anything to keep Medicaid coverage.

Jill is worried about the cost-sharing requirements under the new Medicare prescription drug law. She currently takes 9 prescription medications and worries that her cost-sharing could be as much as $45 per month, which she could not afford.

Jill counts on Medicaid for the following medications: Bupropion (anti-depression), Escitalopram (antidepressant), Fluorocortisone (low blood pressure), Gabapentin (anti-seizure), Metaxalone (back problems), Modafinil (sleep apnea), Omeprazole (anti-ulcer), Rofecoxib (osteoarthritis), and Valproic Acid (anti-seizure).

Will beneficiaries have adequate information to select between private plan options?

A core philosophy underpinning the structure of the new Medicare prescription drug coverage option is that private competition will maximize both efficiencies in the delivery of prescription drugs and benefits for beneficiaries. This perspective is predicated on the existence of an array of choices of prescription drug plans from which beneficiaries would select the option that best meets their individual needs. This requires beneficiaries to have access to information that permits them to make informed decisions about which plan is best for them.

There are also issues and challenges regarding enrollment that could cloud the implementation of the Medicare prescription drug law. Unlike Medicaid, individuals will have to separately identify and enroll in a prescription drug plan. This creates new obligations for beneficiaries and creates new responsibilities for both Medicaid and Medicare to educate and assist beneficiaries with the enrollment process.

Medicare Prescription Drug Coverage

The Medicare prescription drug law guarantees that Medicare beneficiaries will have a choice of at least two private plans from which to purchase coverage.[22] The choices must include at least one stand alone drug plan, but this requirement could be met if individuals have a choice of two prescription drug plans or one prescription drug plan and one Medicare Advantage plan that provides prescription drug coverage. If two choices do not exist in an area, the federal government will step in and contract with a private company to deliver prescription drugs, with the federal government assuming the risk for the cost of prescription drugs.[23]

The law includes provisions that require prescription drug plans to provide certain information to persons eligible to enroll in a Medicare prescription drug plan. This is limited to information about general coverage and general information to compare plans, on the procedures that the prescription drug plan uses to control use of services and spending, and information on the number and aggregate disposition of grievances and appeals.[24]

The law also includes provisions that require prescription drug plans to provide specific information to prescription drug plan enrollees. This includes information about access to specific drugs, how a formulary (if any) works, cost-sharing requirements, and information about the medication therapy management program (for specific targeted groups such as persons with multiple chronic conditions).[25] Prescription drug plans must also have in place mechanisms for providing a timely response to specific beneficiary questions.[26] Medicare beneficiaries who have not enrolled in a prescription drug plan have no rights to receive this type of information.

Issues for Dual Eligibles

The selection of a stand-alone prescription drug plan is a new concept that will be first tested when the Medicare prescription drug coverage option is implemented. Since the availability of informed choice is critical to maximizing the benefits of market competition among competing prescription drug plans, it will be important for Medicare beneficiaries to have access to adequate information.

- **Dual eligibles with disabilities need to be able to determine if specific drugs that they need are covered before enrolling in a prescription drug plan.**

While the Medicare prescription drug law provides for prescription drug plan enrollees to receive a range of information, including responses to individual beneficiary questions, similar requirements do not exist for prospective enrollees. This means that individuals with disabilities or chronic conditions who are trying to assess whether specific drugs are covered—or the level of cost-sharing they will be required to pay—may not be able to receive this information until after they have enrolled in a plan. This could lead to beneficiaries enrolling in prescription drug plans that do not meet their specific needs. At public forums with various stakeholders, CMS officials have indicated that the regulations will ensure that individuals are able to determine prior to enrollment whether or not a prescription drug plan covers specific drugs and the level of cost-sharing to be charged. This information is critical for dual eligibles to have before enrolling in a plan.

Will the Medicare Part D benefit provide a workable system for resolving drug coverage disputes?

Any health benefits program must have an effective and accessible system in place to permit enrollees to dispute plan decisions. This is especially critical when private for-profit entities deliver a benefit—with cost containment for the overall program and profit for the prescription drug plan dependent on limiting coverage for certain benefits.

Medicare Prescription Drug Coverage

The Medicare prescription drug law appeals system has three parts:

- Provisions of law that provide for coverage determinations and reconsiderations with respect to "covered benefits" in the Medicare Advantage program are applied to the Medicare Part D program. These provisions establish standards for how quickly a prescription drug plan must respond to a request for services (i.e. to either approve or deny a request) called an "organization determination", as well as provisions that create a right for individuals to have the prescription drug plan reconsider a decision, called a "reconsideration". These provisions also create an expedited process in cases of emergency. Federal regulations that implement these provisions establish a 14-day standard for making an organization determination to approve or deny a service; 30 days to conduct a reconsideration; and 72 hours to make an expedited organization determination

or reconsideration. All of the time standards specified in regulations give a general time standard, but require the plan to act "as expeditiously as the eligible's health requires"—even if this requires a quicker response than the general standard.[27]

- The establishment of an "exceptions process" to request that a prescription drug plan provide a non-preferred drug and charge the cost-sharing as if it were a preferred drug. This request for an exception can be invoked when a prescribing physician determines that "the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both." Plans retain the discretion to approve or deny requests for any exceptions.[28]
- Provisions of law that provide for appeals of issues with respect to "benefits" in the Medicare Advantage program are applied to the Medicare Part D program. These provisions require the Secretary to contract with an independent outside entity to adjudicate appeals. To be eligible for an appeal, the amount in dispute needs to be at least $100 and to be eligible for judicial review, the amount in dispute needs to be $1,000. There are no statutory time frames for these decisions.[29] Unlike in the Medicare Advantage program which names various parties that are eligible to bring an appeal, including an individual's authorized representative and treating physician, the Medicare prescription drug law specifically limits the appeal right to the individual.[30]

Potential Impact on Dual Eligibles

The Medicare prescription drug law includes several consumer protections intended to help ensure that individuals can challenge drug denials by prescription drug plans. There are gaps in the appeals system, however, that may disproportionately impact dual eligibles because of their low incomes, their extensive reliance on prescription drugs, and the magnitude of problems they face when their treatment is interrupted.

- **Part D allows for dollar thresholds for appeal rights that could leave low-income dual eligibles without access to drugs they can afford and no right to appeal.**

The threshold for an appeal requires that the amount in dispute must be at least $100. There are many dual eligibles with disabilities who may have disputes under $100, but which (because of their very low incomes) they are unable to pay. CMS officials have responded to concerns expressed over this dollar threshold issue by stating their intention to permit the bundling of disputes over a period of several months. Therefore, if an individual has a dispute over access to a drug that costs $30/month, they could wait until they have been denied this drug for four months when they have met the threshold. Similarly, an individual could bundle disputes until their disputes reached more than $1,000, at which point, their dispute would be subject to judicial review.

- **Preventing treating physicians from appealing on behalf of their patients could greatly restrict access to the appeals process.**

Whereas Medicare Advantage participants can have their physicians file an appeal on their behalf, the Medicare prescription drug law limits the right to appeal to the individual. Depending upon the nature of their disability or illness (such as persons with cognitive disabilities) and the complex legalistic nature of the appeals process, many individuals may be unable to navigate the appeals process. Because of the importance of prescription drugs, it is believed that many physicians take on this role for patients who need access to HIV/AIDS drugs, cancer drugs, or others with serious and debilitating conditions. Not allowing individuals to have others appeal on their behalf is a serious restriction on the appeal right.

- **Exclusion of non-formulary drugs from the exceptions process would minimize the value of this important consumer protection.**

It is unclear how important the exceptions process will become, as it is too early to tell how extensively prescription drug plans will limit access to higher cost drugs by establishing multiple cost-sharing tiers. For dual eligibles who receive significant cost-sharing protections, however, the larger concern is that the exceptions process will be meaningless unless it is extended to requests for coverage of non-formulary drugs—when a treating physician determines that a non-formulary drug meets the standard for requesting an exception. CMS has stated that non-formulary drugs are eligible for the exception process. Regulations could clarify this issue.

- **The absence of provisions for dispensing an emergency supply of drugs, pending an appeal resolution, could cause significant harm.**

For many conditions, treatment interruptions can lead to serious short-term and long-term problems. In the case of persons who are successfully managing their mental illnesses, for example, treatment interruptions can result in destabilization, possibly culminating in hospitalization. For people with HIV/AIDS, even temporary interruptions in treatment can spur the development of drug resistant strains of HIV that have broad implications for the public health, and that influence an individual's ability to use not just their current drug treatment, but in some cases, all available HIV medications. For people with other disabilities, treatment interruptions can cause pain and hardship with equally serious consequences.

This concern is heightened due to the absence of clear protections that ensure that individuals can receive an expedited appeal if a prescription drug plan denies coverage for a non-formulary drug that is prescribed by a physician. Because the standard timeframe is 14 days to make a determination and 30 days for a reconsideration, the absence of any consumer protections that assure that prescription medications will be provided pending the resolution of an appeal is especially problematic.

For a Dual Eligible with Bipolar Disorder and Schizophrenia Access to Prescription Drugs Allows Her to Care for Her Family and Participate in Community Life

Dawn Cherry is a 28 year-old mother of four who resides in Baltimore, Maryland. She is a dual eligible who was diagnosed with bipolar disorder as a child, and diagnosed as schizophrenic in the last five years. She is currently doing much better on her drug regimen, which consists of: benztropine mesylate (lock-jaw), lithium (bipolar disorder), risperidone (schizophrenia), sertraline and trazodone (antidepressants).

She says that access to medicine is critical or she will end up in the hospital. In the past, it has not been uncommon for her to require a 3-week hospital stay in a psychiatric facility to stabilize her.

Dawn's condition is currently fairly well managed, but getting out of the house is still a big deal for her. She says that, on average, she leaves her home only twice a month. She likes to shop, but going to a shopping mall is a real challenge for her. She says that if she stays too long, she would inevitably have a breakdown.

She says that she once had an experience where a pharmacist told her that she couldn't get her medications because her Medicaid card wasn't working. Luckily, this was a simple error that she was able to easily correct. She hopes that when she must start getting her drug coverage through Medicare, she won't have to fight for her medications.

CONCLUSION

While it is impossible to predict definitively how effectively the private market will respond to meet the diverse needs of Medicare beneficiaries, prescription drug coverage will change for millions of low-income dual eligibles with uncertain implications for access. Interruptions and barriers to prescription drugs can be especially problematic for dual eligibles suffering from serious and debilitating conditions, including HIV/AIDS, epilepsy, and severe mental illness, among others.

Policymakers could address the gaps in protection between the existing Medicaid benefit and the new Medicare prescription drug coverage option in at least two ways. They could respond to the specific issues identified here through legislative and regulatory changes. Alternatively, they could permit Medicaid programs to provide wrap around coverage for dual eligibles, an option that is currently prohibited. Some policymakers may prefer to allow Medicare Part D to be implemented and monitored before making any changes in the law. However, given the potential that the dual eligible population could be adversely affected by the current legislation, it may be prudent to give serious consideration to the issues highlighted in this brief as the new benefit is being implemented.

This paper was prepared by Jeffrey S. Crowley, Health Policy Institute, Georgetown University. We would like to thank the individuals who are profiled in this report for sharing their experiences in accessing prescription drugs.

[1] Public Law 108-173. For additional information and resources related to the Medicare prescription drug law, see the "Resources on the Medicaid Prescription Drug Benefit" section of the Kaiser Family Foundation website at www.kff.org/medicare/rxdrugdebate.cfm.
[2] Public Law 108-173. For additional information and resources related to the Medicare prescription drug law, see the "Resources on the Medicaid Prescription Drug Benefit" section of the Kaiser Family Foundation website at www.kff.org/medicare/rxdrugdebate.cfm.
[3] For additional information about the implications of the Medicare prescription drug law on Medicare beneficiaries residing in institutions, see *Dual Eligibles in Nursing Facilities and Medicare Drug Coverage at www.kff.org/medicaid/4156.cfm*.
[4] This description of the Medicaid prescription drug benefit is taken from Andy Schneider and Linda Elam, *Medicaid: Purchasing Prescription Drugs, Kaiser Commission on Medicaid and the Uninsured*, January 2002.
[5] For detailed information on state management of the Medicaid prescription drug benefit, see *Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003,* Jeffrey Crowley, Deb Ashner and Linda Elam, Kaiser Commission on Medicaid and the Uninsured, December 2003.
[6] §1860D-2(e)(1) of the Social Security Act, as added by P.L. 108-173, referencing Medicaid law provisions at §1927(k)(2) of the Social Security Act. .
[7] Drugs covered by Medicare Parts A and B include injectable drugs, immunosuppressive drugs used by organ transplant recipients, epoetin alfa (which is used by persons with cancer and end-stage renal disease and other conditions to treat anemia), and certain vaccines. Medicare also covers oral cancer drugs if they are also available in injectable form. Oral cancer drugs not available in injectable form, however, are not currently covered by Medicare and prescription drug plans will be permitted to cover these drugs
[8] The following drugs or classes of drugs (or their medical uses) may be restricted from coverage or otherwise restricted by state Medicaid programs: 1) Drugs when used for anorexia, weight loss, or weight gain; 2) drugs when used to promote fertility; 3) drugs when used for cosmetic purposes or hair growth; 4) drugs when used for the symptomatic relief of coughs and colds; 5) drugs when used to promote smoking cessation; 6) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; 7) nonprescription drugs; 8) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; 9) barbiturates; and, 10) benzodiazepines.
[9] §1860D-4(b)(3)(A) of the Social Security Act, as added by P.L. 108-173.
[10] §1860D-4(b)(3)(B) of the Social Security Act, as added by P.L. 108-173.
[11] §1860D-4(b)(3)(C) of the Social Security Act, as added by P.L. 108-173.
[12] §1860D-4(c) of the Social Security Act, as added by P.L. 108-173.
[13] See, for example, "Medicare scrutinizing off-label uses for medicine," by Christopher Rowland, *The Boston Globe*, February 10, 2004 and Analysis and Commentary: "Medicare vs. Cancer Patients", *Business Week*, February 16, 2004.
(http://www.businessweek.com/magazine/content/04_07/b3870063.htm).
[14] *Health Insurance Premiums and Cost-Sharing: Findings from the Research on Low-Income Populations*, Kaiser Commission on Medicaid and the Uninsured, March 2003.
[15] Stuart, Bruce and Christopher Zacker, "Who Bears the Burden of Medicaid Drug Copayment Policies?" *Health Affairs,* Vol. 18(2): 201-212, March/April, 1999.
[16] Motheral B, Fairman K. Effect of a three-tier prescription copay on pharmaceutical and other medical utilization. *Medical Care.* 2001; 19(12):1293-1304.
[17] Tamblin R, Laprise R, Hanley JA, Abrahamowicz M, Scott S, Mayo N, Hurley J, Grad R, Latimer E, Perreault R, Mc Leod P, Huang, A, Larochelle P, Mallet L. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. *Journal of the American Medical Association.* 2001; 285(4):421-428.
[18] For a graphic illustration of beneficiary cost-sharing under the Medicare prescription drug law for regular beneficiaries (not including dual eligibles and other low-income beneficiaries eligible for the low-income subsidy, see the *New Medicare Benefit At-A-Glance Chart at* www.kff.org/medicare/medicarebenefitataglance.cfm.
[19] For the cost-sharing and co-insurance requirements for basic prescription drug coverage, see §1860D-2 of the Social Security Act, as added by P.L. 108-173. For the federal subsidies provided to prescription

drug plans and Medicare Advantage plans for paying cost-sharing for low-income beneficiaries, see §§1860D-14 and 1860D-15 of the Social Security Act, as added by P.L. 108-173.

[20] Companies that sponsor Medicare prescription drug plans must offer at least one "basic coverage" plan or an actuarially equivalent plan. Plan sponsors can offer additional coverage options that provide supplemental benefits, but only the cost for providing basic coverage is included in calculating the "average" premium cost in an area.

[21] Although dual eligibles will not pay a premium for enrollment in an average or lower cost prescription drug plan, they could be charged a late enrollment penalty. The Medicare prescription drug law imposes a late enrollment penalty on premiums charged to Part D eligible individuals who do not enroll in creditable prescription drug coverage within 63 days of becoming eligible for Part D coverage. This penalty is the greater of an amount determined by the Secretary or 1% of the premium for each month that the individual remains uncovered. For low-income individuals including dual eligibles, the late penalty charge is also subsidized. The beneficiary will pay only 20% of the late enrollment penalty attributable to the penalty for the first 5 years of non-enrollment in a prescription drug plan. Dual eligibles will not be responsible for any of the late enrollment penalty associated with a late-enrollment period of more than 5 years.

[22] §1860D-3(a) of the Social Security Act, as added by P.L. 108-173.

[23] §1860D-11(g) of the Social Security Act, as added by P.L. 108-173.

[24] §1860D-4(a)(2) of the Social Security Act, as added by P.L. 108-173.

[25] §1860D-4(a)(1)(B) of the Social Security Act, as added by P.L. 108-173.

[26] §1860D-4(a)(3) of the Social Security Act, as added by P.L. 108-173.

[27] For general requirements, see §1860D-4(g)(1) of the Social Security Act, as added by P.L. 108-173. For regulatory standards, see 42 CFR §§ 422.568-422.572 and § 422.590.

[28] §1860D-4(g)(2) of the Social Security Act, as added by P.L. 108-173.

[29] In 1998, it took on average 524 days for Medicare Part B appeals to be decided at the ALJ level. See, "Testimony of Mike Hash, Deputy Administrator, HCFA," before the House Ways and Means Subcommittee on Health, April 22, 1999.

[30] §1860D-4(h) of the Social Security Act, as added by P.L. 108-173.

Appendix A: Drug Coverage for Dual Eligibles: Comparison of the Medicare Prescription Drug Program to Medicaid.

	Medicare Prescription Drug Program	Medicaid
COMPREHENSIVE ACCESS		
Open Formularies Required	No	Yes
Cover Off-Label Uses	Plan Discretion	Yes
Coverage for Newly Approved Drugs	Plan Discretion	Yes
Off-Formulary Drugs for Persons Who've Failed All Other Treatments	Plan Discretion	Yes
AFFORDABILITY		
Beneficiaries Shielded From Premiums	Depends on Plan Choice*	Yes
Beneficiaries Shielded From Deductibles	Yes	Up to $2/month per family
Beneficiaries Shielded From Cost-Sharing	In Institutions: Yes In Community:** Below Poverty: $1/Rx and $3/Rx Above Poverty: $2/Rx and $5/Rx	In Institutions: Yes In Community State Option ($0.50 to $3.00/Rx)
Drugs Must Be Dispensed When Beneficiary Cannot Pay Cost-Sharing	No	Yes
INFORMATION		
Before Enrollment, Beneficiary Will Know:		
Premium Cost	Yes	Not Applicable
Deductible Cost	Yes	Not Applicable
Cost-Sharing Rules	Yes	Yes
Specific Drugs Covered	No	Yes
Cost-Sharing for Specific Drugs	No	Yes
APPEALS SYSTEM		
Any Size Dispute Eligible for Appeal	$100 or more for appeal, $1,000 or more for judicial review	Yes
Treating Physician Can File Appeals	No	Yes***
Expedited Appeals for Non-Formulary Drug Denials	No	Yes
Provisions for emergency supply of drugs, pending appeal resolution	No	Yes

Notes: Formularies are lists of approved drugs that will be covered. The Medicare Prescription Drug Program is considered to have a "closed" formulary because private plans can exclude specific drugs, at their discretion, without regard for the individual needs of their eligibles. Medicare cost-sharing provisions in this table apply to dual eligibles, and do not apply to Medicare beneficiaries ineligible for low-income subsidies.

*There is no premium if the individual selects an average cost plan. For enrollees in higher cost plans, individuals must pay premium costs above premium in average cost plan.

**The two levels of cost-sharing are for preferred drugs and non-preferred drugs that are on a prescription drug plan's formulary.

***Medicaid beneficiaries can files grievances, appeals, and request a State Fair Hearing. If the state permits providers to act as an enrollee's representative, then providers, with written consent of the beneficiary, can file a grievance and request a State Fair Hearing.

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