

Undermining Stability: The Plight of Mentally Ill Americans Under the 2006 Medicare Drug Benefit

August 2005

Medicare Rights Center

1460 Broadway, 17th Floor
New York, NY 10036

1030 15th Street, NW Suite 250
Washington, DC 20005

212-869-3850

www.medicarerights.org

Acknowledgements

This research was supported by grants from the Van Amerigan and Ittelson Foundations. Kim Glaun is the report's principal author, and special thanks goes to Kirsten Beronio from the National Mental Health Association for her helpful insights on access to necessary mental health treatments.

Medicare Rights Center (MRC) is the nation's largest independent source of health care information and assistance for people with Medicare. Founded in 1989, MRC helps older adults and people with disabilities get high-quality, affordable health care.

I. Introduction

One in five older adults and over half of younger people eligible for Medicare due to a disability have mental or cognitive impairments.¹ Untreated mental health conditions can lead to poor health, reduced quality of life, limited ability to function, and higher mortality rates as well as homelessness and incarceration. Psychiatric medications are a crucial treatment to alleviate the symptoms of mental illness and to promote recovery.

In recognition of the importance of prescription drugs to the health and well-being of Medicare beneficiaries, The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established a voluntary, outpatient prescription drug benefit to begin on January 1, 2006. The Medicare drug law presents new opportunities and challenges for poor and low-income older adults and persons with disabilities to obtain crucial psychiatric medications.

First, the MMA could jeopardize access to needed medications for the 6.4 million “dual eligibles” who are enrolled in both Medicare and Medicaid. Nearly forty percent of “dual eligibles” -- 2.5 million individuals -- have a cognitive or mental impairment.² Medicaid currently covers drugs for this vulnerable population. Effective January 1, 2006, the MMA ends Medicaid drug coverage for “dual eligibles” and moves them into the Medicare drug benefit. The transition process could cause harmful disruptions in care for Medicare consumers with mental illness. The current enrollment timeframe is too short to implement the extensive systems changes and the education efforts needed to: (1) shift millions of individuals to Medicare plans; (2) ensure persons know their coverage has changed; and (3) help persons understand their new coverage. Moreover, Medicare coverage for psychiatric medications may be far more restricted than many Medicaid programs. Because mental health medications, even within the same class, are not interchangeable, most Medicaid programs cover the full range of mental health medications an individual may need. Because private sector Medicare drug plans and Medicare Advantage plans will be at risk for the cost of care, plans have incentives to use restrictive benefit management practices to limit coverage of new, generally more effective medications, which cost more than older drugs for the same conditions.

While the new drug benefit could make “dual eligibles” worse off, the benefit could improve access to psychiatric medications for low-income Medicare consumers who do not meet Medicaid’s strict financial requirements. As compared to other Medicare consumers, these individuals are less likely to have existing prescription drug coverage.³ The low-income drug benefit, which provides, on average, \$2,800 in assistance with drug costs,⁴ could substantially improve access to medically necessary psychiatric medications

¹ The Henry J. Kaiser Family Foundation, *The Faces of Medicare: Medicare and the Under-65 Disabled*, July 1999.

² MedPAC, *Report to Congress: New Approaches in Medicare*, June 2004, p. 72.

³ Congressional Budget Office, *Issues in Designing a Prescription Drug Benefit for Medicare*, October 2002.

⁴ Congressional Budget Office, *A Detailed Description of CBO’s Cost Estimate for the Medicare Prescription Drug Benefit*, July 2004.

for many of these individuals. However, the record of enrolling eligible beneficiaries in existing Medicare-subsidy programs is poor -- less than one-third of eligible persons nationwide are enrolled.⁵ Lack of awareness about the benefits and complicated enrollment procedures hamper widespread enrollment in these programs. Similarly, the value of the subsidy could be undermined if coverage offered by drug plans prevents individuals from accessing needed psychiatric medications.

This issue brief discusses these issues and recommends pragmatic solutions the federal government can take to promote the ability of low-income Medicare consumers with mental illnesses to access medications they need under the new Part D benefit. These solutions would help ensure:

- coverage by Medicare drug plans of the full range of mental health medications without overly restrictive benefit management practices;
- continuity of care during the transition process; and
- greater participation in the low-income subsidy.

These recommendations build upon the existing framework of the MMA and do not address more widespread changes in the law that would assure access to medically necessary psychiatric medications.

Background

Under the Medicare drug benefit, CMS will contract with private sector drug plans or Medicare Advantage plans to offer drug coverage. The average cost of participating in these plans is projected to be \$32 per month. To help poor and low-income individuals afford the Part D benefit, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 will subsidize premium payments for Part D plans at or below the \$37 average, as well as related costs, premiums and related costs for some low-income Medicare beneficiaries when it commences in 2006.

To receive assistance with their Part D costs, individuals must both be:

- determined eligible for the subsidy and
- enrolled in a Part D drug plan or Medicare Advantage plan with a prescription drug benefit.

Full Medicaid benefit “dual eligibles” or individuals who are eligible for a Medicare Savings Program will be “deemed” eligible for the low-income subsidy, obviating the need for them to apply for extra help. All other individuals must affirmatively apply for the low-income subsidy and prove that their income and assets are sufficiently low to qualify for help with their premiums, deductibles and co-payments.

⁵ Congressional Budget Office, July 2004. These estimates pertain to the Medicare Savings Programs, which subsidize Medicare costs for low-income Medicare consumers.

To join a Part D plan, most individuals must formally select a plan. Full Medicaid benefit “dual eligibles” and Medicare Savings Programs recipients who fail to elect Part D coverage themselves, however, will be automatically assigned to a prescription drug plan in their region for which a premium subsidy is available.

Figure 1: The Low-Income Drug Subsidy

The low-income subsidy has two basic levels of assistance. Persons with incomes below 135 percent of the Federal Poverty Line (FPL) and assets below \$7,500 for individuals and \$12,000* for couples qualify for the “full subsidy,” paying no premium, no deductible and small co-payments.** Persons with incomes between below 150 percent FPL and assets valued less than \$11,500 for individuals and \$23,000* for couples qualify for a “reduced subsidy,” paying a sliding-scale premium, a \$50 deductible, 15 percent co-insurance up to \$5,100 in total drug spending and small co-payments*** for additional drug expenditures.

* Asset levels will be indexed to inflation. These asset figures include burial fund exclusions.

** Full benefit dual eligibles with incomes below the poverty level will have co-payments of \$1/generic; \$3 brand name. These co-payments are indexed to inflation. Other full subsidy recipients will have co-payments of \$2 generic; \$5 brand name. These co-payments are indexed to average per capita Part D spending.

*** Co-payments of \$2 generic/\$5 brand name will apply. These co-payments are indexed to average per capita Part D spending.

II. Ensuring Access to Needed Mental Health Medications

Access to needed psychiatric medications for low-income Medicare consumers will hinge on the design of private plan coverage. Adequate coverage is essential because, by definition, persons with limited incomes lack the financial ability to purchase excluded drugs themselves. Best treatment guidelines for mental health conditions require that patients have access to a wide of array of available medications. Significant scientific and clinical evidence demonstrates that mental health medications are not generally interchangeable. Many drugs, even those within the same class, target different areas or chemicals in the brain and individual responses to medications may differ greatly. A drug's effectiveness and side effects hinge on many factors, including the patient's race, ethnicity, gender, other illnesses and medications.⁶ (use studies cited in <http://www.nmha.org/state/PBMtoolkit/brief1.pdf> ; <http://www.mobudget.org/psychotropic.pdf>)

It is especially important to minimize side effects to encourage compliance. Accordingly, physicians need reasonable latitude to prescribe medications customized to the patient's individual circumstances, including their current illness, treatment history, other medical conditions and medications, likely reaction to known side effects, and safety in the event of an overdose.

Second, once persons are stabilized on a psychiatric drug, changing medications can lead to dangerous drug interactions, suffering, possible deterioration of conditions, and premature death. Abrupt changes can lead to dangerous drug interactions because medications take multiple weeks to leave an individual's system. Further, many older persons have multiple health conditions and often take several medications that make it more difficult to change their drug regimen. The best practice in geriatrics is to make one change at a time so that physicians can identify how the medication change affected the patient's condition. If more than one medication is changed simultaneously, and the person's condition declines, it is difficult to isolate which medication caused the harmful effect. Accordingly, the use of common private sector utilization management practices, such as prior-authorization, fail-first, step-therapy, and restrictive drug lists are inappropriate for persons with mental illnesses.

Third even if formularies or other cost management tools may be clinically appropriate, their implementation can undermine access to vital medications. A recent study of the mandatory Medicaid managed care in Pennsylvania reported numerous examples of harm to patients and increased provider frustration and workload caused by deficient plan processes for managing formularies.⁷ These problems included: insufficient fax capacity

⁶ Burroughs, V., Maxey, R. and Levy, R. "Racial and Ethnic Differences in Response to Medicines: Towards Individualized Pharmaceutical Treatment," *Journal of the National Medical Association*, Volum 94, Number 10, pp. 1-26; Horn, S. "Unintended Costs and Outcomes: The Fiscal Case for Open Access," *Drug Benefit Trends*, Volume 15, Supplement 1.

⁷ Gene Bishop, MD, "One State's Medicaid Managed Care Formulary Operations: A Look at Pennsylvania, 2001-2002," Kaiser Commission on Medicaid and the Uninsured, March 2005.

to process prior authorization request; too few personnel to field provider and patient questions; inadequate training for plan staff about patient safeguards; violations of patient protections such as deadlines for processing determinations for drug requests and prior authorizations; burdensome requirements for emergency supplies; and no monitoring of retail pharmacy practices. Moreover, communications between physicians, patients, pharmacists, and the plan often broke down. For example, when the pharmacist denied their prescription, many patients assumed they had no remedy and that they must do without it and the doctors remained unaware that the prescription had not been filled. Further, there was no monitoring of retail pharmacies practices although they bear a large role in formulary implementation. Retail pharmacists determine the patient's ability to receive the prescription and notify, or fail to notify, the doctor or health plan of a non-filled prescription.⁸

A recent analysis of enrollment issues for individuals with Medicare and Medicaid coverage also concluded that formularies and prior authorization requirements systems may be particularly difficult to navigate for mental health patients.⁹ Mental health patients may experience difficulty waiting at the pharmacy, returning for their prescriptions at another time, or sending someone else to pick the drug up later. These problems are complicated by many low-income beneficiaries' limited English proficiency and limited literacy skills.

Given the severe problems cost-management tools pose for mental health consumers, many Medicaid programs have excluded psychiatric medications from restrictive prior authorization lists or prior authorization limits imposed on other medications.¹⁰ Furthermore, negative results have occurred where states have continued to impose strict prior authorization requirements. For example, Michigan rolled back many restrictive policies for mental health medications after they resulted in problems for patients in obtaining crucial anti-depressants

States like Missouri and Pennsylvania have recently adopted more appropriate benefit management tools that aim to alter prescribing behaviors and align them with best practice treatment guidance. For example, Missouri implemented a "Smart Authorization Program," where review is activated by certain prescribing actions and dosages that far surpass FDA recommendations. CMS has acknowledged that restrictive management tools lead to non-compliance and poor health results and has recommended that Medicaid programs adopt these promising alternatives to traditional cost management tools.¹¹

⁸ Bishop, 2005.

⁹ Richard Jensen, "The New Medicare Prescription Drug Law: Issues for Enrolling Dual Eligibles into Drug Plans," Kaiser Commission on Medicaid and the Uninsured, January 2005.

¹⁰ National Mental Health Association, *Comments on Draft Guidelines on Formulary Review for the Medicare Prescription Drug Benefit*, December 29, 2004, p. 9.

¹¹ Centers for Medicare and Medicaid Services, "Psychotropic Medications: Addressing Costs without Restricting Access," http://www.cms.hhs.gov/promising_practices/psychotropicmeds.pdf (accessed July 27, 2005).

Will Medicare Drug Plans Provide Comprehensive Coverage for Mental Health Medications?

The use of private plans to deliver the drug benefit could undermine the ability of Medicare consumers to access the full complement of needed mental health medications. As a general matter, CMS permits plans to use benefit management tools, such as, formularies (preferred drugs lists), prior authorizations, fail-first, therapeutic substitutions.¹² Further, because plans are at risk for the cost of the benefit, plans have financial incentives to reduce access to newer, more expensive psychiatric medications yet these are frequently drugs that have fewer side effects and are generally more effective than older medications for the same conditions. Drug plans have little incentive to achieve the best drug regime for an individual because they are not at risk for the cost of other care, such as hospitalizations and physician visits.

On the other hand, the MMA and CMS regulations contain certain safeguards to limit plans' usage of restrictive cost management tools for psychiatric medications. Foremost, CMS can reject plan benefit designs that aim to discourage enrollment by persons with certain health conditions.¹³ Discriminatory practices include those that discourage enrollment "on the basis of health status, including medical conditions (related to mental as well as physical illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability and disability."¹⁴ Plans' therapeutic categories and pharmacologic classes will be considered per se non-discriminatory if they adhere to the U.S. Pharmacopeia model classification system.

CMS says it will rely on widely-used, "effective" cost-containment strategies and best practices from private sector and government payers to review drug plan formularies and procedures to assure plans provide individuals access to all medically necessary drugs and do not discriminate against groups or discourage enrollment. Further, CMS indicates that "[w]hen medically necessary, beneficiaries should be permitted to continue utilizing a drug that is providing clinically beneficial outcomes."¹⁵ This standard is vague because CMS does not define "best practice" or medical necessity. However, in the final formulary guidance for 2006, CMS generally requires plan formularies to contain at least two drugs within a class. With respect to mental health, CMS adds that it will analyze formularies to determine if they comport with "widely accepted national treatment guidelines" for dementia, depression, bipolar disorder, schizophrenia. In this regard, plans must include "all or substantially all" drugs in the antidepressant and antipsychotic categories (in addition to the anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories) on their formularies and beneficiaries who have been stabilized on

¹² Centers for Medicare and Medicaid Services, "Medicare Modernization Act Final Guidelines – Formularies," <http://www.cms.hhs.gov/pdps/FormularyGuidance.pdf> (accessed July 27, 2005).

¹³ Social Security Act, 1860D-11(E)(2)(D)(i)

¹⁴ 70 *Federal Register* 4297, January 18, 2005.

¹⁵ Centers for Medicare and Medicaid Services, "Medicare Modernization Act Final Guidelines – Formularies."

these medications should generally be exempt from prior authorization and other drug utilization tools.¹⁶

The meaningfulness of these safeguards will depend on how they are implemented by the plans. For example, it is still unclear how plans will provide continued coverage of mental health medications without drug utilization restrictions.¹⁷ How will plans know which of their members are eligible for continuation coverage? How will consumers, doctors, and providers know about their right to be exempted from drug utilization tools and how easy will it be to access the exemption? Will the process be automatic or will individuals need to file exceptions or other take other steps?

Additionally, CMS's formulary guidance omits certain protections. For example, CMS does not require that plans cover all Part D covered-drugs in the anti-anxiety category. In addition, CMS expressly permits the use of cost-utilization tools for new prescriptions for anti-psychotic and anti-depressant medications.

Another potential safeguard against overly restrictive plan benefit designs is the statute's requirement that plans use Pharmacy and Therapeutic Committees to develop and revise the formularies. P& T Committees are a means to combat the profit motives of plans and must premise their review on "the strength of scientific evidence and standards of practice."¹⁸ CMS has declined to vigorously implement this protection. For example, although P&T Committee decisions about the content of the formulary are binding, their decisions about the operation of the formulary, (i.e., tier-placement and prior authorization) are not.¹⁹ Further, CMS rules call into question whether the P&T Committees will be entirely independent of the plan or have sufficient expertise in mental health. Regardless of the size of the committee, there must be one independent practicing physician and one independent practicing pharmacist. At least two members must specialize in the care of older adults and persons with disabilities, but there is no requirement that these individuals be experts in treating mental illness.

Finally, rigorous CMS oversight of plans is required to assure that benefit packages allow for physicians to make individualized treatment decisions for their mental health patients.

Recommendations

In implementing the Medicare drug benefit and in reviewing prescription drug formularies, CMS should:

- 1. Explicitly define best practices for review not just as those most prevalently used, but those that lead to the best results for consumers, including the least***

¹⁶ Id.

¹⁷ CMS Final Guidelines -- Formularies, revised by <http://www.cms.hhs.gov/pdps/formularyqafinalmmrevised.pdf> (accessed July 27, 2005).

¹⁸ 1860D-4(b)(3)(B)(i)

¹⁹70 Federal Register 4256, January 28, 2005.

- complications, side effects, hospitalizations, and relapse rates. Additionally, the best practices should comport with sentinel treatment guidelines.*
- 2. To ensure persons stabilized on mental health medications have seamless access to them, without application of drug utilization tools, CMS should require plans to automatically provide this coverage at the point of sale; require Medicaid agencies (with adequate federal financing) to send prescription drug information for individuals to plans; and educate plans, pharmacists, and providers about these protections.*
 - 3. Limit approval of formulary management techniques, such as prior authorization, and favor alternative cost management approaches, such as those that aim to educate providers and adjust prescribing patterns behaviors to comply with best practices.*
 - 4. Require Pharmacy and Therapeutic Committees to include psychiatrists*
 - 5. Ensure that health plans have adequate systems and administrative infrastructure to manage formularies, to help patients, pharmacists and physicians, and to comply with patient protections. Recommended practices include: well-staffed help lines for physicians and pharmacists, prompt handling of complaints and requests for assistance, on-line trainings for contracted pharmacists, and computer-generated notices of patient protections at the point of sale. Plans should be required to monitor pharmacies' service delivery as well to apply quality assurance programs to reduce problems at the retail pharmacy level.*
 - 6. Quality assurance monitoring by CMS should include monitoring of formulary operations, including plan customer service and retail pharmacy practices as well as their effect on clinical outcomes.*
 - 7. Initiate comprehensive reviews of formularies when plans make multiple changes to formularies.*
 - 8. CMS should identify plans with high numbers of exceptions and appeals and require plans to make appropriate changes in formularies and benefit management techniques.*

III. Continuity of Care for “Dual Eligibles”

The process of transferring millions of “dual eligibles” – people enrolled in both Medicare and Medicaid – from Medicaid to Medicare drug coverage could cause dangerous disruptions in care for many persons with mental illness. To maintain drug coverage, “dual eligibles” must enroll in a Part D plan. CMS will notify “dual eligibles” in October 2005 of their available Part D selections. Individuals who fail to select a Part D Plan themselves will be randomly assigned to a plan effective January 1, 2006. While the automatic enrollment measures are critical to ensure “dual eligibles” are not left without any drug coverage, the transition process raises numerous serious concerns for this vulnerable population. First, the process of moving millions of persons from one program to several private plans will require massive systems changes and data transfers between states, CMS, and multiple drug plans. Incomplete information, inaccurate or outdated data, and or unexpected systems errors could cause automatic assignment to fail and persons to fall through the cracks. Data problems are inevitable given the immense

volume of data that must be exchanged in a very short period.²⁰ As a result, large numbers of “dual eligibles” with mental illness are likely to experience gaps in coverage, at least initially, and end up with no coverage when their Medicaid ends.

Second, CMS plans to assign “dual eligibles,” including those with mental illness, to Part D plans with premiums at or below the low-income premium subsidy on a completely random basis.²¹ This random auto-enrollment may result in an individual transitioning to Medicare prescription drug coverage finding themselves in a Part D plan that does not include their local pharmacy, does not serve the long-term care facility they live in, does not include their specific medications on its formulary, or is otherwise inappropriate.

Third, even if automated systems work flawlessly and persons are assigned to a Part D plan, the compressed timeframe to move “dual eligibles” into Medicare (at most 12 weeks) is insufficient to adequately inform and educate “dual eligibles” about their change in drug coverage. Persons cannot access needed medications unless they know their coverage has changed and understand the new benefits. “Dual eligibles” are, on average, significantly poorer, sicker, less educated, and more underserved. Also, they have higher drug utilization and are far more likely to have cognitive impairments than other Medicare beneficiaries.²² State experience with automatic enrollment of “dual eligibles” into mandatory managed care demonstrate that this group is extremely difficult to reach and educate.²³ As a result, adequate education requires several interventions, including repeated information, through multiple channels and in multiple formats, about their change in coverage as well as personalized education and counseling to help persons make informed plans choices.

Further, post assignment education is critical to help individuals access needed psychiatric medications since Medicare plans will likely have very different coverage rules and pharmacy networks than their old coverage through Medicaid. Many persons who have been assigned to plans may not know their coverage has changed or may have been assigned to a plan that does not match their treatment needs. In theory, “dual eligibles” can access non-covered drugs through the exception process or can change to a new plan. However, many “dual eligibles” may be unaware of these rights and will need information and assistance to exercise them. According to Medicare Payment Advisory Commission (MedPAC), an independent federal body that advises Congress on Medicare issues, accomplishing these tasks in private-sector plan transitions takes a minimum of six, and preferably nine, months.²⁴ Transition tasks for “dual eligibles” will be far more difficult and require more time given the number of persons involved and the increased information, education, and counseling needs of this vulnerable population.

²⁰ Due to data errors, some auto-assignments into the drug discount card by state pharmacy assistance programs failed.

²¹ Centers for Medicare and Medicaid Services, *Draft PDP Guidance: Eligibility, Enrollment and Disenrollment*, July 22, 2005, 30.1.4(A)(2)

²² *Id.*, Chapter Three

²³ Jensen, 2005.

²⁴ MedPAC, *Report to Congress: New Approaches in Medicare*, June 2004.

To minimize harm to “dual eligibles” as they move into Medicare drug coverage, CMS will require plans to provide for “an appropriate transition process” for individuals whose drugs are not on the formularies. The CMS guidance defining this requirement imposes very minimal requirements on Part D plans. Plans are not required to grandfather existing medications except those in six specific categories described above. Rather, CMS proposes, but does not require that plans provide a one-time supply of medications to dual eligibles and others with critical medication needs even if the medications are not on plan formularies. Persons could be expected to pursue an exception to obtain the transition supply. The guidance indicates that a transition supply of 30 days “may be reasonable,” even though the appeals regulation requires a 60-day supply for plan enrollees when formularies change and persons have not received advance notice of the changes.²⁵ (See 423.120(b)(3)). Finally, the CMS transition guidance does not require plans to cover out-of-network pharmacies even though persons with mental illness may be incapable of changing their customary provider in time to fill their new prescription. In the event that plans authorize out-of-network care, dual eligibles will be required to pay out of pocket for their medications and then seek reimbursement from the plan.

CMS also envisions that “dual eligibles” will secure needed off-formulary drugs through the exceptions process. However, the appeals process is not user-friendly. First, exceptions will be difficult to initiate because presenting the prescription at a pharmacy (the point-of-sale transaction) does not count as a coverage determination that is subject to appeal. Instead, in order to begin the appeals process, an enrollee must contact his/her plan directly to request a formulary exception.²⁶ Second, unlike Medicaid, Part D does not require an emergency supply pending the appeal. Third, plans are not required to defer to the treating physician’s judgment about what is medically necessary for the enrollee. In addition, as MedPAC has noted, only a small minority of patients pursue appeals for formulary exceptions – which, in combination with the more limited appeals process under Part D, has prompted MedPAC to recommend that CMS closely monitor access to appropriate medications as “dual eligibles” try to navigate an unfamiliar exceptions process during the transition to Part D.²⁷

As a final note, CMS has moved to ensure access to medications pending appeal for a subgroup of “dual eligibles” – nursing home residents, who must receive their medications without delay. In a follow-up to the agency’s guidance on long-term care issues, CMS clarified that plans must cover temporary supplies of non-formulary medications while a formulary exception is being adjudicated.²⁸

Recommendations

²⁵ Centers for Medicare and Medicaid Services, “Information for Part D sponsors on Requirements for a Transition Process,” March 16, 2005.

²⁶ 70 Federal Register 4349, January 28, 2005.

²⁷ MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005.

²⁸ <http://www.cms.hhs.gov/pdps/qafirstfillforltcresidents-final.pdf>, (accessed July 27, 2005).

To ensure the safe and smooth transition of “dual eligibles” into Part D coverage, Congress should extend the availability of Medicaid as backup drug coverage during a reasonable transition period to Part D. The backup coverage would be used for: (1) “dual eligibles” not enrolled in a Part D plan on January 1, 2006; (b) “dual eligibles” who have not received notice of their plan assignment or do not yet know how to obtain education on using their Part D plan; and (3) “dual eligibles” who must be evaluated for, and stabilized on, new drug regimens to comply with their Part D plan formularies.

In the event that Congress fails to act, during the transition from Medicaid to Medicare drug coverage, CMS should require plans to adopt stop-gap measures that assist persons to temporarily maintain access to their current medications and customary pharmacy. These protections should:

1. Transition Guidance to Part D Plans.

- make it mandatory for Part D plans to provide a transitional supply of medication for people whose current drugs are subject to any cost-utilization tools*
- make the transitional supply at least 60 days for non-institutionalized persons*
- clarify that the transitional supply is not dependent on filing an appeal/exception (otherwise, person will have to (1) learn how to appeal (2) leave drugstore to appeal and (3) return to drugstore to receive transitional supply)*
- make transitional supply available for people whose usual pharmacy is out-of-network of new plan*

2. Establish a CMS-directed Helpline for All Transition Problems

- helpline should be able to tell any “dual eligible” (or authorized representative) which plan s/he is in and which pharmacies are in the network*
- if “dual eligible” is not enrolled in any plan, helpline should have clear protocol for resolving the eligibility issue (i.e., not just refer person to state Medicaid program)*
- single number should be advertised and promoted nationally to pharmacists, caregivers, beneficiaries, and counselors.*

3. Facilitate “Smart” Automatic Enrollment Whenever Possible.

- permit states to do smart automatic enrollment into appropriate plans based on pharmacy preference, medication needs, residential status, etc. of “dual eligible” whenever possible (i.e., “dual eligibles” in nursing homes, with specific medication needs)*

IV. Spurring Enrollment in the Low-Income Subsidy for Persons with Mental Illness

Many low-income Medicare consumers without Medicaid currently lack insurance to cover costly medications, including those to treat mental illness. The new low-income drug subsidy could enable these individuals to afford drug coverage and achieve better access to psychiatric medications that will improve their health and well-being. Nonetheless, the promise of this benefit could be illusory for many individuals. The record of enrolling eligible beneficiaries in existing Medicare-subsidy programs is poor -- less than one-third of eligible persons nationwide are enrolled.²⁹ Low participation rates stem from a pervasive lack of awareness about the benefit and complicated and onerous application processes.

Automatic Enrollment

Automatic enrollment is the most efficient way to combat these obstacles and to maximize enrollment in low-income health insurance programs.³⁰ While most of the 1.5 million individuals who received transitional assistance with prescription drug costs by December of 2004 were automatically enrolled through their Medicare Advantage plan or State Pharmaceutical Assistance Program (SPAP), federal, state and private sector outreach efforts failed to enroll large numbers of individuals in the discount program. Based on this experience, MedPAC has noted that auto-enrollment will be a critically important step to ensuring that low-income people with Medicare enroll in the Part D benefit.³¹ CMS has already taken steps to extend automatic enrollment to several classes of individuals who qualify for the LIS. As mentioned earlier, “dual eligibles” and Medicare Savings Programs participants are deemed eligible for the LIS and need not submit an application to enroll in the LIS. Additionally, these groups will be automatically defaulted to a Part D plan if they do not chose one themselves within certain periods.

Recommendation

CMS should maximize its use of automatic enrollment processes and extend auto-enrollment to additional populations who are eligible for the LIS. CMS should particularly look to SPAP programs and other benefit programs that serve a substantially similar population.

Streamlining the Application Process

Short of automatic enrollment, existing law permits the federal government to take additional steps to streamline enrollment processes and create a more user-friendly process. SSA has taken some steps to simplify its LIS application form and the application process. For example, individuals will be able to apply on-line or over the phone and with

²⁹ Congressional Budget Office (CBO), *A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit*, July 2004. These estimates pertain to the Medicare Savings Programs, which subsidize Medicare costs for low-income Medicare consumers.

³⁰ See Dahlia K. Remler and Sherry A. Glied, *What Other Programs Can Teach Us: Increasing Participation in Health Insurance Programs*, *American Journal of Public Health*, January 2003. [Hereafter *Remler and Glied: What Other Programs Can Teach Us*].

³¹ MedPAC, *Report to the Congress: Issues in a Modernized Medicare Program*, June 2005, p. 24.

the assistance of a third party, such as a family member or a social worker. In addition, the application instructions will be in 14 languages, although the application itself will only be available in English and Spanish, making the process somewhat more accessible to people with limited English skills. SSA will also allow people to self-attest to their income and assets, reducing their burden to collect documents. Nonetheless, the application still presents significant barriers for persons with mental illness to complete. For example, the form contains unnecessary and intrusive questions about in-kind support and maintenance. Questions that require information related to an applicant's in-kind support undermine efforts to simplify and streamline eligibility determinations. The questions are confusing and intrusive. Furthermore, answers will require individual follow-up to ensure accurate assessment of in-kind support levels and appropriate exclusions. They may also lead to the unfair denial of benefits to individuals who self-exclude based upon misreading or miscalculation of in-kind support resources.

There is precedent and authority for excluding questions about in-kind support from applications for programs -- especially health-care related programs -- whose eligibility standards are based on the SSI. CMS' model Medicare Savings Programs (MSP) application does not request information on "in-kind support" from applicants,³² even though the MSPs, like the Part D LIS program, have eligibility standards that include income and resource limits based on the requirements of sections 1612 and 1613 of the Social Security Act. Since CMS was able to exclude questions about in-kind support from its model MSP application, CMS and SSA (who are jointly responsible for developing eligibility standards for the Part D LIS) have the same authority to do so for the Part D LIS application. Moreover, it is a wide-spread practice among states not to request information about applicants' in-kind support in their MSP applications.³³ States with a wide variety of MSP application forms have excluded all questions about in-kind support.

Congressional intent and policy considerations also support excluding questions about in-kind support from the LIS application. Congress clearly intended that the LIS application be simplified and streamlined to maximize enrollment in the LIS and, therefore, in the Part D benefit.³⁴

Further, the application form requests information about the cash value of life insurance and pre-paid burial accounts. Calculating the value of these policies may be difficult for applicants, and the confusing and personally intrusive nature of the questions on the proposed application may serve to dissuade applicants from applying for the LIS at all. Further, counting these assets runs afoul of Congressional intent to simplify and streamline the LIS application and CMS' proposed rules that would count only "liquid" assets or assets convertible to cash in determining an LIS applicant's resource

³² See the Model MSP Application at: <http://www.cms.hhs.gov/dualeligibles/modelapp.pdf>

³³ While states have authority under section 1902(r)(2) of the Social Security Act to use more flexible methodologies than those prescribed by SSI rule in assessing eligibility for MSPs, several states have excluded questions about in-kind support while explicitly declining to use their 1902(r)(2) flexibility.

³⁴ See the Social Security Act (SSA) and Medicare Modernization Act (MMA): SSA § 1860 D-14 (a)(2)(E)(ii), (iii); MMA Conference Report (H.R. Rep. 108-391) at 433: "It is also critical that eligibility determination forms and paperwork should be as simple as possible."

eligibility.³⁵ Life insurance policies or burial accounts that theoretically have a cash value may not in fact be easily converted to cash by applicants or be otherwise transferable.

Removing questions related to in-kind support and life insurance could also reduce administrative costs for SSA and states.³⁶ Currently the MSP and SSI rules count all but \$1,500 worth of life insurance and burial funds as assets. Most low-income persons have burial funds or life insurance policies below \$10,000.³⁷ An independent analysis concluded that Louisiana saved \$1.5 million per year in administrative costs by raising the amount of life insurance and burial funds excluded – or “disregarded” – from eligibility determination to \$10,000.³⁸

Recommendations

A more consumer-friendly policy would:

- ***Exclude questions about in-kind support and maintenance from the LIS application.***
- ***Specifically exclude the cash value of life insurance policies and burial funds.***

Ensuring that all LIS applicants are Screened for the Medicare Savings Programs and Enrolled in these Programs

The MMA requires that LIS applicants be screened by states for the MSP and enrolled in these programs. The LIS application lends itself to screening for MSP programs because information needed to determine LIS eligibility will also demonstrate whether persons qualify for the MSP and Medicaid. Combining these eligibility processes would increase the efficiency of applying for the Part D subsidy, since applicants can be informed that completing the application may result in drug assistance and cost-sharing assistance for Medicare Parts A and B. Additionally, since Medicare Savings Programs recipients are deemed eligible for the LIS regardless of their income or assets, unifying the application processes could enable more persons to qualify for the LIS in states that have adopted more liberal Medicare Savings Programs rules than used for the low-income subsidy determinations.³⁹

³⁵ See 69 Fed. Reg. 46632, 46726 (Aug. 3, 2004)

³⁶ Asset rules for low-income subsidy eligibility determinations can be more generous than SSI standards. See Footnote 27, *infra*.

³⁷ Laura Summer and Lee Thompson, *How Asset Tests Block Low-Income Medicare Beneficiaries from Needed Benefits*, the Commonwealth Fund, May 2004 [Hereafter *Summer Asset Tests*]

³⁸ Laura Summer, *Administrative Costs Associated with Enrollment and Renewal for the Medicare Savings Programs in Louisiana*, Prepared for State Solutions, August 12, 2004 [Hereafter *Summer Administrative Costs*].

³⁹ The Medicare Savings Programs employ the SSI methodology for counting resources, but federal law has permitted states to adopt more generous policies than those used by SSI. SSA § 1902(r)(2). Alabama, Arizona, Delaware and Mississippi have eliminated consideration of assets for the MSP altogether.

Given the demonstrated value of the MSP programs⁴⁰ and their serious under-enrollment despite significant outreach efforts, Medicaid programs are required to screen for Medicare Savings Programs and Medicaid as part of the LIS eligibility process. In that regard, the MMA requires that LIS applicants be screened for the MSP and offered enrollment in these programs.

Current plans for processing of LIS determinations will not assist this goal of ensuring that LIS applicants be enrolled, when eligible, in MSP programs. Applicants will be encouraged to apply for the LIS through the SSA, but the agency, unlike states, lacks the legal obligation to screen applicants for the MSP and Medicaid. Thus far, SSA plans to send automated referrals to states that do not include income and asset information and to mail LIS applicants an award letter that includes information about the Medicare Savings Programs with instructions to contact their Medicaid office to apply. Given the characteristics of the population applying for LIS, including persons with mental illness, it is unrealistic to expect that most applicants would follow through in contacting their Medicaid office and applying for the MSP. In addition, given the demands on state Medicaid personnel, it is hard to imagine who would follow up on SSA leads and find LIS applicants' phone numbers, contact them individually, and solicit individually-signed consent forms to obtain asset and income information from SSA. The federal government should adopt the policies recommended below.

Recommendations

Short-Term Recommendations

- 1. SSA should provide to states individuals' verified income and asset information used in LIS determinations.⁴¹ This information would minimize administrative costs for states by obviating the need to separately solicit it from individuals and to complete verifications. Likewise, applicants would be relieved of the burden of submitting exactly the same information twice.***
- 2. CMS should require states to upgrade their automated systems to receive automated LIS income and asset information. Through a Medicaid Director Letter, CMS should instruct states that compliance with their legal obligation to***

Connecticut and New York disregard consideration of all assets for QI-1. Maine disregards the first \$10,000 of assets for individuals and \$12,000 for couples, while Minnesota excludes the first \$10,000 of assets for individuals and \$18,000 for couples.

⁴⁰ Recent research suggests that enrollment in the Medicare Savings Program promotes access to care. Alex D. Federman, Bruce C. Vladeck, and Albert L. Sui, *Avoidance of Health Care Services Because of Cost: Impact of the Medicare Savings Program*, *Health Affairs*, Vol. 24, No. 1 (January/February 2005).

⁴¹ Privacy concerns can be addressed if (1) SSA provides states with the Summary of Income and Asset Information (as opposed to affording access to SSA's automated verification database itself) and (2) the LIS form is amended to obtain consent from/provide notice to the applicant to send their information to other agencies for the purpose of determining if they qualify for other benefits.

screen and enroll LIS applicants for the MSP and Medicaid will require states to maintain automated systems capable of receiving the automated SSA Income and Resource Summary. Until states have made these improvements, SSA should send them a paper copy of the SSA Income and Resource Summary that will be sent to all LIS applicants with their award letter.

3. CMS should require states to treat the income and resource summary in the SSA LIS award letter as an MSP Application. Also through a State Medicaid Director letter, CMS should require states to treat the SSA Income and Resources Summary as a verified application for the MSP and Medicaid. States should enroll eligible persons in the MSP and/or Medicaid if they qualify and then notify them of their enrollment and their ability to opt-out. (The LIS form can notify individuals that they will be enrolled in other programs if they are screened and qualify for them.)

4. CMS should apply enhanced federal match rates to help states fund and maintain systems improvements to receive and process the automated SSA Income and Resource Summary. By statute, the federal match for “the design, development, or installation” of any changes to a state system to accommodate the SSA summary should be a 90 percent federal match, and its ongoing operation should be matched at 75 percent.⁴²

Long-term Recommendation

- Ultimately, SSA itself should screen LIS applicants for the MSP and enroll them in these programs. This would obviate the need for multiple entities to share data and ensure that LIS applicants do not fall through the cracks and miss getting screened for the MSP. Further, SSA has already demonstrated its ability to assist in the MSP enrollment process. During an SSA demonstration project on increasing MSP participation from March 1999 to February 2001, interventions that maximized SSA involvement in the enrollment process yielded the strongest results. Finally, present law may permit SSA to contract with states to conduct MSP eligibility determinations, similar to the way SSA presently processes eligibility for some state SSI supplements.*

Streamlining renewal procedures

Experience with Medicaid and Medicare Savings Programs shows that re-enrollment procedures could undermine stable participation in the low-income drug subsidy. If elderly individuals and persons with disabilities must complete quarterly or semi-annual reviews, fill out lengthy forms or even complete mail-in re-enrollment forms, many will not stay in the program.⁴³ Losing the subsidy will make Part D unaffordable for many low-income Medicare consumers; even if they regain benefits, premium penalties

⁴² Social Security Act § 1903(a)(3).

⁴³ See *Glaum Medicare Savings Programs*; the Kaiser Commission on Medicaid and the Uninsured, *Barriers to Medicaid Enrollment for Low-Income Seniors: Focus Group Findings*, January 2002.

resulting from gaps in creditable coverage may make re-enrolling in Part D too expensive. In any event, most persons with Medicare have fixed incomes and stay eligible for the programs from year to year.⁴⁴ Further, cumbersome renewal processes increase workload and administrative costs for government agencies. Independent estimates predict that Louisiana will save more than \$1.5 million by streamlining their renewal process for the Medicare Savings Programs, while applying an *ex parte* process that entails an internal staff review would save the state \$2.4 million annually.⁴⁵

SSA draft regulations raise concerns that the renewal process will be unduly complicated for low-income Medicare consumers with mental health conditions. The MMA allows redeterminations to occur no more frequently than annually.⁴⁶ While an individual's initial determination will last for the rest of a remaining calendar year, SSA seems to reserve the right to conduct redeterminations on a rolling basis, and more frequently than annually. Additionally, the law permits the use of simplified renewals that, at a minimum, should use a pre-printed renewal post card with instructions to return the card only if corrections about their eligibility status are needed. Yet, the regulations are silent regarding what steps SSA will require the individual take to renew their eligibility.

Recommendations

- ***Renewals should occur no more frequently than annually***
- ***Simplified renewal procedures should apply that, at a minimum, use a pre-printed renewal post card with instructions to return the card only if corrections about their eligibility status are needed.***

⁴⁴ See *Summer Asset Tests*; Susan Haber *Evaluation of QMB*.

⁴⁵ *Summer Administrative Costs*.

⁴⁶ SSA §1860D-14(a)(3)(B)(ii).