

medicaid
and the uninsured

**Dual Eligible Home and Community-Based
Waiver Program Participants and the
New Medicare Drug Benefit**

Prepared by

Heidi Reester, Anne Tumlinson and Jonathan Blum
Avalere Health

for the

Kaiser Commission on Medicaid and the Uninsured

October 2005

kaiser commission medicaid and the uninsured

The Kaiser Commission on Medicaid and the Uninsured provides information and analysis on health care coverage and access for the low-income population, with a special focus on Medicaid's role and coverage of the uninsured. Begun in 1991 and based in the Kaiser Family Foundation's Washington, DC office, the Commission is the largest operating program of the Foundation. The Commission's work is conducted by Foundation staff under the guidance of a bipartisan group of national leaders and experts in health care and public policy.

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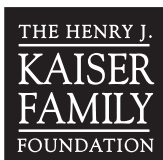
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Executive Summary

The new Medicare drug benefit grants a range of protections to those living in nursing homes, but does not grant similar protections to a group of patients who are medically similar but live outside the institutional setting. These beneficiaries, who are dually eligible for Medicare and Medicaid, are participating in Medicaid home and community-based service (HCBS) waiver programs which allow them to continue to live in the community in their home or home-like setting. The lack of protections may put these beneficiaries at risk for interruptions in access to needed drugs, increased financial hardship, and costly medical complications. Additionally, this inequality unintentionally creates a bias toward institutionalized living for this dually-eligible population.

In 2001, there were 229 waivers in 49 states and the District of Columbia and over 50 percent of these waivers provided services to Medicaid beneficiaries who are elderly or disabled.¹ HCBS waiver programs served 920,000 Medicaid beneficiaries in 2002; however, there are no data available regarding dual eligible participation.² Unlike institutionalized beneficiaries, HCBS waiver program participants usually do not have a centralized care provider to manage their health care benefits and services. No individual is designated to assist participants with their Medicare Part D prescription drug plan selection, comparison of formularies, and if necessary, management of their exceptions and appeals should a medication be denied by their plan. State and Federal policymakers should carefully monitor HCBS waiver participants to ensure that they maintain equal access to prescription drugs as their institutionalized peers, and can remain in HCBS programs without increased physical harm or financial hardship.

Initially states should monitor medication access for waiver program participants by asking:

- *Are Dual Eligible HCBS Waiver Program Participants Getting Needed Part D Excluded Drugs?* Medications such as benzodiazepines and barbiturates are excluded from Part D coverage. Without some stop-gap coverage, program participants may struggle to pay for these medications and choose not to take them as prescribed with potentially harmful consequences;
- *Are the New Medicare Part D Co-Payments Causing Dual Eligible HCBS Waiver Program Participants to Forgo Needed Medications?* Dual eligibles in nursing facilities will not pay co-payments for the prescription drugs they receive from their prescription drug plans, but HCBS waiver participants must personally absorb this new cost. Dual eligibles in HCBS waiver programs may elect to remain in or enter a nursing facility or other institution because they cannot afford the co-payments they will be charged when living in the community;
- *Are These Participants Having Difficulty Navigating the Prescription Drug Plan Formularies?* Part D formularies will be different from previous Medicaid drug coverage, and this change could be problematic for HCBS program participants who must navigate new formularies, manage their many medications, and switch plans if

their initial auto-enrolled assignment proves inadequate -- all without a centralized pharmacy provider or institution overseeing their care;

- *Are Coverage Determinations Delaying Access to Needed Medications?* HCBS waiver participants may not have care coordinators or other provider supports to obtain exceptions and appeals for some of their medications. If prescription drug plan exceptions and appeals processes are inadequate, onerous, or not timely for this population, access to necessary medications may be delayed; and
- *Is the Transition to Medicare Part D Going Smoothly for HCBS Waiver Program Participants?* Due to the sheer size and complexity of implementing Part D, unintended problems for dual eligibles participating in HCBS waiver programs may arise. These problems, such as enrollment delays or inadequate education for providers, might exacerbate medication access challenges.

States and CMS should actively work with their HCBS dual eligible populations to ensure the new Part D benefit supports ongoing efforts to keep dual eligible beneficiaries out of institutions such as nursing facilities, and does not block transitions for currently institutionalized beneficiaries out of nursing homes or other facilities. CMS and states can work closely with each other to prevent or avoid medication access problems for dual eligibles participating in HCBS waiver programs. Potential activities include:

- States ensuring that HCBS waiver program administrators have identified their dual eligible enrollees and have a transition plan in place for these participants;
- States providing co-payment coverage to dual eligibles living in the community;
- States establishing explicit medication management and other pharmacy services as a waiver service in HCBS waiver programs;
- State HCBS waiver programs, state medical, nursing, and pharmacy boards, and CMS establishing improved oversight of medication therapy standards for HCBS waiver program participants through improved state survey and certification processes and state board certification and licensing;
- CMS requiring all states to include a plan to coordinate HCBS dual eligibles' care with Medicare Part D in their HCBS waiver applications or HCBS waiver program renewals; and
- CMS encouraging prescription drug plans or state quality initiatives focused on improving medication and other care management for dual eligible HCBS waiver program participants enrolled in Part D.

Introduction

In November 2003 Congress enacted the Medicare Modernization Act of 2003 (MMA), which made several changes to the Medicare program. Most significantly, the MMA added a voluntary prescription drug benefit, called Medicare Part D, for Medicare beneficiaries. Private prescription drug plans will provide voluntary prescription drug coverage to all Medicare beneficiaries, including the 6.4 million persons eligible for both Medicare and Medicaid or “dual eligibles.”³ All dual eligibles will have their Medicaid drug coverage replaced by Medicare Part D beginning in 2006. This shift in prescription drug coverage from Medicaid to Medicare has raised a number of issues about dual eligibles because they are generally frailer than typical Medicare beneficiaries, use more medications, and are more likely to suffer from chronic illnesses.

The MMA statute and CMS Part D program implementing regulations include specific provisions to address prescription drug access and quality issues for dual eligibles residing in institutions such as nursing facilities and Intermediate Care Facilities for the Mentally Retarded (ICF/MRs). However, dual eligibles who participate in home and community-based service (HCBS) waiver programs and have similar care needs to institutionalized dual eligibles will have fewer Part D protections. These differences may have important implications for the many dual eligible persons who have high medication management needs and are struggling to remain in the community using the support of HCBS waiver programs as well as states which operate these programs.

This paper will highlight the pharmacy services dual eligible HCBS waiver program participants receive today and then discuss how the changes in Medicare Part D may jeopardize access to medications and pharmacy services for program participants. The paper discusses the implications for HCBS waiver program participants, administrators, and state Medicaid agencies. Finally, it recommends state and federal initiatives that could improve medication access for dual eligibles participating in these programs.

Overview: Dual Eligibles in Institutional and Community Settings

6.4 million individuals in the United States are eligible for both Medicare and some form of Medicaid coverage.⁴ These individuals use a wide array of health care services. The amount of these services depends on their age, health status, and whether they have chronic health care needs. Many dual eligibles have more serious and complex medical, social, and long-term care needs than Medicare-only or Medicaid-only beneficiaries. They are also more likely to be living alone or have minimal social supports and consequently must coordinate their own care and health insurance benefits with multiple payers and providers.⁵ This care coordination can be complicated for these beneficiaries because they are often medically fragile and low-income. Care is further complicated because dual eligibles that reside in the community, as opposed to nursing facilities or other institutions, do not have a centralized care provider to coordinate their care.

For most dual eligibles, Medicare pays for acute care services and Medicaid functions as a secondary payer. Medicaid pays for all Medicare cost-sharing, prescription drugs, and other services not traditionally covered by Medicare (i.e. transportation, vision).⁶ Medicaid also pays for the nursing facility or ICF/MR care for dual eligibles once their

Medicare Part A skilled nursing facility stay ends or if they meet state-defined criteria for nursing facility or ICF/MR care. Currently, there are approximately 1.5 million dual eligibles receiving care in nursing facilities.⁷

Some dual eligibles participate in Medicaid HCBS waiver programs. Medicaid beneficiaries who qualify for these waivers receive a wide array of supports and services such as home health, personal care services, housekeeping, meal services, and home adaptations to allow them to reside in their own homes, the homes of family members, or in small group homes in the community. In 2001, there were 229 waivers in 49 states and the District of Columbia and over 50 percent of these waivers provided services to Medicaid beneficiaries who are elderly or disabled.⁸ HCBS waiver programs served 920,000 Medicaid beneficiaries in 2002; however, there are no data available regarding dual eligible participation.⁹ The officials we interviewed for this issue paper reported that the number of participants is increasing rapidly and a recent Maryland case study shows 63 to 90 percent of waiver participants are dual eligibles.¹⁰

HCBS waiver and institutional populations, including dual eligible groups, have many common characteristics and support needs. A growing number of waivers are geared toward the aged 65 years and older population and physically disabled individuals who would otherwise receive care from a fragmented network of providers and family members or would reside in a nursing facility.¹¹ Hence, many waiver participants are similar to the nursing facility population in terms of age, diagnoses and co-morbidities, the daily assistance they require, and the costs of medication they are prescribed. Table 1 provides of the common characteristics between nursing facility residents and HCBS waiver program participants.

Table 1: Similar Characteristics of Frail Elderly and Physically Disabled Dual Eligibles by Setting

	HCBS Waiver Program Participant	Nursing Facility Resident
Age	Majority 75 years or older ¹	Majority 75 years or older ²
ADLs	Needs assistance with 2 or more ¹	Needs assistance with 3.75 ³
Medication Expenditures	\$1811 average annual spending, 1999 ⁴	\$1830 average annual spending, 1999 ⁵

1/ Phillips, et al, “Prescription Drug Costs for Dually Eligible People in a Medicaid Home and Community Based Services Program.” *J Am Geriatric Society* 50:1283-1288, 2002.

2/ *National Nursing Home Survey*, Dept of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, Hyattsville, MD, 1999.

3/ *American Health Care Association: Facts and Trends, 2001* (Washington, DC: American Health Care Association, 2001).

4/ Avalere Health calculation using MSIS data from 1997-1999. A per capita annual growth rate for prescription drug expenditures was used to inflate an average annual spending figure of \$1500 from 1997 dollars to 1999 dollars. The \$1500 figure was taken from (1) Phillips, et al.

5/ Calculation from 1999 Medicaid Analytic Extract (MAX) Files, Source:

www.cms.hhs.gov/researchers/projects/Medicaid_rx

Table 1 shows that dual eligibles, whether they are in HCBS waiver programs or are in nursing facilities, are generally 75 years or older and need assistance with at least 2, if not more, activities of daily living (ADLs). According to the data, these similar characteristics have also translated into similar high medication needs. As the example shows, dual eligible HCBS waiver program participants and nursing facility residents have similar average annual spending per person on medications. Average annual prescription drug spending for dual eligibles in nursing facilities is only slightly higher than average annual prescription drug spending for dual eligibles in HCBS waiver programs.

Nursing facility residents frequently use more medications than the ambulatory population.¹² Tobias and Sey have found that the average nursing facility resident routinely takes 6.7 medications routinely and 2.6 medications on an as needed basis.¹³ There are no comparable quantitative data available for HCBS waiver program participants. However, one waiver administrator reported that most clients in the waiver program receive 5 to 10 medications per month.¹⁴

Current Pharmacy Services for Dual Eligible HCBS Waiver Program Participants

Pharmacy services are a broad category of supports associated with dispensing medications, including:

- *Medication Management.* Obtaining any prior authorization or formulary exception approvals needed to dispense a medication, managing medications in the context of a comprehensive medical and provider history, and conducting regular drug utilization or drug regimen reviews;
- *Specialized Packaging.* Re-packaging medications into bubble-wrap or punch-cards to create an individualized panel of medications for each patient with the appropriate dosage and frequency for each day of the week or month; and
- *Frequent Delivery.* Providing delivery of regularly scheduled medication refills and emergency prescription orders on a frequent basis.

States do not generally establish pharmacy services as an explicit HCBS waiver program service.¹⁵ In contrast, the majority of nursing facility residents receive prescription drugs and pharmacy services from LTC pharmacies. Table 2 compares pharmacy services for these two settings.

Federal and state regulations guide many LTC pharmacies' practices.¹⁶ These pharmacy providers often serve as the single medication and pharmacy services provider for nursing facility residents. There are no similar guidelines for HCBS waiver programs. Frequently, HCBS waiver program pharmacy services are provided in a fragmented fashion by individual HCBS providers and the clinicians responsible for overseeing the programs.

Table 2: Comparison of Current Pharmacy Services for Dual Eligibles

	Medication Management			Provides Specialized Packaging	Makes Frequent Deliveries	Uses One Central Pharmacy Provider
	Conducts Prior Authorization	Uses a Complete Medical Record	Completes Drug Utilization/ Drug Regimen Reviews			
Institutional Settings (served by a LTC pharm.)	Always	Often	Always	Always	Always	Almost Always
HCBS Settings	Varies by State	Rarely	Often*	Rarely	Rarely	Rarely

* Through HCBS waiver program medical director or oversight of designated registered nurse.

Source: Avalere Health analysis of HCBS waiver program applications and LTC pharmacy market practices.

The limited pharmacy services HCBS waiver participants currently receive can impede their access to medications. There are few federal regulatory requirements for waiver program administrators to monitor participant medications on a regular basis, to identify adverse drug events, or otherwise ensure the safety of their participant’s medication use.¹⁷ In addition, relative to nursing facilities, there is little or no federal involvement in state survey and certification efforts for HCBS waiver program caregivers and providers.¹⁸

Medicare Part D for Dual Eligibles Enrolled in HCBS Waiver Programs

CMS published final regulations for implementing the MMA on January 21, 2005. There are several provisions, including Part D formulary protections, coverage determinations, co-payments, and the transition period to Part D, that directly affect medication access for dual eligibles in HCBS waiver programs. These regulatory provisions have since been reinforced by CMS sub-regulatory guidance. Table 3 outlines some of the provisions that will likely affect dual eligibles in these programs.

Table 3: Provisions of the Medicare Drug Benefit and Dual Eligibles in HCBS Waiver Programs

	Part D Covered Drugs	Formulary	Coverage Determinations	Co-Payments	Transition to Part D
Description of Issue	<ul style="list-style-type: none"> Part D statute excludes coverage of benzodiazepines and barbiturates 	<ul style="list-style-type: none"> Each prescription drug plan will have its own formulary 	<ul style="list-style-type: none"> Prescription drug plans will their own exceptions and appeals processes for obtaining off-formulary medications 	<ul style="list-style-type: none"> \$1 to \$5 per prescription for dual eligibles living in the community, including HCBS program participants 	<ul style="list-style-type: none"> The initial transition period to Part D will make significant changes at one time
Potential Impact on Dual Eligible HCBS Waiver Program Participants	<ul style="list-style-type: none"> HCBS program participants might forgo these medications if required to pay out-of-pocket 	<ul style="list-style-type: none"> New formularies and structures may be difficult to navigate without a centralized pharmacy or health care provider that is responsible for assisting HCBS waiver program participants with 	<ul style="list-style-type: none"> HCBS program participants may need assistance to navigate exceptions and appeals processes and to switch plans if their auto-assigned plan is inadequate for their drug needs 	<ul style="list-style-type: none"> HCBS program participants might forgo medications because they do not have the financial resources to make co-payments 	<ul style="list-style-type: none"> Without monitoring and outreach, dual eligible HCBS waiver program participants might experience problems that limit their medication access

		their drug regimens and drug coverage			
Potential Protections for Dual Eligible HCBS Waiver Program Participants	<ul style="list-style-type: none"> Recent information suggests many state Medicaid programs that currently cover these drugs will continue to cover them¹ 	<ul style="list-style-type: none"> Policy guidance requires Part D plans to cover "all or substantially all" drugs in 6 therapeutic classes² Regulations prohibit plans from constructing formularies that discriminate against certain populations Regulations require 60 day notification of formulary change 	<ul style="list-style-type: none"> Regulations permit states to be beneficiaries' appointed representative and act of their behalf³; states could include HCBS waiver program administrators or providers as appointed representatives 	<ul style="list-style-type: none"> Statute permits pharmacists to waive co-payments on a case-by-case basis 	<ul style="list-style-type: none"> None

1/ Avalere Health survey of state Medicaid programs, September 2005.

2/ The classes are antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants, and antineoplastics.

3/ States may be required to enact laws to authorize state programs to act as representatives for dual eligibles or other Part D beneficiaries (<http://www.cms.hhs.gov/medicarereform/drugcoveragefaqs.asp>).

Source: Avalere Health analysis of final Part D regulations and CMS Part D guidance.

Covered Part D Drugs. The MMA statute excludes benzodiazepines and barbiturates from Part D coverage.¹⁹ This exclusion could potentially harm those dual eligibles who rely on these medications to relieve anxiety, reduce seizures, and treat other disorders. Without coverage of these medications, dual eligibles participating in HCBS waiver programs and in nursing facilities may forgo important stabilizing medications or incur heavy costs purchasing out of pocket. HCBS dual eligibles will likely choose to forgo medications they cannot afford. Forgoing medications could result in poor health outcomes requiring additional, potentially costly medical care such as physician office visits or readmission to nursing facilities.

CMS has recently released policy guidance explaining that state Medicaid programs can continue coverage of these products, as well as over-the-counter medications, after implementation of Part D and continue to receive federal financial funds if they offer coverage to all non-dual eligible and dual eligible Medicaid beneficiaries.²⁰ Many state Medicaid programs that currently cover these Part D excluded drugs have stated that they will continue to cover these drugs for their Medicaid beneficiaries, including those enrolled in the new Medicare drug benefit.²¹

Formulary. The new Medicare Part D benefit permits prescription drug plans significant flexibility to establish formularies to manage prescription drug costs. This change may put dual eligibles participating in HCBS waiver programs in the difficult position of selecting a plan that covers some, but not all prescription drugs they are currently taking.²² HCBS waiver program administrators may have to invest significant resources in educating participants, waiver caregivers, and family about formularies, how to evaluate them, and what to consider when selecting a prescription drug plan.

CMS has emphasized in its regulations, public forums, and sub-regulatory guidance that formularies will be reviewed carefully to ensure they do not discriminate against Part D beneficiaries with certain conditions. Recently, the agency clarified that “all or substantially all” of the medications in six therapeutic drug classes important to many dual eligibles’ care must be covered,²³ including antiretrovirals, antipsychotics, antidepressants, immunosuppressives, antineoplastics, and anticonvulsants. Beneficiaries will also receive 60 days notice when a medication is removed from the plan’s formulary and CMS will require prescription drug plans to develop an appropriate transition process for new plan enrollees who are taking Part D drugs that are not on the plan’s formulary.²⁴ These protections may give dual eligibles in HCBS waiver programs a minimum floor of protection against limited prescription drug plan formularies that could exclude critical medications or entire therapeutic classes of medications.

Coverage Determinations. The final regulation requires prescription drug plans to provide a process for their Part D plan enrollees to obtain exceptions to formulary restrictions, to appeal cost-sharing amounts or drug tier placement, and to determine whether a drug is medically necessary or not. These actions, called coverage determinations, must be completed within 72 hours for standards requests and 24 hours for expedited requests.²⁵ Appointed representatives are allowed to make coverage determination requests on behalf of plan enrollees. CMS defines appointed representatives as prescribing physicians, any individual appointed by the enrollee, or authorized by the state.²⁶ Appointed representatives could include nursing facility providers, LTC pharmacies, and HCBS waiver program care coordinators.

Recent CMS guidance requires prescription drug plans to establish procedures to cover one-time temporary or “first-fill” supplies of non-formulary medications ordered for LTC residents until exceptions are resolved.²⁷ While this “first-fill” is recommended for all plan enrollees, CMS will not require it for non-LTC residents such as dual eligible HCBS waiver participants. These individuals have to manage the processes to obtain exceptions from non-formulary medications on their own or with informal supports from appointed representatives such as their families, physicians, and waiver caregivers.

HCBS waiver program participants who attempt to manage the process without assistance from a pharmacy provider or a care coordinator may experience delays in the exceptions and determinations process because it may take them longer to gather the information they need to initiate a request or contact their appointed representative. In the interim, some will not have access to one-time “first-fill” supplies of medication, putting them at risk for hospitalization or other poor outcomes.²⁸

Co-Payments. The MMA requires dual eligibles living in the community, including HCBS waiver program participants, to pay a co-payment between \$1 and \$5 for each prescription.²⁹ In addition, CMS final rules stipulate that dual eligible HCBS waiver program participants as well as other dual eligibles must pay the full co-payment to receive their prescriptions.³⁰ In contrast, the MMA explicitly prohibited cost-sharing for full-benefit dual eligibles residing in institutions.³¹ These dual eligibles will not pay

premiums or co-payments. This difference may be a particularly significant problem for persons attempting to transition out of nursing facilities to HCBS waiver programs because cost sharing is covered in its entirety when residing in the institution and not in the community.

Current Medicaid law requires pharmacies to dispense a Medicaid prescription regardless of whether the beneficiary can pay the co-payment or not.³² This policy protects all low-income Medicaid beneficiaries from high out-of-pocket costs for their medications. This protection is important for those beneficiaries, particularly dual eligibles in HCBS waiver programs, who take several medications per month, are low-income, and have other costly medical expenses. Table 4 shows how the changes in co-payment policies will affect a dual eligible HCBS waiver program participant enrolled in Part D.

Table 4 shows the variable cost-sharing for a dual eligible elderly HCBS waiver program participant residing in Maryland. Using data from Table 1, the person is taking eight prescription medications per month. For this example, the person also spends \$20 per month on an over-the-counter heartburn medication. With Medicaid, the person’s local pharmacy provider does not require the beneficiary to pay a co-payment for their prescription.

Table 4: Prescription Drug and OTC Co-Payments Under Medicaid and Medicare Part D

	Medicaid	Medicare Part D
Monthly Co-Pays for Prescription Medications	\$0 ¹	\$24 - \$40 ³
Monthly Costs for Over-The-Counter Medications	\$0 ²	\$20
Total Monthly Cost to Beneficiary	\$0	\$44 - \$60
Total Annual Cost to Beneficiary	\$0	\$528 - \$720

1/ Medicaid statute requires pharmacists to dispense prescription drugs to Medicaid beneficiaries regardless of their ability to make co-payments.

2/ Many Medicaid programs, like Maryland, include OTC medications in their pharmacy benefit.

3/ Co-payments can range from \$3.00 - \$5.00 per Rx for dual eligibles in Part D.

CMS enrollment guidance does permit pharmacies to waive co-payments on a case-by-case basis if they choose.³³ In addition, states can elect to cover co-payments for dual eligible HCBS waiver program participants and other community dwelling dual eligibles with state-only funds, including through State Pharmaceutical Assistance Programs (SPAPs).³⁴ Early information from states indicates some will provide co-payment coverage to previous SPAP enrollees. However, these programs typically serve higher income populations and may not include dual eligibles.

Transitional Protections. CMS will begin auto-enrolling all dual eligibles into Medicare prescription drug plans after October 15, 2005.³⁵ Advocates, states, and federal policymakers are concerned about educating and enrolling dual eligibles and have already begun outreach. They are also concerned about any interruption of dual eligibles’

drug therapies during the transition from Medicaid to their new Part D formulary. Preventing interruptions is of paramount concern for HCBS waiver programs as well as state Medicaid administrators who must deal with unintended consequences when medications are missed or changed such as additional physician office visits or readmission to nursing facilities.³⁶ CMS has issued guidance to plans to provide an emergency supply of non-formulary Part D drugs to nursing facility residents during their initial transition to the drug benefit and during other transitional periods for residents.³⁷ There are no such requirements for dual eligible HCBS waiver program participants.

Recommendations for States and Federal Policy Makers

Dual eligibles participating in HCBS waiver programs may encounter significant hurdles during the transition to the Medicare Part D drug benefit in January 2006. Prescription drug plan formularies could be more restrictive and Part D excluded drugs such as benzodiazepines and barbiturates could be more difficult to access from state Medicaid programs. The burden may fall to program participants' families and waiver program staff to conduct coverage determinations and increased co-payments may place a serious financial burden on this vulnerable, low-income population.

States and CMS must actively work with their HCBS dual eligible populations to ensure the new Part D benefit supports ongoing efforts to keep dual eligible beneficiaries out of institutions such as nursing facilities and does not block transitions for currently institutionalized beneficiaries out of nursing homes or other facilities. CMS and states can work closely with each other to prevent or avoid medication access problems for dual eligibles participating in HCBS waiver programs. Potential steps include:

- States ensuring that HCBS waiver program administrators have identified their dual eligible enrollees and have a transition plan in place for these participants;
- States providing co-payment coverage to dual eligibles living in the community;
- States establishing explicit medication management and other pharmacy services as a waiver service in HCBS waiver programs;
- State HCBS waiver programs, state medical, nursing, and pharmacy boards, and CMS establishing improved oversight of medication therapy standards for HCBS waiver program participants through improved state survey and certification processes and state board certification and licensing;
- CMS requiring all states to include a plan to coordinate HCBS dual eligibles' care with Medicare Part D in their HCBS waiver applications or HCBS waiver program renewals; and
- CMS encouraging prescription drug plans or state quality initiatives focused on improving medication and other care management for dual eligible HCBS waiver program participants enrolled in Part D.

¹ Arizona is the only state that does not have 1915(c) HCBS waiver program because the entire Medicaid program is operated under an 1115 waiver in that state. “Disabled” refers to persons with physical disabilities or serious and persistent mental illness; it does not include waivers for the developmentally disabled. Harrington, Charlene. CMS 372 Data 1992-2001 for the Kaiser Commission, July 2003.

² Kaiser Commission on Medication and the Uninsured. “Medicaid 1915(c) home and community-based waiver programs: data update.” July 2005.

³ Kaiser Family Foundation. *Medicare Fact Sheet: The Medicare Prescription Drug Benefit*. March 2005.

⁴ Kaiser Family Foundation. *Medicare Fact Sheet: The Medicare Prescription Drug Benefit*. March 2005.

⁵ O’Brien and Rowland. *Medicare and Medicaid for the Elderly and Disabled Poor*, The Kaiser Commission on Medicaid and Uninsured, May 1999.

⁶ There are two groups of dual eligibles: (1) Medicare beneficiaries who receive assistance for some or all of only cost-sharing assistance (Medicare Part B premiums and co-payments) through Medicaid, and (2) Medicare beneficiaries eligible for full Medicaid coverage. This second group of dual eligibles is the focus of this policy brief. These individuals receive full health care coverage, including prescription drugs, and represent about 85% of dual eligibles. [Kaiser Family Foundation. www.statehealthfacts.org, Urban Institute estimates using MSIS data, prepared for the Kaiser Commission on Medicaid and the Uninsured.]

⁷ Kaiser Commission on Medicaid and the Uninsured. “Dual Eligibles: Medicaid’s Role in Filling in Medicare’s Gaps,” March 2004.

⁸ Arizona is the only state that does not have 1915(c) HCBS waiver program because the entire Medicaid program is operated under an 1115 waiver in that state. “Disabled” refers to persons with physical disabilities or serious and persistent mental illness; it does not include waivers for the developmentally disabled. Harrington, Charlene. CMS 372 Data 1992-2001 for the Kaiser Commission, July 2003.

⁹ Kaiser Commission on Medication and the Uninsured. “Medicaid 1915(c) home and community-based waiver programs: data update.” July 2005.

¹⁰ Milligan, C. “Impact of the Medicare Prescription Drug Benefit on Home-and-Community-Based Services Waiver Programs.” The Commonwealth Fund, April 2005.

¹¹ This policy brief focuses on elderly and disabled dual eligibles residing in nursing facilities and/or participating in HCBS waiver programs. However, many of the issues addressed are similar to those faced by people with developmental disabilities and their caregivers in HCBS waiver programs or ICF/MRs.

¹² American Society of Consultant Pharmacists. “ASCP Final Comments to CMS Proposed Rules for Medicare Drug Benefit.” October 1, 2004. <http://www.ascp.com/MedicareRx/>

¹³ Tobias, DE, Sey M. “General and psychotherapeutic medication use in 328 facilities: a year 2000 national survey,” *Consultant Pharmacist* 2001; 16(1):54-64.

¹⁴ Personal communication with Catherine McAvoy and Jerald Ulrich, Home and Community Services, Region 4 (Seattle area), Washington State, February 2005.

¹⁵ The Centers for Medicare and Medicaid Services. “Home and Community-Based Services Summary Report.” November 2003 and US Department of Health and Human Services/ASPE. “Understanding Medicaid and Home and Community Services: A Primer.” October 2000.

¹⁶ Nursing facilities must meet federal and state regulatory requirements to ensure the safety of their residents. Federal regulations require Medicare and Medicaid certified nursing facilities to have low medication error rates [42CFR§483.25(m)], reduce unnecessary drug use [42CFR§483.25(l)], and conduct monthly drug regimen reviews for residents [42CFR§483.60]. State nursing home and board of pharmacy regulations often mirror these federal regulations or require more stringent standards for facilities.

¹⁷ Only the CMS State Medicaid Manual designates HCBS waiver program administrators as responsible for ensuring the health, safety, and welfare of waiver participants, including with respect to medication administration (SMM 4442.4, 4652).

¹⁸ US General Accounting Office. “Long-Term Care: Federal Oversight of Growing Medicaid Home and Community-Based Program Waivers Should Be Strengthened.” GAO-03-576, June 2003.

¹⁹ Social Security Act §1860-D(2)(e)(1).

²⁰ State Medicaid Director Letter #05-002, Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services, June 3, 2005. If these medications are covered for dual eligibles they must be covered for all Medicaid participants in that state.

²¹ Avalere Health analysis of state Medicaid programs, September 2005.

²² Federal Medicaid law requires dispensing of all medically necessary medications and states cannot operate formularies. The Social Security Act §1927(d)(4) permits states to establish formularies or Preferred Drug Lists (PDLs) that require prior authorization to obtain some medications.

²³ Centers for Medicare and Medicaid Services. “Clarification – Formulary Review,” June 2005.

²⁴ 42CFR§423.100(b).

²⁵ 42CFR§423.568 and 42CFR§423.572.

²⁶ 42CFR§423.560 and ²⁶ 42CFR§423.566.

²⁷ Centers for Medicare and Medicaid Services. “Clarification – Emergency Fill for LTC Residents,” June 2005.

²⁸ CMS recommends PDPs offer one-time “first-fills” to plan enrollees. PDPs may choose to do this for certain population groups, including community-dwelling dual eligibles or other vulnerable populations.

²⁹ 42CFR§423.782, non-institutionalized full dual eligibles at or below 100% FPL will pay \$1 (generic), \$3 (brand name), and non-institutionalized full dual eligibles regardless of assets above 100% FPL will pay \$2 (generic), \$5 (brand name).

³⁰ Preamble Text for MMA Title I Proposed Regulation. Federal Register Notice, Vol. 70, No. 18, January 28, 2005, page 4387.

³¹ Section 1860 D-14(a)(1)(D)(i)

³² 42CFR§447.53(e) and S.S.A§1916(e)

³³ CMS Coordination of Benefits Guidance. <http://www.cms.hhs.gov/pdps/cobguidancefinal.pdf>, page 24-25, August 2005.

³⁴ 42CFR§423.464(a)

³⁵ 42CFR§423.34.

³⁶ The American Society of Consultant Pharmacists.

<http://www.ascp.com/public/news/2005/02/15/cmscomments/> and Kitchin, Tina MD, “Testimony presented to the Senate Special Committee on Aging.” March 3, 2005.

³⁷ Centers for Medicare and Medicaid Services. “Clarification –Emergency Fill for LTC Residents.” June 2005.

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