# Medicare Drug Benefit Update

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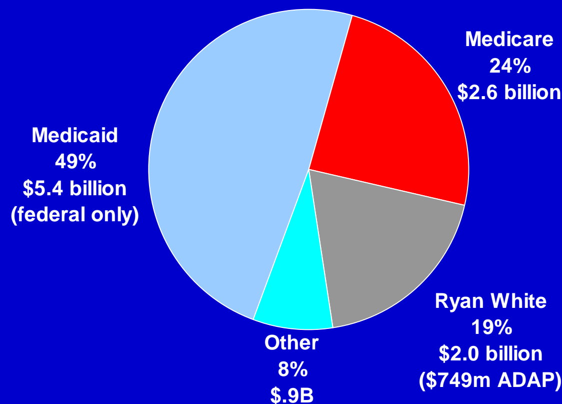
for

National Alliance of State and Territorial AIDS Directors

November 10, 2004

## Medicare is the Second Largest Source of Federal Funding for AIDS Care in the U.S.




SOURCES: Kaiser Family Foundation, *Trends in U.S. Government Funding for HIV/AIDS: Fiscal Years 1981 to 2004*, March 2004; Medicare and Medicaid Estimates from CMS, Office of the Actuary, 2004 and HHS Office of Budget, 2004.

## Medicare is an Important Source of Coverage for People with HIV/AIDS

- Estimated Medicare coverage of people with HIV/AIDS in care:
  - 19% or approximately 85,000 people
  - Most are disabled, non-elderly
  - More likely to be at advanced stage of HIV disease
  - More likely to be lower income
  - About two-thirds, or 55,000, are dual Medicaid-Medicare beneficiaries with HIV/AIDS

SOURCES: Bozzette, et al. "The Care of HIV-Infected Adults in the United States." *NEJM*, Vol. 339, No. 26. December, 1998; Fleishman, J., Personal Communication, Analysis of HCSUS Data, January 2002.Kaiser Family Foundation, *Fact Sheet: Medicare and HIV/AIDS*, September 2004; Medicare and Medicaid Estimates from CMS, Office of the Actuary, 2004 and HHS Office of Budget, 2004.

## Medicare Eligibility Pathways for People with HIV/AIDS

| Eligibility Category | Eligibility Criteria |
|---|---|
| • Individuals age 65 and older | • Sufficient number of work credits to qualify for Social Security payments |
| • Individuals under age 65 with permanent disability | • Sufficient number of work credits to qualify for SSDI payments due to disability; and have been receiving SSDI payments for at least 24 months |
| • Individuals with End-Stage Renal Disease(ESRD), any age | • Sufficient number of work credits to qualify for Social Security payments |

## ADAPs Have Complicated Relationship to Medicare (and to Medicaid)

- Annually, ADAPs serve approximately 136,000, or an estimated 30% of people living with HIV/AIDS in care
- In June 2003, ADAPs served 85,825 clients
  - 7% had Medicaid coverage
  - 8% had Medicare coverage
- ADAP, as payer of last resort or gap filler for Medicaid and Medicare, picks up/carries clients before these programs kick in, between these programs, where there are gaps, and when clients are no longer eligible – may vary over the course of a year
- Medicaid and Medicare coverage for ADAP clients at any one point in time most likely underestimates their role and importance for ADAP clients

SOURCES: NASTAD/KFF/ATDN, *National ADAP Monitoring Project Annual Report*, May 2004..

## Medicare Prescription Drug, Improvement, and Modernization Act of 2003

### Phase 1 – 2004 and 2005

- Access to Medicare-approved discount drug cards for all beneficiaries except those with Medicaid (duals)
- $600 annual drug subsidy for low-income beneficiaries (<135% poverty) in each year

### Phase 2 – Begins in 2006

- Beneficiaries will have access to private plans that provide new prescription drug benefit under Medicare

## Phase 1: Medicare-Approved Drug Discount Card
### June 2004 – December 31, 2005

- Cards provide discounts on the purchase of drugs
  - Studies show card offer 12-21% savings off national average retail price (CMS, 9/04)
- Beneficiaries with Medicaid drug coverage not eligible for discount card
- Also pays $600 credit toward drug costs for beneficiaries with incomes <135% FPL – up to $1,200 in TA for 2004 and 2005
- 4.4 million enrolled as of Oct 2004 (most auto-enrolled by health plan or SPAP)
- List of programs available at: http://www.cms.hhs.gov/partnerships/news/autoenroll/sponsors.pdf

## Discount Card $600 Transitional Assistance

- $600 built into card like mass transit or prepaid phone card
  - Amount automatically subtracted as beneficiaries use card
  - Can be used for prescription copays for discounted drugs and for cost of non-discounted drugs
  - Any leftover funds from 2004 rollover to 2005
  - After TA used up, beneficiaries can get add'l savings from some drug companies in conjunction with certain discount cards
- Beneficiaries with drug coverage through Medicaid, Tricare, FEHPB, VA, or employer are not eligible for TA (but ADAP clients are eligible)
- CMS working with Access to Benefits Coalition on education and outreach campaign for discount card and TA
- 1.3 million receiving $600 subsidy; "facilitated enrollment" of another 1.8 million (MSP enrollees) (of ~7.2 million eligible)

## Phase 2: Medicare Prescription Drug Benefit
### January 2006 and Beyond

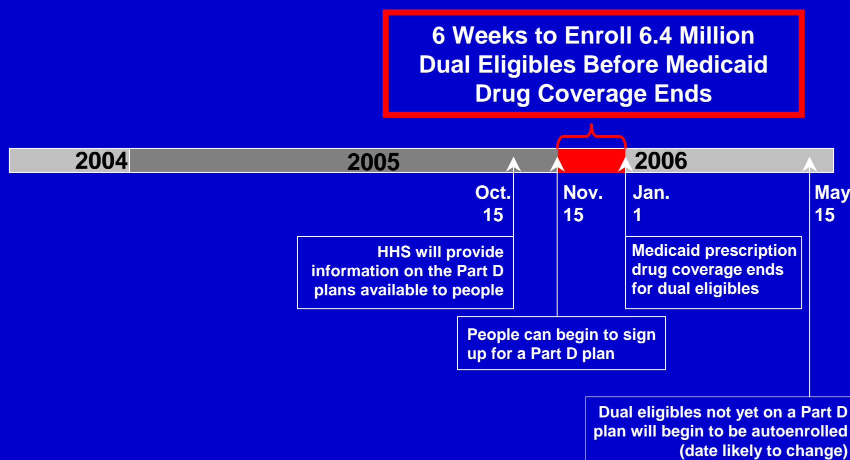
- Beginning in 2006, beneficiaries have choice of:
  - Fee-for-service Medicare, with access to private prescription drug-only plans (PDPs)
  - Medicare Advantage plans for Medicare benefits and Rx drugs (MA-PDs)
- New plans provide "standard" prescription drug benefit or its actuarial equivalent
- Premium and cost-sharing subsidies for low-income beneficiaries with incomes up to 150% poverty and modest assets

## Key Issues For Dual Eligibles and ADAP Clients

## Treatment of Dual Eligibles in the Medicare Law

- As of January 1, 2006, full benefit dual eligibles no longer are eligible for Medicaid-financed prescription drug coverage
  - Loss of Medicaid coverage applies even if a dual eligible is not enrolled in a Part D plan
- Instead, full benefit dual eligibles are expected to enroll in the new Medicare prescription drug benefit (“Part D”)
  - Full benefit dual eligibles will be auto-enrolled in a Part D plan if necessary; proposed MMA regulations leave unclear who will handle
  - All dual eligibles are deemed automatically eligible for a Part D subsidy
- Dual eligibles will receive extensive Part D subsidies, but gaps in their Rx coverage may remain
  - Risk of no coverage during a transitional period
  - The drugs they need may not be covered by their Part D plan, particularly because full subsidies are limited to average or low-cost plans
  - Some co-payment obligations
- States will no longer provide prescription drugs to dual eligibles under Medicaid, but must send money to the federal government to pay for much of the cost of their Part D benefit

## Key Dates Related to Enrollment of Full Benefit Dual Eligibles in Part D Plans



# Implementation Challenges: Now – January 2006

**November 15-December 31, 2004**
Annual coordinated election period for 2005 discount card program

**January 1, 2005**
- **CMS announces PDP & MA regions**
- **CMS releases financing & solvency requirements for plans**

**February 18, 2005**
CMS publishes risk-adjustment methodology for 2006 payment rates

**Early 2005**
CMS publishes final rules for Medicare drug benefit and MA program

**June 6, 2005**
**PDP & MA-PD plan bids submitted**

**June 31, 2005**
CMS "pre-qualifies" bidders for eligible fallback plans starting in 2006

**July 1, 2005**
States begin accepting applications for low-income subsidies

**July 1, 2005**
CMS establishes procedures for coordination between Part D plans and state pharmacy assistance programs and other insurers

**September 2005**
**CMS awards bids to PDP and MA-PD plans**

**October 15, 2005**
CMS disseminates information comparing Part D coverage to beneficiaries via mail and 1-800-MEDICARE

**October 15, 2005**
Secretary notifies states of per capita drug payments for 2006 ("clawback" for dual eligibles)

**November 15, 2005-May 15, 2006**
**Annual coordinated election period for 2006 Part D for all beneficiaries**

**December 31, 2005**
- **Medicare discount card program ends**
- **Medicaid Rx coverage ends for "full benefit" dual eligibles**

**January 1, 2006**
- **Part D coverage begins for all beneficiaries enrolled in PDP or MA-PD**
- **Low-income subsidies for Part D coverage begin**
- **Retiree drug subsidy program begins**
- **Secretary implements billing and benefit coordination for determining beneficiaries' true out-of-pocket (TrOOP) costs**
- **States begin making monthly "clawback" payments to federal government for dual eligibles**

# Challenges in Helping Dual Eligibles Make the Transition to Medicare Part D

- To avoid coverage gaps, 6.4 million dual eligibles will need to be signed up for Part D plans in 6 weeks
- Dual eligibles unlikely to voluntarily enroll; autoenrollment likely will be necessary for many
- Once autoenrolled in a plan, dual eligibles still will need help before they can use their Part D coverage
  - Need enrollment cards
  - Need to learn how to use their Part D plans
  - May need to switch their prescriptions to drugs covered by their Part D plan
- Dual eligibles in nursing homes will require special assistance

## Perspectives of Dual Eligibles on Pending Changes: Findings from Focus Groups

- Prescription drugs play a vital role in the lives of dual eligibles
- They are generally content with their Medicaid drug coverage
  - Most report they can get all of the medications that they need under Medicaid
  - The few that have faced problems usually have been able to overcome them with the help of doctors
- No knowledge of pending changes in their prescription drug coverage
  - Limited awareness of the new Medicare prescription drug benefit
  - To the extent they are aware of the MMA, they believe it does not affect them because they already have Medicaid drug coverage
- When told about changes, very concerned

[Without my medication], I'd be six feet under.

-- Individual with physical disabilities in Baltimore, MD

"It doesn't apply to me because my [medications] are taken care of with both Medicare and Medicaid."

-- Low-income senior in Tampa, Florida

## Specific Issues for People with HIV: Findings from an L.A. Focus Group

- More sophisticated in their understanding of prescriptions than other dual eligibles
- Very concerned about temporary problems securing prescription drugs due to resistance issues
- More concerned about the prospect of substituting medications than other dual eligibles
- Particularly interested in whether Part D plans will cover new drugs

"So if you have a month break, a week break, or whatever you've got this nasty virus when you start back on the same medication, that's resistant to those medications"

"These different plans where only certain medications are covered. That's the part that concerns me."

## Key Issues in Implementing the MMA: Drug Plan Formularies and UM Tools

- Role of United States Pharmacopeia (USP)
  - Developing model guidelines of drug categories and classes to provide "standard framework" that "may be used" by PDPs to develop formularies
  - Draft guidelines released in August (includes 43 therapeutic categories, 138 pharmacologic drug classes); final guidelines expected in December 2004
- Part D plan formularies
  - Must be developed by pharmacy and therapeutic (P&T) committee
  - Must include 2 drugs from each therapeutic category and class
  - CMS: "Choices must represent full range of drug therapies necessary to adequately support current medical practice"
  - Two drugs in each might be sufficient, but more will likely be needed to meet adequate access standard
  - In classes where therapeutic substitution is clinically appropriate (e.g., cardiovascular, gastrointestinal), plans will be allowed to negotiate best prices, but not in others (e.g., anti-retrovirals for HIV, where 4 separate classes have been specified by USP)

## Drug Utilization Management Tools

- Regardless of formulary structure, utilization management strategies can affect access
- PDPs and MA-PDs can decide which UM tools to use (subject to certain constraints)
  - MMA does not prohibit use of tiered cost sharing, step therapy, prior authorization, therapeutic substitution, mail order, quantity limits
  - Plans can change drug categories and classes once/year
  - Changes to covered drugs, preferred status, or tiered cost-sharing can be made anytime with 30-day notification of "affected" individuals
- Plans also can develop their own pharmacy network and out-of-network coverage policies

## Formulary Review Standards

- **CMS's role in reviewing plan design is critical**
  - **CMS will review plan formularies to rule out discriminatory drug exclusions, tiered cost-sharing, administrative requirements**
  - **Plans using the USP classification system to structure their formulary are protected from review but not the drugs selected for each category/class**
  - **Plans that do not follow standard benefit design responsible for meeting actuarial equivalence standard**
- **Proposed regs provide little guidance about Secretary's role in enforcing nondiscrimination rule or process for review**
  - **CMS says it is developing formulary review standards and will share for public comment in "fall of 2004"**
- **Implications for dual eligibles/ADAP clients**
  - **Low incomes may limit their capacity to purchase non-formulary drugs**
  - **Rules could delay their access to latest newly-approved medications to treat their conditions**

## Key Issues in Implementing the MMA: Appeals Procedures

- **Beneficiaries can challenge drug plan decisions/ denials regarding payment and covered drugs**
- **Different parts to the appeals process:**
  - Right to coverage determinations within 14 days and reconsiderations of decisions within 30 days
    - **Expedited procedures (72 hours) in emergencies**
  - Exceptions process to request non-preferred/non-formulary drugs at preferred cost-sharing level
  - Appeals process for reconsideration and adjudication by independent outside entity (IRE / ALJ)
    - **Must exceed $100 threshold for ALJ; $1,000 for judicial review ("bundling" of appeals allowed)**
    - **Only individual beneficiary can appeal (not physician)**

## Implications for Duals/ADAP Clients

- **Low incomes could prevent access to needed medications while outcome of plan decision is pending**
  - No provisions for dispensing emergency supply of drugs pending appeal resolution
  - Temporary interruption in treatment could exacerbate health problems, as well as lead to drug resistance/intolerance
- **Inability of physicians to appeal on behalf of patients could be more burdensome for duals and uninsured ADAP clients**
  - Process could be lengthy, cumbersome, and difficult to navigate since not automatic

## Key Issues in Implementing the MMA: What is TrOOP?

- **Accurate TrOOP (true out-of-pocket costs) calculation is critical**
  - **$3,600 in TrOOP is threshold for catastrophic benefit**
  - **Equal to $5,100 in total costs under standard drug benefit**
- **What <u>counts</u> toward TrOOP limit:**
  - **Unreimbursed payments by beneficiaries or another individual**
  - **Medicare Part D subsidies for low-income people**
  - **State Pharmaceutical Assistance Programs (SPAPs) payments**
- **What <u>does not count</u>:**
  - **Payments from insurers, including employers (retiree coverage)**
  - **Payments from supplemental coverage sources (e.g., Medigap)**
  - **Any other third-party payments (including ADAPs, according to proposed regs)**
  - **Out-of-pocket costs for non-formulary drugs**
- **Unknowns:**
  - **Differential between retail and mail order price?**
  - **Out-of-pocket cost of drugs filled at out-of-network pharmacies?**

## Tracking TrOOP

- For beneficiary with ADAP coverage, TrOOP could mean a delay in the start of the catastrophic benefit
  - If ADAP fills in "doughnut hole" with 75% coinsurance, catastrophic coverage would begin at $13,650 in total spending, not $5,100
- Uncertain which entity/ies will be responsible for tracking
  - Pharmacies need information about secondary payers, correct billing order, and appropriate amount of beneficiary cost-sharing liability
  - CMS will work with plans and third-party payers to construct a data-sharing system to coordinate benefits and track sources of cost-sharing payments