

HIV Medicare and Medicaid Working Group

Medicare Part D: ADAP Expenditures Must Count Towards TrOOP

What is the Issue? When Congress established the Medicare Part D program, drug spending by other government programs was prohibited from counting toward the calculation of so-called true out-of-pocket costs (TrOOP), with one exception, state pharmaceutical assistance programs. The Centers for Medicare and Medicaid Services (CMS) has interpreted the law such that AIDS Drug Assistance Programs (ADAPs) are not to be considered state pharmaceutical assistance programs even though they are supported by significant state contributions and must ensure that they are the payer of last resort.

How does it affect people living with HIV/AIDS? TrOOP spending is a critical issue because it determines when “catastrophic coverage” begins. Catastrophic coverage begins when individuals with exceptionally high drug costs move through the coverage gap by spending \$4,050 in out-of-pocket costs and their cost sharing falls to 5% of drug costs. TrOOP also is significant because these expenses are used to determine when individuals exit the coverage gap known as the donut hole. Because ADAP spending does not count toward TrOOP, individuals can not move out of the coverage gap and are therefore unable to access their Medicare drug formularies for approximately between 9 to 10 months out of the plan year. These individuals must rely only on ADAP, which in almost all cases has a much more limited formulary than the typical Medicare plan.

Reasons to Support Policy Change:

- **Cost to Medicare is Minimal:** The CHAMP Act passed by the House last session included a provision to allow ADAP and Indian Health Service spending to count towards TrOOP. Those two programs combined were only expected to cost \$100 million over five years.
- **States Make Significant Contributions to ADAPs:** On average, state spending accounts for 22% of the total ADAP budget. Fifteen states contribute more than 25% of their state’s overall ADAP budget (Alabama, California, Colorado, Georgia, Idaho, Illinois, Iowa, Missouri, Pennsylvania, Tennessee, Texas) and five states contribute 40% or more of the ADAP budget (Idaho, Nebraska, North Carolina, Rhode Island, Wyoming).
- **Provide Cost Savings to Lifesaving Discretionarily Funded Program:** Total ADAP spending reached almost \$1.4 billion in FY2006, with states contributing \$305 million to the total. ADAPs provide access to critical medications for approximately 140,000 individuals in communities across the U.S. every year. Unfortunately, ADAPs are limited in their services by the annual appropriations process and meeting demand for HIV drugs is an ongoing challenge. A number of states have been forced to maintain waiting lists over the last several years.
- **Catastrophic Coverage Frees Up ADAP to Cover Other Unmet Needs:** When ADAP does not count toward TrOOP, it requires ongoing ADAP spending that cannot be used to help other needy people with HIV/AIDS. However, when ADAP does count toward TrOOP, catastrophic coverage frees up ADAP dollars to help other needy individuals. The National Alliance of State and Territorial AIDS Directors has estimated that if ADAP expenditures counted towards TrOOP, it would save ADAP programs \$25 to \$44 million.
- **The Majority of ADAP Clients Live in Poverty:** 82% of ADAP clients live at or below 200% of the poverty level (\$1,701 a month in 2007) and 55% are at or below 100% FPL. For those who just miss qualifying for the Medicare low income subsidy, the cost of drugs can easily total \$3,000 per month during the donut hole period. In addition to their HIV regimen, people with HIV/AIDS also need to pay for a host of other medications to treat co-occurring conditions and side effects from their HIV treatment.
- **On Average, 17% of ADAP Clients are Medicare Beneficiaries:** 69% of these ADAP clients who are Medicare beneficiaries are also eligible for the full or partial LIS. Approximately 30% of these clients are standard beneficiaries who currently experience the coverage gap.

The HIV Medicaid and Medicare Working Group (HMMWG) HMMWG is a coalition of nearly 100 national and community-based AIDS service organizations that represent HIV medical providers, advocates and people living with HIV/AIDS and provide critical HIV-related health care and support services. For more information, contact the HMMWG co-chairs Laura Hanen with the National Alliance of State and Territorial AIDS Directors at 202.434.8091 or Robert Greenwald with the Treatment Access Expansion Project at 617.390.2584.

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Medicare Part D: Codifying Six Protected Classes to Ensure Access to Critical Medicines

What is the Issue? The transition to Medicare Part D for beneficiaries living with HIV/AIDS has been complicated over the last two years. Making the transition smoother than anticipated has been an essential consumer protection implemented by the Centers for Medicare and Medicaid (CMS) requiring Part D to cover “all or substantially all” drugs in six key classes, including antiretrovirals used to treat HIV/AIDS. Drugs covered by the all or substantially all policy include: Anticonvulsants, Antidepressants, Antineoplastics, Antipsychotics, Antiretrovirals, and Immunosuppressants. They are vital to the health of Medicare beneficiaries with HIV/AIDS, mental illnesses, epilepsy, cancer, and autoimmune diseases. CMS grants additional protections to the antiretroviral class by prohibiting the use of utilization management techniques for all antiretrovirals. Unfortunately, this critical protection is only granted in plan guidance and is subject for review on an annual basis. This formulary access protection must be enacted into law so that vulnerable beneficiaries living with HIV/AIDS can count on access to these essential medications at no additional cost to the federal government.

Reasons to Support this Patient Protection:

- **HIV/AIDS Drugs are Not Interchangeable:** Unlike other drug classes, where drugs may be chemically similar and it may be safe to substitute one drug for another, drugs in these six classes are less interchangeable. Physicians need the flexibility to prescribe any of the drugs within these classes to meet the individualized needs of their patients. Coverage of nearly all of the drugs in these categories is standard practice among state Medicaid programs and private insurers.
- **People Living with HIV/AIDS are a Vulnerable Population:** When enacting this guidance, CMS recognized the particular vulnerabilities of beneficiaries living with HIV/AIDS can not afford to have any interruption in the complex treatment regimen necessary to maintain health.
- **High Cost Drugs Threaten Access:** Most of the drugs in these classes are the latest generation pharmaceuticals, which remain on patent. This means that they can often be among the most costly drugs available. We have seen that many Part D plans utilize the 4th tier, or specialty tier for the new antiretrovirals. This suggests that without specific protections, plans will attempt to restrict access for financial considerations without due concern for the patient’s health.
- **Formulary Restrictions Can be Harmful:** Surveys of HIV and mental health medical providers indicate that Medicare beneficiaries with these conditions have been hospitalized or have experienced dangerous treatment interruptions due to challenges with Medicare Part D coverage, including burdensome prior authorization processes.
- **Most Cannot Afford to Purchase Non-Covered Drugs:** Most affected individuals cannot afford to pay out-of-pocket to purchase drugs not covered by their Part D plan. Medicare beneficiaries with disabilities who depend on drugs in the six protected classes are likely to be dual eligibles—meaning that they qualify for Medicaid on the basis of having low incomes. Many receive Supplemental Security Income (SSI), which provides income up to \$623 per month in 2007. These individuals do not have the financial resources to pay for needed drugs that are not covered by their Part D plans.
- **Codifying this Guidance Would not Increase Part D Costs:** A provision to codify the protection for the six classes was included in the House CHAMP Act last year and was scored by the Congressional Budget Office to cost nothing over five years.

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