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Department of Health and Human Services  
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We the undersigned organizations are national and community-based AIDS service organizations that represent people living with HIV/AIDS, medical providers, advocates and program administrators that deliver HIV-related health care and support services. We have a number of concerns about the implementation of the prescription drug benefit provided by the *Medicare Modernization Act* (MMA) and appreciate the opportunity to comment on the proposed rule for implementing the drug benefit. In light of the number of questions that the Center for Medicare and Medicaid Services (CMS) raised in the preamble to the proposed rule and the ambiguity that remains in a number of critical areas, we strongly encourage CMS to issue a second notice of proposed rulemaking to provide us the opportunity to comment on the decisions made by CMS regarding these issues.

The development of highly active antiretroviral therapy (HAART) for the treatment of HIV disease over the past decade has led to profound and widespread declines in HIV/AIDS morbidity and mortality. We strongly urge CMS to publish a final rule that ensures that Medicare beneficiaries living with HIV/AIDS at all income levels have affordable access to the full pharmacopoeia of FDA-approved medications. The following comments represent our highest priority concerns regarding access to life-saving drug therapies for Medicare beneficiaries with AIDS under Medicare Part D. Separately, many of our members are providing more detailed comments, and many members are also signing onto comments developed through other coalitions. We hope that CMS will give serious consideration to the issues outlined in this document and will be responsive through publishing a final rule that adequately and appropriately addresses these critical issues.

We feel the two issues highlighted below warrant special and serious consideration because of their potential impact on Medicare beneficiaries with AIDS accessing daily life-sustaining regimen drug regimens.

- **DESIGNATE PEOPLE LIVING WITH AIDS AS A “SPECIAL POPULATION.”**

We strongly encourage CMS to designate “special populations” and require drug plans to exempt these populations from formulary restrictions and grant them special protections from cost-sharing requirements and other cost-containment

measures that may impede access to prescription drugs. We strongly recommend that CMS designate people living with AIDS as a “special population.” Please see our comments on page 6 with details on this recommendation.

- **A POTENTIAL LAPSE IN DRUG COVERAGE IS UNACCEPTABLE. DELAY IMPLEMENTATION OF THE MMA FOR DUAL ELIGIBLES.**

We are very concerned that the current proposed timeframe which begins enrollment on November 15, 2005 will not ensure that the nearly 60,000 dual eligible with AIDS along with more than 6 million other dual eligible individuals are enrolled in a Medicare Part D prescription drug plan before they lose their Medicaid drug coverage on December 31, 2005. The regulations do not appear to ensure that there will be no breach in drug coverage for dual eligibles if these enrollment processes cannot be completed by the last day of 2005. Not enrolling dual eligibles who do not select a plan before they lose Medicaid drug coverage until May 15, 2006 as the regulations would seem to call for is completely unacceptable. The final regulations must ensure that dual eligibles do not lose drug coverage during the transition, even if that requires maintaining individuals with Medicaid-covered drugs—with federal matching funding—until Medicare Part D coverage is in place. It would be far preferable to delay coverage under Part D for this vulnerable group of beneficiaries than to threaten individual and public health by leaving persons with AIDS and other dual eligibles without any drug coverage at all for as long as four months.

Based on our collective experience, six weeks is not enough time to work with this medically complex and difficult to reach population to ensure that they are enrolled in a prescription drug plan, and if they are not, to conduct a reliable auto-enrollment process that includes educating the beneficiary on the prescription drug plan that they have been enrolled in and informing them of their right to change plans. It is absolutely critical to the health of dual eligibles with AIDS that they not experience any disruption in their access to prescription drugs during the transition to a Medicare Part D prescription drug benefit.

We sincerely hope that CMS will work with key stakeholders including Medicare beneficiaries and their health care providers to ensure the implementation of a Medicare drug benefit that delivers on the promise to provide seniors and people with disabilities access to affordable and meaningful prescription drug coverage. We recognize that this delay and many of the issues we raise may require legislative changes—we hope that, when necessary, CMS will support efforts to remedy critical issues through legislation.

## **COMMENTS ON PREAMBLE AND PROPOSED RULE**

### **SUBPART B—ELIGIBILITY AND ENROLLMENT**

**§423.30(D)(1) DUALS ELIGIBLES MUST NOT BE LIMITED TO THE “AVERAGE COST PLAN.”**

The federal premium subsidy for the dual eligible population will be limited to the premium for the average cost plan in their area. The restriction could leave dual eligibles without meaningful access to the full range of prescription drug plans in their area. Dual eligibles are the sickest and poorest Medicare beneficiaries and have extensive prescription drug needs and minimal or no resources to pay for them. It is imperative that the Medicare beneficiaries who are most dependent on drugs have access to the plan that will best meet their needs rather than limiting them to what could be the plan with the weakest drug benefit. Dual eligible individuals should not be charged a premium for enrolling with any plan. At a minimum, if the beneficiary or his or her medical provider can attest that a higher premium plan will better meet their medical needs, then the beneficiary should be allowed to enroll in the plan at no cost to the beneficiary.

**§423.44(D)(2) PRESCRIPTION DRUG PLANS SHOULD NOT BE ALLOWED TO DISENROLL BENEFICIARIES FOR DISRUPTIVE BEHAVIOR.**

We are very concerned that the proposed rules would allow prescription drug plans to disenroll beneficiaries if their behavior is “disruptive, unruly, abusive, uncooperative or threatening.” In the absence of clearly defining these terms, drug plans would have the latitude to discontinue drug coverage for behaviors that they deem “threatening” and places beneficiaries at risk who simply may be questioning a plan’s coverage decision. Most concerning is that there is no protection for individuals who may be exhibiting behaviors that could be perceived as “disruptive or threatening” due to a drug interaction or reaction; untreated or inappropriately treated mental illness or diminished mental capacity due to another condition. We ask that the standard and definitions of these terms be clearly defined by CMS and that the behavior not be due to diminished mental capacity or treatment noncompliance.

**§423.50 STRICT GUIDELINES MUST BE APPLIED TO THE RELEASE OF INDIVIDUAL IDENTIFYING INFORMATION TO PRESCRIPTION DRUG PLANS.**

We have grave concerns regarding the provision in the MMA law that allows the Secretary to disclose personal identifying information to prescription drug plans. Disclosure of personal information for these purposes is contrary to fair information practice principles and is particularly unacceptable for Medicare beneficiaries with diseases that carry significant stigma and whose populations experience discrimination such as HIV/AIDS and mental illnesses. While we understand that the sharing of the information is intended to allow prescription drug plans to assist with outreach and enrollment activities, other opportunities exist for prescription drug plans to assist with these efforts such as through distributing materials at community health or senior centers.

It is critical that CMS include the provisions below in the final rule to govern the disclosure of individual identifying information to prescription drug plans.

1. Personal identifiable information should only be provided to prescription drug plans that are distributing specifics regarding the plan's drug formulary and associated cost sharing.
2. Personal identifiable information disclosed must be limited to the minimum amount necessary, which would be the potential beneficiary's name and address. Phone numbers must not be disclosed and absolutely no health data or income data should be disclosed to drug plans prior to enrollment. We foresee numerous opportunities for serious misuse of health and financial data and strongly advise CMS to prevent potential negative consequences by explicitly prohibiting the release of this information.
3. If the Secretary decides to disclose individual identifiable information, Medicare beneficiaries must have the option to not have their information disclosed. We recommend an opt-in approach that requires beneficiaries to consent to the sharing of information rather than forcing beneficiaries to request that their information not be shared. The notice requesting a beneficiary's permission to disclose information must be written in plain, easily understood language that clearly specifies the information to be disclosed, who it is being disclosed to and what it will be used for. Furthermore, materials should be printed in large type, written at an 8<sup>th</sup> grade literacy level and translated into languages appropriate to the community.

Finally, it is important to reiterate in the final rule that if the Secretary discloses identifiable information that use of the information is strictly limited to the purposes for which it is intended.

We also have a number of concerns regarding privacy issues raised by CMS in the preamble to the proposed rule that we will address collectively in this paragraph. Since the beginning of the HIV/AIDS epidemic in the United States, people living with HIV/AIDS have been subject to pervasive stigma and discrimination. Inappropriate disclosure of HIV status and other personal health information has led to lost employment, personal violence, and other serious consequences. Over the last decade, many of our member organizations have been actively engaged in the policy debate over the establishment of a national floor of privacy protections. Indeed, because of the unique role of people living with HIV/AIDS both as recipients of quality health and medical services that are made possible by the free flow of individually identifiable health information and potential victims resulting from inappropriate disclosures of personal health information, we have been engaged in the policy debate over the HIPAA privacy rule and other privacy issues. We view the marketing provisions addressed in the proposed rule as inextricably linked to need for critical privacy protections. These protections cannot be extended to Medicare beneficiaries simply by asserting that prescription drug plans must follow the HIPAA privacy rule. We strongly recommend that prescription drug plans be banned from telemarketing. We also strongly disagree with the CMS suggestion that it could be beneficial for prescription drug plans to be allowed to market other services such as financial services to beneficiaries. It is

inappropriate for private companies to have the opportunity to sell other services to seniors and people with disabilities under the guise of the federal government. We see absolutely no benefit to this approach, but many opportunities for fraud and abuse. We strongly recommend that CMS prohibit prescription drug plans from marketing or providing other goods and services “in conjunction with” with the part D benefit. Finally, we strongly recommend that prescription drug plans and other entities be prohibited from obtaining or using individual identifiable health information collected or maintained by a Medicare Drug Discount Card Program for marketing.

### **SUBPART C—BENEFITS AND BENEFICIARY PROTECTIONS**

#### **THE INTERACTION OF THE PART D PROGRAM WITH STATE AIDS DRUG ASSISTANCE PROGRAMS (ADAPs) REQUIRES THOUGHTFUL CONSIDERATION**

While we appreciate the opportunity to weigh-in on possible coordination between AIDS Drug Assistance Programs (ADAPs) and private Part D plans, we are deeply troubled by the CMS denial of a comprehensive prescription drug benefit to people living with HIV/AIDS. Explicitly excluding ADAPs from being able to provide wrap-around coverage in a manner that would allow beneficiaries to reach the catastrophic limit seriously undermines the federal government’s priority of providing comprehensive health care to people living with HIV/AIDS. ADAPs are an integral component of the safety net for people living with HIV/AIDS in this country and have a long history of filling gaps left by other Federal programs, including Medicaid and Medicare. We strongly recommend that the final rule count cost-sharing subsidies from ADAPs as incurred costs.

Congress appropriates federal funds for ADAP programs on a discretionary basis. Notwithstanding the decision by a state to use ADAP funds to subsidize Part D cost-sharing, federal costs do not increase. It makes little sense for the federal government to restrict use of state ADAP funds in this fashion. Further, ADAP funding has not kept pace with growing need over the past decade, and this has led to increases in the number of individuals on waiting lists for ADAP services, as well as restrictions and limitations in ADAP formularies and eligibility. Regrettably the availability of the Part D benefit will do little to reduce financial pressure on ADAP funds because such funds cannot count toward the catastrophic limit and the benefit itself is too limited to respond to the needs of Medicare beneficiaries with AIDS. In this environment, federal policy should not create a disincentive for states to wrap-around the Medicare Part D benefit. .

When the Medicare prescription drug benefit begins, ADAPs may have several roles to play. While we understand that CMS is hopeful that all prescription drug plans (PDPs) will include all necessary HIV-related drugs on their formularies, it is not required. Therefore, even individuals who benefit from the low-income protections included in the benefit may find themselves turning to ADAPs to receive all the necessary medications. In addition, even Medicare subsidized cost-sharing for low-income Medicare Part D enrollees could provide a significant barrier to prescription drugs. This has grave implications both for the medical management of HIV/AIDS in the affected individual,

but also public health implications resulting from increased risk of the development of resistance to currently available HIV-related antiretroviral medications and therefore an increased risk of transmission. ADAPs will also play a vital role for Medicare beneficiaries living with HIV who have incomes above 150% FPL. These individuals will most likely need assistance with drug costs during the “donut-hole.” Not allowing ADAP expenses spent on premiums, deductibles, cost-shares or the amount spent filing in the donut hole, allows people living with HIV/AIDS who receive Medicare benefits to fall through the cracks.

In several places in the proposed regulations, CMS has acknowledged the unique situation of Medicare beneficiaries living with HIV/AIDS. The treatment of HIV disease is extremely complex and specific to the infected individual. Specific drug combinations and adherence to the prescribed medications is essential to the successful treatment of HIV. Disallowing ADAP expenses to count towards “incurred costs” runs counter to CMS’ apparent understanding of the circumstances of individuals living with HIV/AIDS.

We are very concerned that the regulations also specifically state that state-appropriated dollars spent by ADAPs cannot be counted as incurred costs. It is discriminatory and unacceptable to single out state dollars used to provide medications to people living with HIV/AIDS while at the same time allowing state dollars to be used for State Pharmaceutical Assistance Programs’ (SPAPs) expenditures on behalf of a beneficiary. Under the proposed regulations, SPAPs are allowed to wrap-around in a way that all costs spent on the behalf of a beneficiary count as incurred costs. States should have the flexibility to provide prescription drugs to a variety of populations, including people living with HIV/AIDS, with the state dollars appropriated. It is inexcusable to exempt people living with HIV/AIDS from receiving this type of help from their state, while allowing people with other medical conditions to benefit from their state dollars. Ironically, persons with AIDS who live in states with SPAPs and who are eligible for their assistance, will have SPAP costs count toward incurred costs, while those who rely on ADAP will not.

States recognize the importance of providing prescription drugs to individuals living with HIV/AIDS. In the majority of states, ADAPs are a mix of federal and state dollars. In FY2003 states contributed over \$171 million dollars of state general revenue money to their ADAPs, not including required state match dollars. To ban states from using the state funds that have they designated to provide drugs to people living with HIV/AIDS in a way that contributes to a Medicare beneficiary’s incurred costs overreaches the federal government’s authority.

The regulations encourage state ADAPs to move toward the model of purchasing their drugs directly, under the 340B program, instead of using a rebate model. We feel it is completely inappropriate for CMS to use these proposed regulations to comment on the mechanics of a program that is not under its purview. Participation in the 340B Program is not mandatory, but rather is strongly encouraged by the Health Resources and Services Administration (HRSA), the federal agency that oversees the Ryan White CARE Act and the 340B Program.

As mentioned, there are several states that use a rebate option model available to ADAPs under 340B to purchase drugs instead of the direct purchase model. These states, including California and New York, the two largest ADAPs, have carefully analyzed the cost benefits and risks of each drug purchasing and distribution system. California recently conducted an extensive study which demonstrated that after calculating rebates, they receive prices for HIV pharmaceuticals comparable to those paid by states using direct purchase mechanisms. Direct purchase ADAPs often have additional dispensing and distribution costs that also must be considered in the total cost when comparing these two purchasing mechanisms. Additionally, there are many factors that states must consider to minimize access barriers when choosing a model for drug purchasing, including the size and geography and demographics of the populations they are trying to serve. The state's existing health care and pharmacy infrastructure are also key considerations in the model chosen. ADAPs have and will continue to use every mechanism available to receive the best prices for their HIV-related drugs, including negotiating for supplemental rebates and discounts.

Any coordination between ADAPs and the Medicare Part D PDPs is, under the proposed rules, completely voluntary on the part of the PDPs. There are several issues that would inhibit the coordination of benefits between ADAPs and PDPs. Most importantly, since ADAPs' expenditures for beneficiaries would not count as incurred costs and thereby not allowing many of the HIV-positive beneficiaries' living with HIV/AIDS to reach the catastrophic limit, ADAPs would have no strong incentive to collaborate with private drug plans. Furthermore, PDPs could charge ADAPs for any coordination between the two entities. The proposed coordination would not result in any significant amount of cost savings and would not be cost-effective for the ADAPs. Finally, it could potentially be very difficult for ADAPs to coordinate with multiple PDPs participating in the Medicare program in a given area. Under these proposed rules, it is not feasible for ADAPs to coordinate with PDPs. However, if CMS would allow payments made by ADAPs to count as incurred costs, coordination between ADAPs and PDPs could result in substantial costs savings and therefore provide incentive for ADAPs to collaborate with PDPs.

State HIV/AIDS program staff are interested in exploring methods of collaboration between ADAPs and PDPs that could allow beneficiaries living with HIV/AIDS to benefit from the 340B pricing. We understand that several 340B entities have begun entering into partnerships with various state and local government programs to provide more individuals access to 340B pricing. However, there are so many complexities and unknowns about the Medicare Part D prescription drug program and its effects on ADAPs that it is premature to comment or offer details on any such collaboration.

## **§423.120 ACCESS TO COVERED PART D DRUGS**

**PEOPLE LIVING WITH HIV/AIDS ARE A SPECIAL POPULATION THAT REQUIRE SPECIAL TREATMENT AND ACCESS TO AN OPEN FORMULARY**

We strongly support the CMS recommendation to implement “open formularies” for special populations and strongly recommend that people with AIDS be defined as a special population. We feel this is critical to ensuring that Medicare beneficiaries with AIDS have continued and unhindered access to all of the drugs that are medically necessary for treating the disease. Furthermore, an “open formulary” will prove cost effective because it will prevent the use of more intensive and costly health care resources such as inpatient hospitalization that will occur if Medicare beneficiaries with AIDS are denied access to medically necessary prescription drugs. While the private drug plans are not at risk for this potential cost shifting, the federal government will incur these costs either through higher Medicaid expenditures or higher Medicare Part A and B expenditures.

Antiviral drugs, the linchpin of successful HIV treatment, are a very unique set of compounds that are not interchangeable even within the same drug class. Positive treatment outcomes depend on people living with AIDS having access to all anti-HIV drugs available to suppress the virus. If drug plans fail to cover all anti-HIV drugs and at the lowest tier of cost sharing, it is extremely unlikely that Medicare beneficiaries will have the resources to obtain these life-saving drug therapies.

Furthermore, an “open formulary” that provides access to all medically necessary drugs would serve as a safeguard for Medicare beneficiaries with AIDS, many who are dually eligibles. Failure to adopt an “open formulary” for Medicare beneficiaries with AIDS will make it impossible to guarantee that they maintain the level of access to prescription drugs that is comparable to that provided by Medicaid programs. However, in order for the “open formulary” to be meaningful, other protections must be clearly stated in the regulation including requiring plans to include anti-HIV drugs in the lowest cost-sharing tier and ensuring that physicians are not required to pursue a burdensome prior approval process before prescribing anti-HIV medications.

For Medicare beneficiaries with HIV/AIDS, access to all medically necessary drugs is critical. We strongly recommend that “open formulary” be defined according to a specific population such as Medicare beneficiaries with HIV/AIDS rather than a class of drugs such as anti-HIV drugs. HIV clinicians must take into account drug interactions with therapies for co-morbid conditions when prescribing medications for people living with AIDS, which necessitates access to particular medications that clinicians deem appropriate for treating serious co-morbid conditions such as hepatitis C, depression, heart disease, diabetes, and liver disease. All of these are increasingly common co-morbid conditions among people living with AIDS. As with other complex conditions, successful treatment of HIV disease requires access to all of the drugs necessary to treat an individual’s comorbid conditions and side effects. Failure to effectively treat comorbid conditions significantly affects adherence to the HIV therapy regimen<sup>1</sup> and results in more rapid progression of the disease. It is critical that clinicians are not restricted in their ability to prescribe the appropriate medications for all of the medical needs of people

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<sup>1</sup> Reynolds NR, Testa MA, Marc LG, et al. Factors influencing medication adherence beliefs and self-efficacy in persons naïve to antiretroviral therapy: a multicenter, cross-sectional study. *AIDS Behav.* 2004;8(2):141-150.

living with HIV/AIDS. As discussed earlier, Medicare beneficiaries with AIDS under 65 who by definition are completely disabled and unable to work do not have the resources to supplement inadequate drug coverage if the drug that they need is not included on the drug plan's formulary.

**WE STRONGLY SUPPORT THE NEED FOR SPECIAL PROVISIONS AND PROTECTIONS FOR SPECIAL POPULATIONS WITH REGARDS TO COST CONTAINMENT MEASURES.**

We appreciate the acknowledgment by CMS that certain populations may be discriminated against and adversely affected by cost containment measures implemented by prescription drug plans. We strongly encourage CMS to learn from the experience of Medicaid programs that have tried to balance containing costs with maintaining access to medically necessary medications. Based on their experience, most Medicaid programs have exempted people living with HIV/AIDS and other complex conditions from cost containment measures such as preferred drug lists or monthly drug limits.<sup>2</sup>

We also appreciate that CMS is recognizing the need for protections for special populations in the context of cost containment measures. Again, we strongly encourage CMS to learn from the experience of Medicaid programs, such as Colorado and Oregon which had initiated measures such as monthly drug limits or burdensome approval processes that they later rescinded or relaxed. Health services research strongly supports the use of special cost containment measures for public programs serving individuals who have low incomes and/or are disabled that are different from those used by programs in the private market serving a healthier and working population.<sup>3</sup>

We ask that the non-discrimination rule be enforced by ensuring that plans cannot place HIV medications on the higher cost-sharing tiers. Medicare beneficiaries with AIDS, especially low-income beneficiaries, will not be able to afford their medications if they are not available at the lowest cost-sharing level. If an individual with HIV/AIDS needs an HIV-related medication, or a non-HIV drug, the drug should be available at the lowest cost-sharing tier. We encourage CMS to grant serious consideration to the numerous studies that demonstrate that even modest levels of cost sharing result in low-income individuals, people with chronic illnesses and seniors being deprived of medically necessary prescription drugs.<sup>4</sup>

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<sup>2</sup> Kaiser Commission on Medicaid and the Uninsured. Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003. December 2003. Available online at [www.kff.org/rxdrugs/medicaid.cfm](http://www.kff.org/rxdrugs/medicaid.cfm). Kaiser commission on Medicaid and the uninsured. Model Prescription Drug Prior Authorization Process for State Medicaid Programs. April 2003. Available online at [www.kff.org/rxdrugs/medicaid.cfm](http://www.kff.org/rxdrugs/medicaid.cfm).

<sup>3</sup> See testimony presented by Health Care Strategies Consultancy to the West Virginia Legislative Panel in July 2003. The testimony is available by emailing [info@healthstrategies.net](mailto:info@healthstrategies.net). Additional evaluations of Medicaid programs and preferred drug lists are available from the Kaiser Family Foundation at [www.kff.org/rx.drugs/medicaid.cfm](http://www.kff.org/rx.drugs/medicaid.cfm).

<sup>4</sup> See: Goldman DP, Joyce GF, Escarce JJ et al. Pharmacy benefits and the use of drugs by the chronically ill. *Journal of the American Medical Association*. 2004;291:2285. Cunningham, PJ. Affording prescription drugs: not just a problem for the elderly. April 2002. Center for Studying Health System Change. Online at [www.hschange.org](http://www.hschange.org). Leighton K. Charging the more for health care: cost-sharing in Medicaid. May 2003. Center on Budget and Policy Priorities. Online at [www.cbpp.org](http://www.cbpp.org).

**§423.120(B)(1) FORMULARY POLICIES MUST RESPOND TO THE CLINICAL NEEDS OF MEDICARE BENEFICIARIES.**

We strongly support the CMS recommendations to require greater independence and increased specialty representation on the Pharmaceutical and Therapeutic (P&T) Committees and other efforts to enhance their authority.

We support the CMS interpretation of the law that would make formulary decisions made by P&T Committees binding. We feel if the P&T Committees are not granted the authority to make binding decisions that their rigorous evaluations could be rendered meaningless if not accepted by the prescription drug plans. Furthermore, prescription drug plans are unlikely to have the expertise to make such decisions and may be unduly influenced by cost as opposed to quality of care.

We do not feel that one independent physician and one independent pharmacist is adequate to ensure a formulary that is based on medical evidence rather than cost. We recommend that CMS require that a majority of P&T Committee members be independent and free of conflict with respect to the PDP sponsor and the prescription drug plan to ensure that recommendations by independent members are not ignored or outvoted. We also strongly support requiring representation from multiple medical specialties that represent the diversity of people served by the Medicare program on the Committee. Additionally, all HIV-related decisions should be made by or in consultation with an HIV experienced clinician. P&T Committees will play a critical role in determining the prescription drugs available to Medicare beneficiaries with AIDS have access to, and it is essential that these decisions are grounded in the latest medical evidence and are not compromised by possible conflicts of interest.

We recommend “requiring” instead of “encouraging” P&T Committees to include representation from a variety of medical specialties. In recognition of the fact that it will be impossible for committees to include members from all medical specialties, we also recommend requiring plans to have formal contractual relationships with an HIV experienced provider to advise the P&T Committee on HIV-related treatment decisions and other specialists whose expertise is not represented on the committee. The requirement that the P&T Committee include one practicing physician member with expertise in the care of elderly and disabled is vague and inadequate. Neither seniors nor people with disabilities are homogenous populations. It is not feasible for one physician to have the expertise to evaluate the prescription drug needs of people with serious conditions such as multiple sclerosis, diabetes, schizophrenia and HIV/AIDS.

We strongly recommend that drug plans be required to cover more than two drugs per category or class for certain categories and for “special populations.” Limiting coverage to two per class is wholly inadequate and will result in a federally funded program that does not support the basic standard for HIV care. Drugs within the anti-HIV classes are very different compounds, are not interchangeable, and are not available in generic form.

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Furthermore, people living with HIV/AIDS must change the drugs within the HAART regimen multiple times due to drug resistance or toxicity. Failure to require prescription drug plans to cover all anti-HIV drugs will have detrimental effects on Medicare beneficiaries with AIDS, which for some beneficiaries could include premature death.

We strongly recommend strengthening the CMS reference to P&T Committees' consideration of the Public Health Service guidelines for the treatment of HIV disease and related opportunistic infections by requiring P&T Committees to cover all drugs referenced in the federal guidelines. The enormous variation in drug resistance<sup>5</sup>, drug tolerance and toxicity,<sup>6</sup> drug interactions, co-morbid conditions<sup>7</sup>, and virulence of the HIV strain requires that clinicians have access to all of the drug therapies available to treat HIV disease. Requiring drug plans to cover all of the drugs recommended in the federal guidelines is critical to ensuring that all of the prescription drug plans cover the range of anti-HIV drugs that are medically-necessary for successful treatment of HIV disease.

We also support involvement of P&T Committees in designing policies that will be used to encourage use of preferred drugs such as the cost sharing tier structure. It is very important for these decisions to be made with serious consideration given to ensuring that certain populations who have chronic conditions, such as people with AIDS, who require a daily regimen of prescription drugs, do not face discrimination in regard to cost sharing. P&T Committees would provide the appropriate insight and expertise necessary for making these decisions.

**DRUG PLANS SHOULD BE REQUIRED TO COVER THE PRESCRIBING OF DRUGS FOR OFF-LABEL PURPOSES WITHOUT PLACING UNDUE BURDEN ON CLINICIANS WHEN SUCH PRESCRIBING IS STANDARD PRACTICE WITHIN THE MEDICAL COMMUNITY.**

We strongly recommend strengthening the language regarding coverage of drugs for off-label uses. We feel it is imperative that prescription drug plans be required to cover medically accepted uses of drugs for off-label uses that are standard practice in the medical community. For HIV disease, as with many complex conditions, actual clinical use frequently runs ahead of label indications as practicing physicians learn what drug combinations best target their patient's symptoms and side effects. As examples, tenofovir (Viread) has proven effective for treating hepatitis B for people with HIV,

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<sup>5</sup> Fifty to seventy percent of treatment-experienced people living with AIDS develop drug resistance. Source: Wensing AM, Boucher CA. Worldwide transmission of drug-resistant HIV. *AIDS Rev.* 2003;5(3):140-155.

<sup>6</sup> According to HIV experts, fifty percent of people living with HIV develop toxicity that precludes continued use of certain antiretrovirals. Decisions regarding substitutions need to be made from the broad selection of antiretrovirals due to overlapping toxicities.

<sup>7</sup> As examples, 30 percent of people with HIV are co-infected with hepatitis C. Source: Fleming CA, Christiansen D, Nunes D, et al. Health-related quality of life of patients with HIV disease: impact of hepatitis C coinfection. *Clinical Infectious Diseases.* 2004;38:572-578. At least 50 percent of people with HIV have psychiatric diagnosis. Source: Bing EG, Burnam A, Longshore D, et al. Psychiatric disorders and drug use among human immunodeficiency virus-infected adults in the United States. *Arch Gen Psychiatry.* 2001;58:721-728.

although treatment for hepatitis B is not an indicated use of the drug. In addition, many protease inhibitors have been shown to be more effective in suppressing the HIV virus if they are boosted with ritonavir (Norvir), although in most cases there is no label indication for this. Atazanavir (Reyataz) and saquinavir (Invirase) are two examples of protease inhibitors that are used in conjunction with ritonavir.

We also feel it is inappropriate to place undue administrative burdens on physicians by requiring them to “clearly document and justify” off-label drug use if such prescribing is recognized as commonly accepted practice in the medical community. We are concerned that requiring clinicians to “clearly document and justify” off-label prescribing is an attempt to shift medical decision making from clinicians to CMS and/or drug plan sponsors.

**REQUIRE DRUG PLANS TO COVER NEW ANTI-HIV DRUG THERAPIES.**

We strongly recommend that prescription drug plans be required to add new categories or classes of anti-HIV therapies upon approval by the Food and Drug Administration. The standard of care for HIV disease rapidly changes and many Medicare beneficiaries with AIDS have already exhausted the current drug therapies available. It is critical that they have timely access to the newest therapeutic advances. Federal HIV treatment guidelines are revised quickly when a new HIV drug is approved; the drug plans providing these lifesaving medications to beneficiaries should be required to do the same.

**REQUIRE DRUG PLANS TO EVALUATE PROTOCOLS QUARTERLY.**

We strongly encourage CMS to outline clear requirements regarding prescription drug plans evaluations of protocols. CMS should define “periodically” to be quarterly and specify criteria for which the drug plans should base their evaluations, e.g., the number of exception requests filed for off-formulary drugs; trends in exception and appeals requests for certain drugs; and the average length of time it takes to process prior authorization requests (if applicable). Additionally, drug plans should be required to have a mechanism for beneficiaries and health care providers to provide feedback which will be incorporated into the evaluation process. Furthermore, we feel it is critical for evaluations to incorporate indicators that ensure a beneficiary’s health status is not compromised due to inability to access medically necessary prescription drugs.

**REQUIRE A MINIMUM 90-DAY NOTIFICATION FOR FORMULARY CHANGES.**

We strongly recommend extending the period of time that is required for drug plans to notify affected enrollees and other parties when removing a drug from a formulary to at least 90 days. We feel this is the minimum amount of time required to allow Medicare beneficiaries with AIDS to consult with their physicians and apply for an exception if their physicians do not think it clinically prudent to switch medications. We also strongly recommend that drug plans be required to provide notice in written format.

**PROVIDE BENEFICIARIES WITH DETAILED BENEFIT INFORMATION BEFORE THEY SELECT A PLAN.**

We strongly recommend that CMS provide detailed information on drug plan formularies to health care providers and beneficiaries before beneficiaries are required to select a plan. The information should be translated into languages based on the needs of the community. At a minimum, drug plans should be required to disclose and CMS should publicize the prescription drugs and dosages drug plans cover, cost sharing associated with respective drugs and any special cost containment rules that apply to the drug. We support a model similar to the online database used by the Medicare Drug Discount Cards. However, it is essential that this information is available in other formats such as written mailings to prospective enrollees. Furthermore, Medicare beneficiaries with AIDS should have the option to request detailed information before they make a selection and not be penalized if the information is not presented in a timely manner. We strongly recommend that the 24 hour/7 day a week toll free information lines be publicized and available to Medicare beneficiaries before they are required to select a plan to respond to prospective enrollees questions regarding coverage. It is absolutely critical that Medicare beneficiaries with AIDS know whether a drug plan covers the multiple medications that comprise their lifesaving daily drug regimen and the associated out-of-pocket costs before they are required to enroll in a drug plan.

**DO NOT PENALIZE BENEFICIARIES WHEN THEY MUST OBTAIN DRUGS FROM OUT-OF-NETWORK PHARMACIES.**

We object to the requirement making Medicare beneficiaries responsible for cost differentials if they must obtain drugs from an out-of-network pharmacy. It is inappropriate to penalize the beneficiary – particularly those who are dually eligible – if their condition requires them to obtain medically necessary drugs from an out-of-network pharmacy whether it is because they get sick when away from home or because an in-network pharmacy is closed. People living with AIDS may develop complications or experience serious side effects that require immediate attention and should not be penalized if their health status requires them to obtain drugs from an out-of-network pharmacy. We recommend that the regulation be revised to stipulate that beneficiaries are not responsible for cost differentials if it is medically necessary for the beneficiary to fill the prescription, and there is no access to an in-network pharmacy.

**THE US PHARMACOPEIA’S PROCESS FOR DEVELOPING THE “MODEL GUIDELINES” DID NOT PROVIDE SUFFICIENT OPPORTUNITY FOR PUBLIC DIALOGUE AND INPUT INTO THE DEVELOPMENT OF THE “MODEL GUIDELINES.”**

We were very disappointed in the US Pharmacopeia’s (USP) process for developing and soliciting public comment on the “model guidelines.” At the one public meeting that was held, less than four hours was devoted to public comment. While we appreciate the opportunity to submit written comments, the lack of an opportunity for dialogue or to publicly voice concerns is very troubling given the magnitude of the decisions made by USP and the millions of beneficiaries who will be affected. Furthermore, the lack of a

transparent and appropriate process is troubling given that prescriptions drug plans that adhere to the recommended categories and classes developed by USP will be virtually free from scrutiny or oversight by CMS. It is completely inappropriate for a drug plan that reflects the USP model formulary to be shielded from potential charges of discrimination against specific subpopulations based on formulary

### **SUBPART M—GRIEVANCES, COVERAGE DETERMINATIONS, AND APPEALS**

#### **THE PROPOSED REGULATIONS FAIL TO MEET CONSTITUTIONAL DUE PROCESS REQUIREMENTS AND FAIL TO SATISFY THE REQUIREMENTS OF THE STATUTE.**

As interpreted by the United States Supreme Court, due process requires adequate notice and hearing when public benefits are being terminated. Medicaid beneficiaries whose prescription requests are not being honored currently receive a 72-hour supply of medications pending the initial coverage request. They are entitled to notice, face-to-face hearings, and aid paid pending an appeal if their request is denied and they file their appeal within a specified time frame. All state Medicaid appeals processes are completed more expeditiously than Medicare appeals. The appeals process as described in Subpart M does not accord dual eligible and other Part D enrollees with adequate notice of the reasons for the denial and their appeal rights, with an adequate opportunity to a face-to-face hearing with an impartial trier of fact, with an adequate opportunity to have access to care pending resolution of the appeal, or with a timely process for resolving disputes. While we recognize that the most efficient means of protecting enrollees, amending the MMA to provide for an appeals process similar to Medicaid, is beyond the authority of CMS, CMS can take steps in the final regulations to improve notice and the opportunity for speedy review.

Sections 1860D-4(f), (g), and (h) require that Part D plan sponsors establish grievance, coverage determination and reconsideration, and appeals processes in accordance with Sections 1852(f), (g) of the Social Security Act. In addition, CMS, in implementing Section 1852(c) and in settlement of *Grijalva v. Shalala*, adopted 42 C.F.R. 422.626, which establishes the right to a fast-track, pre-termination review by an independent review entity. The proposed Subpart M fails to incorporate the same fast-track, pre-termination review for Part D. CMS needs to incorporate a similar process for Part D in order to establish a process in accordance with Section 1852(c). A similar fast-track process would also be more in keeping with due process requirements.

#### **THE FINAL RULE MUST PROVIDE FOR DISPENSING AN EMERGENCY SUPPLY OF DRUGS PENDING THE RESOLUTION OF AN EXCEPTION REQUEST OR PENDING RESOLUTION OF AN APPEAL.**

It is unconscionable for CMS to publish a final rule that does not include mandatory, enforceable provisions for preventing treatment interruptions and for requiring plans to dispense a temporary supply of covered Part D drugs pending the resolution of an exceptions request (or in the case of an exception denial, final resolution of an appeal).

For many conditions, treatment interruptions can lead to serious short-term and long-term problems. Successful treatment of HIV disease requires near perfect adherence to a daily regimen of at least three to four drugs. For people with HIV/AIDS, even temporary interruptions in treatment can spur the development of drug resistant strains of HIV that have broad implications for the public health, and seriously compromise the likelihood that an individual will continue to benefit from their current drug regimen and jeopardize treatment success with any of the available anti-HIV medications. Fifty to seventy percent of people living with AIDS develop drug resistance.<sup>8</sup> Failure to prevent treatment interruptions by supplying a temporary drug supply will contribute to this statistic. Beyond concerns about resistance, treatment interruptions can also lead to serious consequences including irreversible declines in immune functioning, unnecessary hospitalizations, or the development of HIV-related opportunistic infections.

Our concerns over treatment interruptions are heightened due to the absence of adequate protections that ensure that individuals can receive a timely resolution of an appeal, and the lengthy period that will pass before an individual has access to a fair and independent review of an appeal by a decision maker completely independent and free of conflict with the plans at the Administrative Law Judge (ALJ) level. We recognize that the expedited timeframes and the general 72-hour standard are a significant improvement over the standard timeframe of 14 days to make a determination and 30 days for a reconsideration. Nonetheless, from the perspective of the clinical management of HIV infection, 72 hours is an unacceptable delay. We strongly recommend that the final rule clearly specify that all disputes relating to coverage of Part D drugs for people living with HIV/AIDS automatically qualify for an expedited decision (for all types of requests including a request for an exception, a grievance, and all level of the appeals). Moreover, we strongly recommend that the final rule clearly require plans to dispense a temporary supply of the drug in dispute pending the final outcome of an appeal in all cases of emergency, including all cases involving people living with HIV/AIDS.

**THE PROPOSED EXCEPTIONS PROCESS IS UNWORKABLE AND NEEDS TO BE SIGNIFICANTLY REVAMPED.**

The provisions in the MMA that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with HIV/AIDS and other persons with serious and complex conditions receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. We appreciate that the proposed rule clarifies that non-formulary drugs are eligible for consideration by the exceptions process. As structured in the proposed rule, however, the exceptions process would not serve a positive role for ensuring access to medically necessary covered Part D drugs. Rather, the exceptions process only adds to the burden on beneficiaries and physicians by creating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process.

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<sup>8</sup> Wensing AM, Boucher CA. Worldwide transmission of drug-resistant HIV. *AIDS Rev.* 2003;5(3):140-155.

We recommend that CMS revamp the exceptions process to achieve the following goals:

- Establish clear standards by which prescription drug plans must evaluate all exceptions requests;
- Minimize the time and evidence burdens on treating physicians. We are particularly troubled that the proposed rule would require treating physicians to assert that an exceptions request is based both on clinical experience and scientific evidence. This is an inappropriate standard that most HIV physicians could not meet because scientific evidence is not always available to support the knowledge they gain through clinical experience treating people living with HIV. We also believe that this requirement goes well beyond the statute, which states, “Under such an exception, a nonpreferred drug could be covered under the terms applicable for a preferred drug if the prescribing physician determines that the preferred drug for the treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both”;
- Ensure that all drugs provided through the exceptions process are made available under the terms applicable for a preferred drug for the treatment of the same condition.
- Require reporting to CMS of statistical data related to the exceptions and appeals processes. This including requiring plans to report to CMS the number of exceptions requests, the nature of exception requested and the specific drugs involved, the average time that passes for resolution of an exceptions request and all in-plan steps of the grievance and appeals processes, and the final resolution of each exception, grievance, and appeal request. Furthermore, the final rule should require CMS to annually analyze statistical information and make plan-specific summary information available to the public.

**CMS MUST ENSURE DRUGS ARE NOT INAPPROPRIATELY CLASSIFIED AS EXCLUDED DRUGS AND COVERAGE DISPUTES OVER EXCLUDED DRUGS MUST BE ELIGIBLE FOR AN APPEAL.**

The MMA references the Medicaid Act in prohibiting Part D plans from providing coverage for drugs that are excludable under §§1927(d)(2) and (3) of the Social Security Act, except for smoking cessation agents. We are troubled to learn through informal communications that CMS is developing a list of excluded drugs that Part D plans are prohibited from covering. Many of the categories of excludable drugs in §1927(d)(2) refer to drugs when used for a specific purpose. Therefore, it is inappropriate to simply provide a listing of drugs that Part D plans must exclude because this could include drugs that are excludable or coverable depending on the specific clinical use. We recommend that the final rule clearly state that Part D plans are only permitted to prohibit coverage for specific drugs when they meet the statutory requirements of §1927(d)(2) and they must provide coverage for potentially excludable drugs when they are prescribed for a clinical use not covered by this section.

We are also deeply troubled that the proposed rule would deny access to the exceptions and appeals process for coverage disputes involving excluded drugs. Experience in the Medicaid program with several high-cost, but clinically important drugs used in the treatment of HIV/AIDS illustrates the risk by not providing Medicare beneficiaries due process with respect to coverage disputes involving excluded drugs. In the past, state Medicaid programs have denied coverage for drugs used to treat AIDS wasting, a serious, life-threatening condition, by inappropriately claiming that a drug was excludable. It only has been through reliance on access to the Medicaid appeal system and consumer advocacy that Medicaid beneficiaries with HIV/AIDS in some states have gained access to drugs necessary for the treatment of AIDS wasting. We strongly recommend that the final rule delete all provisions in the proposed rule that restrict access to the exceptions, grievance, and appeals systems for coverage disputes related to excluded drugs.

**SUBPART P –PREMIUMS AND COST SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS**

**§423.782(A)(2)(III) DUAL ELIGIBLE BENEFICIARIES MUST NOT BE DENIED MEDICATIONS FOR FAILURE TO PAY CO-PAYMENTS.**

Dual eligible beneficiaries will be required pay to \$1 for generic drugs and \$3 for brand-name drugs under Medicare Part D. Currently under Medicaid statute, an individual cannot be denied a medication for failure to pay a co-payment. People with HIV/AIDS depend on a daily regimen of multiple medications (most of which are non-generic). Even minimal co-payments will create a financial burden for individuals who will be left to choose between paying for medications and meeting other needs, like food and housing. Dual eligibles must maintain the protection that they currently have under Medicaid and not be denied a drug for failure to pay cost sharing. [423.782(a)(iii)]

**§423.782(A)(IV) AND §423.782(B)(2) LOW-INCOME INDIVIDUALS SHOULD NOT BE DENIED MEDICATIONS FOR FAILURE TO PAY CO-PAYMENTS.**

Low-income Medicare beneficiaries between 100% and 150% of the FPL face considerable cost-sharing requirements in the proposed regulations that could prevent them from filling necessary prescriptions. As previously referenced, a number of studies have demonstrated that even minimal levels of cost sharing restrict access to necessary medical care for individuals with low incomes. Individuals between 100% and 135% of FPL must pay \$2 for generics and \$5 for brand-name drugs. Those between 135% and 150% are required to pay a 15% co-insurance for their drugs. HIV medications are some of the most expensive on the market. This requirement will impose an enormous financial burden on thousands of individuals who will be unable to pay out-of-pocket for these medications. Beneficiaries eligible for the full or partial low-income subsidy should not be denied a prescription for failure to pay a co-payment or other co-insurance.

Again, we thank you for the opportunity to comment on these important regulations on the Medicare Part D prescription drug benefit. We would be happy to speak with you further about our comments and recommendations. Please feel free to contact us through

Laura Hanen, Director of Government Relations, National Alliance of State and Territorial AIDS Directors, at (202) 434-8090 or Christine Lubinski, Executive Director, HIV Medicine Association, at (703) 299-1215.

Sincerely,

[List in Formation]

HIV Medicine Association, Alexandria, VA

National Alliance of State and Territorial AIDS Directors, Washington, DC