2006-0003-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the Presidential Materials Staff.

Record Group/Collection: Al Gore Vice Presidential Records				
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Series: David Beier				
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OA/ID Number: 1017				
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until it's over
AIDSACTION

August 25, 1998

The Honorable Donna Shalala
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Shalala:

On behalf of AIDS Action, the national voice on AIDS, representing all Americans affected by HIV/AIDS and the 3,200 community-based service organizations that serve them, I am writing to highlight two important issues that are expected to be addressed in CDC's upcoming recommendations and report (R&R) on HIV surveillance. First, we want to stress the importance of anonymous HIV testing as a critical component of any effective HIV surveillance protocol. Second, we want to underscore the need to establish **reasonable** HIV/AIDS performance standards that states can realistically meet and not risk losing federal funding. I have also enclosed our resolution in opposition to a "one size fits all" approach to HIV surveillance which we discussed in a meeting in June with Deputy Secretary Kevin Thurm.

AIDS Action urges you to incorporate anonymous HIV testing requirements as a critical testing option in its upcoming R&R on HIV/AIDS surveillance. Numerous studies show that anonymous testing increases the number of people who get tested for HIV. For example, an HIV anonymous test site evaluation in Colorado indicated that people prefer anonymous testing over confidential testing, and are therefore more likely to undergo testing. Another HIV testing survey of 2,370 HIV-negative or untested persons at risk for HIV found that 85 percent would undergo anonymous testing, whereas only 75 percent would accept a confidential test. At least 230 high-risk people from this group would not seek testing without the guarantee of anonymity, suggesting that the elimination of anonymous testing programs would result in a decrease in the number of people who seek testing.

A publicly funded counseling and testing site comparison indicates that the impact of anonymous testing is especially pronounced in communities of color. This is a crucial finding given the fact that women and communities of color are now one of the most likely groups for contracting HIV. According to recent reports, African-American women are eight times more likely to contract HIV than white women. Anonymity is also an especially influential factor for other high-risk groups such as injection drug users (IDUs) and men who have sex with men (MSM). An Arizona study found that 22 percent of MSMs delayed testing until an anonymous option was available. Thus, anonymous testing encourages more people, especially those at higher risk, to come forward and get tested.

Indiana's recent elimination of anonymous testing programs coupled with Illinois' push towards the elimination of anonymous testing programs signal the need for the CDC to insist on the availability of anonymous testing in the context of a national HIV surveillance discussion. It was

studies suggest, the individuals at highest risk for contracting HIV – women, people of color, IDUs, MSMs – were deterred from testing for fear of having their name reported, health authorities would obtain less accurate and incomplete data on the epidemic. It is imperative that an anonymous testing option be included as part of any comprehensive HIV surveillance protocol *regardless* of how HIV infection is reported in those states.

We are also concerned with the performance standards promulgated in earlier drafts of the R&R. An analysis of the CDC's most recent *HIV/AIDS Surveillance Report* for 1997 exposes the shortcomings of the data for both AIDS and HIV surveillance programs. Despite the fact that AIDS surveillance is touted as the gold standard for disease surveillance, only 78% of AIDS cases listed a reported or identified risk. These statistics would fail to meet the CDC's performance standards. The data for states that are collecting names for HIV infection also falls short by reporting or identifying a risk for only 60% of all adult/adolescent cases, well below the 85% target mandated in earlier drafts of the R&R.

In addition, the populations with the highest percentages of HIV infections with risk not reported or identified for HIV coincide with the populations with the highest rates of new infection. When data is broken down by race/ethnicity, risk exposure is identified or reported, at best, for 75% and, at worst, for only 50% of cases. In the female subpopulation, percentages of cases with reported or identified risks fall even shorter than their male counterparts, across all race/ethnicity populations. An increased effort to include other surveillance tools like sentinel studies, sampling, and behavioral studies is needed to capture more complete data, especially for higher-risk populations.

Anonymous testing is crucial to collecting comprehensive data for the purpose of HIV/AIDS surveillance. According to the CDC, approximately one-third of all HIV-infected persons are unaware of their HIV status, having not sought testing through any source. Without anonymous testing, these individuals will continue to elude the surveillance reports, rendering such reports inaccurate and minimally useful. It is essential for the CDC to incorporate the need for anonymous testing in the upcoming R&R. The CDC should also ensure that performance standards are set at levels that state surveillance systems can realistically meet. Thank you for considering our views.

Sincerely,

Daniel Zingale

Daniel Zingale
Executive Director

cc: Kevin Thurm
Chris Jennings
David Beier

Performance Standards

According to the Center for Disease Control and Prevention (CDC), state and local HIV/AIDS surveillance systems must develop reporting methods that provide complete and timely case reporting of unduplicated surveillance data that identifies modes of risk exposure

The CDC Performance Standards from the CDC Guidelines for HIV Surveillance[1] would mandate

- ≥ **85%** of cases must provide complete information
- ≥ **66%** of cases must be reported within 6 months
- ≥ **95%** of cases must be unduplicated
- ≥ **85%** or representative sample of cases must identify HIV risk information

The CDC contends that names-based reporting methods are more likely to successfully meet the above mentioned performance standards, and therefore should be implemented by state and local HIV-surveillance programs. However, an analysis of the CDC's *HIV/AIDS Surveillance Report* for 1997, reveals that names-based reporting states are not meeting the performance standards.

Despite the fact that AIDS surveillance is touted as the gold standard for disease surveillance, even the most recent names-based AIDS report failed to meet the CDC's performance standard. According to the 1997 surveillance data, only 78% of AIDS cases[2] list a reported or identified risk[3]. The 1997 names-based HIV report also founders by reporting or identifying a risk for only 60% of all adult/adolescent cases.

The populations with the highest percentages of HIV infections with risk not reported or identified for HIV coincide with the populations with the highest rates of new infection. When data is broken down by race/ethnicity, risk exposure is identified or reported, at best, for 75% and, at worst, for only 50% of cases. In the female subpopulation, percentages of cases with reported or identified risks fall even shorter than their male counterparts, across all race/ethnicity populations.

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[1] Department of Health and Human Services. *Guidelines for National HIV Case Surveillance, Including Monitoring for HIV Infection and Acquired Immunodeficiency Syndrome (AIDS)*. 1998, p.10.

[2] Numbers were tabulated using data for adult/adolescent AIDS and HIV infection cases; pediatric cases were not included, as the real numbers of pediatric cases were negligible.

[3] The data for our tabulations of "Adult/adolescent AIDS and HIV Infection Cases with Non-reported or Non-identified Risk, by Race/ethnicity and Sex, 1997," was compiled from Tables 4,5 and Tables 28,29 of Vol. 9, No. 2 of the CDC *HIV/AIDS Surveillance Report* (through December 1997).

Our category heading "Risk Not Reported (RNR)" is shorthand for the CDC risk exposure category "Other/Risk Not Reported or Identified." "Other/Risk Not Reported or Identified" cases include persons who fall into one of the following categories (taken from p. 26 (figure 7), 41-42 of Surveillance Report):

1) persons who are currently under investigation by local health department officials;

2) persons whose exposure history is incomplete because they died, declined to be interviewed, or were lost to follow-up;

3) persons who were interviewed or for whom other follow-up information was available and no exposure mode was identified;

4) persons possibly infected through heterosexual contact with a partner who is not known to be HIV infected or at risk for HIV infection;

5) cases formerly reported as Pattern-II associated (i.e. Adults/adolescents born, or who had sex with someone born, in a country where heterosexual transmission is/was believed to be the predominant mode of HIV transmission);

6) health care workers with documented or possible occupationally acquired AIDS or HIV infection;

7) persons who acquired HIV infection perinatally but were diagnosed with AIDS after age 13

Adult/adolescent AIDS and HIV Infection Cases with Non-reported or Non-identified Risk, by Race/ethnicity and Sex, 1997

AIDS Cases

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	9,423	47,056	20%	80%
Female Adult/Adolescent	3,684	13,105	28%	72%
Adult/Adolescent Total	13,107	60,161	22%	78%

Percent with Risk Reported **78%**

AIDS -- White, Not Hispanic

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	1,986	17,649	11%	89%
Female Adult/Adolescent	546	2,485	22%	78%
Adult/Adolescent Total	2,532	20,134	13%	87%

Percent with Risk Reported **87%**

AIDS -- Black, Not Hispanic

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	4,925	18,903	26%	74%
Female Adult/Adolescent	2,457	7,880	31%	69%
Adult/Adolescent Total	7,382	26,783	28%	72%

Percent with Risk Reported **72%**

AIDS -- Hispanic

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	2,330	9,778	24%	76%
Female Adult/Adolescent	623	2,578	24%	76%
Adult/Adolescent Total	2,953	12,356	24%	76%

Percent with Risk Reported **76%**

AIDS -- Asian/Pacific Islander

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	84	381	22%	78%
Female Adult/Adolescent	18	64	28%	72%
Adult/Adolescent Total	102	445	23%	77%

Percent with Risk Reported **77%**

AIDS -- American Indian/Alaska Native

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	22	168	13%	87%
Female Adult/Adolescent	7	36	19%	81%
Adult/Adolescent Total	29	204	14%	86%

Percent with Risk Reported **86%**

HIV Infection Cases

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	3,513	9,894	36%	64%
Female Adult/Adolescent	2,170	4,362	50%	50%
Adult/Adolescent Total	5,683	14,256	40%	60%

Percent with Risk Reported **60%**

HIV -- White, Not Hispanic

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	845	3,879	22%	78%
Female Adult/Adolescent	362	954	38%	62%
Adult/Adolescent Total	1,207	4,833	25%	75%

Percent with Risk Reported **75%**

HIV -- Black, Not Hispanic

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	2,201	4,942	45%	55%
Female Adult/Adolescent	1,615	3,016	54%	46%
Adult/Adolescent Total	3,816	7,958	48%	52%

Percent with Risk Reported **52%**

HIV -- Hispanic

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	309	792	39%	61%
Female Adult/Adolescent	134	305	44%	56%
Adult/Adolescent Total	443	1,097	40%	60%

Percent with Risk Reported **60%**

HIV -- Asian/Pacific Islander

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	17	38	45%	55%
Female Adult/Adolescent	9	14	64%	36%
Adult/Adolescent Total	26	52	50%	50%

Percent with Risk Reported **50%**

HIV -- American Indian/Alaska Native

	Risk Not Reported	Cumulative Total	Percent RNR	Percent RR
Male Adult/Adolescent	17	62	27%	73%
Female Adult/Adolescent	7	21	33%	67%
Adult/Adolescent Total	24	83	29%	71%

Percent with Risk Reported **71%**

AIDS ACTION RESOLUTION IN SUPPORT OF HIV REPORTING BY UNIQUE IDENTIFIER AND OTHER NON NAME-BASED SURVEILLANCE SYSTEMS

WHEREAS, AIDS surveillance and AIDS case reporting do not provide an accurate view of the extent of the epidemic nor give a timely and complete indication of trends in the epidemic; and

WHEREAS, generating data which is more representative of the scope of the epidemic can help us better allocate limited resources, target and evaluate prevention efforts, educate the public about the epidemic, and project where the epidemic is going; and

WHEREAS, HIV names reporting may discourage individuals from seeking HIV testing and treatment and the implementation of HIV names reporting is not currently accompanied by guaranteed access to care and treatment; and

WHEREAS, no strong federal privacy law governing health information currently exists and state privacy protections are inadequate; and

WHEREAS, recent court decisions suggest limited or no discrimination protections for asymptomatic HIV positive individuals under the Americans with Disabilities Act (ADA); and

WHEREAS, the negative aspects of name reporting, in the absence of guaranteed access to health care and strong privacy protections, outweigh the potential benefits of this approach; and

WHEREAS, non name-based surveillance systems, such as unique identifier reporting and population based sampling, will support the public health goals of providing data which can help us allocate limited resources, targeting and evaluating prevention efforts, educating the public about the epidemic and projecting where the epidemic is going, while protecting confidentiality and not discouraging people from seeking HIV testing

BE IT RESOLVED:

That AIDS Action supports the development of non name-based HIV surveillance systems, including unique identifiers, to achieve the public health goals of HIV surveillance.

That AIDS Action opposes name based HIV surveillance.

That AIDS Action calls on the federal government to provide the resources necessary to support the efforts of states to create and improve unique identifier reporting systems and other non name-based surveillance systems without reducing the funding available for prevention programs.

That AIDS Action calls on the federal government to require states which have adopted or may adopt a names reporting system to provide and/or continue a publicly-funded anonymous testing option to ensure that individuals are not deterred from seeking HIV testing.

That AIDS Action calls on the Clinton Administration and the United States Congress to move forward expeditiously to enact and implement a strong federal confidentiality law which serves as a minimum standard for protecting the privacy of all health-related information.

That AIDS Action calls on the federal government to initiate efforts to guarantee access to care and treatment for all HIV positive individuals.

Adopted by the Board of Directors of the AIDS Action Council, October 18, 1997

To: Dan Mendelson
Fr: Richard
FYI - What we sent to the agencies

Office of Management and Budget
Executive Office of the President
Washington, DC 20503

To: Terry Brown 216-3393
Jim Painter
Fax: Duff Gillespie

From: Mike Cassell & Richard Tumman

Anne Richard 647-1681
Richard Sourides 66218
David Beier 66231
Sandy Thurman 62438
Eric Goosby 690-7560
Bill Beldon 690-6896
Jeff Koplan 404-639-7111

Number of Pages (excluding cover):

Subject: We have updated the DRAFT program funding summary and back-up documents. Please fill in the back-up documents so the initiative's outputs/outcomes can be described; we continue to operate on a short turn-around time, so please give us your programmatic input by 10:00AM on WEDNESDAY, 7/14. Please give us a call with any questions. This is NOT ready for release, so please handle CAREFULLY. Thanks!

Voice Numbers:

Health Division (Front Office)	202/395-4922
Health & Human Services Branch	202/395-4925
Health Programs & Services Branch	202/395-4926
Health Financing Branch	202/395-4930

Fax Numbers:

Health Division (Front Office)	202/395-3910
Health Division (Room 7001)	202/395-7840
Health Division (Room 7002)	202/395-5648

Four Prong Strategy:

1) Enhanced USG Commitment: Multi-year, prevention-focused strategy, growing existing base of $78 million USAID and approximately $30 million HHS, by $70-100 million in FY2000, with outyear amounts to be determined as the program evolves.

2) Private Sector: Pursue public and private partnerships to expand existing commitment from business and labor.

3) Leverage Multilateral Assistance: Convene a multinational partners meeting to enhance support from around the world. Mrs. Clinton is committed to doing this session. Other organizations in attendance include UNAIDS, World Bank, WHO, UNICEF, Corporate, CEOs, other interested countries, as well as African leaders.

4) Develop Support within African Nations: Engage host countries in collaborative efforts to combat AIDS pandemic.

Goals of Foreign Assistance Effort[1], Targeted to Actively Participating Host Countries (Multi-year initiative; FY2000 is Year 1)

1) The incidence of HIV infection will be reduced by 25% among 15-24 year olds by 2005 (need baseline)
2) At least 75% of all HIV-positive persons will have access to basic care at home and community levels, and drugs for common opportunistic infections (e.g., TB, pneumonia, diarrhea) (need baseline)
3) Orphans will have access to education and food on an equal basis with their non-orphan peers (need baseline)
4) By 2002, domestic and external resources available for HIV/AIDS responses in Africa will have doubled to $300 million per year.
5) Existing initiatives will be used as opportunities to include HIV/AIDS and to involve donors and countries to commit themselves to the multilateral partnership. (Need baseline)

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[1]SOURCE: UNAIDS

July 12, 1999
DRAFT

AIDS Initiative: Program Summary

Primary Prevention: **1) Program Delivery** **2) Technical Assistance and Training** **3) Prevention activities for African military**	USAID: $29M HHS: $13 M DOD: $10M TOTAL: $52M
Surveillance and Associated Prevention	HHS: $15M
Children Affected by AIDS	USAID: $10M
Infrastructure & Capacity Development	USAID: $6M
Home/Community-Based Treatment (STDs and Opportunistic Infections) **1) Program Delivery** **2) Technical Assistance and Training**	 USAID: $10M HHS: $7M

TOTAL: USAID $55M
HHS: $35 M
DOD: $10M

Program Element #1: PRIMARY PREVENTION

Definition: Develop strategies to slow the spread of HIV infection including mass education efforts, as well as social marketing, condom distribution, counseling and testing, blood supply screening, and AZT short-course therapy to prevent further mother to child HIV transmission, as appropriate.

[illegible]
1) Program Delivery **USAID:** $29 million Output: Provide HIV testing, education, condoms, and counseling in X countries. Deliver mass media services to X million persons to increase awareness. Train X counselors, educators, and trainers. **2) Technical Assistance and Training** **HHS:** $13 million Output: Provide technical assistance and training to X countries to establish comprehensive prevention programs. Provide short-course AZT therapy, as appropriate, to X HIV-positive pregnant women to prevent transmission to an additional X newborns. **3) Prevention activities for African military** **DOD:** $10 million Output: Provide prevention activities to XX African military personnel in X countries.

Program Element #2: SURVEILLANCE AND ASSOCIATED PREVENTION

Definition: Develop and expand systems to track spread of HIV infection and the effects of interventions to appropriately target HIV/AIDS programs in each participating country.

[redacted]
HHS: $15 million Output: Develop surveillance programs to understand the health impact of HIV in X countries.

Program Element #3: CARING FOR CHILDREN AFFECTED BY AIDS
Definition: Assist families and communities in caring for affected children.

USAID: $10 million Output: Assist families and communities in caring for affected children/orphans, in X countries. Support X AIDS orphans, through food assistance allowing them to remain with their extended families or communities.

July 12, 1999
DRAFT

Program Element #4: INFRASTRUCTURE AND CAPACITY DEVELOPMENT

Definition: Strengthen host country ability to implement interventions by focusing on government, private sector, NGOs, and research institution capability.

[illegible]
USAID: $6 million Output: Strengthen government, private sector, NGOs, and research institutions to plan and implement interventions, in X countries. Further expand capacity of monitoring systems to assess overall impact of HIV on sustainable development.

July 12, 1999
DRAFT

Program Element #5: HOME AND COMMUNITY-BASED CARE AND TREATMENT

Definition: Provide medical and social services to HIV infected individuals, including treatment of sexually transmitted diseases (STDs), opportunistic infections (OIs), and tuberculosis (TB).

USAID: $10 million

Output: Provide counseling, support, palliative, and OI infection care through community-based clinics and home workers. Provide preventive therapy to eliminate active TB in HIV-infected persons in X countries. Treat X HIV infected persons for simple OIs.

HHS: $7 million

Output: Provide technical assistance and training for X persons in X countries.

July 9, 1999

Treatment Access Workgroup

Information

July 15, 1998

UCSF Study on Medicaid Expansion (with press release)

"Expansion of US Medicaid system to cover HIV drugs will prevent thousands of deaths and AIDS diagnoses, and is affordable," James G. Kahn, UCSF et al, July 1998.

Press release on study results through Kaiser Family Foundation

Yale Study on Patterns and Costs of Care

"Changes in HIV/AIDS patterns of care and estimated costs at an urban medical center during the era of HAART," James Rawlings, Yale et al, July 1998.

ADAP Report

"National ADAP Monitoring Project: Interim Technical Report," Arnold Doyle et al, March 1998.

Relevant Newsclips

"Penny Wise, Pound Foolish," by David Gilden, *POZ Magazine*, July 1998

"Administration Drops Effort to Extend Medicaid Coverage for AIDS Therapies," by Amy Goldstein, *Washington Post*, Dec. 5, 1997.

Advocacy Paper on Medicaid Expansion

"Expanding Eligibility for Medicaid to Persons with HIV Disease," AIDS Action Council, AIDS Action Committee of Boston, undated.

Treatment Access Workgroup

Agenda

July 15, 1998

Introductions

Purpose of Workgroup – Sandra Thurman

Review of Information Provided – Todd Summers

Perspective of the Secretary of HHS – Marsha Martin

Work to Date

Health Care Financing Administration – Nancy-Ann Minn Deparle
Health Care Resources Services Administration – Joseph O'Neill

Analysis of Options – Sandra Thurman and Dan Mendelson

Next Steps

List of Participants

David Beier (Office of the VP)
Nancy-Ann Minn Deparle (HCFA)
Earl Fox (cannot attend) (HRSA)
Eric Goosby (cannot attend) (HHS/OS)
Chris Jennings (White House)
Marsha Martin (HHS/OS)
Dan Mendelson (OMB)
Joseph O'Neill (HRSA)
Sandra Thurman (ONAP)
Gordon Agress (OMB)
Sarah Bianchi (White House)
Toby Donenfeld (Office of the VP)
Robin Funston (HHS/ASMB)
Kathy King (HRSA)
John Palenicek (HRSA)
Todd Summers (ONAP)
Richard Turman (OMB)
Deborah vonZinkernagel (HHS/OS)
Greg White (OMB)

Treatment Access Workgroup

Issues Brief from OMB

July 15, 1998

Better Coordination Between Ryan White and Medicaid

Problem: The HHS Inspector General has recently pointed out that Medicaid managed care organizations and Ryan White programs do not adequately coordinate the services they provide to persons with HIV/AIDS.

Solution: The IG recommended that HCFA and HRSA disseminate technical assistance and guidance on strategies Medicaid programs can use to establish appropriate managed care contracts for needed medical services and costs related to these services. HRSA and 14CFA have begun to meet on these issues. The agencies could provide states with model contract language requiring coordination between Ryan White and Medicaid providers.

Discussion: Although Ryan White providers and Medicaid MCOs often serve the same population, they often do not coordinate services. For instance, the medical providers are often not aware of the Ryan White services, such as nutrition counseling and supplements, psycho-social services, home attendant care and case management, that the person is also getting. These social services, however, can help to support clients' ability to access health care and comply with health maintenance routines. Better coordination could result in better drug compliance and higher quality health care.

Higher Quality of HIV/AIDS Care in Medicaid

Problem: A recent study by the Agency for Health Care Policy and Research (AHCPR) has found that HIV+ persons with Medicaid received significantly inferior health care compared to privately insured persons. African-Americans, Latinos and women also received inferior care compared to whites and men.

Solution: Medicaid providers should be providing care based on the HHS guidelines on combination therapy that were released last year. HCFA and the States should ensure through contracting with managed care organizations or through direct contact with providers that all providers who serve the HIV+ population are aware of and adhere to the guidelines. Providing more services to HIV+ Medicaid recipients could impact the Medicaid baseline,

Discussion: At a time when it is possible to diminish radically the mortality and morbidity associated with HIV, this study suggests that Medicaid is not providing as high quality care to the HIV+ population as the insured population receives, even taking into account CD+4 lymphocyte counts. For instance, while only 13% of privately insured persons had one or more emergency room visits without an associated hospitalization, almost one third of Medicaid recipients had such an ER visit. Likewise, while 28% of privately insurance patients did not

receive protease inhibitors, almost one half of Medicaid beneficiaries did not. Differences in outcomes and quality between Medicaid recipients and private insured persons may occur between HIV-negative persons as well.

HCFA currently estimates that there are 50,000 asymptomatic persons who know their status plus 41,000 persons who are asymptomatic and do not know their status on Medicaid. Most of these people would be women eligible through the AFDC/TANF program. Providers should be encouraging all at-risk women to be tested for HIV.

Consumer Bill of Rights Could Improve Care for HIV+ Persons

Problem: Although privately insured HIV+ persons had the best health care access indicators in the AHCPR study, many privately insured persons are still not receiving adequate care. From the study, it is unclear whether the lack of adequate care is related to limited insurance coverage for appropriate care or poor provision of care by health providers.

Solution: Just as government employees in the Federal Employees Health Benefits program (FEHBP) have a guarantee to high quality care through the adoption of the Consumer Bill of Rights, all private employees and members of health plans should have a guarantee of high quality care consistent with the Consumer Bill of Rights.

Discussion: The President's Consumer Bill of Rights calls for improvements in the quality of managed care that would enhance care for persons with HIV. For instance, the Consumer Bill of Rights requires that consumers with complex or serious medical conditions have direct access to qualified specialists. Consumers who are undergoing treatment for a chronic condition, such as AIDS, at the time they involuntarily change health plans or when a provider is terminated by a plan should be able to continue to see their original specialty provider for up to 90 days. Consumers should have the right to considerate, respectful care and should not be discriminated against based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information or source of payment.

Reductions in AIDS Deaths Vary by Race and Gender

Problem: AIDS death rates for women and African-Americans have not fallen as dramatically as have AIDS death rates for men and for whites -- possibly because women and African-Americans may not be receiving the same quality and/or amount of care as men and whites.

Possible Solutions: Exactly what improvements would be most efficient is not yet clear from the data, but there are some potential starting points.

- Address the inexperience of many physicians by better disseminating HHS clinical practice guidelines, or by referring patients to more experienced doctors.
- Imposition of some "quality of care" standard among Ryan White grantees.
- Use Ryan White's AIDS Education and Training Center component to identify and address gaps in physicians' knowledge of care for I-IIV/AIDS.
- Increase awareness in community of benefits from early intervention.

Data: CDC AIDS data show that death rates have not fallen as dramatically among women and blacks as they have among whites and men.

Merck data show that "women and minorities are more likely to be HIV symptomatic than white men when starting HIV treatment," and "a smaller proportion of women and minorities than white men are treated by the most experienced physicians."

Access to Combination Therapy May Vary By State

Problem: Some Southern and Western states tend to have waiting lists for ADAP and/or combination therapy.

Possible Solutions: If the access problems in these States are driven by resource levels, then finding more resources -- either from individuals, companies, the State or local governments or the Federal government -- is probably the only way to address the problems.

We could seek to increase the contributions made by the States. States with AIDS cases greater than 1% of the national total* are currently required to provide State resources equal to 50% of the Title 11 grants (which include ADAP), but States can meet this requirement with "in kind" contributions such as facilities and staff. States could be required to increase the match they make to ADAP grants, or could be required to make their matching contributions in cash. This has been discussed in the past, and would be fairly controversial, but it is worth thinking about.

Increased funding for Title 11 and ADAP would help, but because these funds are distributed by formula, increases to them are unlikely to have a large impact in the States with problems. We could increase funding for Title III, which makes grants directly to clinics, and target the funds to States with access problems. We could also propose changes to the Title 11 and ADAP formulas, but these are unlikely to occur quickly,

Discussion: Nationwide, States provided 30% of the funds used by ADAPs in FY 1997. States that AIDS Action lists as having waiting lists for combination therapy contributed 20% of ADAP funds in their State -- less than the national average for ADAP.

Insurance Continuation

Problem: States cannot use ADAP funds to pay premiums for clients' health insurance even when that health insurance would cover combination therapy, and the cost of the premiums is less than the cost of buying the drugs directly.

Solution: Let States use ADAP funds to pay for health insurance when the insurance is the chcapest way of providing access to combination therapy, and when clients cannot afford to pay for such insurance themselves. As in any other public insurance program, the public insurance may be substituting for private insurance that people would have purchased if the public insurance was not available -- a phenomenon known as "crowd-out." Policy could be proposed which would reduce the level of “crowd-out.”

Discussion: The FY 1999 President's Budget included appropriations language signaling support for this idea, but this language has been viewed by the community as inadequate to give States the authority they need. The House Labor/HHS Appropriations Subcommittee report says States should have the flexibility to do insurance continuation.

Cost of Drugs

Problem: Ryan White grantees and Medicaid programs may be spending more than they have to for AIDS drugs.

Solution: Insure these activities use the minimum price available to them by making maximum use of HHS 340B program and Medicaid rebates and discounts.

Discussion: We do not have much evidence to suggest that significant savings are available through cost minimization efforts. However, given the high cost of combination therapy drugs, small percentage reductions in the prices paid for these drugs could result in large dollar savings. HHS is already publishing a rule that would allow States to use a rebate program to capture the savings from this program (now currently available only as a discount).

*CDC estimates that 242,000 people were living with AIDS in 1996, and that 641,000 total cases had been reported by the end of 1996. The law imposes the matching requirement on States whose AIDS cases are "in excess of 1 percent of the aggregate number of such cases" -- it is unclear whether this refers to living persons or all AIDS cases.

emergency medical services to acutely ill and seriously injured children.

Black Lung Clinics

The Committee provides $5,000,000 for black lung clinics, which is $24,000 above the fiscal year 1998 comparable level and the same as the Administration request. The program supports 14 grantees which treat a declining population of coal miners with respiratory and pulmonary impairments. The clinics presently receive more than one-third of their funding from other sources, such as Medicaid and Medicare. Of the 14 grantees, three actually receive community health center funding as well as black lung grants.

Payment to Hawaii for Treatment of Hansen's Disease

The Committee provides $2,045,000 for the treatment of persons with Hansen's Disease in the State of Hawaii, which is the same as both the fiscal year 1998 comparable level and the Administration request. The program, which provides a partial matching payment to the State of Hawaii, dates to the period of Father Damien's facility for sufferers of Hansen's disease (leprosy). That facility now has only 67 residents who live there by choice, and the grounds have been converted to a historical site. Most patients diagnosed with Hansen's disease in Hawaii are now treated in the same manner as new patients on the mainland; their care is handled on an out-patient basis, with the program paying for about 5,300 outpatient visits per year.

Ryan White AIDS Programs

The Committee provides $1,330,600,000 for Ryan White AIDS programs, which is $181,088,000 above the fiscal year 1998 comparable level and $17,618,000 above the Administration request. The Committee recognizes that each Part of the Ryan White CARE Act provides services, which enable individuals to adhere to HIV drug treatments and access needed medical care.

The Ryan White CARE Act Amendments of 1996 requires States to comply with certain requirements in order to receive Federal funding for Ryan White activities. There is some concern that the Department is certifying States as being in compliance with these requirements when, in fact, they are not. Therefore, the Committee requests that the Secretary submit, by October 15, 1998, the following information: (1) a copy of the guidelines that were provided to State's to comply with section 300ff-21 et. seq. and section 300ff-47 of the Act; (2) a copy of the criteria used by the Department to evaluate and certify a State's compliance with these sections; (3) a copy of what each State submitted to the Department for its compliance evaluation; and (4) a copy of each State's final evaluation and certification approval document by the Department.

Emergency assistance

The Committee provides $500,200,000 for the Part A, emergency assistance program, which is $35,464,000 above the fiscal year 1998 comparable level and $11,226,000 above the Administration request. These funds provide grants to metropolitan areas with very high numbers of AIDS cases for outpatient and ambulatory

health and social support services. Half of the amount appropriated is allocated by formula and half is allocated to eligible areas demonstrating additional need through a competitive grant process.

Comprehensive care programs

The Committee provides $670,000,000 for Part B, comprehensive care programs, which is $127,217,000 above the fiscal year 1998 comparable level and $1,130,000 above the Administration request. The funds provided support formula grants to States for the operation of HIV service delivery consortia in the localities most heavily affected, for the provision of home and community-based care, for continuation of health insurance coverage for infected persons, and for purchase of therapeutic drugs.

The Committee is encouraged by the success of new drugs and combination therapies for HIV and AIDS, whose purchase is principally financed under Part B, and has included bill language identifying $385,500,000 specifically for the purchase of AIDS drugs. The fiscal year 1998 bill designated $285,500,000 for this purpose.

The Committee is concerned about the wide variation in State ADAP and Medicaid policies regarding eligibility, benefits, and formularies. The Committee is also concerned about the wide variation in State contributions to funding of ADAP and urges States that receive more than $1,000,000 under the targeted formula to match no less than twenty percent of the Federal contribution. The Committee directs the program to use all means necessary to reduce the purchase price of AIDS drugs.

The Committee expects HRSA to encourage States to utilize Federal ADAP funding in the most cost effective manner possible to maximize access to and use of HIV drug therapies. States should be allowed, with ADAP funding, the flexibility to purchase and maintain insurance policies for eligible clients, or continue to pay premiums on existing insurance policies, which provide a full range of HIV treatments and access to comprehensive primary care services as determined by the State. Funds should not be used to purchase insurance which provides inadequate access to HIV treatments or primary care as determined by the State.

Early intervention program

The Committee provides $91,300,000 for Part C, the early intervention program, which is $15,089,000 above the fiscal year 1998 comparable level and $5,146,000 above the Administration request. Funds are used for discretionary grants to migrant and community health centers, health care for the homeless grantees, family planning grantees, hemophilia centers and other private non-profit entities that provide comprehensive primary care services to populations with or at risk for HIV disease. The grantees provide testing, risk reduction counseling, transmission prevention, and clinical care; case management, outreach, and eligibility assistance are optional services. Approximately 79,000 HIV positive persons or persons at high risk for HIV infection are expected to be served in fiscal year 1999.

The Committee is concerned about the continued disparity in health outcomes for people with HIV and AIDS in communities of color and recognizes the need to provide additional services specifi-

cally targeted to HIV infected individuals in these communities. The Committee encourages HRSA to give priority consideration to allocating grants to grantees serving primarily minority populations.

Pediatric demonstrations

The Committee provides $44,000,000 for Part D, the pediatric AIDS demonstrations, which is $3,197,000 above the fiscal year 1998 comparable level and $74,000 above the Administration request. The program supports demonstration grants to foster collaboration between clinical research institutions and primary community-based medical and social service providers for the target population of HIV-infected children, pregnant women and their families. The projects are intended to increase access to comprehensive care, as well as to voluntary participation in NIH and other clinical trials.

AIDS dental services

The Committee provides $7,800,000 for AIDS dental services, which is $37,000 above the fiscal year 1998 comparable level and $13,000 above the Administration request. The program provides grants to dental schools and postdoctoral dental education programs to assist with the cost of providing unreimbursed oral health care to an estimated 73,000 patients with human immunodeficiency virus disease. Over one hundred dental schools and hospitals are expected to receive awards in fiscal year 1999. Dental students and residents participating in this program receive extensive training in the management of oral care of people living with AIDS.

The Committee notes that the program funding formula and reporting requirements have been revised in fiscal year 1998, and therefore, requests that the agency provide adequate time and technical assistance so that grantees can comply with these revisions and any future program changes allowing for their continued participation in the program.

Education and training centers

The Committee provides $17,300,000 for AIDS education and training centers, which is $84,000 above the fiscal year 1998 comparable level and $29,000 above the Administration request. The centers train health care personnel who care for AIDS patients and develop model education programs.

Family Planning

The Committee provides $202,903,000 for the family planning program, which is the same as the fiscal year 1998 comparable level and $15,174,000 below the Administration request. The program provides grants to public and private non-profit agencies to support projects which provide a range of family planning and reproductive services, as well as screening for ancillary health problems such as hypertension and diabetes. The program also supports training for providers, an information and education program, and a research program which focuses on family planning service delivery improvements. During fiscal year 1999, an estimated 4.6 million clients are expected to be served.

The bill repeats language from the 1998 appropriations bill making clear that these funds shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that these funds shall not be used to promote public opposition to or support of any legislative proposal or candidate for public office.

Rural Health Research

The Committee provides $7,500,000 for rural health research, which is $4,156,000 below the fiscal year 1998 comparable level and $4,191,000 below the Administration request. The activity supports several rural health research centers and the Office for Rural Health Policy's advisory committee.

Health Care Facilities

The Committee has not included funding for health care facilities. $28,000,000 was provided for this purpose in fiscal year 1998; no funding was included in the Administration request. This expired authority provides funds to public and private nonprofit entities for construction or modernization of outpatient medical facilities. This activity has not been funded by the Committee on a regular annual basis.

Buildings and Facilities

The Committee provides $250,000 for buildings and facilities, which is $2,248,000 below the fiscal year 1998 comparable level and the same as the Administration request. These funds are used to finance the repair and upkeep of buildings at the Gillis W. Long Hansen's Disease Center at Carville, Louisiana.

National Practitioner Data Bank

The Committee does not provide funding for the national practitioner data bank for fiscal year 1999, which is the same as both the fiscal year 1998 action on appropriations and the Administration request. The Committee recommendation and the Administration request assume that the data bank will be self-supporting, with collections of $12,000,000 in user fees.

The national data bank receives, stores and disseminates information on paid medical malpractice judgments and settlements, sanctions taken by professional societies, and certain professional review actions. Insurance companies, State license boards and professional societies are required to report information to the data bank within 30 days of each action. The coverage of the data bank includes dentists and physicians, and, with respect to malpractice settlements, other categories of licensed health professionals. Hospitals are required to search the data bank when a health care provider applies for employment and once every two years thereafter. State licensing boards and other health care entities also have access to the data bank. Traditional bill language is included to ensure that user fees are collected to cover all costs of processing requests and providing such information to data bank users.

disease, kidney disease, and other health problems that disproportionately afflict the elderly. Last year the Committee encouraged HCFA to conduct a demonstration project on coverage of medical nutrition therapy by registered dietitians and other licensed or nationally certified medical practitioners under Part B of Medicare to investigate its impact on program costs and beneficiary health and quality of life. The Committee is concerned that no progress has been made on this demonstration and urges HCFA to proceed with this project and provide a report on its status by December 31, 1998.

The Committee notes that congestive heart failure (CHF) has been identified as the leading condition regarding readmission, with the majority of those readmissions occurring through emergency rooms. This problem is particularly acute in the "stroke belt" region, which encompasses several Southern and Midwestern states. The Committee encourages HCFA to undertake research to demonstrate the cost effectiveness of a CHF clinic in reducing hospital admissions and improving compliance and quality of life.

Treatment guidelines issued by the Department in 1997 recognize the need to provide early treatment for HIV disease. Several States are considering applications for Medicaid waivers for demonstration projects that would extend Medicaid eligibility to HIV positive individuals who meet State Medicaid income eligibility requirements, but are not diagnosed with AIDS. The Committee encourages HCFA to evaluate and provide technical assistance to states which are preparing waiver applications for these demonstration projects.

Recent evidence from the states indicates that many Medicaid recipients with the most severe and disabling mental illnesses can achieve higher levels of recovery if the appropriate treatment and supports are available in the community. While a model of intensive case management known as the Program for Assertive Community Treatment (PACT) has been successful as part of Medicaid programs in many states, there is little information about how many states are funding PACT services. The Committee encourages HCFA to undertake a survey of which states are funding PACT services for adult Medicaid beneficiaries with severe mental illnesses and develop a model on how states can successfully integrate PACT into managed care programs.

The Committee supports the efforts to reach underserved and vulnerable populations through telemedicine and expects that projects will be supported in both rural and urban communities to meet the health care needs of underserved and minority populations.

Medicare contractors

The bill includes $1,269,700,000 to support Medicare claims processing contracts, which is $53,559,000 above the fiscal year 1998 comparable level and $165,300,000 above the Administration request. The Committee does not concur with the Administration's new user fee proposal.

Medicare contractors are responsible for paying Medicare providers promptly and accurately. In addition to processing claims, contractors also identify and recover Medicare overpayments, as well

Todd A. Summers @ EOP
07/15/98 09:45:15 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Today's Treatment Access Meeting - Agenda and Participant List

Here is a draft agenda for this afternoon's meeting, along with a list of participants. **If there are others attending who require clearance, please call me ASAP at 456-2437.**

Thanks, Todd

Treatment Access Workgroup

Agenda

July 15, 1998

Introductions

Purpose of Workgroup – Sandra Thurman

Review of Information Provided – Todd Summers

Perspective of the Secretary of HHS – Marsha Martin

Work to Date

Health Care Financing Administration – Nancy-Ann Minn Deparle
Health Care Resources Services Administration – Joseph O'Neill

Analysis of Options – Sandra Thurman and Dan Mendelson

Next Steps

List of Participants

Principals **Senior Staff**

David Beier (Office of the Vice President)
Nancy-Ann Minn Deparle (HCFA)
Earl Fox (cannot attend) (HRSA)
Eric Goosby (cannot attend) (HHS/OS)
Chris Jennings (White House)
Marsha Martin (HHS/OS)
Dan Mendelson (OMB)
Joseph O'Neill (HRSA)
Sandra Thurman (ONAP)
Gordon Agress (OMB)
Sarah Bianchi (White House)
Toby Donenfeld (Office of the Vice President)
Robin Funston (HHS/ASMB)
Kathy King (HRSA)
John Palenicek (HRSA)
Todd Summers (ONAP)
Richard Turman (OMB)
Deborah vonZinkernagel (HHS/OS)

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Todd A. Summers @ EOP
07/14/98 11:42:24 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Treatment Access Meeting - OMB Thoughts

Dan Mendelson from OMB has provided some helpful suggestions for discussion at tomorrow's Treatment Access meeting (I own any typos!). I thought I'd forward this on to you for your consideration. See you tomorrow.

Todd

= =

Better Coordination Between Ryan White and Medicaid

Problem: The HHS Inspector General has recently pointed out that Medicaid managed care organizations and Ryan White programs do not adequately coordinate the services they provide to persons with HIV/AIDS.

Solution: The IG recommended that HCFA and HRSA disseminate technical assistance and guidance on strategies Medicaid programs can use to establish appropriate managed care contracts for needed medical services and costs related to these services. HRSA and 14CFA have begun to meet on these issues. The agencies could provide states with model contract language requiring coordination between Ryan White and Medicaid providers.

Discussion: Although Ryan White providers and Medicaid MCOs often serve the same population, they often do not coordinate services. For instance, the medical providers are often not aware of the Ryan White services, such as nutrition counseling and supplements, psycho-social services, home attendant care and case management, that the person is also getting. These social services, however, can help to support clients' ability to access health care and comply with health maintenance routines. Better coordination could result in better drug compliance and higher quality health care.

Higher Quality of HIV/AIDS Care in Medicaid

Problem: A recent study by the Agency for Health Care Policy and Research (AHCPR) has found that HIV+ persons with Medicaid received significantly inferior health care compared to privately insured persons. African-Americans, Latinos and women also received inferior care compared to whites and men.

Solution: Medicaid providers should be providing care based on the HHS guidelines on combination therapy that were released last year. HCFA and the States should ensure through contracting with managed care organizations or through direct contact with providers that all providers who serve the HIV+ population are aware of and adhere to the guidelines. Providing more services to HIV+ Medicaid recipients could impact the Medicaid baseline,

Discussion: At a time when it is possible to diminish radically the mortality and morbidity associated with HIV, this study suggests that Medicaid is not providing as high quality care to the HIV+ population as the insured population receives, even taking into account CD+4 lymphocyte counts. For instance, while only 13% of privately insured persons had one or more emergency room visits without an associated hospitalization, almost one third of Medicaid recipients had such an ER visit. Likewise, while 28% of privately insurance patients did not receive protease inhibitors, almost one half of Medicaid beneficiaries did not. Differences in outcomes and quality between Medicaid recipients and private insured persons may occur between HIV-negative persons as well.

HCFA currently estimates that there are 50,000 asymptomatic persons who know their status plus 41,000 persons who are asymptomatic and do not know their status on Medicaid. Most of these people would be women eligible through the AFDC/TANF program. Providers should be encouraging all at-risk women to be tested for HIV.

Consumer Bill of Rights Could Improve Care for HIV+ Persons

Problem: Although privately insured HIV+ persons had the best health care access indicators in the AHCPR study, many privately insured persons are still not receiving adequate care. From the study, it is unclear whether the lack of adequate care is related to limited insurance coverage for appropriate care or poor provision of care by health providers.

Solution: Just as government employees in the Federal Employees Health Benefits program (FEHBP) have a guarantee to high quality care through the adoption of the Consumer Bill of Rights, all private employees and members of health plans should have a guarantee of high quality care consistent with the Consumer Bill of Rights.

Discussion: The President's Consumer Bill of Rights calls for improvements in the quality of managed care that would enhance care for persons with HIV. For instance, the Consumer Bill of Rights requires that consumers with complex or serious medical conditions have direct access to qualified specialists. Consumers who are undergoing treatment for a chronic condition, such as AIDS, at the time they involuntarily change health plans or when a provider is terminated by a plan should be able to continue to see their original specialty provider for up to 90 days. Consumers should have the right to considerate, respectful care and should not be discriminated against based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information or source of

payment.

Reductions in AIDS Deaths Vary by Race and Gender

Problem: AIDS death rates for women and African-Americans have not fallen as dramatically as have AIDS death rates for men and for whites -- possibly because women and African-Americans may not be receiving the same quality and/or amount of care as men and whites.

Possible Solutions: Exactly what improvements would be most efficient is not yet clear from the data, but there are some potential starting points.

- Address the inexperience of many physicians by better disseminating HHS clinical practice guidelines, or by referring patients to more experienced doctors.
- Imposition of some "quality of care" standard among Ryan White grantees.
- Use Ryan White's AIDS Education and Training Center component to identify and address gaps in physicians' knowledge of care for I-IIV/AIDS.
- Increase awareness in community of benefits from early intervention.

Data: CDC AIDS data show that death rates have not fallen as dramatically among women and blacks as they have among whites and men.

Merck data show that "women and minorities are more likely to be HIV symptomatic than white men when starting HIV treatment," and "a smaller proportion of women and minorities than white men are treated by the most experienced physicians."

Access to Combination Therapy May Vary By State

Problem: Some Southern and Western states tend to have waiting lists for ADAP and/or combination therapy.

Possible Solutions: If the access problems in these States are driven by resource levels, then finding more resources -- either from individuals, companies, the State or local governments or the Federal government -- is probably the only way to address the problems.

We could seek to increase the contributions made by the States. States with AIDS cases greater than 1% of the national total* are currently required to provide State resources equal to 50% of the Title 11 grants (which include ADAP), but States can meet this requirement with "in kind" contributions such as facilities and staff. States could be required to increase the match they make to ADAP grants, or could be required to make their matching contributions in cash. This has been discussed in the past, and would be fairly controversial, but it is worth thinking about.

Increased funding for Title 11 and ADAP would help, but because these funds are distributed by formula, increases to them are unlikely to have a large impact in the States with problems. We could increase funding for Title III, which makes grants directly to clinics, and target the funds to States with access problems. We could also propose changes to the Title 11 and ADAP formulas, but these are unlikely to occur quickly,

Discussion: Nationwide, States provided 30% of the funds used by ADAPs in FY 1997. States that AIDS Action lists as having waiting lists for combination therapy contributed 20% of ADAP funds in their State -- less than the national average for ADAP.

Insurance Continuation

Problem: States cannot use ADAP funds to pay premiums for clients' health insurance even when that health insurance would cover combination therapy, and the cost of the premiums is less than the cost of buying the drugs directly.

Solution: Let States use ADAP funds to pay for health insurance when the insurance is the chcapest way of providing access to combination therapy, and when clients cannot afford to pay for such insurance themselves. As in any other public insurance program, the public insurance may be substituting for private insurance that people would have purchased if the public insurance was not available -- a phenomenon known as "crowd-out." Policy could be proposed which would reduce the level of "crowd-out."

Discussion: The FY 1999 President's Budget included appropriations language signaling support for this idea, but this language has been viewed by the community as inadequate to give States the authority they need. The House Labor/HHS Appropriations Subcommittee report says States should have the flexibility to do insurance continuation.

Cost of Drugs

Problem: Ryan White grantees and Medicaid programs may be spending more than they have to for AIDS drugs.

Solution: Insure these activities use the minimum price available to them by making maximum use of HHS 340B program and Medicaid rebates and discounts.

Discussion: We do not have much evidence to suggest that significant savings are available through cost minimization efforts. However, given the high cost of combination therapy drugs, small percentage reductions in the prices paid for these drugs could result in large dollar savings. HHS is already publishing a rule that would allow States to use a rebate program to capture the savings from this program (now currently available only as a discount).

*CDC estimates that 242,000 people were living with AIDS in 1996, and that 641,000 total cases had been reported by the end of 1996. The law imposes the matching requirement on States whose AIDS cases are "in excess of 1 percent of the aggregate number of such cases" -- it is unclear whether this refers to living persons or all AIDS cases.

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Expansion of US medicaid system to cover HIV drugs will prevent thousands of deaths and AIDS diagnoses, and is affordable

James G. Kahn[1] B. Haile[1] S.W. Chang[2]. [1]Center for AIDS Prevention Studies, UCSF, Inst. for Health Pol Stud., UCSF, Box 0936, San Francisco, CA; [2]HJ Kaiser Family Foundation, Menlo Park, USA

Objectives: To assess the health and federal fiscal implications of expanding Medicaid, the US insurance system for the poor, to cover HIV care for those without access to HIV medications.

Design: Computer spreadsheet modeling of HIV disease progression, treatment costs, and financing.

Methods: We compared projected outcomes with and without an expansion, over 5 years. The expansion assessed is for all individuals lacking medical insurance for antiRetroviral medications and with income below $10,000 per year (125% of poverty for a single person). It covers medications and outpatient care. The analysis incorporates estimates of the number of people living with HIV infection by disease stage; current access to antiRetroviral therapy, insurance status, and income; likelihood of qualifying for and enrolling in the expansion; a natural history model of HIV disease progression, calibrated to cohort studies; the efficacy of combination antiRetroviral therapy in reducing HIV disease progression, based on clinical studies; the costs of HIV medications and care; and federal government costs for the expansion.

Results: An estimated 37,100 individuals would enroll in the expansion, 83% pre-AIDS and 17% with AIDS. Over 5 years, there are 5,200 fewer deaths with the expansion than without. 6,700 fewer individuals with early HIV disease progress to an AIDS diagnosis or early death. The expansion increases total life years by 14,500 over the 5 years. Total federal costs for the expansion itself are $1.3 billion over 5 years; these are offset by decreased federal expenditures of $765 million: Medicaid, due in part to slowed progression to AIDS ($385 million), AIDS Drug Assistance Program ($240 million), and other programs ($140 million). Federal budget neutrality, currently required to approve Medicaid waivers to states, can be achieved by an 18% reduction in Medicaid prices for HIV drugs. Despite this price reduction, total spending for HIV drugs increases by $175 million.

Conclusion: This analysis suggests that expansion of the US Medicaid system to provide wider access to combination antiRetroviral therapy would prevent thousands of deaths and AIDS diagnoses, leading to 14,500 more years of life for persons with HIV disease over 5 years. The program is affordable from a federal perspective, with budget neutrality achievable if the expansion is accompanied by an 18% reduction in HIV drug prices for Medicaid.

A new HIV benefit in the U.S. Medicaid system: Health and federal fiscal implications

12th World AIDS Conference
July 1, 1998

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Background

- Advent of potent triple ARV therapy
- Formal treatment guidelines - ARVs recommended for very large group
- Funding crisis in AIDS Drug Assistance Program (uninsured HIV+ individuals)
- Many still have financial barriers to ARVs

Objective

- Assess the health and federal fiscal effects of expanding Medicaid to cover HIV care for those lacking financial access to HIV medications

Health effects:	New AIDS diagnoses Deaths Years of life
Fiscal effects:	Medical care spending Income support for disabled Budget neutrality

Methods

- **Spreadsheet model**
  - HIV disease stages, clinical progression
  - Federal costs: Medicaid, Medicare, AIDS Drug Assistance Program, SSDI/SSI
  - 5 years, all of U.S.
- **Data inputs**
  - **Clinical:**
    HIV natural history
    Current use of ARVs
    Clinical effects of ARV triple therapy
  - **Costs:**
    costs of medical care and ARV therapy
    enrollment in insurance, income programs

Methods (cont'd)

- New Medicaid benefit

Eligibility:

- CD4 < 500 or elevated viral load
- inadequate or absent medication coverage
- income < $10,000 per year

Coverage:

- Limited: drugs and outpatient
- Full: drugs, outpatient, inpatient, etc.

assume 90% use ARV triple therapy

Initial HIV/AIDS Disease Distribution

	Number	Proportion aware of serostatus
Asymptomatic CD4 > 500	167,000	0.42
Asymptomatic CD4 < 500	167,000	0.45
Symptomatic	167,000	0.79
AIDS (1993 definition)	150,000	0.92
AIDS (1987 definition)	100,000	1.00
Total	750,000	0.70

Clinical effect of ARV triple therapy

Pre-AIDS to:

AIDS (6 viral load studies):	60% reduction
Death (1 clinical study):	70% reduction

AIDS to:

AIDS events (10 clin. studies):	50% reduction
Death (8 clin. studies):	60% reduction

Projected Number of Benefit Participants

No prior access to ARV triple therapy	17,200
Access to triple therapy via subsidies	20,776

Early Access to HIV Treatments for Underserved Populations Found to be Cost Effective

- AIDS Activists Applaud New Research That Puts Added Pressure on

Government Officials to Expand Treatment Access -

GENEVA, July 2 /PRNewswire/ -- New pharmacoeconomic research presented today at the 12th World AIDS Conference demonstrates that providing early access to AIDS treatment for the poor and uninsured would be cost-effective. This study challenges underlying assumptions supporting current Medicaid requirements that withhold treatment from HIV-infected patients until they exhibit the symptoms of full-blown AIDS. Medicaid is the largest payer of HIV-related medical services in the United States.

Current Medicaid eligibility rules extend health care coverage to HIV-infected patients only after they have suffered an AIDS defining illness or after their CD4 count has declined to below 200. Patients living with the HIV virus but without the symptoms of full-blown AIDS are ineligible and, if unable to gain access to AIDS drugs through other means, must delay treatment until they experience the symptoms of AIDS. Although federally funded state-administered AIDS Drug

Assistance Programs (ADAPs) generally cover the drug costs for patients ineligible for Medicaid, many state programs have experienced financial shortfalls due to rapidly increasing enrollments and per patient costs and, as a result, have responded by restricting access to their programs.

AIDS activists attending the conference characterized the pharmacoeconomic study as a solid first step in the development of a critical policy basis for the expansion of life-saving AIDS drug therapies to the uninsured and underinsured. The research, which was conducted by a consortium of academic researchers, professional pharmacoeconomists, AIDS organizations and research-based pharmaceutical interests called the Treatment Access Expansion Project (TAEP), uses established pharmacoeconomic simulation techniques and data from existing clinical trials (Roche clinical trials NV15182 and NV15355) to draw two conclusions:

-- early initiation of treatment with AIDS drug cocktails delays the

progression of AIDS, and

-- providing early treatment (i.e., when the patient has a CD4 count

between 200 and 500 and has never experienced an AIDS defining event)

would result in prolonged survival and would be cost-effective, when

compared to delayed treatment (when the patient has a CD4 count of less

than 200 or has experienced an AIDS defining event).

"At the most basic level, our research shows that patients receiving early, aggressive treatment experience increased lifespan," said Gary Rose, T.II.C.A.N.N. (Ryan White CARE Act Title II Community AIDS National Network) public policy director and community liaison with the Treatment Access Expansion Project and a chief researcher on the project. "Moreover, the overall cost of providing patients with this survival benefit is negligible."

In April 1997, Vice President Al Gore directed federal health officials to determine the feasibility of expanding Medicaid coverage to make new AIDS drugs available to the uninsured for early HIV treatment. In December, the Clinton Administration announced that an expansion in Medicaid along these lines would be too costly. "Ability to pay should not have to be a barrier to early intervention for people with HIV," said Daniel Zingale, Executive Director of the AIDS Action Council.

The new pharmacoeconomic study shows that early HIV treatment would increase life expectancy of currently infected asymptomatic patients (patients with a CD4 count between 200-500 and never having experienced an AIDS defining event) by 0.43 years (unadjusted for quality of life). The researchers determined that these gains in life expectancy would result in longer treatment with protease inhibitors and an expected increase in lifetime costs per patient of 2.2%. Ultimately, however, early AIDS treatment is projected to delay progression of AIDS-defining events and prolong survival, at a cost well within the range of generally accepted cost-effective medical interventions.

"This pharmacoeconomic study provides an important addition to any discussion on early treatment," said Dr. John Hornberger, Director of Health Economics in Roche Global Pharmacoeconomic Research. "By delaying the onset of the symptoms of AIDS, early treatment only slightly increases medical-care costs over the first 5 years by $241 per patient per year."

The principal sponsor of the TAEP pharmacoeconomic study is Hoffmann-La Roche. Roche Laboratories, a subsidiary of Hoffmann-La Roche, markets more than 35 medications in major therapeutic areas including AIDS, oncology, transplantation, infectious diseases, cardiovascular diseases and dermatology.

Treatment Access Expansion Project: TAEP was initiated to develop and disseminate sophisticated pharmacoeconomic models for use by federal, state and local governments and other entities concerned with the budget

implications of providing treatment to people living with HIV/AIDS. TAEP consists of a consortium of academic researchers, professional pharmacoeconomists, AIDS organizations and research-based pharmaceutical interests.

T.II.C.A.N.N.: The Ryan White CARE Act Title II Community AIDS National Network (T.II.C.A.N.N.) is a non-profit organization dedicated to initiating and supporting activities that ensure access to care for all Americans living with or affected by HIV.

Roche Laboratories Inc.: Roche Laboratories Inc. is the marketing and sales subsidiary of Hoffmann-La Roche Inc., a leading research-intensive pharmaceutical company. Roche Laboratories markets more than 35 medications in major therapeutic areas including AIDS, oncology, transplantation, infectious diseases, cardiovascular diseases and dermatology.

SOURCE Treatment Access Expansion Project

CO: Treatment Access Expansion Project; Roche Laboratories Inc.; T.II.C.A.N.N.

Changes in HIV/AIDS patterns of care and estimated costs at an urban medical center during the era of heart

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Objective: To estimate the patterns and costs of HIV/AIDS inpatient and outpatient care at a 700 bed urban hospital in the era of highly active Retroviral therapy (HAART).

Methods: Evaluation of utilization of inpatient and outpatient hospital services; all patients with HIV/AIDS related admissions identified by ICD-9 coded discharge diagnoses; outpatients identified by attendance at hospital-based HIV-specific primary care clinic. Cost of care determined by Resource Information Management System (RIMS), a computerized fiscal data system which assigns costs for all inpatient and outpatient hospital-related services. Antiviral and nursing home costs were estimated from separate patient matched databases.

	10/94-9/95*	10/95-9/96*	10/96-9/97*
Admissions	830(-10%)	801(-3%)	662(-17%)
Inpatient days	9102(-12%)	7258(-20%)	5368(-26%)
Average Length of Stay	10.9(-4%)	9(-15%)	8.1(-10%)
Unique outpatients	660	692(5%)	741(7%)
Outpatient visits	5523(+3%)	5920(+7%)	6522(+9%)
Inpatient service costs	$10,101,399	$8,542,171(-15%)	$6,483,350(-24%)
Outpatient service costs	$1,554,761	$1,588,857	$1,754,634
AIDS nursing home	--	$693,600	$658,920
Antiviral costs (estimated)	$1,481,000	$1,992,000(+35%)	$4,039,000(+103%)
Viral load costs	--	--	$125,031
Total cost	$13,137,160	$12,816,628	$13,060,935
Cost/patient/year	$19,904	$17,519	$16,736

*Changes compared to previous year.

Conclusion: During the period of introduction and availability of HAART, acceleration of already-occurring favorable shifts in utilization of services and associated costs occurred. Outpatient and non-hospital utilization/cost and antiviral costs increased, but were offset by dramatic decreases in utilization/cost of inpatient care. Although the total number of patients in care increased, overall costs remained level and cost/patient/year decreased. Our analysis suggests that HAART is cost-effective.