

THE CITY OF NEW YORK

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Michael R. Bloomberg
Mayor

Thomas R. Frieden, M.D., M.P.H.
Commissioner

nyc.gov/health

September 14, 2006

The Honorable Michael B. Enzi
Chairman
Health, Education, Labor, and Pensions
Committee
835 Hart Senate Office Building
Washington, DC 21510

The Honorable Edward M. Kennedy
Ranking Member
Health, Education, Labor, and Pensions
Committee
527 Hart Senate Office Building
Washington, DC 21510

The Honorable Joe Barton
Chairman
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable John D. Dingell
Ranking Member
Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

Dear Chairmen Enzi and Barton, and Ranking Members Kennedy and Dingell:

On behalf of New York City, I am writing to comment on the draft of the Ryan White Treatment Modernization Act of 2006 discussed at the stakeholder meeting held on September 11, 2006. I would like to recognize the Committees for their continued efforts to improve and modernize this critical program. The latest discussion draft has much to commend, including the attempt to transition to consideration of all living HIV and AIDS cases as the basis for funding. The latest draft also includes modifications to counseling and testing requirements for Title III that will significantly reduce barriers to HIV testing and allow more people to learn their status.

However, I am seriously concerned that should this legislation pass in its current form, New York City stands to lose a significant amount of funding that provides critical life-saving treatment and care to persons living with HIV/AIDS in New York. This is unacceptable.

New York City has the oldest, the largest, and the most complex HIV/AIDS epidemic in the United States. New York City accounts for one of every six reported AIDS cases in the United States, and each year reports more AIDS cases than Los Angeles, San Francisco, Miami, and Washington, D.C. combined. Based on conservative fiscal estimates using Government Accountability Office (GAO) reports, New York City stands to lose more than \$17.8 million in 2007. Moreover, the GAO projects New York State's loss at \$8.7 million. These devastating losses are due to the inclusion of HIV case counts from code-based states in the Title I and Title II funding formulas. This is a flawed approach that is scientifically unsound and arbitrary. These losses are almost assured to be even greater in subsequent years when the hold-harmless

September 14, 2006

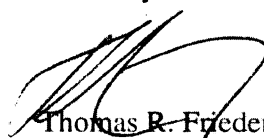
provision, as currently proposed, is phased out. These projected losses would destabilize the HIV treatment and care infrastructure that New York City and New York State have developed together over the past two decades, and would have a devastating impact on persons living with HIV disease in New York. Our citizens with HIV disease who depend on our comprehensive system of care will bear the brunt of deep cuts in covered drugs and the elimination of essential health care and support services.

I have been informed that during the recent stakeholder meeting there was promising discussion on ways to ensure that New York's funding is maintained, and I applaud those efforts. As you move forward in this process, I urge you to consider carefully the impact of changes to key funding provisions, and ask you to ensure that any changes do not result in a devastating loss of funding to New York. In particular, I urge the authorizers to review carefully provisions regarding the Title I and Title II formulas, hold-harmless, and carryover, as well as the overall appropriations and authorizations for the CARE Act. Given continuing uncertainties regarding the accuracy and reliability of code-based HIV reporting, to allocate funding using HIV case counts in states that do not have name-based HIV reporting is problematic and would be fundamentally inequitable. By improving the hold-harmless provisions and extending them through the life of the Act, the devastating reductions in funding to New York and other high prevalence areas could perhaps be mitigated. I also ask you to maintain flexibility around the use of unobligated funds, and allow EMAs and States to continue to have access to needed funding without arbitrary restrictions.

The City of New York continues to strongly support the reauthorization of the Ryan White CARE Act. As you continue your work, I urge you to consider that of the estimated 1.1 million persons living with HIV disease in the United States, more than 10 percent live in New York City, and any significant reductions in funding would have a devastating impact on their ability to access the care and treatment that can improve and lengthen their lives. I look forward to seeing how future drafts of this important legislation reflect the discussion at the September 11th stakeholder meeting.

Thank you in advance for your consideration of these concerns and for your hard work on this important issue.

Sincerely,



Thomas R. Frieden, M.D., M.P.H.
Commissioner



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ANTONIA C. NOVELLO, M.D., M.P.H., Dr. P.H.
Commissioner

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August 28, 2006

The Honorable Michael Enzi
Chairman
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379A Russell Senate Office Building
Washington, DC 20510

The Honorable Ted Kennedy
Ranking Member
Senate Health, Education, Labor
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317 Russell Senate Office Building
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The Honorable Joe Barton
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House Energy and Commerce Committee
2109 Rayburn House Office Building
Washington, DC 20515

The Honorable John Dingell
Ranking Member
House Energy and Commerce Committee
2328 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Enzi, Chairman Barton, Ranking Member Kennedy, and Ranking Member Dingell:

I am writing to express great concern about the proposed Ryan White HIV/AIDS Treatment Modernization Act of 2006. New York State applauds the work that has gone into the proposed bill and the commitment of Senate and House leaders to reauthorize the Ryan White CARE Act. However, we are alarmed about the bill's potential impact on states as well as the proposed precedent-setting policy related to disease surveillance.

It is our understanding that bill mark-up is tentatively scheduled for the week of September 11, 2006. We are concerned about this timeline, primarily because the impact of the proposed Ryan White bill on individual states has not been determined. In order to assess the proposal, states must be able to see accurate evaluations of the impact of the proposed changes in each year of the authorization period. However, data on the cases that will be used to allocate resources are not universally available. That the data required to assess the impact of the proposed bill have not been accessible begs the question of whether data will be available -- and sound -- when they are used to allocate resources in just a few months.

In New York, based on the limited data available, we estimate that resources will be shifted. Twenty-five years into this epidemic, a bill that shifts resources away from any jurisdiction will disrupt long-established medical care and essential services for persons living with HIV/AIDS. This is not acceptable.

More than one million people are living with HIV and AIDS in the U.S. Medical advances have resulted in many more people with HIV and AIDS living longer and many who do not progress to AIDS for years. Despite these medical advances, we continue to see new infections. The CDC reports that nationally, 40,000 new infections are identified each year. New York remains the epicenter of the HIV/AIDS epidemic. Almost 8,000 individuals were newly diagnosed with HIV or AIDS in 2004, and more than 110,000 New Yorkers are living with HIV/AIDS. Moreover, the centers of the epidemic have remained constant over the years. An examination of validated HIV/AIDS cases demonstrates that more than half of all people living with HIV/AIDS reside in five states: New York, California, Florida, Texas, and New Jersey. If Ryan White resources are to follow the epidemic, they must continue to flow to all jurisdictions to address the needs of increasing numbers of persons living with HIV and AIDS.

The proposed dual "tracks" for HIV reporting establish a troublesome precedent associated with disease surveillance in that the proposal legislates a double standard for HIV reporting. Currently, all reportable diseases except HIV are universally reported using patient name. The proposed dual reporting system will hold 33 name-based states to rigorous CDC validation requirements and restrictions, while code-based and transitioning jurisdictions will not be held to the same stringent standards. The proposal has the potential to divert resources away from strengthening name-based HIV reporting, and it is not clear how the confidentiality and security of a second system of reporting will be maintained. In addition, the proposed duplication penalty is problematic. Although CDC cannot provide a definitive assessment of the level of duplicative cases in code-based states, it is our understanding that CDC has determined that the number of duplicate reports of HIV cases varies greatly from state to state, with many states showing greater than five percent duplication. As such, mandating in legislation a duplication penalty of five percent for all code-based states is patently unfair and not scientifically based. It is our understanding that experts in the science of public health surveillance, specifically the Council of State and Territorial Epidemiologists, support the inclusion of HIV data -- as reported to and validated by CDC -- in the funding formula, but believe the adoption of dual tracks for HIV reporting is not defensible.

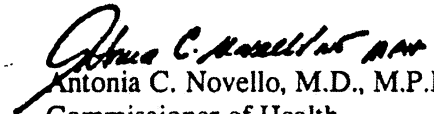
New York State strongly supports reauthorization of the CARE Act. However, hasty reauthorization could well reverse national gains made in saving lives and dramatically improving quality of life for persons with HIV/AIDS. We are committed to a reauthorized CARE Act that is based in science and sound policy, recognizes increased need for HIV services in all jurisdictions and avoids harm for persons with HIV and AIDS throughout the nation.

New York State would support a bill that allocates resources based on uniform, validated living HIV and AIDS case data with an improved hold harmless provision for the entire reauthorization period. A hold harmless provision will assure ongoing care for persons living with HIV and AIDS in states with relatively young HIV reporting systems. The 2000 CARE Act recognized the potential for unintended consequences resulting from policy and formula changes and thus included hold harmless provisions to protect jurisdictions from dramatic swings in funding. At a minimum, we hope a reauthorized bill will offer similar protections, particularly in light of the numerous changes being proposed.

As an alternative to a hurried reauthorization, we suggest consideration be given to delaying it. Until such time that the impact of the proposed reauthorized CARE Act can be assessed for and by all jurisdictions over the entire authorization period, and until experts in the science of public health surveillance can study the use of data in the allocation of resources, we ask that reauthorization be postponed. Should this suggestion be positively considered, while such deliberations occur, the existing law allows funding to flow according to validated cases while offering protection for states and cities through hold harmless provisions. In addition, appropriators have seen the wisdom of increasing the FY 2007 Title II allocation for states, acknowledging the need for increased resources in all jurisdictions and further protecting states from dramatic losses.

Thank you for your consideration of our comments and concerns. We look forward to the opportunity to offer feedback on the draft bill and impact assessments when they become available.

Sincerely,


Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner of Health

Testimony

*Guthrie S. Birkhead, M.D., M.P.H.
Director, AIDS Institute
New York State Department of Health*



*Ryan White CARE Act Stakeholder Meeting
Monday, September 11, 2006
Washington, D.C.*

Comments on Proposed Ryan White HIV/AIDS Treatment Modernization Act

I am pleased to have the opportunity to offer comments on the proposed Ryan White HIV/AIDS Treatment Modernization Act. We recognize the challenges associated with reauthorizing the Ryan White CARE Act. We are committed to working with you to address these challenges, and we urge you to resolve the outstanding issues associated with the proposed bill.

The HIV/AIDS Epidemic in New York State

Despite what you might have heard about HIV/AIDS in the rest of the country, New York State still leads the nation in the number of persons living with HIV and AIDS – now more than 110,000 – and the number of new HIV and AIDS cases each year. New York also has seen a sustained drop in the number of HIV/AIDS deaths each year, so the number of people living with HIV and AIDS in New York in need of services continues to grow. The number of new AIDS cases reported in 2004 increased by 15.5 percent over the number reported in 2003.

New York bears a disproportionate share of the epidemic, with 17 percent of all persons living with AIDS but just seven percent of the U.S. population. At 39.7 per 100,000, New York's annual rate of new AIDS cases in 2004 was the highest of any jurisdiction other than the District of Columbia. The epidemic in New York State is dominated by HIV/AIDS in people of color. More than 75 percent of living HIV/AIDS cases in New York State are persons of color.

New York State's epidemic is widespread, encompassing every county in the State. Large numbers of people with HIV and AIDS reside in the Title I EMA regions – New York City, Long Island, and the Lower Hudson region – but even without these cases, the State ranks tenth in the nation in terms of people living with HIV and AIDS. New York State has more people living with HIV and AIDS outside of the Title I regions than most other states have statewide.

Unfortunately, as these data indicate, New York's epidemic has not "stabilized." There are more than 6,000 new HIV infections each year in New York, and in 2004, New York State reported more new AIDS cases and more new HIV cases – almost 8,000 -- than any other state.

Some have claimed that the HIV epidemic in the U.S. has “shifted.” Certainly, the epidemic has expanded, but it has not shifted. More than half of all people living with AIDS in the U.S. still are concentrated in just five states. New York and California continue as major epicenters of the epidemic, followed by Florida, Texas, and New Jersey. These five states accounted for more than 52 percent of all new AIDS cases in 2004. More than 40 percent of all Blacks or African Americans living with AIDS reside in four states: New York, Florida, California, and Texas. More than 60 percent of all Hispanics living with AIDS reside in these four states.

These data illustrate the disproportionate impact of this epidemic on a few jurisdictions. If Ryan White resources are to follow the epidemic, they must continue to flow to all jurisdictions and be increased. It does not make sense to reduce funding to the most heavily impacted states, which continue to see increases in persons living with HIV/AIDS in need of services.

Impact of the CARE Act in New York State

In discussing the impact of the Ryan White CARE Act on New York State, it must be noted that New York began to organize its response to the HIV/AIDS epidemic with the creation of the AIDS Institute within the State Health Department in 1983. By 1991, the State had built a system of HIV care and support services financed by Medicaid and State and federal grant dollars. When federal Ryan White funding became available in 1991, New York State’s system of HIV care was already well developed. Ryan White funds were used, along with increases in State and CDC resources, to expand and augment this system. Specifically, Ryan White resources were used to:

- Augment existing initiatives, most notably the ADAP and home care programs for the uninsured;
- Extend primary care services to the uninsured;
- Fund new community-based case management and supportive services programs; and
- Establish Ryan White HIV care networks throughout the State. The care networks are local groups of providers in 16 geographic areas, as well as one statewide body, who work with

the State health department to determine local program priorities and to improve coordination of services.

No state spends more to prevent the spread of HIV infection and care for persons with HIV/AIDS, and Ryan White funding is an essential source of support for New York's continuum of HIV services. The CARE Act has had a tremendous impact on improving the health and quality of life for New Yorkers with HIV/AIDS.

Comments on Senate Ryan White Modernization Act of 2006

The proposed Ryan White HIV/AIDS Treatment Modernization Act, dated September 7, 2006, will be devastating for persons with HIV and AIDS living in New York State. According to the GAO data, New York State stands to lose more than \$78 million over four years of the authorization period. Losses in year five cannot be estimated. The bill will result in deep cuts in medications and services for persons living with HIV and AIDS throughout New York State.

The bill proposes to limit losses to states in the first three years of the CARE Act, after which the hold harmless provision is eliminated. The proposed Title II hold harmless provision allows for a reduction of five percent in year one, an additional five percent in year two, and an additional five percent in year three. The hold harmless protections are eliminated in year four. The hold harmless provisions are insufficient to limit devastating losses that will harm persons living with HIV and AIDS.

In addition, the proposed dual "tracks" for HIV reporting establish a troublesome precedent associated with disease surveillance in that the proposal legislates a double standard for HIV reporting. Currently, all reportable diseases except HIV are universally reported to states using patient name. The proposed dual reporting system will hold 33 name-based states to rigorous CDC validation requirements and restrictions, while code-based and transitioning jurisdictions will not be held to the same stringent standards. The proposal has the potential to divert resources away from strengthening name-based HIV reporting, and it is not clear how the confidentiality and security of a second system of reporting will be maintained. In addition, the proposed duplication penalty is

problematic. Although CDC cannot provide a definitive assessment of the level of duplicative cases in code-based states, it is our understanding that CDC has determined that the number of duplicate reports of HIV cases varies greatly from state to state, with many states showing greater than five percent duplication. As such, mandating in legislation a duplication penalty of five percent for all code-based states is patently unfair and not scientifically based. The proposed funding formula will overestimate cases in some states and undercount cases in others. As a result, funding cannot flow to persons living with HIV disease in need of services.

The proposal to use data that have not been validated in a funding formula sets a shocking precedent. The formula that will allocate scarce Ryan White resources over the next five years cannot be arbitrary and applied unevenly. Rather, it must be grounded in evidence and sound policy, and it must be applied uniformly. It is our understanding that experts in the science of public health surveillance, specifically the Council of State and Territorial Epidemiologists, support the inclusion of HIV data -- as reported to and validated by CDC -- in the funding formula but believe the adoption of dual tracks for HIV reporting is not defensible.

Also, the bill requires that consortia expenses be considered part of the cap on administrative costs. In New York, we have 16 regional consortia and one statewide consortium. For 15 years, consortia have been one of the allowable program activities and expenses within Title II. States are allowed to use program funds for medications, insurance continuation, health care and support services, and HIV care consortia. It is through the consortia that states receive input from service providers on the front lines and persons living with HIV/AIDS. The consortia are the foundation of the Ryan White tradition of inclusiveness. They give regional representatives, providers, and consumers a voice in program and policy development, and they play an important role in meeting legislative mandates around needs assessments and state plans. Our administrative and evaluation dollars are used to comply with extensive requirements imposed on us related to management of the grant, management and monitoring of contracts, conducting needs assessments, statewide planning, client-level data systems, etc. We cannot absorb the expenses

associated with consortia within our administrative cap. In effect, placing consortia expenses within the administrative cap will result in the elimination of consortia in New York State. The elimination of the consortia will silence many voices, including the voices of persons living with HIV/AIDS, and destroy the CARE Act tradition of inclusion.

Further, the proposed bill calls for Title II formula grants to be allocated using a severity of need index beginning in FY 2011 at the earliest and FY 2013 at the latest. New York State has grave concerns about the inclusion of such a mandate in the CARE Act. The structure and impact of such an index cannot be determined. In addition, as the proposed funding formula points out, data associated with one of the most straightforward indicators of need – HIV cases – are not yet universally available. As such, it is premature to propose such an index in legislation.

We have serious concerns about the proposed structure of a severity of need index, which is currently in development by work groups convened by HRSA. It has been suggested that the index will consider factors such as generosity of state Medicaid programs and other resources available for HIV services, thereby punishing states, like New York, that have devoted effort and resources to the development of comprehensive HIV/AIDS services, rewarding jurisdictions that have not, and providing a disincentive for jurisdictions to allocate local resources to meet the needs of their residents with HIV/AIDS. The provision has the potential to slash resources in those states that have devoted their own resources to HIV/AIDS and done the most pioneering work in HIV/AIDS care and treatment. It is unacceptable for the CARE Act to mandate a potentially problematic, yet-to-be-tested severity of need index.

Moreover, the bill restricts the ability of states to carry forward unexpended funds into subsequent grant periods. It must be noted that responsible management and monitoring of grants, particularly large grants with multiple sub-grantees, will result in routine underspending of a small percentage of funds. In New York, we incorporate the utilization of unexpended funds into our planning process. Our ADAP program grows at approximately \$20 million per year. Increases in federal funds have not kept pace with program growth. We carry forward a small percentage of

unexpended funds to help fill the ADAP hole. In 2006, we carried forward two percent of our grant which remained unspent at the end of the 2005 grant year. It is very important to note that all of our unexpended funds have been spent in the subsequent grant year. Consequently, New York State has never had funds that have gone unspent. States should continue to have the ability to carry forward a small percentage of unexpended funds to support essential services. States should not be penalized in subsequent grant years for normal underspending associated with careful grants management.

Finally, we are concerned about the impact assessments that have been provided with the September 7 draft bill. We question whether the data used in the assessments are accurate. In addition, we are concerned about the true impact on Title I jurisdictions, given that there are no estimates of the impact of the Title I supplemental with the proposed shift in Title I resources from the supplemental to the formula awards. We are concerned about the potential losses to New York's Title I EMAs. In order to assess the proposal, states must be able to see accurate evaluations of the impact of the proposed changes in each year of the authorization period on all jurisdictions. However, data on the cases that will be used to allocate resources are not universally available. We question whether data will be available – and sound -- when they are used to allocate resources in just a few months.

Recommendations

New York State supports reauthorization of the CARE Act and would support a bill that allocates resources fairly while it protects all jurisdictions from wide shifts in funding. Our recommendations include:

1. Allocate resources based on validated HIV and AIDS cases, with a strong hold harmless provision, or transition factor, that will assure ongoing care for persons living with HIV and AIDS in states with relatively young HIV reporting systems.
2. The improved hold harmless provision must remain in effect for the entire authorization period. The 2000 CARE Act recognized the potential for unintended consequences

resulting from policy and formula changes and thus included hold harmless provisions to protect jurisdictions from dramatic swings in funding. We hope a reauthorized bill will offer similar protections, particularly in light of the numerous changes being proposed. We support the recommendations of the CSTE and the community compromise proposal. Specifically, losses to states should be limited to 1.5 percent in each year of the authorization period, using FY 06 as the base year, for a maximum loss of 7.5 percent in year five.

3. Consortia must remain as an allowable program expense within Title II. Consortia provide a voice for providers and consumers in Ryan White policy and program development.
4. Change the Severity of Need Index (SONI) provision to allow for continued development and testing of a SONI for this authorization period and consideration of its use only in the next authorization period after the structure and impact of a SONI has been determined.
5. As an alternative to hurried reauthorization, consideration should be given to delaying it, until such time that the impact of the proposed reauthorized CARE Act can be assessed for and by all jurisdictions over the entire authorization period, and until experts in the science of public health surveillance can study the use of data in the allocation of resources. While such deliberations occur, it is our understanding that the existing law allows funding to flow according to validated cases while offering protection for states and cities through hold harmless provisions. In addition, appropriators have seen the wisdom of increasing the FY 2007 Title II allocation for states, acknowledging the need for increased resources in all jurisdictions and further protecting states from dramatic losses.

Conclusion

We appreciate your commitment to reauthorize the CARE Act. However, we are gravely concerned about the devastating losses New York State will suffer under the proposed bill. New York State has more persons living with HIV and AIDS than any other state in the nation, yet New York faces extraordinary reductions in resources under this bill.

New York State strongly supports reauthorization of the CARE Act. However, hasty reauthorization could well reverse national gains made in saving lives and dramatically improving quality of life for persons with HIV/AIDS. We are committed to a reauthorized CARE Act that is based in science and sound policy, recognizes increased need for HIV services in all jurisdictions and avoids harm for persons with HIV and AIDS throughout the nation.

Thank you for the opportunity to offer comments on the Ryan White bill. We remain committed to working with you to address the challenges associated with reauthorizing the Ryan White CARE Act.