

Original: 2185

May 19 2001

Mr. Joel Hersh
Director
Bureau of Epidemiology
Commonwealth of Pennsylvania
Department of Health
P.O. Box 90
Harrisburg, PA 17108

BUREAU OF EPIDEMIOLOGY

01 MAY 24 AM 10:53

2001 MAY 21 AM 9:18
RECEIVED
COMMISSIONER

DEPARTMENT OF HEALTH

Re: Names Based HIV Reporting

Dear Mr. Hersh:

As a concerned citizen, I am writing to express my grave concern with the proposed draft regulations on HIV reporting currently under consideration and out for public comment.

I oppose reporting the names of people with HIV to the Commonwealth. As you are aware, based on the overwhelming message delivered in the public hearings conducted statewide by the department on this subject, and in the academic publications available to date, there is significant evidence that HIV reporting by name can and will deter individuals from seeking HIV test. This is particularly true of those individuals who are perhaps at the greatest risk of infection. I support the development of a non name-based HIV surveillance system to achieve the public health goals of HIV surveillance in Pennsylvania.

Regarding testing, while I favor the department's intent to continue the availability of anonymous testing, I feel that opportunities for anonymous testing should be increased throughout the state. Though the Department has stated that more than 100 such testing sites are now available, I believe this number includes sites offering confidential testing, which cannot be confused with anonymous. Indeed, in the Counties of Philadelphia and Allegheny, where nearly 80% of the reported AIDS cases are concentrated, there are approximately 10 genuine anonymous testing providers currently available. The proposed regulations seem to potentially limit the availability of anonymous testing by requiring that anonymous testing be conducted only at a "State-designated anonymous testing site." Through the regulations, the Commonwealth of Pennsylvania should encourage increased publicly-funded anonymous testing options to ensure that individuals are not deterred from seeking HIV testing, and that true anonymous tests are available and accessible to all Pennsylvanians.

On the subject of reporting risk factors, the regulations as drafted ask only for "probable mode of transmission," a subjective assessment. Here, providers must be provided with the most current categories of transmission risk as delineated by the CDC and should be instructed to use only those categories. Requiring subjective risk factors to be reported allows for judgments to be made about an individual. Identifying specific, nationally

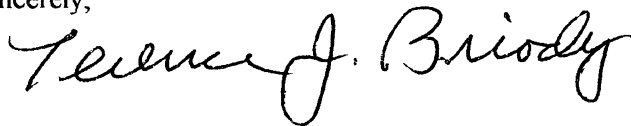
aggregated risk factors is far more accurate, reasonable, and appropriate and will provide standardized data that can be compared in CDC reporting.

On the subject of reporting by the many entities reference in the regulations, I remind you that only physicians can make a diagnosis of HIV. The results of a laboratory test, independent of a physician's judgment, are not a diagnosis of HIV nor should it constitute grounds for a public health intervention. Neither laboratories nor "entities providing HIV services" should be required to report information about an individual's HIV status or other markers, as they cannot clinically interpret that information. Only a clinician can and should make a diagnosis or moderate clinical progress. It is unrealistic and inappropriate to require these entities to abide by these regulations.

In closing, I am further concerned about area of the regulations lacking specificity. Here, clear language must be provided around the security of any required electronic transmission of HIV and related data. Additionally, any "public health interventions" as described in the regulatory narrative must be accompanied by regulatory language describing these activities, involving community-based organizations in these interventions and designing these interventions using best practice models. Further, they should only be implemented as a the "court of last resort" and not as the first step as the regulations suggest.

My thanks for your consideration, I look forward to seeing significant revisions of the regulations in the near future.

Sincerely,

A handwritten signature in cursive script that reads "Terence J. Briody". The signature is written in black ink and is positioned below the word "Sincerely,".

cc: Senator Vincent Hughes
Representative Dennis M. O'Brien
Representative Frank L. Oliver
Senator Harold F. Mowery

Original: 2185

IRRC

From: Harris, Mary Lou
Sent: Tuesday, September 04, 2001 5:06 PM
To: IRRC
Subject: FW: HIV Reporting System Final Regulation

-----Original Message-----

From: barrybusch [mailto:barry@CritPath.Org]
Sent: Sunday, August 26, 2001 11:37 PM
To: Jhersh@state.pa.us
Cc: sjohnson@pasen.gov; rrummel@pahousegop.com; Maryh@irrc.state.pa.us
Subject: HIV Reporting System Final Regulation

Their are many humanitarian endeavors calling for our attention, yet ,when it comes to Pennsylvania ,non call more strongly than Pennsylvania adopting an HIV reporting system that will lead to an accurate statewide control plan . It is our hope and our prayer that the final regulation formulated in your mind and now coming into print has been formulated in a manner which will aid in the protection of all our friends,families and children from the HIV virus.
WE are hopeful.
WE await.

2001 SEP -5 AM 8:06
REVIEW COMMISSION

Original: 2185

IRRC

From: Harris, Mary Lou
Sent: Monday, June 25, 2001 8:40 AM
To: IRRC
Subject: FW: IRRC Comments - Department of Health Regulation #10-166

-----Original Message-----

From: barrybusch [mailto:barry@CritPath.Org]
Sent: Friday, June 22, 2001 10:01 PM
To: maryh@IRRC.STATE.PA.US
Subject: Re: IRRC Comments - Department of Health Regulation #10-166

Thank you so much for sending me the IRRC comments on DOH reg. 10-166. There were alot of really important aspects to why names reporting would in the future be shown to be a disaster ,if adopted, which where never so much as hinted at. However at the same time I think enough hints were given that I should be appreciative. I am. I hope DOH does not take until 2004 to present final regulation,I hope they abandon reg 10-166 and come up with a whole new rewrite. My health is already lost, but it is in the interest of saving everyone elses health that I communicate with you for. Can we set up a meeting at the appropriate time to make sure you are aware of pitfalls we've mentioned, yet not mentioned in IRRC comment ? For instance, are you aware names reporting has a built in propensity to collect inaccurate data?

maryh@IRRC.STATE.PA.US wrote:

> Comments attached, as requested. <<com2185.doc>>
>
> -----
>
> Name: com2185.doc
> com2185.doc Type: Microsoft Word Document (application/msword)
> Encoding: base64

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June 21, 2001

John R. McGinley, Jr., Esq.
Chairman
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, PA 17101

Re: HIV reporting by name as proposed by the DOH

Dear Mr. McGinley:

I disagree completely with the proposal by the Pennsylvania Department of Health to require mandatory reporting by name of those citizens who test positive for HIV antibodies. I believe that such a policy would be counterproductive and, in fact, would be literally dead wrong.

I am a physician and pathologist in practice in Lewisburg and in Sunbury, two semi-rural communities about an hour north of Harrisburg. I am the Director of Clinical Laboratories at both the Sunbury Community Hospital and the Evangelical Community Hospital. I am the Chairman of the Infection Control Committee at Evangelical Hospital and the immediate past Chairman of the Infection Control Committee at the Sunbury Hospital. At Evangelical Hospital I also hold the position of Vice President for Medical Affairs. I have more than 30 years experience in laboratory medicine and medical microbiology. In addition, I am board certified in pathology and in medical microbiology and am a member of the faculty of the Penn State University Medical School in Hershey.

We have had several people with AIDS in Lewisburg and Sunbury. For every one of these people with AIDS there are at least three or four other HIV-infected people. So, HIV/AIDS is not a problem from which Lewisburg and Sunbury are isolated.

Although many citizens of these communities are relatively enlightened and broad-minded, it is clear to me that people with AIDS here are subject to the same types of discrimination that are reported all over the country. They have lost their jobs and homes and have become isolated and shunned. Instead of compassion, they have been shown contempt and have been made the object of

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cruel jokes. It is this treatment that those who wonder if they might be HIV-infected particularly fear. They ask me to send their blood for testing under bogus names or invented ID numbers that only they and I can recognize.

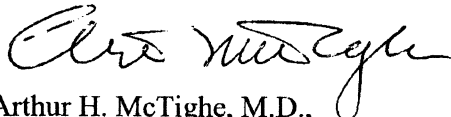
For me to tell these people that I will have a legal obligation to report them to the government, **by name**, will simply dry-up testing. No one is served by such a policy. Not the HIV-infected patient who for optimal treatment should be diagnosed early, nor the sex partners of a person who does not know that he or she is already infected. To require reporting of HIV infection **by name** will actually help further spread HIV infection. It is for this reason that such a policy is literally dead wrong.

But if there is a need to have more accurate epidemiological information regarding the incidence of HIV infection, then adopt a system of unique identifiers for reporting, as has been done in Maryland, Illinois, California, and several other states.

It is also absolutely necessary to preserve the ability for me to test patients for HIV in a completely anonymous fashion, in the event that the patient will not otherwise consent to be tested. This cannot be limited to only selected Health Department sites.

I appreciate your consideration and trust that you will reject mandatory reporting of HIV infection status by name.

Sincerely,

A handwritten signature in cursive script, appearing to read "Arthur H. McTighe".

Arthur H. McTighe, M.D.,
Vice President for Medical Affairs
Director of Laboratories

Original: 2185

John R. McGinley, Jr. Esq. Chairman
Independent Regulatory Review Commission
14th Floor, Harrisstown 2
333 Market Street
Harrisburg, PA 17101

6/16/01

RECEIVED
2001 JUN 21 AM 8:51

INDEPENDENT REGULATORY
REVIEW COMMISSION

Re: DOH Proposed Rulemaking HIV Reporting System

Dear Chairman McGinley,

I write you out of grave concern for the health of Pennsylvania. I have AIDS and it is my utmost desire to educate those in the decision making process so that Pennsylvania will adopt a HIV reporting system that will allow for the voluntary testing of as many citizens as possible while at the same time insure the most accurate data possible is collected for state planning purposes.

I will not belittle this communication by repeating the comments you have recieved from the DOH and the Senate and House Health committees. But it is my goal to help Pennsylvania adopt a reporting system that will achieve the desired results. I hope we have the foresight to develop a system that will identify HIV positive citizens ASAP so that our people do not remain ignorant of their infection and only realize their disease when they become debilitated by AIDS, the medical cost of which to future state coffers will dwarf any pennies saved by DOH if we ultimately decide to label the files by name.

My intention here is simply to bring up a few points I feel are of the utmost import yet may not be brought to your attention. There has been some say about how the states who have adopted name-based reporting have no data that labeling the files by name has scared people away. Why would anyone expect any of the states with name-based HIV reporting to have any evidence of how many people have avoided testing? People who are scared away from testing have removed themselves from the data stream. Thus, there will never be statistical reports, in fact can never be, on how many people do not get tested due to names reporting. Why? Because there's no data on them. They've walked away. There never will be any data on them until they become debilitated from AIDS, years down the road. But they do exist.

Ask any of the healthworkers out in the streets talking people into being voluntarily tested and they'll tell you they exist. It is shortsighted to assume just because you can't see them on a paper report that they don't exist.

What HIV/AIDS activists are arguing for is a reporting system that will allow for the voluntary testing of everyone while collecting the most accurate data possible. The same data will be collected be the file labeled by name or a code based identifier. But there will be a difference which will have enormous impact on state planning. The only thing guareanteed to be accurate(assumming people at risk don't give an alias or someone elses name to protect there identity) in a name based system will be the name. The price though will be flawed information. Remember we're talking about how to label a file here. Answer Honestly, if you know the answers you give in response to the personal lifestyle questions that will need to be asked to develop a state plan are going into a state file with your name on it won't you with every question asked be considering the personal consequences of each reply. Won't you answer each question with the least embarrassing reply? You bet your bibbi you will. You, me, everyone out of our human instinct of selfpreservation will lie.

A statewide plan crafted from inaccurate data is an inaccurate plan. Just because 34 other states have decided to settle for a reporting system that has a built in propensity for inaccurate data collection and thus inaccurate planning is no reason for Pennsylvania to do likewise. Sometimes the right thing to do is not the easiest method. I suggest to promote both voluntary HIV testing and the most accurate state control plan possible the Proposed HIV Reporting Regulation be set up to identify the file by a unique-identifier and also with unrestricted code based anonymous testing.

Sincerely Hopeful,



Barry Busch
840 Upland Ave.
Upland, Pa. 19015
610-876-6750<barry@critpath.org

cc: Robert S. Zimmerman, Jr, Secretary of Health
Joel H. Hersh, Director, Bureau of Epidemiology
Robert E. Nyce, Executive Director, IRRC
Harold F. Mowery, Jr, Chairman Senate Public Health & Welfare
Timothy F. Murphy, Vice-Chairman, Senate Public Health & Welfare
Vincent J. Hughes, Minority Chairman, Senate Public Health & Welfare
Dennis M. O'Brien, Majority Chairman, House Health & Human Services
Frank Oliver, Minority Chairman, House Health & Human Services



Department of Health

HARRISBURG

May 31, 2001

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2001 JUN -5 AM 10:20
INDEPENDENT REGULATORY
REVIEW COMMISSION

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor
333 Market Street
Harrisburg, Pennsylvania 17101

Re: DOH Regulation No. 10-166
Reporting of Certain HIV Test Results, CD4 T-Lymphocyte Counts Below
Certain Level, and Perinatal Exposure of Newborns to HIV

Dear Mr. Nyce:

The Pennsylvania Department of Health has recently received the enclosed public comment(s) to the above-referenced regulations.

Sincerely,

A handwritten signature in black ink that reads "Joel H. Hersh".

Joel H. Hersh, Med MPA
Director
Bureau of Epidemiology

Enclosure(s)

cc: Deborah Griffiths
Joel Hersh
Yvette Kostelac

YMK/jab

Original: 2185

PENNSYLVANIA COALITION OF
PCASO
AIDS SERVICE ORGANIZATIONS

June 14, 2001

Mr. Joel Hersh
Director
Bureau of Epidemiology
Commonwealth of Pennsylvania
Department of Health
P.O. Box 90
Harrisburg, PA 17108

RECEIVED
2001 JUN 15 PM 1:42
COMMISSION

(nine pages via fax 717 772.6975, hard copy to follow, USPS)

Re: Comments of the Wilkes-Barre Health Department on proposed
rulemaking 10-166

Dear Mr. Hersh:

J.H.L.

Through a colleague, I am in receipt of comments submitted to the Department of Health by the Wilkes Barre Health Department and signed by Director Henry Radulski, concerning the pending HIV reporting regulations now under consideration in the regulatory review process.

Though we are in complete agreement with the letter's first few paragraphs stating the need for and potential use of an HIV reporting system, much of the letter seeks solely (and subjectively) to make a case for reporting by names while failing to address the myriad other details of the regulations or to present any information on the other side of the names/unique identifier argument. The letter also contains a significant amount of "public health" information and assertions which are dubious, and seem to reflect a lack of understanding of HIV disease as it has evolved in the Commonwealth in recent years.

I am writing in an effort to present the other side of this picture, and to the degree space and time allow, discuss some of the letter's assertions in the context of the public health.

Let me begin with some of the letter's statements that are most troubling. On page two, paragraph three he writes "[w]ith the advent of protease inhibitors and combination therapies, treatment of HIV infection has improved dramatically. Name reporting

Joel Hersh, June 15, 2001, Page 2

systems would therefore result in more people benefitting from early intervention program (sic)."

Here, though one can hardly argue with the benefits of contemporary treatment, there is no information presented in the letter supporting why or how such public health interventions would result in more people benefitting from early intervention. As I state in my comment of May 21, 2001, the "public health intervention" devil is in the details; poorly designed programs and interventions could greatly exacerbate a deterrent effect on those testing positive. From our experience and general clinical guidelines and practice, this intervention is best left to community based providers and testing sites, whose ability to develop trust and work patients through a very difficult diagnosis (more often than not, now complicated by the co-morbidities of drug/ alcohol dependence and significant mental health issues) is essential.

"Government" in any intervention, should be the court of last resort for intervening as it is not generally viewed with trust, particularly from those in marginalized groups including the underclass, injecting drug users, specific sub-groups of racial minorities, etc. (though, it should be noted that certain government health departments with combined clinical and social service staff on site such as those in Pittsburgh and Philadelphia offer excellent, accessible healthcare and are the primary healthcare providers in many underprivileged communities). Generally, though, to allow health departments to act as the primary agents of intervention, as this letter seems to indicate, is potentially dangerous, and the very services proposed to be provided to individuals (page two, paragraph two) ("treatment, counselling and various medical and social services"), are routinely provided in existing publically-funded testing sites and at clinical providers. In this area, to be frank, some of Pennsylvania's municipal health departments can provide these services well, others are ill-equipped to do so.

In the final paragraph of page two, the assertion is made that owing to names reporting, more individuals would receive "health care benefits." The letter then goes along to cite the Federal prevention funding levels for year 2000, at \$26 million. This is completely inaccurate. Currently, the Feds appropriate \$3.387 million, (see Governor's 2001-02 proposed budget) to the state for "AIDS Health Education"--the line item used to support "testing, counselling and prevention programs." Though this figure is supplemented with limited state-generated funds, the letter's numbers are grossly mis-tated and inaccurate.

To return to the point, whether names or unique identifiers are collected in the final analysis, PA is not at risk of losing this prevention funding, unless it fails to begin collecting HIV incidence data. More importantly, prevention funding and "health care benefits" are two very different things. Healthcare in the United States is not an

Joel Hersh, June 15, 2001, Page 3

entitlement. "Health care benefits" are provided by private insurers, Medicaid and Medicare, and by many uninsured individuals paying out-of-pocket or relying on hospitals and clinics mandated to provide (more often sporadic and emergency-based) care to all in need. Though some unique clinical care options exist at a few sites in PA for individuals to receive free HIV care through Ryan White Care Act funded projects, and limited additional Ryan White dollars may be available for the care of the some indigent patients, Ryan White dollars are in no way related to the "at risk" dollars cited in the letter (those CDC funds cannot, by Congressional mandate, be used for care).

Ultimately, those without private insurance who are also ineligible for Medicaid, etc. are simply not going to get healthcare benefits by virtue of being identified as having HIV. If only it were so simple.

Page three of the letter offers a unique paradox. The author states that the CDC does not collect names etc., but rather converted SOUNDEX codes--all that they require for sound epidemiology, one assumes. If this is true of the Feds, why can it not be true to PA? Other than the practice of conducting public health interventions, something we already do successfully and in a patient-sensitive manner at the provider level, there appears to be no specific benefit or justification for collecting names. As suggested in our May 21 comments to the Department on the regulations, some description of these interventions need to be included in regulatory language to insure that DoH intervention is, in fact, the court of last resort, and that its interventions are conducted using the best contemporary public health practices.

In the final two paragraphs of page three, the author goes on to make some unusual statements. Here, he writes "people who are HIV positive are more likely to find ways to remain anonymous as compared with AIDS patients who are in frequent contact with medical and social services . . ." Though sometimes denial can play a role in an individual's initial decision to seek testing, it has not been our experience that individuals are reluctant to enter care.

Recognizing the value of care in the face of a potentially life threatening illness, and the benefits treatment has to offer, people with HIV seek out care as readily as those with case-definition AIDS--most, in fact, were being treated for HIV long before their AIDS diagnosis. I daresay, intimating that people seek out means of staying outside of care betrays a rather paternalistic, out-of-touch attitude towards people with HIV disease. From my own observation, as a former volunteer in an anonymous testing site, an individual seeking testing is not doing so on a lark, but rather because they recognize their own risk factors and are in a place where they can be willfully transitioned into care, when necessary. The October 28, 1998 JAMA anonymous testing study

Joel Hersh, June 15, 2001, Page 4

("Multistate Evaluation of Anonymous HIV testing and Access to Medical Care," abstract attached) sheds some very favorable light on the prognosis and entry into care of those testing anonymously vs. those seeking confidential tests.

In the page's final paragraph, it argues against any form of anonymous testing, a recommendation that flies in the face of the Department's wishes and that of the community. Again, the above cited JAMA article speaks strongly to the significant benefits of anonymous testing.

Page four states that Smallpox and TB were controlled by the collection of names. This is, at best, a simplistic analysis. Smallpox was controlled by the introduction of a vaccine. TB was arrested, historically, through internment (it is now again endemic, drug-resistant and very much on the rise). In recent years, TB's control has been conducted either by using the established medical protocols with compliant cases, or, in cases where the patient could or would not follow medication regimens, through very invasive interventions called directly observed therapy (DOT) which entails following patients daily at medication time(s), dispensing, and observing the patient taking their medications. As TB is an airborne pathogen that can be transmitted by coughing, sneezing, etc., is highly virulent, and puts all in proximity with an infected individual at some risk of infection, such invasive public health measures have been justified.

The letter next cites a study published in the Journal of the American Medical Association whose findings demonstrate the "before and after" experience of a number of states which have instituted name-based reporting. For your review, I attach a copy of the article's abstract.

Curiously, in the very same publication, (JAMA, Vol. 280, No. 16, October 28, 1998), another peer-reviewed article whose research was funded by the CDC appears. Entitled "Multistate Evaluation of Anonymous HIV Testing and Access to Medical Care," the publication's findings are fascinating. Essentially, the authors demonstrate that individuals initially seeking out anonymous testing enter care earlier and have significantly better health outcomes than their counterparts seeking confidential tests (those for which names are required). Though it does not directly refute the findings of its sister publication, it raises the argument, which we have made all along, that as the academic community has yet to reach consensus in any way on the potential deterrent effects of name-based reporting, it is the mandate of the Commonwealth to err on the side of caution and pursue an identifier-based reporting system. To borrow the credo which is the basis of medicine, "first, do no harm."

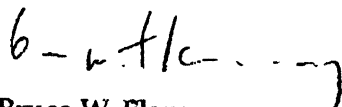
On close read, the letter's final paragraph's are difficult to understand and seem to represent a string of non sequiturs. Stating that name reporting is most likely to

Joel Hersh, June 15, 2001, Page 5

benefit intravenous drug users, bisexuals, etc . . . flies in the face of anecdotal evidence of those most concerned about having their names reported to government authorities, and those least likely to appreciate a visit from a Department official. Paragraph five of page six states that gay men will probably not benefit because HIV awareness is generally high in gay communities. This was true 15 years ago, but hardly the case today. With every passing week a new study is published announcing alarming new infection rates among young gay men and particularly young minority gay men.

I thank you for your further consideration and look forward to seeing the next iteration of the regulations.

Sincerely,



Bruce W. Flannery
Executive Director

cc: IRRC

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JAMA

Vol. 280 No. 16,
 October 23, 1998

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Effect of HIV Reporting by Name on Use of HIV Testing in Publicly Funded Counseling and Testing Programs

[1] *Alynn K. Nakashima, MD; Rosemarie Horaley; Robert L. Frey, PhD; Patricia A. Sweeney, MPH; J. Todd Weber, MD; Patricia L. Fleming, PhD*

Context.— Policies requiring confidential reporting by name to state health departments of persons infected with the human immunodeficiency virus (HIV) have potential to cause some of them to avoid HIV testing.

Objective.— To describe trends in use of HIV testing services at publicly funded HIV counseling and testing sites before and after the implementation of HIV reporting policies.

Design and Setting.— Analysis of service provision data from 6 state health departments (Louisiana, Michigan, Nebraska, Nevada, New Jersey, and Tennessee) 12 months before and 12 months after HIV reporting was introduced.

Main Outcome Measure.— Percent change in numbers of persons tested at publicly funded HIV counseling and testing sites after implementation of confidential HIV reporting by risk group.

Results.— No significant declines in the total number of HIV tests provided at counseling and testing sites in the months immediately after implementation of HIV reporting occurred in any state, other than those expected from trends present before HIV reporting. Increases occurred in Nebraska (15.8%), Nevada (48.4%), New Jersey (21.3%), and Tennessee (52.8%). Predicted decreases occurred in Louisiana (10.5%) and Michigan (2.0%). In all areas, testing of at-risk heterosexuals increased in the year after HIV reporting was implemented (Louisiana, 10.5%; Michigan, 225.1%; Nebraska, 5.7%; Nevada, 303.3%; New Jersey, 482.6%).

have sex with men in Louisiana (4.3%) and Tennessee (4.1%) after HIV reporting; testing increased for this group in Michigan (5.3%), Nebraska (18.6%), Nevada (12.6%), and New Jersey (22.4%). Among injection drug users, testing declined in Louisiana (15%), Michigan (34.3%), and New Jersey (0.6%) and increased in Nebraska (1.7%), Nevada (18.9%), and Tennessee (16.6%).

Conclusions.— Confidential HIV reporting by name did not appear to effect use of HIV testing in publicly funded counseling and testing programs.

JAMA. 1998;280:1421-1426

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Author/Article
Information

Author/Article Information

From the Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Ga.

Reprints: Alyn K. Nakashima, MD, Centers for Disease Control and Prevention, 1600 Clifton Rd, MS E-47, Atlanta, GA 30333 (e-mail: aln1@cdc.gov).

Presented in part at the 125th Annual Meeting of the American Public Health Association, Indianapolis, Ind, November 9-13, 1997.

The authors thank the following people for providing information about their HIV counseling and testing and HIV surveillance programs: Jeffrey Hanson, MPH, Maria Ludwick, and Sue Truder, Louisiana Department of Health and Hospitals, New Orleans; Gerry Goza, MS (Lansing), Kris Judd (Lansing), Eve Motokoff, MPH (Detroit), and Lisa Randall (Lansing), Michigan Department of Community Health; Tina Brubaker, MPH, and Steve Jackson, Nebraska Department of Health and Human Services, Lincoln; Bill Hill and Rick Reich, Nevada Department of Human Resources, Carson City; Samuel Costa, MA, and Helena Cross, MA, New Jersey Department of Health and Senior Services, Trenton; Chris Freeman and Herb Stone, MSSW, Tennessee Department of Health, Nashville.

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<http://jama.ama-assn.org/issues/v280n16/abefjoc80227.html>

06/15/2001

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Vol. 280 No. 16,
October 23, 1998

Original Contribution

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Multistate Evaluation of Anonymous HIV Testing and Access to Medical Care

See Related:
Articles
Authors' Articles

by Andrew B. Bindman, MD; Dennis Diamond, PhD; Frederick M. Hocht, MD; J. Stan Lehman, MPH; Karen Vranizan, MA; Dennis Keane, MPH; Arthur Reingold, MD; and the Multistate Evaluation of Surveillance of HIV (MES-H) Study Group

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Context.— Infection with the human immunodeficiency virus (HIV) is the only infectious disease for which anonymous testing is publicly funded, an exception that has been controversial.

Author/Article
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Objective.— To assess whether anonymous HIV testing was associated with earlier HIV testing and HIV-related medical care than confidential HIV testing.

Design.— Retrospective cohort.

Setting.— Arizona, Colorado, Missouri, New Mexico, North Carolina, Oregon, and Texas.

Participants.— Probability sample of 636 new acquired immunodeficiency syndrome (AIDS) cases reported to the state health department's HIV/AIDS Reporting System from May 1995 through December 1996. All had responded to the AIDS Patient Survey; 643 had been tested confidentially for HIV, and 192 had been tested anonymously.

Main Outcome Measures.— First CD4⁺ cell count; number of days from HIV-positive test result to first HIV-related medical care, from first HIV-related medical care to AIDS, and from first HIV-positive test result to AIDS.

Results.— Persons tested anonymously sought testing and medical care earlier in the course of HIV disease than did persons

*

▲
 Author/Article
 Information
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persons tested anonymously vs $0.267 \times 10^9/\text{L}$ in persons tested confidentially. Persons tested anonymously experienced an average of 918 days in HIV-related medical care before an AIDS diagnosis vs 691 days for persons tested confidentially. The mean time from learning they were HIV positive to the diagnosis of AIDS was 1245 days for persons tested anonymously vs 718 days for persons tested confidentially. After adjustment for the subject's age, sex, race/ethnicity, education, income, insurance status, HIV exposure group, whether the respondent had a regular source of care or symptoms at the time of the HIV test, and state residence, anonymous testing remained significantly associated with earlier entry into medical care ($P < .001$).

Conclusion. — Anonymous testing contributes to early HIV testing and medical care.

JAMA. 1998;280:1416-1420

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Author/Article Information

From the Primary Care Research Center (Drs Bindman and Omond, Ms Vranizan, and Mr Keane) and AIDS Division (Dr Hecht), San Francisco General Hospital, and Departments of Medicine (Drs Bindman and Hecht, Ms Vranizan, and Mr Keane) and Epidemiology and Biostatistics (Drs Bindman and Omond), University of California, San Francisco; Division of HIV/AIDS Prevention, Surveillance and Epidemiology, Centers for Disease Control and Prevention, Atlanta, Ga (Mr Letman); and Department of Epidemiology, University of California, Berkeley (Dr Reingold).

Corresponding author: Andrew B. Bindman, MD, San Francisco General Hospital, Bldg 50/Ward 95, 1001 Polk Ave, San Francisco, CA 94110 (e-mail: bindman@biza.ucsf.edu).

Support for this project was provided by the CDC (DHHS 262-62-0048).

The MESH Study Group comprises John Ward, MD, MPH, and Patricia Fleming, PhD, CDC, Atlanta, Ga; Denise K. Boyd, MS, MPH, and Vjolica Berisha, MD, MPH, Arizona Public Health Department, Phoenix; Kenneth Gerstman, MD, MPH, and Melanie Mason, Colorado Public Health Department, Denver; John Newman and Craig Thompson, Mississippi Public Health Department, Jackson; Robert Hamm, MD, MPH, Kristin Wandt, MPH, and Linda Bell, Missouri Public Health Department, Jefferson City; Michael Samuel, DrPH, and Mark Stenger, MS, New Mexico Public Health Department, Santa Fe; Steven Modait, RN, MPH, Roger Wirt, PhD, and David Fleming, MD, Oregon Public Health Department, Portland; and Ann S. Robbins, PhD, Sharon A. King, MA, and Douglas Hensler, Texas Public Health Department, Austin. The participants from the North Carolina Public Health Department requested that their names not be included.

PENNSYLVANIA COALITION OF
PCASO
 AIDS SERVICE ORGANIZATIONS

Facsimile Cover Sheet

To: the Independent Regulatory Review Commission

Fax Number: _____

No. of Pages 10 (including cover)

From: Bruce Flannery, Executive Director
 Telephone: (610) 518 0886
 Fax: (610) 518 0885

Re: Proposed regulation 10-166

RECEIVED
 2001 JUN 15 PM 1:42
 BRUCE FLANNERY
 REGULATORY REVIEW COMMISSION

Please call (610) 518 0886 should you have any problems receiving this transmission.

Dr. Walter Tsou
Health Commissioner
Philadelphia Department of Public Health
1101 Market Street, Suite 840
Philadelphia, PA 19107

RECEIVED
2001 JUN -1 11 5:40
PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH
HEALTH COMMISSIONER

Dear Commissioner Tsou,

I am writing to express concern about the Pennsylvania Health Department's plan to require that the names of people living with HIV infection be reported to the State. *Although the Pennsylvania Health Department says that name reporting does not discourage people from access to HIV testing and care, research shows that it does!*

Name reporting of HIV will only undermine the hard work being done by your department and community-based organizations in the Delaware Valley to encourage people to access HIV testing and care.

I urge you to tell the Pennsylvania Health Department that Philadelphia cannot comply with HIV name reporting requirements. Mayor Street supported this position in his 1992 campaign when he wrote that name-based HIV reporting, "could deter people from getting tested and seeking care."

Please tell the State Health Department that Philadelphia is only willing to cooperate with HIV reporting by Unique Identifier (letter/number codes that take the place of names). The ten states and territories that chose to use Unique Identifiers have proven that states can measure the spread of HIV accurately and do effective service planning without risking the privacy of their residents.

We need you and Mayor Street to protect the health of Philadelphians. We are looking to you to stand up for the right of all Philadelphians to ensure that HIV testing will not be compromised by name-based reporting!

Sincerely,

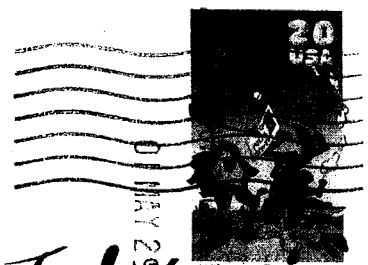
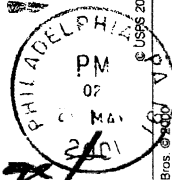
Name Mr. Tyreese Rogers

Address 13512 Bustleton Ave # 7-101, Phila, PA 19116

Phone 215-464-1641

E-mail _____

Greg Searey
THE 2004 WILE E. COYOTE & ROAD RUNNER STAMP
748 S. 10th Street
Phila, PA 19147



Dear Sir,
Would you get tested if you thought you were positive and new your "name" would be reported? Did you hesitate? So will others.
HIV Testing for everyone.

Mr. Joel Heish
Bureau of Epidemiology
Commonwealth of Pennsylvania
Dept. of Health
PO Box 90
Harrisburg, PA
17108

greg

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RECEIVED
2001 JUN -5 10:10:21
HEALTH COMMISSION

Original: 2185

2001 MAY 29 AM 10:29

REVIEW COMMISSION

Dr. Walter Tsou
Health Commissioner
Philadelphia Department of Public Health
1101 Market Street, Suite 840
Philadelphia, PA 19107

Dear Commissioner Tsou,

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We need you and Mayor Street to protect the health of Philadelphians. We are looking to you to stand up for the right of all Philadelphians to ensure that HIV testing will not be compromised by name-based reporting!

Sincerely,

Jonathan Lantz-Trissel
216 E Durham St
Philadelphia, PA 19119
lantztrissel@yahoo.com

Original: 2185

Joel H. Hersh
Director, Bureau of Epidemiology
Pennsylvania Department of Health
P. O. Box 90
Harrisburg PA 17180

RECEIVED
2001 JUN -1 AM 9:45
01 MAY 29 AM 10:02
DEPARTMENT OF HEALTH
BUREAU OF EPIDEMIOLOGY

Dear Mr. Hersh,

**Comments on Proposed Rulemaking: Reporting of AIDS, HIV Test Results,
CD4 T-
Lymphocyte Counts and Perinatal Exposure of Newborns to HIV**

I am writing in response to the above-mentioned regulations published in the Pennsylvania Bulletin on Saturday April 21, 2001. I applaud the proposal to start HIV surveillance in Pennsylvania. It would enable more accurate estimates of the burden of HIV infections. I am, however, opposed to reporting HIV by names. My comments on the regulations are:

reporting HIV infection by name, though implementable in other US States, may deter testing and subsequent care in southwest PA because

- i. minorities and intravenous drug addicts are over-represented among newly diagnosed AIDS cases
- ii. these populations are already distrustful of government and its role in healthcare proposed multiple HIV reporting systems (laboratories, case management agencies, etc) is burdensome and invasive of the patients' privacy

- ✍ security of electronic reporting cannot be guaranteed
- ✍ ramifications of electronic reporting goes beyond providing software
- ✍ mechanisms for state-designation of anonymous HIV test sites are unclear and of concern
- ✍ timeline given especially to physicians (five days) to report positive tests is unrealistic unless reports are expected to be filed even before the client is given post test counseling as required
- ✍ cost implications are grossly underestimated
- ✍ proposed effective date is unrealistic (publicity, training etc need to be accomplished first)

Yours sincerely,

Signature and Date

Floyd M. Patterson, MSW, Monday, May 21, 2001
Pittsburgh AIDS Task Force

Dr. Walter Tsou
Health Commissioner
Philadelphia Department of Public Health
1101 Market Street, Suite 840
Philadelphia, PA 19107

Dear Commissioner Tsou,

I am writing to express concern about the Pennsylvania Health Department's plan to require that the names of people living with HIV infection be reported to the State. Although the Pennsylvania Health Department says that name reporting does not discourage people from access to HIV testing and care, research shows that it does!

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We need you and Mayor Street to protect the health of Philadelphians. We are looking to you to stand up for the right of all Philadelphians to ensure that HIV testing will not be compromised by name-based reporting!

Sincerely,

Name Thomas Neilson
Address 2808 Belgrade St PHILA 19134
Phone 215-426-1696
E-mail Edn2@aol.com

RECEIVED
2001 MAY 29 AM 10:28
PHILADELPHIA
HEALTH COMMISSIONER
OFFICE

Joel H. Hersh
Director, Bureau of Epidemiology
Pennsylvania Department of Health
P. O. Box 90
Harrisburg PA 17180

RECEIVED
01 MAY 29 AM 10:02

Dear Mr. Hersh,

Comments on Proposed Rulemaking: Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV

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- ✍ cost implications are grossly underestimated
- ✍ proposed effective date is unrealistic (publicity, training etc need to be accomplished first)

Yours sincerely,

Cheryl E. Massimo, CSW

5/22/01

RECEIVED
MAY 29 10 02 AM '01
MAY 29 10 02 AM '01



**WILKES-BARRE CITY
HEALTH DEPARTMENT**



Original: 2185

Mayor Thomas D. McGroarty

Henry A. Radulski
Director

PHONE (570) 208-4268
(570) 208-4269
FAX(570) 208-4272

May 25, 2001

Joel H. Hersh
Director Bureau of Epidemiology
PA Department of Health
P.O. Box 90
Harrisburg, PA 17108

RECEIVED
2001 JUN -5 AM 10:21
HEALTH COMMISSION

Dear Mr. Hersh:

Many state and local health departments work in conjunction with the Centers for Disease Control (CDC) to track and monitor the course of human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS). Using numerous surveillance programs and studies, CDC monitors the occurrence of HIV infection, disease and death. The further analysis of the data focuses on the behaviors that place people at risk and HIV-related knowledge and testing behaviors. This information if disseminated to provide public health systems and communities the most thorough and current information possible on the ongoing and emerging HIV/AIDS epidemic.

The ongoing and systematic collection of the information necessary that will result is valid, timely and complete data and is the key facet to any surveillance system. The problem in Pennsylvania is that HIV is not a reportable disease. According to PA Code, Title 28, Chapter 27, the Pennsylvania Department of Health identifies 52 reportable diseases by name including AIDS. Noticeably absent from the list is HIV, despite the fact that sound epidemiologic principles and public health practice necessitates the reporting of communicable diseases of a public health nature.

AIDS cases have provided information on the trends of the HIV epidemic, however recent highly effective treatments that many people, but not all, have had with new very active antiretroviral therapies has limited this premise. Researchers could take into account the time between HIV infection and the progression to AIDS and estimate where and how many new infections were occurring based on observed cases of the disease. Currently, information on AIDS cases and deaths may only provide us information on groups for whom the highly effective treatment is not available or has not been successful. The data no longer tells us the critical information about where and how many infections are occurring. This information is necessary to address the need for prevention and treatment services. In order for public health to target programs and resources, it is imperative to track where the epidemic is going. Since it is important to improve our ability to monitor early HIV infection, before it progresses to AIDS, it is mandatory that HIV becomes a reportable disease in the Commonwealth of Pennsylvania.

Not only is the reporting of HIV necessary, but the method of identification is concurrent with the reporting process. A name-base reporting system of people with infectious diseases has great potential to benefit both the individual and the public health system. Health departments can contact individuals for treatment, counseling and various medical and social services, however name reporting compromises confidentiality.

Name reporting of people infected with HIV started in 1985 (CDC, 1998). This was the time HIV antibody testing became available. With the advent of protease inhibitors and combination therapies, treatment of HIV infection has improved dramatically. Name reporting systems would therefore result in more people benefiting from early intervention program. This is more reason for Pennsylvania to make HIV a reportable disease.

If the policy of HIV reporting by a name based system is adopted in Pennsylvania, more HIV-infected people would receive health care benefits and health departments could possibly receive more funding to aid their HIV prevention programs. According to the 2000 Pennsylvania Department of Health budget, the state receives approximately \$26 million from the federal government to implement HIV/AIDS testing, counseling and prevention programs. The possibility exists that if Pennsylvania does not make HIV a reportable disease it may lose its HIV/AIDS funding.

There has been an increase in the number of states that have adopted name reporting for HIV infection.

The Centers for Disease Control and Prevention determine which infectious diseases are reportable on a national level. Individual states set their own priorities on which diseases are reportable.

CDC requires that HIV/AIDS data held by state and local health departments is maintained in physically secure environments with limited access by only authorized health department officials.

The names of persons diagnosed with HIV/AIDS are reported to state and local health departments, but names and other personal identifiers are not sent to the CDC. The CDC does not collect names, social security numbers, addresses or phone numbers of HIV-infected persons or their physicians.

With confidentiality being a major concern, AIDS cases are reported to the CDC by all 50 states using the SOUNDINDEX system. The system translates names into specific sets of numbers or letters. When these codes are combined with other information, individual cases can be followed without revealing names.

All state and local health departments receive the names of AIDS patients as they are reported to them. States who use the name-based reporting systems for HIV utilize a name-based reporting system very similar to the AIDS reporting system. HIV surveillance would be more complete, timely and representative in a name reporting method.

People who are HIV positive are more likely to find ways to remain anonymous as compared with AIDS patients who are in frequent contact with medical and social services who require positive identification.

Anonymous testing will limit the surveillance potential of name reporting data and makes it more difficult to unduplicate records which leads to invalid data. It complicates the collection of information missing from case reports and the evaluation treatment and health services is lessened. Anonymous testing also makes it difficult to conduct epidemiologic investigations of public health importance such as unusual modes of exposure, new viral strains, etc. Providing comprehensive patient follow-up care is also minimized.

Texas and Maryland have tried to address the problems of anonymity by using a unique identifier system. In the unique identifier system, persons tested anonymously supply in a code, parts of the name, social security number, date of birth, sex and race. The non-name identifier system is not anonymous as it may be possibly linked to a specific individual. To do record follow-up for missing information such as HIV risk or to provide follow-up care, coded records need to be linked to an individual's name usually in a log maintained by providers or other reporting sources. Multiple logs with names may create multiple opportunities for breaks of confidentiality.

Smallpox and tuberculosis are examples of endemic diseases that have been controlled by name reporting. These diseases were monitored by name reporting. These diseases were monitored by public health workers as long term therapy was used to control the diseases.

Name reporting could allow public health employees to find and counsel people who are tested but do not return for their results. Follow-up care could lead to medical referrals and earlier viral load and CD4 testing. The testing results in reductions in viral loads that not only improves an individual's health, but also improves public health by reducing the infectiousness of the individual.

Name reporting allows public health personnel to interview clients to assess their need for a variety of community services including competent medical care, dental care, financial assistance, housing, transportation, education, pharmaceutical assistance, support groups, drug and alcohol treatments and other specialized treatments. Clients could be offered free tuberculosis skin testing and free treatment with Isoniazid if they are found to have the tuberculosis infection.

Partner notification programs are also aided when HIV is reported by name. Partner notification is an effective method of identifying individuals who are at high risk for HIV infection. Public health nurses are able to assist clients in notifying sexual and intravenous drug users of their need for testing and counseling and where they could actually obtain that service in the community.

HIV-infected women are educated about the risks of pregnancy, especially passing their infection to their baby and how to minimize that risk.

The two main risks to reporting people by name is the information could be used to harm infected persons and the fear of being reported by deter infected individuals from being tested which could delay receiving appropriate counseling and medical care.

Concern about name reporting databases being leaked or infiltrated or previously believed confidential information being revealed during extenuating circumstances may be sufficient to reduce or delay testing. The delay could be especially harmful to individuals who are already being tested late in the course of the HIV infection.

A 1998 study in *JAMA* described trends in the use of HIV testing before and after the implementation of HIV reporting studies. The study revealed that in 5 states HIV reporting was implemented after data collection was in place. In Louisiana, HIV reporting was implemented in February 1993; in Nebraska, September 1995; in Nevada, February 1992; in New Jersey, October 1991; and in Tennessee, January 1992. In Michigan, HIV reporting was required by regulation beginning in 1988. However, the health department did not actively solicit HIV case reports from physicians and other providers, including clinicians, laboratories and institutions until April 1992. In these 6 states, the number of HIV tests, the number of positive HIV test results and the distribution of these tests by sex, race or ethnicity, type of testing site and risk exposure group were compared for the 12 months before and the 12 months after HIV reporting was introduced. Sites who reported less than 50 tests in a 25 month period were excluded from the study.

During the 25 month period before and after implementation of HIV reporting, the total numbers of HIV tests provided through the states in the study were as follows: Louisiana, 86,734 tests at 50 sites; Michigan, 138,802 tests at 53 sites; Nebraska, 9,749 tests at 8 sites; Nevada, 25,002 tests at 3 sites; New Jersey, 141,946 tests at 84 sites; and Tennessee, 56,721 tests at 29 sites. These tests represented 63% of HIV tests performed in Louisiana during this period, 95% in Michigan, 77% in Nebraska, 88% in Nevada, 84% in New Jersey and 79% in Tennessee.

When the total number of tests performed in the year before and the year after HIV reporting 4 states, Nebraska, Nevada, New Jersey and Tennessee had increases in the number of tests performed after implementation.

The chart below illustrates the number of HIV tests performed before and after name reporting for HIV was instituted.

Number of HIV Tests Performed

State	Before Reporting	After Reporting	% Change
Louisiana	43,955	39,359	-10.5
Michigan	66,704	65,398	-2.0
Nebraska	4,348	5,035	15.8
Nevada	9,613	14,264	48.4
New Jersey	61,440	74,324	21.3
Tennessee	20,684	33,675	62.8

Among whites, the number of HIV tests increased after HIV reporting was implemented in all states but Louisiana, which had a 10% decline. A 22% decline for Hispanic persons was seen after HIV reporting in Louisiana. Among blacks, the number of tests performed after HIV reporting declined in Louisiana (10%), Michigan (26%) and New Jersey (2%).

Among the Men who Have Sex With Men (MSM), the risk group that reports have suggested would be the most likely to avoid testing if HIV reporting was implemented, the number of tests increased in 4 states in the year after HIV reporting was implemented. Louisiana and Tennessee experienced decreases in testing of less than 5% for this group. Among injection drug users, declines in testing occurred in Louisiana and Michigan. Among at-risk heterosexuals, which included persons with sexually transmitted diseases, persons who had exchanged money or drugs for sex, and those whose sex partners were at risk for HIV, increases in testing were seen in all areas after HIV reporting was implemented.

In Louisiana, both the number of anonymous tests and the proportion of total HIV tests that were anonymous decreased after HIV reporting was implemented. At the same time, the number of proportion of confidential tests increased.

The study shows that information on HIV-infected non-AIDS cases obtained through HIV case reporting will be needed for monitoring, planning, and allocation of resources for prevention and clinical services. The data indicates that the impact of surveillance on those seeking HIV testing will be small and should not hinder HIV prevention efforts.

A 1997 study in the Journal of General Internal Medicine indicated 5 HIV name reporting states found that only 31% of individuals at risk for HIV knew that their state reported HIV test results by name, 59% did not know their states reporting policy and 11% thought that there was no name reporting in their state.

The impact of reporting HIV-infected persons by name is likely to vary from community to community. In urban areas, people have more knowledge about HIV infection that there would not be as much benefit from being reported and then counseled about risk behaviors or care opportunities. However, that does not mean that everyone would not be in need of counseling and medical care, therefore name reporting would still be essential. In comparison, in areas of low rates of HIV infection, HIV knowledge could be limited. In these areas, the infected persons could benefit from interventions and referrals made possible by name reporting.

The results of name reporting could vary by risk groups also. Gay men are probably less likely than other groups to benefit from being tracked by health departments and offered educational materials or care referrals because HIV awareness is generally high in gay communities. Name reporting is more likely to benefit intravenous drug users, bisexuals, sex partners of such individuals and pregnant women. Education and facilitation into the health care systems may be more beneficial to these groups.

It does not matter if the HIV-infected persons are from the city or rural, gay or heterosexual communities, instead it matters that prevention practices can help someone....somewhere....at some time, and this could only happen with name reporting. To allow Pennsylvania to target programs and resources most effectively, the public health system must keep pace with where the HIV epidemic is going. Improvement of our ability to track early HIV infection before it progresses to AIDS is essential.

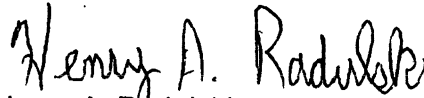
A 1998 study, HIV Cost and Service Utilization, shows that AIDS care costs the nation \$6.7 billion each year, at \$20,000 a patient. The study finds patients receive care from teaching hospital (30%), and office-based physicians, community hospitals and clinics (70%). While 20% of HIV patients do not have health insurance, 29% of HIV patients depend on Medicaid and 19% receive care under Medicare.

The 335,000 HIV-infected patients receiving care are fewer than one-half to one-third the total number of people living with HIV.

HIV infection should be treated like other reportable communicable diseases, namely, name reporting. It is time to stop treating AIDS and HIV infection differently. The Pennsylvania State Health Department should make HIV positivity reportable by name.

The Wilkes-Barre Health Department strongly supports the amendments to 28 PA Code Chapter 27 dealing with the reporting of HIV by name.

Sincerely,

A handwritten signature in black ink that reads "Henry A. Radulski". The signature is written in a cursive style with a large initial "H".

Henry A. Radulski
Director of Health

Cc: Michael Huff

Dr. Walter Tsou
Health Commissioner
Philadelphia Department of Public Health
1101 Market Street, Suite 840
Philadelphia, PA 19107

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Sincerely,

Name Kristhe Cardé

Address 2808 Belgrade St

Phone 215 424 1696

E-mail KRIScollectibles@AOL.com

RECEIVED
2001 MAY 29 AM 10:30
HEALTH COMMISSIONER
OFFICE



Planned Parenthood®
Association of Bucks County

721 New Rodgers Road., Bristol, PA 19007 • 215/785-4594/FAX 785-3535

BIRTH CONTROL
01 MAY 29 09:16:02

May 25, 2001

Mr. Joel Hersh, Director
Bureau of Epidemiology
Commonwealth of Pennsylvania
P.O. Box 90
Harrisburg, PA 17108

RECEIVED
MAY 29 2001
BUREAU OF EPIDEMIOLOGY
HARRISBURG, PA

Dear Mr. Hersh,

I am writing in response to the Department of Health's proposed name-based HIV testing regulations as published in the April 21, 2001 Pennsylvania Bulletin.

Our Planned Parenthood affiliate currently offers anonymous testing in our five sites. We are concerned about a lack of availability of anonymous testing sites in our county if the proposed regulations are passed. At the present, the county health department sites and our sites are the only places to receive this service. The county health department has a limited amount of time when people can get tested. These hours are inconvenient to young people especially, who work or go to school. They already use our services for other purposes, and our comfortable here and with our staff.

We would hope that along with using "unique-identifiers", instead of names, that you would also make provisions for organizations that currently offer these services to continue to do so. Our clients value the anonymity of our agency and the service that is provided and prefer to stay within our agency for this service.

Thank you for your time and consideration.

Sincerely,

Alison Tartaglia, CHES

Alison Tartaglia, CHES
HIV Coordinator

Allegheny County Health Department

DIRECTOR
Bruce W. Dixon, M.D.



STD/AIDS Program
3333 Forbes Avenue
Pittsburgh, PA 15213
412 578-8081

May 25, 2001

BOARD OF HEALTH
Roy L. Titchworth, M.D.
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Janet Summers, O.D.
Robert Thompson, M.D.

Mr. Joel H. Hersh
Director, Bureau of Epidemiology
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, PA 17108

Dear Mr. Hersh:

I would like to comment on the proposed changes to PA Code 28, Chapter 27, relating to reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV.

I support fully the intention of your office that would add HIV infection to the list of reportable diseases and that this disease be reported by name. Furthermore, we support the following additional requirements:

- the reporting of a CD4 T-lymphocyte count of less 200 cells per microliter
- reporting a CD4 T-lymphocyte percentage of total lymphocytes of less than 14%
- reporting of the perinatal exposure of newborns to HIV

I request, however, that you consider adding to the regulations a penalty for those individuals that do not report HIV or AIDS. Currently, under Article V. Reporting of HIV, the Allegheny County Health Department requires a summary offense for any person or entity who violates the regulation of a fine up to \$300 and the costs of prosecution. In addition, the County may assess a civil penalty of up to \$10,000.

RECEIVED
2001 JUN -5 AM 10:21
HEALTH COMMISSION

Also, a change in the language is recommended that requires reporting by a physician, hospital or person or entity and who receives HIV or CD4 T-lymphocyte test results; Section 27.32, (a) and (3). A physician, hospital or person or entity who receives CD4 T-lymphocyte test results on a patient infected with HIV should report all CD4 T-lymphocyte test results, regardless of the cells/uL or percentage.

Thank you for the opportunity to comment on these proposed regulations and if you need any clarification or additional information please call me at 412-578-8008.

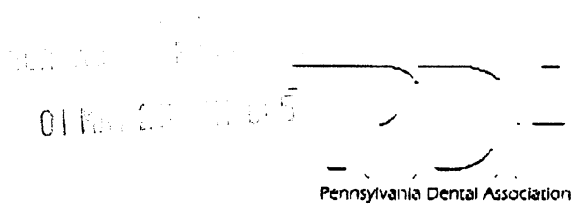
Sincerely yours,

A handwritten signature in cursive script that reads "Bruce W. Dixon" followed by "M.D." written in a larger, more stylized font.

Bruce W. Dixon, M.D. *MS*
Director

BWD:jms

Original: 2185



Pennsylvania Dental Association

**Pennsylvania
Dental
Association**

CAMILLE KOSTELAC-CHERRY, ESQ.
Executive Director

May 24, 2001

Mr. Joel H. Hersh, MPH
Director, Bureau of Epidemiology
Pennsylvania Department of Health
P.O. Box 90
Harrisburg, Pennsylvania 17108

Dear Mr. Hersh:

As you suggested during recent telephone conversations you had with Melissa DiSanto Simmons, the Pennsylvania Dental Association would like to submit the following question relative to 28 PA Code Ch. 27 Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts, and Perinatal Exposure of Newborns to HIV:

Are dentists, whether generalists or specialists, considered provider reporters under the proposed HIV reporting regulations?

It is the PDA's interpretation that dentists should not be considered provider reporters because:

- dentists do not diagnose or treat HIV/AIDS
- all information regarding HIV/AIDS received by a dentist would be provided by the physician, laboratory, or infected patient/employee - in all cases, the dentist does not have firsthand knowledge of the HIV/AIDS diagnosis

I understand from Melissa that a written answer to the above question will be published in the Pennsylvania Bulletin. I thank you for your kind attention to this matter.

Sincerely,

Camille Kostelac-Cherry

Camille Kostelac-Cherry, Esquire
Chief Executive Officer

- cc: Dr. George A. Kirchner, President
Dr. Michael Corveris, President Elect
Dr. Samuel E. Selcher, Board of Trustees
Dr. Philip T. Siegel, Chair, Council on Government Relations
Dr. Gary S. Davis, Council on Government Relations
Dr. Veasey Cullen

REVIEW COMMISSION

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05/24/01

3501 North Front Street • P.O. Box 3341 • Harrisburg, PA 17105
(717) 234-5941 • (717) 232-7169 Fax

FAX

Pennsylvania Dental Association

3501 North Front Street

PO Box 3341

Harrisburg, PA 17105

Date: May 24, 2001
Number of pages including cover sheet 2

From: Marisa S. Fenice
Phone: 717-234-5941
Fax Phone: 717-232-7169
E-Mail: msf@padental.org

To: Mr. Joel H. Hersh

Phone: 772-6975

CC:

REMARKS:

- Urgent
- For your review
- Reply ASAP
- Please comment

Mr. Hersh:

Melissa Simmons asked me to fax this letter to you as she is on vacation until Tuesday, May 29. It pertains to the question the Pennsylvania Dental Association has regarding dentistry's involvement in the draft HIV reporting regulations.

Please call me if you have any questions.

Thank you,
Marisa Fenice
Pennsylvania Dental Association
Government Relations Department

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Original: 2185

Stuart N. Fisk, RN, MSN
6941 Meade St. #2
Pittsburgh, PA 15208
Sfisk@wpahs.org

01 MAY 25 11:12 AM '01

Joel Hersh, Director
Bureau of Epidemiology
Commonwealth of Pennsylvania
Department of Health
P.O. Box 90
Harrisburg, PA 17108

via fax 717 772 6975, hard copy to follow

Re: Draft HIV reporting regulations

Dear Mr. Hersh:

As a health care professional with a 15 year history of working in AIDS care and research, I am writing to express my concern about several aspects of the proposed draft regulations on HIV reporting currently under consideration.

I am currently a registered nurse working at Allegheny General Hospital's Infectious Disease Clinic. In that capacity I help to coordinate care for over 170 persons living with HIV disease, many of whom also are struggling with addiction, mental illness, poverty, and a host of other social and medical problems. I also sit on the Allegheny County Board of Health's HIV/AIDS Advisory Committee. I am Vice-Chair of the Allegheny County Drug and Alcohol Planning Council and Chair of the Clinical Services Planning Committee for the Southwest Pennsylvania AIDS Planning Coalition. I am a member of the Board of Directors for The Partnership for Minority HIV/AIDS Prevention. I have been a clinical Trainer for the Pennsylvania/Mid-Atlantic AIDS Education and Training Centers since 1997 and have trained many health and human service providers on the care of HIV-positive drug users. In that role I also helped develop and teach a curriculum for Inmate HIV Peer Educators in for the Department of Corrections, a program that has been implemented in all of the State Correctional Institutions in Pennsylvania. Prior to moving to Pennsylvania, I was an AIDS nurse in San Francisco during the peak years of the AIDS epidemic there.

Based on my experience in these various capacities and the understanding I have developed of the complexities of issues related to HIV among the patients with whom I have worked, I strongly oppose the proposed plan for developing a system of reporting HIV cases by name. In my years of experience working with persons living with HIV and at risk for HIV infection, I have found that even in situations where an individual's anonymity is assured, patients are often extremely reluctant to agree to be tested. This is based on their legitimate fear of the stigma and discrimination those who test positive for HIV continue to face in our society. A system of HIV reporting that includes individuals' names, birth dates, or other identifying information would be an even greater deterrent. I strongly encourage the Commonwealth to develop a system of HIV surveillance in Pennsylvania that uses unique identifier codes. This type of system has been successfully implemented in a number of other states.

I further encourage the Commonwealth to increase publicly-funded anonymous testing options to ensure that individuals are not deterred from seeking HIV testing, and that true anonymous tests are available and accessible to all Pennsylvanians. The proposed regulations seem to potentially limit the availability of anonymous testing by requiring that anonymous testing be conducted only at a "State-designated anonymous testing site." In the interest of encouraging individuals to undergo HIV testing, anonymous testing should become standard procedure throughout the Commonwealth.

Joel Hersh,
May 21, 2001, page 2

DEPARTMENT OF HEALTH
BUREAU OF EPIDEMIOLOGY

01 MAY 25 PM 1:27

I am also concerned about the proposed requirement of reporting by a variety of entities as referenced in the regulations. This would result in confusing and overlapping responsibility for reporting. Only a clinician can and should make a diagnosis of HIV. The proposed regulations would apparently require laboratories to report test results, independent of a physician's judgement and would require "entities providing HIV services" to report information about an individual's HIV status or other markers. This places inappropriate responsibility on AIDS social service providers, drug treatment providers, and others to make clinical diagnoses and interpretations of such information.

With regard to the language on reporting of risk factors, the proposed regulations ask for "probable mode of transmission." This requires a subjective assessment and I am concerned that this opens the door for judgments to be made about an individual. Instead, providers should be instructed to use only those categories of transmission risk delineated by the CDC. Identifying specific, nationally-aggregated risk factors is far more accurate, reasonable, and appropriate and will provide standardized data that can be compared in CDC reporting.

A final area of concern is with regard to the use of the term "public health intervention." This term is neither described nor defined in the regulatory language and as such is open to broad interpretation. Any such "interventions" should be specifically designed using best practice models and described in detail in the regulatory language. Further, they should only be implemented as a last resort after a clinician has exhausted all other avenues of contacting an individual known to them to have tested positive for HIV, not as the first step as the regulations suggest.

I do feel that a responsible policy of HIV reporting incorporating the concerns noted above will aid in the development of a clearer picture of the HIV epidemic in Pennsylvania. Such a picture will facilitate prevention and treatment of this serious public health problem.

Thank you for your careful consideration of these important issues.

Sincerely,

Stuart N. Fisk, RN, MSN

cc: Senator Vincent Hughes
Representative Dennis M. O'Brien
Representative Frank L. Oliver
Senator Harold F. Mowery

Original: 2185

**Prevention
Point
Pittsburgh**
907 West Street 5th Floor
Pittsburgh, PA 15221
412-247-3404 (Office) 412-491-0916 (Exchange) 412-241-5970 (fax)

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May 21, 2001

Joel Hersh, Director
Bureau of Epidemiology
Commonwealth of Pennsylvania
Department of Health
P.O. Box 90
Harrisburg, PA 17108

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via fax 717 772 6975, hard copy to follow

Re: Draft HIV reporting regulations

Dear Mr. Hersh:

As a professional who works with injection drug users, a population with a high degree of risk of contracting the HIV virus, I am writing to express my concern about several points in the proposed draft regulations on HIV reporting.

I am a Licensed Social Worker in the Commonwealth of Pennsylvania and the Coordinator of Prevention Point Pittsburgh, an organization which provides HIV prevention services and supplies to injection drug users in Allegheny County. Prior to taking this position, I was a psychotherapist here in Allegheny County for several years, serving a client population with a large number of injection drug users. I also worked as a Children's Protective Services Worker in Oakland, California at the height of the crack cocaine epidemic.

In these various capacities, I have worked with the most marginalized individuals in our society, those suffering from drug addiction, mental illness, homelessness, and poverty. This is also the segment of the population at highest risk for contracting HIV and the population most likely to be suspicious of getting tested for HIV. Even with an assurance of complete anonymity, people are often afraid to submit to HIV testing for fear of stigmatization. Without that assurance, we are even less likely to be able to convince individuals of the wisdom of having their HIV status determined. A system of HIV surveillance based on the use of unique identifier codes can achieve the public health goals of HIV surveillance in Pennsylvania without acting as a deterrent to testing as evidenced by the successful use of such systems in other states.

While I am firmly convinced of the importance of establishing a system of HIV reporting in the Commonwealth, the adoption of regulations that include reporting by name will only undermine this important effort. Instead, the options for publicly-funded anonymous testing should be increased in order to ensure that individuals are not deterred from seeking HIV testing, and that true anonymous tests are available and accessible to all Pennsylvanians. The proposed regulations seem to potentially limit the availability of

Joel Hersh, May 21, 2001, page 2

anonymous testing by requiring that anonymous testing be conducted only at a "State-designated anonymous testing site." In the interest of encouraging individuals to undergo HIV testing, anonymous testing should become standard procedure.

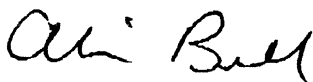
I would also like to express my concern with the proposed language regarding reporting of risk factors. The regulations as drafted ask only for "probable mode of transmission." Requiring subjective risk factors to be reported allows for judgments to be made about an individual. Instead, reporting of risk factors should only be based on current categories of transmission risk as delineated by the CDC and should use only those categories. This is a more accurate, reasonable, and appropriate standard and will allow for the collection of uniform data that can be compared in CDC reporting.

Another area of concern is the proposed requirement of reporting by the many entities referenced in the regulations. It seems that this type of system would result in confusing and overlapping responsibility for reporting. It seems to me that only the primary treating medical clinician should make and report a diagnosis of HIV. The proposed regulations would require "entities providing HIV services" to report HIV status. This would apparently require laboratories, AIDS social service providers, drug treatment providers, to report test results, independent of a physician's judgement. This is an inappropriate responsibility for such treatment and service providers to make clinical diagnoses and interpretation.

Finally, I would like to address the use of the term "public health interventions." The regulations do not clearly describe or delineate the parameters of intervention and would therefore allow for a range of interpretations. Any such interventions should be clearly defined, based on best practice models, and described in detail in the regulatory language. Furthermore, such interventions should only be used as an extreme measure of last resort, not as the first step as the regulations suggest.

Thank you for your careful consideration of these important issues.

Sincerely,



Alice Bell, L.S.W.,
Coordinator

Southwestern
Pennsylvania
AIDS
Planning
Coalition

May 20, 2001
Mr. Joel Hersh
Director
Bureau of Epidemiology
Commonwealth of Pennsylvania
Department of Health
Health and Welfare Building
P. O. Box 90
Harrisburg PA 17108

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DEPARTMENT OF HEALTH
HARRISBURG, PA



Dear Mr. Hersh,

Comments on the Proposed Rulemaking: Reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV

ALLEGHENY
ARMSTRONG
BEAVER
BUTLER
CAMBRIA
FAYETTE
GREENE
INDIANA
SOMERSET
WASHINGTON
WESTMORELAND

On behalf of the Board of Directors and the entire membership of the Southwestern Pennsylvania AIDS Planning Coalition, I am forwarding our comments on the above-mentioned regulations published in the Pennsylvania Bulletin on Saturday April 21, 2001. As you are aware, the Coalition depends on HIV/AIDS epidemiological data to plan for services in the region. When the Coalition testified during statewide public hearings on this issue two years ago, we applauded the Bureau for proposing HIV surveillance. This, we still believe to be necessary. We are however dismayed and concerned that the proposed rule making, contrary to ours and other testimonies at that time, require HIV reporting by names.

We are convinced, based on the experiences of our member agencies conducting HIV counseling and testing, and the populations in which new AIDS cases are diagnosed (minorities, intravenous drug users and others already distrustful of government), that names reporting will be a deterrent to testing.

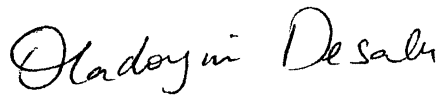
In addition, we note the following with regards to the proposed rule making:

- i. The proposed multiple reporting systems that include laboratories and case management agencies is burdensome and invasive of the patients' privacy.
- ii. The electronic reporting proposed is fraught with possible security violations.
- iii. There is an existing anonymous HIV testing site within an agency in our region. The mechanisms for state-designation of anonymous testing sites in the proposed regulations are unclear and concern us greatly.
- iv. The deadlines given especially to physicians to report positive HIV tests are unrealistic and may result in patient's names being forwarded to the state before the patients are personally notified.

Fifth Floor
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Pittsburgh, PA
15221-2841
412/242-2441
1-888-379-3755
Fax 412/247-1640

The Coalition's broad-based membership of over 130 individuals who are consumers of HIV services, who work as AIDS service providers, as behavioral health service providers, as other service providers or who are simply interested in HIV/AIDS, again, strongly urge that HIV reporting in Pennsylvania be implemented by a unique identifier system for reasons already presented in our previous testimonies and re-stated above. We look forward to your positive consideration of our comments and a revision of the proposals.

Sincerely,

A handwritten signature in cursive script that reads "Doyin Desalu".

Doyin Desalu
Executive Director

cc: Senator Vincent Hughes
Representative Dennis M. O'Brien
Representative Frank L. Oliver
Senator Harold F. Mowery

Original: 2185

PENNSYLVANIA COALITION OF
PCASO
 AIDS SERVICE ORGANIZATIONS

Facsimile Cover Sheet

*HIV Key
Comments*

To: Joel Hersh

Fax Number: _____

No. of Pages 12 (including cover)

From: Bruce Flannery, Executive Director
 Telephone: (610) 518 0886
 Fax: (610) 518 0885

Re: Comments on draft resp.

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*Joel - Thanks for your years of work on this -
 I hope our comments prove useful.*

br

Please call (610) 518 0886 should you have any problems receiving this transmission.

PENNSYLVANIA COALITION OF
PCASO
 AIDS SERVICE ORGANIZATIONS

May 21, 2001

Mr. Joel Hersh
 Director
 Bureau of Epidemiology
 Commonwealth of Pennsylvania
 Department of Health
 P.O. Box 90
 Harrisburg, PA 17108

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via fax 717 772 6975, hard copy to follow, USPS Express Mail

Re: Draft HIV reporting regulations

Dear Mr. Hersh: *Joel:*

On behalf of the Pennsylvania Coalition of AIDS Service Organizations (PCASO), our Board of Directors, members organizations, and consumers of their services, I am writing to express our grave concern with the proposed draft regulations on HIV reporting currently under consideration and out for public comment.

First and foremost, we oppose reporting the names of people with HIV to the Commonwealth for reasons stated clearly in our dialogue with the Department of Health over the years and reflected in our testimony during public hearings on the subject as well as a policy adopted by us in December, 1997. As you are aware, based on the overwhelming message delivered in the public hearings conducted statewide by the department on this subject, and in the academic publications available to date, there is significant evidence that HIV reporting by name can potentially deter individuals from seeking HIV test. This is particularly true of those individuals who are perhaps at the greatest risk of infection. In light of the fact that the peer reviewed publications to date are evenly split as to the potential for deterring individuals from testing, we strongly believe it is a mandate to the Commonwealth to err on the side of caution and develop a non-name-based HIV surveillance system to achieve the public health goals of HIV surveillance in Pennsylvania.

Regarding testing, while we favor the department's intent to continue the availability of anonymous testing, we feel that opportunities for anonymous testing should be increased throughout the state. Though the Department has stated that more than 100

Joel Hersh, May 21, 2001, Page 2

such testing sites are now available, we believe this number includes sites offering only confidential testing, which cannot be confused with anonymous testing. Indeed, in the Counties of Philadelphia and Allegheny, where nearly 80% of the reported AIDS cases are concentrated, there are approximately 10 genuine anonymous testing providers currently available with fewer than 50 testing sites. The proposed regulations seem to potentially limit the availability of anonymous testing by requiring that anonymous testing be conducted only at a "State-designated anonymous testing site." Through the regulations, the Commonwealth of Pennsylvania should encourage increased publicly-funded anonymous testing options to ensure that individuals are not deterred from seeking HIV testing, and that true anonymous tests are available and accessible to all Pennsylvanians.

On the subject of reporting risk factors, the regulations as drafted ask only for "probable mode of transmission," a subjective assessment. Here, providers must be provided with the most current categories of transmission risk as delineated by the CDC and should be instructed to use only those categories. Requiring subjective risk factors to be reported allows for judgments to be made about an individual. Identifying specific, nationally-aggregated risk factors is far more accurate, reasonable, and appropriate and will provide standardized data that can be compared in CDC reporting.

On the subject of reporting by the many entities reference in the regulations, we remind you that only physicians can make a diagnosis of HIV. The results of a laboratory test, independent of a physician's judgment, is not a diagnosis of HIV nor should it constitute grounds for a "public health intervention" (a term though referenced in the regulatory narrative, is neither described nor defined in the actual draft regulatory language). Such interventions on the part of the Commonwealth or other governmental entity should take place only as a court of last resort after a testing provider or clinician has exhausted all avenues of contacting an individual known to them testing positive for HIV. Further, "entities providing HIV services" should not be required to report information about an individual's HIV status or other markers, as they cannot clinically interpret that information. Only a clinician can and should make a diagnosis or moderate clinical progress. It is unrealistic and inappropriate to require these entities (AIDS social service providers, e.g.) to abide by these regulations.

In closing, we are further concerned about area of the regulations lacking specificity. Here, clear language must be provided around the security of any required electronic transmission of HIV and related data and to whom that data is to be transmitted (current language would suggest it go to the county Health department, when in most counties, it would be transmitted to the regional district office of the Department of Health). Additionally, as previously mentioned, any "public health interventions" in the regulatory narrative must be accompanied by actual regulatory language describing these activities, involving non-government-based community-based organizations

Joel Hersh, May 21, 2001, Page 3

in these interventions and designing these interventions using best practice models. Further, they should only be implemented as a the "court of last resort" and not as the first step as the regulations suggest.

For your reference, I attach a separate point by point list of concerns of the regulations, with proposed language changes or suggested alterations/ clarifications needed.

Our thanks for your consideration. I look forward to seeing significant revisions of the regulations in the next iteration in the near future. Please add me to a the mailing list being created for communicating further changes, etc.

Sincerely,

b -

Bruce W. Flannery
Executive Director

/attachments

cc: Helen Burns, Deputy Secretary for Health Planning and Assessment
Gary L. Gurian, Deputy Secretary for Public Health Programs
Senator Vincent Hughes
Representative Dennis M. O'Brien
Representative Frank L. Oliver
Senator Harold F. Mowery
Secretary Robert S. Zimmerman, Jr.

PENNSYLVANIA COALITION OF

PCASO

AIDS SERVICE ORGANIZATIONS

**Comments of the
Pennsylvania Coalition of AIDS Service Organizations (PCASO)
on the proposed amendments to the Title 28, part III, Chapter 27.
May 21, 2001**

§ 27.1 Definitions

"LMRO" - As we understand the intent of the Department is to collect this information at the health district level (or in few cases, at the municipal/county level). Expand definition to minimize potential of reporting to state health centers or other entities perceived to be county health departments. Inadvertent reports to county offices might create breaches of confidentiality, particularly in PA's most rural counties.

"Perinatal exposure . . ." - Drop the current language and insert in its place a new definition:

"Possible Vertical Transmission --Potentially exposing a fetus to HIV during the pregnancy of an HIV positive woman, regardless of the final serostatus of the infant."

It is important that this language be as non-judgmental of the woman as possible and when, in the judgement of the patient, the risk of bearing a child while HIV-infected outweighs the benefits. Only information about newborns who come to term is useful in preventing vertical transmission. Additionally, the regulations should request at § 27.32 a report of counselling re: treatment, any prophylaxis(es) followed (or denied) by the patient (and reason for denial, if any) and mode of birth--caesarean/vaginal, etc. This would be useful in insuring that best practices are in place and being utilized, when in the judgement of the woman, the treatment is in their interests and those of their unborn child.

Definitions should be added to define unique identifier, both confidential and anonymous testing, as well as define "State-designated anonymous testing sites." Reference should be made somewhere in the regulations that periodic audits insure that anonymous HIV testing sites are accessible to all Pennsylvanians; i.e., at a minimum of one site per county. Further, all state and municipal testing sites should be required to counsel patients as to the availability of anonymous testing, and to provide the location of a local site so that individuals seeking testing may exercise that option.

Comments of the
Pennsylvania Coalition of AIDS Service Organizations (PCASO)
on the proposed amendments to the Title 28, part III, Chapter 27.
May 21, 2001, Page 2

§ 27.2 Reportable Diseases

Change "Perinatal exposure of a newborn to HIV to "Possible Vertical Transmission."

Subchapter B Reporting of Diseases, General

§ 27.22 Reporting results indicative of certain infections . . .

(c) (1) . . . similarly, (c) (2) Strike name and address of the person from whom the specimen was obtained. Insert "Unique Identifier of the person from whom . . ."

(c) (2) (iii) Strike date of birth. Insert year of birth.

(d) 5 . . . similarly, § 27.32 (a) (2) Strike "positive results of any test . . ." Insert "Results of any test approved by the FDA to indicating and/or establishing the presence of HIV including serologic, virologic, nucleic acid (DNA or RNA) or any other type of test . . ."

This, because many of these tests' results are not positive/negative. Many markers (CD4 assays, e.g.) are merely points on a continuum. They are never positive or negative.

§ 27.32 Reporting AIDS. HIV, CD4 . . .

(a) paragraph 2 (A physician, hospital or person or entity providing HIV services . . ." Strike "or person or entity providing HIV services." Only clinicians can make a diagnosis of HIV. Social service and drug & alcohol providers can and should not, under any circumstances, unless they have clinicians on staff. For this reason, they should not report, as well.

(a) (4) Strike "A perinatal exposure." Insert "Possible vertical transmission." Add language somewhere in § 27.32 requiring submission of advice of counselling on treatment/ prophylaxes, mode of prophylaxis(es) chosen, mode of delivery and/or other indicators of efforts made to prevent vertical transmission, as are current, per current clinical guidelines.

(a) (4) (b) Strike "in a timely manner." Insert a period of time consistent with other providers. Strike individuals name address and phone number and insert Unique Identifier and other pertinent information as identified in § 27.22 (c) (1), above.

(b) (8) See § 27.22 (d) (5), above. Strike "Positive", etc.

Comments of the
Pennsylvania Coalition of AIDS Service Organizations (PCASO)
on the proposed amendments to the Title 28, part III, Chapter 27.
May 21, 2001, Page 3

(b) (10) Strike "The probable mode of transmission." Insert language referencing current risk factors as collected by the CDC for identification of probable mode(s) of transmission.

§ 27.32a Counselling, testing, referral and partner notification . . .

(a) Strike "persons or entities reporting as required in this section shall offer all HIV and AIDS-related services confidentially and may not provide anonymous testing, or consider any test or its results to be anonymous." This line is extraordinarily confusing and seems to indicate that anonymous providers have to report confidentially.

(b) See comments on § 27.32. Not collecting names but having individuals' addresses and dates of birth is hardly anonymous, unless of course, a set of twins happen to live together.

§ 27.32b The line suggesting that "A person providing HIV test results to a patient may ask for the Department's assistance . . . and if doing so would not violate Act 1990-148" seems legally questionable to this non-attorney. Seems to suggest that this regulation may supercede statute. Not the practice, as I understand it.

§ "37.32c" (I think this is intended to be § 27.32c) Strike "all other persons or entities providing HIV services" for reasons cited at 27.32 (a). The Department should have the right to do audits of client records at publically funded social service sites, but not for reasons of seeking out new or existing cases of HIV. That is a practice which must be limited to clinical record audits. AIDS service (and other social service/ drug & alcohol) providers cannot diagnose, except in cases where they have clinicians on staff.

§ 27.32d See § "37.32c," above. Also, strike "The Department may audit records going back to January 1, 2000 for this purpose." This language may put those providers required to submit to retroactive audit in a legal bind, as they may have signed consent releases from individuals not permitting this release of information. Again, this writer is not an attorney, but it strikes me as shaky legal ground . . . and if the individual is in active care (as they would be if in the care of a social service agency), they will have periodic tests to assess viral load, CD4, etc., which in the course of the year, would add them to the registry through contemporary channels.

PENNSYLVANIA COALITION OF
PCASO
AIDS SERVICE ORGANIZATIONS

Testimony of Bruce Flannery
to the Pennsylvania Department of Health
on HIV Reporting
Children's Hospital of Philadelphia
Philadelphia, PA

April 22, 1999

Good Evening:

Over the past year, I as the Executive Director of PCASO, have had numerous conversations with each of you, not to mention the Secretary, the Acting Secretary and the Governor's office on the subject of HIV reporting. Though I suspect you are all well aware of my organization's perspective on this issue, I am nonetheless compelled to appear before you tonight. I hope I can present a few new perspectives for your consideration.

I would like take a moment to acknowledge the hard work and fairness which I have observed in your consideration. I'd also like to thank Jane Bratz, Gary Gurian, Joel Hersch, Janice Kopelman and Joe Pease for their leadership on this critical issue. Finally, I'd like to acknowledge the responsible stewardship of the Bureau of Epidemiology staff in their management of the existing AIDS registry.

There are two issues I'd like to address this evening, that of the objective of collecting HIV incidence data and secondly, the way we collect that data. Let me begin with a discussion of the overall objectives.

In my conversations around HIV reporting, I have gotten, at times, the impression that there are differences of opinion around the overall objective of our HIV collection efforts. There appear to be those who believe that by collecting either names or unique identifiers we can create an accurate, effective system of surveillance as well as those who seek to achieve that objective with the added notion that by seeking names we will be able to "link" individuals to care.

Though I appreciate the good intentions of those who seek to provide such a linkage to care, I strongly believe that it grossly oversimplify a very complex problem.

**PCASO Resolution in Support of of HIV Reporting by Unique Identifier and Other
Non Name-based Surveillance Systems**
Page 2

Be it resolved:

That PCASO supports the development of non name-based HIV surveillance systems, including unique identifiers, to achieve the public health goals of HIV surveillance in Pennsylvania and other states and territories.

That PCASO opposes name-based HIV surveillance.

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

That PCASO calls on the Federal government to require states which have adopted or may adopt a name-based reporting system to provide and/or continue a publicly funding anonymous testing option to insure that individuals are not deterred from seeking HIV testing.

That PCASO calls on the Clinton and Ridge administrations, the Congress and General Assembly, to enact and enforce strong confidentiality laws which serve as a minimum standard for protecting the privacy of all health-related information.

That PCASO calls on the Federal government and Commonwealth of Pennsylvania to initiate efforts to guarantee access to care and treatment for all HIV positive individuals.

Adopted 12.5.97

PCASO Testimony on HIV Reporting, April 22, 1999
Page 2

Knowledge of a person's name and address doesn't provide a willingness or ability on an individual's part to overcome denial, or to seek out or remain in care. It doesn't protect them from reprisal from family and friends, or worse yet, abusive parents or partners. It doesn't engender trust. Nor does it address the very real issue of providing a payer for their care or provide a compassionate supportive environment in which they might effectively deal with HIV. I am aware of many individuals who for a variety of very different reasons, chose not to acknowledge their HIV status, often even to themselves, for a very long time. I'm afraid that it's human nature to deny something until such a time as you can deal with it. To expect someone to remain in care just because they have been diagnosed and "linked" is naive, and might very well have a deterrent effect on testing and care.

We cannot forget that far more than other diagnoses, HIV is supercharged with personal issues involving behaviors (often illegal), culpability, guilt, misinformation, paranoia and prejudice. Add to this mix the fear of discovery, disability and death, and you've got a problem far better solved by experienced clinicians, community-based efforts, traditional shoe leather epidemiologists, effective planning and priority setting and targeted outreach. The good news here is that experience has proven that you can lead a horse to water *and* make him drink. The bad news is that you've got to do it on the horse's terms.

I think the appropriate role of government is to insure that competent clinical and social services are readily available and that pharmaceuticals are truly accessible. Equally important, we need to refocus on eliminating the real root problems--the continued misunderstanding of HIV disease, its prognosis and treatment, as well as the barriers posed by race, poverty, addiction, incarceration, immigration status, family, culture, age, gender, sexual orientation and the stigma of HIV.

Moving ahead, you'll find PCASO's resolution on name-based reporting attached to this testimony. Rather than reiterate the public health principles under which we call for the adoption of a system of unique identifiers and preservation of anonymous testing programs, I want to call to your attention the fact that this resolution has been adopted pretty much verbatim by the the Commonwealth of Pennsylvania Integrated HIV Planning Council, the Philadelphia EMA Planning Commission, a number of regional planning coalitions and HIV service providers, and the City of Philadelphia Board of Public Health. It was also recently endorsed by DASPOP, the Drug and Alcohol Service Providers of Pennsylvania.

Let me begin by recounting a recent broadcast on National Public Radio* in which a

*Amitai Etzioni, PhD, *All Things Considered, Weekend Edition*, March 7, 1999

PCASO Testimony on HIV Reporting, April 22, 1999
Page 3

Harvard University sociologist discussed his research around issues of privacy and specifically, medical confidentiality. In discussing the issue, the professor noted that his office had recently collected 103 complaints from individuals with various cancers who had allegedly lost insurance coverage due to breaches of medical confidentiality. Unfortunately, confidential medical information—not just information about HIV status—is of great interest to many and much of that interest is based in the potential abuse of that information.

On a variety of levels, I think we share the concern that our medical, financial and other highly personal information might fall into the wrong hands. Increasingly, we're all mindful of how well information is safeguarded in light of rapidly developing technology. Who in this room isn't justifiably paranoid about misuse of their credit cards or financial information? What few secrets do we still have? The truth is, we live in a world in which billions of bits of information can be—and is—transferred across the world with a keystroke, with technology taking regular quantum leaps ahead. Our only hope for the future is that institutions entrusted with our personal data maintain the highest degree of care in encoding and safeguarding this information.

Now, with all due respect to the Department of Health and their solid stewardship of the AIDS registry, the world in which we live today is not the world in which we established our first systems of name-based disease registries. Imagine hypothetically that no disease incidence were reported at present, and that the CDC was just now approaching the state's and requesting surveillance and incidence data for 40 or 50 diseases and infections. How would we respond? Knowing of the need for absolute confidentiality as well of the perils posed by the nature of media transmission and future technological breakthrough, would we choose to collect names or would we assign a coded identifier to all cases? I am confident that we would build a system based on coded identifiers. In this day and age, taxpayers, increasingly mindful about privacy, would demand it.

Rather than base the decision to use names on the "technology" created in the early part of this Century when names were scrawled in a ledger and stored in an unlocked drawer, I challenge the Commonwealth to look to the 21st Century to design and implement this effort. I propose that using HIV reporting as a pilot, that we create a secure, encoded, state of the art system of disease reporting mindful of the privacy, confidentiality and technology issues of the next millennium. Once designed and implemented, we could then retrofit all other data on disease entities using this system and its algorithms to provide all Pennsylvanians affected by reportable diseases with the peace of mind they deserve.

Thank you.

PENNSYLVANIA COALITION OF
PCASO
AIDS SERVICE ORGANIZATIONS

**Resolution in Support of 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 plan 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 name reporting has been shown to discourage individuals from seeking HIV testing and treatment, and the implementation of HIV name reporting is not currently accompanied by guaranteed access to care and treatment; and

Whereas, other than PA Act 148 (35 P.S. § 7601 et seq., concerning the confidentiality of HIV-related information), no strong Federal or state privacy law governing health information currently exists; 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, support our public health goals, by providing data which can help us allocate limited resources while supporting efforts to target and evaluate prevention efforts, educate the public about the epidemic and project where the epidemic is going, while protecting confidentiality and not discouraging people from seeking HIV testing and care;

Original: 2185



BERKS AIDS NETWORK

429 Walnut St., P.O. Box 8626, Reading, PA 19603-8626
(610) 375-6523 FAX: (610) 375-8333
Se Habla Espanol

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01 MAY 2001 10:55

May 21, 2001

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BERKS COUNTY'S
ONLY COMPREHENSIVE
AIDS SERVICES
ORGANIZATION

Berks AIDS Network is a registered non-profit organization, number 0011244. The official registration and financial information of Berks AIDS Network may be obtained from the Pennsylvania Department of State by calling toll free, within PA, at 1-800-732-0999. Registration does not imply endorsement.

Mr. Joel Hersh, Director
Commonwealth of Pennsylvania
Department of Health, Bureau of Epidemiology
P.O. Box 90
Harrisburg, PA 17108

Dear Mr. Hersh,

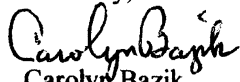
On behalf of Berks AIDS Network, I would like to express our support of the Commonwealth's proposed regulations for HIV reporting by name. Although there has been much opposition to the concept of names reporting we recognize that AIDS cases have been reported by name, without incident, in the Commonwealth for two decades.


We applaud the Commonwealth's decision to preserve the option of anonymous testing for those at risk individuals who may, otherwise, choose not to test. While those who choose to test anonymously may represent a small percentage of the population, it is essential that this option continue to be available to all of our residents.

We do have several serious concerns regarding the proposed HIV reporting process. Although the intent is to ensure that no HIV+ test results slip through the cracks, the proposed process seems unreasonably cumbersome. Given the Department's record with software systems in the area of HIV services (namely lifeplan) we question whether any systems implementation will accurately track the data entered. Furthermore, the time line for implementation of the names reporting system does not seem feasible. Since the regulations have yet to be finalized, and the target date for implementation is little more than six months away, it hardly seems reasonable that all providers will be prepared to report data effective January 2002. Finally, the budget line for names reporting indicates that limited staff will be available to facilitate implementation of the regulation. It is difficult to imagine that a system of this magnitude can be adequately implemented with such limited resources.

The establishment and implementation of an HIV reporting system is critical to the future of HIV prevention and services. It would be unfortunate if, in a desire to achieve timely implementation of the system, an unworkable system was put in place. Therefore, we urge the Department to carefully consider the realities of implementation and adjust plans accordingly.

Sincerely,


Carolyn Bazik
Executive Director


Nadine J. Smet-Weiss
Director of Prevention Education

Original: 2185

May 19, 2001

Mr. Joel Hersh
Director
Bureau of Epidemiology
Commonwealth of Pennsylvania
Department of Health
P.O. Box 90
Harrisburg, PA 17108

RECEIVED
BUREAU OF EPIDEMIOLOGY
01 MAY 24 AM 10:58

Re: Opposition to Names Reporting for HIV Surveillance

Dear Mr. Hersh:

As a concerned citizen and medical student, I oppose reporting the names of people with HIV to the Commonwealth as proposed in the draft regulations published in the PA Bulletin dated 4/20/01.

I agree that the tracking of HIV is essential. Using names, however, will deter the most vulnerable and at-risk people from seeking testing and seeking care. I support, instead, the development of a non name-based HIV surveillance system to achieve the public health goals of HIV surveillance in Pennsylvania.

You should be aware that 95% of people testifying in public hearings you held around the state opposed names reporting. That is because, even with anonymous test sites, the practice of name-reporting frightens people and deters them from getting tested and treated.

By implementing reporting using unique identifiers instead of names, the Health Department can easily accomplish several essential goals at once: 1) the protection of people living with HIV, 2) effective tracking of the epidemic, and 3) increased funding from federal sources for prevention and treatment.

This is the time to demonstrate your leadership and vision. I urge you to do so.

Thank you.

Sincerely,



Sue Sun Yom
MD/PhD Candidate, 2002
University of Pennsylvania

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2001 MAY 31 AM 9:18
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10



Western Psychiatric Institute and Clinic

A hospital of
UPMC Health System

Neuropsychology Research Program

Original: 2185

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LABORATORY
REVIEW COMMISSION

830 Oxford Building
3501 Forbes Avenue
Pittsburgh, PA 15213-3418
412-624-0142
Fax: 412-383-1755

May 18, 2001

Joel H. Hirsch
Director, Bureau of Epidemiology
Department of Health
Commonwealth of Pennsylvania
PO Box 90
Harrisburg PA 17108

RE: Pennsylvania Code 28, Chapter 27
Reporting of AIDS, HIV Test Results, CD4T Lymphocyte Counts, and Perinatal
Exposure of Newborns to HIV

Dear Mr. Hirsch:

Thank you very much for the opportunity to respond to the proposal by the Department of Health to require reporting of HIV-related test results (including HIV antibody, viral load, and the like). The proposed rule changes, published in the Pennsylvania Bulletin on 21 April 2001, are somewhat vague in terms of who and what type of facilities might be required to report such results.

I am the Principal Investigator of a research project funded by the National Institute of Mental Health (National Institutes of Health) concerning the neuropsychological consequences of HIV infection and AIDS in adults. I have previously participated in deliberations with the Armed Forces Epidemiology Board related to HIV/AIDS and military flight status, and have participated in two consultations with UNAIDS concerning the cognitive and neurological consequences of HIV/AIDS. The research that we have been able to accomplish here in Pittsburgh has been critical for helping to develop rational treatment programs, as well as to develop national and international policies regarding management of individuals with HIV/AIDS.

As currently formulated, the rules for reporting do not specifically address the problems that this would pose for research endeavors such as ours. We have worked hard to identify a sample of individuals with HIV/AIDS who represent, as well as is possible, individuals living within Allegheny County and seeking primary care. As such, any factor that would alter a potential research subject's willingness to participate in research would have a significant negative impact on our ability to recruit subjects, fulfill our obligations to the NIMH/NIH, and would reduce our understanding of the effects of HIV/AIDS on the nervous system. It is clear to me that this was not one of the intentions of the law, but it certainly will be one of the consequences. Therefore, I strongly encourage you to modify the rule to exclude research projects and research laboratories, and data acquired for research purposes from these rules.

May 18, 2001

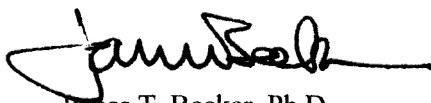
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Having such a change in the rule would have no measurable impact on the goal of the reporting. To the extent that you are interested in accurate counting of individuals with HIV infection, our project requires subjects to have a primary care physician, and these individuals would have been (anonymously) reported by virtue of their diagnosis of AIDS. Second, to the extent that you might be interested in identifying individuals who are infected, but are unaware of their infection, you may also rest assured that our research study will have little impact on that goal. First, the majority of our research subjects are HIV seropositive, and thus are aware of their infection status. Second, our HIV seronegative individuals know that they will be tested, and if they are found to be seropositive (less than 1% of all of our testing) we immediately counsel these individuals to obtain primary medical care, and facilitate their entry into the health care system. Thus, *requiring* us to report HIV infection would have no impact on the goals of the Department of Health's program.

That having been said, even the requirement of clinical reporting of HIV infection status *by name* would have a negative impact on our research. It is particularly true that the "hard to reach" clients, both HIV seropositive and seronegative, will be disproportionately affected by such a requirement - clearly the opposite of the intention of the rule. At this point, even our HIV seronegative volunteers, are comfortable with having their HIV status tested since they know the results will not be reported; but, they are also aware that if they are seropositive they will be counseled about treatment. If such counseling about treatment also had to require disclosure of their HIV status (by the treating clinician) this would almost certainly reduce the likelihood that they would seek such care, and would mean they would be less likely to come to our research study in the first place.

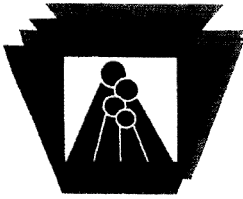
Therefore, I would strongly encourage you to exempt all research studies, laboratories, and related facilities from the mandatory requirements of reporting by name. Furthermore, I must also indicate that it is my opinion, based on an understanding of the available data, that requiring *name* reporting by clinicians would have the opposite effect that you hope in that it would deter individuals from getting tested or from seeking medical care.

Respectfully submitted,



James T. Becker, Ph.D.
Professor of Psychiatry and Neurology

JTB/bhp



PA Alliance for Children & Families

Original: 2185

May 18, 2001

Joel H. Hersh, Director
Bureau of Epidemiology
Dept. of Health
P.O. Box 90
Harrisburg, PA 17108

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Audrie Zettick Schaller

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01 MAY 22 AM 8:16

REVIEW COMMISSION

2001 MAY 31 AM 9:16

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Dear Mr. Hersh:

I am writing in response to the proposed regulations on HIV reporting published in the Pennsylvania Bulletin in Volume 31-16. As State Director of the PA Alliance for Children and Families, I represent family services agencies from across the Commonwealth.

These agencies provide behavioral health services, employee assistance plans, and other types of family counseling to families across the state. Many of these agencies run programs that specifically address the many physical, emotional, and healthcare needs of person with HIV infection or AIDS or their partners and families.

I have polled my member agencies about the proposed regulations. Overall, they agree that some sort of enhanced tracking is needed for HIV infection rates, in order to improve prevention and treatment outcomes. **Overwhelmingly, however, our family service agencies believe that HIV reporting should be done with a unique identifier, NOT with the specific name of the individual.** There is great concern that name reporting will discourage people from pre-test counseling, as well as the actual test.

As a former member of the U.S. Dept. of Health and Human Services Secretary's Task Force on Pediatric AIDS (Reagan Administration), I know well the many issues being dealt with by the Administration. I caution you to *take the road that is least intrusive* but that can still improve outcomes for treatment and prevention. We firmly believe the solution is a unique identifier system.

I am aware that there are some figures reported that show "improved" statistics after the implementation of names reporting. However, most often this methodology replaced a system of no reporting of HIV infection at all—obviously there would be an improvement. We believe that using a unique identifier system will improve outcomes, maintain eligibility for Ryan White Funds (since a system of HIV reporting will be in place) and keep government in the role of the least intrusion practical.

We also want some assurance that anonymous testing sites will continue to be available. We are concerned that the proposed regulations will limit anonymous testing sites to "those designated by the Department." *Will there be adequate availability in all regions of the state, including rural areas?*

My member agencies which run HIV/AIDS programs are available to testify on the estimated impact of name reporting on their programs. Feel free to contact me.

Sincerely,

Audrie Z. Schaller
State Director

2245 Southpoint Drive
Hummelstown, PA 17036
(717) 583-0904
fax (215) 790-6274
AlliancePA@paonline.com
www.alliancepa.org

Original; 2185

May 18, 2001

Mr. Joel Hersh
Director
Bureau of Epidemiology
Commonwealth of Pennsylvania
Department of Health
P.O. Box 90
Harrisburg, PA 17108

Re: Opposition to Names Reporting for HIV Surveillance

Dear Mr. Hersh:

As a medical student at the University of Pennsylvania and a patient advocate, I oppose reporting the names of people with HIV to the Commonwealth as proposed in the draft regulations published in the PA Bulletin dated 4/20/01.

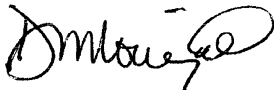
I agree that the tracking of HIV is essential. Using names, however, will deter the most vulnerable and at-risk people from seeking testing and seeking care. I support, instead, the development of a non name-based HIV surveillance system to achieve the public health goals of HIV surveillance in Pennsylvania.

You should be aware that 95% of people testifying in public hearings you held around the state opposed names reporting. That is because, even with anonymous test sites, the practice of name-reporting frightens people and deters them from getting tested and treated.

By implementing reporting using unique identifiers instead of names, the Health Department can easily accomplish several essential goals at once: 1) the protection of people living with HIV, 2) effective tracking of the epidemic, and 3) increased funding from federal sources for prevention and treatment.

This is the time to demonstrate your leadership and vision. I urge you to please do so.

Sincerely,



Donna M. Louizides, University of Pennsylvania 4th year medical student

cc: Senator Vincent Hughes
Representative Dennis M. O'Brien
Representative Frank L. Oliver
Senator Harold F. Mowery

01 MAY 29 PM 2:46

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2001 JUN -5 AM 10:20
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01 MAY 24 AM 10:58



May 18, 2001

Mr. Joel Hersh
Director, Bureau of Epidemiology
Commonwealth of Pennsylvania
P.O. Box 90
Harrisburg, PA 17108

RECEIVED
2001 MAY 31 AM 9:19
BUREAU OF EPIDEMIOLOGY
COMMONWEALTH OF PENNSYLVANIA

Dear Mr. Hersh:

As representatives of one the largest federally funded HIV clinics in Pennsylvania, we are pleased that the Department of Health has proposed amendments to Title 28, Part III, Chapter 27 requiring the mandatory reporting of patients infected with the Human Immunodeficiency Virus (HIV).

With more than 500 HIV-infected patients followed by our office, we recognize the imperative of accurately monitoring the epidemic on a local, state and national level. The implementation of statewide HIV surveillance will serve many functions:

- ensuring accurate measurement of the HIV epidemic in Pennsylvania
- providing a better perspective of the changing landscape of the epidemic over time
- helping to allocate properly federal funds for the delivery of HIV care services as determined by the Ryan White CARE Act
- eventually improving the system of care delivery throughout the state by guaranteeing that all infected individuals have adequate voluntary access to medical management, counseling and case management services.

A stylized logo with the text "A Celebration of Community" in a cursive, script font.

We recognize that a name-based reporting system will be very controversial. Issues of confidentiality and proper disclosure of information stand at the heart of the debate. Studies analyzing the determinants of “test seeking” and “test avoidance” behaviors have failed to demonstrate convincingly that a name-based surveillance system will have a *dramatic* impact upon the number of patients tested for HIV. Nonetheless, it is clear *some* individuals are likely to defer or avoid testing altogether based upon fears about potential disclosure. For these individuals, we feel very strongly that the state should make every effort to expand the number of anonymous testing sites. The new proposals indicate that anonymous testing will only be limited to “Department-designated sites.” If this is the case, the location and availability of these sites should be clearly established and publicized prior to institution of the new reporting plan.

By continuing to fund existing anonymous testing sites and expanding to new sites, the State will allow all individuals to make informed decisions not obscured by concerns about breaches in confidentiality or loss of anonymity. Our quest to accurately enumerate the extent of this epidemic should not alienate *even a few* who would ultimately benefit from early detection, intervention and education about risk reduction. Disregard for this issue may ultimately endanger the health of “at-risk” individuals and jeopardize the state’s public health infrastructure.

The day-to-day activities of our organization are supported by limited funds. We currently have learned to “make a little go a long way” in terms of the financial support that we receive. A major concern with the new system of HIV surveillance is the amount of time and resources necessary to comply with the recommendations outlined in the new proposal. Specifically, we will be expected to report any “positive test results of any test approved by the Food and Drug Administration to establish the presence of HIV, including serologic, virologic, nucleic acid (DNA or RNA)” and any “CD4 T-lymphocyte count less than 200 cells per microliter of a CD4 percentage of total lymphocytes of less than 14%”. With an estimated 510 HIV-infected patients in our practice – each undergoing CD4 and viral load testing approximately every three months – the number of “reportable” tests results will be exceedingly high. We worry about the time and manpower that will be required to meet these ambitious expectations. The fact that our local laboratory and case management service organizations will also be expected to generate reports for each of these tests seems like an excessive, time-consuming and costly proposition. The proposal fails to elaborate in any detail the time requirements that will be associated with the new surveillance system or the manner in which these activities will be financially supported.

Reporting the results of low CD4 counts carries another potential danger. At present, state and national surveillance systems monitor only tests that accurately reflect infection or prior exposure to “reportable” pathogens. The CD4 count is not a diagnostic test for HIV infection or AIDS; it is a surrogate marker used to monitor disease progression and immunologic function. While the presence of reduced CD4 counts is most often associated with HIV infection, many conditions (including almost any life-threatening acute illness or the use of high doses of corticosteroids) have been associated with transient reductions in CD4 lymphocytes. Mandating the reporting of low CD4 counts may unknowingly bring uninfected individuals under the scrutiny of the HIV surveillance system. By designating the CD4 count as a test acceptable for use in HIV surveillance, we fear that the state will encourage inexperienced providers to use this test as a screening tool – a use not intended for this test.

Informed consent remains a hallmark of the HIV testing protocols recommended by the CDC and mandated by federal and state legislation. A system that allows individuals to bypass obtaining informed consent (and performing the recommended pre-test counseling that should accompany any testing for HIV) may undermine the trust and confidence between patients and their health care providers. Until the right of a patient to accept or decline testing on a voluntary basis is revoked, we should avoid establishing a system that may compromise this right

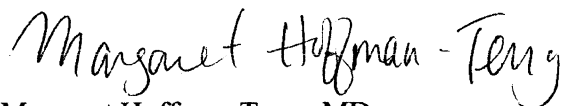
In closing, while we remain enthusiastic about the plans to change Pennsylvania’s HIV reporting protocol, we are concerned about the proposal in its current form. The language employed in the proposal remains very vague in certain key areas:

- mechanisms of guaranteeing patient confidentiality and the preservation of informed consent;
- provisions and ongoing support for anonymous testing centers throughout the state;
- security of the electronic record and mechanism to safeguard all reported information;
- definitions of “public health interventions” that will follow the diagnosis of HIV;
- definitions of “providers” expected to report information (i.e., ordering physician, specialists, emergency room physicians, dieticians, counselors, etc.) – the document specifies “physicians, hospitals and other persons and entities diagnosing AIDS or providing or receiving reportable HIV ... test results”,
- exact details of the reporting process (including the time and resources that will be necessary to adhere to recommendations for reporting)

Further elaboration and revision of these areas will strengthen the proposal and, hopefully, lead to more universal acceptance.

Many thanks for your consideration. We look forward to reviewing revisions of the guidelines in the near future.

Sincerely,



Margaret Hoffman-Terry, MD
Medical Director
AIDS Activities Office



Timothy Friel, MD
Associate Medical Director
AIDS Activities Office



Judith Natale Sabino, MPH
Program Director
AIDS Activities Office

Cc: Mark Young, MD
Katie Kinney

Original: 2185

Joel Hersh
Director, Bureau Of Epidemiology
Department of Health
P.O.Box 90
Harrisburg, PA 17108

01 MAY 22 AM 8:15

May 18, 2001

Dear Sir:

I received a copy of the HIV Reportability Regulations just yesterday. I am a member of a Patient Advisory Board (we refer to as a Peer Advisory Board) at the clinic where I receive my HIV care. I'm compelled to write to you with my objection to name based reporting.

I was diagnosed ten years ago and have been in care since that time. I am a Registered Nurse so I do understand the importance of knowing just how many individuals are infected and the need to get them into care. Also, the need to get at risk people tested. I'm afraid that people (think of adolescents) will be afraid of getting tested because their name... is on your database. We still live in a world where discrimination, not matter how subtle is rampant. How can you assure us that the info we must provide will not be accessible to "hackers"? Etc. I am not ashamed of this disease, but although we as a society have come a long way since the "plague" mentality of the early eighties, there are many who are still ignorant of the facts about HIV.

With the start of the "cocktail" 4 years ago, myself, like so many others literally have a future. I am finally cautiously optimistic about my health.

Working as an RN, I would be making \$40,000+. However, I am not able to handle the stress of such a work environment. I am working fulltime now for the first time in 6 years, but making \$12,000 a year. I cannot obtain life insurance. My husband and I separated several years ago and if we do not reconcile, I will not be able to retire ever. If and when I need to get another job I have a legitimate concern about an employer finding "reason" to choose someone else. I have made the difficult decision to keep my diagnose known to my immediate family only. This interferes with past and present friendships, relationships with other family members... I am the one who suffers because of it, but I needed to weigh the risk vs benefit for me.

The information you really need for your desired outcome; i.e. ELISA test results, CD4 counts, where we're receiving treatment, can be obtained using unique identifiers.

Please help me (US) to hold on to the one thing I've been able to control. My health and well-being depend on it.

Sincerely,

128578409

01 MAY 21 AM 9:54
01 MAY 22 AM 8:15



UPMC HEALTH SYSTEM

Original: 2185

Pitt Treatment Evaluation Unit

P.O. Box 7256
Pittsburgh, PA 15213
412-647-8125

01 MAY 26 11 11 AM '01

Joel H. Hersh
Director, Bureau of Epidemiology
Department of Health
P.O. Box 90
Harrisburg, PA 17108

May 17, 2001

Dear Mr. Hersh,

We would like to comment on the proposed changes to PA Code 28, Chapter 27, relating to reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV. Specifically, we propose that HIV research facilities such as ours be exempt from the reporting requirements as argued below.

Our HIV program at the University of Pittsburgh Medical Center's (UPMC) HIV program currently provides primary care to ~ 800 HIV-infected individuals, and has ~ 150 HIV-infected individuals enrolled in clinical trials. Our research clinic is an NIH-funded AIDS Clinical Trial Unit (ACTU) and also conducts a number of industry-sponsored clinical trials.

Although we are supportive of the Department of Health's goal to have an accurate picture of the prevalence of HIV/AIDS in Pennsylvania; to implement and evaluate community-based public health interventions for HIV-infected persons and at-risk partners; and to enhance opportunities to link HIV-infected individuals with life-sustaining medical care and necessary social service support systems, we would like to express significant concerns related to the proposed reporting changes.

In the proposed rule changes, published in the Pennsylvania Bulletin on Saturday, April 21, 2001, there is no apparent reporting exemption for research facilities and research laboratories. We believe that facilities whose primary purpose is research should be exempted from these reporting requirements for the following reasons:

- ◆ HIV-infected research at our research unit are expected to have a primary care physician. The research unit is not a primary "tester", and although confirmatory HIV tests may be ordered, all test results are sent (with the written consent of the research volunteer) to the individuals primary care provider.
- ◆ The requirement for research facilities to report HIV results may present a substantial barrier to participating in research for potential volunteers who are concerned about confidentiality. Recruitment of women and minorities in particular remains a challenge and we must strive to reduce any such barriers.
- ◆ Research units assign a unique identifier/study ID number for all tests related to a study subject. No demographic data is currently provided to the diagnostic laboratories. Provision of such data to a laboratory is prohibited by the informed

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COMMISSION

consent documents that our research subjects have signed. Furthermore, in most cases, the laboratories have been contracted to provide their services using a unique identification number and are unable to accept additional information.

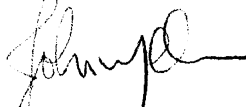
- ◆ Research laboratories currently have no system to report communicable diseases. They generate data solely for the purpose of a research protocol. All clinically relevant data is sent to the participant's primary care provider after obtaining written permission from the subject.
- ◆ In our HIV clinical research unit, the Pitt Treatment Evaluation Unit (PTEU), we strive to maintain a higher level of confidentiality than is customary for medical facilities. We have engendered a high degree of trust within our community and among our research participants, many of who need constant reassurance regarding the confidentiality of their HIV status. The PTEU provides state-of-the-art therapy in the context of clinical research to participants who might otherwise choose to forego treatment until the advanced stages of HIV disease. Mandating that research facilities report volunteers' HIV status will threaten our relationship with such persons and may result in an increase in HIV-infected individuals who are not receiving appropriate care.

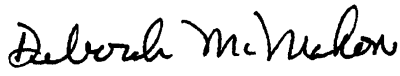
In addition, there will be considerable increased burden on research units and research laboratories to implement HIV reporting, including staff time and the cost of dedicated computer equipment and telephone line for remote reporting.

We are aware that the State of New York has included a research exemption in their recently implemented HIV reporting law and we urge the Commonwealth of Pennsylvania to do the same. Exempting research facilities from this regulation will not inhibit the Department of Health's goal to collect accurate HIV prevalence data because these individuals will be reported by their primary care provider.

Thank you for the opportunity to comment on this important issue and we welcome the opportunity to discuss this with you or your staff.

Sincerely,


John W. Mellors, M.D.
Director, HIV Program
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For the Staff of the Pitt Treatment Evaluation Unit

cc: George Board, III
Vice President, Commonwealth Relations, UPMC

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Joel H. Hersh
Director, Bureau of Epidemiology
Department of Health
P.O. Box 90
Harrisburg, PA 17108

May 17, 2001

Dear Mr. Hersh,

We would like comment on the proposed changes to PA Code 28, Chapter 27, relating to reporting of AIDS, HIV Test Results, CD4 T-Lymphocyte Counts and Perinatal Exposure of Newborns to HIV.

The University of Pittsburgh Medical Center's (UPMC) HIV program currently provides primary care to approximately 800 HIV-infected individuals, and has approximately 150 HIV-infected volunteers enrolled in clinical trials. Our program includes a National Institutes of Health (NIH) funded AIDS Clinical Trial Unit (ACTU) and a Ryan White Title III-funded treatment center (Health Resources Service Administration). The latter allows us to provide ongoing medical care to HIV-infected individuals regardless of their ability to pay.

We support goals of the Department of Health to determine the prevalence of HIV/AIDS in Pennsylvania; to implement and evaluate community-based public health interventions for HIV-infected persons and at-risk partners; and to enhance opportunities to link HIV-infected individuals life-sustaining medical care and necessary social service support systems. We have been directly impacted by the current lack of HIV prevalence data, as this information is critical to our efforts to obtain federal funding for HIV early intervention services.

We have a long-standing collaborative relationship with Dr. Bruce Dixon, the Commissioner for the Allegheny County Health Department (ACHD) and have always cooperated fully with AIDS case reporting requirements. Dr. Susan Hunt, the Medical Director of our Treatment Center, was Chair of the Advisory Committee convened by the ACHD for HIV reporting in Allegheny County. We are working closely with the ACHD to implement HIV reporting by name or unique identifier as required beginning on June 1, 2001.

We have carefully read and reviewed the proposed regulations. Our comments, highlighted below, are focused on four major areas of concern: 1) name-based reporting, 2) the burden of implementation, 3) anonymous testing sites, and 4) perinatal exposure.

- ◆ **Name-based Reporting:** Although we have confidence that the Department of Health will take all necessary precautions to assure confidentiality of an individual patients' HIV status, many of our patients have expressed concern and fear about name based reporting. They

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believe that disclosure of their HIV status is possible as a result of the reporting. This perception, however unfounded, is likely to delay individuals being tested for HIV-1 infection and contribute to the delay of individuals entering treatment until the later stages of disease. We are concerned that name-based reporting threatens our patients' right to privacy, interferes with the doctor-patient relationship, and creates a barrier to seeking HIV testing and medical care. A unique identifier reporting methodology, such as the approach taken in State of Maryland, would not hamper the state's ability to collect accurate prevalence data. Maryland's system of assigning a unique identifier also helps guard against duplicate reporting.

- ◆ **Reporting Burden:** The current system for AIDS reporting has been facilitated through cooperation with the Allegheny County Health Department, which performs onsite data collection for reporting of AIDS cases. Given the number of patients to whom we provide care, the information required in the current proposal for HIV reporting, including treatment information, will add an unmanageable workload to our clinic staff. There does not seem to be any provision for increasing the staff of the county health departments to assist in collecting and reporting this data. Although reporting electronically may simplify the process, there is still additional workload for our staff as well as the need for additional computers to report remotely.

In addition, the requirement to report "within 5 days of the reportable diagnosis or receipt of the test results" is not feasible given the amount of information that is expected.

We understand the software program to be used for reporting is the CDC's HARS system. This existing DOS-based system will be difficult to implement in a clinic setting. Additionally, we have used this system in collaboration with the Allegheny County Health Department and have found that data retrieval is extremely difficult.

- ◆ **Anonymous Testing Sites:** Currently the University of Pittsburgh's HIV program provides anonymous and confidential HIV counseling and testing funded by Ryan White Title III. We believe that it is critically important that all anonymous testing sites are able to continue to provide these services. Anonymous testing sites provide the opportunity for individuals at risk to be tested and offered post-test counseling, which may facilitate their entry into care, even in the face of HIV reporting.

Although the current proposal will continue to provide state-sponsored anonymous testing sites, the additional requirements for reporting, particularly HIV RNA levels have no provision for anonymity. As a result, those who test positive at the anonymous test centers will certainly be reluctant to seek out appropriate medical care. The Allegheny County reporting program allows an individual to choose whether reporting is performed by name or unique identifier. This reporting choice would minimize the barrier of getting HIV infected individuals into appropriate care.

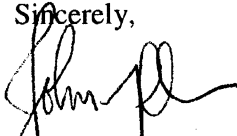
- ◆ **Perinatal exposure:** The availability of potent antiretroviral therapy has dramatically reduced the rate of vertical transmission of HIV. We are concerned that, under the proposed regulations, pregnant women may refuse testing or forego prenatal care due to name-based

reporting. We are further concerned that children exposed to HIV during pregnancy will be tracked by name, even if they are not infected. There is no provision for removing the names from the data base of those children who are HIV uninfected by confirmed negative test results. We strongly encourage the Department of Health to include a mechanism for purging the names of uninfected children from its database.

In summary, we appreciate the effort and thoughtfulness that has been put forth in the design of these proposed regulations; however, we strongly believe that modifications of the regulations are needed as outlined above. Therefore, we cannot support the proposed regulations as written. We urge the Department of Health to create regulations that will be less intrusive to infected individuals and care providers, offer the choice of a unique identifier for reporting, maintain anonymous test sites, reduce barriers for the testing and prenatal care of pregnant women and protect their children.

Thank you for the opportunity to comment on this critical issue and we invite you to contact us for further discussion.

Sincerely,



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