~~SEP 29 3:00~~

INVITATION TO A MEETING

September 25, 1987

FROM: Domestic Policy Council

SUBJECT: Health Policy Working Group Meeting on AIDS Awareness Month Materials

TIME: 3:00 pm

DATE: Tuesday, September 29

LENGTH: 1-1/2 hour

PLACE: Old EOB, Room 208

RSVP TO: Mary (x2564)

COMMENTS: You may bring someone if you like.

ACCEPT _____ DO NOT ACCEPT _____

SEND SOMEONE ELSE _____ IF SO, WHO _____?

BRING SOMEONE ALONG _____ IF SO, WHO?_____?

fpo

TGM
cc Arlene H
Francine

THE WHITE HOUSE

WASHINGTON

October 21, 1987

MEMORANDUM FOR THE HEALTH POLICY GROUP

FROM JAMES H. WARNER

SUBJECT WORKING GROUP MEETING

There will be a meeting of the Health Policy Working Group on Friday, Oct. 23 at 3:00 p.m. in room 324 of the Old Executive Office Building. The subject of the meeting will be AIDS and Catastrophic Health Insurance.

THE WHITE HOUSE

WASHINGTON

February 16, 1988

MEMORANDUM FOR MEMBERS OF THE HEALTH POLICY WORKING GROUP

FROM: GARY L. BAUER G.L.B.

SUBJECT: AIDS

- In his decision memo of September 29, 1987, the President directed the Centers for Disease Control to provide the Domestic Policy Council with quarterly estimates of the incidence of HIV and its rate of spread. The first report is due on February 29, 1988 and a progress report will be presented to the working group by Dr. Robert Windom.

- In addition the President directed HHS and OSTP to develop an integrated, scientific modeling effort to evaluate data already obtained and guide further data collection. A Progress report on this project will be presented to the working group by Dr. William Graham.

- John Walters from the Department of Education will present a proposal on AIDS testing for the working group to consider. (See Attached)

- A representative from HCFA will discuss a proposed final rule for Medicare, Medicaid and clinical laboratories on confidentiality for persons tested for HIV. (See Attached)

Because of the length of the agenda we are scheduling the working group meeting for one and one-half hours. It will be held in Room 324 of the Old Executive Office Building on Monday, [redacted].

PREVENTING THE SPREAD OF AIDS THROUGH ROUTINE AND VOLUNTARY TESTING

The Federal government has initiated a variety of efforts to combat AIDS. In FY 1988, almost $1.5 billion in Federal funding has been proposed for research, treatment, testing, counseling and education, and income support. Increased funding for AIDS is expected in FY 1989. However, even with all of the activity currently underway, critical information is not available on the spread of the disease, and the vast majority of people infected do not know they are infected.

The best available research suggests that between 1.0 million and 1.5 million people are infected with the AIDS virus in the United States, and that as many as 90 percent of them may not be aware that they are infected and that they can transmit the virus to others. This research also indicates that certain groups are at greater risk of infection. If individuals in these groups change their behavior, they could substantially reduce the spread of the AIDS epidemic.

Importance of Testing

One key activity essential to prevention and control of the AIDS epidemic is testing.

- Testing plays an important role in preventing the spread of the AIDS virus to the uninfected. Persons who know they are infected will, in many cases, take steps to prevent others from becoming infected. They also can take measures to improve their overall health and thus delay progression of the disease.

- Testing provides essential information needed to formulate public health policy. It provides data for tracking the disease's progress and for the evaluation of public health measures taken to prevent and control the disease.

- Testing also can result in significant cost savings. Each AIDS patient costs $60,000, or more, on the average in medical costs alone. About 15,000 tests can be given for that amount. This means that if only one case is prevented for every 15,000 tests, testing would save money as well as lives.

New Program Needed

More than $90 million in Federal funding is proposed for AIDS testing and counseling in FY 1988, an increase of $57 million

over the $33 million spent in FY 1987. But even greater resources are needed, and merely expanding the current program is not sufficient. A coordinated testing program is needed that concentrates substantial resources on the groups at greatest risk, but also collects the data needed to track the progress of the disease, both within those groups and as it spreads into other segments of the population.

Legislative Proposal

Federal legislation to expand and improve AIDS testing should include:

- Expanded assistance for testing and counseling, with concentration of resources on geographic areas and populations in which the disease has spread or is advancing.

- Specific reporting requirements to provide data needed by Federal and State agencies responsible for the development and implementation of public health measures.

- Establishment of procedural safeguards to ensure the protection of AIDS victims and those not infected.

The Department of Health and Human Services, through the Centers for Disease Control, would provide assistance to State agencies and other public and private non-profit agencies and organizations to implement and improve testing and counseling programs.

Priority for High Prevalence Geographic Areas

Providing funds to locations with the highest number of reported AIDS cases should also reach those areas with the highest infection rates as well. Recent data suggest that, at the present time, HIV seroprevalence is closely correlated with AIDS prevalence. Currently, the 20 cities and surrounding areas with the highest AIDS prevalence have about 70 percent of the AIDS cases in the U.S but only about 27 percent of the total population.

This legislative proposal would give priority to applicants from metropolitan areas with the highest AIDS prevalence: 70 percent of funds would be reserved for applicants from those areas, with the remaining funds distributed to applicants from lower-prevalence areas.

Application Requirements

All institutions and agencies receiving funding under this program would be required to:

- Establish procedures that will assure the confidentiality of all tests. Release of information must be prohibited except to those specifically authorized to receive the information. Severe penalties should be set for revealing the identity of anyone tested, except in compliance with specified requirements.

- Conduct cost-effective contact tracing and notification of spouses, other sexual partners, those who have shared hypodermic needles, and any others who might be in danger because of contact with the blood or sexual secretions of the person tested. Priority may be given to tracing and notifying persons who are less likely to be aware that their partner was engaging in risky behavior.

- Report summary test results for all tests on a monthly basis to the State health department and to the Centers for Disease Control (CDC), with the following information: age, sex, race, zip code of residence, HIV risk factor, HIV infection status, prior testing results.

- Report positive test results to the State health department, along with the name and address of the person tested, if permitted by State law.

- Employ staff who are well-qualified and trained for testing and counseling persons at risk for HIV infection.

- Use laboratory facilities which follow high standards to be set by CDC for testing procedures and staffing.

Eligible applicants

Eligible applicants include: State and local governments and public and private non-profit agencies and institutions, including hospitals, sexually transmitted disease clinics, prenatal clinics, drug treatment centers, and prisons and jails.

Eligible activities

Funds would be used for administering and processing tests, including follow-up tests for positives; appropriate counseling to prevent the spread of the virus; confidential contact tracing and notification; and data collection and reporting.

Funding

Awards would be made for up to three years. Payments would be made on the basis of the number of tests conducted and the number of individuals counseled and/or traced through contact notification. Up to 10 percent of the funds could be used for administration, confidential record-keeping, and reporting.

Since costs to set up programs are greater in the early years, the Federal government would match the recipient on a declining basis: in high prevalence areas, at 75 percent of the award in the first year, 50 percent in the second, and 25 percent in the third year and for any future awards; in low prevalence areas, at 40 percent in the first year, 30 percent in the second, and 20 percent in the third year and for any future awards.

Federal Costs

Estimated total costs of testing and counseling under this program would be about $369 million for the first year of the program. The Federal share would be $220 million; the State and local contribution would be $149 million.

ESTIMATED FEDERAL AND LOCAL SHARES OF TESTING COSTS

	High Prevalence Areas	Low Prevalence Areas	Total
Federal share	$154,000,000	$66,000,000	$220,000,000
Local share	$50,000,000	$99,000,000	$149,000,000
Total cost	$204,000,000	$165,000,000	$369,000,000

ASSUMPTIONS USED IN DEVELOPING COST ESTIMATES

The following assumptions were used in the development of testing, counseling, and notification costs:

- For all testing except in hospitals: $3 per ELISA test and $20 per Western Blot test (CDC Conference paper, Appendix V, April 30, 1987). In hospitals: $20 per ELISA and $30 per Western blot (hospitals' higher charges).
- Assumes that only a certain proportion of each group to be tested will require the two-step procedure (i.e., that there will be a positive result on the ELISA).
- Post-test counseling of $135 per person - About six hours of counseling. (CDC Conference paper, see above.)
- Contact notification - $90 per person (CDC Conference paper, see above).

ESTIMATED COSTS OF AIDS TESTING

(COSTS IN HIGH PREVALENCE AREAS)

CATEGORY	NUMBER OF PERSONS TESTED	TESTING COSTS	POST-TEST COUNSELING (POSITIVES)	CONTACT NOTIFICATION	TOTAL COST
STATE PRISONERS/JAILS	167,130	$876,931	$2,256,255	$1,504,170	$4,637,356
MARRIAGE PARTNERS	1,350,000	$4,040,240	$182,250	$121,500	$4,343,990
STD CLINICS	1,100,000	$5,771,700	$14,850,000	$9,900,000	$30,521,700
FAMILY-PLANNING CLINICS	1,350,000	$4,040,240	$182,250	$121,500	$4,343,990
DRUG CLINICS	52,920	$277,671	$714,420	$476,280	$1,468,371
HOSPITAL ADMISSIONS	6,255,360	$125,404,330	$4,222,368	$2,814,912	$132,441,610
VOLUNTARY TESTING	120,000	$1,039,500	$4,050,000	$2,700,000	$7,789,500
TOTAL	14,164,050	$141,450,611	$26,457,543	$17,638,362	$185,546,516
ADMINISTRATION AND REPORTING (@ 10%)					$18,554,652
TOTAL COSTS IN HIGH PREVALENCE AREAS					$204,101,168

Note: Assumes higher testing costs for hospitals ($20 for ELISA and $50 for a second ELISA and a Western blot.) Also, assumes testing of hospital admissions who are between the ages of 15 and 64 or newborn, only.

VERSION II and Final

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Care Financing Administration
42 CFR Parts 74, 405 and 441

MEDICARE AND MEDICAID PROGRAMS

HSQ-150-FC

Medicare, Medicaid,, and Clinical Laboratories Improvement Act (CLIA) Patient Confidentiality Rules

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This rule eliminates the requirement that a laboratory maintain the name and other identification of individuals undergoing testing to determine the presence of the Human Immunodeficiency Virus (HIV) antibody or causative agent, if the laboratory is not seeking Medicare or Medicaid payment for these tests. However, it does not excuse a laboratory from maintaining such information if it is required to do so by State law. Those laboratories or entities seeking payment from the Medicare or Medicaid programs for HIV testing must continue to provide the name and other identification of persons tested to assure proper payment of claims. However, State Medicaid programs may choose to approve the use of alternative identifiers in place of the patient's name for HIV testing of Medicaid recipients. Laboratories licensed under CLIA also will not be required to

maintain the names and other identification of individuals being tested to determine the presence of the HIV antibody or causative agent. The intent of this change is to add further protection of confidentiality of HIV test results and to encourage voluntary testing.

DATE: This regulation is effective [date of publication in the Federal Register]. However, we will consider any comments received by [60 days after publication]. To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and received by 5:00 p.m. on [60 days after the date of publication].

ADDRESS: Mail comments to the following address:

Health Care Financing Administration
Department of Health and Human Services
Attention: HSQ-150-FC
P.O. Box 26676
Baltimore, Maryland 21207

In commenting, please refer to file code HSQ-150-FC. If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building
200 Independence Ave., SW.
Washington, D.C., or

Room 132, East High Rise Building
6325 Security Boulevard
Baltimore, Maryland.

Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION, CONTACT:

Pam Renner
(301) 594-3539

SUPPLEMENTARY INFORMATION:

I. Background

Acquired Immune Deficiency Syndrome (AIDS) is a major public health issue. In order to promote the laboratory testing of persons who suspect they may have been exposed to HIV, the virus associated with AIDS, current public health practice is to protect the privacy of these individuals and to maintain the strictest confidentiality concerning their health records. A number of States have enacted statutes

that protect the anonymity of persons tested for the presence of the HIV antibody.

However, most facilities performing HIV testing are approved as hospital or independent laboratories in the Medicare program. The Medicare regulations (42 CFR 405.1316(f)(2) for independent laboratories and 42 CFR 482.27(b) for hospital based facilities) specify that the names and other identification of the individuals whose specimens are being tested must be obtained and maintained by the testing facility, and the regulations at §405.1316(f)(2) and (3) and §482.27(b) require laboratories to maintain the name of the licensed physician or other authorized person or clinical laboratory that submitted the specimen and the names of individuals presenting themselves for testing. Also, laboratories that test specimens for Medicaid recipients must meet the Medicare requirements for these facilities (section 1902(a)(9)(C) of the Social Security Act). Laboratories testing specimens in interstate commerce under the provisions of the Clinical Laboratories Improvement Act of 1967 (CLIA) must meet similar recordkeeping requirements, as specified at 42 CFR 74.53(b) and (c).

II. Changes to the Regulations

As a result of the growing need to heighten public understanding of AIDS and to encourage voluntary testing for the disease, we have decided to amend §405.1316 to delete the requirement for laboratories to maintain names and identification of individuals undergoing testing to determine the presence of the HIV antibody or the causative agent, provided that Medicare or Medicaid payment for testing is not sought. Laboratories or entities seeking payment for HIV testing under the Medicare program will have to continue to provide the name and other identification of persons tested to assure proper payment of claims but are not required to maintain records linking the results of the test with any patient identifier. We are adding a new §441.16 to set forth in regulations the Medicaid requirements for laboratories under section 1902(a)(9)(C) of the Act, and to allow States the flexibility under their Medicaid programs to provide a mechanism that assures anonymity while maintaining the integrity of the payment process: State Medicaid programs may choose to approve the use of alternative identifiers in place of the patient's name for HIV testing of Medicaid recipients.

We are using this occasion to announce that CLIA licensed laboratories will not be required to maintain the names and other identification of individuals being tested for the

presence of the HIV antibody or causative agent. Specifically, we are amending §74.53(b) to delete the requirement for CLIA licensed laboratories to maintain the names and other identification of individuals undergoing testing to determine the presence of the HIV antibody or for the isolation and identification of the causative organism. We also are amending §74.53(c) to permit individuals who submit their own specimens for testing to maintain their anonymity.

Since §482.27(b), the laboratory management requirement of the hospital conditions of participation, is cross-referenced to the independent laboratory requirement at §405.1316, the change to §405.1316 will also apply to records maintained in hospital-based laboratories, without a specific revision to the conditions of participation for hospitals. Also, the change is applicable to records maintained by clinical laboratories located in skilled nursing facilities (SNFs) because SNFs that maintain laboratories are required, by cross reference, to meet the conditions of participation of hospital-based laboratories (see §405.1128, Condition of Participation - laboratory and radiologic services, Standard (a). Provision for services). Of course, these changes do not excuse laboratories from maintaining records required by State law. Therefore, they provide flexibility for the State to elect whether or not to require reporting of positive test results.

III. Waiver of Proposed Rulemaking

The Administrative Procedure Act (5 U.S.C. 553) requires us to publish general notice of proposed rulemaking in the Federal Register, and afford prior comment on proposed rules. Such notice includes a statement of the time, place, and nature of rulemaking proceedings, reference to the legal authority under which the rule is proposed, and the terms or substance of the proposed rule or a description of the subjects and issues involved. However, this requirement does not apply when an agency finds good cause that such a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons in the rules issued.

This final rule with comment period amends our current recordkeeping requirement for Medicare participating independent laboratories and other such entities in order to encourage voluntary HIV testing programs in high-risk groups. Waiving proposed rulemaking would not only accelerate the process for individuals seeking HIV testing but would foster increased testing and promote patient confidentiality. This objective may be best accomplished by immediate implementation of this regulation. Affording a proposed rulemaking process is impracticable, unnecessary,

and not in the public interest. Therefore, we find good cause to waive proposed rulemaking for these necessary regulatory provisions.

IV. Waiver of 30-Day Delay in Effective Date

We usually publish our rules not less than 30 days before their effective dates unless we find good cause and publish that rationale with the rule. For the reasons discussed above with reference to waiving the proposed rulemaking requirement, we find that it is not in the public interest to provide for a 30-day delay in the effective date of this final rule with comment period. Therefore, we find good cause to waive that delay.

V. Regulatory Impact Statement

A. Executive Order 12291

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for any major rule. A major rule is defined as any document that is likely to: (1) Have an annual effect on the economy of $100 million or more (2) cause a major increase in costs or prices for consumers, individuals, industries, government

agencies, or geographic regions, or (3) result in significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States based enterprises in domestic or export markets.

We have determined that this final rule will neither result in an annual economic impact of $100 million or more nor meet any other criteria of the Executive Order 12291. A regulatory impact analysis is not required.

B. Regulatory Flexibility Act

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all laboratories to be small entities.

This rule will allow affected laboratories to conform their operations to accepted public health practices regarding the confidentiality of HIV testing. It will not impose any burdens or costs on affected

entities. Therefore, we have determined, and the Secretary certifies, that this final rule with comment period will not have a significant economic impact on a substantial number of small entities.

VI. Other Required Information

A. Response to Comments.

Because of the large number of comments we receive on regulations published for comment, we cannot acknowledge or respond to them individually. However, we will consider all comments received timely and, if we decide to change the regulations, we will publish an additional Federal Register document and respond to the major issues raised by commenters in the preamble to the subsequent Federal Register document.

B. Paperwork Reduction Act

Sections 74.53, 405.1316, and 441.16 contain information collection requirements that are subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501). A notice will be published in the Federal Register when

approval is obtained. Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the agency official whose name appears in the preamble and to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, D.C. 20503, Attention: Allison Herron.

VII. List of Subjects

42 CFR Part 74

Laboratories, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 441

Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Prescription drugs, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, Title 42 of the Code of Federal Regulations is amended as set forth below:

A. Part 74 is amended as set forth below:

Part 74 CLINICAL LABORATORIES

1. The authority citation for Part 74 continues to read as follows:

AUTHORITY: Sec. 215, 58, Stat. 690; 42 U.S.C. 216.

2. In §74.53 the introductory language is republished and paragraphs (b) and (c) are revised to read as follows:

§74.53 Specimen records.

Daily accession records shall contain the following information:

* * * * *

(b) The name and other identification of the person from whom the specimen was taken, if available. However, the name and other identification is not required of an individual whose specimen is tested for --

(i) The presence of the Human Immunodeficiency Virus (HIV) antibody; or

(ii) The isolation and identification of the HIV causative agent.

(c) The name of the licensed physician or other person or clinical laboratory who or which submitted the specimen, except the name of the other person is not required if the other person is an individual

submitting his or her own specimen to be tested for --

(i) The presence of the HIV antibody; or

(ii) The isolation and identification of the HIV causative agent.

* * * * *

B. Part 405 is amended as follows:

Part 405 - FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for Part 405 Subpart M is revised to read as follows:

AUTHORITY: Secs. 1102, 1861(s)(3), (12), and (13), 1864, and 1871 of the Social Security Act as amended (42 U.S.C. 1302, 1395x(s)(3), (11), and (12), 1395aa, and 1395hh).

2. In §405.1316(f), the introductory language is republished and paragraphs (f)(2) and (3) are revised to read as follows:

§405.1316 Condition--clinical laboratory; management.

* * * * *

(f) Standard; specimens - records. The laboratory maintains a record indicating the daily accession of specimens, each of which is numbered or otherwise appropriately identified. The factor explaining the

standard is as follows: Records contain the following information:

* * * * *

(2) The name and other identification of the person from whom the specimen was taken, except for individuals for whom a request for payment is not being made under the Medicare program and whose specimens are being tested for--

(i) The presence of the Human Immunodeficiency Virus (HIV) antibody; or

(ii) The isolation and identification of the HIV causative agent.

(3) The name of the licensed physician or other authorized person or clinical laboratory who or which submitted the specimen, except that when request for Medicare payment is not being made, the name of the other authorized person is not required, if the other authorized person is an individual submitting his or her own specimen to be tested for--

(i) The presence of the HIV antibody; or

(ii) The isolation and identification of the HIV causative agent.

* * * * *

C. Part 441 is amended as follows:

Part 441- SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

1. The authority citation for Part 441 continues to read as follows:

AUTHORITY: Sec. 1102 of the Social Security Act; 42 U.S.C 1302.

2. The table of Contents for Part 441 is amended by adding a new section 441.16 as follows:

Subpart A - General Provisions

* * * * *

§441.16 Laboratory Services

* * * * *

3. Section 441.16 is added to read as follows:

§441.16 Laboratory Services

(a) The plan must provide for payment of laboratory services as defined in § 440.30 of this subchapter if provided by--

(1) An independent laboratory that meets the requirements for participation in the Medicare program found in §405.1316 of this title;

(2) A hospital-based laboratory that meets the requirements for participation in the Medicare program found in §482.27 of this title;

(3) A rural health clinic, as defined in §491.9 of this title; or

(4) A skilled nursing facility - based clinical laboratory, as defined in §405.1128(a) of this title.

(b) Except as provided under paragraph (c), if a laboratory or other entity is requesting payment under Medicaid for testing for the presence of the human immunodeficiency virus (HIV) antibody or for the isolation and identification of the HIV causative agent as described in §§405.1316(f)(2) and (3) of this title, the laboratory records must contain the name and other identification of the person from whom the specimen was taken.

(c) An agency may choose to approve the use of alternative identifiers, in place of the requirement for patient's name, in paragraph (b) of this section for HIV antibody or causative agent testing of Medicaid recipients.

(Catalog of Federal Domestic Assistance Program No. 13.714 Medical Assistance Program: Medicare - Hospital Insurance and 13.744; Medicare - Supplementary Medical Insurance.)

DATED: _____

_____
Administrator, Health Care
Financing Administration

APPROVED: _____

_____
Secretary

4120-01

F. Copy to LaLonde

THE WHITE HOUSE

WASHINGTON

March 1, 1988

MEMORANDUM FOR MEMBERS OF THE HEALTH POLICY WORKING GROUP

FROM: GARY L. BAUER

SUBJECT: FOLLOW-UP TO FEBRUARY 22, AIDS DISCUSSION

The following items will be discussed:

- o follow-up on proposed HCFA final rule on confidentiality for HIV tests in clinical laboratories; [Dr. Roper]
- o proposal to prevent the spread of AIDS through routine and voluntary testing; [John Walters]
- o review and approval of format to be used for quarterly CDC reports to the DPC on prevalence and incidence of HIV; [Dr. Mason]
- o HHS/OSTP proposal on scientific modeling; [Dr. Windom/ Dr. Berger]

The meeting will be held in room 248 of the Old Executive Office Building on Thursday, March 3, 1988, from 2:00 to 3:00 p.m.

March 11 a/14