## 30:4D-6

#### LEGISLATIVE HISTORY CHECKLIST

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**LAWS OF**: 2003 **CHAPTER**: 294

NJSA: 30:4D-6 (Medicaid coverage of HIV drug resistance testing)

**BILL NO**: A2444/1933 (Substituted for S2256)

**SPONSOR(S)** Roberts and others

DATE INTRODUCED: June 13, 2002

**COMMITTEE:** ASSEMBLY: Health and Human Services; Appropriations

SENATE: Health and Human Services and Senior Citizens

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: ASSEMBLY: March 3, 2003

SENATE: January 8, 2004

**DATE OF APPROVAL:** January 14, 2004

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL Assembly Committee Substitute (1R) enacted

(Amendments during passage denoted by asterisks)

A2444/1933

**SPONSOR'S STATEMENT (A2444)**: (Begins on page 7 of original bill) Yes

**SPONSOR'S STATEMENT (A1933)**: (Begins on page 7 of original bill) Yes

COMMITTEE STATEMENT: ASSEMBLY: Yes 10-21-2002 (Health)

12-9-2002 (Approp.)

**SENATE**: Yes <u>5-8-2003 (Health)</u>

12-4-2003 (Budget)

FLOOR AMENDMENT STATEMENT: No

<u>LEGISLATIVE FISCAL ESTIMATE</u>: <u>Yes</u>

S2256

**SPONSOR'S STATEMENT**: (Begins on page 7 of original bill)

Yes

**COMMITTEE STATEMENT:** ASSEMBLY: No

SENATE: Yes <u>5-8-2003 (Health)</u>

12-4-2003 (Budget)

Identical to Senate Statements for A2444

FLOOR AMENDMENT STATEMENT: No

<u>LEGISLATIVE FISCAL ESTIMATE</u>: <u>Yes</u>

VETO MESSAGE:	No
GOVERNOR'S PRESS RELEASE ON SIGNING:	No
FOLLOWING WERE PRINTED:  To check for circulating copies, contact New Jersey State Government Publications at the State Library (609) 278-2640 ext. 103 or mailto:refdesk@njstatelib.org.	
REPORTS:	No
HEARINGS:	No
NEWSPAPER ARTICLES:	No

## P.L. 2003, CHAPTER 294, *approved January 14*, 2004 Assembly Committee Substitute (*First Reprint*) for Assembly, Nos. 2444 and 1933

1 **AN ACT** concerning Medicaid coverage of HIV drug resistance testing 2 and amending P.L.1968, c.413.

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**BE IT ENACTED** by the Senate and General Assembly of the State of New Jersey:

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- 7 1. Section 6 of P.L.1968, c.413 (C.30:4D-6) is amended to read 8 as follows:
- 9 6. a. Subject to the requirements of Title XIX of the federal Social Security Act, the limitations imposed by this act and by the rules and regulations promulgated pursuant thereto, the department shall provide medical assistance to qualified applicants, including authorized services within each of the following classifications:
  - (1) Inpatient hospital services;
  - (2) Outpatient hospital services;
    - (3) Other laboratory and X-ray services;
  - (4) (a) Skilled nursing or intermediate care facility services;
  - (b) Such early and periodic screening and diagnosis of individuals who are eligible under the program and are under age 21, to ascertain their physical or mental defects and such health care, treatment, and other measures to correct or ameliorate defects and chronic conditions discovered thereby, as may be provided in regulations of the Secretary of the federal Department of Health and Human Services and approved by the commissioner;
  - (5) Physician's services furnished in the office, the patient's home, a hospital, a skilled nursing or intermediate care facility or elsewhere.
- As used in this subsection, "laboratory and X-ray services" includes
  HIV drug resistance testing, including, but not limited to, genotype

  1 assays that have been cleared or approved by the federal Food and
- 30 <u>Drug Administration, laboratory developed genotype assays</u><sup>1</sup>.
- 31 <u>phenotype</u> <sup>1</sup>[and virtual phenotype] <sup>1</sup> assays <sup>1</sup>, and other assays
- 32 <u>using phenotype prediction with genotype comparison, for persons</u>
- 33 diagnosed with HIV infection or AIDS.
- b. Subject to the limitations imposed by federal law, by this act, and by the rules and regulations promulgated pursuant thereto, the medical assistance program may be expanded to include authorized services within each of the following classifications:
- 38 (1) Medical care not included in subsection a.(5) above, or any 39 other type of remedial care recognized under State law, furnished by

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

<sup>&</sup>lt;sup>1</sup> Assembly AAP committee amendments adopted December 9, 2002.

- 1 licensed practitioners within the scope of their practice, as defined by
- 2 State law;

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- 3 (2) Home health care services;
- 4 (3) Clinic services;
- 5 (4) Dental services;
- 6 (5) Physical therapy and related services;
- 7 (6) Prescribed drugs, dentures, and prosthetic devices; and 8 eyeglasses prescribed by a physician skilled in diseases of the eye or by 9 an optometrist, whichever the individual may select;
- 10 (7) Optometric services;
- 11 (8) Podiatric services;
- 12 (9) Chiropractic services;
- 13 (10) Psychological services;
- 14 (11) Inpatient psychiatric hospital services for individuals under
- 21 years of age, or under age 22 if they are receiving such services
- 16 immediately before attaining age 21;
- 17 (12) Other diagnostic, screening, preventive, and rehabilitative 18 services, and other remedial care;
- 19 (13) Inpatient hospital services, nursing facility services and 20 intermediate care facility services for individuals 65 years of age or 21 over in an institution for mental diseases;
  - (14) Intermediate care facility services;
  - (15) Transportation services;
  - (16) Services in connection with the inpatient or outpatient treatment or care of drug abuse, when the treatment is prescribed by a physician and provided in a licensed hospital or in a narcotic and drug abuse treatment center approved by the Department of Health and Senior Services pursuant to P.L.1970, c.334 (C.26:2G-21 et seq.) and whose staff includes a medical director, and limited to those services eligible for federal financial participation under Title XIX of the federal Social Security Act;
- 32 (17) Any other medical care and any other type of remedial care 33 recognized under State law, specified by the Secretary of the federal 34 Department of Health and Human Services, and approved by the 35 commissioner;
- (18) Comprehensive maternity care, which may include: the basic 36 37 number of prenatal and postpartum visits recommended by the American College of Obstetrics and Gynecology; additional prenatal 38 and postpartum visits that are medically necessary; necessary 39 40 laboratory, nutritional assessment and counseling, health education, 41 personal counseling, managed care, outreach and follow-up services; treatment of conditions which may complicate pregnancy; and 42 physician or certified nurse-midwife delivery services; 43
- 44 (19) Comprehensive pediatric care, which may include: 45 ambulatory, preventive and primary care health services. The 46 preventive services shall include, at a minimum, the basic number of

1 preventive visits recommended by the American Academy of 2 Pediatrics;

3 (20) Services provided by a hospice which is participating in the 4 Medicare program established pursuant to Title XVIII of the Social Security Act, Pub.L.89-97 (42 U.S.C. s.1395 et seq.). Hospice 5 services shall be provided subject to approval of the Secretary of the 6 federal Department of Health and Human Services for federal 7 8 reimbursement;

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- (21) Mammograms, subject to approval of the Secretary of the federal Department of Health and Human Services for federal reimbursement, including one baseline mammogram for women who are at least 35 but less than 40 years of age; one mammogram examination every two years or more frequently, if recommended by a physician, for women who are at least 40 but less than 50 years of age; and one mammogram examination every year for women age 50 and over.
- c. Payments for the foregoing services, goods and supplies furnished pursuant to this act shall be made to the extent authorized by this act, the rules and regulations promulgated pursuant thereto and, where applicable, subject to the agreement of insurance provided for under this act. Said payments shall constitute payment in full to the provider on behalf of the recipient. Every provider making a claim for payment pursuant to this act shall certify in writing on the claim submitted that no additional amount will be charged to the recipient, his family, his representative or others on his behalf for the services, goods and supplies furnished pursuant to this act.

No provider whose claim for payment pursuant to this act has been denied because the services, goods or supplies were determined to be medically unnecessary shall seek reimbursement from the recipient, his family, his representative or others on his behalf for such services, goods and supplies provided pursuant to this act; provided, however, a provider may seek reimbursement from a recipient for services, goods or supplies not authorized by this act, if the recipient elected to receive the services, goods or supplies with the knowledge that they were not authorized.

d. Any individual eligible for medical assistance (including drugs) may obtain such assistance from any person qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability on a prepayment basis), who undertakes to provide him such services.

No copayment or other form of cost-sharing shall be imposed on any individual eligible for medical assistance, except as mandated by federal law as a condition of federal financial participation.

44 Anything in this act to the contrary notwithstanding, no payments for medical assistance shall be made under this act with 46 respect to care or services for any individual who:

- (1) Is an inmate of a public institution (except as a patient in a medical institution); provided, however, that an individual who is otherwise eligible may continue to receive services for the month in which he becomes an inmate, should the commissioner determine to expand the scope of Medicaid eligibility to include such an individual, subject to the limitations imposed by federal law and regulations, or
- (2) Has not attained 65 years of age and who is a patient in an institution for mental diseases, or
- (3) Is over 21 years of age and who is receiving inpatient psychiatric hospital services in a psychiatric facility; provided, however, that an individual who was receiving such services immediately prior to attaining age 21 may continue to receive such services until he reaches age 22. Nothing in this subsection shall prohibit the commissioner from extending medical assistance to all eligible persons receiving inpatient psychiatric services; provided that there is federal financial participation available.
- f. (1) A third party as defined in section 3 of P.L.1968, c.413 (C.30:4D-3) shall not consider a person's eligibility for Medicaid in this or another state when determining the person's eligibility for enrollment or the provision of benefits by that third party.
- (2) In addition, any provision in a contract of insurance, health benefits plan or other health care coverage document, will, trust agreement, court order or other instrument which reduces or excludes coverage or payment for health care-related goods and services to or for an individual because of that individual's actual or potential eligibility for or receipt of Medicaid benefits shall be null and void, and no payments shall be made under this act as a result of any such provision.
- (3) Notwithstanding any provision of law to the contrary, the provisions of paragraph (2) of this subsection shall not apply to a trust agreement that is established pursuant to 42 U.S.C. s.1396p(d)(4)(A) or (C) to supplement and augment assistance provided by government entities to a person who is disabled as defined in section 1614(a)(3) of the federal Social Security Act (42 U.S.C. s.1382c (a)(3)).
- g. The following services shall be provided to eligible medically needy individuals as follows:
- (1) Pregnant women shall be provided prenatal care and delivery services and postpartum care, including the services cited in subsection a.(1), (3) and (5) of this section and subsection b.(1)-(10), (12), (15) and (17) of this section, and nursing facility services cited in subsection b.(13) of this section.
- 42 (2) Dependent children shall be provided with services cited in 43 subsection a.(3) and (5) of this section and subsection b.(1), (2), (3), 44 (4), (5), (6), (7), (10), (12), (15) and (17) of this section, and nursing 45 facility services cited in subsection b.(13) of this section.
- 46 (3) Individuals who are 65 years of age or older shall be provided

with services cited in subsection a.(3) and (5) of this section and subsection b.(1)-(5), (6) excluding prescribed drugs, (7), (8), (10), (12), (15) and (17) of this section, and nursing facility services cited in subsection b.(13) of this section.

- (4) Individuals who are blind or disabled shall be provided with services cited in subsection a.(3) and (5) of this section and subsection b.(1)-(5), (6) excluding prescribed drugs, (7), (8), (10), (12), (15) and (17) of this section, and nursing facility services cited in subsection b.(13) of this section.
- (5) (a) Inpatient hospital services, subsection a.(1) of this section, shall only be provided to eligible medically needy individuals, other than pregnant women, if the federal Department of Health and Human Services discontinues the State's waiver to establish inpatient hospital reimbursement rates for the Medicare and Medicaid programs under the authority of section 601(c)(3) of the Social Security Act Amendments of 1983, Pub.L.98-21 (42 U.S.C. s.1395ww(c)(5)). Inpatient hospital services may be extended to other eligible medically needy individuals if the federal Department of Health and Human Services directs that these services be included.
  - (b) Outpatient hospital services, subsection a.(2) of this section, shall only be provided to eligible medically needy individuals if the federal Department of Health and Human Services discontinues the State's waiver to establish outpatient hospital reimbursement rates for the Medicare and Medicaid programs under the authority of section 601(c)(3) of the Social Security Amendments of 1983, Pub.L.98-21 (42 U.S.C. s.1395ww(c)(5)). Outpatient hospital services may be extended to all or to certain medically needy individuals if the federal Department of Health and Human Services directs that these services be included. However, the use of outpatient hospital services shall be limited to clinic services and to emergency room services for injuries and significant acute medical conditions.
- (c) The division shall monitor the use of inpatient and outpatienthospital services by medically needy persons.
  - h. In the case of a qualified disabled and working individual pursuant to section 6408 of Pub.L.101-239 (42 U.S.C. s.1396d), the only medical assistance provided under this act shall be the payment of premiums for Medicare part A under 42 U.S.C. ss.1395i-2 and 1395r.
  - i. In the case of a specified low-income Medicare beneficiary pursuant to 42 U.S.C. s.1396a(a)10(E)iii, the only medical assistance provided under this act shall be the payment of premiums for Medicare part B under 42 U.S.C. s.1395r as provided for in 42 U.S.C. s.1396d(p)(3)(A)(ii).
- j. In the case of a qualified individual pursuant to 42 U.S.C. s.1396a(aa), the only medical assistance provided under this act shall be payment for authorized services provided during the period in which the individual requires treatment for breast or cervical cancer, in accordance with criteria established by the commissioner.

## [1R] ACS for A2444

1	(cf: P.L.2001, c.186, s.2)
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3	2. The Commissioner of Human Services, pursuant to the
4	"Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
5	seq.), shall adopt rules and regulations to effectuate the purposes of
6	this act.
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8	3. This act shall take effect on the 180th day after enactment
9	except that the Commissioner of Human Services may take such
10	anticipatory administrative action in advance as shall be necessary for
11	the implementation of the act.
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16	Requires Medicaid coverage of HIV drug resistance testing.

## ASSEMBLY, No. 2444

## STATE OF NEW JERSEY

## 210th LEGISLATURE

INTRODUCED JUNE 13, 2002

**Sponsored by:** 

Assemblyman JOSEPH J. ROBERTS, JR. District 5 (Camden and Gloucester)
Assemblyman LOUIS D. GREENWALD
District 6 (Camden)

#### **SYNOPSIS**

Provides Medicaid coverage for certain HIV drug resistance testing.

## **CURRENT VERSION OF TEXT**

As introduced.



1 **AN ACT** providing for Medicaid coverage of certain HIV drug resistance testing and amending P.L.1968, c.413.

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4 **BE IT ENACTED** by the Senate and General Assembly of the State of New Jersey:

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- 7 1. Section 6 of P.L.1968, c.413 (C.30:4D-6) is amended to read as 8 follows:
- 9 6. a. Subject to the requirements of Title XIX of the federal Social Security Act, the limitations imposed by this act and by the rules and regulations promulgated pursuant thereto, the department shall provide medical assistance to qualified applicants, including authorized services within each of the following classifications:
- 14 (1) Inpatient hospital services;
- 15 (2) Outpatient hospital services;
- 16 (3) Other laboratory and X-ray services;
  - (4) (a) Skilled nursing or intermediate care facility services;
- 18 (b) Such early and periodic screening and diagnosis of individuals 19 who are eligible under the program and are under age 21, to ascertain 20 their physical or mental defects and such health care, treatment, and 21 other measures to correct or ameliorate defects and chronic conditions 22 discovered thereby, as may be provided in regulations of the Secretary 23 of the federal Department of Health and Human Services and approved 24 by the commissioner;
  - (5) Physician's services furnished in the office, the patient's home, a hospital, a skilled nursing or intermediate care facility or elsewhere.
- As used in paragraph (3) of this subsection, "other laboratory and X-ray services" includes HIV drug resistance testing for persons diagnosed with HIV infection or AIDS in the form of genotype assays
- 30 that have been determined to be safe and clinically effective by the
- 31 <u>federal Food and Drug Administration and phenotype assays.</u>
- b. Subject to the limitations imposed by federal law, by this act, and by the rules and regulations promulgated pursuant thereto, the medical assistance program may be expanded to include authorized services within each of the following classifications:
- 36 (1) Medical care not included in subsection a.(5) above, or any 37 other type of remedial care recognized under State law, furnished by 38 licensed practitioners within the scope of their practice, as defined by 39 State law;
- 40 (2) Home health care services;
- 41 (3) Clinic services;
- 42 (4) Dental services;
- 43 (5) Physical therapy and related services;

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

- 1 (6) Prescribed drugs, dentures, and prosthetic devices; and 2 eyeglasses prescribed by a physician skilled in diseases of the eye or by 3 an optometrist, whichever the individual may select;
- 4 (7) Optometric services;
- 5 (8) Podiatric services;
- 6 (9) Chiropractic services;
- 7 (10) Psychological services;
- 8 (11) Inpatient psychiatric hospital services for individuals under 9 21 years of age, or under age 22 if they are receiving such services
- 10 immediately before attaining age 21;
- 11 (12) Other diagnostic, screening, preventive, and rehabilitative 12 services, and other remedial care;
- 13 (13) Inpatient hospital services, nursing facility services and 14 intermediate care facility services for individuals 65 years of age or 15 over in an institution for mental diseases;
- 16 (14) Intermediate care facility services;
- 17 (15) Transportation services;

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- (16) Services in connection with the inpatient or outpatient 18 19 treatment or care of drug abuse, when the treatment is prescribed by 20 a physician and provided in a licensed hospital or in a narcotic and 21 drug abuse treatment center approved by the Department of Health 22 and Senior Services pursuant to P.L.1970, c.334 (C.26:2G-21 et seq.) 23 and whose staff includes a medical director, and limited to those services eligible for federal financial participation under Title XIX of 24 25 the federal Social Security Act;
- 26 (17) Any other medical care and any other type of remedial care 27 recognized under State law, specified by the Secretary of the federal 28 Department of Health and Human Services, and approved by the 29 commissioner;
- 30 (18) Comprehensive maternity care, which may include: the basic 31 number of prenatal and postpartum visits recommended by the 32 American College of Obstetrics and Gynecology; additional prenatal and postpartum visits that are medically necessary; necessary 33 34 laboratory, nutritional assessment and counseling, health education, personal counseling, managed care, outreach and follow-up services; 35 treatment of conditions which may complicate pregnancy; and 36 physician or certified nurse-midwife delivery services; 37
  - (19) Comprehensive pediatric care, which may include: ambulatory, preventive and primary care health services. The preventive services shall include, at a minimum, the basic number of preventive visits recommended by the American Academy of Pediatrics;
- 42 (20) Services provided by a hospice which is participating in the 43 Medicare program established pursuant to Title XVIII of the Social 44 Security Act, Pub.L.89-97 (42 U.S.C. s.1395 et seq.). Hospice 45 services shall be provided subject to approval of the Secretary of the 46 federal Department of Health and Human Services for federal

reimbursement;

- (21) Mammograms, subject to approval of the Secretary of the federal Department of Health and Human Services for federal reimbursement, including one baseline mammogram for women who are at least 35 but less than 40 years of age; one mammogram examination every two years or more frequently, if recommended by a physician, for women who are at least 40 but less than 50 years of age; and one mammogram examination every year for women age 50 and over.
- c. Payments for the foregoing services, goods and supplies furnished pursuant to this act shall be made to the extent authorized by this act, the rules and regulations promulgated pursuant thereto and, where applicable, subject to the agreement of insurance provided for under this act. Said payments shall constitute payment in full to the provider on behalf of the recipient. Every provider making a claim for payment pursuant to this act shall certify in writing on the claim submitted that no additional amount will be charged to the recipient, his family, his representative or others on his behalf for the services, goods and supplies furnished pursuant to this act.

No provider whose claim for payment pursuant to this act has been denied because the services, goods or supplies were determined to be medically unnecessary shall seek reimbursement from the recipient, his family, his representative or others on his behalf for such services, goods and supplies provided pursuant to this act; provided, however, a provider may seek reimbursement from a recipient for services, goods or supplies not authorized by this act, if the recipient elected to receive the services, goods or supplies with the knowledge that they were not authorized.

d. Any individual eligible for medical assistance (including drugs) may obtain such assistance from any person qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability on a prepayment basis), who undertakes to provide him such services.

No copayment or other form of cost-sharing shall be imposed on any individual eligible for medical assistance, except as mandated by federal law as a condition of federal financial participation.

- e. Anything in this act to the contrary notwithstanding, no payments for medical assistance shall be made under this act with respect to care or services for any individual who:
- (1) Is an inmate of a public institution (except as a patient in a medical institution); provided, however, that an individual who is otherwise eligible may continue to receive services for the month in which he becomes an inmate, should the commissioner determine to expand the scope of Medicaid eligibility to include such an individual, subject to the limitations imposed by federal law and regulations, or
  - (2) Has not attained 65 years of age and who is a patient in an

1 institution for mental diseases, or

- (3) Is over 21 years of age and who is receiving inpatient psychiatric hospital services in a psychiatric facility; provided, however, that an individual who was receiving such services immediately prior to attaining age 21 may continue to receive such services until he reaches age 22. Nothing in this subsection shall prohibit the commissioner from extending medical assistance to all eligible persons receiving inpatient psychiatric services; provided that there is federal financial participation available.
  - f. (1) A third party as defined in section 3 of P.L.1968, c.413 (C.30:4D-3) shall not consider a person's eligibility for Medicaid in this or another state when determining the person's eligibility for enrollment or the provision of benefits by that third party.
  - (2) In addition, any provision in a contract of insurance, health benefits plan or other health care coverage document, will, trust agreement, court order or other instrument which reduces or excludes coverage or payment for health care-related goods and services to or for an individual because of that individual's actual or potential eligibility for or receipt of Medicaid benefits shall be null and void, and no payments shall be made under this act as a result of any such provision.
  - (3) Notwithstanding any provision of law to the contrary, the provisions of paragraph (2) of this subsection shall not apply to a trust agreement that is established pursuant to 42 U.S.C. s.1396p(d)(4)(A) or (C) to supplement and augment assistance provided by government entities to a person who is disabled as defined in section 1614(a)(3) of the federal Social Security Act (42 U.S.C. s.1382c (a)(3)).
  - g. The following services shall be provided to eligible medically needy individuals as follows:
  - (1) Pregnant women shall be provided prenatal care and delivery services and postpartum care, including the services cited in subsection a.(1), (3) and (5) of this section and subsection b.(1)-(10), (12), (15) and (17) of this section, and nursing facility services cited in subsection b.(13) of this section.
- 35 (2) Dependent children shall be provided with services cited in 36 subsection a.(3) and (5) of this section and subsection b.(1), (2), (3), 37 (4), (5), (6), (7), (10), (12), (15) and (17) of this section, and nursing 38 facility services cited in subsection b.(13) of this section.
  - (3) Individuals who are 65 years of age or older shall be provided with services cited in subsection a.(3) and (5) of this section and subsection b.(1)-(5), (6) excluding prescribed drugs, (7), (8), (10), (12), (15) and (17) of this section, and nursing facility services cited in subsection b.(13) of this section.
- 44 (4) Individuals who are blind or disabled shall be provided with 45 services cited in subsection a.(3) and (5) of this section and subsection 46 b.(1)-(5), (6) excluding prescribed drugs, (7), (8), (10), (12), (15) and

## A2444 ROBERTS, GREENWALD

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1 (17) of this section, and nursing facility services cited in subsection 2 b.(13) of this section.

3 (5) (a) Inpatient hospital services, subsection a.(1) of this section, 4 shall only be provided to eligible medically needy individuals, other than pregnant women, if the federal Department of Health and Human 5 6 Services discontinues the State's waiver to establish inpatient hospital 7 reimbursement rates for the Medicare and Medicaid programs under 8 the authority of section 601(c)(3) of the Social Security Act 9 Amendments of 1983, Pub.L.98-21 (42 U.S.C. s.1395ww(c)(5)). 10 Inpatient hospital services may be extended to other eligible medically needy individuals if the federal Department of Health and Human 11

Services directs that these services be included.

- 13 (b) Outpatient hospital services, subsection a.(2) of this section, 14 shall only be provided to eligible medically needy individuals if the federal Department of Health and Human Services discontinues the 15 State's waiver to establish outpatient hospital reimbursement rates for 16 17 the Medicare and Medicaid programs under the authority of section 601(c)(3) of the Social Security Amendments of 1983, Pub.L.98-21 18 19 (42 U.S.C. s.1395ww(c)(5)). Outpatient hospital services may be 20 extended to all or to certain medically needy individuals if the federal 21 Department of Health and Human Services directs that these services 22 be included. However, the use of outpatient hospital services shall be 23 limited to clinic services and to emergency room services for injuries and significant acute medical conditions. 24
  - (c) The division shall monitor the use of inpatient and outpatient hospital services by medically needy persons.
  - h. In the case of a qualified disabled and working individual pursuant to section 6408 of Pub.L.101-239 (42 U.S.C. s.1396d), the only medical assistance provided under this act shall be the payment of premiums for Medicare part A under 42 U.S.C. ss.1395i-2 and 1395r.
  - i. In the case of a specified low-income Medicare beneficiary pursuant to 42 U.S.C. s.1396a(a)10(E)iii, the only medical assistance provided under this act shall be the payment of premiums for Medicare part B under 42 U.S.C. s.1395r as provided for in 42 U.S.C. s.1396d(p)(3)(A)(ii).
- j. In the case of a qualified individual pursuant to 42 U.S.C. s. 1396a(aa), the only medical assistance provided under this act shall be payment for authorized services provided during the period in which the individual requires treatment for breast or cervical cancer, in accordance with criteria established by the commissioner.
- 42 (cf: P.L.2001, c.186, s.2)

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2. The Commissioner of Human Services, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt rules and regulations to effectuate the purposes of this act.

## A2444 ROBERTS, GREENWALD

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1 3. This act shall take effect on the 90th day after enactment, except 2 that the Commissioner of Human Services may take such anticipatory 3 administrative action in advance as shall be necessary for the 4 implementation of the act. 5 6 7 **STATEMENT** 8 9 This bill would provide Medicaid coverage for certain HIV drug 10 resistance testing, for persons diagnosed with HIV infection or AIDS, in the form of genotype assays that have been determined to be safe 11 and clinically effective by the federal Food and Drug Administration 12 and phenotype assays. 13 14 This testing is useful in determining the combinations of 15 medications that are effective in controlling HIV infection in individual patients, especially among those whose current drug regimen is 16 17 unsuccessful, and can help to explain treatment failures and guide 18 treatment decisions. The bill takes effect on the 90th day after enactment, but authorizes 19 20 the Commissioner of Human Services to take anticipatory

administrative action in advance as necessary for its implementation.

## ASSEMBLY, No. 1933

# STATE OF NEW JERSEY 210th LEGISLATURE

INTRODUCED FEBRUARY 28, 2002

Sponsored by:

Assemblywoman CHARLOTTE VANDERVALK District 39 (Bergen) Assemblywoman LORETTA WEINBERG District 37 (Bergen)

## Co-Sponsored by:

Assemblymen Gusciora, Conaway, Conners, Cryan, Assemblywoman Quigley, Assemblymen Thompson and Munoz

## **SYNOPSIS**

Requires Medicaid coverage of HIV drug resistance testing.

## **CURRENT VERSION OF TEXT**

As introduced.



(Sponsorship Updated As Of: 9/20/2002)

1 **AN ACT** concerning Medicaid coverage of HIV drug resistance testing 2 and amending P.L.1968, c.413.

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4 **BE IT ENACTED** by the Senate and General Assembly of the State of New Jersey:

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- 7 1. Section 6 of P.L.1968, c.413 (C.30:4D-6) is amended to read as 8 follows:
- 9 6. a. Subject to the requirements of Title XIX of the federal Social 10 Security Act, the limitations imposed by this act and by the rules and 11 regulations promulgated pursuant thereto, the department shall 12 provide medical assistance to qualified applicants, including authorized 13 services within each of the following classifications:
  - (1) Inpatient hospital services;
  - (2) Outpatient hospital services;
  - (3) Other laboratory and X-ray services;
    - (4) (a) Skilled nursing or intermediate care facility services;
- 18 (b) Such early and periodic screening and diagnosis of individuals 19 who are eligible under the program and are under age 21, to ascertain 20 their physical or mental defects and such health care, treatment, and 21 other measures to correct or ameliorate defects and chronic conditions 22 discovered thereby, as may be provided in regulations of the Secretary 23 of the federal Department of Health and Human Services and approved 24 by the commissioner;
- 25 (5) Physician's services furnished in the office, the patient's home, a hospital, a skilled nursing or intermediate care facility or elsewhere.
  - As used in this subsection, "laboratory and X-ray services" includes HIV drug resistance testing in the form of phenotype assays and genotype assays for persons diagnosed with HIV infection or AIDS.
  - b. Subject to the limitations imposed by federal law, by this act, and by the rules and regulations promulgated pursuant thereto, the medical assistance program may be expanded to include authorized services within each of the following classifications:
- 34 (1) Medical care not included in subsection a.(5) above, or any 35 other type of remedial care recognized under State law, furnished by 36 licensed practitioners within the scope of their practice, as defined by 37 State law;
- 38 (2) Home health care services;
- 39 (3) Clinic services;
- 40 (4) Dental services;
- 41 (5) Physical therapy and related services;
- 42 (6) Prescribed drugs, dentures, and prosthetic devices; and 43 eyeglasses prescribed by a physician skilled in diseases of the eye or by
- an optometrist, whichever the individual may select;

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

- 1 (7) Optometric services;
- 2 (8) Podiatric services;
- 3 (9) Chiropractic services;
- 4 (10) Psychological services;
- 5 (11) Inpatient psychiatric hospital services for individuals under
- 6 21 years of age, or under age 22 if they are receiving such services
- 7 immediately before attaining age 21;
- 8 (12) Other diagnostic, screening, preventive, and rehabilitative 9 services, and other remedial care;
- 10 (13) Inpatient hospital services, nursing facility services and 11 intermediate care facility services for individuals 65 years of age or 12 over in an institution for mental diseases;
- 13 (14) Intermediate care facility services;
- 14 (15) Transportation services;

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- 15 (16) Services in connection with the inpatient or outpatient treatment or care of drug abuse, when the treatment is prescribed by 16 17 a physician and provided in a licensed hospital or in a narcotic and drug abuse treatment center approved by the Department of Health 18 19 and Senior Services pursuant to P.L.1970, c.334 (C.26:2G-21 et seq.) and whose staff includes a medical director, and limited to those 20 21 services eligible for federal financial participation under Title XIX of 22 the federal Social Security Act;
  - (17) Any other medical care and any other type of remedial care recognized under State law, specified by the Secretary of the federal Department of Health and Human Services, and approved by the commissioner;
- 27 (18) Comprehensive maternity care, which may include: the basic 28 number of prenatal and postpartum visits recommended by the 29 American College of Obstetrics and Gynecology; additional prenatal 30 and postpartum visits that are medically necessary; necessary 31 laboratory, nutritional assessment and counseling, health education, 32 personal counseling, managed care, outreach and follow-up services; 33 treatment of conditions which may complicate pregnancy; and 34 physician or certified nurse-midwife delivery services;
- 35 (19) Comprehensive pediatric care, which may include: ambulatory, 36 preventive and primary care health services. The preventive services 37 shall include, at a minimum, the basic number of preventive visits 38 recommended by the American Academy of Pediatrics;
- 39 (20) Services provided by a hospice which is participating in the 40 Medicare program established pursuant to Title XVIII of the Social 41 Security Act, Pub.L.89-97 (42 U.S.C. s.1395 et seq.). Hospice 42 services shall be provided subject to approval of the Secretary of the 43 federal Department of Health and Human Services for federal 44 reimbursement;
- 45 (21) Mammograms, subject to approval of the Secretary of the 46 federal Department of Health and Human Services for federal

reimbursement, including one baseline mammogram for women who are at least 35 but less than 40 years of age; one mammogram examination every two years or more frequently, if recommended by a physician, for women who are at least 40 but less than 50 years of age; and one mammogram examination every year for women age 50 and over.

7 c. Payments for the foregoing services, goods and supplies 8 furnished pursuant to this act shall be made to the extent authorized 9 by this act, the rules and regulations promulgated pursuant thereto and, where applicable, subject to the agreement of insurance provided 10 11 for under this act. Said payments shall constitute payment in full to 12 the provider on behalf of the recipient. Every provider making a claim 13 for payment pursuant to this act shall certify in writing on the claim 14 submitted that no additional amount will be charged to the recipient, 15 his family, his representative or others on his behalf for the services, goods and supplies furnished pursuant to this act. 16

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No provider whose claim for payment pursuant to this act has been denied because the services, goods or supplies were determined to be medically unnecessary shall seek reimbursement from the recipient, his family, his representative or others on his behalf for such services, goods and supplies provided pursuant to this act; provided, however, a provider may seek reimbursement from a recipient for services, goods or supplies not authorized by this act, if the recipient elected to receive the services, goods or supplies with the knowledge that they were not authorized.

d. Any individual eligible for medical assistance (including drugs) may obtain such assistance from any person qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability on a prepayment basis), who undertakes to provide him such services.

No copayment or other form of cost-sharing shall be imposed on any individual eligible for medical assistance, except as mandated by federal law as a condition of federal financial participation.

- e. Anything in this act to the contrary notwithstanding, no payments for medical assistance shall be made under this act with respect to care or services for any individual who:
- (1) Is an inmate of a public institution (except as a patient in a medical institution); provided, however, that an individual who is otherwise eligible may continue to receive services for the month in which he becomes an inmate, should the commissioner determine to expand the scope of Medicaid eligibility to include such an individual, subject to the limitations imposed by federal law and regulations, or
- 43 (2) Has not attained 65 years of age and who is a patient in an institution for mental diseases, or
- 45 (3) Is over 21 years of age and who is receiving inpatient 46 psychiatric hospital services in a psychiatric facility; provided,

- 1 however, that an individual who was receiving such services
- 2 immediately prior to attaining age 21 may continue to receive such
- 3 services until he reaches age 22. Nothing in this subsection shall
- 4 prohibit the commissioner from extending medical assistance to all
- 5 eligible persons receiving inpatient psychiatric services; provided that
- 6 there is federal financial participation available.

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- f. (1) A third party as defined in section 3 of P.L.1968, c.413 (C.30:4D-3) shall not consider a person's eligibility for Medicaid in this or another state when determining the person's eligibility for enrollment or the provision of benefits by that third party.
  - (2) In addition, any provision in a contract of insurance, health benefits plan or other health care coverage document, will, trust agreement, court order or other instrument which reduces or excludes coverage or payment for health care-related goods and services to or for an individual because of that individual's actual or potential eligibility for or receipt of Medicaid benefits shall be null and void, and no payments shall be made under this act as a result of any such provision.
  - (3) Notwithstanding any provision of law to the contrary, the provisions of paragraph (2) of this subsection shall not apply to a trust agreement that is established pursuant to 42 U.S.C. s.1396p(d)(4)(A) or (C) to supplement and augment assistance provided by government entities to a person who is disabled as defined in section 1614(a)(3) of the federal Social Security Act (42 U.S.C. s.1382c (a)(3)).
  - g. The following services shall be provided to eligible medically needy individuals as follows:
  - (1) Pregnant women shall be provided prenatal care and delivery services and postpartum care, including the services cited in subsection a.(1), (3) and (5) of this section and subsection b.(1)-(10), (12), (15) and (17) of this section, and nursing facility services cited in subsection b.(13) of this section.
  - (2) Dependent children shall be provided with services cited in subsection a.(3) and (5) of this section and subsection b.(1), (2), (3), (4), (5), (6), (7), (10), (12), (15) and (17) of this section, and nursing facility services cited in subsection b.(13) of this section.
- 36 (3) Individuals who are 65 years of age or older shall be provided 37 with services cited in subsection a.(3) and (5) of this section and 38 subsection b.(1)-(5), (6) excluding prescribed drugs, (7), (8), (10), 39 (12), (15) and (17) of this section, and nursing facility services cited 40 in subsection b.(13) of this section.
- 41 (4) Individuals who are blind or disabled shall be provided with 42 services cited in subsection a.(3) and (5) of this section and subsection 43 b.(1)-(5), (6) excluding prescribed drugs, (7), (8), (10), (12), (15) and 44 (17) of this section, and nursing facility services cited in subsection 45 b.(13) of this section.

## A1933 VANDERVALK, WEINBERG

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- 1 (5) (a) Inpatient hospital services, subsection a.(1) of this section,
- 2 shall only be provided to eligible medically needy individuals, other
- 3 than pregnant women, if the federal Department of Health and Human
- 4 Services discontinues the State's waiver to establish inpatient hospital
- 5 reimbursement rates for the Medicare and Medicaid programs under
- 6 the authority of section 601(c)(3) of the Social Security Act
- 7 Amendments of 1983, Pub.L.98-21 (42 U.S.C. s.1395ww(c)(5)).
- 8 Inpatient hospital services may be extended to other eligible medically
- 9 needy individuals if the federal Department of Health and Human
- 10 Services directs that these services be included.
- 11 (b) Outpatient hospital services, subsection a.(2) of this section,
- shall only be provided to eligible medically needy individuals if the
- 13 federal Department of Health and Human Services discontinues the
- 14 State's waiver to establish outpatient hospital reimbursement rates for
- 15 the Medicare and Medicaid programs under the authority of section
- 16 601(c)(3) of the Social Security Amendments of 1983, Pub.L.98-21
- 17 (42 U.S.C. s.1395ww(c)(5)). Outpatient hospital services may be
- 18 extended to all or to certain medically needy individuals if the federal
- 19 Department of Health and Human Services directs that these services
- 20 be included. However, the use of outpatient hospital services shall be
- 21 limited to clinic services and to emergency room services for injuries
- 22 and significant acute medical conditions.
  - (c) The division shall monitor the use of inpatient and outpatient hospital services by medically needy persons.
  - h. In the case of a qualified disabled and working individual
- 26 pursuant to section 6408 of Pub.L.101-239 (42 U.S.C. s.1396d), the
- 27 only medical assistance provided under this act shall be the payment
- 28 of premiums for Medicare part A under 42 U.S.C. ss.1395i-2 and
- 29 1395r.

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- i. In the case of a specified low-income Medicare beneficiary
- pursuant to 42 U.S.C. s.1396a(a)10(E)iii, the only medical assistance
- 32 provided under this act shall be the payment of premiums for Medicare
- part B under 42 U.S.C. s.1395r as provided for in 42 U.S.C.
- 34 s.1396d(p)(3)(A)(ii).
- j. In the case of a qualified individual pursuant to 42 U.S.C. s.
- 36 1396a(aa), the only medical assistance provided under this act shall be
- 37 payment for authorized services provided during the period in which
- 38 the individual requires treatment for breast or cervical cancer, in
- 39 accordance with criteria established by the commissioner.
- 40 (cf: P.L.2001, c.186, s.2)

- 42 2. The Commissioner of Human Services, pursuant to the
- 43 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
- 44 seq.), shall adopt rules and regulations to effectuate the purposes of
- 45 this act.

## A1933 VANDERVALK, WEINBERG

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3. This act shall take effect on the 180th day after enactment, except that the Commissioner of Human Services may take such anticipatory administrative action in advance as shall be necessary for the implementation of the act.

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#### **STATEMENT**

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This bill requires Medicaid coverage of HIV drug resistance testing in the form of phenotype assays and genotype assays for persons diagnosed with HIV infection or AIDS.

12 In addition to other laboratory tests that are already widely used for patients with HIV infection or AIDS, such as CD-4 cell counts and 13 14 HIV viral load testing, drug resistance testing is reported to be making 15 its way into clinical use and is expected to make its way into more clinical laboratories in the very near future. This testing is useful in 16 17 determining the combinations of medications that are effective in controlling HIV infection in individual patients, particularly among 18 those whose current drug regimen is unsuccessful, and can help to 19 explain treatment failures and guide treatment decisions. Phenotyping 20 21 assesses the vulnerability of the dominant strain of HIV in a particular 22 patient's body to specific antiretroviral drugs, and genotyping identifies 23 genetic mutations in the virus that permit it to develop resistance to 24 medications.

The International AIDS Society-USA recently published its recommendations for the clinical use of HIV drug resistance testing, which include the following situations:

- c after many highly active antiretroviral therapy regimens have failed;
- c after the failure of an initial regimen, if poor compliance and pharmacokinetic (drug action) reasons are not believed to be responsible for the failure; and
- C for pregnant women, especially those living in communities with a high prevalence of drug-resistant HIV virus.

The bill takes effect on the 180th day after enactment, but authorizes the Commissioner of Human Services to take anticipatory administrative action in advance as necessary for its implementation.

## ASSEMBLY HEALTH AND HUMAN SERVICES COMMITTEE

## STATEMENT TO

# ASSEMBLY COMMITTEE SUBSTITUTE FOR ASSEMBLY, Nos. 2444 and 1933

## STATE OF NEW JERSEY

DATED: OCTOBER 21, 2002

The Assembly Health and Human Services Committee reports favorably an Assembly Committee Substitute for Assembly Bill Nos. 2444 and 1933.

This committee substitute would require Medicaid coverage of HIV drug resistance testing, including, but not limited to, genotype, phenotype and virtual phenotype assays for persons diagnosed with HIV infection or AIDS.

In addition to other laboratory tests that are already widely used for patients with HIV infection or AIDS, such as CD-4 cell counts and HIV viral load testing, drug resistance testing is reported to be making its way into clinical use and is expected to make its way into more clinical laboratories in the very near future. This testing is useful in determining the combinations of medications that are effective in controlling HIV infection in individual patients, particularly among those whose current drug regimen is unsuccessful, and can help to explain treatment failures and guide treatment decisions.

Genotyping identifies genetic mutations in the virus that permit it to develop resistance to medications; phenotyping assesses the vulnerability of the dominant strain of HIV in a particular patient's body to specific antiretroviral drugs; and virtual phenotyping provides a quantitative, biologically-based prediction of resistance that is derived from a large database of linked genotypes and phenotypes based on the genetic sequence of the virus.

The International AIDS Society-USA recently published its recommendations for the clinical use of HIV drug resistance testing, which include the following situations:

- C after many highly active antiretroviral therapy regimens have failed;
- C after the failure of an initial regimen, if poor compliance and pharmacokinetic (drug action) reasons are not believed to be responsible for the failure; and
- C for pregnant women, especially those living in communities with a high prevalence of drug-resistant HIV virus.

The substitute takes effect on the 180th day after enactment, but authorizes the Commissioner of Human Services to take anticipatory administrative action in advance as necessary for its implementation.

## ASSEMBLY APPROPRIATIONS COMMITTEE

## STATEMENT TO

# ASSEMBLY COMMITTEE SUBSTITUTE FOR ASSEMBLY, Nos. 2444 and 1933

with Assembly committee amendments

## STATE OF NEW JERSEY

DATED: DECEMBER 9, 2002

The Assembly Appropriations Committee reports favorably Assembly Bill No. 2444 and 1933 (ACS), with committee amendments.

Assembly Bill Nos. 2444 and 1933 (ACS), as amended, requires Medicaid coverage of HIV drug resistance testing, including, but not limited to, genotype assays, phenotype assays, and other assays using phenotype prediction with genotype comparison.

In addition to other laboratory tests that are already widely used for patients with HIV infection or AIDS, such as CD-4 cell counts and HIV viral load testing, drug resistance testing is reported to be making its way into clinical use and is expected to make its way into more clinical laboratories in the very near future. This testing is useful in determining the combinations of medications that are effective in controlling HIV infection in individual patients, particularly among those whose current drug regimen is unsuccessful, and can help to explain treatment failures and guide treatment decisions.

Genotyping identifies genetic mutations in the virus that permit it to develop resistance to medications; phenotyping assesses the vulnerability of the dominant strain of HIV in a particular patient's body to specific antiretroviral drugs; and phenotype prediction with genotype comparison provides a quantitative, biologically-based prediction of resistance that is derived from a large database of linked genotypes and phenotypes based on the genetic sequence of the virus.

The International AIDS Society-USA recently published its recommendations for the clinical use of HIV drug resistance testing, which include the following situations:

- C after many highly active antiretroviral therapy regimens have failed;
- C after the failure of an initial regimen, if poor compliance and pharmacokinetic (drug action) reasons are not believed to be responsible for the failure; and
- C for pregnant women, especially those living in communities with a high prevalence of drug-resistant HIV virus.

The legislation takes effect on the 180th day after enactment, but authorizes the Commissioner of Human Services to take anticipatory administrative action in advance as necessary for its implementation.

## **FISCAL IMPACT**:

No fiscal information has been obtained on this legislation. However, sources have indicated cost estimates as follows: genotype testing - \$300; phenotype testing - \$600. A specific patient may need two tests of each type yearly for an annual cost of \$1,800. However, the number of specific patients needing these tests is not known.

## **COMMITTEE AMENDMENTS:**

The amendments clarify the assays that are included under medicaid coverage by using more general and generic terms to describe the assays.

## SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

## STATEMENT TO

## [First Reprint]

# ASSEMBLY COMMITTEE SUBSTITUTE FOR ASSEMBLY, Nos. 2444 and 1933

## STATE OF NEW JERSEY

**DATED: MAY 8, 2003** 

The Senate Health, Human Services and Senior Citizens Committee reports favorably the Assembly Committee Substitute for Assembly Bill Nos. 2444 and 1933 (1R).

This committee substitute requires Medicaid coverage of HIV drug resistance testing, including, but not limited to, genotype assays, phenotype assays, and other assays using phenotype prediction with genotype comparison.

In addition to other laboratory tests that are already widely used for patients with HIV infection or AIDS, such as CD-4 cell counts and HIV viral load testing, drug resistance testing is reported to be making its way into clinical use and is expected to make its way into more clinical laboratories in the very near future. This testing is useful in determining the combinations of medications that are effective in controlling HIV infection in individual patients, particularly among those whose current drug regimen is unsuccessful, and can help to explain treatment failures and guide treatment decisions.

Genotyping identifies genetic mutations in the virus that permit it to develop resistance to medications; phenotyping assesses the vulnerability of the dominant strain of HIV in a particular patient's body to specific antiretroviral drugs; and phenotype prediction with genotype comparison provides a quantitative, biologically-based prediction of resistance that is derived from a large database of linked genotypes and phenotypes based on the genetic sequence of the virus.

The International AIDS Society-USA recently published its recommendations for the clinical use of HIV drug resistance testing, which include the following situations:

- C after many highly active antiretroviral therapy regimens have failed;
- C after the failure of an initial regimen, if poor compliance and pharmacokinetic (drug action) reasons are not believed to be responsible for the failure; and

c for pregnant women, especially those living in communities with a high prevalence of drug-resistant HIV virus.

The substitute takes effect on the 180th day after enactment, but authorizes the Commissioner of Human Services to take anticipatory administrative action in advance as necessary for its implementation.

This substitute is identical to Senate Bill No.2256 (Vitale/Singer), which the committee also reported favorably on this date.

## SENATE BUDGET AND APPROPRIATIONS COMMITTEE

## STATEMENT TO

## [First Reprint]

# ASSEMBLY COMMITTEE SUBSTITUTE FOR ASSEMBLY, Nos. 2444 and 1933

## STATE OF NEW JERSEY

DATED: DECEMBER 4, 2003

The Senate Budget and Appropriations Committee reports favorably Assembly Bill Nos. 2444 and 1933 ACS (1R).

This bill requires Medicaid coverage of HIV drug resistance testing, including, but not limited to, genotype assays, phenotype assays, and other assays using phenotype prediction with genotype comparison.

In addition to other laboratory tests that are already widely used for patients with HIV infection or AIDS, such as CD-4 cell counts and HIV viral load testing, drug resistance testing is reported to be making its way into clinical use and is expected to make its way into more clinical laboratories in the very near future. This testing is useful in determining the combinations of medications that are effective in controlling HIV infection in individual patients, particularly among those whose current drug regimen is unsuccessful, and can help to explain treatment failures and guide treatment decisions.

Genotyping identifies genetic mutations in the virus that permit it to develop resistance to medications; phenotyping assesses the vulnerability of the dominant strain of HIV in a particular patient's body to specific antiretroviral drugs; and phenotype prediction with genotype comparison provides a quantitative, biologically-based prediction of resistance that is derived from a large database of linked genotypes and phenotypes based on the genetic sequence of the virus.

The International AIDS Society-USA recently published its recommendations for the clinical use of HIV drug resistance testing, which include the following situations:

- \* after many highly active antiretroviral therapy regimens have failed;
- \* after the failure of an initial regimen, if poor compliance and pharmacokinetic (drug action) reasons are not believed to be responsible for the failure; and
- \* for pregnant women, especially those living in communities with a high prevalence of drug-resistant HIV virus.

The bill takes effect on the 180th day after enactment, but authorizes the Commissioner of Human Services to take anticipatory administrative action in advance as necessary for its implementation.

The provisions of this bill are identical to those of Senate Bill No. 2256, which the committee also reports this day.

## **FISCAL IMPACT**

The Department of Human Services advises that it has adopted a plan to implement the HIV testing coverage mandated under this bill, and that the State's FY2004 budget for Medicaid includes sufficient funding to support such testing. The annual cost of the program is estimated to be about \$500,000, of which cost the State will be responsible for one half while the remaining portion is met through federal funds.

## LEGISLATIVE FISCAL ESTIMATE ASSEMBLY COMMITTEE SUBSTITUTE FOR

## ASSEMBLY, Nos. 2444 and 1933 STATE OF NEW JERSEY 210th LEGISLATURE

DATED: JANUARY 9, 2003

## **SUMMARY**

**Synopsis:** Requires Medicaid coverage of HIV drug resistance testing.

**Type of Impact:** Possible increase/decrease in State expenditures.

**Agencies Affected:** Department of Human Services; local health departments.

## **Office of Legislative Services Estimate**

Fiscal Impact	<b>Year 1 to 3</b>
State Cost	Indeterminable.
Local Cost	Indeterminable.

! Potential costs/savings cannot be determined as: (a) The cost associated with conducting genotype, phenotype and virtual phenotype assays is not known; (b) the number of persons that may be tested annually is not known; and (c) it is uncertain whether such tests will reduce unnecessary medications prescribed on behalf of persons with HIV or AID.

#### **BILL DESCRIPTION**

Assembly Committee Substitute for Assembly Bill Nos. 2444 and 1933 would require Medicaid coverage of HIV drug resistance testing, including, but not limited to, genotype, phenotype and virtual phenotype assays for persons diagnosed with HIV infection or AIDS.

## FISCAL ANALYSIS

#### EXECUTIVE BRANCH

None received.

#### OFFICE OF LEGISLATIVE SERVICES

The Office of Legislative Services (OLS) is not able to estimate the fiscal impact of including



genotype, phenotype and virtual phenotype assays for persons diagnosed with HIV infection or AIDS as OLS has no information as to: (a) the cost associated with conducting these assays or (b) the number of persons that may require such testing.

Though available literature indicates that genotype, phenotype and virtual phenotype assays are much more expensive to conduct than other types of tests for HIV, such as CD-4 cell counts or HIV viral load testing, cost information for conducting such tests is not specified in the literature.

While the use of the tests is intended to reduce the inappropriate use of drugs by persons with AIDS/HIV, whether the tests will actually reduce prescription drug costs incurred by the Medicaid program is uncertain.

The requirement that Medicaid provide coverage for the additional HIV tests, may result in local health departments having to provide the tests to persons who are not covered by Medicaid. This may increase costs for local health departments.

Section: Human Services

Analyst: Jay Hershberg

Approved: Alan R. Kooney

Legislative Budget and Finance Officer

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67.

## SENATE, No. 2256

# STATE OF NEW JERSEY 210th LEGISLATURE

**INTRODUCED JANUARY 23, 2003** 

Sponsored by: Senator JOSEPH F. VITALE

District 19 (Middlesex)

Senator ROBERT W. SINGER

District 30 (Burlington, Mercer, Monmouth and Ocean)

#### **SYNOPSIS**

Requires Medicaid coverage of HIV drug resistance testing.

## **CURRENT VERSION OF TEXT**

As introduced.



(Sponsorship Updated As Of: 1/28/2003)

1 AN ACT concerning Medicaid coverage of HIV drug resistance testing 2 and amending P.L.1968, c.413.

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4 BE IT ENACTED by the Senate and General Assembly of the State 5 of New Jersey:

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- 7 1. Section 6 of P.L.1968, c.413 (C.30:4D-6) is amended to read as 8 follows:
- 9 6. a. Subject to the requirements of Title XIX of the federal Social 10 Security Act, the limitations imposed by this act and by the rules and 11 regulations promulgated pursuant thereto, the department shall 12 provide medical assistance to qualified applicants, including authorized 13 services within each of the following classifications:
  - (1) Inpatient hospital services;
- 15 (2) Outpatient hospital services;
- 16 (3) Other laboratory and X-ray services;
- 17 (4) (a) Skilled nursing or intermediate care facility services;
- (b) Such early and periodic screening and diagnosis of individuals 18 who are eligible under the program and are under age 21, to ascertain 19 their physical or mental defects and such health care, treatment, and 20 other measures to correct or ameliorate defects and chronic conditions 21 22 discovered thereby, as may be provided in regulations of the Secretary 23 of the federal Department of Health and Human Services and approved 24 by the commissioner;
- 25 (5) Physician's services furnished in the office, the patient's home, 26 a hospital, a skilled nursing or intermediate care facility or elsewhere.
- 27 As used in this subsection, "laboratory and X-ray services" includes
- 28 HIV drug resistance testing, including, but not limited to, genotype
- 29 assays that have been cleared or approved by the federal Food and
- Drug Administration, laboratory developed genotype assays, 31 phenotype assays, and other assays using phenotype prediction with
- 32 genotype comparison, for persons diagnosed with HIV infection or
- 33 AIDS.

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- 34 b. Subject to the limitations imposed by federal law, by this act, 35 and by the rules and regulations promulgated pursuant thereto, the 36 medical assistance program may be expanded to include authorized 37 services within each of the following classifications:
- (1) Medical care not included in subsection a.(5) above, or any 38 39 other type of remedial care recognized under State law, furnished by 40 licensed practitioners within the scope of their practice, as defined by 41 State law;
- 42 (2) Home health care services;
- 43 (3) Clinic services;

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and intended to be omitted in the law.

- 1 (4) Dental services;
- 2 (5) Physical therapy and related services;
- 3 Prescribed drugs, dentures, and prosthetic devices; and 4 eyeglasses prescribed by a physician skilled in diseases of the eye or by
- an optometrist, whichever the individual may select; 5
- 6 (7) Optometric services;
- (8) Podiatric services; 7
- 8 (9) Chiropractic services;
- 9 (10) Psychological services;
- 10 (11) Inpatient psychiatric hospital services for individuals under 11 21 years of age, or under age 22 if they are receiving such services
- 12 immediately before attaining age 21;
- 13 (12) Other diagnostic, screening, preventive, and rehabilitative 14 services, and other remedial care;
- 15 (13) Inpatient hospital services, nursing facility services and intermediate care facility services for individuals 65 years of age or 16 over in an institution for mental diseases; 17
  - (14) Intermediate care facility services;
- 19 (15) Transportation services;

the federal Social Security Act;

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- 20 (16) Services in connection with the inpatient or outpatient 21 treatment or care of drug abuse, when the treatment is prescribed by a physician and provided in a licensed hospital or in a narcotic and 22 23 drug abuse treatment center approved by the Department of Health and Senior Services pursuant to P.L.1970, c.334 (C.26:2G-21 et seg.) 24 25 and whose staff includes a medical director, and limited to those 26 services eligible for federal financial participation under Title XIX of
- (17) Any other medical care and any other type of remedial care 29 recognized under State law, specified by the Secretary of the federal Department of Health and Human Services, and approved by the commissioner;
- (18) Comprehensive maternity care, which may include: the basic 32 33 number of prenatal and postpartum visits recommended by the 34 American College of Obstetrics and Gynecology; additional prenatal and postpartum visits that are medically necessary; necessary 35 36 laboratory, nutritional assessment and counseling, health education, 37 personal counseling, managed care, outreach and follow-up services; 38 treatment of conditions which may complicate pregnancy; and 39 physician or certified nurse-midwife delivery services;
- 40 (19) Comprehensive pediatric care, which may include: ambulatory, preventive and primary care health services. The preventive services 41 42 shall include, at a minimum, the basic number of preventive visits 43 recommended by the American Academy of Pediatrics;
- 44 (20) Services provided by a hospice which is participating in the 45 Medicare program established pursuant to Title XVIII of the Social Security Act, Pub.L.89-97 (42 U.S.C.s.1395 et seq.). Hospice 46

services shall be provided subject to approval of the Secretary of the federal Department of Health and Human Services for federal reimbursement;

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- (21) Mammograms, subject to approval of the Secretary of the federal Department of Health and Human Services for federal reimbursement, including one baseline mammogram for women who are at least 35 but less than 40 years of age; one mammogram examination every two years or more frequently, if recommended by a physician, for women who are at least 40 but less than 50 years of age; and one mammogram examination every year for women age 50 and over.
- 12 Payments for the foregoing services, goods and supplies 13 furnished pursuant to this act shall be made to the extent authorized 14 by this act, the rules and regulations promulgated pursuant thereto 15 and, where applicable, subject to the agreement of insurance provided for under this act. Said payments shall constitute payment in full to 16 the provider on behalf of the recipient. Every provider making a claim 17 18 for payment pursuant to this act shall certify in writing on the claim 19 submitted that no additional amount will be charged to the recipient, 20 his family, his representative or others on his behalf for the services, 21 goods and supplies furnished pursuant to this act.
  - No provider whose claim for payment pursuant to this act has been denied because the services, goods or supplies were determined to be medically unnecessary shall seek reimbursement from the recipient, his family, his representative or others on his behalf for such services, goods and supplies provided pursuant to this act; provided, however, a provider may seek reimbursement from a recipient for services, goods or supplies not authorized by this act, if the recipient elected to receive the services, goods or supplies with the knowledge that they were not authorized.
  - d. Any individual eligible for medical assistance (including drugs) may obtain such assistance from any person qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability on a prepayment basis), who undertakes to provide him such services.
  - No copayment or other form of cost-sharing shall be imposed on any individual eligible for medical assistance, except as mandated by federal law as a condition of federal financial participation.
  - e. Anything in this act to the contrary notwithstanding, no payments for medical assistance shall be made under this act with respect to care or services for any individual who:
- 42 (1) Is an inmate of a public institution (except as a patient in a 43 medical institution); provided, however, that an individual who is 44 otherwise eligible may continue to receive services for the month in 45 which he becomes an inmate, should the commissioner determine to 46 expand the scope of Medicaid eligibility to include such an individual,

- 1 subject to the limitations imposed by federal law and regulations, or
- 2 (2) Has not attained 65 years of age and who is a patient in an institution for mental diseases, or

- (3) Is over 21 years of age and who is receiving inpatient psychiatric hospital services in a psychiatric facility; provided, however, that an individual who was receiving such services immediately prior to attaining age 21 may continue to receive such services until he reaches age 22. Nothing in this subsection shall prohibit the commissioner from extending medical assistance to all eligible persons receiving inpatient psychiatric services; provided that there is federal financial participation available.
- f. (1) A third party as defined in section 3 of P.L.1968, c.413 (C.30:4D-3) shall not consider a person's eligibility for Medicaid in this or another state when determining the person's eligibility for enrollment or the provision of benefits by that third party.
- (2) In addition, any provision in a contract of insurance, health benefits plan or other health care coverage document, will, trust agreement, court order or other instrument which reduces or excludes coverage or payment for health care-related goods and services to or for an individual because of that individual's actual or potential eligibility for or receipt of Medicaid benefits shall be null and void, and no payments shall be made under this act as a result of any such provision.
- (3) Notwithstanding any provision of law to the contrary, the provisions of paragraph (2) of this subsection shall not apply to a trust agreement that is established pursuant to 42 U.S.C. s.1396p(d)(4)(A) or (C) to supplement and augment assistance provided by government entities to a person who is disabled as defined in section 1614(a)(3) of the federal Social Security Act (42 U.S.C. s.1382c (a)(3)).
- g. The following services shall be provided to eligible medically needy individuals as follows:
- (1) Pregnant women shall be provided prenatal care and delivery services and postpartum care, including the services cited in subsection a.(1), (3) and (5) of this section and subsection b.(1)-(10), (12), (15) and (17) of this section, and nursing facility services cited in subsection b.(13) of this section.
- 37 (2) Dependent children shall be provided with services cited in subsection a.(3) and (5) of this section and subsection b.(1), (2), (3), (4), (5), (6), (7), (10), (12), (15) and (17) of this section, and nursing facility services cited in subsection b.(13) of this section.
- 41 (3) Individuals who are 65 years of age or older shall be provided 42 with services cited in subsection a.(3) and (5) of this section and 43 subsection b.(1)-(5), (6) excluding prescribed drugs, (7), (8), (10), 44 (12), (15) and (17) of this section, and nursing facility services cited 45 in subsection b.(13) of this section.

- 1 (4) Individuals who are blind or disabled shall be provided with 2 services cited in subsection a.(3) and (5) of this section and subsection 3 b.(1)-(5), (6) excluding prescribed drugs, (7), (8), (10), (12), (15) and 4 (17) of this section, and nursing facility services cited in subsection 5 b.(13) of this section.
- (5) (a) Inpatient hospital services, subsection a.(1) of this section, shall only be provided to eligible medically needy individuals, other than pregnant women, if the federal Department of Health and Human Services discontinues the State's waiver to establish inpatient hospital reimbursement rates for the Medicare and Medicaid programs under the authority of section 601(c)(3) of the Social Security Act Amendments of 1983, Pub.L.98-21 (42 U.S.C. s.1395ww(c)(5)). Inpatient hospital services may be extended to other eligible medically needy individuals if the federal Department of Health and Human
- Inpatient hospital services may be extended to other eligible medically
   needy individuals if the federal Department of Health and Human
   Services directs that these services be included.
   (b) Outpatient hospital services, subsection a.(2) of this section,
- shall only be provided to eligible medically needy individuals if the 17 18 federal Department of Health and Human Services discontinues the 19 State's waiver to establish outpatient hospital reimbursement rates for 20 the Medicare and Medicaid programs under the authority of section 21 601(c)(3) of the Social Security Amendments of 1983, Pub.L.98-21 22 (42 U.S.C. s.1395ww(c)(5)). Outpatient hospital services may be extended to all or to certain medically needy individuals if the federal 23 24 Department of Health and Human Services directs that these services 25 be included. However, the use of outpatient hospital services shall be 26 limited to clinic services and to emergency room services for injuries 27 and significant acute medical conditions.
- 28 (c) The division shall monitor the use of inpatient and outpatient 29 hospital services by medically needy persons.
  - h. In the case of a qualified disabled and working individual pursuant to section 6408 of Pub.L.101-239 (42 U.S.C. s.1396d), the only medical assistance provided under this act shall be the payment of premiums for Medicare part A under 42 U.S.C. ss.1395i-2 and 1395r.
- i. In the case of a specified low-income Medicare beneficiary pursuant to 42 U.S.C. s.1396a(a)10(E)iii, the only medical assistance provided under this act shall be the payment of premiums for Medicare part B under 42 U.S.C. s.1395r as provided for in 42 U.S.C. s.1396d(p)(3)(A)(ii).
- j. In the case of a qualified individual pursuant to 42 U.S.C.s.1396a(aa), the only medical assistance provided under this act shall be payment for authorized services provided during the period in which the individual requires treatment for breast or cervical cancer, in accordance with criteria established by the commissioner.
- 45 (cf: P.L.2001, c.186, s.2)

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1	2. The Commissioner of Human Services, pursuant to the
2	"Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
3	seq.), shall adopt rules and regulations to effectuate the purposes of
4	this act.

 3. This act shall take effect on the 180th day after enactment, except that the Commissioner of Human Services may take such anticipatory administrative action in advance as shall be necessary for the implementation of the act.

#### **STATEMENT**

This bill requires Medicaid coverage of HIV drug resistance testing, including, but not limited to, genotype assays, phenotype assays, and other assays using phenotype prediction with genotype comparison.

In addition to other laboratory tests that are already widely used for patients with HIV infection or AIDS, such as CD-4 cell counts and HIV viral load testing, drug resistance testing is reported to be making its way into clinical use and is expected to make its way into more clinical laboratories in the very near future. This testing is useful in determining the combinations of medications that are effective in controlling HIV infection in individual patients, particularly among those whose current drug regimen is unsuccessful, and can help to explain treatment failures and guide treatment decisions.

Genotyping identifies genetic mutations in the virus that permit it to develop resistance to medications; phenotyping assesses the vulnerability of the dominant strain of HIV in a particular patient's body to specific antiretroviral drugs; and phenotype prediction with genotype comparison provides a quantitative, biologically-based prediction of resistance that is derived from a large database of linked genotypes and phenotypes based on the genetic sequence of the virus.

The International AIDS Society-USA recently published its recommendations for the clinical use of HIV drug resistance testing, which include the following situations:

- C after many highly active antiretroviral therapy regimens have failed;
- C after the failure of an initial regimen, if poor compliance and pharmacokinetic (drug action) reasons are not believed to be responsible for the failure; and
- c for pregnant women, especially those living in communities with a high prevalence of drug-resistant HIV virus.

The bill takes effect on the 180th day after enactment, but authorizes the Commissioner of Human Services to take anticipatory administrative action in advance as necessary for its implementation.

## SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

## STATEMENT TO

SENATE, No. 2256

## STATE OF NEW JERSEY

**DATED: MAY 8, 2003** 

The Senate Health, Human Services and Senior Citizens Committee reports favorably Senate Bill No. 2256.

This bill requires Medicaid coverage of HIV drug resistance testing, including, but not limited to, genotype assays, phenotype assays, and other assays using phenotype prediction with genotype comparison.

In addition to other laboratory tests that are already widely used for patients with HIV infection or AIDS, such as CD-4 cell counts and HIV viral load testing, drug resistance testing is reported to be making its way into clinical use and is expected to make its way into more clinical laboratories in the very near future. This testing is useful in determining the combinations of medications that are effective in controlling HIV infection in individual patients, particularly among those whose current drug regimen is unsuccessful, and can help to explain treatment failures and guide treatment decisions.

Genotyping identifies genetic mutations in the virus that permit it to develop resistance to medications; phenotyping assesses the vulnerability of the dominant strain of HIV in a particular patient's body to specific antiretroviral drugs; and phenotype prediction with genotype comparison provides a quantitative, biologically-based prediction of resistance that is derived from a large database of linked genotypes and phenotypes based on the genetic sequence of the virus.

The International AIDS Society-USA recently published its recommendations for the clinical use of HIV drug resistance testing, which include the following situations:

- C after many highly active antiretroviral therapy regimens have failed;
- C after the failure of an initial regimen, if poor compliance and pharmacokinetic (drug action) reasons are not believed to be responsible for the failure; and
- C for pregnant women, especially those living in communities with a high prevalence of drug-resistant HIV virus.

The bill takes effect on the 180th day after enactment, but authorizes the Commissioner of Human Services to take anticipatory administrative action in advance as necessary for its implementation.

This bill is identical to the Assembly Committee Substitute for Assembly Bill Nos. 2444 and 1933(1R) (Roberts/Greenwald/Vandervalk/Weinberg), which the committee also reported favorably on this date.

## SENATE BUDGET AND APPROPRIATIONS COMMITTEE

## STATEMENT TO

## **SENATE, No. 2256**

## STATE OF NEW JERSEY

DATED: DECEMBER 4, 2003

The Senate Budget and Appropriations Committee reports favorably Senate Bill No. 2256.

This bill requires Medicaid coverage of HIV drug resistance testing, including, but not limited to, genotype assays, phenotype assays, and other assays using phenotype prediction with genotype comparison.

In addition to other laboratory tests that are already widely used for patients with HIV infection or AIDS, such as CD-4 cell counts and HIV viral load testing, drug resistance testing is reported to be making its way into clinical use and is expected to make its way into more clinical laboratories in the very near future. This testing is useful in determining the combinations of medications that are effective in controlling HIV infection in individual patients, particularly among those whose current drug regimen is unsuccessful, and can help to explain treatment failures and guide treatment decisions.

Genotyping identifies genetic mutations in the virus that permit it to develop resistance to medications; phenotyping assesses the vulnerability of the dominant strain of HIV in a particular patient's body to specific antiretroviral drugs; and phenotype prediction with genotype comparison provides a quantitative, biologically-based prediction of resistance that is derived from a large database of linked genotypes and phenotypes based on the genetic sequence of the virus.

The International AIDS Society-USA recently published its recommendations for the clinical use of HIV drug resistance testing, which include the following situations:

- \* after many highly active antiretroviral therapy regimens have failed:
- \* after the failure of an initial regimen, if poor compliance and pharmacokinetic (drug action) reasons are not believed to be responsible for the failure; and
- \* for pregnant women, especially those living in communities with a high prevalence of drug-resistant HIV virus.

The bill takes effect on the 180th day after enactment, but authorizes the Commissioner of Human Services to take anticipatory administrative action in advance as necessary for its implementation.

The provisions of this bill are identical to those of Assembly Bill Nos. 2444 and 1933 ACS (1R), which the committee also reports this day.

## FISCAL IMPACT

The Department of Human Services advises that it has adopted a plan to implement the HIV testing coverage mandated under this bill, and that the State's FY2004 budget for Medicaid includes sufficient funding to support such testing. The annual cost of the program is estimated to be about \$500,000, of which cost the State will be responsible for one half while the remaining portion is met through federal funds.

# LEGISLATIVE FISCAL ESTIMATE SENATE, No. 2256

## STATE OF NEW JERSEY

## 210th LEGISLATURE

DATED: DECEMBER 18, 2003

#### **SUMMARY**

**Synopsis:** Requires Medicaid coverage of HIV drug resistance testing.

**Type of Impact:** None as the Department of Human Services has implemented the

testing program in question.

**Agencies Affected:** Department of Human Services; local health departments.

## Office of Legislative Services Estimate

Fiscal Impact	Year 1 to 3
State Cost	None (as the department has recently implemented the testing program in question).
<b>Local Cost</b>	Indeterminable as some local health department may already be providing such tests.

\* The number of persons that may be tested annually is not known; and it is uncertain whether such tests will reduce unnecessary medications prescribed on behalf of persons with HIV or AIDS.

## **BILL DESCRIPTION**

Senate Bill No. 2256 of 2003 would require Medicaid coverage of HIV drug resistance testing, including, but not limited to, genotype, phenotype and virtual phenotype assays for persons diagnosed with HIV infection or AIDS.

## FISCAL ANALYSIS

## **EXECUTIVE BRANCH**

None received.



#### OFFICE OF LEGISLATIVE SERVICES

The Department of Human Services, Division of Medical Assistance and Health Services has recently implemented the HIV testing program required by the legislation. Therefore is no new cost associated with the legislation. The program is funded within the division's overall Medicaid appropriation.

While the use of such tests is intended to reduce the inappropriate use of drugs by persons with AIDS/HIV, whether the tests will actually reduce prescription drug costs incurred by the Medicaid program is uncertain.

As the Medicaid program now covers the HIV tests in question, local health departments may have to provide the tests to persons who are not covered by Medicaid. However, as some local health departments may already provide such tests, the cost impact on local health departments cannot be determined.

Section: Human Services

Analyst: Jay Hershberg

Principal Fiscal Analyst

Approved: Frank W. Haines III

Assistant Legislative Budget and Finance Officer

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67