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 5-8-2003 (Health)
12-4-2003 (Budget)

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: Yes

S2256

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

COMMITTEE STATEMENT: **ASSEMBLY**: No

SENATE: Yes 5-8-2003 (Health)
12-4-2003 (Budget)
Identical to Senate Statements for A2444

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: Yes

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: No

FOLLOWING WERE PRINTED:

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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

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

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

1. Section 6 of P.L.1968, c.413 (C.30:4D-6) is amended to read as follows:

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 Drug Administration, laboratory developed genotype assays[1] , phenotype [1]**[**and virtual phenotype**]**[1] assays [1], and other assays using phenotype prediction with genotype comparison,[1] 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:

(1) Medical care not included in subsection a.(5) above, or any 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:
[1] Assembly AAP committee amendments adopted December 9, 2002.

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

(2) Home health care services;

(3) Clinic services;

(4) Dental services;

(5) Physical therapy and related services;

(6) Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select;

(7) Optometric services;

(8) Podiatric services;

(9) Chiropractic services;

(10) Psychological services;

(11) Inpatient psychiatric hospital services for individuals under 21 years of age, or under age 22 if they are receiving such services immediately before attaining age 21;

(12) Other diagnostic, screening, preventive, and rehabilitative services, and other remedial care;

(13) Inpatient hospital services, nursing facility services and intermediate care facility services for individuals 65 years of age or 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;

(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;

(18) Comprehensive maternity care, which may include: the basic number of prenatal and postpartum visits recommended by the American College of Obstetrics and Gynecology; additional prenatal and postpartum visits that are medically necessary; necessary laboratory, nutritional assessment and counseling, health education, personal counseling, managed care, outreach and follow-up services; treatment of conditions which may complicate pregnancy; and physician or certified nurse-midwife delivery services;

(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;

(20) Services provided by a hospice which is participating in the 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 services shall be provided subject to approval of the Secretary of the 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 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.

(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.

(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 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.

(cf: P.L.2001, c.186, s.2)

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.

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.

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.

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

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

1. Section 6 of P.L.1968, c.413 (C.30:4D-6) is amended to read as follows:

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.

<u>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 that have been determined to be safe and clinically effective by the 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:

(1) Medical care not included in subsection a.(5) above, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice, as defined by State law;

(2) Home health care services;

(3) Clinic services;

(4) Dental services;

(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.

Matter underlined <u>thus</u> is new matter.

(6) Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select;

(7) Optometric services;

(8) Podiatric services;

(9) Chiropractic services;

(10) Psychological services;

(11) Inpatient psychiatric hospital services for individuals under 21 years of age, or under age 22 if they are receiving such services immediately before attaining age 21;

(12) Other diagnostic, screening, preventive, and rehabilitative services, and other remedial care;

(13) Inpatient hospital services, nursing facility services and intermediate care facility services for individuals 65 years of age or 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;

(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;

(18) Comprehensive maternity care, which may include: the basic number of prenatal and postpartum visits recommended by the American College of Obstetrics and Gynecology; additional prenatal and postpartum visits that are medically necessary; necessary laboratory, nutritional assessment and counseling, health education, personal counseling, managed care, outreach and follow-up services; treatment of conditions which may complicate pregnancy; and physician or certified nurse-midwife delivery services;

(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;

(20) Services provided by a hospice which is participating in the 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 services shall be provided subject to approval of the Secretary of the 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

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.

(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.

(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 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.

(cf: P.L.2001, c.186, s.2)

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.

3. This act shall take effect on the 90th 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 would provide Medicaid coverage for certain HIV drug resistance testing, for persons diagnosed with HIV infection or AIDS, in the form of genotype assays that have been determined to be safe and clinically effective by the federal Food and Drug Administration and phenotype assays.

This testing is useful in determining the combinations of medications that are effective in controlling HIV infection in individual patients, especially among those whose current drug regimen is unsuccessful, and can help to explain treatment failures and guide treatment decisions.

The bill takes effect on the 90th day after enactment, but authorizes 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)

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

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

1. Section 6 of P.L.1968, c.413 (C.30:4D-6) is amended to read as follows:

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.

<u>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.</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:

(1) Medical care not included in subsection a.(5) above, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice, as defined by State law;

(2) Home health care services;

(3) Clinic services;

(4) Dental services;

(5) Physical therapy and related services;

(6) Prescribed drugs, dentures, and prosthetic devices; and 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.

Matter underlined <u>thus</u> is new matter.

(7) Optometric services;

(8) Podiatric services;

(9) Chiropractic services;

(10) Psychological services;

(11) Inpatient psychiatric hospital services for individuals under 21 years of age, or under age 22 if they are receiving such services immediately before attaining age 21;

(12) Other diagnostic, screening, preventive, and rehabilitative services, and other remedial care;

(13) Inpatient hospital services, nursing facility services and intermediate care facility services for individuals 65 years of age or 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;

(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;

(18) Comprehensive maternity care, which may include: the basic number of prenatal and postpartum visits recommended by the American College of Obstetrics and Gynecology; additional prenatal and postpartum visits that are medically necessary; necessary laboratory, nutritional assessment and counseling, health education, personal counseling, managed care, outreach and follow-up services; treatment of conditions which may complicate pregnancy; and physician or certified nurse-midwife delivery services;

(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;

(20) Services provided by a hospice which is participating in the 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 services shall be provided subject to approval of the Secretary of the 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 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.

(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.

(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 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.

(cf: P.L.2001, c.186, s.2)

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.

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 in the form of phenotype assays and genotype 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. Phenotyping assesses the vulnerability of the dominant strain of HIV in a particular patient's body to specific antiretroviral drugs, and genotyping identifies genetic mutations in the virus that permit it to develop resistance to medications.

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.

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:

- 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 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:

- 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 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:

- 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 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	**Year 1 to 3**
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)

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

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

1. Section 6 of P.L.1968, c.413 (C.30:4D-6) is amended to read as follows:

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 assays that have been cleared or approved by the federal Food and Drug Administration, laboratory developed genotype assays, phenotype assays, and other assays using phenotype prediction with genotype comparison, 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:

(1) Medical care not included in subsection a.(5) above, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice, as defined by State law;

(2) Home health care services;

(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.

Matter underlined thus is new matter.

(4) Dental services;

(5) Physical therapy and related services;

(6) Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select;

(7) Optometric services;

(8) Podiatric services;

(9) Chiropractic services;

(10) Psychological services;

(11) Inpatient psychiatric hospital services for individuals under 21 years of age, or under age 22 if they are receiving such services immediately before attaining age 21;

(12) Other diagnostic, screening, preventive, and rehabilitative services, and other remedial care;

(13) Inpatient hospital services, nursing facility services and intermediate care facility services for individuals 65 years of age or 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;

(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;

(18) Comprehensive maternity care, which may include: the basic number of prenatal and postpartum visits recommended by the American College of Obstetrics and Gynecology; additional prenatal and postpartum visits that are medically necessary; necessary laboratory, nutritional assessment and counseling, health education, personal counseling, managed care, outreach and follow-up services; treatment of conditions which may complicate pregnancy; and physician or certified nurse-midwife delivery services;

(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;

(20) Services provided by a hospice which is participating in the 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

services shall be provided subject to approval of the Secretary of the 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 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.

(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.

(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 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.

(cf: P.L.2001, c.186, s.2)

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.

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:

- 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.

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.

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- 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).
Local Cost	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.

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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