

HB 1754 -- Redline

Printer's No. PN2133 to Printer's No. PN3198 -- An Act amending the act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921, in casualty insurance, providing for coverage for biomarker testing.

Deletions ~~struck~~ · Insertions underlined

PRIOR PRINTER'S NO.

~~2133 THE PRINTER'S GENERAL NO. ASSEMBLY OF PENNSYLVANIA HOUSE BILL Session of No.~~

~~17543198 2023 THE INTRODUCED GENERAL BY ASSEMBLY MULLINS, OF CUTLER, PENNSYLVANIA STURLA, HOUSE STENDER, BILL DONAHUE, Session BURGOS, OCTOBER 16, 2023 BOROWSKI, SANCHEZ AND CERRATO, REFERRED TO COMMITTEE ON INSURANCE, OCTOBER 16, 2023 AN ACT Amending the act of May No. 17, 1921 (P.L.682, No.284), entitled "An act relating to insurance;~~

1754 2023 INTRODUCED BY MULLINS, CUTLER, STURLA, STENDER, DONAHUE, BURGOS, MADDEN, FREEMAN, BOROWSKI, SANCHEZ, CERRATO, HOGAN, GILLEN, E.

NELSON, FRITZ, MARSHALL, SCHEMEL, SHUSTERMAN, FRANKEL, FRIEL, KRAJEWSKI, ORTITAY, HADDOCK, ABNEY, A. BROWN, RYNCAVAGE, DALEY, PICKETT, KUZMA, DAVANZO, STAATS, WEBSTER, BRENNAN, O'MARA, HOWARD, LEADBETER, MARCELL, PIELLI, TAKAC, HANBIDGE AND BERNSTINE, OCTOBER 16, 2023 AS REPRESENTATIVES, AS AMENDED, JUNE 3, 2024 SE OF AN ACT Amending the act of May 17, 1921 (P.L.682, No.284), entitled "An act relating to insurance;

Coverage for Biomarker Testing.--(a) An <-- insurer or medical assistance or Children's Health Insurance Program managed care plan that amends, delivers or renews a health insurance policy or an agreement with the Department of Human Services on or after January 1, 2024, shall include biomarker testing as a covered benefit.

(d) If prior authorization is required for biomarker testing, an insurer or medical assistance or Children's Health Insurance Program managed care plan shall approve or deny a prior authorization request and notify the enrollee, the 20230HB1754PN3198 - 2 - enrollee's health care provider and any entity requesting authorization of the service within 72 hours for nonurgent requests or within 24 hours for urgent requests.

~~20230HB1754PN2133 - 2 -~~ (e) The patient and prescribing practitioner shall have access to clear, readily accessible and convenient processes to request an exception to a coverage policy or an adverse utilization review determination of a health insurer, nonprofit health service plan and health maintenance organization.

20230HB1754PN3198 - 3 - (5) The number of exception requests by exception that were initially denied and then appealed.

(6) The number of exception requests by exception that were ~~20230HB1754PN2133 - 3 -~~ initially denied and then subsequently reversed by internal appeals or external reviews.

These statements should be aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the 20230HB1754PN3198 - 4 - outcomes of clinical care.

"Covered benefit." A health care service as specified in the terms of a health insurance policy or an agreement with the ~~20230HB1754PN2133 - 4 -~~ Department of Human Services.

20230HB1754PN3198 - 5 - (2) The act of December 29, 1972 (P.L.1701, No.364), known as the Health Maintenance Organization Act.

61 (relating to hospital plan ~~20230HB1754PN2133 - 5 -~~ corporations).

(2) For health insurance policies for which neither rates nor forms are required to be filed with the Federal Government or the Insurance Department, the addition of 20230HB1754PN3198 - 6 - section 635.9 of the act shall apply to any policy issued or renewed on or after 120 days after the effective date of this section.

~~20230HB1754PN2133 - 6 -~~ Section 3.

~~20230HB1754PN2133~~ SECTION -635.9.-7-

COVERAGE FOR BIOMARKER TESTING.--(A) AN <-- INSURER THAT OFFERS, ISSUES OR RENEWS A HEALTH INSURANCE POLICY IN THIS COMMONWEALTH SHALL INCLUDE BIOMARKER TESTING AS A COVERED BENEFIT.

THE FOLLOWING SHALL APPLY:

(1) AN INSURER'S COVERAGE FOR BIOMARKER TESTING SHALL BE REQUIRED FOR THE PURPOSES OF DIAGNOSIS, TREATMENT, APPROPRIATE MANAGEMENT OR ONGOING MONITORING OF A COVERED PERSON'S DISEASE OR CONDITION TO GUIDE TREATMENT DECISIONS FOR THE COVERED PERSON.

BIOMARKER TESTING COVERED UNDER THIS SUBSECTION SHALL BE SUBJECT TO:

(I) ARTICLE XXI OF THIS ACT.

(II) APPLICABLE FEDERAL LAWS AND REGULATIONS.

(III) APPLICABLE LAWS AND REGULATIONS OF THIS COMMONWEALTH.

(IV) THE TERMS AND CONDITIONS OF A HEALTH INSURANCE POLICY, INCLUDING DETERMINATIONS OF MEDICAL

NECESSITY AND CLINICAL REVIEW CRITERIA USED FOR UTILIZATION REVIEW OF HEALTH CARE SERVICES ALONG WITH COPAYMENT, DEDUCTIBLE AND COINSURANCE PROVISIONS.

(2) COVERAGE FOR BIOMARKER TESTING SHALL BE ADMINISTERED IN A SIMILAR MANNER TO OTHER HEALTH CARE SERVICES PROVIDED FOR UNDER THE TERMS AND CONDITIONS OF A HEALTH INSURANCE POLICY.

(3) NOTHING IN THIS SUBSECTION SHALL BE CONSTRUED AS REQUIRING AN INSURER TO COVER BIOMARKER TESTING FOR THE PURPOSE OF SCREENING BEYOND THE BRCA-RELATED SCREENINGS REQUIRED UNDER SECTION 633.1.

(B) SUBJECT TO FEDERAL APPROVAL, AS NECESSARY, A MEDICAL 20230HB1754PN3198 - 7 - ASSISTANCE OR CHILDREN'S HEALTH INSURANCE PROGRAM MANAGED CARE PLAN SHALL PROVIDE COVERAGE OF BIOMARKER TESTING.

THE FOLLOWING SHALL APPLY:

(1) A MEDICAL ASSISTANCE OR CHILDREN'S HEALTH INSURANCE PROGRAM MANAGED CARE PLAN'S COVERAGE FOR BIOMARKER TESTING UNDER THIS SUBSECTION SHALL BE SUBJECT TO:

(I) ARTICLE XXI OF THIS ACT.

(II) APPLICABLE FEDERAL LAWS AND REGULATIONS.

(III) APPLICABLE LAWS AND REGULATIONS OF THIS COMMONWEALTH.

(IV) THE TERMS AND CONDITIONS OF AN AGREEMENT WITH THE DEPARTMENT OF HUMAN SERVICES, INCLUDING DETERMINATIONS OF MEDICAL NECESSITY AND CLINICAL REVIEW CRITERIA USED FOR UTILIZATION REVIEW OF HEALTH CARE SERVICES ALONG WITH COPAYMENT, DEDUCTIBLE AND COINSURANCE PROVISIONS.

(2) COVERAGE FOR BIOMARKER TESTING SHALL BE ADMINISTERED IN A SIMILAR MANNER TO OTHER HEALTH CARE SERVICES PROVIDED UNDER THE TERMS AND CONDITIONS OF AN AGREEMENT WITH THE DEPARTMENT OF HUMAN SERVICES.

(3) NOTHING IN THIS SUBSECTION SHALL BE CONSTRUED AS REQUIRING A MEDICAL ASSISTANCE OR CHILDREN'S HEALTH INSURANCE PROGRAM MANAGED CARE PLAN TO COVER BIOMARKER TESTING FOR THE PURPOSE OF SCREENING.

(C) THE TERMS IN THIS SECTION SHALL BE GIVEN THE SAME DEFINITIONS AS THE TERMS DEFINED PURSUANT TO SECTION 2102 UNLESS OTHERWISE NOTED.

AS USED IN THIS SECTION, THE FOLLOWING WORDS AND PHRASES SHALL HAVE THE MEANINGS GIVEN TO THEM IN THIS SUBSECTION UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE:

"AGREEMENT WITH THE DEPARTMENT OF HUMAN SERVICES." AN AGREEMENT BETWEEN A MEDICAL ASSISTANCE OR CHILDREN'S HEALTH INSURANCE PROGRAM MANAGED CARE PLAN AND THE DEPARTMENT OF HUMAN 20230HB1754PN3198 - 8 - SERVICES.

"BIOMARKER." A DEFINED CHARACTERISTIC THAT IS MEASURED AS AN INDICATOR OF NORMAL BIOLOGICAL PROCESSES, PATHOGENIC PROCESSES OR RESPONSES TO AN EXPOSURE OR INTERVENTION, INCLUDING THERAPEUTIC INTERVENTIONS. MOLECULAR, HISTOLOGIC, RADIOLOGIC OR PHYSIOLOGIC CHARACTERISTICS ARE TYPES OF BIOMARKERS.

A BIOMARKER IS NOT AN ASSESSMENT OF HOW A COVERED PERSON OR ENROLLEE FEELS, FUNCTIONS OR SURVIVES.

"BIOMARKER TESTING." THE ANALYSIS OF A COVERED PERSON OR ENROLLEE'S TISSUE, BLOOD OR OTHER BIOSPECIMEN FOR THE PRESENCE OF A BIOMARKER.

BIOMARKER TESTING INCLUDES, BUT IS NOT LIMITED TO, SINGLE-ANALYTE TESTS AND MULTI-PLEX PANELS PERFORMED AT A PARTICIPATING IN-NETWORK LABORATORY THAT IS CLIA CERTIFIED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION.

"MEDICAL ASSISTANCE" OR "CHILDREN'S HEALTH INSURANCE PROGRAM MANAGED CARE PLAN." A HEALTH CARE PLAN THAT USES A GATEKEEPER TO MANAGE THE UTILIZATION OF HEALTH CARE SERVICES, INCLUDING BIOMARKER TESTING, BY MEDICAL ASSISTANCE OR CHILDREN'S HEALTH INSURANCE PROGRAM ENROLLEES AND INTEGRATES THE FINANCING AND DELIVERY OF HEALTH CARE SERVICES, INCLUDING BIOMARKER TESTING.

"SCREENING." A MEDICAL PROCEDURE OR TEST FOR A COVERED PERSON OR ENROLLEE WHO HAS YET TO DISPLAY SYMPTOMS OF A PARTICULAR DISEASE OR CONDITION FOR THE PURPOSE OF DETERMINING THEIR LIKELIHOOD OF HAVING THE DISEASE OR CONDITION.

SECTION 2.

THIS ACT SHALL APPLY AS FOLLOWS:

(1) FOR HEALTH INSURANCE POLICIES FOR WHICH EITHER RATES OR FORMS ARE REQUIRED TO BE FILED WITH THE FEDERAL GOVERNMENT OR THE INSURANCE DEPARTMENT, THE ADDITION OF SECTION 635.9(A) OF THE ACT SHALL APPLY TO ANY POLICY FOR WHICH A FORM OR RATE IS FIRST FILED ON OR AFTER THE EFFECTIVE DATE OF THIS 20230HB1754PN3198 - 9 - SECTION.

(2) FOR HEALTH INSURANCE POLICIES FOR WHICH NEITHER RATES NOR FORMS ARE REQUIRED TO BE FILED WITH THE FEDERAL GOVERNMENT OR THE INSURANCE DEPARTMENT, THE ADDITION OF SECTION 635.9(A) OF THE ACT SHALL APPLY TO ANY POLICY ISSUED OR RENEWED ON OR AFTER 120 DAYS AFTER THE EFFECTIVE DATE OF THIS SECTION.

(3) FOR MEDICAL ASSISTANCE AND CHILDREN'S HEALTH INSURANCE PROGRAM MANAGED CARE PLANS, THE ADDITION OF SECTION 635.9(B) SHALL APPLY BEGINNING JANUARY 1, 2026.

SECTION 3.

THIS ACT SHALL TAKE EFFECT IN 180 DAYS.

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