PRINTER'S NO. 2133

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1754 Session of 2023

INTRODUCED BY MULLINS, CUTLER, STURLA, STENDER, DONAHUE, BURGOS, MADDEN, FREEMAN, BOROWSKI, SANCHEZ AND CERRATO, OCTOBER 16, 2023

REFERRED TO COMMITTEE ON INSURANCE, OCTOBER 16, 2023

AN ACT

Amending the act of May 17, 1921 (P.L.682, No.284), entitled "An act relating to insurance; amending, revising, and consolidating the law providing for the incorporation of insurance companies, and the regulation, supervision, and protection of home and foreign insurance companies, Lloyds associations, reciprocal and inter-insurance exchanges, and fire insurance rating bureaus, and the regulation and supervision of insurance carried by such companies, associations, and exchanges, including insurance carried by the State Workmen's Insurance Fund; providing penalties; and repealing existing laws," in casualty insurance, providing for coverage for biomarker testing.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921, is amended by adding a section to read:

Section 635.9. 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.

(b) Biomarker testing shall be covered for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an insured or enrollee's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to, any of the following:

(1) labeled indications for an FDA-approved or cleared test;

(2) indicated tests for an FDA-approved drug;

(3) warnings and precautions on FDA-approved drug labels;

(4) Centers for Medicare and Medicaid Services National Coverage Determinations or Medicare Administrative Contractor Local Coverage Determinations; or

(5) nationally recognized clinical practice guidelines and consensus statements.

(b.1) The information obtained through biomarker testing is to be used only for the purposes specified in subsection (b) and is protected by the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936). The information shall not be used for any other purpose by an insurer.

(c) Biomarker testing covered under subsections (a) and (b) shall be provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(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 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.

(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. The process shall be made readily accessible on the health insurer's, nonprofit health service plan's or health maintenance organization's publicly accessible Internet website.

(f) An insurer shall submit a report to the Insurance Department and a medical assistance or Children's Health Insurance Program managed care plan shall submit to the Department of Human Services by January 31 of the following year, the following data from the preceding calendar year in a form and manner prescribed by the respective department, which the respective department shall publish to the President pro tempore of the Senate, the Speaker of the House of Representatives, the members of the Banking and Insurance Committee of the Senate and the members of the Insurance Committee of the House of Representatives:

(1) The number of exception requests received by exception.

(2) The type of health care providers or the medical specialties of the health care providers submitting exception requests.

(3) The number of exception requests by exception that were denied and the reasons for the denials.

(4) The number of exception requests by exception that were approved.

(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

initially denied and then subsequently reversed by internal appeals or external reviews.

(7) The medical conditions for which patients are granted exceptions due to the likelihood that not receiving biomarker testing will likely result in treatment decisions that could cause an adverse reaction or physical harm to the insured.

(g) 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:

"Biomarker." A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered. The term includes gene mutations, characteristics of genes or protein expression.

"Biomarker testing." The analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker. The term includes single-analyte tests, multi-plex panel tests, protein expression and whole exome, whole genome and whole transcriptome sequencing.

"Consensus statements." Statements developed by an independent, multidisciplinary panel of experts utilizing a transparent methodology and reporting structure and with a conflict-of-interest policy. These statements should be aimed at specific clinical circumstances and base the statements on the best available evidence for the purpose of optimizing the 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

Department of Human Services.

"Health insurance policy." A policy, subscriber contract, certificate or plan issued by an insurer that provides medical or health care coverage. The term does not include any of the following:

(1) An accident only policy.

(2) A credit only policy.

(3) A long-term care or disability income policy.

(4) A specified disease policy.

(5) A Medicare supplement policy.

(6) A TRICARE policy, including a Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) supplement policy.

(7) A fixed indemnity policy.

(8) A hospital indemnity policy.

(9) A worker's compensation policy.

(10) An automobile medical payment policy under 75 Pa.C.S. (relating to vehicles).

(11) A homeowner's insurance policy.

(12) Any other similar policies providing for limited benefits.

(13) A dental only policy.

(14) A vision only policy.

"Insurer." An entity licensed by the Insurance Department that offers, issues or renews a health insurance policy and governed under any of the following:

(1) Section 630 and Article XXIV of this act.

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

(3) 40 Pa.C.S. Ch. 61 (relating to hospital plan

corporations).

(4) 40 Pa.C.S. Ch. 63 (relating to professional health services plan corporations).

"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.

"Nationally recognized clinical practice guidelines." Evidence-based clinical practice guidelines developed by independent organizations or medical professional societies utilizing a transparent methodology and reporting structure and with a conflict-of-interest policy. Clinical practice guidelines establish standards of care informed by a systemic review of evidence and an assessment of the benefits and risks of alternative care options and include recommendations intended to optimize patient care.

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 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 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 of the act shall apply to any policy issued or renewed on or after 120 days after the effective date of this section.

Section 3. This act shall take effect in 60 days.