SENATE ENROLLED ACT No. 273

AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-15-5-21.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2024]: **Sec. 21.5. (a) As used in this section, "biomarker" means a characteristic that is objectively measured and evaluated as an indicator of:**

(1) normal biological processes;

(2) pathogenic processes; or

(3) 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, and protein expression.

(b) As used in this section, "biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker. The term includes:

(1) single-analyte tests;

(2) multiplex panel tests;

(3) protein expression; and

(4) whole exome, whole genome, and whole transcriptome sequencing.

(c) As used in this section, "consensus statement" means a

statement that is:

(1) issued by an independent, multidisciplinary panel of experts that:

(A) uses a transparent methodology and reporting structure; and

(B) has a conflict of interest policy;

(2) aimed at specific clinical circumstances;

(3) based on the best available evidence; and

(4) developed for the purpose of optimizing the outcomes of clinical care.

(d) As used in this section, "nationally recognized clinical practice guidelines" means evidence based clinical practice guidelines that:

(1) are developed by an independent organization or medical professional society that:

(A) uses a transparent methodology and reporting structure; and

(B) has a conflict of interest policy;

(2) establish standards of care informed by:

(A) a systematic review of evidence; and

(B) an assessment of the benefits and risks of alternative care options; and

(3) include recommendations intended to optimize patient care.

(e) The office shall provide, as a Medicaid program service, biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when biomarker testing is supported by medical and scientific evidence, including:

(1) labeled indications for a test approved or cleared by the United States Food and Drug Administration;

(2) indicated tests for a drug approved by the United States Food and Drug Administration;

(3) a warning or precaution on the label of a drug approved by the United States Food and Drug Administration;

(4) a national coverage determination of the Centers for Medicare and Medicaid Services (CMS);

(5) a local coverage determination of a Medicare administrative contractor; or

(6) nationally recognized clinical practice guidelines or consensus statements.

The service required by this section must be provided in a manner

that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(f) Nothing in this section shall be construed to require coverage of biomarker testing for screening purposes.

(g) The office shall apply to the United States Department of Health and Human Services for approval of any waiver necessary under the federal Medicaid program for the purpose of providing biomarker testing. The office may not implement a waiver under this section until the office files an affidavit with the governor attesting that the federal waiver applied for under this section is in effect. The office shall file the affidavit under this subsection not later than five (5) days after the office is notified that the waiver is approved.

(h) If the office receives a waiver under this section from the United States Department of Health and Human Services and the governor receives the affidavit filed under subsection (g), the office shall implement the waiver not more than sixty (60) days after the governor receives the affidavit.

(i) Before November 1, 2025, and before November 1 of each year thereafter, the office of the secretary shall report to the budget committee on the Medicaid reimbursement rates provided for biomarker testing. The report shall include the following statewide aggregate information for the state fiscal year 2023 and the state fiscal year most recently ended:

(1) The total number of patients who received biomarker testing.

(2) The total number of patients who received biomarker testing for each biomarker test type.

(3) The total amount of state funding expended for biomarker testing.

(4) The ten (10) most common conditions or treatments for which biomarker testing was ordered.

(5) As a result of the biomarker testing, how many patients:

(A) were placed on particular therapies;

(B) avoided certain treatments; and

(C) were subject to any other treatment impacts.

(6) Any other information requested by the budget committee.

Each provider that receives state Medicaid funding under this section shall provide the information described in subdivisions (1) through (6) to the office of the secretary not later than August 1 of each year.

SECTION 2. IC 27-8-14.3 IS ADDED TO THE INDIANA CODE

AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2024]:

Chapter 14.3. Coverage for Biomarker Testing

Sec. 1. This chapter applies to:

(1) a policy of accident and sickness insurance or a health maintenance organization contract that is issued, renewed, or entered into after June 30, 2024;

(2) Medicaid managed care provided by a managed care organization under a contract with the office of Medicaid policy and planning that is entered into or renewed after June 30, 2024; and

(3) coverage provided by a state employee health plan after June 30, 2024.

Sec. 2. (a) As used in this chapter, "accident and sickness policy" means an insurance policy that provides at least one (1) of the types of insurance described in IC 27-1-5-1, Classes 1(b) and 2(a).

(b) The term "accident and sickness policy" does not include the following:

(1) Accident only, credit, dental, vision, Medicare supplement, long term care, or disability income insurance.

(2) Coverage issued as a supplement to liability insurance.

(3) Worker's compensation or similar insurance.

(4) Automobile medical payment insurance.

(5) A specified disease policy.

(6) A short term insurance plan that:

(A) may be renewed for the greater of:

(i) thirty-six (36) months; or

(ii) the maximum period permitted under federal law;

(B) has a term of not more than three hundred sixty-four (364) days; and

(C) has an annual limit of at least two million dollars ($2,000,000).

(7) A policy that provides indemnity benefits not based on any expense incurred requirement, including a plan that provides coverage for:

(A) hospital confinement, critical illness, or intensive care; or

(B) gaps for deductibles or copayments.

(8) A supplemental plan that always pays in addition to other coverage.

(9) A student health plan.

(10) An employer sponsored health benefit plan that is:

(A) provided to individuals who are eligible for Medicare; and

(B) not marketed as, or held out to be, a Medicare supplement policy.

Sec. 3. (a) As used in this chapter, "biomarker" means a characteristic that is objectively measured and evaluated as an indicator of:

(1) normal biological processes;

(2) pathogenic processes; or

(3) pharmacologic responses to a specific therapeutic intervention, including known gene-drug interactions for medications being considered for use or already being administered.

(b) The term includes gene mutations, characteristics of genes, and protein expression.

Sec. 4. (a) As used in this chapter, "biomarker testing" means the analysis of a patient's tissue, blood, or other biospecimen for the presence of a biomarker.

(b) The term includes:

(1) single-analyte tests;

(2) multiplex panel tests;

(3) protein expression; and

(4) whole exome, whole genome, and whole transcriptome sequencing.

Sec. 5. As used in this chapter, "consensus statement" means a statement that is:

(1) issued by an independent, multidisciplinary panel of experts that:

(A) uses a transparent methodology and reporting structure; and

(B) has a conflict of interest policy;

(2) aimed at specific clinical circumstances;

(3) based on the best available evidence; and

(4) developed for the purpose of optimizing the outcomes of clinical care.

Sec. 6. As used in this chapter, "covered individual" means an individual who is entitled to coverage under a health plan.

Sec. 7. (a) As used in this chapter, "health plan" means any of the following:

(1) A policy of accident and sickness insurance.

(2) A contract with a health maintenance organization (as

defined in IC 27-13-1-19) that provides coverage for basic health care services (as defined in IC 27-13-1-4).

(3) The Medicaid risk based managed care program operated under IC 12-15.

(4) A state employee health plan.

(b) The term includes a person that administers a health plan.

Sec. 8. As used in this chapter, "nationally recognized clinical practice guidelines" means evidence based clinical practice guidelines that:

(1) are developed by an independent organization or medical professional society that:

(A) uses a transparent methodology and reporting structure; and

(B) has a conflict of interest policy;

(2) establish standards of care informed by:

(A) a systematic review of evidence; and

(B) an assessment of the benefits and risks of alternative care options; and

(3) include recommendations intended to optimize patient care.

Sec. 9. (a) As used in this chapter, "state employee health plan" refers to either of the following:

(1) A self-insurance program established under IC 5-10-8-7(b).

(2) A contract with a prepaid health care delivery plan that is entered into or renewed under IC 5-10-8-7(c).

(b) The term includes a person that administers prescription drug benefits on behalf of a state employee health plan.

Sec. 10. (a) A health plan shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when biomarker testing is supported by medical and scientific evidence, including:

(1) labeled indications for a test approved or cleared by the United States Food and Drug Administration;

(2) indicated tests for a drug approved by the United States Food and Drug Administration;

(3) a warning or precaution on the label of a drug approved by the United States Food and Drug Administration;

(4) a national coverage determination of the Centers for Medicare and Medicaid Services (CMS);

(5) a local coverage determination of a Medicare

administrative contractor; or

(6) nationally recognized clinical practice guidelines or consensus statements.

(b) The coverage required by this section must be provided in a manner that limits disruptions in care, including the need for multiple biopsies or biospecimen samples.

(c) Nothing in this section shall be construed to require coverage of biomarker testing for screening purposes.

(d) If a prior authorization requirement applies to biomarker testing under a health plan, the health plan or a third party acting on behalf of the health plan must:

(1) approve or deny a request for prior authorization for biomarker testing; and

(2) notify the covered individual and any person requesting prior authorization of the biomarker testing on behalf of the covered individual;

in not more than five (5) business days after the request in the case of a nonurgent request or in not more than forty-eight (48) hours after the request in the case of an urgent request.

(e) A health plan shall ensure that a covered individual and the practitioner who prescribes biomarker testing for the covered individual have access to a clear, readily accessible, and convenient process for requesting an exception to:

(1) a coverage policy; or

(2) a prior authorization determination;

of the health plan that is adverse to the coverage of biomarker testing for the covered individual. The process required by this subsection shall be made readily accessible on the health plan's website.

President of the Senate

President Pro Tempore

Speaker of the House of Representatives

Governor of the State of Indiana

Date: _____ Time: _____