SB-1191 Medi-Cal: pharmacogenomic testing. (2021-2022)

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CALIFORNIA LEGISLATURE— 2021–2022 REGULAR SESSION

SENATE BILL NO. 1191

Introduced by Senator Bates

February 17, 2022

An act to add Section 14132.08 to the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

SB 1191, Bates. Medi-Cal: pharmacogenomic testing.

Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Existing law sets forth a schedule of covered benefits under the Medi-Cal program.

This bill, the Utilizing Pharmacogenomics to Greatly Reduce Adverse Drug Events (UPGRADE) Act, subject to an appropriation, would add pharmacogenomic testing as a covered benefit under Medi-Cal. The bill would define pharmacogenomic testing as laboratory genetic testing, by a laboratory with specified licensing, accreditation, and certification, to identify how a person's genetics may impact the efficacy, toxicity, and safety of medications. The bill would cover the benefit under Medi-Cal if a medication is being considered for use, or is already being administered, and is approved for use, in treating a Medi-Cal beneficiary's condition and is known to have a gene-drug or drug-drug-gene interaction that has been demonstrated to be clinically actionable, as specified, if the test is ordered by an enrolled Medi-Cal clinician or pharmacist.

The bill would authorize the department to implement the above-described provisions through all-county or plan letters, or similar instructions, until the department promulgates regulations.
Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 14132.08 is added to the Welfare and Institutions Code, to read:

14132.08. (a) This section shall be known, and may be cited, as the Utilizing Pharmacogenomics to Greatly Reduce Adverse Drug Events (UPGRADE) Act.

(b) Pharmacogenomic testing shall be a covered Medi-Cal benefit pursuant to this section.

(c) Pharmacogenomic testing shall be covered under the Medi-Cal program if a medication is being considered for use, or is already being administered, and is approved for use, in treating a Medi-Cal beneficiary's condition and is known to have a gene-drug or drug-drug-gene interaction that has been demonstrated to be clinically actionable, as defined by the United States Food and Drug Administration or by the Clinical Pharmacogenetics Implementation Consortium (CPIC) Guidelines for Level A, A/B, or B, if the test is ordered by an enrolled Medi-Cal clinician or pharmacist pursuant to paragraph (12) of subdivision (a) of Section 4052 of the Business and Professions Code.

(d) (1) Medi-Cal reimbursement for pharmacogenomic testing is subject to the use of only one Current Procedural Terminology (CPT) code, or only one Healthcare Common Procedure Coding System (HCPCS) code, for the test. Each individual gene of a panel test shall not be billed with multiple CPT or HCPCS codes.

(2) Sample collection for purposes of performing pharmacogenomic testing may be completed at home, within a pharmacy, or at a health facility. The location of sample collection shall not impact Medi-Cal reimbursement for pharmacogenomic testing.

(e) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, until the department promulgates regulations.

(f) This section shall become operative upon an appropriation by the Legislature for the express purpose of implementing this section.

(g) For purposes of this section, the following definitions apply:

(1) "Pharmacogenomics" means the evaluation of how a person's genes affect how the person responds to medications. Pharmacogenomics enables the selection of drugs and doses best suited to reduce toxicity and adverse drug events, including treatment failures, severe harm, or even death.

(2) "Pharmacogenomic testing" means laboratory genetic testing, including, but not limited to, a panel test, by a California-licensed laboratory with accreditation by the College of American Pathologists (CAP) or another accrediting agency approved by the federal Centers for Medicare and Medicaid Services (CMS) and a valid CLIA certificate to identify how a person's genetics may impact the efficacy, toxicity, and safety of medications.