SUBSTITUTE FOR

HOUSE BILL NO. 4350

A bill to amend 1984 PA 323, entitled

"The health care false claim act,"

by amending sections 2 and 4a (MCL 752.1002 and 752.1004a), section 4a as amended by 2020 PA 317.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 2. As used in this act:

(a) "Claim" means any attempt to cause a health care corporation or health care insurer to make the payment of a health care benefit.

(b) "Deceptive" means making a claim to a health care corporation or health care insurer ~~which~~ **that** contains a statement of fact or ~~which~~ fails to reveal a material fact, which statement or failure leads the health care corporation or health care insurer

to believe the represented or suggested state of affair to be other than it actually is.

(c) "False" means wholly or partially untrue or deceptive.

(d) "Health care benefit" means the right under a contract or a certificate or policy of insurance to have a payment made by a health care corporation or health care insurer for a specified health care service.

(e) "Health care corporation" means a nonprofit dental care corporation incorporated under ~~Act No. 125 of the Public Acts of 1963, being sections 550.351 to 550.373 of the Michigan Compiled Laws;~~ **1963 PA 125, MCL 550.351 to 550.373;** a hospital service corporation, medical care corporation, or a consolidated hospital service corporation and medical care corporation incorporated or reincorporated under ~~Act No. 350 of the Public Acts of 1980, being sections 550.1101 to 550.1704 of the Michigan Compiled Laws, or incorporated or consolidated under Act No. 108 or 109 of the Public Acts of 1939;~~ **the nonprofit health care corporation reform act, 1980 PA 350, MCL 550.1101 to 550.1704;** or a health maintenance organization licensed under ~~Act No. 368 of the Public Acts of 1978, being sections 333.1101 to 333.25211 of the Michigan Compiled Laws.~~**chapter 35 of the insurance code of 1956, 1956 PA 218, MCL 500.3501 to 500.3573.**

(f) "Health care insurer" means any insurance company authorized to provide health insurance in this state or any legal entity ~~which~~ **that** is self-insured and providing health care benefits to its employees.

(g) "Health facility or agency" means ~~a health facility or agency, as~~ **that term as** defined in section 20106 of the public health code, ~~Act No. 368 of the Public Acts of 1978, being section~~

~~333.20106 of the Michigan Compiled Laws.~~**1978 PA 368, MCL 333.20106.**

(h) "Knowing" and "knowingly" means that a person is in possession of facts under which he or she is aware or should be aware of the nature of his or her conduct and that his or her conduct is substantially certain to cause the payment of a health care benefit. "Knowing" or "knowingly" does not include conduct ~~which~~ **that** is an error or mistake unless the person's course of conduct indicates a systematic or persistent tendency to cause inaccuracies to be present.

(i) "Person" means an individual, corporation, partnership, association, or any other legal entity.

Sec. 4a. (1) ~~Neither~~ **None** of the following ~~violates~~ **violate** section 4:

(a) ~~A~~ **Through December 31, 2022, a** rebate or discount from a drug manufacturer or from a company that licenses or distributes the drugs of a drug manufacturer to or for the benefit of a consumer for the administration or the consumer's use of a drug manufactured, ~~or~~ licensed, or distributed by the drug manufacturer or company, including for consumer cost-sharing requirements for the administration or drug. ~~As used in this subdivision, "administration" means injection, infusion, or similar means of application.~~

(b) Beginning January 1, 2023, a rebate, discount, product voucher, or other reduction in a consumer's out-of-pocket expenses, including a copayment or deductible, from a drug manufacturer or a company that licenses or distributes the drugs of a drug manufacturer to or for the benefit of the consumer for the administration or the consumer's use of a drug manufactured, licensed, or distributed by the drug manufacturer or company,

including for consumer cost-sharing requirements for the administration or drug, but only if the rebate, discount, product voucher, or other reduction is not for a drug that has a generically equivalent drug product, unless any of the following apply:

(*i*) The consumer obtains access to the drug through prior authorization, a step-therapy protocol, or a health care insurer's or health care corporation's exception process.

(*ii*) The consumer's prescriber has instructed a pharmacist to dispense the drug as written under section 17755(3) of the public health code, 1978 PA 368, MCL 333.17755.

(*iii*) The drug is required under a United States Food and Drug Administration Risk Evaluation and Mitigation Strategy for the purpose of monitoring or facilitating the use of the drug in a manner consistent with the prescribing information for the drug.

(c) ~~(b)~~ A monetary payment from a drug manufacturer to a consumer, the consumer's health professional, or a vendor that has a contract with the drug manufacturer, for a health care service that, **through December 31, 2022,** the prescribing information of a qualified drug requires or recommends for initiating drug therapy **or that, beginning January 1, 2023, the prescribing information of a drug requires or recommends for initiating drug therapy.**

(d) A product provided by a drug manufacturer or company that licenses or distributes the drugs of a drug manufacturer to a consumer at no cost to the consumer.

(2) This section does not alter any copayment, deductible, coinsurance, or other cost-sharing requirements under a contract, certificate, or policy issued by a health care corporation or health care insurer.

(3) As used in this section:

(a) "Administration" means injection, infusion, or similar means of application.

(b) ~~(a)~~ "Consumer's health professional" means a health professional who did not prescribe the ~~qualified~~ drug or who does not have a financial relationship to the health professional who prescribed the ~~qualified~~ drug.

(c) "Generically equivalent drug product" means a drug that meets both of the following requirements:

(*i*) The United States Food and Drug Administration has designated the drug as therapeutically equivalent in "Approved Drug Products with Therapeutic Equivalence Evaluations", a publication by the United States Food and Drug Administration.

(*ii*) The drug is nationally available.

(d) ~~(b)~~ "Health care service" means any of the following:

(*i*) Monitoring for bradycardia or atrioventricular conduction.

(*ii*) Monitoring blood pressure.

(*iii*) An electrocardiogram.

(*iv*) A cardiac evaluation by a physician.

(*v*) A complete blood count test.

(*vi*) A liver function test.

(*vii*) An eye examination for macular edema.

(*viii*) A pulmonary function test, if clinically indicated.

(*ix*) A vaccination.

(*x*) An additional service included in the prescribing information by the United States Food and Drug Administration.

(e) ~~(c)~~ "Health professional" means an individual who is licensed or otherwise authorized to engage in a health profession

under article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838.

(f) ~~(d)~~ "Physician" means an individual licensed or otherwise authorized to engage in the practice of medicine under part 170 of the public health code, 1978 PA 368, MCL 333.17001 to 333.17097, or to engage in the practice of osteopathic medicine and surgery under part 175 of the public health code, 1978 PA 368, MCL 333.17501 to 333.17556.

(g) ~~(e)~~ "Qualified drug" means a drug that has a United States Food and Drug Administration approved indication to treat multiple sclerosis.