OLR Bill Analysis
HB 6003
Emergency Certification

AN ACT CONCERNING DIABETES AND HIGH DEDUCTIBLE HEALTH PLANS.

SUMMARY:

This bill (1) requires pharmacists, in certain emergency situations, to prescribe and dispense up to a 30-day supply of certain diabetes-related drugs and devices, including diabetic ketoacidosis devices, to a patient in a 12-month period, (2) limits how much pharmacists can charge for the emergency drugs and supplies in these situations, and (3) expands the prescription drug monitoring program to include them (§§ 2-12). By October 1, 2020, the bill requires the Department of Consumer Protection (DCP) commissioner to notify each retail pharmacy of the bill's emergency drugs and devices requirements (§ 4).

The bill requires certain health insurance policies to:

- 1. expand coverage for diabetes screening, drugs, and devices;
- 2. limit out of pocket costs (e.g., coinsurance, copayments, and deductibles) for covered diabetes-related drugs and devices, including diabetic ketoacidosis devices; and
- 3. cover emergency diabetes-related drugs and devices prescribed and dispensed by a pharmacist under the bill's provisions (§§ 13-14).

The bill also requires the Department of Social Services (DSS) commissioner to establish, by November 1, 2020, an 11-member working group, to determine whether she should establish a program to refer people diagnosed with diabetes, regardless of their health

insurance coverage status, to federally-qualified health centers (FQHCs) and other covered entities for treatment. If the working group determines that the commissioner should establish the program, it must develop the criteria DSS must apply in recommending FQHCs or other covered entities to individuals. By January 1, 2022, the bill requires the DSS commissioner to establish the referral program, using the working groups' criteria, except under specified circumstances (§ 1).

Finally, the bill makes several changes to conform insurance statutes referencing health savings accounts (HSA) to federal law by adding references to medical savings accounts and Archer Medical Savings Accounts (MSAs) (§§ 15-36).

EFFECTIVE DATE: January 1, 2021, except the DSS working group and DCP pharmacy notice provisions are effective upon passage; the technical and conforming changes related to HSAs are effective October 1, 2020; and the expanded health insurance coverage and out-of-pocket limit provisions are effective January 1, 2022.

§§ 2-12 — PHARMACISTS AND EMERGENCY PRESCRIPTIONS

In certain emergency situations, the bill requires pharmacists to prescribe and dispense no more than one 30-day emergency supply of certain diabetes-related drugs and devices to a patient in a 12-month period. It establishes a price cap for these prescriptions and expands the prescription drug monitoring program to include them.

The bill's requirements apply to the following prescription or nonprescription drugs and devices:

- insulin drugs, which are drugs containing insulin (including an insulin pen) prescribed for self-administration on an outpatient basis and approved by the federal Food and Drug Administration (FDA) to treat diabetes;
- 2. glucagon drugs, which are drugs containing glucagon prescribed for self-administration on an outpatient basis and

- FDA-approved to treat low blood sugar;
- 3. diabetes devices, which are used to cure, diagnose, mitigate, prevent, or treat diabetes or low blood sugar, including blood glucose test strips, glucometers, continuous glucometers, lancets, lancing devices, and insulin syringes; and
- 4. diabetic ketoacidosis devices, which are used to screen for or prevent diabetic ketoacidosis.

Requirement to Prescribe and Dispense (§§ 3 & 5)

The bill requires pharmacists, provided certain criteria are met, to immediately prescribe and dispense up to a 30-day supply of diabetes-related drugs and devices unless the patient is uninsured and cannot pay for them out-of-pocket. The bill authorizes these prescriptions when:

- the patient informs the pharmacist that he or she has less than a week's supply of insulin drugs, glucagon drugs, or diabetic ketoacidosis devices;
- 2. the pharmacist determines, using professional judgment, that the patient will likely suffer significant physical harm within a week if the patient does not get more diabetes-related drugs and devices;
- 3. the pharmacist reviews the state's electronic prescription drug monitoring program and determines that no pharmacist prescribed and dispensed an emergency supply of diabetes-related drugs and devices under the bill's provisions in the last 12 months, unless the program is unavailable or the pharmacist otherwise makes the determination; and
- 4. within 72 hours of dispensing the emergency supply, the pharmacist or his or her representative notifies the previous practitioner who most recently prescribed the diabetes-related

drugs or equipment.

The bill correspondingly expands the prescription drug monitoring program to require each pharmacy, nonresident pharmacy (e.g., out of state pharmacies that ship drugs or devices into the state), outpatient pharmacy in a hospital or institution, and dispenser to report information to the DCP commissioner for all diabetes-related drugs and devices prescribed and dispensed. The bill requires pharmacies to report the information at least daily to the consumer protection commissioner in a way that is consistent with how controlled substance prescriptions are reported under existing law. Reports must be electronic or, for pharmacies that do not maintain records electronically, in a format approved by the DCP commissioner.

The pharmacist may otherwise determine that no pharmacist dispensed a supply of diabetes-related drugs and devices in the last 12 months by (1) contacting the pharmacy that filled the patient's most recent prescription, (2) examining another prescription database, or (3) reviewing the patient's most recent prescription for diabetes-related drugs and devices or a prescription label containing information on the most recent prescription.

Price Cap

The bill limits how much a pharmacist can charge a patient for emergency diabetes-related drugs and devices in these situations to:

- 1. the coinsurance, copayment, deductible, or other out-of-pocket expense required by a patient's health insurance; or
- 2. for patients without insurance, the usual customary charge to the public for these items.

Under the bill, the usual customary charge to the public is a provider's charge for a particular prescription to the patient group accounting for the largest number of prescriptions not covered by Medicaid, excluding charges made to third-party payors and special discounts offered to individuals (e.g., senior citizens).

Referral Requirement

If a patient who requests diabetes-related drugs or devices does not have insurance coverage or is uninsured and cannot pay for the drugs or devices, the bill requires pharmacists to refer the patient to a federally-qualified health center (FQHC).

Patient Document and Payment Requirements

Under the bill, a pharmacist can require a patient to submit any of the following before prescribing or dispensing diabetes-related drugs or devices:

- 1. proof of health insurance coverage,
- 2. personal identification,
- 3. contact information for a health care provider treating the patient,
- 4. information on previous insulin prescriptions,
- 5. the patient's sworn statement that they cannot timely obtain the diabetes-related drugs and devices without suffering significant physical harm, and
- 6. payment, subject to the price cap described above.

(By allowing pharmacists to require proof of insurance before prescribing, this provision appears to allow pharmacists to refuse to prescribe to those without insurance.)

The bill also makes technical and conforming changes (§§ 6-12).

§§ 13-36 — DIABETES COVERAGE AND OUT-OF-POCKET LIMITS Required Coverage

Current law requires certain health insurance policies (described below) to cover (1) laboratory and diagnostic tests for all types of diabetes and (2) medically necessary treatment (including equipment, drugs, and supplies) for insureds diagnosed with insulin-dependent diabetes, insulin-using diabetes, gestational diabetes, or non-insulinusing diabetes. The bill expands this coverage by requiring the applicable health insurance plans to cover the treatment of all types of diabetes, including medically necessary:

- 1. laboratory and diagnostic tests and screening, including hemoglobin A1c testing and retinopathy screening;
- 2. prescribed insulin and "non-insulin drugs" (i.e. a drug FDA-approved to treat diabetes that does not contain insulin, including glucagon drugs and glucose tablets and gels);
- 3. emergency insulin and glucagon drugs prescribed and dispensed by a pharmacist according to the bill (see § 3), up to once per policy year;
- 4. diabetes devices in accordance with the insured's treatment plan, including emergency diabetes devices prescribed and dispensed by a pharmacist (see § 3), up to once per policy year; and
- 5. diabetic ketoacidosis devices in accordance with the insured's treatment plan, including emergency diabetic ketoacidosis devices prescribed and dispensed by a pharmacist (see § 3), up to once per policy year.

Out-of-Pocket Limits

For the health insurance policies described below, the bill limits outof-pocket expenses to:

- 1. \$25 for each 30-day supply of medically necessary covered insulin or non-insulin drug prescribed to the insured, and
- 2. \$100 for each 30-day supply of medically necessary diabetes devices and diabetic ketoacidosis devices in accordance with an insured person's treatment plan.

Emergency Drugs and Devices. Additionally, the bill limits out-of-pocket expenses for (1) emergency insulin and glucagon drugs and (2) diabetes devices and diabetic ketoacidosis devices prescribed and dispensed according to the bill (see § 3) to \$25 and \$100, respectively, for each 30-day supply. This limit applies once per policy year.

Applicability

The bill's coverage and out-of-pocket cost provisions apply to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; or (4) hospital or medical services, including those provided under an HMO plan. Because of the federal Employee Retirement Income Security Act (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

The bill's out-of-pocket cost provisions also apply to high deductible health plans (HDHPs) to the maximum extent permitted by federal law that does not disqualify insureds from certain federal tax benefits. (Under federal law, individuals with eligible HDHPs may make pre-tax contributions to health savings accounts (HSAs) or Archer MSAs and use the accounts for qualified medical expenses. To maintain the accounts' tax advantaged status under Internal Revenue Service (IRS) rules, the associated HDHPs cannot limit deductibles except for certain preventive care items, which may include certain insulin and diabetes supplies).

Existing law, unchanged by the bill, already requires these same policies, as well as those covering accidents only and group policies covering limited benefits, to cover hypodermic needles and syringes. The bill's expanded coverage and out-of-pocket cost provisions apply regardless of this existing requirement.

§ 1 — DIABETES REFERRAL PROGRAM WORKING GROUP

The bill requires the DSS commissioner to establish a working group by November 1, 2020, that is responsible for determining whether she should establish a program to refer people diagnosed with diabetes, regardless of health coverage status, to federally-qualified health centers (FQHCs) and other covered entities for treatment (see BACKGROUND). The bill gives the commissioner the authority to adopt regulations to establish the working group and then, on the group's recommendation, the referral program.

If the working group determines that the commissioner should

establish the program, it must develop the criteria that DSS must apply when recommending an FQHC or other covered entity to someone, based on (1) his or her residential address and diabetic condition, (2) medically necessary care for that condition, and (3) any other factors the group finds relevant to the program's purposes.

Working Group Membership

Under the bill, this working group must consist of 11 members, appointed by November 1, 2020, with expertise in specified areas. Table 1 describes this expertise, along with the appointing authority for each member. The appointing authority must fill any vacancy that occurs.

Table 1: Working Group Membership

Appointing Authority	Appointee(s)
Senate chairperson of the Insurance	Advocate for insulin coverage or
and Real Estate Committee	public health
House chairperson of the Insurance and Real Estate Committee	Advocate for hospitals' interests
Senate ranking member of the	Experience with health care
Insurance and Real Estate	equity or an advocate for
Committee	hospitals' interests
House ranking member of the	Advocate for insulin coverage or
Insurance and Real Estate	public health
Committee	
DSS Commissioner	Self or designee
Department of Public Health Commissioner	Self or designee
Office of Policy and Management secretary	Self or designee
CEO of Community Health Center,	Two appointees

Inc., or its legal successor	
CEO of Community Health Center Association of Connecticut, Inc., or its legal successor	Two appointees

Chairperson, Meetings, and Voting

The bill requires the DSS commissioner to choose the chairperson from the group's members, who must then hold the group's first meeting by January 11, 2021. A majority of the group's members must be present for a quorum and their majority vote is required for action.

Working Group Recommendations and Duration

Under the bill, the group must submit its recommendation for program development, along with criteria, if any, to the DSS commissioner and the Insurance and Real Estate Committee by May 1, 2021. The group terminates on the date it reports to the committee or May 1, 2021, whichever is earlier.

Working Group Reestablishment

The bill allows the DSS commissioner to reestablish the group after the date when the working group submits its recommendation and criteria, if any, or after May 1, 2021, whichever is earlier, so that the group can develop new criteria for recommending an FQHC or other covered entity to someone. (The bill does not specify whether the criteria must be in addition to those in the previously submitted report or must replace them entirely.) The commissioner must notify each appointing authority of the reestablishment date. Within 60 days after that date, the appointing authorities must appoint all members of the reestablished group. The commissioner must schedule the first meeting of the group within 90 days after its reestablishment.

Within 240 days after the group's reestablishment date, the group must submit its new criteria to the commissioner and the Insurance and Real Estate Committee. The group terminates on the report submission date or 240 days after the reestablishment date, whichever

is later.

§ 1 — REFERRAL PROGRAM ESTABLISHMENT

The bill requires the DSS commissioner to establish the referral program for patients with diabetes by January 1, 2022, using the criteria developed by the working group described above except under two circumstances.

Exemptions from Program Establishment

The bill authorizes the commissioner not to establish the referral program if the (1) working group recommends that or (2) commissioner reports to the Insurance and Real Estate Committee either one of two findings by October 1, 2021. The commissioner may report either (1) a memo from DSS general counsel detailing federal law barriers to the program's establishment and successful implementation or (2) her own determination that the program goals could be better accomplished by applying for a Medicaid research and demonstration waiver under federal law.

Medicaid Waiver Process

If the commissioner determines that applying for the Medicaid research and demonstration waiver would better accomplish the referral program's goals, the bill requires her to apply to the Centers for Medicare and Medicaid Services (CMS) for the waiver and, upon CMS's approval, to establish the referral program according to the waiver's terms and all governing federal and state law.

Program Website

If the commissioner does establish the referral program the bill requires her to also establish and maintain a website to collect information from, and provide information to, people diagnosed with diabetes who are referred to an FQHC or other covered entity for treatment, whether or not they have health coverage.

The website must meet certain minimum capability requirements. It must enable individuals diagnosed with diabetes to disclose the following to DSS: (1) name, age, and home address; (2) contact

information, including email address or phone number; (3) income and race; (4) diabetes diagnosis; and (5) names of prescribed outpatient drugs for diabetes treatment.

Additionally, the website must enable DSS to determine whether each disclosed outpatient prescription drug is a covered outpatient drug available at a reduced cost to the diagnosed individual through an FQHC or any other covered entity.

It also must disclose to the diagnosed individual the following information:

- 1. name, business address, and phone number of any FQHC or other covered entity that DSS recommends to the individual and
- 2. general information about health care that the recommended FQHC or other covered entity provides, including any information that would help to obtain primary care through the recommended entity.

Finally, the website must be able to disclose to the recommended FQHC or other covered entity the person's name, contact information, and a statement that DSS recommended the entity to the person.

Provider Entity Responsibilities

Under the bill, each FQHC or other covered entity must make a good faith effort to schedule an appointment for a person after receiving his or her name, contact information, and the statement that DSS recommended the entity to the person. This appointment should be within 30 days after the date when DSS disclosed the above information to the provider entity.

BACKGROUND

Covered Entities

As defined in the federal Public Health Service Act, a "covered entity" includes the following entities, among others, many of which are federally funded: an FQHC, a family planning project, an entity

receiving grants for outpatient early intervention services for HIV, a state-operated AIDS drug purchasing assistance program, a comprehensive hemophilia diagnostic treatment center, an urban Indian organization, and certain hospitals and rural referral centers. These entities must also meet several requirements relating to drug discounts, rebates, and resale (42 U.S.C. § 256b(a)(4)-(5)).