OLR Bill Analysis

HB 6003 (as amended by House "A" and "B")*

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).

HB 6001, July Special Session, allows the Department of Public Health (DPH) commissioner to temporarily modify, waive, or suspend certain regulatory requirements she deems necessary to reduce the spread of COVID-19 and protect the public health. The bill allows the commissioner to take such action only for the purpose of providing residents of this state with telehealth services from out-of-state practitioners.

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).

*House Amendment “A” (1) amends the definition of “usual customary charge to the public” to remove consideration of the patient group accounting for the largest number of prescriptions for purposes of calculating the price cap on emergency diabetes-related drugs and devices prescribed and dispensed by pharmacists and (2) makes other minor changes.

*House Amendment “B” adds the provision limiting the DPH commissioner’s regulatory authority concerning telehealth under HB 6001, July Special Session, as amended by House “A.”

EFFECTIVE DATE: January 1, 2021, except the DSS working group, DCP pharmacy notice, and telehealth services 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:

1. 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 a diabetic ketoacidosis device, insulin drug, or glucagon drug, and any diabetes devices necessary to administer the drugs, unless the patient is uninsured and cannot pay for them out-of-pocket. The bill authorizes these prescriptions when:

1. the patient informs the pharmacist that he or she has less than a week’s supply of these diabetes-related drugs or 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 monitoring 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 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 concerned that the patient’s net cost for the drugs or devices is unaffordable, 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 prescriptions for diabetes-related drugs or devices,

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-insulin-using 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 out-of-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...
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>
<thead>
<tr>
<th>Appointing Authority</th>
<th>Appointee(s)</th>
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<tbody>
<tr>
<td>Senate chairperson of the Insurance and Real Estate Committee</td>
<td>Advocate for insulin coverage or public health</td>
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<tr>
<td>Position</td>
<td>Role</td>
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<tr>
<td>House chairperson of the Insurance and Real Estate Committee</td>
<td>Advocate for hospitals’ interests</td>
</tr>
<tr>
<td>Senate ranking member of the Insurance and Real Estate Committee</td>
<td>Experience with health care equity or an advocate for hospitals’ interests</td>
</tr>
<tr>
<td>House ranking member of the Insurance and Real Estate Committee</td>
<td>Advocate for insulin coverage or public health</td>
</tr>
<tr>
<td>DSS Commissioner</td>
<td>Self or designee</td>
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<tr>
<td>Department of Public Health Commissioner</td>
<td>Self or designee</td>
</tr>
<tr>
<td>Office of Policy and Management secretary</td>
<td>Self or designee</td>
</tr>
<tr>
<td>CEO of Community Health Center, Inc., or its legal successor</td>
<td>Two appointees</td>
</tr>
<tr>
<td>CEO of Community Health Center Association of Connecticut, Inc., or its legal successor</td>
<td>Two appointees</td>
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**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)).