PA 20-4, July 2020 Special Session—HB 6003
Emergency Certification

AN ACT CONCERNING DIABETES AND HIGH DEDUCTIBLE HEALTH PLANS

SUMMARY: This act (1) requires pharmacists, in certain emergency situations, to prescribe and dispense to a patient up to a 30-day supply of certain diabetes-related drugs and devices once 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 state's prescription drug monitoring program to include them (§§ 3 & 5). The act requires the Department of Consumer Protection (DCP) commissioner to notify each retail pharmacy about these emergency drugs and devices requirements by October 1, 2020 (§ 4).

Under the act, certain health insurance policies must do the following:

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; and
3. cover emergency diabetes-related drugs and devices prescribed and dispensed by a pharmacist under the act's provisions (§§ 13-14).

The act requires the Department of Social Services (DSS) commissioner to establish, by November 1, 2020, an 11-member working group to determine if she should establish a program to refer people diagnosed with diabetes, regardless of health insurance coverage status, to federally-qualified health centers (FQHCs) and other covered entities for treatment. If the working group recommends doing so, it must also develop the applicable referral criteria. The act requires the DSS commissioner to establish the referral program by January 1, 2022, using the working groups' criteria, except under specified circumstances (§ 1).

PA 20-2, § 1, July Special Session, allows the Department of Public Health (DPH) commissioner to temporarily modify, waive, or suspend certain regulatory requirements as she deems necessary to reduce the spread of COVID-19 and protect the public health. The act limits this authority by only allowing the commissioner to take these actions for the purpose of providing Connecticut residents with telehealth services from out-of-state practitioners (§ 37).

Finally, the act makes technical and conforming changes, including several that conform insurance statutes referencing health savings accounts (HSAs) to federal law by adding references to medical savings accounts (MSAs) and Archer MSAs (§§ 2, 6-12, and 15-36).

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.

§§ 3 & 5 — PHARMACISTS AND EMERGENCY PRESCRIPTIONS

In certain emergency situations, the act 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. For individuals without health insurance coverage or who cannot pay, the act allows but does not require pharmacists to prescribe and dispense these drugs or devices.

The act also establishes a price cap for these prescriptions and expands the prescription drug monitoring program to include them.

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

1. insulin drugs, which are drugs with insulin (including insulin pens) 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 with 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 such things as 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

The act requires pharmacists, when 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 act 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 or 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 or devices in the last 12 months, unless the monitoring program is unavailable or the pharmacist otherwise makes the determination by (a) contacting the pharmacy that filled the patient's most recent prescription, (b) examining another prescription database, or (c) reviewing the patient's most recent prescription for diabetes-related drugs or devices or a prescription label with information on the most recent prescription; and
4. within 72 hours of dispensing the emergency supply, the pharmacist or his

or her representative notifies the practitioner who most recently prescribed the diabetes-related drug or device.

The act correspondingly expands the prescription drug monitoring program to require each pharmacy, nonresident pharmacy (i.e., out of state pharmacy that ships drugs or devices into the state based on a prescription), 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 act requires these entities to report the information at least daily 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 electronic records, in a format the DCP commissioner approves.

Price Cap

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

1. the coinsurance, copayment, deductible, or other out-of-pocket expense required by the patient's health insurance (which in certain instances the act limits, see §§ 13 & 14 below) or
2. for patients without insurance, the usual customary charge to the public for these items (i.e., a charge for a particular prescription not covered by Medicaid, excluding charges made to third-party payors and special discounts offered to individuals.)

Patient Document and Payment Requirements

The act allows a pharmacist to 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 he or she cannot timely obtain the diabetes-related drugs or devices without suffering significant physical harm; and
6. payment, subject to the price cap described above.

Referral Requirement

If a patient who requests diabetes-related drugs or devices does not have insurance coverage or is concerned that his or her net cost for the drugs or devices is unaffordable, the pharmacists must refer him or her to a FQHC.

§§ 13 & 14 — DIABETES HEALTH INSURANCE COVERAGE AND OUT-OF-POCKET LIMITS

Required Coverage

Prior law required certain health insurance policies (see "Applicability," 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 act 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 testing and screening such as hemoglobin A1c testing and retinopathy screening;
2. prescribed insulin and "non-insulin drugs" (i.e., FDA-approved drugs to treat diabetes without insulin such as glucagon drugs and glucose tablets and gels);
3. emergency insulin and glucagon drugs prescribed and dispensed by a pharmacist, up to once per policy year (see § 3 above);
4. diabetes devices in accordance with the insured's treatment plan, including emergency devices prescribed and dispensed by a pharmacist, up to once per policy year (see § 3 above); and
5. diabetic ketoacidosis devices in accordance with the insured's treatment plan, including emergency devices prescribed and dispensed by a pharmacist, up to once per policy year (see § 3 above).

Out-of-Pocket Limits

For the health insurance policies described below, the act limits an insured's 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.

Additionally, it limits out-of-pocket expenses to $25 for emergency insulin and glucagon drugs, and to $100 for emergency diabetes devices and diabetic ketoacidosis devices, prescribed and dispensed by a pharmacist. The limits apply to each 30-day supply, once per policy year (see § 3 above).

Applicability

The act's coverage 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 act's out-of-pocket cost provisions also apply to these policies, but with respect to high deductible health plans (HDHPs), they apply only 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 or Archer MSAs and use the accounts for qualified medical expenses. To maintain the accounts' tax advantaged status, the associated HDHPs cannot limit deductibles except for certain preventive care items, which may include certain insulin and diabetes supplies.)

By law, these same policies, as well as those covering accidents only and group policies covering limited benefits, must cover hypodermic needles and syringes. The act's expanded coverage and out-of-pocket cost provisions apply regardless of this existing requirement.

§ 1 — DIABETES REFERRAL PROGRAM WORKING GROUP

The act requires the DSS commissioner to establish a working group by November 1, 2020, to determine whether she should establish a program to refer people diagnosed with diabetes, regardless of their health coverage status, to FQHCs and other covered entities for treatment (see BACKGROUND).

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. the medically necessary care for that condition, and
3. any other relevant factors.

The act authorizes the commissioner to adopt regulations to establish the working group and the referral program.

Working Group Membership

Under the act, the working group consists of 11 members with expertise in specified areas, as described in the table below. Appointments must be made by November 1, 2020, and the appointing authority fills any vacancy.

Working Group Membership

Appointing Authority	*Appointee(s)*
Senate chairperson of the Insurance and Real Estate Committee	Insulin coverage or public health advocate
House chairperson of the Insurance and Real Estate Committee	Advocate for hospitals' interests
Senate ranking member of the Insurance and Real Estate Committee	Experience with health care equity or is an advocate for hospitals' interests

Appointing Authority	*Appointee(s)*
House ranking member of the Insurance and Real Estate Committee	Insulin coverage or public health advocate
DSS Commissioner	Self or designee
DPH Commissioner	Self or designee
Office of Policy and Management secretary	Self or designee
CEO of Community Health Center, Inc., or its legal successor	Two members
CEO of Community Health Center Association of Connecticut, Inc., or its legal successor	Two members

Chairperson, Meetings, and Voting

The act 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 constitute a quorum for transacting business, and a majority vote of members present is required for action.

Working Group Recommendations and Duration

Under the act, 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 when it submits the information or May 1, 2021, whichever is earlier.

Working Group Reestablishment

After the original working group terminates as required, the act allows the DSS commissioner to reestablish the group so that it can develop new criteria for recommending an FQHC or other covered entity to someone. In reestablishing the group, 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, to be held within 90 days after its reestablishment.

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

§ 1 — REFERRAL PROGRAM ESTABLISHMENT

The act requires the DSS commissioner to establish the referral program using the criteria developed above by January 1, 2022, unless the:

1. working group recommends not establishing it;

2. commissioner finds the program goals could be better accomplished by applying for a Medicaid research and demonstration waiver under federal law, in which case she must apply to the Centers for Medicare and Medicaid Services for one and, upon approval, establish the referral program in accordance with the waiver requirements and applicable law; or
3. DSS general counsel finds federal law barriers to successfully establishing and implementing the program.

In the second and third instances above, the commissioner must submit these findings to the Insurance and Real Estate Committee by October 1, 2021.

Program Website

If the commissioner establishes the referral program, she must also create 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, regardless of their health coverage status.

The website must enable diabetics to disclose to DSS the following information:

1. name, age, and home address;
2. contact information, including email address or phone number;
3. income and race;
4. diabetes diagnosis; and
5. prescribed outpatient diabetes drugs.

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

1. name, business address, and phone number of any FQHC or other covered entity that DSS recommends to the individual and
2. general health care information provided by the recommended FQHC or other covered entity, 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 individual's name, contact information, and a statement that DSS recommended the entity to the individual.

Provider Entity Responsibilities

Under the act, each FQHC or other covered entity must make a good faith effort to schedule an appointment for a person within 30 days after receiving his or her name, contact information, and recommendation from DSS.

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)).