CHAPTER 133
FORMERLY
SENATE SUBSTITUTE NO. 1

FOR

SENATE BILL NO. 35

AN ACT TO AMEND TITLE 18 OF THE DELAWARE CODE RELATING TO SPECIALTY TIER PRESCRIPTION DRUG COVERAGE.

WHEREAS, as the costs of specialty drugs increase, the practice of health plans creating a cost-sharing mechanism known as specialty-tiers has begun to occur, greatly increasing the potential financial burden on patients; and

WHEREAS, the Delaware Health Care Commission completed a study of the effect of specialty-tiers in Delaware summarizing the issue of specialty tier pricing, the impact on patient access and care when specialty-tier pricing is used; and

WHEREAS, the increased cost-sharing associated with specialty tiers drugs potentially presents a significant financial strain on seriously ill Delawareans and their families facing serious health conditions such as: hemophilia, human immunodeficiency virus (HIV), hepatitis, multiple sclerosis, lupus, some cancers, rheumatoid arthritis, and others.

NOW THEREFORE:

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 33 Title 18 of the Delaware Code by making insertions as shown by underlining and deletions as shown by strike through as follows:

§ 3364. Specialty Tier Prescription ~~Study~~ Coverage.

~~The Delaware Healthcare Commission shall conduct a study for specialty tier prescription drugs to determine the impact on access and patient care. The Delaware Healthcare Commission shall submit a report to the General Assemble summarizing this impact by March 15, 2012.~~

(a) Unless otherwise specifically provided, the definitions herein apply throughout this section.

"Class of drugs" means a group of medications having similar actions designed to treat a particular disease

process.

"Coinsurance" means a cost-sharing amount set as a percentage of the total cost of the drug.

"Commissioner" means the Insurance Commissioner of this State.

"Copayment" means a cost-sharing amount set as a dollar value.

"Non-preferred drug" means a Specialty drug formulary classification for certain Specialty drugs deemed non-preferred and therefore subject to limits on eligibility for coverage or to higher cost-sharing amounts than preferred Specialty drugs.

"Preferred drug" means a Specialty drug formulary classification for certain Specialty drugs deemed preferred and therefore not subject to limits on eligibility for coverage or not subject to higher cost-sharing amounts than non-preferred Specialty drugs.

"Specialty drug" means a prescription drug that:

(1) is prescribed for a person with: (a) a complex or chronic medical condition, defined as a physical, behavioral, or developmental condition that may have no known cure and/or is progressive and/or can be debilitating or fatal if left untreated or under-treated, such as multiple sclerosis, hepatitis C, and rheumatoid arthritis; or (b) a rare medical condition, defined as any disease or condition that affects fewer than 200,000 persons in the United States, or about 1 in 1,500 people, such as cystic fibrosis, hemophilia, and multiple myeloma; and

(2) The total monthly cost of the prescription is $600 or more; and

(3) The drug is not stocked at a majority of retail pharmacies; and

(4) The drug has one or more of the following characteristics:

(a) It is an oral, injectable, or infusible drug product.

(b) It has unique storage or shipment requirements, such as refrigeration.

(c) Patients receiving the drug require education and support beyond traditional dispensing activities.

"Specialty drug formulary" means a specialty drug benefit design that distinguishes for purposes of eligibility for coverage or for cost sharing between Preferred drugs and Non-Preferred drugs.

"Specialty drug tier" means a tier of cost sharing designed for Specialty drugs that imposes a cost-sharing obligation for Specialty drugs that exceeds the amount for non-Specialty drugs and such a cost sharing amount is based on a coinsurance.

(b) A health plan that provides coverage for prescription drugs and utilizes a Specialty drug tier shall ensure that any required copayment or coinsurance applicable to specialty drugs on a specialty tier does not exceed $150 per month for each specialty drug up to a 30-day supply of any single drug.

(c) A health plan that provides coverage for prescription drugs and utilizes a Specialty drug formulary shall implement an exceptions process that allows enrollees to request an exception to the formulary. Under such an exception, a non-formulary specialty drug could be deemed covered under the formulary if the prescribing physician determines that the formulary drug for treatment of the same condition either would not be as effective for the individual, or would have adverse effects for the individual, or both. In the event an enrollee is denied an exception, such denial shall be considered an adverse event and will be subject to the health plan internal review process set forth in 18 Del. C. § 332 and the state external review process set forth in 18 Del. C. § 6416.

(d) A health plan that provides coverage for prescription drugs shall be prohibited from placing all drugs in a given class of drugs on a specialty tier.

(e) Nothing in this section shall be construed to require a health plan to:

(1) provide coverage for any additional drugs not otherwise required by law;

(2) implement specific utilization management techniques, such as prior authorization or step therapy; or

(3) cease utilization of tiered cost-sharing structures, including those strategies used to incent use of preventive services, disease management, and low-cost treatment options.

(f) Nothing in this section shall be construed to require a pharmacist to substitute a drug without the consent of the prescribing physician.

(g) Nothing contained in any other provision of Delaware law or regulation shall preclude a health plan or other entity subject to this chapter from requiring specialty drugs to be obtained through a designated pharmacy or other source of such drugs.

Section 2. Amend Chapter 35 Title 18 of the Delaware Code by making insertions as shown by underlining and deletions as shown by strike through as follows:

§ 3580. Specialty Tier Prescription Coverage.

(a) Unless otherwise specifically provided, the definitions herein apply throughout this section.

"Class of drugs" means a group of medications having similar actions designed to treat a particular disease

process.

"Coinsurance" means a cost-sharing amount set as a percentage of the total cost of the drug.

"Commissioner" means the Insurance Commissioner of this State.

"Copayment" means a cost-sharing amount set as a dollar value.

"Non-preferred drug" means a Specialty drug formulary classification for certain Specialty drugs deemed non-preferred and therefore subject to limits on eligibility for coverage or to higher cost-sharing amounts than preferred Specialty drugs.

"Preferred drug" means a Specialty drug formulary classification for certain Specialty drugs deemed preferred and therefore not subject to limits on eligibility for coverage or not subject to higher cost-sharing amounts than non-preferred Specialty drugs.

"Specialty drug" means a prescription drug that:

(1) is prescribed for a person with: (a) a complex or chronic medical condition, defined as a physical, behavioral, or developmental condition that may have no known cure and/or is progressive and/or can be debilitating or fatal if left untreated or under-treated, such as multiple sclerosis, hepatitis C, and rheumatoid arthritis; or (b) a rare medical condition, defined as any disease or condition that affects fewer than 200,000 persons in the United States, or about 1 in 1,500 people, such as cystic fibrosis, hemophilia, and multiple myeloma; and

(2) The total monthly cost of the prescription is $600 or more; and

(3) The drug is not stocked at a majority of retail pharmacies; and

(4) The drug has one or more of the following characteristics:

(a) It is an oral, injectable, or infusible drug product.

(b) It has unique storage or shipment requirements, such as refrigeration.

(c) Patients receiving the drug require education and support beyond traditional dispensing activities.

"Specialty drug formulary" means a specialty drug benefit design that distinguishes for purposes of eligibility for coverage or for cost sharing between Preferred drugs and Non-Preferred drugs.

"Specialty drug tier" means a tier of cost sharing designed for Specialty drugs that imposes a cost-sharing obligation for Specialty drugs that exceeds the amount for non-Specialty drugs and such a cost sharing amount is based on a coinsurance.

(b) A health plan that provides coverage for prescription drugs and utilizes a Specialty drug tier shall ensure that any required copayment or coinsurance applicable to specialty drugs on a specialty tier does not exceed $150 per month for each specialty drug up to a 30-day supply of any single drug.

(c) A health plan that provides coverage for prescription drugs and utilizes a Specialty drug formulary shall implement an exceptions process that allows enrollees to request an exception to the formulary. Under such an exception, a non-formulary specialty drug could be deemed covered under the formulary if the prescribing physician determines that the formulary drug for treatment of the same condition either would not be as effective for the individual, or would have adverse effects for the individual, or both. In the event an enrollee is denied an exception, such denial shall be considered an adverse event and will be subject to the health plan internal review process set forth in 18 Del. C. § 332 and the state external review process set forth in 18 Del. C. § 6416.

(d) A health plan that provides coverage for prescription drugs shall be prohibited from placing all drugs in a given class of drugs on a specialty tier.

(e) Nothing in this section shall be construed to require a health plan to:

(1) provide coverage for any additional drugs not otherwise required by law;

(2) implement specific utilization management techniques, such as prior authorization or step therapy; or

(3) cease utilization of tiered cost-sharing structures, including those strategies used to incent use of preventive services, disease management, and low-cost treatment options.

(f) Nothing in this section shall be construed to require a pharmacist to substitute a drug without the consent of the prescribing physician.

(g) Nothing contained in any other provision of Delaware law or regulation shall preclude a health plan or other entity subject to this chapter from requiring specialty drugs to be obtained through a designated pharmacy or other source of such drugs.

Section 3. This act shall take effect and be in force from and after January 1, 2014. The provisions above shall apply to a health plan contract issued, amended, or renewed on or after January 1, 2014.

Section 4. The Commissioner shall have the authority to promulgate regulations regarding the enforcement processes for this act.

Approved July 23, 2013