TO: All Councilmembers

FROM: Chairman Phil Mendelson
      Committee of the Whole

DATE: December 6, 2016


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I. COMMITTEE RECOMMENDATION

The Committee of the Whole reports favorably on Bill 21-32, the “Specialty Drug Copayment Limitation Amendment Act of 2016,” and adopts the report on this measure as approved by the Committee of the Whole Subcommittee on Consumer Affairs. The Committee Print makes technical changes to the measure as approved by the Subcommittee on Consumer Affairs, and recommends adoption of Bill 21-32, as amended, by the Council.

II. COMMITTEE REASONING AND SECTION-BY-SECTION ANALYSIS

The Committee of the Whole makes several technical amendments to the Subcommittee on Consumer Affairs Print to Bill 21-32. The most substantive of these is a minor amendment to section 3(a)(2) to align the Consumer Price Index language with standard language provided by the Bureau of Labor Statistics.

III. COMMITTEE ACTION

On December 6, 2016, the Committee met to consider Bill 21-32, the “Specialty Drug Copayment Limitation Act of 2016.” The meeting was called to order at 11:55 a.m., and Bill 21-32 was item IV-A on the agenda. After ascertaining a quorum (Chairman Mendelson and Councilmembers Alexander, Allen, Bonds, Cheh, Evans, Grosso, May, McDuffie, Nadeau,
Silverman, Todd, and White present), Chairman Mendelson moved *en bloc* the report and the print with leave for staff to make technical and conforming changes. After an opportunity for discussion, the vote on both the report and the print was unanimous (Chairman Mendelson and Councilmembers Alexander, Allen, Bonds, Cheh, Evans, Grosso, May, McDuffie, Nadeau, Silverman, Todd, and White voting aye). The meeting adjourned at 4:38 p.m.

IV. ATTACHMENTS

2. Committee Print for Bill 21-32.
TO: All Councilmembers

FROM: Councilmember Brianne K. Nadeau
Chairperson, Subcommittee on Consumer Affairs

DATE: November 16, 2016


The Subcommittee on Consumer Affairs, to which Bill 21-0032, the “Specialty Drug Copayment Limitation Act of 2015” was referred, reports favorably thereon with amendments, and recommends approval by the Council.

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I. BACKGROUND AND NEED

On January 20, 2015, Bill 21-0032, the “Specialty Drug Copayment Limitation Act of 2015” was introduced by Councilmembers Cheh and Bonds. Bill 20-0032 would set a price cap of $150 per month on specialty tier drug copayments and coinsurance plans, to be adjusted annually according to the Consumer Price Index for the Baltimore-Washington statistical area promulgated by the U.S. Department of Labor Bureau of Labor Statistics. Capping patients’ payments for specialty drugs does not require insurance companies to change non-price-related practices such as drug coverage and designation of preferred pharmacists.

High Patient Copayment and Coinsurance Costs

In recent years, patients have faced increasingly high copayments and coinsurance rates when paying for their prescription drugs. A copayment is a fixed amount that a patient pays after having paid his or her deductible.1 Alternatively, coinsurance is a proportional rate that a patient

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pays after having paid his or her deductible. Naturally, different plans involve different rates of payment and coverage, and insurance companies' inclination to use percentage-based rates rather than dollar-amounts increases with the cost of medication. Generally, copayments are between $0 and $50. However, some patients have reported having copayments or coinsurance costs which are much higher, and these high costs have not been limited to simply the most expensive plans. In acknowledgement of the effect that such high medical costs can have on families' finances, this legislation seeks to set a limit on what patients can expect to have to pay for medications, specifically the more expensive specialty drugs.

**Other Jurisdictions' Efforts to Address High Patient Costs**

Many states have enacted or considered legislation to address why patient copayments and coinsurance rates are so high. Jurisdictions broadly agree that there is a problem. Where there is great disagreement, however, is on how to address the problem. Some states have enacted or considered legislation like B21-0032 imposing a price cap on copayments and coinsurance rates for specialty drugs. Other states have enacted or considered transparency legislation.

Legislation targeting specialty tier drugs has fallen into several categories. Delaware, Louisiana, and Maryland passed legislation imposing out-of-pocket price caps on specialty drugs similar to B21-0032. Maine and Vermont passed similar legislation with annual out-of-pocket price caps. New York has prohibited specialty tiers entirely. California, Colorado, Florida, and Montana have regulatory out-of-pocket price caps. Further, Alaska, Arkansas, Illinois, New Mexico, Oklahoma, and Virginia require notification of changes in insurance formularies.

Further, many states have chosen to pursue drug transparency requirements for insurance companies, drug manufacturers, or pharmacy benefits managers. For example, bills introduced in California would require drug manufacturers to notify various parties when the wholesale acquisition cost of a drug was set to increase by 10% or more and to file cost reports for certain qualifying drugs. Alternatively, South Dakota enacted a transparency bill requiring insurance companies to provide information regarding plan information, lists of providers, and information on prior authorizations. Finally, Maine enacted legislation requiring pharmacy benefits managers to make certain disclosures regarding pricing. Despite receiving testimony in favor of adding a transparency requirement for drug manufacturers, the Subcommittee on Consumer Affairs declines to add such language but may pursue alternative, separate legislation in the future.

**Changes to the Bill as Introduced**

Input from healthcare organizations and from the Executive prompted changes to the bill as introduced, specifically by adjusting the definition of "specialty drug", conforming the language of "specialty tier" to that in the other definitions, adding a cap for 90-day prescriptions, and setting an effectiveness date. As introduced, the definition of "specialty drug" included four requirements,

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3 See Copayments and Coinsurance for Prescription Drugs, National Conference of State Legislatures, fig. 9, Share of Plans Using Copayments and Coinsurance for Generic, Preferred, Nonpreferred, and Specialty Drugs, 2015 (2015).
4 See testimony of Dr. Angus Worthing, M.D., Medical Society of the District of Columbia, October 28, 2015.
5 See testimony of Stephen Taylor, Acting Commissioner, Department of Insurance, Securities, and Banking, October 28, 2015.
7 Cal. S. 1010, 2016 Leg. (Cal. 2016); Cal. A. 463, 2015 Leg. (Cal. 2015).
9 Me. S.B. 647, 127th Leg., 2015 Sess. (Me. 2015).
including that a particular drug not be available at a majority of pharmacies in the United States. Determining the exact availability of a drug would be exceedingly challenging while adding minimal assistance to patients. Accordingly, the requirement has been removed, and “specialty drug” will include only three requirements. Additionally, the original definition of “specialty tier” makes reference to non-preferred drugs rather than non-specialty drugs. The new language makes this change. Further, the bill as introduced included only a $150 cap for a 30-day supply of drugs. Feedback from the Executive indicated that 90-day prescriptions are common and are usually less than simply three times the 30-day cost. The bill has accordingly been changed to add a $300 cap for a 90-day supply. Finally, both the insurance industry and the Executive requested an effective date of January 1, 2017, to permit ample time to create and review insurance plans in compliance with B21-0032. At the time this date was proposed, an effective date of January 1, 2017, would have been over a year away. To compensate for the elapsed time between the public hearing in October, 2015, and the markup in November, 2016, the effectiveness date has been adjusted to January 1, 2018, to provide a comparable period of time to create and approve insurance plans compliant with the legislation.

Conclusion
This legislation seeks to limit the amount that patients pay for the most expensive prescription drugs. By setting a cap of $150 for copayments and coinsurance on specialty drugs, patients can better predict their medical costs and plan their other finances accordingly. The limit of $150 is in general accord with legislation passed by other jurisdictions, including neighboring and nearby states. Accordingly, the Subcommittee anticipates that passing B21-0032 will appropriately balance the health access needs of patients and the legitimate business needs of the insurance industry.

II. LEGISLATIVE CHRONOLOGY


January 30, 2015 Notice of Intent to Act on Bill 21-0032 is published in the District of Columbia Register.

September 11, 2015 Notice of a Public Hearing on Bill 21-0032 is published in the District of Columbia Register.

October 28, 2015 The Committee on Business, Consumer, and Regulatory Affairs holds a public hearing on Bill 21-0032.


November 16, 2016 The Subcommittee on Consumer Affairs marks-up Bill 21-0032.
III. POSITION OF THE EXECUTIVE

Acting Commissioner Taylor testified on behalf of the Executive in support of the underlying goals of Bill 21-0032. A more complete summary of such testimony is provided below.

IV. COMMENTS OF ADVISORY NEIGHBORHOOD COMMISSIONS

The Committee received no testimony or comments from any Advisory Neighborhood Commission.

V. SUMMARY OF TESTIMONY

The Committee of the Whole held a public hearing on Bill 21-0032 on Wednesday, October 28, 2015. The testimony summarized below is from that hearing. Copies of written testimony are attached to this report.

Elizabeth Glidden, Patient Navigator, South Atlantic Division, American Cancer Society, Inc., testified about her organization’s experience helping cancer patients. Modern cancer treatments are expensive, and patients covered by private insurance plans face many financial barriers to accessing available treatments. She and her organization believe that passing this bill into law will help patients.

Dr. Angus Worthing, M.D., Medical Society of the District of Columbia, testified that patients would benefit from having a cap on copayments or coinsurance. Until recently, the cost of such payments had been between $0 and $50, which did not pose a serious barrier to treatment, but recent breakthroughs in medicine have driven insurance costs and copayments higher. Placing a cap on patient payments would ensure continued access to critical, new medication.

Jessica Gilbart, Director of Public Policy, The Immune Deficiency Foundation, testified that the high cost of specialty drugs may lead patients to forego treatment, which increases the cost of healthcare when the patient reenters the system. Placing a cap on copayments and coinsurance would bring stability and predictability to patients’ drug payments and increase the likelihood that treatments are completed in the proper manner.

Bonita Pennino, MS, Maryland & DC Government Relations Director, American Cancer Society Cancer Action Network, Inc., testified that many patients, especially those seeking new, expensive cancer treatments, are delaying healthcare decisions based on the high cost they will have to pay. Setting a cap on copayments and coinsurance will improve the lives of District patients and fill a crucial gap in federal regulation of healthcare costs.

Lauren Werling, National Patient Advocate Foundation, testified about her family’s personal experience with high drug costs. After her mother was diagnosed with cancer, the monthly prescription cost was $6,000 each month, and because the treatment was in pill form, it
did not qualify for the $8,000 annual deductible cap. As a result of these high prices, the family was forced to drain their savings and eventually had their home foreclosed.

*Kathy Radford, Children’s National Health System, Director of Clinical Resources Management,* testified that many patients have difficulty making copayments and coinsurance payments for certain drugs and that placing a cap on the amount insurance companies can charge would improve patients’ access to important medicine.

*Mark Guimond, Arthritis Foundation,* testified that, in contrast to the previous insurance method of charging fixed-dollar amounts for patient copayments, insurance companies are now charging percentage rates for very expensive specialty medications. These higher costs act as a barrier to treatment for patients who cannot afford the high copayments.  

*Donna Ginn Kaufman, East Coast Field Director, National Patient Advocate Foundation,* testified that high copayment and coinsurance costs, set as a percentage of the total cost of medication rather than at a fixed dollar amount, have imposed a serious burden on low-income patients. Sixteen states have enacted legislation seeking to address this problem. Delaware, Louisiana, and Maryland have placed monthly caps on coinsurance or copayment costs. Maine and Vermont have set annual caps on copayment or coinsurance costs. New York has prohibited specialty tiering. California, Colorado, Florida, and Montana have regulatory limits on patient costs. Alaska, Arkansas, Illinois, New Mexico, Oklahoma, and Virginia require notification of changes to insurance formulas. Accordingly, this legislation will ensure patients can remain on their healthcare treatment plans without having to sacrifice other obligations.

*Laurie Kuiper, Senior Director, Government Relations, Kaiser Permanente,* testified in opposition to the legislation and provided recommended changes to the legislation. Specifically, the changes would refine the definition of “specialty drug” to better reflect the process of providing medications. These changes would (1) remove the requirement that drugs not be available at a majority of pharmacies in the United States because such availability would be burdensome to determine while having only minimal effect on patient access and (2) remove the language limiting the forms of administering medicine because it was piecemeal. Additionally, the changes would (1) strike language relating to insurance companies’ formulary and tier management because it allows the companies to lower costs in the long run by preferring, when available, generic medications over name brands and (2) strike redundant language permitting appeal of unfavorable tiering decisions. Further, the changes would create a new, substantive section requiring drug manufacturers to make annual, audited financial reports detailing certain expenses and programs to make and market drugs. Finally, the proposal would move the bill’s implementation date to January 1, 2017, in order to allow insurance companies to finish their already-approved 2016 plans.

*Alan Friedman, Manager, Regulatory, Quality and Professional Affairs, Kaiser Permanente,* testified in opposition to the legislation.

*Geralyn Trujillo, MMP, Regional Director, Mid-Atlantic/Mideast Region State Affairs, America’s Health Insurance Plans,*
Kevin Wrege, Esq., D.C. Association of Health Plans, testified in favor of the changes proposed by Kaiser and America’s Health Insurance Plans. Under the current marketing system, the drug manufacturers are required to provide relatively little information while retaining tight control over the product. Accordingly, improving the transparency by requiring annual, audited financial reports would bring such clarity.

Brian Hujdich, HealthHIV, testified that HIV/AIDS patients in the District rely on access to affordable medications simply to stay alive. Many patients are particularly vulnerable to major upticks in the price of medications, and the Affordable Care Act’s impact has been limited by the difficulty of using the system. Passing this bill would provide a more straightforward solution to high drug prices.

Kelly Fitzgerald, Patient Services, Inc., testified that the high cost of prescriptions poses a heavy burden on the finances of many District residents. Further, nearby states have either enacted or at least considered similar legislation, so the impact on the insurance industry would not likely be unbearable.

Stephen Taylor, Acting Commissioner, Department of Insurance, Securities, and Banking, testified that the Executive supports fundamental goal of B21-0032, ensuring that patients do not pay high copayment or coinsurance prices. To that effect, acting Commissioner Taylor highlighted seven points of concern, areas for improvement, and general observations. Firstly, the proposed cap on specialty drug copayments would not impose a completely new requirement for insurance companies as many states have implemented similar laws to avoid high costs. However, such legislation is relatively new, making comparison of successful programs outside the District more difficult. Secondly, current insurance practices for specialty drugs are largely in line with the $150 cap proposed by B21-0032. Of the specialty drug plans offered on DC Health Link, most of the plans using copayments set the rate at $150 with some at $200, and the plans using coinsurance set a range of 20–40% but often with a specific dollar-cap for the patient. However, specialty tier drugs were not the only medications with high costs for patients, with some non-specialty drugs having copayments in the $200–300 range. Thirdly, the federal Patient Protection and Affordable Care Act passed in 2010 and implemented in 2014 sets a cap on out-of-pocket costs. Plans offered on the DC Health Link in 2015 included a cap of $6,600 for individuals and $13,200 for families, after which point the insurance company would cover 100% of the remaining costs. However, such cap does not include premiums, out-of-network costs, or non-essential health benefits. Fourthly, the bill as introduced does not recognize that patients often receive a 90-day prescription with a price less than three times that of a 30-day supply. Adding a $300 cap for a 90-day prescription while keeping the $150 cap for a 30-day prescription would bring the bill into line with common practice. Fifthly, the requirement that a drug not be available at a majority of retail pharmacies in order to qualify as a “specialty drug” is both vague and difficult to implement. The definition references “retail pharmacies” but does not define which pharmacies are included in such category, i.e., hospital pharmacies and mail-order pharmacies versus large chain pharmacies. Further, ascertaining the inventory of such pharmacies nationwide may be immeasurable. Accordingly, the Department recommends changing the “and” at line 102 to an “or”, which would require a drug to meet only one of the elements of a specialty drug rather than all four. Sixthly, the bill’s language is unclear whether it includes Medicaid plans, which cover one in three District patients. Finally, a specific implementation date should be set for the first of
the year in order to allow insurance companies time to create and the Department time to approve plans that comply with B21-0032. The date proposed in the testimony was January 1, 2017.

VI. IMPACT ON EXISTING LAW

Bill 21-0032 is a standalone bill and does not amend existing District law except insofar as it sets new requirements not previously provided for by law.

VII. FISCAL IMPACT

The attached November 14, 2016, fiscal impact statement from the District’s Chief Financial Officer states that funds are sufficient in the FY 2017 through FY 2020 budget and financial plan to implement the bill.

VIII. SECTION-BY-SECTION ANALYSIS

Section 1  Short title.

Section 2  Creates a list of definitions.

Paragraph (1) Defines “class of drugs”.

Paragraph (2) Defines “coinsurance”.

Paragraph (3) Defines “copayment”.

Paragraph (4) Defines “health benefit plan”, including its exclusions.

Paragraph (5) Defines “health insurer”.

Paragraph (6) Defines “member”.

Paragraph (7) Defines “member representative”.

Paragraph (8) Defines “non-preferred drug”.

Paragraph (9) Defines “preferred drug”.

Paragraph (10) Defines “specialty drug”.

Paragraph (11) Defines “specialty tier”.

Paragraph (12) Defines “step therapy”.
**Paragraph (13)** Defines “tiered formulary”.

**Section 3** Sets a copayment and coinsurance cap.

**Paragraph (a)(1)** Prevents insurance companies from setting copayment or coinsurance costs for specialty drugs at more than $150 for a 30-day supply or $300 for a 90-day supply.

**Paragraph (a)(2)** Adjusts the cap set in paragraph (3)(a)(1) according to inflation in the Washington-Baltimore statistical area.

**Subsection (b)** States that the bill does not require insurance companies to cover drugs not previously required by law, implement specific utilization management techniques, or cease the use of tiered cost-sharing structures.

**Subsection (c)** States that the bill does not require pharmacists to substitute drugs without first obtaining the consent of the prescribing physician.

**Subsection (d)** States that the bill does not prevent insurance companies from requiring specialty drugs be obtained from a favored pharmacy.

**Section 4** States the Fiscal Impact of Bill 21-0032.

**Section 5** Sets an effective date of January 1, 2018.

**IX. SUBCOMMITTEE ACTION**

On November 16, 2016, the Committee met to consider Bill 21-0032, the “Specialty Drug Copayment Limitation Act of 2015.” The meeting was called to order at 12:07 p.m., and Bill 21-0032 was item III-1 on the agenda. After ascertaining a quorum (Chairperson Nadeau and Councilmembers Allen, Silverman, Todd, and White present), Chairperson Nadeau moved the print with leave for staff to make technical and conforming changes. Councilmember Allen thanked the subcommittee for moving to address the high cost of prescription drugs and shared his family’s own experience with high prescription costs. Councilmember Todd echoed Councilmember Allen’s sentiments and emphasized that ensuring affordable medications, particularly for elderly District residents, should be a priority. After an opportunity for additional discussion, the vote on the print was unanimous (Chairperson Nadeau and Councilmembers Allen, Silverman, Todd, and White present).

The Chairman then moved the report with leave for staff to make technical, conforming, and editorial changes. After an opportunity for discussion, the vote on the report was unanimous (Chairperson Nadeau and Councilmembers Allen, Silverman, Todd, and White present). The meeting adjourned at 12:55 p.m.
X. ATTACHMENTS

1. Bill 21-0032 as introduced.
2. Written Testimony.
4. Legal Sufficiency Determination for Bill 21-0032.
5. Subcommittee Print for Bill 21-0032.
A BILL

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To impose a limit on the amount that a person must pay in copayment or coinsurance through a health benefit plan for a prescription for a specialty drug.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the “Specialty Drug Copayment Limitation Act of 2016”.

Sec. 2. Definitions.

For the purposes of this act, the term:

(1) "Class of drugs" means a group of medications having similar actions designed to treat a particular disease process.

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

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

(4)(A) "Health benefit plan" means a policy, contract, certificate, or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

(B) The term "health benefit plan" does not include:
(i) Coverage only for accident or disability income insurance, or any combination thereof;

(ii) Liability insurance, including general liability insurance and automobile liability insurance;

(iii) Coverage issued as a supplement to liability insurance;

(iv) Workers' compensation or similar insurance;

(v) Automobile medical payment insurance;

(vi) Credit-only insurance;

(vii) Coverage for on-site medical clinics; or

(viii) Other similar insurance coverage, specified in federal regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996, approved August 21, 1996 (110 Stat. 1936; scattered sections of the United States Code) ("HIPAA"), under which benefits for health care services are secondary or incidental to other insurance benefits.

(C) The term "health benefit plan" does not include the following benefits if they are provided under a separate policy, certificate of insurance, or contract of insurance, or are otherwise not an integral part of the plan:

(i) Limited scope dental or vision benefits;

(ii) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof; or

(iii) Other similar, limited benefits specified in federal regulations issued pursuant to HIPAA.

(D) The term "health benefit plan" does not include the following benefits
if the benefits are provided under a separate policy, certificate of insurance, or contract of
insurance, and there is no coordination between the provision of the benefits and any exclusion
of benefits under any group health plan maintained by the same health insurer, and the benefits
are paid with respect to an event without regard to whether benefits are provided with respect to
such an event under any group health plan maintained by the same health insurer:

(i) Coverage only for a specified disease or illness; or

(ii) Hospital indemnity or other fixed indemnity insurance.

(E) The term "health benefit plan" does not include the following if
offered as a separate policy, certificate of insurance, or contract of insurance:

(i) A Medicare supplemental policy as defined in section
1882(g)(1) of the Social Security Act, approved June 9, 1980 (94 Stat. 476; 42 U.S.C. §
1395ss(g)(1));

(ii) Coverage supplemental to the coverage provided under An
ACT to amend titles 10, 14, and 32, United States Code, to codify recent military law, and to
improve the Code, approved September 2, 1958 (72 Stat. 1437; 10 U.S.C. § 1071 et seq.); or

(iii) Similar supplemental coverage provided under a group health
plan.

(5) "Health insurer" means any person that provides one or more health benefit
plans or insurance in the District of Columbia, including an insurer, a hospital and medical
services corporation, a fraternal benefit society, a health maintenance organization, a multiple
employer welfare arrangement, or any other person providing a plan of health insurance subject
to the authority of the Commissioner of the Department of Insurance, Securities and Banking.

(6) "Member" means an individual who is enrolled in a health benefit plan.
(7) “Member representative” means a:

(A) Person acting on behalf of a member with the member’s consent;

(B) Person authorized by law to provide substituted consent for a member;

(C) Family member of the member;

(D) Member’s treating health care professional when the member is unable to provide consent; or

(E) In the case of a request regarding an emergency or urgent medical condition, a health-care professional with knowledge of the member’s medical condition.

(8) “Non-preferred drug” means a specialty drug formulary classification for certain specialty drugs that are subject to limits on eligibility for coverage or to higher cost-sharing amounts than preferred specialty drugs.

(9) “Preferred drug” means a specialty drug formulary classification for certain specialty drugs that are not subject to limits on eligibility for coverage or to higher cost-sharing amounts than a non-preferred drug.

(10) “Specialty drug” means a prescription drug that:

(A) Is prescribed for a person with:

(i) A physical, behavioral, or developmental condition that may have no known cure, is progressive, or can be debilitating or fatal if left untreated or undertreated, such as multiple sclerosis, hepatitis C, or rheumatoid arthritis; or
(ii) A disease or condition that affects fewer than 200,000 persons in the United States or approximately one in 1,500 persons worldwide, such as cystic fibrosis, hemophilia, or multiple myeloma;

(B) Has a total monthly prescription cost of $600 or more; and

(C) Has one or more of the following characteristics:

(i) Is an oral, injectable, or infusible drug product or a drug product that is delivered topically, through inhalation, implantation or transmucosally;

(ii) Requires unique storage or shipment, such as refrigeration; or

(iii) Requires patient education and support beyond traditional dispensing activities.

(11) “Specialty tier” means a tier of cost sharing designed for select specialty drugs that imposes a cost-sharing obligation that is based on a coinsurance or copayment and exceeds that amount for non-specialty drugs.

(12) “Step therapy” means a protocol established by a health insurer that requires a prescription drug or sequence of prescription drugs to be used by an insured or an enrollee before a prescription drug ordered by a prescriber for the insured or the enrollee is covered.

(13) “Tiered formulary” means a formulary that provides coverage for prescription drugs as part of a health benefit plan for which cost-sharing, deductibles, or coinsurance is determined by category or tier of prescription drugs, and that includes at least 2 different tiers.

Sec. 3. Specialty drug copayment or coinsurance limitation.
(a)(1) A health benefit plan that provides coverage for prescription drugs shall ensure that
a required copayment or coinsurance applicable to a drug on a specialty tier does not exceed
$150 per month for up to a 30-day supply of the specialty drug or $300 for a 90-day supply.

(2) On July 1 of each year, the limit on a required copayment or coinsurance
applicable to a drug on a specialty tier provided in paragraph (1) of this subsection shall increase
by a percentage equal to the percentage change from the preceding year in the medical care
component of the March Consumer Price Index for All Urban Consumers, Washington-

(b)(1) For a health benefit plan that provides coverage for prescription drugs and utilizes
a tiered formulary, a member or member representative shall have the right to request that a non-
preferred drug be covered under the cost sharing applicable for preferred drugs if the prescribing
physician determines that the preferred 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.

(2) The denial of a request made pursuant to paragraph (1) of this subsection shall
be considered an adverse event and shall be subject to the health benefit plan’s internal review
process.

(c) A health benefit plan that provides coverage for prescription drugs shall not place all
drugs in a given class of drugs on a specialty tier.

(d) Nothing in this section shall be construed to require a health benefit 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 the use of tiered cost-sharing structures, including strategies used to incentivize use of preventive services, disease management, and low-cost treatment options.

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

f) A health insurer shall not be precluded from requiring specialty drugs to be obtained through a designated pharmacy or other source of specialty drugs.

Sec. 4. Fiscal impact statement.


Sec. 5. Effective date.

This act shall take effect on a plan's effective date or first renewal on or after January 1, 2018, following approval by the Mayor (or in the event of veto by the Mayor, action by the Council to override the veto), a 30-day period of congressional review as provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 788; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of Columbia Register.
A BILL

Bill 21-32

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To impose a limit on the amount that a person must pay in copayment or coinsurance through a health benefit plan for a prescription for a specialty drug.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "Specialty Drug Copayment Limitation Act of 2016".

Sec. 2. Definitions.

For the purposes of this act, the term:

(1) "Class of drugs" means a group of medications having similar actions designed to treat a particular disease process.

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

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

(4)(A) "Health benefit plan" means a policy, contract, certificate, or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

(B) The term "health benefit plan" does not include:
(i) Coverage only for accident or disability income insurance, or
any combination thereof;

(ii) Liability insurance, including general liability insurance and
automobile liability insurance;

(iii) Coverage issued as a supplement to liability insurance;

(iv) Workers' compensation or similar insurance;

(v) Automobile medical payment insurance;

(vi) Credit-only insurance;

(vii) Coverage for on-site medical clinics; or

(viii) Other similar insurance coverage, specified in federal
regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996,
approved August 21, 1996 (110 Stat. 1936; scattered sections of the United States Code)
("HIPAA"), under which benefits for health care services are secondary or incidental to other
insurance benefits.

(C) The term "health benefit plan" does not include the following benefits
if they are provided under a separate policy, certificate of insurance, or contract of insurance, or
are otherwise not an integral part of the plan:

(i) Limited scope dental or vision benefits;

(ii) Benefits for long-term care, nursing home care, home health
care, community-based care, or any combination thereof; or

(iii) Other similar, limited benefits specified in federal regulations
issued pursuant to HIPAA.

(D) The term "health benefit plan" does not include the following benefits
if the benefits are provided under a separate policy, certificate of insurance, or contract of
insurance, and there is no coordination between the provision of the benefits and any exclusion
of benefits under any group health plan maintained by the same health insurer, and the benefits
are paid with respect to an event without regard to whether benefits are provided with respect to
such an event under any group health plan maintained by the same health insurer:

(i) Coverage only for a specified disease or illness; or

(ii) Hospital indemnity or other fixed indemnity insurance.

(E) The term "health benefit plan" does not include the following if
offered as a separate policy, certificate of insurance, or contract of insurance:

(i) A Medicare supplemental policy as defined in section
1882(g)(1) of the Social Security Act, approved June 9, 1980 (94 Stat. 476; 42 U.S.C. §
1395ss(g)(1));

(ii) Coverage supplemental to the coverage provided under An
ACT to amend titles 10, 14, and 32, United States Code, to codify recent military law, and to
improve the Code, approved September 2, 1958 (72 Stat. 1437; 10 U.S.C. § 1071 et seq.); or

(iii) Similar supplemental coverage provided under a group health
plan.

(5) “Health insurer” means any person that provides one or more health benefit
plans or insurance in the District of Columbia, including an insurer, a hospital and medical
services corporation, a fraternal benefit society, a health maintenance organization, a multiple
employer welfare arrangement, or any other person providing a plan of health insurance subject
to the authority of the Commissioner of the Department of Insurance, Securities and Banking.

(6) “Member” means an individual who is enrolled in a health benefit plan.
(7) “Member representative” means a:

(A) Person acting on behalf of a member with the member’s consent;

(B) Person authorized by law to provide substituted consent for a member;

(C) Family member of the member;

(D) Member’s treating health care professional when the member is unable to provide consent; or

(E) In the case of a request regarding an emergency or urgent medical condition, a health-care professional with knowledge of the member’s medical condition.

(8) “Non-preferred drug” means a specialty drug formulary classification for certain specialty drugs that are subject to limits on eligibility for coverage or to higher cost-sharing amounts than preferred specialty drugs.

(9) “Preferred drug” means a specialty drug formulary classification for certain specialty drugs that are not subject to limits on eligibility for coverage or to higher cost-sharing amounts than a non-preferred drug.

(10) “Specialty drug” means a prescription drug that:

(A) Is prescribed for a person with:

(i) A physical, behavioral, or developmental condition that may have no known cure, is progressive, or can be debilitating or fatal if left untreated or undertreated, such as multiple sclerosis, hepatitis C, or rheumatoid arthritis; or
(ii) A disease or condition that affects fewer than 200,000 persons in the United States or approximately one in 1,500 persons worldwide, such as cystic fibrosis, hemophilia, or multiple myeloma;

(B) Has a total monthly prescription cost of $600 or more; and

(C) Has one or more of the following characteristics:

(i) Is an oral, injectable, or infusible drug product or a drug product that is delivered topically, through inhalation, implantation or transmucosally;

(ii) Requires unique storage or shipment, such as refrigeration; or

(iii) Requires patient education and support beyond traditional dispensing activities.

(11) "Specialty tier" means a tier of cost sharing designed for select specialty drugs that imposes a cost-sharing obligation that is based on a coinsurance or copayment and exceeds that amount for non-specialty drugs.

(12) "Step therapy" means a protocol established by a health insurer that requires a prescription drug or sequence of prescription drugs to be used by an insured or an enrollee before a prescription drug ordered by a prescriber for the insured or the enrollee is covered.

(13) "Tiered formulary" means a formulary that provides coverage for prescription drugs as part of a health benefit plan for which cost-sharing, deductibles, or coinsurance is determined by category or tier of prescription drugs, and that includes at least 2 different tiers.

Sec. 3. Specialty drug copayment or coinsurance limitation.
(a)(1) A health benefit plan that provides coverage for prescription drugs shall ensure that a required copayment or coinsurance applicable to a drug on a specialty tier does not exceed $150 per month for up to a 30-day supply of the specialty drug or $300 for a 90-day supply.

(2) On July 1 of each year, the limit on a required copayment or coinsurance applicable to a drug on a specialty tier provided in paragraph (1) of this subsection shall increase by a percentage equal to the percentage change from the preceding year in the medical care component of the March Consumer Price Index for All Urban Consumers, Washington-Baltimore metropolitan area, as published by the Bureau of Labor Statistics of the United States Department of Labor.

(b)(1) For a health benefit plan that provides coverage for prescription drugs and utilizes a tiered formulary, a member or member representative shall have the right to request that a non-preferred drug be covered under the cost sharing applicable for preferred drugs if the prescribing physician determines that the preferred 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.

(2) The denial of a request made pursuant to paragraph (1) of this subsection shall be considered an adverse event and shall be subject to the health benefit plan’s internal review process.

(c) A health benefit plan that provides coverage for prescription drugs shall not place all drugs in a given class of drugs on a specialty tier.

(d) Nothing in this section shall be construed to require a health benefit 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 the use of tiered cost-sharing structures, including strategies used to incentivize use of preventive services, disease management, and low-cost treatment options.

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

(f) A health insurer shall not be precluded from requiring specialty drugs to be obtained through a designated pharmacy or other source of specialty drugs.

Sec. 4. Fiscal impact statement.


Sec. 5. Effective date.

This act shall take effect on a plan’s effective date or first renewal on or after January 1, 2018, following approval by the Mayor (or in the event of veto by the Mayor, action by the Council to override the veto), a 30-day period of congressional review as provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 788; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of Columbia Register.