[First Reprint]

ASSEMBLY COMMITTEE SUBSTITUTE FOR ASSEMBLY, Nos. 954, 653, and 1669

STATE OF NEW JERSEY 219th LEGISLATURE

ADOPTED FEBRUARY 13, 2020

Sponsored by: Assemblyman ROBERT J. KARABINCHAK District 18 (Middlesex) Assemblyman JOHN ARMATO District 2 (Atlantic) Assemblywoman ANNETTE QUIJANO District 20 (Union)

Co-Sponsored by:

Assemblywoman Lampitt, Assemblymen Mazzeo, Freiman, Assemblywomen Vainieri Huttle, Timberlake, Assemblyman Benson, Assemblywomen Downey and Reynolds-Jackson

SYNOPSIS

Provides that purchase of insulin is not subject to deductible and requires health insurers to limit copayments and coinsurance for insulin.

CURRENT VERSION OF TEXT

As reported by the Assembly Appropriations Committee on February 24, 2021, with amendments.



(Sponsorship Updated As Of: 3/8/2021)

1 AN ACT concerning cost sharing for insulin, amending P.L.1995, 2 c.331, and supplementing various parts of the statutory law. 3 4 BE IT ENACTED by the Senate and General Assembly of the State 5 of New Jersey: 6 7 1. (New section) The Legislature finds and declares that: 8 a. The rising cost of insulin has created an affordability crisis that 9 threatens the health and financial well-being of many diabetes patients. 10 b. Research by the non-partisan Health Care Cost Institute found 11 that prices for insulin nearly doubled over the five year period from 12 2012 to 2016 and other studies show that prices for insulin have 13 increased by 700% over the past two decades. 14 c. The lack of competition, transparency, and accountability in 15 the prescription drug market has allowed manufacturers of insulin to 16 exert extraordinary pricing power. 17 d. While insulin products have been on the market for almost a 18 century, there is limited competition from lower-cost generics, in part 19 due to aggressive efforts by brand name drug manufacturers to block 20 the entry of generic insulin products into the market. 21 e. Even consumers with health insurance may face a lack of 22 access to insulin due to the plan design of some health insurance 23 policies. 24 f. For consumers without insurance, or with insurance coverage 25 not subject to New Jersey State law, access to current and reliable cost 26 information may be helpful to consumers and researchers trying to 27 better understand the true cost of insulin. 28 g. It is, therefore, in the public interest to protect consumers by 29 mandating insurance coverage cost sharing maximums in New Jersey 30 to improve consumer access to insulin, and to provide for transparency 31 and publication of drug company pricing of insulin. 32 33 2. Section 1 of P.L.1995, c.331 (C.17:48-6n) is amended to read 34 as follows: 35 1. a. Every individual or group hospital service corporation contract providing hospital or medical expense benefits that is 36 37 delivered, issued, executed or renewed in this State pursuant to 38 P.L.1938, c.366 (C.17:48-1 et seq.) or approved for issuance or 39 renewal in this State by the Commissioner of **Banking and Insurance** 40 on or after the effective date of this act shall provide benefits to any 41 subscriber or other person covered thereunder for expenses incurred 42 for the following equipment and supplies for the treatment of diabetes, 43 recommended or prescribed by a physician or if nurse 44 practitioner/clinical nurse specialist: blood glucose monitors and 45 blood glucose monitors for the legally blind; test strips for glucose

Matter underlined <u>thus</u> is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

¹Assembly AAP committee amendments adopted February 24, 2021.

EXPLANATION – Matter enclosed in **bold-faced brackets** [thus] in the above bill is not enacted and is intended to be omitted in the law.

monitors and visual reading and urine testing strips; insulin; injection aids; cartridges for the legally blind; syringes; insulin pumps and appurtenances thereto; insulin infusion devices; and oral agents for controlling blood sugar. <u>Coverage for the purchase of insulin shall not</u> <u>be subject to any deductible, and no copayment or coinsurance for the</u> <u>purchase of insulin shall exceed \$50 per 30 day supply.</u>

7 b. Each individual or group hospital service corporation contract 8 shall also provide benefits for expenses incurred for diabetes self-9 management education to ensure that a person with diabetes is 10 educated as to the proper self-management and treatment of their 11 diabetic condition, including information on proper diet. Benefits 12 provided for self-management education and education relating to diet 13 shall be limited to visits medically necessary upon the diagnosis of 14 diabetes; upon diagnosis by a physician or nurse practitioner/clinical 15 nurse specialist of a significant change in the subscriber's or other 16 covered person's symptoms or conditions which necessitate changes in 17 that person's self-management; and upon determination of a physician 18 or nurse practitioner/clinical nurse specialist that reeducation or 19 refresher education is necessary. Diabetes self-management education 20 shall be provided by a dietitian registered by a nationally recognized 21 professional association of dietitians or a health care professional 22 recognized as a Certified Diabetes Educator by the American 23 Association of Diabetes Educators or a registered pharmacist in the 24 State qualified with regard to management education for diabetes by 25 any institution recognized by the board of pharmacy of the State of 26 New Jersey.

c. The benefits required by this section shall be provided to thesame extent as for any other sickness under the contract.

d. This section shall apply to all hospital service corporation
contracts in which the hospital service corporation has reserved the
right to change the premium.

e. The provisions of this section shall not apply to a health
benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

f. The Commissioner of <u>Banking and</u> Insurance may, in consultation with the Commissioner of Health, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), promulgate and periodically update a list of additional diabetes equipment and related supplies that are medically necessary for the treatment of diabetes and for which benefits shall be provided according to the provisions of this section.

42 (cf: P.L.1995, c.331, s.1)

43

44 3. Section 2 of P.L.1995, c.331 (C.17:48A-71) is amended to read 45 as follows:

46 2. a. Every individual or group medical service corporation
47 contract providing hospital or medical expense benefits that is
48 delivered, issued, executed or renewed in this State pursuant to

1 P.L.1940, c.74 (C.17:48A-1 et seq.) or approved for issuance or 2 renewal in this State by the Commissioner of **Banking and** Insurance 3 on or after the effective date of this act shall provide benefits to any 4 subscriber or other person covered thereunder for expenses incurred 5 for the following equipment and supplies for the treatment of diabetes, 6 recommended or prescribed by a physician or nurse if 7 practitioner/clinical nurse specialist: blood glucose monitors and 8 blood glucose monitors for the legally blind; test strips for glucose 9 monitors and visual reading and urine testing strips; insulin; injection 10 aids; cartridges for the legally blind; syringes; insulin pumps and 11 appurtenances thereto; insulin infusion devices; and oral agents for 12 controlling blood sugar. Coverage for the purchase of insulin shall not 13 be subject to any deductible, and no copayment or coinsurance for the 14 purchase of insulin shall exceed \$50 per 30 day supply.

15 b. Each individual or group medical service corporation contract 16 shall also provide benefits for expenses incurred for diabetes self-17 management education to ensure that a person with diabetes is 18 educated as to the proper self-management and treatment of their 19 diabetic condition, including information on proper diet. Benefits 20 provided for self-management education and education relating to diet 21 shall be limited to visits medically necessary upon the diagnosis of 22 diabetes; upon diagnosis by a physician or nurse practitioner/clinical 23 nurse specialist of a significant change in the subscriber's or other 24 covered person's symptoms or conditions which necessitate changes in 25 that person's self-management; and upon determination of a physician 26 or nurse practitioner/clinical nurse specialist that reeducation or 27 refresher education is necessary. Diabetes self-management education 28 shall be provided by a dietitian registered by a nationally recognized 29 professional association of dietitians or a health care professional 30 recognized as a Certified Diabetes Educator by the American 31 Association of Diabetes Educators or a registered pharmacist in the 32 State qualified with regard to management education for diabetes by 33 any institution recognized by the board of pharmacy of the State of 34 New Jersey.

c. The benefits required by this section shall be provided to thesame extent as for any other sickness under the contract.

d. This section shall apply to all medical service corporation
contracts in which the medical service corporation has reserved the
right to change the premium.

e. The provisions of this section shall not apply to a health
benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

f. The Commissioner of <u>Banking and</u> Insurance may, in
consultation with the Commissioner of Health, pursuant to the
"Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.),
promulgate and periodically update a list of additional diabetes
equipment and related supplies that are medically necessary for the

treatment of diabetes and for which benefits shall be provided
 according to the provisions of this section.

3 (cf: P.L.1995, c.331, s.2)

4

5 4. Section 3 of P.L.1995, c.331 (C.17:48E-35.11) is amended to 6 read as follows:

7 3. a. Every individual or group health service corporation 8 contract providing hospital or medical expense benefits that is 9 delivered, issued, executed or renewed in this State pursuant to 10 P.L.1985, c.236 (C.17:48E-1 et seq.) or approved for issuance or 11 renewal in this State by the Commissioner of **Banking and** Insurance 12 on or after the effective date of this act shall provide benefits to any 13 subscriber or other person covered thereunder for expenses incurred 14 for the following equipment and supplies for the treatment of diabetes, 15 recommended or prescribed by a physician or nurse if 16 practitioner/clinical nurse specialist: blood glucose monitors and 17 blood glucose monitors for the legally blind; test strips for glucose 18 monitors and visual reading and urine testing strips; insulin; injection 19 aids; cartridges for the legally blind; syringes; insulin pumps and 20 appurtenances thereto; insulin infusion devices; and oral agents for 21 controlling blood sugar. Coverage for the purchase of insulin shall not 22 be subject to any deductible, and no copayment or coinsurance for the 23 purchase of insulin shall exceed \$50 per 30 day supply.

24 b. Each individual or group health service corporation contract 25 shall also provide benefits for expenses incurred for diabetes selfmanagement education to ensure that a person with diabetes is 26 27 educated as to the proper self-management and treatment of their 28 diabetic condition, including information on proper diet. Benefits 29 provided for self-management education and education relating to diet 30 shall be limited to visits medically necessary upon the diagnosis of 31 diagnosis by diabetes; upon the a physician or nurse 32 practitioner/clinical nurse specialist of a significant change in the 33 subscriber's or other covered person's symptoms or conditions which 34 necessitate changes in that person's self-management; and upon 35 determination of a physician or nurse practitioner/clinical nurse 36 specialist that reeducation or refresher education is necessary. 37 Diabetes self-management education shall be provided by a dietitian 38 registered by a nationally recognized professional association of 39 dietitians or a health care professional recognized as a Certified 40 Diabetes Educator by the American Association of Diabetes Educators 41 or a registered pharmacist in the State qualified with regard to 42 management education for diabetes by any institution recognized by 43 the board of pharmacy of the State of New Jersey.

c. The benefits required by this section shall be provided to thesame extent as for any other sickness under the contract.

d. This section shall apply to all health service corporation
contracts in which the health service corporation has reserved the right
to change the premium.

e. The provisions of this section shall not apply to a health
 benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A 2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

f. The Commissioner of <u>Banking and</u> Insurance may, in consultation with the Commissioner of Health, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), promulgate and periodically update a list of additional diabetes equipment and related supplies that are medically necessary for the treatment of diabetes and for which benefits shall be provided according to the provisions of this section.

- 11 (cf: P.L.1995, c.331, s.3)
- 12

13 5. Section 4 of P.L.1995, c.331 (C.17B:26-2.11) is amended to 14 read as follows:

15 4. a. Every individual health insurance policy providing hospital 16 or medical expense benefits that is delivered, issued, executed or 17 renewed in this State pursuant to Chapter 26 of Title 17B of the New 18 Jersey Statutes or approved for issuance or renewal in this State by the 19 Commissioner of **Banking and** Insurance on or after the effective date 20 of this act shall provide benefits to any person covered thereunder for 21 expenses incurred for the following equipment and supplies for the 22 treatment of diabetes, if recommended or prescribed by a physician or 23 nurse practitioner/clinical nurse specialist: blood glucose monitors and 24 blood glucose monitors for the legally blind; test strips for glucose 25 monitors and visual reading and urine testing strips; insulin; injection 26 aids; cartridges for the legally blind; syringes; insulin pumps and 27 appurtenances thereto; insulin infusion devices; and oral agents for 28 controlling blood sugar. Coverage for the purchase of insulin shall not 29 be subject to any deductible, and no copayment or coinsurance for the 30 purchase of insulin shall exceed \$50 per 30 day supply.

31 b. Each individual health insurance policy shall also provide 32 benefits for expenses incurred for diabetes self-management education 33 to ensure that a person with diabetes is educated as to the proper self-34 management and treatment of their diabetic condition, including 35 information on proper diet. Benefits provided for self-management 36 education and education relating to diet shall be limited to visits 37 medically necessary upon the diagnosis of diabetes; upon diagnosis by 38 a physician or nurse practitioner/clinical nurse specialist of a 39 significant change in the covered person's symptoms or conditions 40 which necessitate changes in that person's self-management; and upon 41 determination of a physician or nurse practitioner/clinical nurse 42 specialist that reeducation or refresher education is necessary. 43 Diabetes self-management education shall be provided by a dietitian 44 registered by a nationally recognized professional association of 45 dietitians or a health care professional recognized as a Certified 46 Diabetes Educator by the American Association of Diabetes Educators 47 or a registered pharmacist in the State qualified with regard to

management education for diabetes by any institution recognized by
 the board of pharmacy of the State of New Jersey.

3 c. The benefits required by this section shall be provided to the4 same extent as for any other sickness under the policy.

5 d. This section shall apply to all individual health insurance 6 policies in which the insurer has reserved the right to change the 7 premium.

e. The provisions of this section shall not apply to a health
benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

11 f. The Commissioner of <u>Banking and</u> Insurance may, in 12 consultation with the Commissioner of Health, pursuant to the 13 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), 14 promulgate and periodically update a list of additional diabetes 15 equipment and related supplies that are medically necessary for the 16 treatment of diabetes and for which benefits shall be provided 17 according to the provisions of this section.

18 (cf: P.L.1995, c.331, s.4)

19

20 6. Section 5 of P.L.1995, c.331 (C.17B:27-46.1m) is amended to
21 read as follows:

22 5. a. Every group health insurance policy providing hospital or 23 medical expense benefits that is delivered, issued, executed or renewed 24 in this State pursuant to Chapter 27 of Title 17B of the New Jersey 25 Statutes or approved for issuance or renewal in this State by the 26 Commissioner of **Banking and** Insurance on or after the effective date 27 of this act shall provide benefits to any person covered thereunder for 28 expenses incurred for the following equipment and supplies for the 29 treatment of diabetes, if recommended or prescribed by a physician or 30 nurse practitioner/clinical nurse specialist: blood glucose monitors and 31 blood glucose monitors for the legally blind; test strips for glucose 32 monitors and visual reading and urine testing strips; insulin; injection 33 aids; cartridges for the legally blind; syringes; insulin pumps and 34 appurtenances thereto; insulin infusion devices; and oral agents for 35 controlling blood sugar. Coverage for the purchase of insulin shall not 36 be subject to any deductible, and no copayment or coinsurance for the 37 purchase of insulin shall exceed \$50 per 30 day supply.

38 b. Each group health insurance policy shall also provide benefits 39 for expenses incurred for diabetes self-management education to 40 ensure that a person with diabetes is educated as to the proper self-41 management and treatment of their diabetic condition, including 42 information on proper diet. Benefits provided for self-management 43 education and education relating to diet shall be limited to visits 44 medically necessary upon the diagnosis of diabetes; upon diagnosis by 45 a physician or nurse practitioner/clinical nurse specialist of a 46 significant change in the covered person's symptoms or conditions 47 which necessitate changes in that person's self-management; and upon 48 determination of a physician or nurse practitioner/clinical nurse

specialist that reeducation or refresher education is necessary. 1 2 Diabetes self-management education shall be provided by a dietitian 3 registered by a nationally recognized professional association of 4 dietitians or a health care professional recognized as a Certified 5 Diabetes Educator by the American Association of Diabetes Educators 6 or a registered pharmacist in the State qualified with regard to 7 management education for diabetes by any institution recognized by 8 the board of pharmacy of the State of New Jersey.

9 c. The benefits required by this section shall be provided to the 10 same extent as for any other sickness under the policy.

d. This section shall apply to all group health insurance policies inwhich the insurer has reserved the right to change the premium.

e. The provisions of this section shall not apply to a health
benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

16 f. The Commissioner of <u>Banking and</u> Insurance may, in 17 consultation with the Commissioner of Health, pursuant to the 18 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), 19 promulgate and periodically update a list of additional diabetes 20 equipment and related supplies that are medically necessary for the 21 treatment of diabetes and for which benefits shall be provided 22 according to the provisions of this section.

- 23 (cf: P.L.1995, c.331, s.5)
- 24

25 7. Section 6 of P.L.1995, c.331 (C.26:2J-4.11) is amended to read
26 as follows:

27 6. a. Every contract for health care services that is delivered, 28 issued, executed or renewed in this State pursuant to P.L.1973, c.337 29 (C.26:2J-1 et seq.) or approved for issuance or renewal in this State on 30 or after the effective date of this act shall provide health care services 31 to any enrollee or other person covered thereunder for the following 32 equipment and supplies for the treatment of diabetes, if recommended 33 or prescribed by a participating physician or participating nurse 34 practitioner/clinical nurse specialist: blood glucose monitors and 35 blood glucose monitors for the legally blind; test strips for glucose 36 monitors and visual reading and urine testing strips; insulin; injection 37 aids; cartridges for the legally blind; syringes; insulin pumps and 38 appurtenances thereto; insulin infusion devices; and oral agents for 39 controlling blood sugar. Coverage for the purchase of insulin shall not 40 be subject to any deductible, and no copayment or coinsurance for the 41 purchase of insulin shall exceed \$50 per 30 day supply.

b. Each contract shall also provide health care services for diabetes self-management education to ensure that a person with diabetes is educated as to the proper self-management and treatment of their diabetic condition, including information on proper diet. Health care services provided for self-management education and education relating to diet shall be limited to visits medically necessary upon the diagnosis of diabetes; upon diagnosis by a participating physician or

1 participating nurse practitioner/clinical nurse specialist of a significant 2 change in the enrollee's or other covered person's symptoms or 3 conditions which necessitate changes in that person's self-4 management; and upon determination of a participating physician or 5 participating nurse practitioner/clinical nurse specialist that reeducation or refresher education is necessary. 6 Diabetes self-7 management education shall be provided by a participating dietitian 8 registered by a nationally recognized professional association of 9 dietitians or a health care professional recognized as a Certified 10 Diabetes Educator by the American Association of Diabetes Educators 11 or, pursuant to section 6 of P.L.1993, c.378 (C.26:2J-4.7), a registered 12 pharmacist in the State qualified with regard to management education 13 for diabetes by any institution recognized by the board of pharmacy of 14 the State of New Jersey. 15 c. The health care services required by this section shall be 16 provided to the same extent as for any other sickness under the 17 contract. 18 d. This section shall apply to all contracts in which the health 19 maintenance organization has reserved the right to change the schedule 20 of charges. 21 e. The provisions of this section shall not apply to a health 22 benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A-

f. The Commissioner of <u>Banking and</u> Insurance may, in consultation with the Commissioner of Health, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), promulgate and periodically update a list of additional diabetes equipment and related supplies that are medically necessary for the treatment of diabetes and for which benefits shall be provided according to the provisions of this section.

- 31 (cf: P.L.1995, c.331, s.6)
- 32

8. (New section) An individual health benefits plan that provides
hospital and medical expense benefits and is delivered, issued,
executed or renewed in this State pursuant to P.L.1992, c.161
(C.17B:27A-2 et al.), on or after the effective date of P.L. ,

37 C. (C.) (pending before the Legislature as this bill), shall provide 38 coverage to any enrollee or other person covered thereunder for insulin 39 for the treatment of diabetes, if recommended or prescribed by a 40 participating physician or participating nurse practitioner/clinical nurse 41 specialist. Coverage for the purchase of insulin shall not be subject to 42 any deductible, and no copayment or coinsurance for the purchase of 43 insulin shall exceed \$50 per 30 day supply.

44 The benefits shall be provided to the same extent as for any other45 condition under the health benefits plan.

This section shall apply to those health benefits plans in which the carrier has reserved the right to change the premium.

1 9. (New section) A small employer health benefits plan that 2 provides hospital and medical expense benefits and is delivered, 3 issued, executed or renewed in this State pursuant to P.L.1992, c.162 4 (C.17B:27A-17 et seq.), on or after the effective date of 5 P.L., c. (C.) (pending before the Legislature as this bill), shall 6 provide coverage to any enrollee or other person covered thereunder 7 for insulin for the treatment of diabetes, if recommended or prescribed 8 by a participating physician or participating nurse practitioner/clinical 9 nurse specialist. Coverage for the purchase of insulin shall not be 10 subject to any deductible, and no copayment or coinsurance for the 11 purchase of insulin shall exceed \$50 per 30 day supply.

12 The benefits shall be provided to the same extent as for any other 13 condition under the health benefits plan.

14 This section shall apply to those health benefits plans in which the15 carrier has reserved the right to change the premium.

16

17 10. (New section) The State Health Benefits Commission shall 18 ensure that every contract purchased or renewed by the commission 19 on or after the effective date of P.L. , c. (C.) (pending 20 before the Legislature as this bill), shall provide coverage for health 21 care services to any enrollee or other person covered thereunder for 22 insulin for the treatment of diabetes, if recommended or prescribed 23 participating physician or participating by а nurse practitioner/clinical nurse specialist. Coverage for the purchase of 24 25 insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed \$50 per 30 day 26 supply. ¹Nothing in this section shall prevent the State Health 27 28 Benefits Commission from reducing an enrollee's cost-sharing 29 requirement by an amount greater than the amount specified in this 30 section or prevent the commission from utilizing formulary 31 management, including a mandatory generic policy, to promote the 32 use of lower-cost alternative generic drugs that are the therapeutic equivalent of the brand-name drug.¹ 33

34

35 11. (New section) The School Employees' Health Benefits 36 Commission shall ensure that every contract purchased by the 37 commission on or after the effective date of P.L., c. (C. 38 (pending before the Legislature as this bill) that provides hospital 39 and medical expense benefits shall provide health care services to 40 any enrollee or other person covered thereunder for insulin for the 41 treatment of diabetes, if recommended or prescribed by a 42 participating physician or participating nurse practitioner/clinical 43 nurse specialist. Coverage for the purchase of insulin shall not be 44 subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed \$50 per 30 day supply. ¹Nothing in 45 this section shall prevent the School Employees' Health Benefits 46 47 Commission from reducing an enrollee's cost-sharing requirement 48 by an amount greater than the amount specified in this section or

[1R] ACS for A954 KARABINCHAK, ARMATO

1 prevent the commission from utilizing formulary management, 2 including a mandatory generic policy, to promote the use of lower-3 cost alternative generic drugs that are the therapeutic equivalent of the brand-name drug.¹ 4 5 6 ¹[12. (New section) Every manufacturer of an insulin product 7 shall submit, not later than January 1, 2021, and annually thereafter, a 8 report to the Commissioner of Banking and Insurance containing the 9 following information: 10 a. name of the insulin products currently manufactured; b. identification of whether the insulin products are brand name 11 12 or generic drug products; 13 c. total sales of insulin products to New Jersey consumers 14 quantified in total units and total revenue; 15 d. the effective date and amounts of any changes in the wholesale acquisition cost or other list prices for insulin during the prior calendar 16 17 year; 18 e. aggregate, company-level research and development costs for 19 insulin over the prior calendar year; 20 f. the name of each of the manufacturer's insulin products that 21 were approved by the federal Food and Drug Administration in the previous five calendar years; 22 23 g. the name of each of the manufacturer's insulin products that lost patent exclusivity in the United States in the previous five 24 25 calendar years; and 26 h. a statement of rationale regarding the factor or factors that 27 caused the increase in the wholesale acquisition cost or list price increase for insulin.]¹ 28 29 ¹[13.] <u>12.</u>¹ Sections 2 through 4, 6, and 7 of this act shall take 30 effect on the 180th day next following the date of enactment and 31 32 shall apply to plans issued or renewed on or after January 1 of the next calendar year; sections 5, 8, and 9 shall take effect on the 270th 33 day next following the date of enactment and shall apply to plans 34 issued or renewed after January 1 of the next calendar year; sections 35 36 10 and 11 shall take effect on the 90th day next following the date 37 of enactment and shall apply to contracts purchased on or after that date ¹[; and section 12 shall take place immediately]¹. 38