To reduce the price of insulin for patients.

IN THE SENATE OF THE UNITED STATES

Mr. Hawley introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To reduce the price of insulin for patients.

- 1 Be it enacted by the Senate and House of Representa2 tives of the United States of America in Congress assembled,
 3 SECTION 1. SHORT TITLE.
 4 This Act may be cited as the "Cap Insulin Prices
 5 Act".
 6 SEC. 2. REDUCTION IN COST-SHARING FOR COVERED INSU7 LIN PRODUCTS UNDER MEDICARE PART D.
- 9 (42 U.S.C. 1395w–102(b)(9)(D) is amended—
- 10 (1) by redesignating clause (ii) as clause (iii);

Section 1860D–2(b)(9)(D) of the Social Security Act

11 (2) in clause (i)—

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| 1 | (A) by striking "plan years 2023, 2024, |
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| 2 | and 2025" and inserting "plan year 2023"; and |
| 3 | (B) by striking "and" after the semicolon |
| 4 | at the end; |
| 5 | (3) by inserting after clause (i) the following |
| 6 | new clause: |
| 7 | "(ii) during plan years 2024 and |
| 8 | 2025, \$25; and"; and |
| 9 | (4) in clause (iii)(I), as redesignated by para- |
| 10 | graph (1) of this section, by striking "\$35" and in- |
| 11 | serting "\$25". |
| 12 | SEC. 3. REQUIREMENTS WITH RESPECT TO COST-SHARING |
| | |
| 13 | FOR INSULIN PRODUCTS. |
| 13 14 | FOR INSULIN PRODUCTS. (a) IN GENERAL.—Part D of title XXVII of the Pub- |
| | |
| 14 | (a) In General.—Part D of title XXVII of the Pub- |
| 14 15 | (a) In General.—Part D of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-111 et seq.) is |
| 141516 | (a) IN GENERAL.—Part D of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-111 et seq.) is amended by adding at the end the following: |
| 14151617 | (a) In General.—Part D of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-111 et seq.) is amended by adding at the end the following: "SEC. 2799A-11. REQUIREMENTS WITH RESPECT TO COST- |
| 14 15 16 17 18 | (a) In General.—Part D of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-111 et seq.) is amended by adding at the end the following: "SEC. 2799A-11. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS. |
| 14 15 16 17 18 19 | (a) In General.—Part D of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-111 et seq.) is amended by adding at the end the following: "SEC. 2799A-11. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS. "(a) In General.—For plan years beginning on or |
| 14 15 16 17 18 19 20 | (a) In General.—Part D of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-111 et seq.) is amended by adding at the end the following: "SEC. 2799A-11. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS. "(a) In General.—For plan years beginning on or after January 1, 2024, a group health plan or health in- |
| 14 15 16 17 18 19 20 21 | (a) In General.—Part D of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-111 et seq.) is amended by adding at the end the following: "SEC. 2799A-11. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS. "(a) In General.—For plan years beginning on or after January 1, 2024, a group health plan or health insurance issuer offering group or individual health insur- |

| 1 | "(2) impose any cost-sharing requirement in ex- |
|----|--|
| 2 | cess of the lesser of, per 30-day supply— |
| 3 | "(A) \$25; or |
| 4 | "(B) the amount equal to 25 percent of |
| 5 | the negotiated price of the selected insulin prod- |
| 6 | uct net of all price concessions received by or on |
| 7 | behalf of the plan or coverage, including price |
| 8 | concessions received by or on behalf of third- |
| 9 | party entities providing services to the plan or |
| 10 | coverage, such as pharmacy benefit manage- |
| 11 | ment services; or |
| 12 | "(3) impose any utilization management prac- |
| 13 | tices such as prior authorization, step therapy proto- |
| 14 | cols, or other similar conditions on such products, |
| 15 | except as clinically justified and as specified by the |
| 16 | Secretary. |
| 17 | "(b) Definitions.—In this section: |
| 18 | "(1) Selected insulin products.—The term |
| 19 | 'selected insulin products' means at least one of each |
| 20 | dosage form (such as vial, pump, or inhaler dosage |
| 21 | forms) of each different type (such as rapid-acting, |
| 22 | short-acting, intermediate-acting, long-acting, ultra |
| 23 | long-acting, and premixed) of insulin (as defined |
| 24 | below), when available, as selected by the group |
| 25 | health plan or health insurance issuer. |

| 1 | "(2) INSULIN DEFINED.—The term 'insulin' |
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| 2 | means insulin that is licensed under subsection (a) |
| 3 | or (k) of section 351 and continues to be marketed |
| 4 | under such section. |
| 5 | "(c) Out-of-network Providers.—Nothing in |
| 6 | this section requires a plan or issuer that has a network |
| 7 | of providers to provide benefits for selected insulin prod- |
| 8 | ucts described in this section that are delivered by an out- |
| 9 | of-network provider, or precludes a plan or issuer that has |
| 10 | a network of providers from imposing higher cost-sharing |
| 11 | than the levels specified in subsection (a) for selected insu- |
| 12 | lin products described in this section that are delivered |
| 13 | by an out-of-network provider. |
| 14 | "(d) Rule of Construction.—Subsection (a) shall |
| 15 | not be construed to require coverage of, or prevent a group |
| 16 | health plan or health insurance coverage from imposing |
| 17 | cost-sharing other than the levels specified in subsection |
| 18 | (a) on, insulin products that are not selected insulin prod- |
| 19 | ucts, to the extent that such coverage is not otherwise re- |
| 20 | quired and such cost-sharing is otherwise permitted under |
| 21 | Federal and applicable State law. |
| 22 | "(e) Application of Cost-sharing Towards |
| 23 | DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any |
| 24 | cost-sharing payments made pursuant to subsection (a)(2) |

1 shall be counted toward any deductible or out-of-pocket

- 2 maximum that applies under the plan or coverage.".
- 3 (b) No Effect on Other Cost-Sharing.—Section
- 4 1302(d)(2) of the Patient Protection and Affordable Care
- 5 Act (42 U.S.C. 18022(d)(2)) is amended by adding at the
- 6 end the following new subparagraph:
- 7 "(D) Special rule relating to insu-8 LIN COVERAGE.—For plan years beginning on 9 or after January 1, 2024, the exemption of cov-10 erage of selected insulin products (as defined in 11 section 2799A-11(b) of the Public Health Serv-12 ice Act) from the application of any deductible 13 pursuant to section 2799A-11(a)(1) of such 14 Act, section 726(a)(1) of the Employee Retire-15 ment Income Security Act of 1974, or section 16 9826(a)(1) of the Internal Revenue Code of 17 1986 shall not be considered when determining 18 the actuarial value of a qualified health plan 19 under this subsection.".
- 20 (c) Coverage of Certain Insulin Products
- 21 Under Catastrophic Plans.—Section 1302(e) of the
- 22 Patient Protection and Affordable Care Act (42 U.S.C.
- 23 18022(e)) is amended by adding at the end the following:
- 24 "(4) COVERAGE OF CERTAIN INSULIN PROD-
- 25 UCTS.—

| 1 | "(A) IN GENERAL.—Notwithstanding para- |
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| 2 | graph (1)(B)(i), a health plan described in |
| 3 | paragraph (1) shall provide coverage of selected |
| 4 | insulin products, in accordance with section |
| 5 | 2799A-11 of the Public Health Service Act, for |
| 6 | a plan year before an enrolled individual has in- |
| 7 | curred cost-sharing expenses in an amount |
| 8 | equal to the annual limitation in effect under |
| 9 | subsection $(c)(1)$ for the plan year. |
| 10 | "(B) TERMINOLOGY.—For purposes of |
| 11 | subparagraph (A)— |
| 12 | "(i) the term 'selected insulin prod- |
| 13 | ucts' has the meaning given such term in |
| 14 | section 2799A-11(b) of the Public Health |
| 15 | Service Act; and |
| 16 | "(ii) the requirements of section |
| 17 | 2799A-11 of such Act shall be applied by |
| 18 | deeming each reference in such section to |
| 19 | 'individual health insurance coverage' to be |
| 20 | a reference to a plan described in para- |
| 21 | graph (1).". |
| 22 | (d) ERISA.— |
| 23 | (1) In general.—Subpart B of part 7 of sub- |
| 24 | title B of title I of the Employee Retirement Income |

| 1 | Security Act of 1974 (29 U.S.C. 1185 et seq.) is |
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| 2 | amended by adding at the end the following: |
| 3 | "SEC. 726. REQUIREMENTS WITH RESPECT TO COST-SHAR- |
| 4 | ING FOR CERTAIN INSULIN PRODUCTS. |
| 5 | "(a) In General.—For plan years beginning on or |
| 6 | after January 1, 2024, a group health plan or health in- |
| 7 | surance issuer offering group health insurance coverage |
| 8 | shall provide coverage of selected insulin products, and |
| 9 | with respect to such products, shall not— |
| 10 | "(1) apply any deductible; |
| 11 | "(2) impose any cost-sharing requirement in ex- |
| 12 | cess of the lesser of, per 30-day supply— |
| 13 | "(A) \$25; or |
| 14 | "(B) the amount equal to 25 percent of |
| 15 | the negotiated price of the selected insulin prod- |
| 16 | uct net of all price concessions received by or on |
| 17 | behalf of the plan or coverage, including price |
| 18 | concessions received by or on behalf of third- |
| 19 | party entities providing services to the plan or |
| 20 | coverage, such as pharmacy benefit manage- |
| 21 | ment services; or |
| 22 | "(3) impose any utilization management prac- |
| 23 | tices such as prior authorization, step therapy proto- |
| 24 | cols, or other similar conditions on such products, |

except as clinically justified and as specified by the
 Secretary.

"(b) Definitions.—In this section:

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- 4 "(1) Selected insulin products.—The term 5 'selected insulin products' means at least one of each 6 dosage form (such as vial, pump, or inhaler dosage forms) of each different type (such as rapid-acting, 7 8 short-acting, intermediate-acting, long-acting, ultra 9 long-acting, and premixed) of insulin (as defined 10 below), when available, as selected by the group 11 health plan or health insurance issuer.
- "(2) Insulin defined.—The term 'insulin'
 means insulin that is licensed under subsection (a)
 or (k) of section 351 of the Public Health Service
 Act (42 U.S.C. 262) and continues to be marketed
 under such section.
- "(c) Out-of-Network Providers.—Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for selected insulin products described in this section that are delivered by an outof-network provider, or precludes a plan or issuer that has a network of providers from imposing higher cost-sharing than the levels specified in subsection (a) for selected insulin products described in this section that are delivered

by an out-of-network provider.

1 "(d) Rule of Construction.—Subsection (a) shall 2 not be construed to require coverage of, or prevent a group 3 health plan or health insurance coverage from imposing cost-sharing other than the levels specified in subsection 4 5 (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise re-6 7 quired and such cost-sharing is otherwise permitted under 8 Federal and applicable State law. 9 "(e) Application of Cost-sharing TOWARDS 10 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any 11 cost-sharing payments made pursuant to subsection (a)(2) 12 shall be counted toward any deductible or out-of-pocket 13 maximum that applies under the plan or coverage.". 14 (2) CLERICAL AMENDMENT.—The table of con-15 tents in section 1 of the Employee Retirement In-16 come Security Act of 1974 (29 U.S.C. 1001 et seq.) 17 is amended by inserting after the item relating to 18 section 725 the following: "Sec. 726 Requirements with respect to cost-sharing for certain insulin products.". 19 (e) Internal Revenue Code.— 20 (1) In General.—Subchapter B of chapter 21 100 of the Internal Revenue Code of 1986 is amend-22 ed by adding at the end the following new section:

| 1 | "SEC. 9826. REQUIREMENTS WITH RESPECT TO COST-SHAR- |
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| 2 | ING FOR CERTAIN INSULIN PRODUCTS. |
| 3 | "(a) In General.—For plan years beginning on or |
| 4 | after January 1, 2024, a group health plan shall provide |
| 5 | coverage of selected insulin products, and with respect to |
| 6 | such products, shall not— |
| 7 | "(1) apply any deductible; |
| 8 | "(2) impose any cost-sharing requirement in ex- |
| 9 | cess of the lesser of, per 30-day supply— |
| 10 | "(A) \$25; or |
| 11 | "(B) the amount equal to 25 percent of |
| 12 | the negotiated price of the selected insulin prod- |
| 13 | uct net of all price concessions received by or on |
| 14 | behalf of the plan, including price concessions |
| 15 | received by or on behalf of third-party entities |
| 16 | providing services to the plan, such as phar- |
| 17 | macy benefit management services; or |
| 18 | "(3) impose any utilization management prac- |
| 19 | tices such as prior authorization, step therapy proto- |
| 20 | cols, or other similar conditions on such products, |
| 21 | except as clinically justified and as specified by the |
| 22 | Secretary. |
| 23 | "(b) Definitions.—In this section: |
| 24 | "(1) SELECTED INSULIN PRODUCTS.—The term |
| 25 | 'selected insulin products' means at least one of each |
| 26 | dosage form (such as vial, pump, or inhaler dosage |

1 forms) of each different type (such as rapid-acting, 2 short-acting, intermediate-acting, long-acting, ultra 3 long-acting, and premixed) of insulin (as defined 4 below), when available, as selected by the group 5 health plan. 6 "(2) Insulin defined.—The term 'insulin' 7 means insulin that is licensed under subsection (a) 8 or (k) of section 351 of the Public Health Service 9 Act (42 U.S.C. 262) and continues to be marketed 10 under such section. 11 "(c) Out-of-network Providers.—Nothing in this section requires a plan that has a network of providers 12 13 to provide benefits for selected insulin products described in this section that are delivered by an out-of-network pro-14 15 vider, or precludes a plan that has a network of providers from imposing higher cost-sharing than the levels specified 16 in subsection (a) for selected insulin products described in this section that are delivered by an out-of-network pro-18 vider. 19 20 "(d) Rule of Construction.—Subsection (a) shall 21 not be construed to require coverage of, or prevent a group 22 health plan from imposing cost-sharing other than the lev-23 els specified in subsection (a) on, insulin products that are not selected insulin products, to the extent that such cov-

erage is not otherwise required and such cost-sharing is

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- 1 otherwise permitted under Federal and applicable State
- 2 law.
- 3 "(e) Application of Cost-sharing Towards
- 4 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any
- 5 cost-sharing payments made pursuant to subsection (a)(2)
- 6 shall be counted toward any deductible or out-of-pocket
- 7 maximum that applies under the plan.".
- 8 (2) CLERICAL AMENDMENT.—The table of sec-
- 9 tions for subchapter B of chapter 100 of such Code
- is amended by adding at the end the following new
- 11 item:

"Sec. 9826 Requirements with respect to cost-sharing for certain insulin products.".

- 12 (f) IMPLEMENTATION.—The Secretary of Health and
- 13 Human Services, the Secretary of Labor, and the Sec-
- 14 retary of the Treasury shall implement the provisions of
- 15 this section, including the amendments made by this sec-
- 16 tion, through subregulatory guidance or program instruc-
- 17 tion.