

Insulin Coverage Under Private Health Insurance and Medicare Part D: In Brief

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Millions of individuals with diabetes in the United States require daily insulin injections to survive. These individuals may face high list prices and rising cost-sharing requirements under their health plans. Studies have shown that individuals with diabetes who cannot afford their insulin may decide to use less insulin than their physicians prescribed or may decide to switch to lower-cost, less-effective insulin, which can endanger their health. Recently, Congress has considered legislation to make insulin more affordable. P.L. 117-169, the budget reconciliation law often referred to as the Inflation Reduction Act (IRA), included a provision that caps insulin cost sharing in the federal Medicare program starting in 2023. This report provides information on diabetes, insulin, and recent legislation.

Insulin

Insulin is a hormone that regulates cells' storage and use of sugar (glucose). When the pancreas does not make enough insulin (type 1 diabetes) or insulin cannot be used effectively (type 2 diabetes), glucose builds up in the blood, leading to serious complications such as heart disease, blindness, or kidney failure. Prior to the 1921 discovery of insulin,¹ individuals with type 1 diabetes usually died from the disease.

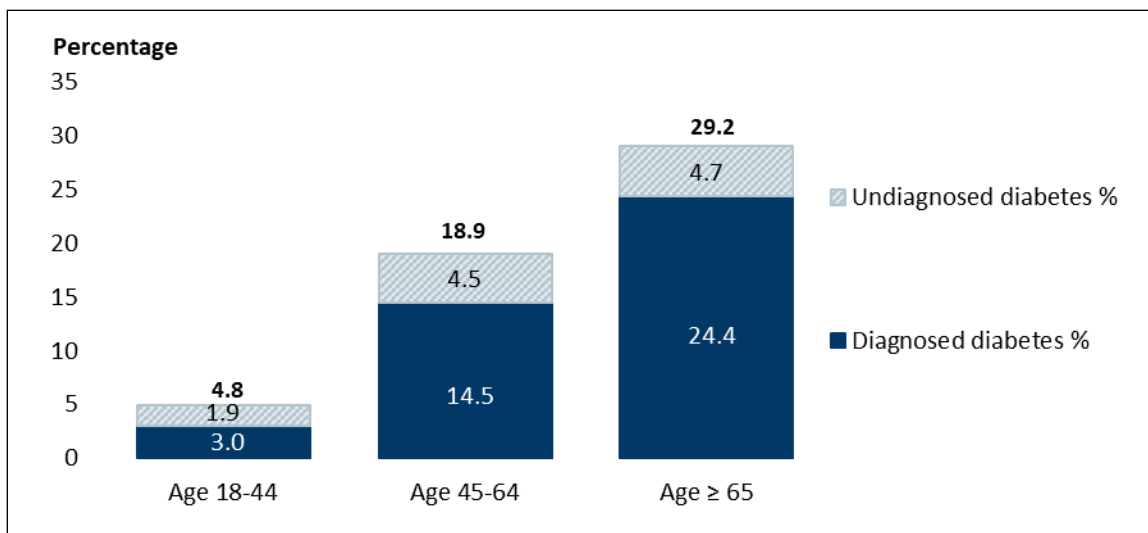
According to the Centers for Disease Control and Prevention (CDC), an estimated 37.3 million (14.7%) U.S. adults aged 18 and older had either type 1 or type 2 diabetes in 2020, including 28.5 million with diagnosed diabetes and 8.5 million with undiagnosed diabetes.² The prevalence of diabetes increases with age (see **Figure 1**). Relative to non-Hispanic White adults, adults in other racial and ethnic groups have higher rates of diabetes and are more likely to suffer complications from the disease.³

¹ Ignazio Vecchio et al., "The Discovery of Insulin: An Important Milestone in the History of Medicine," *Frontiers in Endocrinology*, vol. 9 (October 23, 2018).

² Centers for Disease Control and Prevention, *Diabetes Report Card 2021, 2022*, at <https://www.cdc.gov/diabetes/library/reports/reportcard/national-state-diabetes-trends.html>.

³ *Ibid.*

Figure 1. Estimated Percentage of Adults with Diabetes in the United States by Age, 2017-2020



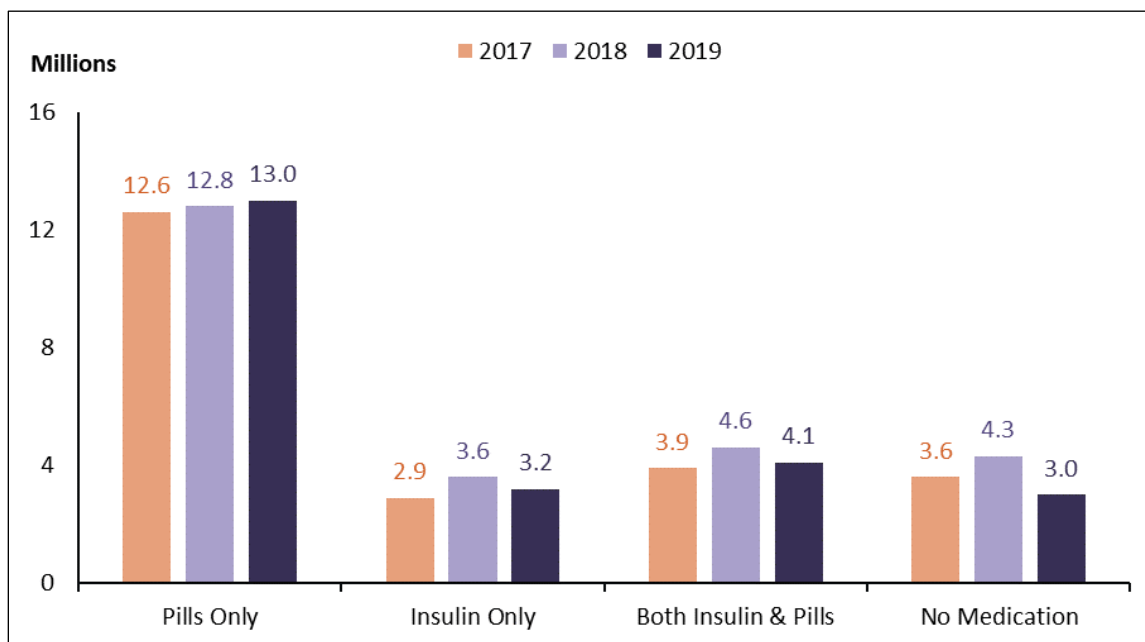
Source: Figure created by CRS based on data from Centers for Disease Control and Prevention (CDC), “National Diabetes Statistics Report: Prevalence of Both Diagnosed and Undiagnosed Diabetes,” Table 1a.

Notes: Data include individuals with both type I and type II diabetes. Figures may not sum precisely due to rounding.

People with type 1 diabetes must use insulin daily to survive. Many individuals with type 2 diabetes can control their blood glucose by following a healthy diet, losing excess weight, and maintaining regular physical activity, but some require insulin and other medications.⁴ Overall, about 7.3 million U.S. adults aged 18 and older were using insulin in 2019, according to the most recent figures from the CDC (see **Figure 2**).

⁴ Kathaleen Briggs Early and Kathleen Stanley, “Position of the Academy of Nutrition and Dietetics: The Role of Medical Nutrition Therapy and Registered Dietitian Nutritionists in the Prevention and Treatment of Prediabetes and Type 2 Diabetes,” *Journal of the Academy of Nutrition and Dietetics*, vol. 118, no. 2. (February 2018), p. 344.

Figure 2. Medication Use for Adults with Diabetes
(Individuals who use pills, insulin, both pills and insulin, and no medication)



Source: Figure created by CRS based on data from CDC, Division of Diabetes Translation, “United States Diabetes Surveillance System,” at <https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html>.

Insulin Development

Insulin is a small protein composed of 51 amino acids. Because insulin is derived from a living organism, it is considered a *biologic*, or *biological product* (the text box below defines biologics and describes their regulatory framework). Since the discovery of insulin, incremental modifications over time have resulted in improvements in safety, effectiveness, and convenience to patients.⁵

Insulin was discovered in 1921 by two University of Toronto researchers who sold their U.S. patents to the university for \$1 each, so the drug could be produced at a reasonable cost.⁶ Facing challenges manufacturing sufficient quantities of insulin for the North American market, in 1923, the University of Toronto team partnered with—and licensed manufacturing rights to—several pharmaceutical companies.⁷

Commercially available insulins today differ from the insulin discovered by the Toronto team. The original insulin was a short-acting product with a duration of action of 6-8 hours, making it less suitable for providing 24-hour coverage. In the late 1930s through the 1950s, researchers altered regular insulin by adding substances (e.g., protamine and zinc) to gain longer action, resulting in what are now called *intermediate-acting insulins*. One such advance, Neutral

⁵ Jeremy A. Greene and Kevin R. Riggs, “Why Is There No Generic Insulin? Historical Origins of a Modern Problem,” *New England Journal of Medicine*, vol. 372, no. 12 (March 19, 2015), pp. 1171-1175 (hereinafter, Greene and Riggs, “Generic Insulin”).

⁶ *Ibid.*

⁷ Jing Luo, Jerry Avorn, and Aaron S. Kesselheim, “Trends in Medicaid Reimbursements for Insulin from 1991 Through 2014,” *JAMA Internal Medicine*, vol. 175, no. 10 (October 2015), pp. 1681-1687.

Protamine Hagedorn (NPH), was patented in 1946. It allowed for the combination of two types of insulin (long-acting and short-acting insulin) in premixed vials, making a single daily injection possible for some patients.⁸

At that time, insulin was obtained by extraction from animals. As animal-derived products, insulins were subject to problems inherent to animal-tissue extracts, such as impurities, which could cause immunologic reactions impacting their safety and effectiveness.⁹

Insulin production has changed over the years, as researchers altered insulin to improve the patient experience. In the late 1970s, advancements in biotechnology allowed for the replacement of animal insulin extracted from cattle and pig pancreases with human insulin produced using recombinant DNA technology. In 1982, Eli Lilly brought the first recombinant human insulins to the U.S. market: Humulin R (regular) and N (NPH). In the late 1980s, advancements in recombinant technology allowed scientists to modify insulin's structure to improve its physiological effects. This advancement resulted in the development of insulin analogs, which more closely replicate normal insulin patterns in the body. In 1996, Humalog (insulin lispro) became the first rapid-acting insulin analog to be approved, followed by Novolog (insulin aspart) in 2000, and others thereafter.¹⁰ This same technology allowed for the development of *long-acting insulin* analogs. In 2000, Lantus (insulin glargine) became the first long-acting insulin analog, and others followed.¹¹

Some studies have questioned whether the more expensive analogs provide an advantage over regular insulin in controlling glucose levels or preventing diabetes-related complications in patients with type 2 diabetes.¹² In addition to modifications to insulin itself, associated delivery devices, such as insulin pens, have provided a more convenient route of administration for patients compared with syringes. Subsequent patenting of these modifications upon approval has shielded insulin products from competition for extended periods. As new insulin products entered the market, insulin manufacturers discontinued many older versions of these products. The regulatory framework created challenges for bringing generic insulins to the market.¹³

⁸ Greene and Riggs, "Generic Insulin," p. 1172.

⁹ Ibid.

¹⁰ Ibid.

¹¹ Ibid.

¹² Kasia J. Lipska et al., "Use and Out-of-Pocket Costs of Insulin for Type 2 Diabetes Mellitus from 2000 Through 2010," *JAMA*, vol. 311, no. 22 (June 2014). Sudipa Sarkar et al., "Trends in Insulin Types and Devices Used by Adults with Type 2 Diabetes in the United States, 2016 to 2020," *JAMA Network Open*, vol. 4, no. 10 (October 1, 2021).

¹³ Greene and Riggs, "Generic Insulin."

Regulation of Biologics and Biosimilars

Biological products, or *biologics*, are medical products such as drugs or vaccines that are derived from living organisms and may be produced by biotechnology. Compared with conventional chemical drugs, biologics are relatively large and complex molecules. A *biosimilar* is a biologic that is highly similar to, and has no clinically meaningful differences from, an already licensed biologic (i.e., the reference product). Because a biosimilar is not structurally identical to the reference product, it is not considered interchangeable with the reference product and thus generally cannot be substituted for the reference product without the prescriber's intervention. For a biosimilar to be considered interchangeable to a biologic, the manufacturer will have to submit additional data. See CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*.

Biologics and biosimilars are *licensed* by the U.S. Food and Drug Administration (FDA) under the Public Health Service Act (PHSA), whereas small-molecule drugs are *approved* by the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA §505; 21 U.S.C. §355). For historical reasons that are beyond the scope of this report, until March 2020, insulin and several other natural source biologics were subject to the drug approval provisions of the FFDCA rather than the PHSA, which created challenges for bringing generic insulins to market.

The Biologics Price Competition and Innovation Act (BPCIA)—enacted as Title VII of the Patient Protection and Affordable Care Act (ACA, as amended; P.L. 111-148)—established an abbreviated licensure pathway for manufacturers to bring biosimilar and interchangeable biologics to the prescription drug market. The BPCIA also included the so-called *deemed to be a license* provision, which required that on March 23, 2020 (i.e., 10 years after the ACA's enactment), biologics approved under the FFDCA (e.g., insulin products) be deemed licensed under the PHSA. These changes were expected to bring more competition to the insulin market. In July 2021, the FDA approved the first interchangeable insulin product, Semglee, which is both biosimilar to and interchangeable with its reference product, Lantus (insulin glargine).

Source: U.S. Food and Drug Administration (FDA), “FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes,” press release, July 28, 2021, at <https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes>.

Insulin Pricing

In the past several decades, the list prices (the prices set by the manufacturers) of many insulins have risen significantly. For example, data from manufacturers and government investigations show that list prices for a range of insulins rose 10% or more annually from 2014 to 2019.¹⁴ Manufacturers say the higher prices, in part, reflect research advances (e.g., delivery mechanisms, new insulin formulations). Some investigations have questioned that rationale, especially for annual price increases for existing insulins, and have suggested manufacturers have engaged in “shadow pricing” by all increasing prices at the same pace.¹⁵

Manufacturers have told Congress that the payment for insulin prices they receive (net prices) are far below the list prices they initially set, because they must provide significant discounts and rebates to pharmacy benefit managers (PBMs) to have their drugs included on health plan

¹⁴ See U.S. Congress, Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, 116th Cong., 2nd sess., January 14, 2021, at <https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-insulin-investigation-uncovering-business-practices-between-drug-companies-and-pbms-that-keep-prices-high>.

¹⁵ Sanofi, “Prescription Medicine Pricing: Our Principles and Perspectives,” p. 10, at <https://www.sanofi.com/dam/jcr:d41dfad7-a0a3-441d-98f3-c04c96192af2/Prescription-Medicine-Pricing-Principles.pdf>. According to the report outlining Sanofi 2022 pricing principles, from 2012 to 2021, list prices for Sanofi insulin rose 143% but net prices declined by 54%. Representatives of Novo Nordisk and Eli Lilly in testimony to Congress made similar statements regarding net pricing for their insulins. For example, see Testimony of Douglas J. Langa, Novo Nordisk Inc., in U.S. Congress, House Energy and Commerce Subcommittee on Oversight and Investigations, 116th Cong., 1st sess., April 10, 2019, at <https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-%20Langa%2004.10.2019.pdf>.

formularies (lists of covered drugs).¹⁶ Some studies suggest the share of insulin prices captured by intermediaries in the drug payment system, including PBMs, has increased over time.¹⁷

Insulin Biosimilar Pricing

The introduction of lower-cost versions of insulins that are already on the market could reduce average prices for insulin products, but the results of doing so have been mixed so far. Sanofi introduced Admelog, which is a biosimilar for Eli Lilly's rapid-acting insulin Humalog (insulin lispro), in 2018. By 2019, Admelog accounted for over one-third of insulin lispro doses dispensed under Medicaid.¹⁸

Semglee, a biosimilar of the long-acting insulin product Lantus was licensed in 2020, and had limited market penetration with the exception of the Medicaid program.¹⁹ In 2021, the FDA licensed a new interchangeable version of Semglee.²⁰ The manufacturer introduced two versions of the product. One was a branded version of interchangeable Semglee, with a list price that was slightly less than that of its reference product.²¹ The manufacturer also introduced an unbranded version of interchangeable Semglee, with a list price that was 65% less than Lantus.²²

The interchangeable versions have gained market share in commercial health plans,²³ with the branded interchangeable Semglee accounting for a combined 15% of commercial prescriptions in

¹⁶ Pharmacy benefit managers (PBMs) are key intermediaries in the U.S. prescription drug distribution and payment chain. PBMs perform various services for health payers, such as insurers or employers, including negotiating drug prices with pharmaceutical manufacturers; developing prescription drug formularies, or lists of covered drugs; contracting with networks of participating pharmacies that agree to dispense drugs for set reimbursement; or operating their own mail-order and specialty-drug pharmacies. Many PBMs are now owned by health plans.

¹⁷ Karen Van Nuys et al., *Untangling the Price of Insulin*, University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics, November 5, 2021, at <https://healthpolicy.usc.edu/research/untangling-the-price-of-insulin/>.

¹⁸ Medicare Payment Advisory Commission (MedPAC), *March 2022 Report to the Congress: Medicare Payment Policy*, March 15, 2022, p. 488, at <https://www.medpac.gov/document/march-2022-report-to-the-congress-medicare-payment-policy/>. Eli Lilly has also introduced a lower-cost version of Humalog, known as Insulin Lispro. Referred to as an authorized generic, this product (and similar products) do not have an 'interchangeable' designation by the FDA; they are the same molecule with minor changes. See <https://www.centerforbiosimilars.com/view/are-authorized-biologics-poised-to-hold-back-biosimilars>.

¹⁹ IQVIA, "Lessons from Semglee: Early Perspectives on Pharmacy Biosimilars," November 2022, available for download at <https://www.iqvia.com/locations/united-states/library/white-papers/lessons-from-semglee-early-perspectives-on-pharmacy-biosimilars>. The company is phasing out non-interchangeable Semglee.

²⁰ The non-interchangeable Semglee was anticipated to be phased out by the end of the 2021 calendar year. Vitaris, Viatriis and Biocon Biologics Announce Launch of Interchangeable SEMGLEE® (insulin glargine-yfgn) Injection and Insulin Glargine (insulin glargine-yfgn) Injection, Nov. 16, 2021, [https://newsroom.viatriis.com/2021-11-16-Viatriis-and-Biocon-Biologics-Announce-Launch-of-Interchangeable-SEMGLEE-R-insulin-glargine-yfgn-Injection-and-Insulin-Glargine-insulin-glargine-yfgn-Injection#:~:text=SEMGLEE%20\(insulin%20glargine%2Dyfgn\),of%20the%202021%20calendar%20year](https://newsroom.viatriis.com/2021-11-16-Viatriis-and-Biocon-Biologics-Announce-Launch-of-Interchangeable-SEMGLEE-R-insulin-glargine-yfgn-Injection-and-Insulin-Glargine-insulin-glargine-yfgn-Injection#:~:text=SEMGLEE%20(insulin%20glargine%2Dyfgn),of%20the%202021%20calendar%20year).

²¹ Mike Hoskins, "Hello Semglee: First of Its Kind 'Interchangeable' Insulin Now Available," *Healthline*, January 19, 2022, <https://www.healthline.com/diabetes/new-low-cost-interchangeable-semglee-insulin>.

²² Semglee was first approved by the FDA as 2020 as an equivalent to Lantus, but was not interchangeable. In 2021, the FDA approved an interchangeable license for Semglee. FDA, "FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes," July 28, 2021, <https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes>. There is also an authorized generic of Lantus, Insulin Glargine and another product that has received interchangeable designation with Lantus, Rezvoglar.

²³ IQVIA, "Lessons from Semglee: Early Perspectives on Pharmacy Biosimilars," November 2022, available for download at <https://www.iqvia.com/locations/united-states/library/white-papers/lessons-from-semglee-early-perspectives-on-pharmacy-biosimilars>.

March 2022.²⁴ The non-branded interchangeable version has picked up market share in Medicaid. Use in Medicare Part D has been lower. Generally, in Medicare Part D, there has been relatively low uptake by plans of the less-expensive biosimilar insulins, such as long-acting Basaglar and rapid-acting Admelog.²⁵ Some of the differences in utilization can be explained by health plan formulary preferences, including pricing agreements with manufacturers.

Press reports have indicated state interest in further development of lower cost insulin. California's state budget, enacted in July 2022, included \$100 million toward enabling the state to manufacture its own biosimilar insulin.²⁶

Insulin Costs for Americans with Health Care Coverage

Most Americans have coverage for insulin through a health insurance plan, either in the commercial market or through a government program, such as Medicare. Such individuals' costs for insulin are generally the co-payment or coinsurance required by their health plan or program when they fill a prescription.²⁷

Many insurers base prescription cost sharing on list prices rather than on net prices after manufacturer rebates are applied. As a result, enrollees may be required to pay more for insulin as list prices rise. (Although insurers may not pass on the value of rebates at the pharmacy counter, they often use the rebate revenues to buy down, or reduce, plan premiums for all enrollees.) List price increases also directly affect the uninsured, who often pay list prices because they do not have insurance.²⁸

Numerous studies show that medication adherence generally declines as prices and out-of-pocket (OOP) costs increase.²⁹ Difficulty in accessing insulin due to cost or loss of insurance may contribute to health complications.³⁰

²⁴ Fraiser Kansteiner "Viatis launched 2 versions of its interchangeable insulin biosimilar. Why?," *Fierce Pharma*, November 16, 2021, <https://www.fiercepharma.com/pharma/viatis-launches-two-versions-its-interchangeable-biosimilar-semglee-bid-to-tackle-pricing>.

²⁵ MedPAC, *March 2022 Report to the Congress: Medicare Payment Policy*, March 15, 2022, p. 487, at <https://www.medpac.gov/document/march-2022-report-to-the-congress-medicare-payment-policy/>.

²⁶ Adam Beam, Associated Press, "California aims to make its own insulin brand to lower price," July 29, 2022, <https://apnews.com/article/health-california-diabetes-government-and-politics-f846c58d4cb327578d1c7b3a9495d496>.

Other states have indicated interest in producing their own insulin; see Gabrielle Wanneh, "Maine Is Third State to Consider Making Its Own Insulin," *Inside Health Policy*, May 18, 2022, at <https://insidehealthpolicy.com/inside-drug-pricing-daily-news/maine-third-state-consider-making-its-own-insulin>.

²⁷ For more information on prescription drugs, see CRS Report R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy*.

²⁸ Although insulin costs for the uninsured are beyond the scope of this report, uninsured individuals may receive reduced-cost prescription drugs through facilities such as health centers. These entities, among other types of covered entities, are able to purchase discounted prescription drugs through the 340B program. For more information, see CRS Report R43937, *Federal Health Centers: An Overview*, and Robert King, "HHS Proposes Nixing Rule Affecting Insulin and EpiPen Discounts for Community Health Centers," June 15, 2021, at <https://www.fiercehealthcare.com/payer/hhs-proposes-nixing-rule-affecting-insulin-and-epipen-discounts-for-community-health-centers>.

²⁹ For example, Darby Herkert et al., "Cost-Related Insulin Underuse Among Patients with Diabetes," *JAMA Internal Medicine*, vol. 179, no. 1 (December 3, 2018), pp. 112-114, at <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2717499>.

³⁰ For example, a 2018 *Health Affairs* study that considered interruptions in private health insurance coverage across 15 years found a fivefold increase in acute health services used by individuals aged 18-64 with type 1 diabetes after an interruption in coverage, compared with before the interruption. For more information, see Mary A. M. Rogers et al., "Interruptions in Private Health Insurance and Outcomes in Adults with Type 1 Diabetes: A Longitudinal Study,"

Insulin Coverage in Private Health Insurance

Prescription drug coverage of insulin products varies among insurers, including which insulin products are included on a plan's formulary and the associated cost-sharing requirements. Cost sharing may include a deductible, a flat co-payment and/or coinsurance based on a percentage of price, and an annual limit on OOP spending.

The Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended) requires that all non-grandfathered health plans offered in the individual and small-group health insurance markets cover certain essential health benefits (EHBs), including prescription drugs. The Department of Health and Human Services (HHS) has clarified in regulation that a health plan meets EHB requirements if it covers at least one drug in every United States Pharmacopeia (USP) category and class or the same number of prescription drugs in each category and class as the plan that serves as the EHB benchmark plan for the state.³¹ Under the USP, insulin is a class within the category of blood glucose regulators.

Although the EHB requirements specify minimum requirements for the range of drugs a plan must offer, no federal requirements limit the amount of OOP spending (or cost sharing) an enrollee can be required to pay for an insulin product (though health plans are subject to the total plan OOP limit). Enrollee cost sharing for insulin varies widely. A study found "tremendous heterogeneity" in cost sharing for insulin, with an average OOP cost for insulin of \$613 per year for people under the age of 65 with private insurance.³²

Most states have imposed requirements regarding insulin coverage and cost sharing on state-regulated health plans. According to the National Council of State Legislatures, as of July 2022, 46 states and the District of Columbia had requirements related to coverage of services, treatments, and/or supplies related to diabetes and 22 states had capped monthly cost sharing for insulin.³³ These state laws apply to state-regulated health plans; they do not apply to self-insured group plans, which are subject to federal regulation.³⁴

Insulin Coverage in Medicare Part D

Medicare Part D is a voluntary program covering outpatient prescription drugs for Medicare enrollees. Individuals qualify for Medicare based on age (65 years or older) or, in certain cases, disability. In 2021, about 76% of Medicare beneficiaries (48.3 million people) were enrolled in Part D plans.³⁵ The standard Part D benefit sets average enrollee cost sharing at 25% of a plan's

Health Affairs, vol. 37, no. 2 (July 2018), at <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0204>.

³¹ 45 C.F.R. §156.122(a).

³² Sherry A. Glied and Benjamin Zhu, *Not So Sweet: Insulin Affordability over Time*, Commonwealth Fund, September 25, 2020, at <https://www.commonwealthfund.org/publications/issue-briefs/2020/sep/not-so-sweet-insulin-affordability-over-time>.

³³ National Conference of State Legislatures, *Diabetes State Mandates and Insulin Copayment Caps*, July 7, 2022, at <https://www.ncsl.org/research/health/diabetes-health-coverage-state-laws-and-programs.aspx>.

³⁴ For more information on the types of private health insurance plans, see CRS Report R45146, *Federal Requirements on Private Health Insurance Plans*.

³⁵ MedPAC, Chapter 13 in *Report to the Congress: Medicare Payment Policy*, March 2022, p. 477, at <https://www.medpac.gov/document/march-2022-report-to-the-congress-medicare-payment-policy/>. According to MedPAC, in 2021, another 2% of Medicare beneficiaries had drug coverage through non-Medicare employer-sponsored plans that received Medicare's Retiree Drug Subsidy (RDS) for serving as the primary provider. (The RDS is paid from the Part D program.) Based on Medicare data from 2018, MedPAC estimates the remaining 22% of Medicare beneficiaries in 2021 were divided roughly equally between those who had creditable drug coverage from

negotiated drug price. However, most Part D plan sponsors (insurers) offer alternative or enhanced plans with tiered cost sharing, where enrollees pay less for low-cost drugs and more for expensive medications. (The plans must be at least as generous as the standard Part D plan.) Most Part D plans have an annual deductible, a period in the benefit where an enrollee pays 100% of costs (a maximum of \$505 in 2023). Currently, there is no annual OOP spending cap in Part D, except for certain enrollees who qualify for the Low Income Subsidy (LIS). Under the IRA, there will be an OOP limit for all enrollees, beginning with the 2024 plan year.

About 30% of Medicare beneficiaries have diabetes. In 2020, 3.3 million Part D enrollees used insulin, including 2 million who either were LIS enrollees with reduced cost sharing or were in special employer-based Part D plans that provide more generous benefits, according to the Medicare Payment Advisory Commission.³⁶ The remaining 1.3 million Part D enrollees may face high or variable insulin cost sharing, including paying 100% in the deductible. A 2017 Kaiser Family Foundation study found \$580 in OOP spending for non-LIS enrollees and that it had been increasing 6% per year on average since 2007.

To improve insulin adherence, the HHS Centers for Medicare & Medicaid Services in 2021 began the Part D Senior Savings Model, which caps monthly co-payments for certain insulins at \$35 in most stages of the benefit. Participating, enhanced Part D plans must offer the \$35 co-payment to all enrollees, except for LIS recipients and those in employer Part D plans. Plans must offer one vial dosage and one pen form of rapid-, short-, intermediate-, and long-acting insulin. In 2022, about 106 Part D sponsors were in the program, covering more than 800,000 enrollees who use insulin.

Under the IRA, beginning in plan year 2023 (Jan-Dec), Medicare Part D enrollees no longer may have a deductible for insulin and must have a maximum \$35 monthly co-payment. Beginning in 2026, the cap could be less than \$35, if 25% of the Part D negotiated price or 25% of the price of an insulin for which the HHS Secretary negotiates a price is lower than that amount. A recent study conducted by HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated beneficiary savings of \$734 million in Medicare Part D if a cap of \$35 had been in place in 2020.³⁷

Insulin and Medicare Part B

The IRA also caps insulin cost sharing in Medicare Part B, which covers physician-administered drugs. Under the IRA, starting July 2023, the Medicare Part B deductible is waived for insulin furnished to a beneficiary via an item of durable medical equipment (DME). In addition, starting in July 2023, the Medicare Part B payment amount to suppliers for insulin furnished through DME is set to be 80% of the Medicare Part B drug payment amount and the amount paid the suppliers for insulin furnished through DME is set to be adjusted so that beneficiary coinsurance for a month's supply of insulin would not exceed \$35. A recent ASPE study estimated savings for beneficiaries of around \$27 million in Part B if a cap of \$35 had been in place in 2020.³⁸

other sources and those with no coverage or coverage less generous than Part D.

³⁶ Centers for Medicare & Medicaid Services, "Part D Senior Savings Model," at <https://innovation.cms.gov/innovation-models/part-d-savings-model>. MedPAC, Chapter 13 in *Report to the Congress: Medicare Payment Policy*, March 2021, p. 427, at https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch13_sec.pdf.

³⁷ Bisma A. Sayed, Kenneth Finegold, and T. Anders Olsen, et al., *Insulin Affordability and the Inflation Reduction Act: Medicare Beneficiary Savings by State and Demographics*, Office of the Assistant Secretary for Evaluation and Planning (ASPE), January 24, 2023, <https://aspe.hhs.gov/reports/insulin-affordability-ira-data-point>.

³⁸ Ibid.

Legislation and Policy Considerations

Congress has recently considered additional proposals to address insulin costs and cost sharing; the 118th Congress could consider similar proposals. Some of the legislative proposals contain caps on cost sharing, which would limit what insured individuals pay OOP for insulin. Although the IRA includes OOP limits for Medicare, these limits do not apply to private health insurance plans.³⁹

The IRA includes a provision allowing High Deductible Health Plans (HDHPs) that qualify for tax-advantaged Health Savings Accounts (HSAs) to cover the costs of selected insulin products before an enrollee meets the annual deductible and still be considered HSA-qualified HDHPs.⁴⁰ This provision is in effect for plan years beginning on or after December 31, 2022. Current Internal Revenue Service guidance already considers insulin a preventive care service (meaning it may be provided pre-deductible) for individuals diagnosed with diabetes.⁴¹ Other, separate legislative proposals would limit list prices manufacturers could charge for insulin or would provide incentives for manufacturers to limit annual list price increases.⁴²

Recent studies suggest that caps on cost sharing could reduce costs for a significant number of insulin users enrolled in private health insurance plans. Findings vary based on the data used. According to a 2021 study from the Health Care Cost Institute, based on 2019 employer health plan data, a \$35 federal cap on monthly insulin cost sharing would reduce cost sharing for approximately 70% of the individuals studied.⁴³ According to a 2022 Petersen-Kaiser Family Foundation evaluation of 2018 data, insulin OOP costs for 26% of insulin users in individual market plans and 31% in the small-group market were more than \$35 per month on average.⁴⁴ The study also found that 19% of insulin users in large-group health plans spent more than \$35 a month on average.⁴⁵

³⁹ The budget reconciliation legislation originally included a provision to limit out-of-pocket (OOP) costs for insulin in private health insurance plans. That provision was removed from the bill during the Senate floor debate.

⁴⁰ A Health Savings Account (HSA) is a tax-advantaged account that individuals can use to pay for unreimbursed medical expenses (e.g., deductibles, co-payments, coinsurance, and services not covered by insurance). Individuals are eligible to establish and contribute to an HSA if they have coverage under an HSA-qualified High Deductible Health Plan (HDHP), do not have disqualifying coverage, and cannot be claimed as a dependent on another person's tax return. To be considered an HSA-qualified HDHP, a health plan must meet several criteria: (1) it must have a deductible above a certain minimum level, (2) it must limit OOP expenditures for covered benefits to no more than a certain maximum level, and (3) it can cover only preventive care services and (for limited time periods) telehealth services before the deductible is met.

⁴¹ Internal Revenue Service, "Additional Preventive Care Benefits Permitted to Be Provided by a High Deductible Health Plan Under §223," Notice 2019-45, at <https://www.irs.gov/pub/irs-drop/n-19-45.pdf>.

⁴² For example, see the draft legislation referred to as the INSULIN Act at <https://www.shaheen.senate.gov/imo/media/doc/Shahen-Collins%20INSULIN%20Act.pdf>. Some other legislation related to insulin may be found with the following search link created by CRS Librarians: <https://www.congress.gov/quick-search/legislation?wordsPhrases=insulin&include=on&wordVariants=on&congresses%5B%5D=117&legislationNumbers=&legislativeAction=&sponsor=on&representative=&senator=>.

⁴³ Aditi Sen and Bianca Silva Gordon, *Capping Out-of-Pocket Spending on Insulin Would Lower Costs for a Substantial Proportion of Commercially Insured Individuals*, Health Care Cost Institute, October 15, 2021, at <https://healthcostinstitute.org/hcci-research/capping-out-of-pocket-spending-on-insulin-would-lower-costs-for-a-substantial-proportion-of-commercially-insured-individuals-1>.

⁴⁴ Krutika Amin et al., *Out-of-Pocket Spending on Insulin Among People with Private Insurance*, Peterson-Kaiser Family Foundation Health System Tracker, March 24, 2022, at <https://www.healthsystemtracker.org/brief/out-of-pocket-spending-on-insulin-among-people-with-private-insurance/>.

⁴⁵ Ibid. In addition, a recent ASPE study found that OOP costs would be higher for people with private health insurance if not for the availability of manufacturer patient assistance programs and coupons. See Bisma A. Sayed, Kenneth

There are concerns that a cap on enrollee cost sharing could cause costs to shift to other players in the U.S. prescription drug distribution and payment chain, such as wholesalers, PBMs, health plans, employers and retailers (e.g., pharmacies).⁴⁶ Everything else being equal, lowering the cost sharing that enrollees using insulin pay would increase the cost of insulin for health insurers, which, in turn, might increase premiums for all enrollees in the health plan. Health plans also might use other tools (as allowed by law) to decrease their costs for insulin, such as trying to obtain more favorable rebates from manufacturers or choosing to remove certain insulins from their formularies. If insulin users increase their adherence due to lower cost sharing or are able to access more expensive insulins, health insurers could see increased costs for the drug. At the same time, health insurers could see reduced costs associated with health complications for individuals with diabetes that regular insulin use can prevent.

A cap on cost sharing for insulin would not address the cost of insulin for the uninsured or the cost of diabetes-related supplies.⁴⁷ The IRA included a cap on cost sharing in Medicare Part B for some insulin-related DME.

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Finegold, and T. Anders Olsen, et al., *Insulin Affordability and the Inflation Reduction Act: Medicare Beneficiary Savings by State and Demographics*, ASPE, January 24, 2023, <https://aspe.hhs.gov/reports/insulin-affordability-ira-data-point>. For more information on manufacturer patient assistance programs and coupons, see CRS Report R44264, *Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)*.

⁴⁶ For example, the Congressional Budget Office (CBO) score for the Affordable Insulin Now Act (H.R. 6833), as introduced on February 25, 2022, and passed by the House of Representatives on March 28, 2022, projected a cost to the federal government of \$6.6 billion over a 10-year period (including Medicare costs and Advanced Premium Tax Credit payments for individual plans purchased on the exchanges). CBO also estimated approximately \$4.8 billion in decreased revenue to the federal government. However, CBO found that the bill did not increase federal spending overall because of a pay-for which delayed implementation of a regulation limiting prescription drug rebates in Medicare. See CBO, *Estimated Budgetary Effects of H.R. 6833, the Affordable Insulin Now Act*, March 30, 2022, at <https://www.cbo.gov/publication/57957>. Similar legislation was introduced in the Senate as S. 3700 on February 17, 2022. Subsequently, the House bill was amended to remove the original language, which was replaced with text related to continuing appropriations for FY2023 and then enacted by the House and the Senate as P.L. 117-180.

⁴⁷ A recent ASPE study found that average OOP costs for insulin were more than twice as high for the uninsured than the overall average, and would have been higher were it not for such things as charity care, safety net providers, and coupons. See Bisma A. Sayed, Kenneth Finegold, and T. Anders Olsen, et al., *Insulin Affordability and the Inflation Reduction Act: Medicare Beneficiary Savings by State and Demographics*, ASPE, January 24, 2023, <https://aspe.hhs.gov/reports/insulin-affordability-ira-data-point>. Examples of diabetes-related supplies include insulin pumps and glucometers. A study of 2018 claims data found the average OOP cost of insulin among those with commercial insurance was \$435 per year, whereas the average OOP cost of diabetes-related supplies was \$490 per year. See Kao-Ping Chua, Joyce M. Lee, and Rena M. Conti, "Out-of-Pocket Spending for Insulin, Diabetes-Related Supplies, and Other Health Care Services Among Privately Insured U.S. Patients with Type 1 Diabetes," *JAMA Internal Medicine*, vol. 180, no. 7 (June 1, 2020), pp. 1012-1014, at <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2766588>.

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