

DRIVERS OF CHANGE

Top drivers of change in the diabetes and obesity market

Four key drivers reshaping the delivery of care for patients with diabetes and obesity

As diabetes and obesity heightened individuals' risk for severe COVID-19, the pandemic placed an outsized spotlight on these diseases over the last two years. We've identified four drivers that are reshaping the delivery of care for patients with diabetes and obesity.

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Read time – 10-min read

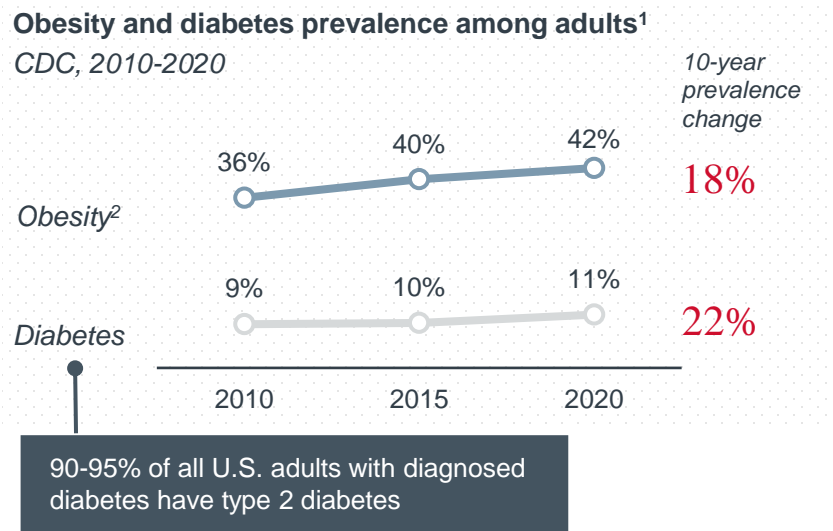
Audience

- All healthcare organizations

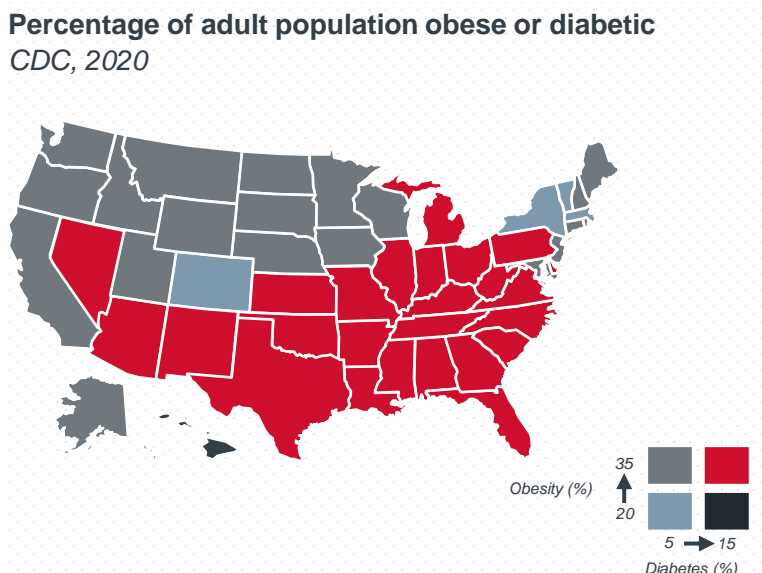
Introduction

Diabetes and obesity prevalence increased in U.S. adults, youth, and children since the start of the COVID-19 pandemic. Diabetic and obese people face an increased risk for severe COVID-19 infection and saw a surge in diabetes-related deaths (unrelated to COVID-19) in 2020 and 2021 compared to pre-pandemic levels. The rise in deaths is likely related to the presence of co-morbidities for these individuals. In US adults, 62% with diabetes are obese, and half of type 2 diabetes deaths worldwide are attributed to cardiovascular diseases. Stakeholders across the healthcare industry continue to prioritize the development of new prevention and management solutions to reduce the burden of these chronic conditions in the U.S.

U.S. diabetes and obesity prevalence is steadily rising.



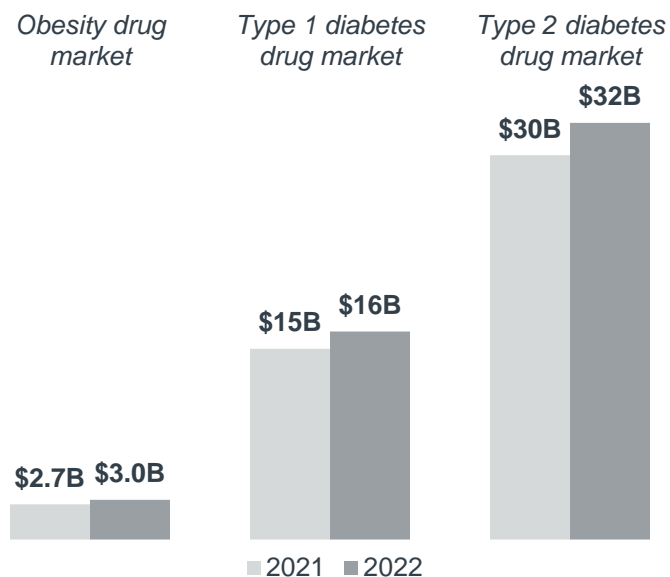
Southern states have the highest prevalence of diabetes and obesity.



1. Projections do not consider the impact of the COVID-19 pandemic.
2. The CDC defines obesity in adults as body mass index (BMI) > 30 kg/m².

Sources: "Early Release of Selected Estimates..." NCHS, 2015; Hales, et al., "Prevalence of obesity among adults and..." NCHS data brief, no 288; Ward, et al., "Projected U.S. State-Level Prevalence of Adult Obesity..." NEJM, 381 (2019): 2440-2450; Lin, et al., "Projection of the future diabetes burden..." Popul Health Metrics 16, 9 (2018); "BRFSS Prevalence & Trends Data," CDC.

High diabetes and obesity prevalence is fueling U.S. drug market growth.





Drivers of change

SECTION	DRIVER	CHANGE
01	Insulin costs on the rise	Soaring costs have spurred multi-stakeholder initiatives aimed at lowering U.S. insulin costs for consumers.
02	Limited uptake of new treatments	A growing range of treatments have attracted attention, but stakeholders require more evidence before supporting widespread use.
03	U.S. prevention efforts remain patchy	The U.S.'s fragmented and ineffective prevention efforts are pushing private industry stakeholders to take the reins in diabetes and obesity prevention.
04	Worsened health disparities	In the wake of COVID-19, health leaders are reckoning with and responding to worsening disparities in diabetes and obesity among certain populations.

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01 Insulin costs on the rise

What's happening?

Rising list prices of insulin products have captured the attention of the American media, with growing scrutiny of wholesalers, PBMs¹ and drug manufacturers. Despite insulin cost reduction efforts by drug manufacturers and PBMs, federal and state legislators continue to push for insulin price reduction policies. Stakeholders across the health industry are launching initiatives to reduce insulin and broader diabetes medication costs.

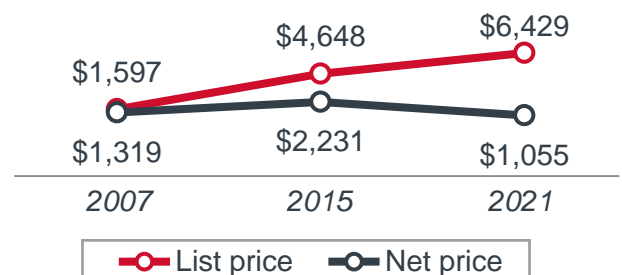
Stakeholder	Example insulin cost reduction initiatives
Federal government	<ul style="list-style-type: none"> \$35 insulin copay cap for Medicare beneficiaries Encouraging biosimilar insulin production with FDA regulations
Pharmaceutical companies	<ul style="list-style-type: none"> Releasing discounted generic versions of insulin products Offering copay cards that lower monthly prescription costs
PBMs	<ul style="list-style-type: none"> Enabling employers and health plan sponsors to offer diabetes medications with \$0 or capped out-of-pocket costs Including lower-cost biosimilar insulin products on preferred formularies
State governments	<ul style="list-style-type: none"> Instituting insulin copay caps for state-regulated health plans Regulating insulin manufacturer and PBM practices

Why does this matter today?

Often touted as the “poster child” for high U.S. prescription drug prices, average list insulin prices have increased by over 300% in the last decade. This has sparked widespread reports of potentially lethal insulin rationing by diabetic patients with financial distress. These reports have drawn the attention of both the public and policymakers.

Insulin analog cost per patient per year²

Milliman, 2007-2021



1. Pharmacy benefit manager.

2. Based on SSR Health estimates of average gross and net costs of treatment.

Sources: “Analysis of insulin competition and costs in the United States,” Milliman, December 2021; “Intermediaries Gain From Rising Insulin Prices in the US,” Medscape, November 2021; Sable-Smith, “Insulin’s High Cost Leads to Lethal Rationing,” NPR, September 2018; Minemyer, “Optum, Sanofi team to make low-cost insulin available to uninsured,” Fierce Healthcare, August 2022; “American Diabetes Association Statement in...,” ADA, March 2022; “FDA Approves First Interchangeable Biosimilar Insulin...,” FDA, July 2021; Konish, “The Inflation Reduction Act caps costs...,” CNBC, August 2022.

Potential impacts of industry actions

Impact to stakeholder expected to be: + Positive – Negative ? Too soon to tell

- + **Consumers** will save on some out-of-pocket diabetes management costs.
- + **Governments** could gain political points and potentially reduce health spending.
- ? **Health plans** may pay higher prescription drug costs as a result of co-pay caps but concealed negotiated prices for insulins by PBMs muddles predictions of widespread impacts.
- **PBMs** will face increased regulation and scrutiny of practices.
- **Pharmaceutical companies** will face increased regulation and reduced revenue from insulins.

Expected stakeholder actions

- **Consumers:** Will become more active shoppers with improved access to affordable insulin.
- **Governments:** Will respond to ongoing litigation from industry groups challenging insulin pricing, drug transparency and PBM regulation policies and pressure from constituencies to adopt drug cost containment legislation.
- **Health plans:** Some plans may pass drugmaker rebates through to members or include lower-priced insulins such as generics and biosimilars in formularies as a result of mandated cost-sharing caps on insulins for state-regulated health plans.
- **PBMs:** Will respond to growing insulin pricing litigation on multiple fronts, additional state-level PBM regulation, and close monitoring of formulary placement decisions by journalists and advocacy groups in the coming years.
- **Pharmaceutical companies:** Also expected to address insulin pricing litigation on multiple fronts; additional imposed state-level drug pricing transparency and emergency insulin policies that could drive down net payments for insulins.
- **Pharmacies:** Will advocate for the passage of state legislation banning “gag” restrictions, prescription overpayment fees, and spread pricing from PBMs (watch for loopholes in these state policies).
- **Physicians:** Some will increase consideration of the cost-effectiveness of insulin products when prescribing regimens.

02 Limited uptake of new treatments

What's happening?

New treatments for diabetes and obesity include virtual diabetes prevention programs (DPPs) and anti-obesity medications. Their reimbursement outlook remains poor—most health plans do not cover the cost of any obesity medications and CMS has not approved Medicare coverage of virtual DPPs. Provider, digital health, and pharmaceutical stakeholders continue to lobby for better reimbursement.

\$890k

Spent by seven organizations on lobbying efforts related to the passage of the **Prevent Diabetes Act**

\$52M+

Spent by seven companies on lobbying to attain anti-obesity medication FDA approval and advocate for the passage of the **Treat and Reduce Obesity Act**

Why does this matter today?

These treatments made headlines following CMS' decision to reimburse virtually delivered DPPs during the COVID-19 public health emergency, as well as Wegovy's favorable clinical results in 2021. Despite some positive outcomes reported by both treatments, limited coverage across all payers has limited their widespread utilization. National estimates suggest relatively few U.S. adults use obesity medications, and the few that do often pay out-of-pocket to attain them. Few participate in Medicare's DPP with in-person requirements—only 3,300 participated in the program (out of an estimated 29.5 million Medicare beneficiaries with prediabetes) as of March 2021. Payers and regulators require more evidence for these treatments before broadening coverage and indications.

Source: "Why the future of the Medicare Diabetes Prevention Program is uncertain," Advisory Board, December 2021; "Medicare Extends COVID-19 Telehealth Coverage in Diabetes Prevention Programs," mHealth, December 2020; "Risk/Reward: Diet drug companies spent \$60 million..." Milwaukee Journal Sentinel, August 2021; "Why the future of the Medicare Diabetes Prevention Program is uncertain," Advisory Board, December 2021; "Wegovy™ Demonstrated Significant and Sustained Weight Loss in Two-Year Study..." PR Newswire, November 2021; "Cost Savings and Reduced Health Care Utilization..." JHEOR, August 2020; "Few Adults Used Prescription Drugs for Weight Loss and Insurance Coverage Varied," GAO, August 2019; Savage & Sanghavi, "The Medicare Diabetes Prevention Program..." Health Affairs, November 2021.

Potential impacts of industry actions

Impact to stakeholder expected to be: + Positive – Negative ? Too soon to tell

- **Consumers** will pay for new treatments out-of-pocket because of limited payer coverage.
- **Digital health companies** will increase spending on evidence generation and advocacy efforts.
- ? **Health plans** may save on treatment costs for expensive diabetes and obesity therapies not proven cost-effective moving forward.
- **Pharmaceutical companies** will increase spending on evidence generation and advocacy efforts.

Expected stakeholder actions

- **Consumers:** Will demand more forms of diabetes and obesity treatment and advocate for their coverage by insurance plans.
- **Device/diagnostics companies:** Before tempering expectations of demand for their diabetes and obesity solutions, many will monitor pharmaceutical companies' progress in advancing anti-obesity medication use.
- **Digital health companies:** Will continue development of independent, peer-reviewed analyses of telehealth's effects on DPPs' outcomes.
- **Health plans:** Will evaluate treatment coverage policies, including reimbursement flexibilities made during the COVID-19 public health emergency and pilot programs designed to address diabetes and obesity directly.
- **Health systems:** Many will increase advocacy for strengthened telehealth reimbursement and broadened patient access to DPPs.
- **Pharmaceutical companies:** Will continue efforts to collect real-world evidence in treatment efficacy, shift plan attitudes to acknowledge obesity as a disease and engage with physician concerns. Some may also partner with digital therapeutics companies or develop their own therapeutic platforms to work with medications.
- **Physicians:** Will continue monitoring new treatment efficacy; some physician practices will adopt virtual DPPs as differentiators.

03 U.S. prevention efforts remain patchy

What's happening?

U.S. federal efforts to set diet and nutrition policy remain fragmented. Both a 2021 GAO¹ report and remarks from a congressional panel of experts emphasized the disorganized and haphazard nature of diet and nutrition efforts led by federal agencies. These reactive and uncoordinated policies have thus far failed to reduce the prevalence of chronic conditions in the U.S. This forces health organizations, such as health plans and health systems, to lead diabetes and obesity prevention strategies.

200

Federal agency efforts related to diet—fragmented across 21 agencies—for reducing Americans' risk of chronic health conditions from 2019-2021.

Why does this matter today?

The failure to reverse trends in U.S. diabetes and obesity prevalence contributes to billions of dollars in medical costs and lost productivity. These rising rates also contribute to the U.S.'s poor performance on most measures of population health compared to other high-income countries.

Potential impacts of industry actions

Impact to stakeholder expected to be: + Positive - Negative ? Too soon to tell

- **Consumers** will remain confused or unmotivated by fragmented and reactive federal policies.
- ? **Digital health companies** may anticipate growth in demand for virtual prevention programs to fill the gaps of federal policy, but patient utilization remains to be seen.
- **Employers** will face increased health insurance premiums and lost employee productivity.
- **Health plans** will experience rising costs associated with diabetes and obesity care.
- **Health systems and physicians** will be pressured to invest in unreimbursed prevention efforts.

Source: "Chronic Health Conditions: Federal Strategy Needed to Coordinate Diet-Related Efforts," GAO, August 2021; "Exclusive: U.S. diabetes deaths top 100,000 for second straight year," Reuters, January 2022; "Economic Costs of Diabetes in the U.S. in 2017," Diabetes Care, March 2018; Ward et al., "Association of body mass index with health care expenditures..." PLoS ONE, March 2021; Radley et al., "Americans, No Matter the State..." The Commonwealth Fund, August 2022.

1. U.S. Government Accountability Office.

Expected stakeholder actions

- **Consumers:** Will remain confused by fragmented diabetes and obesity prevention initiatives.
- **Device/diagnostics companies:** Those that develop technology used in bariatric surgery may respond to increased demand as obesity grows in the absence of strong prevention efforts.
- **Digital health companies:** Will advocate for improved reimbursement of virtually-delivered diabetes and obesity prevention programs to tap into unrealized growth opportunities.
- **Employers:** Likely to increase health insurance premiums and lose employee productivity due to growing disease prevalence.
- **Health plans:** Will invest in a broad range of diabetes and obesity interventions based in prevention and early intervention to reduce treatment costs.
- **Health systems and physicians:** Will partner with social service organizations and other healthcare providers, start-ups, and community groups to design prevention programs that take a holistic view of diabetes and obesity as government policies remain uncoordinated.
- **Public health plans:** Will increase investment in prevention efforts to reduce expenditures associated with rising diabetes and obesity prevalence among public insurance beneficiaries.
- **Pharmaceutical companies:** Will integrate digital therapeutic solutions with current medications to widen access to chronic disease prevention solutions.

04 Worsened health disparities

What's happening?

For decades, American Indian, Alaska Natives, Black Americans, and Hispanic Americans have carried a disproportionate burden of diabetes and obesity in the U.S., driven by social and structural inequities. COVID-19 exacerbated these disparities, prompting organizations across the industry to create initiatives that address these inequities.

Stakeholder	Health disparity initiatives
Health systems	\$2.5 billion invested by health systems for programs addressing SDOH ¹ including housing, food security, and job training.
Commercial payers	40% of U.S. health systems and commercial payers utilized social determinant data in risk assessment, patient outreach, and business decisions in 2020.
Pharmaceutical companies	\$400 million committed to support health equity solutions and diversify biopharmaceutical workforce.
State governments	75% of managed care states reported leveraging Medicaid MCO contracts to promote at least one strategy to address SDOH.

Why does this matter today?

The COVID-19 pandemic worsened health disparities for Alaska Native, Black and Hispanic people. These groups experienced high rates of COVID-19 infection, hospitalizations, and deaths. The pandemic also limited access to healthcare services, increased food insecurity, reduced opportunities for physical activity, and elevated stress and anxiety levels – all of which worsened existing disparities in diabetes and obesity across the country.

1 in 5

Black U.S. households reported food insecurity compared to 7% of White U.S. households in 2021

Potential impacts of industry actions

Impact to stakeholder expected to be: + Positive – Negative ? Too soon to tell

- ? **Consumers** may experience improved outcomes from health equity solutions – if they are intentionally designed.
- + **Digital health companies** will experience rising demand for digital solutions to screen for and address social determinants of health inequities.
- **Governments** will experience high demand for social assistance services.
- **Health systems and physicians** will face higher volumes of patients with complex health needs.
- **Health plans** will grapple with rising costs associated with worsened disparities.

Expected stakeholder actions

- **Consumers:** Will seek programs tailored to address local SDOH needs.
- **Digital health companies:** Will respond to demand from health systems and health plans for digital solutions to screen for and address SDOH among patients with diabetes and obesity.
- **Governments:** Will respond to growing demand for social assistance services among patients with complex needs. Some social assistance programs could reach capacity. Government leaders are also likely to pass policies to respond to ongoing pressure from advocacy groups and researchers for high-quality disaggregated data collection systems to combat health disparities.
- **Health plans:** Will invest in SDOH initiatives to address rising costs associated with treatment of diabetic and obese patients with complex social service needs.
- **Health systems:** Will adopt SDOH screenings and develop other strategies to address health inequities, particularly related to diabetes and obesity. Additionally, many health systems will experience higher volumes of patients with complex health and social service needs.
- **Pharmaceutical companies:** Will continue investing in health equity solutions and generation of evidence on the efficacy of products in different subpopulations.
- **Physicians:** Will treat a growing number of patients with complex health needs—especially in patient populations facing the starkest health disparities in diabetes and obesity education, prevention, and care.

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