Report from the New York State Insulin Workgroup

February **2025**

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EXECUTIVE SUMMARY

Purpose of this Report

Chapter 134 of the New York State laws of 2021 directs the Commissioner of the New York State Department of Health ("DOH"), in consultation with the Superintendent of the New York State Department of Financial Services ("DFS"), to convene an Insulin Workgroup ("Workgroup") tasked with investigating, evaluating, and recommending options to increase access and affordability of insulin to uninsured and underinsured New Yorkers.[1] DOH assembled the Workgroup comprised of a diverse group of experts representing health care providers, insurers, pharmacists, pharmaceutical manufacturers, pharmacy benefit managers, advocacy groups, health policy organizations, and individuals with diabetes who use insulin. Members participated in meetings chaired by DOH, which also included DFS. Workgroup discussion focused on the following options, strategies, and opportunities outlined in the statute:

a. Options for enrolling uninsured eligible individuals into health coverage which provides comprehensive coverage for persons with diabetes;
b. Barriers to access to information regarding costs within the insulin supply chain;
c. Actions that could be undertaken by the state to hold manufacturers accountable for price increases and transparency in drug pricing;
d. Options for increasing affordability and access to insulin for uninsured and underinsured individuals; and
e. Opportunities to engage with insulin pharmaceutical manufacturers for a public/private partnership to provide affordable insulin drugs to those lacking access to such drugs.

The Workgroup was also tasked with addressing the potential cost to individuals, the potential fiscal impact to the state, and any identified opportunities for federal financial participation of the above options and strategies. This report summarizes the discussions and recommendations of the Workgroup. Please note that the Workgroup was convened, and the report was drafted in 2023. Thus, there may be more recent policies, legislation, or strategies that are not reflected in this report.

DOH and DFS would like to thank all the members of the Workgroup for their significant

[1] (Relates to Prescribing Insulin and Related Supplies, 2021)

contributions of time and expertise. The Workgroup brought together a diverse group of stakeholders, with different perspectives on how to increase access and affordability of insulin. Through discussions and surveys, members reached consensus on some recommendations and disagreed on others. The report includes a number of health equity related proposals to address persistent disparities evidenced in the prevalence of diabetes and its complications being greater within communities of color. DOH and DFS will continue to engage stakeholders to reach the best possible solutions to the challenges of high prescription drug prices.

Summary of Recommendations

Below is a summary of the recommendations of the Workgroup. During Workgroup meetings, members discussed the pros and cons, as well as the feasibility, potential impact, and cost of implementing each option. Some strategies received general support and minimal, if any, opposition. Other options received strong support as well as strong opposition. The report documents Workgroup recommendations, any areas of dispute and the dissenting opinions of different members regarding those recommendations. The report was drafted entirely by DOH, and all factual recitations and analysis represent the views of DOH. Individual members of the Workgroup do not necessarily endorse or agree with every statement, sentiment, or opinion stated or implied in this report. Hence, nothing in this report should be construed as an adoption or admission by any individual member of the Workgroup.

A majority of Workgroup members recommended that the state consider the following strategies to increase access and affordability of insulin in New York.

1. **Options for enrolling uninsured eligible individuals into comprehensive health coverage.** Members unanimously prioritized adopting strategies that facilitate enrollment of individuals with diabetes who use insulin into comprehensive coverage, the gold standard for diabetes care. Since 2014, out-of-pocket costs of insulin have increased significantly for uninsured compared to insured individuals, creating a substantial financial burden on the uninsured population.[2] Controlling diabetes not only requires affordable insulin, but also access to comprehensive medical care,

[2] (Lin et al., 2023)

including doctor's visits, diabetes education, and affordable medical devices and supplies. In general, insured adults with diabetes have more frequent health care visits and better glycemic control than those without insurance, leading to better overall health outcomes for insured populations.[3] Poorly managed diabetes can result in significant, costly complications. The American Diabetes Association reported that in 2017, uninsured individuals with diabetes had 168% more Emergency Room visits than insured individuals.[4]

Workgroup members unanimously agreed that enrolling uninsured individuals with diabetes who use insulin into comprehensive coverage is the best, most cost-effective strategy to improve health outcomes and make insulin accessible and affordable for the uninsured population. Members also emphasized the importance of enrolling all uninsured individuals with diabetes into coverage, not just those that use insulin, for all the same reasons stated above. Once enrolled in coverage, insured individuals would be covered by New York State insulin cap laws.[5]

The Workgroup discussed options outlined in the 2022 report entitled "Narrowing New York's Health Insurance Coverage Gap".[6] These options and the estimated financial impact to the state are estimated only for individuals with diabetes who use insulin. However, members recommended that the state adopt these strategies to enroll all uninsured individuals with diabetes, which may impact some cost factors.

A majority of Workgroup members recommended the following four main strategies to increase enrollment of uninsured individuals with diabetes who use insulin into comprehensive coverage. While members noted that these strategies do not address the price of insulin issue, only one member opposed any of the four strategies and that dissent is detailed below.

a. Fund more Navigators to help enroll eligible individuals with diabetes who use insulin into Medicaid and the Essential Plan. Members recommended supplementing Navigator programs with targeted media campaigns. Workgroup members also suggested piloting programs to educate pharmacists on strategies to assist uninsured and underinsured patients with connecting to Navigator programs and/or manufacturer patient assistance programs. One

[3] (Casagrande & Cowie, 2018)
[4] (American Diabetes Association, 2018)
[5] (NYS DFS, 2023b)
[6] (Benjamin et al., 2022)

member dissented, suggesting that individuals needed stronger incentives or penalties to enroll in comprehensive coverage.

b. Amend the State's 1332 Waiver proposal with the Federal Government to provide coverage for immigrants with status issues (undocumented immigrants and those with statuses that currently prohibit enrollment into federally funded coverage) under the Essential Plan. This could be funded through the surplus funds in the State's 1332 pass-through account.

c. Develop a State Premium Assistance Program to provide deeper subsidies to incentivize and make health insurance more affordable for individuals (with incomes up to 600% of Federal Poverty Level) who are eligible for employer or union plans but cannot afford them to enroll in a Qualified Health Plan on the state marketplace. This could be funded through the surplus funds in the State's 1332 pass-through account.

d. ***Implement automatic enrollment via tax returns and other sources such as the Supplemental Nutrition Assistance Program (SNAP) applications.*** Workgroup Members recommended the state consider implementing a pilot program to assess the feasibility and impact of pursuing this strategy.

2. **Actions that could be undertaken by the state to hold manufacturers accountable for price increases and transparency in drug pricing.** Investigations at the state and federal levels demonstrate the complexity of drug pricing in the pharmaceutical chain. Workgroup members discussed the pros and cons of requiring increased transparency throughout the pharmaceutical chain. These Workgroup discussions were supplemented with an online anonymous survey to gather additional feedback. In the discussions and on the survey, the majority of Workgroup members expressed support for implementing policies and regulations at the state level to increase transparency in the pharmaceutical supply chain. Workgroup members, however, did not reach consensus. Some members, representing pharmaceutical manufacturers and insurers, dissented and their concerns are noted below.

   a. ***Increase price transparency of pharmaceutical manufacturers***. A majority of workgroup members recommend that the state require manufacturers to report the following data: price increases over a specific threshold; justification for price increases; and advance notice of price

increases. Some Workgroup members representing drug manufacturers opposed this strategy, stating the following opinions: 1). Manufacturers believe they are as transparent as they can be without disclosing trade secrets; 2). Manufacturers already report this data to other states and they believe that new regulations in New York would be duplicative; and, 3). Members representing manufacturers also contend that the proposed reporting requirements will not help to reduce insulin prices. As a compromise, Workgroup members suggested that the state investigate whether using pharmaceutical price data from other states, such as California, would be available to meet the needs of New York State.[7]

b. ***Expand oversight and increase price transparency of essential drugs, such as insulin, in other links in the supply chain, including wholesalers, insurers and pharmacy benefit managers***. A majority of Workgroup members agreed that collecting data from each link in the supply chain will help policy makers identify all the factors that impact the price of insulin. Members representing insurers did not outright oppose this strategy. Rather, these members recommended that the state review what data is already collected from insurers to determine what additional data would be needed to assess the impact of drug prices and manufacturer rebates on consumer premiums and out-of-pocket costs. Wholesalers were not represented on the Workgroup.

c. ***Require pharmacists to report price data of insulin products to the state***. Most Workgroup members recommended collecting data from pharmacists to identify pricing factors throughout the pharmaceutical chain and to protect pharmacists and consumers from unfair pricing practices of pharmacy benefit managers. Workgroup members, representing pharmacies and advocates, expressed considerable concern over the impact of pharmacy benefit manager pricing practices on independent and rural pharmacies. Many Workgroup members expressed support for strategies that ensure that pharmacies receive adequate reimbursement from pharmacy benefit managers and insurers. Other members argued that the state should not be involved in pricing, as in their opinion, pharmacies are doing fine.

In addition to implementing strategies to increase price transparency, Workgroup members

[7] (California Department of Health Care Access and Information, 2023)

discussed several options to make the insulin supply chain more accountable for price increases and curtail costs for consumers. New York State has already addressed many of the issues related to pharmacy benefit manager pricing practices in recent legislation.[8] Most Workgroup members maintained that collecting and analyzing price data from the various links in the pharmaceutical supply chain will help inform future policy decisions to contain the cost of essential drugs, such as insulin. Until more price transparency is achieved, some members recommended the following to help make insulin and diabetes care more affordable to consumers:

- Require pharmacy benefit managers and insurers to pass on manufacturer rebates to consumers.
- Amend New York State Insurance Law or DOH regulation to include coverage of continuous glucose monitors.
- Include cost-effectiveness analysis in any future discussions of diabetes care coverage.

3. **Options for increasing affordability and access to insulin for uninsured/underinsured individuals.** Workgroup Members reviewed several different strategies to achieve this objective. Insulin manufacturers have offered patient assistance and affordability programs, including ones that provide free and emergency insulin for eligible patients. The recent reduction in insulin product prices and the manufacturer agreements with the New York State Attorney General to provide uninsured individuals with certain key insulin products at no or low cost for the next five years have extended those efforts and shifted workgroup priorities. Of the many options discussed under this category, some Workgroup members prioritized implementation of legislation to increase affordability for insured and underinsured individuals and the creation of an emergency insulin safety net program for uninsured individuals.

   Some workgroup members recommended implementing two key strategies to help make insulin more affordable for insured and underinsured individuals over the long-term. However, other members, mostly those representing insurers, adamantly opposed these options.

   a. ***Lower the cost-sharing cap for insulin****.* Workgroup members, representing advocacy groups, physicians, and pharmacists, expressed strong support for efforts to reduce the insulin price cap

[8] (NYS DFS, 2022)

per prescription from $100 per thirty-day supply to the federal cap of $35 or lower for all insulin prescriptions and diabetic supplies per calendar month.[9] These members supported reducing the insulin price cap either through legislation or as New York State of Health (NYSOH) policy. Some of these members also recommended passing zero-dollar co-pay legislation for diabetes drugs and supplies, noting that decreased cost-sharing can help improve medication adherence and health outcomes. These Workgroup members remarked that co-pays are a barrier to optimal glycemic control and recommended that the state should consider implementing any strategy that eliminates that barrier. Several members of the Workgroup, particularly those representing health plans, questioned this strategy. These members believed that price caps do nothing to reduce the actual price of insulin and may shift consumer cost from co-pays to the premiums and increase employer costs too.

b. ***Exempt insulin from insurance deductibles****.* This strategy is designed to make insulin more affordable for individuals in high-deductible or catastrophic health plans, which require beneficiaries to reach their deductible before the plan covers the cost of prescription drugs. Insulin, which is essential to preventing diabetes complications, is not part of the Affordable Care Act's preventive care requirements. To try to rectify this issue, the Internal Revenue Service expanded the list of preventive care benefits that high-deductible health plans can offer pre-deductible to include insulin.

A majority of Workgroup members recommended that the state pursue this option to increase affordability of insulin for underinsured individuals.[10] However, other Workgroup members representing insurers expressed concern that exempting insulin from deductibles would cause health insurance premiums to increase.

In addition to reducing the cost of insulin for insured and underinsured individuals in New York, Workgroup members recommended the state consider implementing some type of Emergency Safety Net program for individuals who need insulin but remain uninsured. Workgroup members unanimously supported the need for a safety net program but expressed

[9] (Insulin Cap Law, 2023)
[10] (Preventable Care under HDHP, 2019)

different opinions on the role and structure of a state supported emergency safety net law or program.

c. ***Develop a state-sponsored insulin assistance program*** for individuals who remain uninsured. The recent price reductions in insulin and manufacturers' agreements to provide low-cost insulin to the uninsured should help make insulin more affordable and accessible to a large portion of uninsured and some underinsured New Yorkers who have diabetes and use insulin.[11] However, the price reductions are not for all insulin products.

Ensuring that all individuals have access to affordable insulin to maintain glycemic control remains a priority for the Workgroup. Members, representing providers and consumers, recommended that the state consider creating a state-sponsored insulin assistance program which also provides assistance with obtaining diabetic supplies, such as insulin pumps and continuous glucose monitors. Workgroup members, representing insurers, also supported this option because they are of the opinion that it will not increase costs for employers or premiums for insureds. In contrast, members, representing pharmaceutical manufacturers, cautioned the state on implementing any programs that are duplicative rather than additive to existing manufacturer patient assistance programs.

d. ***Emergency Safety Net Program****.* States have implemented two different types of emergency safety net programs. One, modeled after Kevin's Law, which was originally passed in Ohio, allows pharmacists to dispense insulin to someone with an expired prescription if they cannot contact the prescriber.[12] This law helps to increase access, not affordability. Workgroup members unanimously support this type of strategy or legislation.

The second Emergency Safety Net type program is modeled after Alec's Law in Minnesota.[13] It is designed to increase both access and affordability. The law enables pharmacists to dispense a 30-day emergency supply of insulin to an uninsured or underinsured individual at low or no-cost. Alec's Law allows pharmacies to seek reimbursement or replacement of the insulin from manufacturers. Other states have proposed funding this type of program through a public/private partnership instead.

[11] (James, 2023a)
[12] (TI International, 2023)
[13] (Minnesota House of Representatives, 2021)

Approximately half of Workgroup members support this type of Emergency Safety Net Program. Other members, representing insulin manufacturers, disagreed with this approach, stating that an emergency safety net program, modeled after Alec's Law, would be costly and duplicative of existing manufacturer patient assistance programs.

4. **Opportunities to engage with insulin pharmaceutical manufacturers for a public/private partnership to provide affordable insulin drugs to those lacking access to such drugs**. Workgroup members discussed a few different options under this category, including: establishing a state-based insulin manufacturing facility; collaborating with non-profit organizations to obtain or manufacture low-cost insulin; and, developing, in conjunction with a partner or partners, a low-cost insulin product for distribution in New York State. None of these options rose to the top as priorities for Workgroup members.

In general, members expressed support for using existing state partnerships, such as the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) Infuse, to leverage purchasing power.[14] Some members suggested using any future savings realized from these efforts to finance state-sponsored insulin assistance or emergency safety net programs.

[14] (MMCAP Infuse, 2023)

INTRODUCTION

Chapter 134 of the New York State laws of 2021 directs the Commissioner of the New York State Department of Health ("DOH"), in conjunction with the Superintendent of the Department of Financial Services ("DFS"), to convene an Insulin Workgroup ("Workgroup") to study and evaluate options to increase access and affordability of insulin for uninsured or underinsured individuals.[15] DOH assembled a Workgroup comprised of a diverse group of experts representing health care providers, insurers, pharmacists, pharmaceutical manufacturers, pharmacy benefit managers, advocacy groups, health policy organizations, and individuals with diabetes who use insulin. The Workgroup was tasked with identifying, evaluating, and recommending the following:

a. Options for enrolling uninsured eligible individuals into health coverage which provides comprehensive coverage for persons with diabetes;
b. Barriers in access to information regarding costs within the insulin supply chain;
c. Actions that could be undertaken by the state to hold manufacturers accountable for price increases and transparency in drug pricing;
d. Options for increasing affordability and access to insulin for uninsured and underinsured individuals; and
e. Opportunities to engage with insulin pharmaceutical manufacturers for a public/private partnership to provide affordable insulin drugs to those lacking access to such drugs.

The Workgroup met virtually twice, on April 24 and June 8, 2023. During these meetings, Workgroup members raised additional topics of interest, including access to and affordability of diabetic supplies and the importance of continuous glucose monitoring. After each meeting, Workgroup members were asked to complete an online survey, in which they detailed their perspectives concerning Workgroup priorities and potential strategies to recommend to the state. Survey responses were recorded anonymously, and only aggregate responses are shared in this report. The Workgroup met virtually a third time on December 12, 2023, to review the draft report and discuss comments and edits from the Workgroup members. Because this report was drafted in 2023, there may be more recent policies, legislation, or strategies that are not reflected in this report.

[15] (Relates to Prescribing Insulin and Related Supplies, 2021)

Per the legislation, the DOH was directed to issue a report outlining the options, strategies and opportunities explored. In addition, the report was to include the potential cost to individuals, the potential fiscal impact to the state, and any identified opportunities for federal financial participation. This report describes the discussions and recommendations of the Workgroup.

Background:

Approximately 1.58 million New Yorkers have diabetes, a number that has steadily increased over time. The prevalence of diabetes is higher among Black, non-Hispanic adults; Hispanic adults; adults with lower income; adults with less education attainment; and adults living with a disability.[16] Black New Yorkers are more than twice as likely to die from diabetes than white New Yorkers.[17] Insulin is a life-saving, essential drug for the estimated 538,000 adult New York residents with diabetes.[18] The list price of insulin has risen 1,200 percent since the 1990s, almost doubling between 2012 and 2016 alone, with little transparency behind the escalating cost.[19] In 2017, the American Diabetes Association took note of the skyrocketing prices faced by constituents and convened a workgroup to identify barriers to access and affordability and to brainstorm solutions to these challenges.[20] The American Diabetes Association also reported that over 25 percent of respondents in a nationally representative sample had changed their purchasing habits due to the increasing costs of insulin.[21] The American Diabetes Association and others have documented many instances where individuals either ration or forego their life-saving insulin because of cost. Rationing can lead to many long-term and costly complications, including amputations, kidney disease, blindness, cardiovascular disease, and early mortality.

Two U.S. Congressional Investigations on insulin costs followed the American Diabetes Association report: "*Priced Out of a Lifesaving Drug: The Human Impact of Rising Insulin Costs*" and "*Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*".[22,23] These investigations

[16] (NYS DOH BRFSS, 2022)
[17] (Wedenoja, 2022)
[18] (NYS DOH BRFSS, personal communication, Data 2017)
[19] (Roberts, 2019)
[20] (Cefalu et al., 2018)
[21] (American Diabetes Association, 2018)
[22] (*Priced Out of A Lifesaving Drug: The Human Impact of Rising Insulin Costs*, 2019)
[23] (Sen. Grassley & Sen. Wyden, 2021)

prompted federal and state actions to curtail insulin price increases and improve price transparency throughout the pharmaceutical supply chain.

Insulin manufacturers announced significant price decreases of specific insulin products in March 2023.[24] Then in May 2023, the New York Attorney General's office signed agreements with insulin manufacturers Eli Lilly and Sanofi to provide low-cost insulin ($35/month maximum) to New York State adults without governmental health care coverage for a period of five years.[25] In September 2023, a similar agreement was secured with insulin manufacturer Novo Nordisk.[26] All three programs are currently available to residents of New York.[27]

Workgroup discussion:

The rapidly changing landscape of insulin prices precipitated a Workgroup discussion on how to proceed and what to prioritize. Workgroup members representing advocacy groups noted that manufacturers voluntarily reduced prices and stressed the importance of considering state legislation to prevent future spikes in insulin prices. While the task of the Workgroup was to investigate options for increasing access and affordability of insulin, Workgroup members consistently raised concerns about the importance of providing comprehensive health care to all individuals with diabetes, regardless of insulin use. Those concerns are also included in this report. Members also emphasized the need to ensure that individuals who use insulin have access to the essential drug and the full array of health care services and supplies needed to effectively manage their diabetes. Members, representing physicians and advocacy groups, noted that supplies, such as insulin pumps and continuous glucose monitor devices, which help individuals track and manage their blood glucose levels to prevent serious complications and costly emergency room visits, are expensive and often inaccessible to the uninsured and underinsured. One member recommended that the state require insurers to follow the American Diabetes Association and the Endocrine Society's guidance, which considers continuous glucose monitors to be the standard of care for managing Type 1 diabetes.[28]

[24] (Suran, 2023)
[25] (James, 2023a)
[26] (James, 2023b)
[27] (*Insulins ValYOU Savings Program*, n.d.; *Lilly.Com | Eli Lilly and Company*, n.d.; *MyInsulinRx™ Card Registration| Novocare®*, n.d.)
[28] (American Diabetes Association, 2020; Endocrine Society, 2016)

In light of the fluctuating insulin prices and the need for comprehensive coverage to effectively manage diabetes, the Workgroup unanimously identified enrolling individuals, especially eligible ones, into health care coverage as a high priority.

OPTIONS FOR ENROLLING UNINSURED ELIGIBLE INDIVIDUALS WITH DIABETES WHO USE INSULIN INTO COMPREHENSIVE COVERAGE

Background:

Access to affordable health insurance is critical for people with diabetes, especially those who use insulin. Health insurance that covers medication (such as insulin), diabetic supplies, diabetes education, and related health care services helps individuals with diabetes manage the disease and prevent complications. Once enrolled in a state-regulated health insurance plan, insureds would be covered by the state insulin cap laws.[29]

In 2022, the Community Service Society of New York and Citizen's Budget Commission published a report entitled "Narrowing New York's Health Insurance Coverage Gap" which outlined state options for increasing the enrollment of uninsured individuals in New York into coverage.[30] This report served as the basis for examining the feasibility and cost of implementing those same strategies for uninsured New Yorkers with diabetes who use insulin. A brief overview of strategies is outlined in Figure 1.

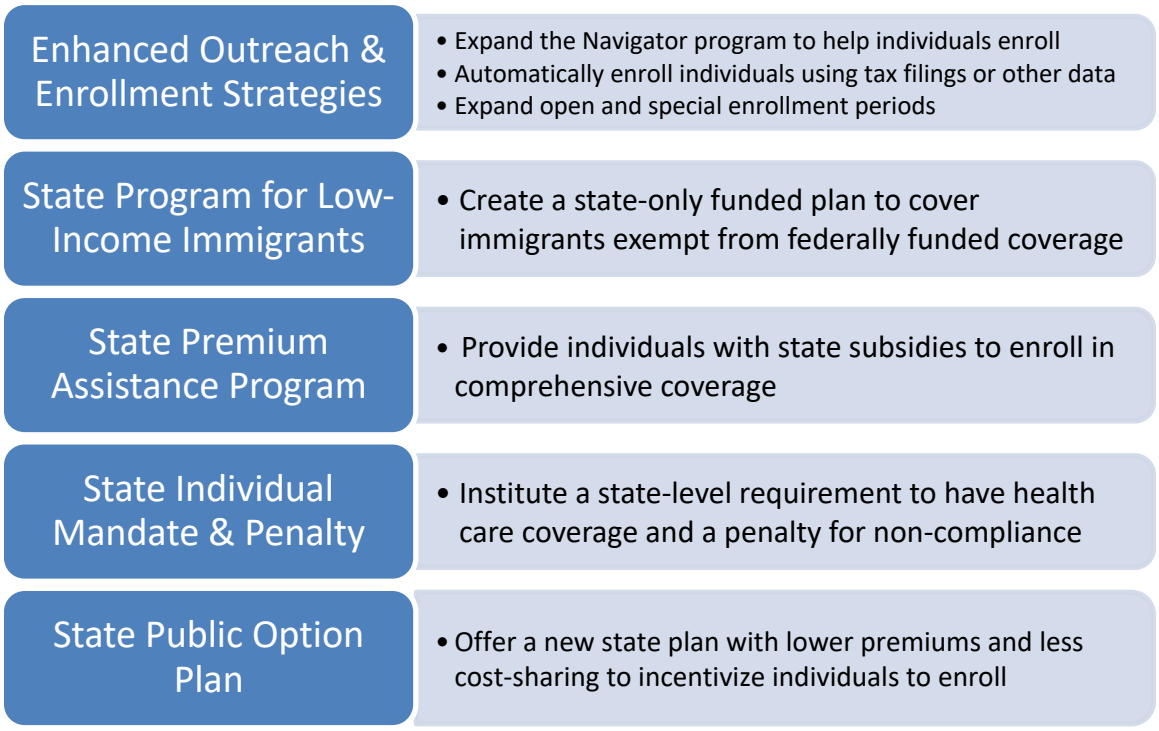


Figure 1: Source: Narrowing New York's Health Insurance Gap

[29] Health insurance plans issued or written outside of New York are subject to the laws of the state where issued, and employer based self-funded/self-insured plans are regulated by federal and not state insurance law.
[30] (Benjamin et al., 2022)

Health Insurance in New York State:

New York State offers various options for obtaining affordable and accessible health insurance on New York State of Health ("NYSOH"), the Official Health Plan Marketplace. A brief synopsis of the state sponsored and regulated options are outlined below in Figure 2.

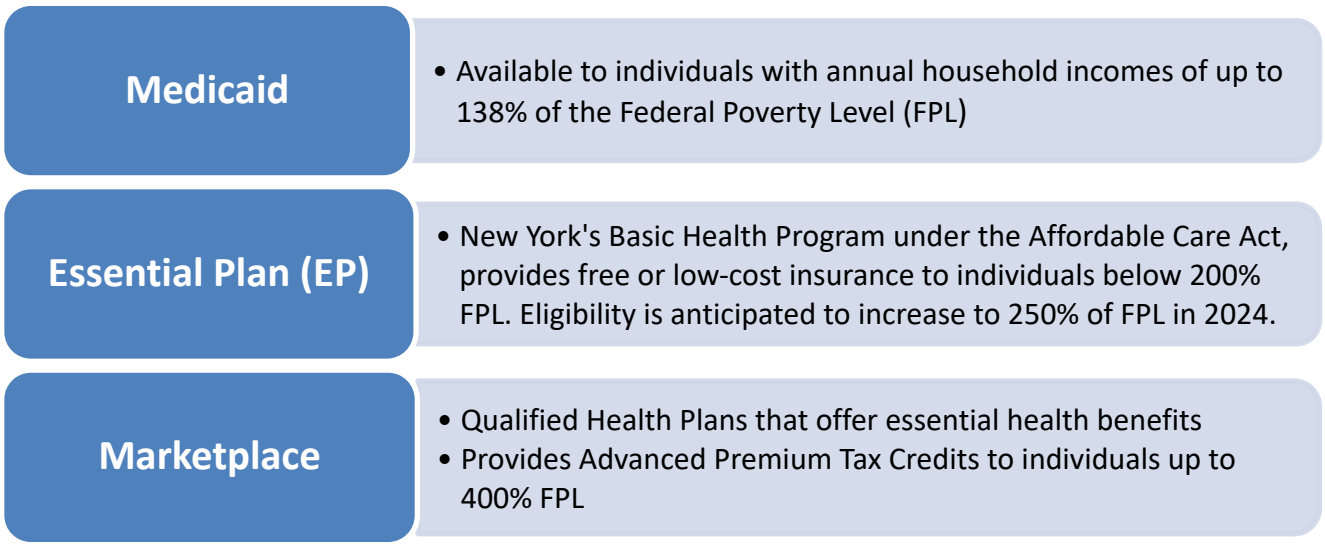


Figure 2: Health insurance options

Uninsured Adults with Diabetes who use Insulin in New York State:

Based on data from the Behavioral Risk Factor Surveillance System (BRFSS)[31], DOH estimates that approximately 33,000 (range 20,900 to 47,800) adults with diabetes who use insulin in New York are uninsured. Of those 33,000 individuals, approximately:

- 11,220 are eligible for Medicaid or the Essential Plan but are not enrolled;
- 7,920 are immigrants with status issues that prevent them from enrolling in federally supported plans; and,
- 13,860 are eligible for employer or union supported plans but have not enrolled for various reasons, including affordability.

Each group faces different barriers to enrollment and no one strategy will work to increase enrollment of uninsured New Yorkers with diabetes who use insulin into comprehensive health care

[31] The BRFSS is an annual random telephone survey designed by the Centers for Disease Control and Prevention. The data is used by health departments and other organizations for planning health promotion and disease prevention programs.

coverage. Figure 3 below matches the strategies available (shown in Figure 1) to increase access and affordability of comprehensive coverage by potential eligibility of the groups listed above. These options are not exhaustive or mutually exclusive.

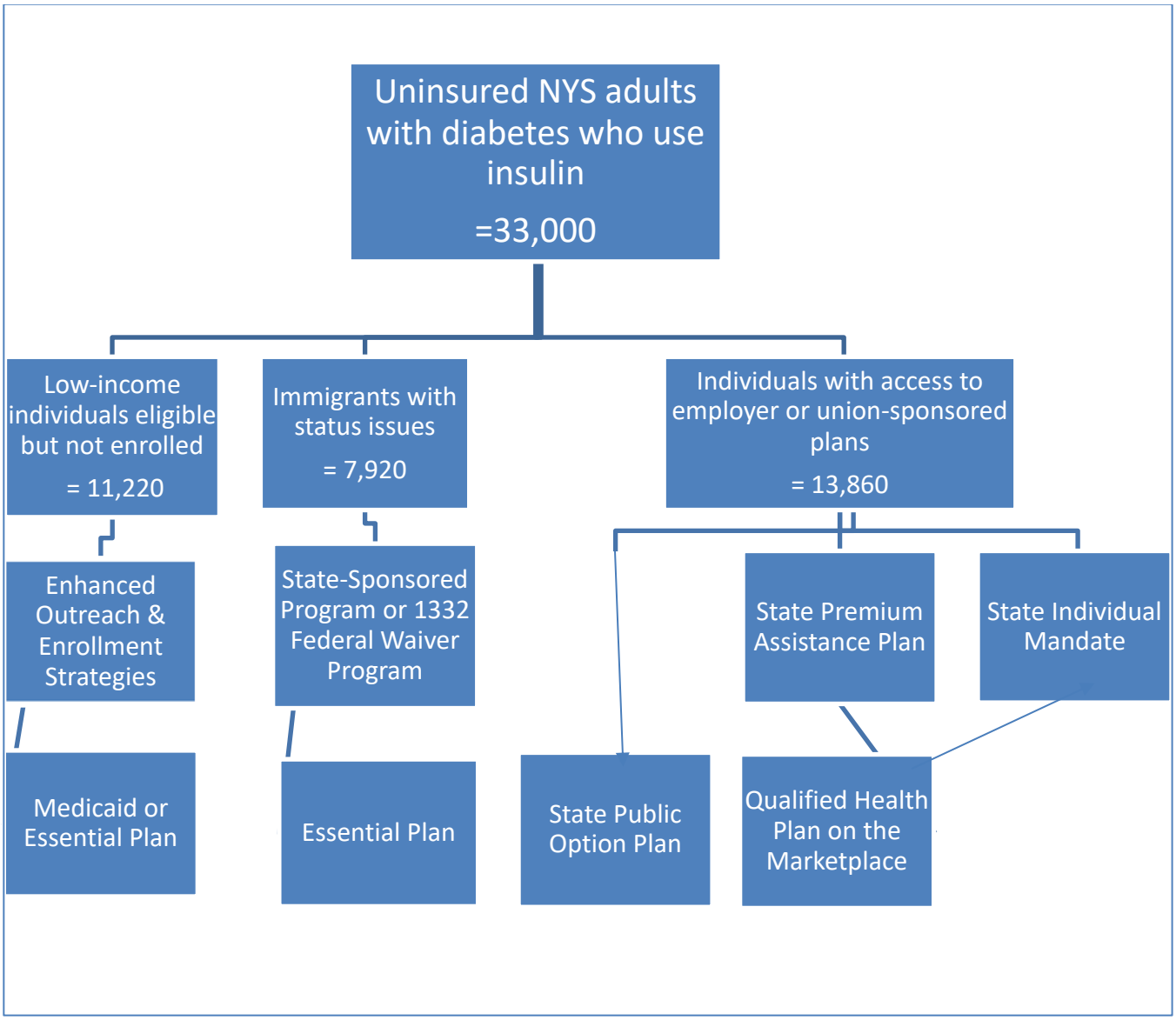


Figure 3: Strategies for increasing access to comprehensive insurance coverage for uninsured New Yorkers with diabetes who use insulin

Strategies to enroll eligible uninsured New Yorkers with diabetes who use insulin into comprehensive coverage

Background:

An estimated 11,220 individuals with diabetes who use insulin are eligible for federally supported insurance, such as Medicaid or the Essential Plan, but remain uninsured in New York State. Eligible uninsured individuals face a number of barriers to attaining health insurance, including lack of knowledge about coverage options and difficulty with the enrollment process.[32] Individuals in this category are often low-income, with limited resources, which can make accessing health care insurance more challenging.

Lawfully present immigrants, who are eligible for state or federally-funded coverage, face additional enrollment barriers. Nationally, lawfully present immigrants are uninsured at a much higher rate than citizens (25% vs. 8%).[33] Confusion, fear, language and literacy challenges are a few of the barriers encountered by immigrants trying to access health care insurance. Eligibility for federally funded health care coverage varies depending on an individual's immigration status.[34] Determining eligibility can be confusing to both providers and consumers since there are a multitude of different immigration statuses that qualify for coverage on the Marketplace. Other eligible immigrants may be reluctant to enroll in federally subsidized insurance programs for fear of jeopardizing their opportunity to obtain permanent legal status in the United States. In 2019, the Trump administration expanded the "Inadmissibility on Public Charge Grounds" regulations, which allowed the Department of Homeland Security to interpret the "public charge" rule to include non-cash public benefits such as food stamps, Medicaid, and housing assistance.[35] While the Biden adminstation reversed these regulations, confusion and fear over whether enrolling in Medicaid or other federally subsidized health care coverage would impact their immigration status, many immigrants disenrolled or refused to seek health care coverage.[36]

[32] (Benjamin et al., 2022).
[33] (Artiga & Diaz, 2019)
[34] (Benjamin et al., 2022)
[35] (Department of Homeland Security, 2019)
[36] (Refki et al., 2021)

Workgroup discussion:

The Workgroup considered enrolling low-income individuals with diabetes who use insulin but remain uninsured into comprehensive coverage under Medicaid or the Essential Plan a priority for the state. Members recognized that these strategies do not address the price of insulin issue but, in their opinion, provide the best opportunity to improve health outcomes for uninsured individuals with diabetes who use insulin.

Enhanced Outreach and Enrollment Strategies*:*

Background:

Since the passing of the Affordable Care Act, states have implemented creative outreach and enrollment strategies to support and incentivize uptake of subsidized insurance. The "Narrowing New York's Health Insurance Coverage Gap" report outlined the following three strategies to incentivize enrollment of eligible uninsured individuals into comprehensive coverage in New York State: [37]

1. Expand the Navigator program.
2. Implement automatic enrollment using tax filings.
3. Expand opportunities to enroll outside of open enrollment periods.

The effectiveness and feasibility of implementing each option in New York for the uninsured population with diabetes who use insulin is reviewed below.

[37] (Benjamin et al., 2022)

Table 1: Strategies for enrolling eligible individuals with diabetes who use insulin into Medicaid or EP coverage			
Enhanced Outreach and Enrollment Strategy	**State Financial Impact**	**Pros**	**Cons**
Expand the Navigator program to help enroll uninsured eligible individuals, especially those with diabetes who use insulin into coverage	• Average cost $100-$300 per enrollee • Estimated total cost $3.4 to $9.9 million to enroll uninsured individuals with diabetes who use insulin • Estimated total costs $9.5 to $28.4 million to enroll all uninsured individuals with diabetes	• Cost-effective • Navigators reach underserved individuals & communities • Navigators can also enroll other uninsured individuals	• Lack of awareness of programs (Workgroup recommended supplementing with targeted media campaign) • Challenge of reaching the specific population with diabetes who use insulin
Automatic enrollment programs	• Administrative & infrastructure costs	• Warm hand-off requires minimal effort from consumer • Automatic enrollment removes barriers & simplifies the process	•Estimated impact is limited • Eligible uninsured individuals may lack sufficient income to require a NYS tax filing • Would not enroll people who work “off the books” and do not file taxes
Extended and Special Enrollment Periods (SEP) for individuals with diabetes who use insulin	• Administrative costs	• Extended & SEP is effective in increasing enrollment • Allows individuals with newly identified insulin need to get coverage immediately, potentially preventing costly complications • Massachusetts does this for people below 300% of the federal poverty level without apparent adverse premium impact	• Strategy may lead to adverse selection, encouraging healthy people to wait to enroll until sick. • May result in higher-risk pool, with higher premium costs, if implemented only for people with diabetes who use insulin

Expand the Navigator Program*:*

Background:

The Navigator program was established by the Affordable Care Act to provide consumers with assistance in understanding and enrolling in the best insurance coverage option available to them on

the Marketplace. New York State has a robust Health Plan Marketplace with a number of insurers offering different plans with varying costs and benefits. The abundance and complexity of options makes it challenging for individuals to select the most appropriate affordable plan for their circumstances.[38] Navigators help consumers understand the options, determine eligibility for Medicaid or subsidies to lower their premiums, and assist with the application process. Navigators conduct outreach and provide assistance to consumers where they live, work and study.

Impact:

According to the NYSOH 2020 open enrollment report, "80% of individuals enrolled with the help of an enrollment assistor, including Navigators, certified application counselors, and licensed insurance brokers." Many states, such as Kentucky, attribute large decreases in uninsured individuals, in part, due to their assistor programs.[39] States credit local in-person assistance through Navigator programs as key to expanding coverage in underserved communities.[40,41] Lack of Navigators can also negatively impact enrollment. Research suggests that decreased funding for the Navigator program during the Trump administration impacted coverage of underserved adults (under age 45), including low-income individuals, Latinos, and U.S. citizens or permanent residents who speak a language other than English at home.[42]

New York State Navigator Program:

New York State has a strong Navigator Program, with assistance available to residents in all counties. Navigator programs partner with community organizations across the state to conduct outreach at a variety of locations, including: libraries, senior centers, community based organizations, social service agencies, community health centers, religious institutions, hospitals, independent living centers, local health departments, town halls, pharmacies, immigration centers, YMCAs, farms, restaurants, schools, and colleges.[43]

[38] (Bhargava et al., 2017)
[39] (Artiga et al., 2016)
[40] (Benjamin et al., 2022)
[41] (Hellpap, 2022)
[42] (Myerson & Li, 2021)
[43] (NY State of Health, 2023c)

Potential Cost and Financial Impact:

The average administrative cost of a navigator is estimated at $100 to $300 per enrollee.[44] Funding an expanded Navigator Program would cost an estimated $3.4 million to enroll approximately 11,220 uninsured eligible individuals with diabetes who use insulin into Medicaid or the Essential Plan; $9.9 million to enroll all the uninsured adult population with diabetes who use insulin into other coverage; and approximately $28.4 million to help enroll all uninsured individuals with diabetes into coverage on the NYSOH (Table 2).

Table 2: Estimated cost of expanded Navigator program to cover uninsured individuals with diabetes in New York State	**Population**	**Total cost** (per person average $300)
All uninsured with diabetes	94,800[45]	$28.4 million
All uninsured individuals with diabetes who use insulin	33,000	$9.9 million
Uninsured Individuals eligible for Medicaid and Essential Plan	11,220	$3.4 million

New York receives some federal matching funds to support its Navigator Program. During the Trump Administration federal funding for Navigator programs decreased eighty percent.[46] The Biden-Harris Administration reversed this funding trend, making a landmark investment in the Navigator Program in 2022 to support outreach and enrollment of underserved individuals into comprehensive health care coverage.[47] Only states with federally-facilitated healthcare exchanges were eligible for this funding. New York, with its own state-based marketplace, was ineligible for this funding opportunity.

Workgroup Discussion:

Workgroup members discussed the option of funding more navigators to help enroll eligible uninsured individuals with diabetes who use insulin into comprehensive health care coverage. Most members supported this strategy. Only one member opposed it, expressing the belief that Navigator

[44] (Benjamin et al., 2022)
[45] (NYS DOH BRFSS, 2022)
[46] (Myerson & Li, 2021)
[47] (Assistant Secretary for Public Affairs, 2022)

programs did not provide enough incentive for individuals to enroll in coverage, and suggested that enforcement programs, such as mandates and penalties, are needed to incentivize enrollment.

The majority of Workgroup members expressed the opinion that Navigator programs are an excellent and cost-effective way to get people connected to coverage. Workgroup members remarked that Navigator programs had the added benefit of providing assistance to all uninsured individuals into Medicaid, the Essential Plan, and Qualified Health Plans, not just those with diabetes who use insulin. Members also stressed the importance of enrolling all uninsured individuals with diabetes into comprehensive coverage. One Workgroup member, representing healthcare professionals, noted that while New York has a very robust outreach program, there may be additional opportunities to embed navigators in other underserved locations, such as in free community clinics.

Challenges to Navigator programs:

Workgroup members discussed several challenges to successfully enrolling uninsured individuals with diabetes who use insulin into comprehensive coverage through an expanded Navigator program. Potential barriers mentioned by Workgroup members include:

- *Lack of awareness of Navigator programs*: One Workgroup member stated that lack of awareness was found to be an issue in the Kentucky Navigator Program.[48]
- *Reaching the uninsured individuals with diabetes who use insulin*: Workgroup members representing Navigator programs indicated that a greater challenge is finding the estimated 33,000 uninsured individuals with diabetes who use insulin in a state with a population of over 19 million residents. Members suggested that although there may be data available to help prioritize deployment of navigators to specific sociodemographic populations and geographic locations, uninsured individuals with diabetes who use insulin likely represent all racial and ethnic populations and live in all counties across the state.[49]
- *More forceful measures are needed or recommended:* One member suggested that enforcement strategies, such as mandates and penalties, were needed to incentivize individuals to enroll in coverage.

[48] Appendix B provides data to support this assertion
[49] Appendix B provides data on groups and locations to prioritize for outreach and enrollment

Recommendations:

- The majority of Workgroup members recommend funding additional navigators and other assistors to enroll eligible individuals with diabetes who use insulin into comprehensive coverage.
- Members agreed that an across-the-board strategy to fund additional navigators and facilitated enrollers would be more practical than trying to locate the estimated 33,000 uninsured insulin users across the state.
- Most Workgroup members recommended supplementing the Navigator programs with additional marketing funding to prioritize outreach to populations to address the potential lack of awareness barrier. Members suggested this could be in the form of a targeted media campaign developed across programs with input from Medicaid, the Essential Plan and Qualified Health Plans.
- The majority of Workgroup members also suggested exploring options to fund pharmacists to assist patients with connecting to resources, such as insurance coverage or patient assistance programs. An additional literature review and environmental scan were conducted to gather information about pharmacy assist programs. A summary of findings is below.

Pharmacy Assist Programs:

Background:

Some Workgroup members proposed the idea of funding pharmacists to help connect patients with comprehensive health care coverage and patient assistance programs as a means of increasing access to insulin for the uninsured and underinsured population. This strategy is worthy of consideration for a variety of reasons. Pharmacies are a valuable resource for communities, not only dispensing medication but providing education to improve health outcomes. Pharmacists are located closer to patient's homes, open more hours, more accessible and visited more frequently than other healthcare providers.[50] Many pharmacists already play a role in connecting patients to resources. For example, pharmacists help enroll eligible Medicare beneficiaries in the Limited Income NET (LINET) program to help cover prescription costs until an individual is approved for Medicare Part D drug coverage.[51] Insurers, such as United Health Care, advise beneficiaries that pharmacists can assist with

[50] (Daly et al., 2020)
[51] (Centers for Medicare & Medicaid Services, 2023c)

reviewing health insurance plans and recommending which plan has the best drug formularies to meet their needs.[52]

A literature search and environmental scan identified a few potential models of pharmacy assist programs to consider. The Senior PharmAssist program of Durham, North Carolina was established in 1992 to provide income eligible Durham residents aged 60 and over with medication therapy management and help obtaining necessary medications. Medication assistance is provided via two methods: direct financial support in the form of a copayment assistance card for use at pharmacies; and/or by connecting patients with other sources of support, such as manufacturer patient assistance programs.[53] Senior PharmAssist utilizes the web-based software program, The Pharmacy Connection, developed by the Virginia Health Care Foundation to automatically determine patient eligibility for manufacturer patient assistance programs. Seniors are referred to the stand-alone program.[54] In Fiscal Year 2022, the program served 2,204 unique individuals, approximately 500 of which received direct financial assistance and another 601 were connected to other resources.

Another small pilot study utilized clinical pharmacists to improve access and affordability of medications for patients. Pharmacists assessed patients, provided medication therapy management, and referred those with limited access to needed medications to a medical assistance program coordinator who helped individuals apply for manufacturer patient assistance programs.[55]

In addition to stand-alone programs, some health insurance companies are providing financial reimbursement to pharmacists for patient care type services. In 2021, CareSource launched a pilot program to reimburse pharmacists for diabetes education and other services under collaborative practice agreements with other healthcare providers.[56]

Impact:

Pharmacy assist programs report positive results both in terms of cost savings and health outcomes. An evaluation of the Senior PharmAssist program found that participants experienced

[52] (Medicare Made Clear(r), 2023)
[53] (Virginia Health Care Foundation, 2023)
[54] Ibid
[55] (Pickett et al., 2023)
[56] (CareSource, 2020)

decreases in emergency room visits and hospital admissions over the previous year.[57] While the pilot clinical pharmacist program reported significant cost savings, no significant differences in urgent care utilization were observed.

New York State Pharmacies and Patient Assistance:

Pharmacies in New York State currently provide some enrollment assistance and patient care services. For example, SUNY Upstate University Hospital recently developed an Outpatient Pharmacy Medication Assistance Program where Pharmacy Patient Advocates help uninsured and underinsured patients gain access to needed prescription medications.[58] That program is currently funded under the pharmacies' operational budget and has served a small number of patients to date. In 2022, several pharmacies in New York State received accreditation to provide patient care services in the form of Diabetes Self-Management Training.[59,60]

Potential Cost and Financial Impact:

The Senior PharmAssist program cost an average of $418 per person in 2022, which included some direct financial support. This is higher than the average cost of Navigator programs. However, the pharmacy assist program reported additional benefits, including improved health outcomes and cost savings to seniors who participated in the program. Seniors saved an average of $673 on prescriptions in 2022 when they changed their Medicare Part D plan to one that works better for them based on recommendations from the Senior PharmAssist program.[61]

The Senior PharmAssist program relies primarily on donations and grants. The National Institutes of Health recently funded an expansion of the program into three other counties. The program also has a contract with the county which allows it to bill $100 per person for patient care services.[62]

[57] (Herity et al., 2018)
[58] (Upstate University Hospital, 2023)
[59] (NYS DOH, 2022)
[60] (Physician and Pharmacists Collaborative Practice, 2023)
[61] (Upchurch, 2022)
[62] (G. Upchurch, personal communication, June 7, 2023)

Cost of reimbursing pharmacists via insurance or a state funded program were not available. The Pharmacy Connection software program, which would help pharmacists connect customers to patient assistance programs, but not insurance coverage, costs approximately $2,000-$2,350 for the license and imposes an annual maintenance fee of $1,000-$1,200.[63]

To provide a PharmAssist type program in New York State for all 33,000 uninsured individuals with diabetes who use insulin would cost approximately $13.79 million.

Table 3: Estimated cost of PharmAssist Program	**Population**	**Total cost** (per person average $418)
Uninsured individuals with diabetes who use insulin	33,000	$13.79 million

Workgroup discussion:

Workgroup members expressed differing opinions regarding the viability of pursuing this strategy. Advocates of this strategy were of the opinion that investing funding to support pharmacist's time and outreach would get the best return on investment. Other members contended that busy pharmacies are not an ideal location for outreach and lack of time and/or staff, as well as lack of patient privacy, would be a barrier to successful implementation. Some members, representing community pharmacies, indicated that they saw very few, if any, customers who pay cash for insulin at their pharmacies, so they were unlikely to reach many uninsured individuals via this strategy.

After further discussion, most Workgroup members agreed that funding Navigator programs should take precedence over piloting a pharmacy assist type program. Some members also recommended that the state support programs to increase awareness and/or educate pharmacists on how to connect patients to Navigator programs and manufacturer PAPs. Other components of the PharmAssist type programs, such as medication therapy management (MTM) and opportunities for pharmacists to conduct comprehensive medication management services under a collaborative agreement with physicians, were considered outside of the purview of the Workgroup.

[63] (L. Hueston, personal communication, July 27, 2023)

Automatic Enrollment Programs:

Background:

A number of states have implemented or are exploring options for enrolling individuals automatically into health insurance using state data from other sources, such as tax filings or the Supplemental Nutrition Assistance Program (SNAP) applications, to determine whether an individual might be eligible for Medicaid or other health insurance.[64] Back in 2010, Louisiana used information from SNAP, the Women Infants and Children nutrition program and other assistance programs to automatically enroll mostly uninsured children into the Medicaid program. More recently, Maryland implemented the Maryland's Easy Enrollment Health Insurance Program (HEEHP) to help uninsured individuals enroll into health care coverage. Maryland taxpayers can check a box on their state income tax form that allows the healthcare exchange authorities to determine the tax payer's eligibility for free or low-cost insurance.[65] In addition, uninsured tax filers with high incomes qualify for a special enrollment period and are encouraged to obtain health insurance through the marketplace. New Jersey recently followed suit, creating an Easy Enrollment program that uses tax fillings and unemployment claims to determine eligibility for either Medicaid or state health insurance available on the marketplace. Uninsured tax filers are notified of coverage options, subsidies, and special enrollment period eligibility. New Jersey residents have an added incentive to enroll in health care coverage. Once enrolled, they no longer have to pay the penalty for the NJ individual mandate law.[66] California, Maine and New Mexico have created similar programs to simplify or streamline the enrollment process.[67]

Impact:

Preliminary findings suggest that automatic enrollment can help states decrease the number of uninsured individuals while lowering individual market premiums. An evaluation of the Maryland program found that automatic enrollment can improve participation by reducing barriers and

[64] (Benjamin et al., 2022)
[65] (Dorn, 2019)
[66] (Holom-Trundy, 2022)
[67] (Pistor, 2022)

simplifying the process. The evaluation reported that the streamlined process requires very little effort from the consumer and may result in little or no premium payment too.[68]

Automatic Enrollment in New York State:

Benjamin et. al. (2022) reviewed the potential impact of implementing an automatic enrollment process using state tax data in New York. In their estimation, automatic enrollment of uninsured New Yorkers via tax data would result in a limited boost in enrollment due to the fact that many eligible uninsured individuals may lack sufficient income to require a New York State tax filing. Other data sources may provide greater reach.

Potential cost and financial impact:

Implementing this option would result in some financial impact for the state, mostly administrative and infrastructure costs. At a minimum, the state would need to implement a new electronic process to integrate the state tax infrastructure into the state of health. Cost estimates are not included here.

Workgroup discussion:

Workgroup members discussed the automatic enrollment option. In general, members indicated support for any strategy that simplified the enrollment process for uninsured individuals with diabetes who use insulin. Members suggested that using tax filings and other information available to the state would help to create a "warm handoff" for enrollment. In a post-meeting survey, a majority (58%) of Workgroup members recommended the state pursue this strategy, potentially as a pilot program, to increase enrollment of uninsured individuals with diabetes who use insulin into comprehensive coverage. Other members raised concerns about the potential effectiveness of implementing this strategy to reach priority populations and suggested the state review which data sources would provide the greatest reach to uninsured individuals.

[68] (Dorn, Capretta, et al., 2018)

Extend Open and Special Enrollment Periods

Background:

Since the passing of the Affordable Care Act, states have continuously adapted the criteria and process to make enrollment easier and more accessible. Two strategies under consideration include extending enrollment periods and implementing Special Enrollment Periods for specific life events.

Under the Affordable Care Act, the federal government controls the period of enrollment for health insurance coverage, called "Open Enrollment" on the Marketplace, which typically occurs from November 1st to January 15th of each year. The federal government also offers Special Enrollment Periods, which fall outside of the open enrollment window, for individuals who experience life events, such as a job change, having a child, or getting married. The COVID-19 epidemic warranted a Special Enrollment Period under the American Rescue Plan that extended the opportunity to enroll in coverage through August 15, 2021.[69]

States that operate their own Marketplaces are able to adapt their open and special enrollment periods to meet the needs of their constituents. Several state-based marketplaces have extended open enrollment periods and/or introduced exceptions to help boost enrollment. Massachusetts permits individuals who are under 300 percent of the federal poverty level or a member of a federally recognized tribe or Alaska Native shareholder to enroll any time during the year.[70] Other states, including New York, have developed special enrollment periods for individuals with certain medical conditions, such as pregnancy, or in response to the pandemic.[71] An environmental scan of state-based marketplaces did not uncover any Special Enrollment Periods for a diagnosis of insulin-prescribed diabetes.

Impact:

Research on the impact of open and special enrollment periods on healthcare coverage is positive. Both strategies increase access to health care coverage. Researchers found strong evidence of an association between New York State's pregnancy Special Enrollment Period and increased

[69] (Centers for Medicare & Medicaid Services, 2021b)
[70] (Massachusetts Health Connector, n.d.)
[71] (Cousart, 2021)

enrollment on the Qualified Health Plan.[72] Several states also experienced increased enrollment, especially of young adults, after instituting COVID-19 special enrollment periods.[73] States with expanded enrollment options reported lower rates of uninsured individuals, although the relationship is not necessarily causal and other factors may impact enrollment rates.

However, health plans generally oppose longer open or special enrollment periods, especially for chronic diseases, such as diabetes. Insurers contend that these strategies ultimately lead to adverse selection, encouraging healthy people to wait until they get sick to enroll in coverage. This can result in a more expensive, higher-risk pool of ill or chronically ill adults who enrolled in coverage once they became sick and immediately began utilizing benefits. Other research indicates that insurer concerns are valid as carriers tend to be underpaid for part-year members, especially for Special Enrollment Period enrollees. Dorn et. al. (2022) recommend "further increases to risk adjustment" to adequately reimburse insurers and support the higher risk associated with individuals covered during Special Enrollment Periods.[74]

New York State open and special enrollment:

New York State has a history of implementing innovative strategies to increase enrollment in comprehensive health care coverage. With its state-based Marketplace, New York has one of the longest open enrollment periods in the country. In 2016, New York was also the first state to institute a special enrollment period for pregnancy.[75]

Potential cost and financial impact:

The premium cost to individuals would be the same as if they enrolled in the "Open Enrollment" period. Subsidies might be available depending on the individual's annual household income. The cost to the state would be limited to administrative costs, which are not modeled here. Health insurance premiums could increase if healthy people wait until they are sick to enroll in coverage.

[72] (Eliason & Steenland, 2023)
[73] (Schwab et al., 2021)
[74] (Dorn, Garrett, et al., 2018)
[75] (Eliason & Steenland, 2023)

Workgroup discussion:

Workgroup members discussed the pros and cons of this option. Approximately half of Workgroup members supported providing a Special Enrollment Period opportunity for individuals with a recent diagnosis requiring insulin. Members representing advocacy groups reported being in favor of treating a new diagnosis as a "life event" similar to birth or marriage. While members agreed that a Special Enrollment Period might incentivize healthy (low cost) individuals to remain uninsured, they believed that the cost borne by insurers for a newly diagnosed individual would be limited to the few months before the next open enrollment period. Other members representing insurers strongly opposed special enrollment periods, stating that it is a bad idea because it would result in adverse selection.

Strategies to enroll uninsured immigrants with status issues with diabetes who use insulin into comprehensive healthcare coverage

Nationally, non-elderly undocumented immigrants are more likely than legally residing immigrants and U.S. citizens to be uninsured (at a rate of 45%, 23% and 8%, respectively).[76] Approximately sixty percent of the undocumented immigrant population in New York State (unauthorized immigrants without lawful status) are uninsured.[77] Of those, an estimated 7,920 individuals with diabetes who use insulin are uninsured due to immigration status issues that make them ineligible for federally funded healthcare coverage options.

Most undocumented immigrants remain ineligible for federally funded coverage options, such as Medicaid or the Essential Plan, and have limited access to employer-sponsored plans. While a majority of undocumented immigrants live in mixed-status households, with legally residing immigrants and citizens, accessibility and affordability of health insurance remains challenging. Many work in low-income jobs that make it less likely they can afford or have access to employer-sponsored health insurance.[78]

State Program for Low-Income Immigrants:

Background:

States have explored a number of options for expanding Medicaid or state funded coverage to certain groups of undocumented individuals. Eighteen states, including New York, have expanded Medicaid eligibility to pregnant women regardless of immigration status. For decades, New York has offered Child Health Plus to undocumented immigrant children under the age of 19 years of age and to pregnant women.[79] In 2020, Illinois passed legislation that enabled undocumented seniors to enroll in state-funded coverage. In 2023, the program was expanded to cover undocumented adults ages 42-64.[80] Likewise, California has opened eligibility for its state-sponsored health care coverage to

[76] (Artiga & Diaz, 2019)
[77] (Benjamin et al., 2022)
[78] (Artiga & Diaz, 2019)
[79] (CSSNY, n.d.)
[80] (Illinois Department of Health and Family Services, 2023)

undocumented immigrants under the age of 26 and over the age of 50, which will expand to all low-income undocumented immigrants in 2024.[81] Colorado and Washington states have likewise begun to offer coverage to their undocumented residents through their respective 1332 Waiver programs.[82] Starting January 1, 2024, New York will begin enrolling undocumented people over the age of 65 into Medicaid Managed Care plans.[83]

In their 2022 report, Benjamin et al. (2022) proposed creating a state-sponsored Essential Plan to cover uninsured individuals with immigration status issues in New York. The proposed new plan would have similar income eligibility standards as the federally funded NYS Essential plan (which is set to expand from 200% to 250% the federal poverty level on April 1, 2024).

Since then, options for federally funded opportunities to cover individuals with immigration status issues have become more feasible. A U.S. Department of Health and Human Services 1332 waiver allows a state to implement "innovative strategies" to provide affordable federally funded health care coverage to its residents. Washington and Colorado applied and received 1332 waivers from the federal government to forego certain requirements of the Affordable Care Act, permitting enrollment of individuals with immigration status issues into federally funded health care coverage.[84]

New York State 1332 Waiver:

Currently, New York is exploring state and federally funded options to expand comprehensive health care coverage to immigrants with status issues. In the 2023 State of the State address, Governor Hochul announced plans to extend state-funded Medicaid coverage to adults aged 65 and older regardless of immigration status.[85] In May 2023, DOH submitted a 1332 waiver application to the Department of Health and Human Services and the U.S. Treasury Department to expand the eligibility requirements for the Essential Plan to include individuals with annual household incomes up to 250% of the federal poverty level. During this process, DOH received over 1,500 public comments urging the state to expand the waiver to include coverage for uninsured immigrants with status issues. The state

[81] (California Department of Health Care Services, 2022)
[82] (Colorado Department of Regulatory Access, n.d.; Washington Health Plan Finder, n.d.)
[83] (NY State of Health, 2023b)
[84] (Centers for Medicare & Medicaid Services, 2023a)
[85] (Gov. Hochul, 2023)

responded that they currently did not have authority to request that modification.[86] In July 2023, DOH submitted a letter to the Centers for Medicare and Medicaid Services and the Department of Health and Human Services requesting input regarding the use of federal funds to provide coverage to undocumented immigrants via a 1332 waiver.[87] In reply, the Administrator of the Centers for Medicare and Medicaid Services confirmed that New York State could use the 1332 Waiver pass-through funds to finance coverage for otherwise ineligible immigrants.[88] New York State has subsequently amended its 1332 waiver request to include coverage for individuals with Deferred Action for Childhood Arrival status, who are not currently eligible for federal Affordable Care Act funding.[89]

Potential Cost and Financial Impact:

Obtaining health care coverage allows individuals with diabetes who use insulin to access the care they need to control their diabetes. In general, individuals enrolled in the Essential Plan pay no premium and no deductible. Cost-sharing under the Essential plan depends on annual household income. All Essential Plan products do not charge monthly premiums, nor do they have deductibles. The remaining costs are imposed on a sliding scale. For example, individuals with incomes at or below 100% of the federal poverty level pay no cost-sharing while individuals with incomes between 100% to 200% (or 250% if the Waiver is approved) of the federal poverty level pay cost-sharing with an annual out-of-pocket maximum of $2,000.[90]

Benjamin et al (2022) proposed funding a state-sponsored Essential Plan for immigrants with status issues through a variety of mechanisms. First, anticipated savings from the Emergency Medicaid program for undocumented immigrants, which cost New York State an estimated $500 million in 2021, could help offset costs of the insurance program.[91] The state would likely experience cost-offsets from reductions in uncompensated care costs to hospitals too. Second, Essential Plan insurers could seek federal matching funds for claims for beneficiaries with incomes below 138% of the federal poverty level. Finally, the state would pay the full cost of coverage for individuals with incomes between 139%

[86] (NY State of Health, 2023b)
[87] (Centers for Medicare & Medicaid Services, 2023a)
[88] Ibid
[89] (NY State of Health, 2023d)
[90] (Centers for Medicare & Medicaid Services, 2023a)
[91] (New York Health Foundation, 2023)

and 200% or 250% of the federal poverty level. Under this proposed funding strategy, the state cost for Essential Plan coverage is estimated at $7,600 per beneficiary. State funded coverage under the Essential Plan for approximately 7,920 individuals with immigration status issues who use insulin would cost the state an estimated $60.2 million.

Pursuing a 1332 waiver from the federal government to cover uninsured immigrants with status issues would significantly reduce the financial impact on the state and by some estimates, actually save the state money.[92]

Table 4: Estimated state cost to enroll New York State immigrants with status issues who have diabetes and use insulin into comprehensive coverage under the Essential Plan

Funding mechanism	Estimated NYS adult population with diabetes who use insulin who have immigration status issues	Total estimated cost (average cost $7,600)*
State subsidized Essential Plan	7,920	$60.2 million
Federal 1332 waiver	7,920	$0 cost to state

*Estimated average cost from "Narrowing NYS Health Insurance Coverage Gap". Actual costs may be higher.

Workgroup Discussion:

Workgroup members discussed options for providing health care coverage for immigrants with status issues who use insulin. Members overwhelmingly supported expanding the current 1332 waiver application --over creating a state-only funded option--to include immigrants who are ineligible for coverage because of their immigration status. In general, members were of the opinion that New York has been very successful at leveraging every federal financial opportunity for the state. In a post-meeting follow-up survey, most members recommended pursuing a federal 1332 waiver that would allow the state to enroll undocumented immigrants into comprehensive health care coverage. With the federal waiver option on the table, there was minimal support for creating a state-funded Essential Plan for this population. There was no stated opposition to pursuing this strategy.

[92] (New York Health Foundation, 2023)

Strategies to enroll uninsured individuals with access to employer or union-sponsored health care plans

Approximately 13,860 adults with diabetes who use insulin in New York have access to private insurance but lack coverage for a variety of reasons. One main reason why individuals who are eligible for employer or union-sponsored health care plans do not enroll in coverage is affordability. Some affordability issues with employer or union-sponsored plans for insulin users are the following:

- The cost of the monthly premium is too high.
- Employers offer a high deductible health plan with low monthly premiums but high cost-sharing, co-payments and deductibles, which make the overall cost of health care unaffordable, especially for individuals with chronic diseases, such as diabetes.
- The majority of employer or union-sponsored large group health care plans, except religious and government plans, are self-funded and covered by the Federal Employment Retirement Income Security Act (ERISA), so they are not subject to state insulin cap laws. Therefore, individuals covered under self-funded employer or union ERISA plans are more susceptible to prescription insulin price increases than individuals covered by a Qualified Health Plan on the State Marketplace or by fully insured large group coverage.
- Out-of-state insurance coverage is also not subject to New York State insulin cap laws. Health insurance isn't required in New York State. Under the Federal Affordable Care Act, employers with 50 or more employees must offer health insurance coverage. Private employers, with employees in more than one state, may offer their New York State employees out-of-state insurance, which could make them more vulnerable to price fluctuations in insulin.

Benjamin et al (2022) outlined three potential strategies New York State could pursue to incentivize uninsured individuals with access to employer or union-sponsored plans into Qualified Health Plans on the New York State Marketplace. These options are designed for uninsured individuals who are not eligible for Medicaid or for the Essential Plan, and are summarized and discussed below, through the lens of implementing them specifically for uninsured adults with diabetes who use insulin in New York State:

1. State Premium Assistance Plan

2. State Mandate and Penalty
3. State Public Option Plan

The effectiveness and feasibility of implementing each option in New York for the uninsured population with diabetes who use insulin is reviewed below. Once enrolled in a Qualified Health Plan on the Marketplace, individuals would be covered by the state insulin cap law.

Table 5: Strategies to enroll uninsured individuals with diabetes who use insulin who have access to employer or union-sponsored coverage but remain unenrolled due to cost issues

Strategy	Financial Impact to State	Pros	Con
State Premium Assistance Program Expand state funded premium assistance to individuals with annual household incomes of up to 600% of the federal poverty level	• Estimated cost per enrollee for deep subsidy is $8,728 • Estimated total program cost ranges from $51 to $121 million to enroll individuals with diabetes who use insulin • CSSNY estimated total costs for providing deep subsidies to enroll all uninsured individuals at $803 million	• Subsidies lower cost barriers, improve affordability, increase enrollment • Uses existing programs to expand coverage • Decreases costs for individuals without increasing employers' costs. • Other states (CA, NJ) have implemented	• COVID-19 legislation increased federal subsidies to individuals. Inflation Reduction Act continues expanded assistance until 2025 • Could adversely impact the experience of state-regulated coverage and cause premiums to increase, if offered solely to individuals with diabetes who use insulin • Cost to state, but could use the 1332 pass-through surplus to finance
State Individual Mandate & Penalty Institute a state mandate for individuals to have health insurance	• Administrative and enforcement costs • Costs could be offset by penalties	• Other states have implemented (CA, MA, NJ, RI, VT & D.C.)	• Estimated impact minimal • Elimination of the federal repeal had minimal impact on enrollment in coverage in New York State
State Public Option Create a state public option with high-value coverage and lower premiums	• Minimal state costs anticipated	• May incentivize uninsured higher-income individuals to enroll	• Easier & more cost effective to leverage existing options rather than create a new one • Enrollment of a relatively small group of uninsured individuals may result in adverse selection • May result in a higher risk pool with higher costs if offered solely to people with diabetes or other chronic conditions

State Premium Assistance Plans

Background:

Both the federal government and states have implemented premium assistance programs to help lower the cost of monthly premiums and to make higher value plans more affordable to constituents. In 2006, Massachusetts debuted the first state premium assistance program using state dollars and federal matching funds to subsidize health coverage. In 2010, the Affordable Care Act passed, which provided federal subsidies for individuals with annual household incomes of up to 400% of the federal poverty level in the form of Advanced Premium Tax Credits. The tax credits helped lower the cost of premiums for Qualified Health Plans available on the marketplace. During the COVID-19 pandemic, the federal government again stepped in to help make coverage more affordable under the American Rescue Plan, which eliminated the income cap, increasing and expanding subsidies to a wider group of individuals.[93] These enhanced subsidies were extended through 2025 in the Inflation Reduction Act.[94] In addition to the federal government, a number of states have established premium assistance programs (CA, CO, CT, MD, NJ, NM, MA, VT & WA). Cost-sharing, premium reduction, and eligibility criteria for the subsidies vary by state. For example, Maryland funds subsidies specifically for young adults while California and New Jersey extended subsidies to all individuals with incomes up to 600% of the federal poverty level.[95]

Impact:

In general, subsidies lower cost barriers, improve affordability and increase enrollment. NYSOH reported that the enhanced subsidies offered during the pandemic "have significantly increased the affordability of Qualified Health Plan coverage, on average by $365 per month."[96]

New York State Option:

Expanding the state premium assistance program in New York is one option available to make coverage more affordable for individuals who use inulin and have access to employer or union-

[93] (Benjamin et al., 2022)
[94] (Cox et al., 2022)
[95] ("Premium Assistance," n.d.)
[96] (NY State of Health, 2023a)

sponsored plans but remain uninsured. Benjamin et al. (2022) analyzed the impact and cost of providing different subsidies on enrollment in "Narrowing New York's Health Insurance Coverage Gap". In this report, deep subsidies were estimated to have the greatest impact on enrollment, followed by modest subsidies and subsidies to higher-income earners with annual household incomes between 400% and 600% of the federal poverty level.

Potential Cost and Financial Impact:

In general, a state premium assistance program is expected to reduce cost barriers to enrolling in comprehensive health care coverage. It could potentially save money for both individuals and employers. The monthly premium cost for a subsidized Qualified Health Plan to an individual with diabetes who uses insulin in New York will vary depending on their annual household income and the tier of coverage purchased. An individuals' monthly premium cost for similar coverage is expected to be lower with a subsidized Qualified Health Plan than an employer or union-sponsored plan and cost-neutral for higher-tier or higher value plans. An added financial bonus is that individuals who gain coverage under a Qualified Health Plan on the New York State Marketplace will be covered by the insulin cap law.

The financial impact to the state also depends on the size of the subsidy and the eligibility criteria. A state premium assistance program offering a deep subsidy to incentivize individuals with diabetes who use insulin to enroll in a Qualified Health Plan on the Marketplace is estimated to cost from $51 to $121 million, depending on the number of enrollees (see table 6).

Table 6: Estimated Costs of State Premium Assistance Programs for individuals with diabetes who use insulin who have access to employer or union-sponsored plans	**Population**	**Total cost**
Total estimated	13,860	$120.58 million
Total with annual household incomes < $50,000	5,906	$ 51.38 million

Workgroup discussion:

Workgroup members expressed interest and support for this option stating that, in their opinion, it would help to bring in more individuals without adversely affecting the marketplace and increasing

costs for employers and currently insured individuals. Most members noted that premium assistance programs with reduced cost-sharing can improve affordability, especially if the cost of the monthly premium is a barrier.

In a post-meeting survey, a majority of members recommended pursuing the strategy to expand the state premium assistance program to help individuals with diabetes who use insulin to pay for premiums. Other members raised concerns that offering premium assistance solely to individuals with diabetes could cause adverse selection in state-regulated coverage and potentially causing premiums to increase.

State Individual Mandate and Penalty

Background:

The Affordable Care Act requires individuals to maintain basic health insurance coverage. To incentivize healthy individuals to enroll in coverage, the Affordable Care Act instituted a "shared responsibility payment" which required individuals without insurance to pay a penalty of up to $695 a year or 2.5% of household income. Enrolling healthy individuals into coverage was expected to help reduce the cost of insurance by spreading the risk to a larger pool of beneficiaries. In 2017, the U.S. Congress passed the "Tax Cut and Job Acts of 2017," which reduced the penalty to zero starting in 2019. The law still requires individuals to hold minimum coverage unless they request a waiver.[97]

With the repeal of the penalty on the individual mandate, states considered implementing their own mandate and penalty to ensure that healthy individuals maintain or enroll in health care coverage. Currently five states (CA, MA, NJ, RI, and VT) and the District of Columbia have passed individual shared responsibility mandates. All of these, except Vermont, impose a penalty for non-compliance.[98]

Impact:

The impact of the individual mandate and penalty is unclear. At the federal level, enrollment increased from 2014 to 2017 while the percent of tax filers claiming a penalty decreased, suggesting an inverse relationship. But other factors, such as expanded Medicaid programs, may account for the

[97] (Congressional Research Service, 2020)
[98] (Crail & Masterson, 2022)

growth in covered individuals.[99] A number of studies suggested that enrollment would decrease once the penalty was eliminated.[100,101] However that was not the case, at least in New York, where enrollment increased in 2019 and 2020 prior to the pandemic.[102]

Understanding the impact of eliminating the federal penalty during the pandemic is complicated. The COVID-19 pandemic significantly impacted employment and health insurance. The U.S. Congress acted to help individuals maintain or enroll in coverage during this difficult time. The Families First Coronavirus Response Act ("FFCRA") of 2020 provided states with funding to maintain eligibility of currently enrolled Medicaid beneficiaries.[103] States with expanded Medicaid programs, such as New York, dramatically increased Medicaid enrollees during the pandemic with simplified enrollment processes and longer open enrollment periods. Then the American Rescue Plan Act of 2021 (ARPA) increased federal assistance for Qualified Health Plans so higher-income individuals paid lower premiums, which also helped to boost enrollment.[104] These actions helped states increase the percent of covered individuals during the pandemic regardless of the elimination of the federal penalty. Due to the negligible impact of the elimination of the federal penalty in New York, Benjamin et. al. (2022) estimated that instituting a similar state mandate would have limited, if any, impact on overall enrollment.

State mandates and penalties are fairly new and so far, the results are mixed, with some states (NJ, VT, & D.C.) reporting decreased and others (CA) increased enrollment during the first year of the mandates.[105]

Potential Cost and Financial Impact:

Individuals that are incentivized by the mandate and penalty to enroll in coverage would be covered by the insulin cap law. The premium and cost-sharing would depend on the individual's income. A state mandate with penalties (similar to the original federal one) could require non-compliant individuals to pay up to $695 dollars or 2.5% of their annual household income in annual

[99] (Congressional Research Service, 2020)
[100] (Benjamin et al., 2022)
[101] (Eibner & Nowak, 2018)
[102] (NY State of Health, 2020)
[103] (Families First Coronavirus Response Act, 2020)
[104] (NY State of Health, 2021)
[105] (Benjamin et al., 2022)

penalties. In 2017, an estimated 2.7% of federal tax returns from New Yorkers reported a penalty for non-compliance for a total amount of $191.1 million.[106] States have used or plan to use penalty collections to fund re-insurance programs, keep premiums low, or to subsidize the state health insurance marketplace.[107]

Workgroup discussion:

Workgroup members expressed very limited support for instituting a state mandate and penalty during the meeting. In a post-meeting survey, a small minority of members favored pursuing this option, stating that it would incentivize individuals to enroll in coverage and might bring in more individuals without adversely affecting the marketplace. Opponents, representing advocacy groups, maintained that this strategy does not address the root cause of the affordability issue and serves to create more pressure on uninsured individuals with diabetes who use insulin.

State Public Option Plan

Background:

A number of states are looking at implementing a state public option plan to help create more accessible and affordable health insurance options. The intent of a state public option plan would be to incentivize uninsured higher-income individuals by offering high-value coverage with lower premiums than are currently available on the existing Marketplace or off-Marketplace.[108] This option would give the state control of the design and implementation of the plan. Costs could be contained through state regulated caps on payments to health care providers and/or instituting other cost-reduction measures.[109]

In some areas of the United States, Qualified Health Plan options offered on the Affordable Care Act Marketplace are severely limited and creating a new public option plan to increase access and affordability makes sense. This was the impetus for Washington to implement the first public option plan in 2021.[110] Other states followed suit, with Colorado launching its public option plan in 2023 and

[106] (Congressional Research Service, 2020)
[107] (Tolbert, et al., 2019)
[108] (Benjamin et al., 2022)
[109] (Monahan et al., 2022)
[110] (Benjamin et al., 2022)

Nevada expected to offer one beginning in 2026. Oregon and Vermont are also considering this option to make coverage more accessible and affordable.

Impact:

The state public option plan is relatively new and evaluation data are limited. Low enrollment, provider participation, and cost containment are major concerns of public option plan administrators. So far, Washington has reported limited uptake of its public option plan. Washington is now implementing a number of revisions to increase access to the plan in more counties and to require more hospitals and insurers to participate in the plan. Another major challenge noted in the literature is bringing insurers and health care providers to the table to contain costs to create affordable public option plans. In light of this issue, Colorado is hoping to implement premium-reduction targets with the use of federal pass-through funds from its 1332 waiver application.[111]

A Public Option Plan in New York State:

New York State has a robust, competitive Marketplace, with residents of all counties having a choice in selecting from multiple Qualified Health Plans. Affordability rather than accessibility would be the primary purpose of implementing a public option plan in the state. For this type of plan to work, the state would have to implement a number of cost containment measures, such as capping provider reimbursement and reducing the amount of administrative overhead allowed.[112]

A public option plan with higher value and lower premiums and lower out-of-pocket costs would be more appealing than a plan with low premiums and high deductibles and high cost-sharing to some uninsured individuals, especially those with diabetes who use insulin. The public option plan modeled in “Narrowing New York's Health Insurance Coverage Gap” anticipates enrollment of a larger, relatively healthy, higher-income population. However, a public option plan specifically designed for individuals with diabetes who use insulin would provide coverage to a smaller, higher-risk pool of beneficiaries, likely resulting in a higher price tag too.

Potential Costs and Financial Impact:

Individuals with diabetes who use insulin covered under a new state public option plan would be

[111] (Monahan et al., 2022)
[112] (Benjamin et al., 2022)

covered by the insulin cap law. Lower premiums and lower cost-sharing would financially benefit these individuals as well, making insulin and access to health care to manage their diabetes more affordable**.**

The financial impact to the state of creating this type of program is not modeled here.[113]

Workgroup discussion:

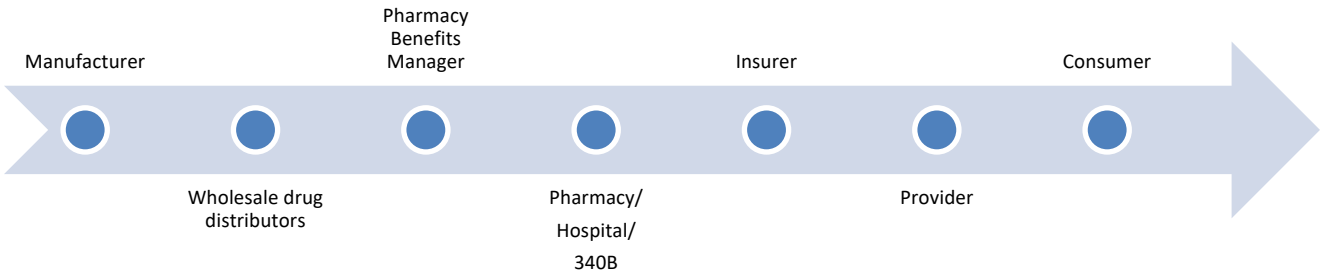
Workgroup members discussed the pros and cons of creating a state public option for uninsured individuals with diabetes who use insulin. Most members opposed this strategy. Workgroup members, particularly those representing health plans, voiced significant concern about the potential impact of creating a new public option for a relatively small group of uninsured individuals on the existing marketplace and delivery system. These members suggested that enrollment of a specific population, such as individuals with diabetes who use insulin, may result in adverse selection and dis-incentivize healthy people from enrolling in health insurance until they receive a diabetes diagnosis. Members, representing insurance plans, asserted that this strategy would likely result in a pool of individuals with increased risk of morbidity and higher costs. Members viewed it as unlikely that the state could offer a new state plan with lower premiums and less cost-sharing to a small group of high-risk beneficiaries with federal subsidies alone. Workgroup members generally agreed that it would be easier and more cost effective to leverage existing options to make insurance more accessible and affordable for this population. This could also help spread the higher risk of morbidity and associated costs to a larger pool of beneficiaries. Members also stated the opinion that it is more feasible to provide a subsidy for an existing insurance channel than create a new channel or program.

In a post-meeting survey, a small minority of Workgroup members recommended this option, stating that it would provide higher-income individuals with diabetes who use insulin with access to higher value coverage at lower costs.

[113] Note: Benjamin et. al. (2022) estimated the cost of implementing a state public option plan in NYS for individuals who have access to employer or union sponsored plans but remain uninsured due to costs. Those estimates may not be applicable to a state public option plan specifically for individuals with diabetes who use insulin due to potentially higher risks and costs.

BARRIERS IN ACCESS TO INFORMATION REGARDING COSTS WITHIN THE INSULIN SUPPLY CHAIN

Drug price transparency is defined as readily available information on the price of pharmaceutical drugs to either authorities or consumers.[114] The U.S. Senate Committee on Finance, headed by Senators Grassley and Wyden, conducted an investigation in 2019 to identify the root causes of the high price of insulin.[115] Their work resulted in a report entitled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug". This report highlights the complexity of the pharmaceutical supply chain and the barriers encountered in each link of the chain. The industry has traditionally instituted broad confidentiality clauses that limit public disclosure of information related to drug pricing which significantly impacts transparency. This section will review the transparency issues identified across the pharmaceutical distribution system, from manufacturers, wholesalers, pharmacy benefit managers, pharmacies, insurers, and providers to the consumer.



Manufacturers

The wholesale acquisition cost of insulin, also known as "list price", is determined by its manufacturers. Information on the wholesale acquisition cost price is publicly available. The 2021 Congressional investigation reported several barriers to achieving full transparency of the factors that influence the list price of insulin, as manufacturers often marked individual data elements as "trade secrets" or "proprietary" information. Manufacturers attributed the rising cost of insulin to some of

[114] (Ahmad et al., 2020)
[115] (Sen. Grassley & Sen. Wyden, 2021)

the following factors, which are reviewed in more detail below:

- competition,
- discounts and rebates,
- marketing costs,
- patent status factors, and
- research and development expenses.

Competition:

One of the major drivers of increasing insulin prices is competition between insulin manufacturers. A main form of competition is exclusion, or threat of exclusion from formularies.[116] This can hurt both patients and manufacturers. If a patient's drug is excluded from their health plan's formulary, they must either switch to a new product which could impact their health or pay an increased price for their preferred medication. Manufacturer exclusion from formularies can reduce their market share and lead to financial loss. Being the sole choice on a formulary increases manufacturer share and revenue, which increases the discounts they offer to be preferred for formularies.

Much of the competition between insulin manufacturers is fostered by pharmacy benefit managers, who manage and/or control the development of formularies. Higher list prices allow manufacturers to offer pharmacy benefit managers and insurers larger rebates or discounts and still achieve significant earnings. Lowering the list price would likely mean that manufacturers would have to decrease the value of rebates offered to pharmacy benefit managers to maintain the same level of earnings. Manufacturers told the committee that when considering lowering prices, the decision against it was made due to fear of formulary exclusion.[117]

The congressional committee experienced several barriers to identifying the root causes of wholesale acquisition cost price increases attributed to competition. Internal documents suggested that some manufacturers increased the wholesale acquisition cost to counter the aggressive rebate and discount activity of competitors; to lock price increases with the introduction of new insulin

[116] Formulary is a list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits.
[117] (Sen. Grassley & Sen. Wyden, 2021)

product and anticipated competition; and to respond to pressure from pharmacy benefit managers to offer larger rebates and discounts.

Discounts/Rebates:

Drug manufacturer rebates are another area lacking transparency considered a major driver of drug price increases. Rebates are payments made by drug manufacturers to pharmacy benefit managers after the point of sale and are usually calculated as a percentage of the wholesale acquisition cost. Rebates and discounts are negotiated between manufacturers and pharmacy benefit managers to secure preferred formulary placements. Manufacturers usually make multiple rebate offers for each drug, with the size of the rebate depending on formulary access and competition for the drug. One example of other discounts and fees is price protection, or inflationary protection fees. This means that when manufacturers raise the wholesale acquisition cost beyond the agreed upon percentage, they must pay additional rebates to plan sponsors.[118]

Historically, pharmacy benefit managers encouraged manufacturers to increase the value of rebates offered to them in exchange for preferred placement of their medications on a formulary. This incentivizes manufacturers to increase the list price of medications so that they can provide a larger rebate to pharmacy benefit managers. As the list price increased, manufacturers reported decreases in net prices received for some insulin products.[119] Although the net price of insulin decreased, the U.S. Senate Finance Committee reported that manufacturer revenue continued to increase. Manufacturers expressed concern that decreasing wholesale acquisition cost prices would dissuade pharmacy benefit managers from placing their medicines on a formulary as pharmacy benefit managers receive administrative fees based on a percentage of the wholesale acquisition cost.[120]

Other manufacturer rebates include those paid to states and the federal government. The Medicaid Drug Rebate Program (MDRP) requires manufacturers to enter into rebate agreements with the Federal government in exchange for almost all their drugs being covered by Medicaid. Under MDRP, for each drug administered to a Medicaid beneficiary the manufacturer must provide a rebate to the state which shares a portion of the rebate with the Federal government. For generic drugs, the

[118] (Sen. Grassley & Sen. Wyden, 2021)
[119] (Van Nuys et al., 2021)
[120] (Sen. Grassley & Sen. Wyden, 2021)

rebate is thirteen percent of the average manufacturer price, and brand name drugs tend to have a rebate of 23.1 percent of the average manufacturer price.[121] In 2022, the Inflation Reduction Act established the Medicare Prescription Drug Inflation Rebate Program which also institutes a penalty for uncontrolled price increases.[122]

There is a significant lack of transparency around pharmaceutical manufacturer rebates. Traditionally, manufacturers, pharmacy benefit managers, and insurers have claimed that rebates fall under "trade secrets" or proprietary information. The manufacturer list or wholesale acquisition cost price of an insulin drug is publicly available, but the actual net price paid by an insurer often is not. When pharmacy benefit managers and insurers do not pass on manufacturer drug rebates and discounts to patients, the gap between net and list price increases.[123] Insurers often require beneficiaries to pay cost-sharing on the list and not the net price. If a manufacturer increases the list price, beneficiaries may pay more in out-of-pocket costs, exacerbating disparities in access to medication.[124] Understanding the amount of a rebate and who retains the rebate (pharmacy benefit manager, insurer, or beneficiary) is key to improving price transparency.

Marketing costs:

The Congressional investigation reported that while marketing costs were not a major driver of the increased cost of insulin, transparency remains an issue. At the request of the Congressional Committee, manufacturers reported marketing expenses which were broken down into four categories: consumer marketing, prescriber marketing, other expenses (which include samples and market research), and patient support. However, manufacturers indicated that marketing expenses may not be accurately allocated to each product but rather spread across a product class. The investigation noted another important barrier to understanding the role of marketing costs in the price of insulin products. They found that manufacturers may outsource their marketing to other companies or via their own tax-exempt organizations, which makes line-item costs difficult to assess.[125]

[121] Ibid
[122] (Centers for Medicare & Medicaid Services, 2023b)
[123] (Rome et al., 2021; Tran, 2022)
[124] (Tran, 2022)
[125] (Sen. Grassley & Sen. Wyden, 2021)

Patent Status Factors:

A patent is an exclusive right granted to produce a drug for 20 years. The original patent for insulin sold for one dollar to the University of Toronto in 1923 to ensure the fast and safe availability of insulin to the public. The university, however, soon realized they didn't have the capacity to produce the needed amounts of insulin, so they teamed up with drug manufacturer Eli Lilly. The collaborative agreement allowed Eli Lilly to acquire U.S. patents for any new manufacturing process improvements while the university would reserve the original patent for the rest of the world. One company they contracted with was Nordisk Insulin in Denmark, which later merged with another company to become Novo Nordisk, one of the biggest companies in insulin today. [126]

Ever since the Drug Price Competition and Patent Term Restoration Act passed in 1984, a pattern has emerged where innovative drugs launch at high prices during the patent protection window and once the patent expires and generic drugs are introduced into the market, the brand price lowers. That has not been the case for insulin. Over the years, manufacturers have extended insulin patents through improvements in insulin and delivery devices with direct benefits to patients with diabetes. One of the first patent extensions made it possible to combine long-acting and short-acting insulin, which allowed many people to change to a once daily injection. Innovations in dose adjustment kept insulin patent protection going into the 1970s.[127] In the 1970s, the manufacturing process was adapted to improve the purity of the insulin and reduce side effects, securing patent extension into the 1980s. In the 1980s, multiple insulin manufacturers introduced human insulin, giving them patents stretching into the 21st century. The first patent for a long-acting analog insulin was approved in 2000 and didn't expire until 2014. Due to these patent extensions, the formulation of generic insulin in North America was delayed adding to the continuous rising costs of insulin in the U.S.[128]

The U.S. Congressional Investigation found that the majority of patent extensions were for improvements in insulin-related devices and equipment rather than improvements in the drug itself.[129]

[126] (Greene & Riggs, 2015)
[127] Ibid
[128] (Greene & Riggs, 2015)
[129] (Sen. Grassley & Sen. Wyden, 2021)

Research and Development (R&D):

Pharmaceutical manufacturers often attribute high list prices to their research and development costs. As a century old drug, this is not the case with insulin. In the Congressional Report, manufacturers reported spending millions of dollars on research and development, yet it still amounts to a small fraction of their total revenue.

Manufacturers often reinvest income in research and development. However, the research and development costs associated with insulin products are far from transparent. The Congressional Committee requested a line-item breakdown of research and development costs, although some manufacturers were only able to provide estimates. Pharmaceutical corporations attributed the lack of transparency in research and development costs to accounting practices, which may not capture all expenses for a specific insulin or may not allocate expenses by product. Manufacturers reported that administrative, training hours, and local medical expenses are often spread evenly across product lines.[130]

Summary:

An investigation by the U.S. Senate Committee on Finance demonstrated that the rising wholesale acquisition cost price of insulin is not primarily supported by any advances in the drug itself but rather dependent on other factors, including pharmacy benefit manager pricing practices.[131] More transparency from manufacturers and other links in the pharmaceutical supply chain are necessary to identify factors that contribute to high insulin prices. The next section of the report reviews transparency issues of the rest of the supply chain.

Wholesalers:

Wholesalers serve as an intermediary that purchases pharmaceuticals from manufacturers in bulk and at a discount and resells and distributes those pharmaceutical products to pharmacy benefit managers and other providers, such as hospitals and pharmacies**.** In the United States, three wholesalers/distributors control 95 percent of the market. In general, a lack of transparency permeates

[130] (Sen. Grassley & Sen. Wyden, 2021)
[131] (Sen. Grassley & Sen. Wyden, 2021)

the prescription wholesale market. While the list price of purchasing the drug is set by the manufacturer, the wholesaler has latitude to negotiate the selling price. The selling price depends on a number of factors, including supply and demand (or the quantity required by the purchasing entity) and negotiating tactics. Wholesalers may also offer incentives to purchasers, such as prompt pay and volume discounts.

The U.S. Congressional investigation uncovered a number of aggressive disruption techniques used by wholesalers to generate advantageous terms and contracts. Some competitive methods include the "refusal to stock new product, reduced service levels on certain drugs, or ordering the slowdown of drug distribution in non-U.S. countries".[132]

Overall, the lack of transparency in wholesaler/distributor practices makes it challenging to identify any hidden costs.

Pharmacy Benefit Managers:

In 2019, the New York State Senate also conducted an investigation to better understand the cost factors associated with the high prices of essential drugs. Their investigation focused on pharmacy benefit managers and pharmacy benefit manager practices on accessibility and affordability of pharmaceuticals in New York State. Pharmacy benefit managers were created in the 1960s to control the cost of drugs and manage prescription claims in the United States due to increasing prescription drug claims. They serve as fiscal intermediaries between members of the healthcare industry, such as insurers, pharmacies, and drug manufacturers. In the U.S., pharmacy benefit managers manage pharmacy benefits for over 266 million insured Americans. The pharmacy benefit managers that exist today came to prominence when the Medicare Modernization Act was passed in 2003 and pharmacy benefit managers role stretched to include identifying patients, reducing administrative burden on plan sponsors, and formulating drug prices with manufacturers by negotiating discounts and rebates for Medicare Part D.[133]

Three pharmacy benefit managers, CVS Caremark, Express Scripts Inc., and OptumRx, control eighty-five percent of the market in the United States. Since pharmacy benefit managers determine

[132] (Sen. Grassley & Sen. Wyden, 2021)
[133] (Sen. Skoufis & Sen. Rivera, 2019)

which pharmacies will be included in plan networks, which medications will be in a plan's formulary, and receive rebates to include or exclude medications, they hold a lot of power.[134] The Senate investigation found that pharmacy benefit managers began implementing formulary exclusions in the insulin therapeutic class in the early 2010s, stopping manufacturers from reaching many patients.[135] The investigation also found that insulin prices had already been on the rise, but exclusions led manufacturers to increase wholesale acquisition cost prices for insulin so that they could offer pharmacy benefit managers larger rebates to place their insulin on formularies. They feared lowering wholesale acquisition cost prices would negatively impact their relationship with pharmacy benefit managers, as it would lower rebate amounts and other administrative fees, which are based on a percentage of wholesale acquisition cost.[136]

Pricing Models:

The transparency issues of pharmacy benefit managers tend to lie in its pricing models, which include spread and pass through pricing and direct and indirect remuneration methods. Spread pricing is when plan sponsors are charged a different price for a prescription drug than the amount pharmacists are reimbursed for dispensing the drug. Spread pricing refers to the difference between these amounts, which becomes an additional profit for the pharmacy benefit manager. This has been utilized by pharmacy benefit managers to profit off of state Medicaid programs.[137] The 2019 report on pharmacy benefit manager practices in New York State estimated that NY Medicaid managed care was overcharged at least $300 million due to spread pricing from pharmacy benefit managers. This led to the New York State Enacted Fiscal Year 2019-2020 budget banning the use of spread pricing in the State's Medicaid Program.[138]

In the pass-through model, a pharmacy benefit manager charges plans the exact amount the pharmacy benefit manager spends on prescriptions and instead earns income through an administrative fee collected from manufacturers, which are usually a percentage of the wholesale acquisition cost price. The higher the wholesale acquisition cost price, the more the pharmacy benefit

[134] Ibid
[135] (Sen. Grassley & Sen. Wyden, 2021)
[136] (Sen. Grassley & Sen. Wyden, 2021)
[137] Ibid
[138] (Sen. Skoufis & Sen. Rivera, 2019)

manager earns for each medication dispensed, which further disincentivizes pharmacy benefit managers to push for lower wholesale acquisition cost prices.[139] Under this model, pharmacy benefit managers also negotiate reimbursement rates with pharmacies which are then paid by the clients.

Another pricing model is direct and indirect remuneration fees, known as "DIR". These fees were created by the Centers for Medicare and Medicaid Services to track rebates and price adjustments made to pharmacy benefit managers so that they could accurately determine reimbursement on lowest price.[140] DIR fees are payments or adjustments to payments made to pharmacy benefit managers after point-of-sale that alter Part D covered drug costs. However, DIR fees can be charged months after the initial point of sale, and contract language makes it difficult for pharmacies to know how much they will eventually be charged.[141] Claw backs or trying to recover money already disbursed can result in some pharmacy benefit managers charging more for medication that has already been dispensed than pharmacies receive for it.[142]

Rebates:

As previously mentioned under barriers to transparency in the supply chain, manufacturer discounts and rebates distort actual costs of insulin. Manufacturers set the prescription drug list price and the pharmacy benefit managers then negotiate price concessions for drugs utilized in its plan sponsor as an exchange to include the drugs in the formulary. Pharmacy benefit managers can negotiate large rebates and save beneficiaries money in some situations, but in other cases, pharmacy benefit managers use of rebates increases pharmaceutical prices.[143] Pharmacy benefit managers receive rebates after point of sale and can make more than 40% of the drug's list price in rebates alone.[144] Since rebates are frequently calculated as a percentage of a drug's list price, pharmacy benefit managers are incentivized to prioritize more expensive prescription drugs.[145] Up until recently, the federal government and states have not required pharmacy benefit managers to disclose rebate information.

[139] (Sen. Grassley & Sen. Wyden, 2021)
[140] (Centers for Medicare & Medicaid Services, 2017)
[141] (Sen. Skoufis & Sen. Rivera, 2019)
[142] (Sen. Skoufis & Sen. Rivera, 2019)
[143] Ibid(Sen. Skoufis & Sen. Rivera, 2019)
[144] Ibid(Sen. Skoufis & Sen. Rivera, 2019)
[145] Ibid

Self-dealing:

Pharmacy benefit managers can own both retail and mail order pharmacies and this type of business model can result in what is known as "self-dealing", or taking advantage of their ownership in both arenas to maximize profit and/or cut costs.[146] The vertical integration of pharmacy benefit managers, pharmacies, and health plans provide numerous opportunities for self-dealing, such as:

- Selling a prescription drug at a lower price to their own pharmacy and a higher price to a non-pharmacy benefit manager owned one. Reduced reimbursement rate of smaller, community pharmacies have led to financial hardship and eventual buyout offers from the pharmacy benefit managers.[147]
- Allowing pharmacy benefit manager-owned pharmacies to offer price incentives to consumers, such as a 90-day medication supply for the price of a 60-day supply, while denying other pharmacies in their pharmacy benefit manager network the same opportunity.[148]

Pharmacy benefit manager self-dealing practices have led to the closure of many smaller independent pharmacies, diminishing access to medication.[149] In Iowa alone, over 70 community pharmacies have closed due to inability to compete with pharmacy benefit managers-owned pharmacies and many more have had to reduce their hours.[150] According to the New York State Senate Investigative Report, pharmacy benefit managers reimbursed smaller pharmacies at reduced rates, which led to financial hardship, and ultimately store closures. Many of the smaller pharmacies received buyout offers from the pharmacy benefit managers not long after closing their doors.[151] In addition, both CVS and Express Scripts have been fined for claiming that clients who utilize community pharmacies instead of the pharmacy benefit managers-owned pharmacy will have to pay higher prices.[152]

The lack of transparency in pharmacy benefit manager pricing structures has impacted both affordability and accessibility at various links in the pharmaceutical chain. Manufacturer and pharmacy

[146] Ibid
[147] Ibid(Sen. Skoufis & Sen. Rivera, 2019)
[148] (Bertram, 2023)
[149] (Bertram, 2023)
[150] (Iowa Pharmacy Association, 2020)
[151] (Sen. Skoufis & Sen. Rivera, 2019)
[152] (Bertram, 2023)

benefit manager pricing strategies are clearly intertwined. Analysis indicates that pharmacy benefit manager revenues have steadily increased while manufacturer net prices have declined in recent years due to these commercial practices.[153] These investigative reports show that some pharmacy benefit manager practices have increased consumer costs and undermined patient choice.[154] Due to continued lack of transparency, the Federal Trade Commission launched an investigation into pharmacy benefit manager pricing practices in 2022.[155]

Pharmacies:

Pharmacies are typically reimbursed for insulin they dispense via three main methods: a cash price, a contract rate, and the drug cost plus a dispensing fee. Uninsured individuals would normally pay a cash price. Pharmacists who dispense insulin to insured individuals are typically reimbursed by health plans or pharmacy benefit managers via an agreed upon rate or the cost of insulin plus a dispensing fee. Pharmacists may also collect a co-payment from insured individuals, which varies by health plan and tier of the formulary. The price of the drug to both the pharmacist and the patient depends on the reimbursement vehicle. The various payment methods create a lack of transparency over pricing.

The price of insulin at the pharmacy counter also depends on the ability of the pharmacy to negotiate a favorable contract rate or dispensing fees. Chain pharmacies and those owned by pharmacy benefit managers are better placed to sign advantageous agreements.[156] As indicated previously under the Pharmacy Benefit Manager section, community pharmacies sometimes are reimbursed less than the cost of a dispensed drug.

The complexity of payment and reimbursement methods at pharmacies impact price transparency in this part of the pharmaceutical supply chain, with independent pharmacists and consumers often paying the brunt of higher costs.[157]

[153] (Sen. Grassley & Sen. Wyden, 2021; Van Nuys et al., 2021)
[154] (Sen. Skoufis & Sen. Rivera, 2019)
[155] (Becker, 2022)
[156] (Bertram, 2023; Shepherd, 2020)
[157] (Sen. Skoufis & Sen. Rivera, 2019)

Insurers:

A number of factors contribute to the lack of transparency on drug prices offered by health plans, including the creation of drug formularies, the placement of insulin on different drug tiers, co-payments, co-insurance, and manufacturer rebates.

Formularies and drug tiers:

A formulary is a list of prescription drugs covered by the insurer. Usually insurers offer tiered formularies, which divide the drugs offered into groups based on cost. The lowest tier is typically generic drugs with the lowest co-payments. Higher tiers are comprised of brand-name drugs with higher co-pays. The highest tier is generally dedicated to specialty, high-cost drugs with high co-insurance or co-pay costs. Placement of a drug on a formulary can impact consumer out-of-pocket costs, co-pays, co-insurance and deductibles.

The development of formularies is a complicated process. Typically, a health plans' independent Pharmacy and Therapeutics Committee reviews the medication's clinical value and recommends its placement on formularies. Insurers negotiate with pharmacy benefit managers over the placement of a drug on the tier, which dictate cost and access, such as prior authorization and step therapy factors.[158] The complicated formulary structure to determine what drugs are placed on which tier makes understanding the costs very challenging.

Another concern regarding formularies is the inclusion or exclusion of less expensive biosimilar products. A 2022 investigation by the Office of Inspector General at the Department of Health and Human Services found that while inclusion of biosimilars has increased in formularies, not all plans include or promote the use of them. [159]Other research has reported exclusion of biosimilars in some plan formularies.[160]

While pharmacy benefit managers typically offer multiple formularies, smaller insurers have less ability to negotiate the placement of drugs on their formularies. The resulting contracts frequently contain broad confidentiality clauses that limit public disclosure of contracting practices, thereby

[158] (Sen. Grassley & Sen. Wyden, 2021)
[159] (Murrin, 2022)
[160] (Biosimilars Council, 2023)

inhibiting transparency.[161]

A recent investigation of formularies offered by Qualified Health Plans in three states found that formularies became more complex and co-insurance rates increased from 2014 to 2018. The researchers also reported limited transparency regarding cost-sharing of covered medications.[162] Another major concern is the exclusion or less preferential formulary tier placement of biosimilar insulins. Research conducted by the Office of the Inspector General at the Department of Health and Human Services and others found evidence that some insurers excluded or imposed restrictions on less expensive biosimilars.[163]

Cost-sharing:

Health insurers typically require that beneficiaries share prescription costs through a combination of co-pays, deductibles, and co-insurance**.** The different tiers of coverage and formularies can make it extremely challenging for beneficiaries to understand the true cost of a medication under their health plan. For example, beneficiaries with high-deductible plans may have to pay a lot of out-of-pocket costs before their insurance contributes. Other high-deductible plans may offer "pre-deductible" coverage for insulin, which makes it more affordable to beneficiaries. [164]

Rebates:

Again, manufacturer rebates impact the access and affordability of insulin drugs available on a health plan's formulary. Manufacturers will often provide a rebate to insurers in exchange for placing the drug on their health plan formulary, or on a lower cost-sharing tier, or for achieving a previously agreed volume-based milestone of drugs dispensed. Manufacturers sometimes even offer additional rebates for making their drug the only option in a pharmaceutical class on a priority tier of the formulary.[165]

However, there is a lack of transparency in how rebates are utilized by insurers. Health plans report using rebates to lower-premiums or cost-sharing or to create wellness programs. These efforts

[161] (Shepherd, 2020)
[162] (Hung & Sauvageau, 2021)
[163] (Murrin, 2022; Yu et al., 2023)
[164] (American Diabetes Association, 2023b)
[165] (Mulcahy et al., 2021; The Health Strategies Consultancy LLC, 2005)

may provide more benefit to healthy beneficiaries rather than individuals with diabetes who uses insulin. Typically, high priced insulin comes with higher rebates for insurers. Depending on their insurance plan, patients may have higher cost-sharing, which they pay on the list, not the net price. Or the beneficiary may pay the full cost of the insulin because they are in a high deductible plan. If an insurer applies the rebate to lower the premium of all beneficiaries rather than pass it on to the insulin user, the cost may actually be higher for the patient. When questioned about rebate practices during the 2019 federal investigation, health plan representatives indicated that it would be impractical to pass the rebate on directly to the individual beneficiary who uses insulin because the rebates are received months after the medication is dispensed.[166]

Providers:

A review of the literature suggests several potential conflicts of interest that create barriers to transparency in the health care provider link of the pharmaceutical drug supply chain. Pharmaceutical manufacturers offer physicians and other health care providers free meals and honoraria which can influence prescribing decisions. Providers may also have investments in pharmaceutical companies, which consciously or subconsciously can incentivize them to prescribe medications produced by these manufacturers. In addition, manufacturers offer research grants to health care providers. Physicians who receive grant funding from pharmaceutical manufacturers may feel some obligation to promote or prescribe their brand.[167]

Due to potential conflicts of interest, some states and the federal government now require drug manufacturers to publicly report most gifts or payments to providers. However, research suggests that the disclosure laws have not been fully effective in making physician-industry interactions transparent, particularly to consumers. In 2013, the federal government implemented the Physician Payments Sunshine Act of the Affordable Care Act. The law mandates that manufacturers must annually provide detailed information about payments to providers. Payments covered by the act include charitable contributions, education, entertainment, food and beverage costs, gifts, honoraria, royalties, and travel and lodging, among other items. The Centers for Medicare and Medicaid Services posts this

[166] (Sen. Grassley & Sen. Wyden, 2021)
[167] (Chao & Larkin, 2020; Rodwin, 2019)

information on their Open Payments website.[168] This has helped to make provider payments more transparent, yet research indicates that less than five percent of patients know about the website or have used it.[169]

[168] (Richardson, 2014)
[169] (Duff-Brown, 2019)

STATE ACTIONS TO IMPROVE PRICE TRANSPARENCY

Manufacturers

Over the past few years, states have implemented various strategies to improve transparency of drug prices and to hold manufacturers accountable for price increases. Vermont was the first state to pass drug transparency legislation in June 2016. It did so with the purpose of understanding drug cost drivers statewide. The main objective was to provide the state and key stakeholders with more information to effectively respond to rising prices and possibly even decrease drug costs through increased scrutiny. A number of states followed suit, with California passing comprehensive drug transparency legislation in 2017. California SB-17 requires both pharmaceutical manufacturers and insurers to disclose price information to the state. Since then, at least 13 states (CA, CT, ME, MN, NV, ND, OR, TX, UT, VT, VA, WA & WV) have implemented laws requiring pharmaceutical manufacturers to report data on the following:[170]

- Price increases over a certain amount or threshold,
- Wholesale acquisition cost of new drugs entering the market,
- Biosimilar products with launch wholesale acquisition cost that is not at least 15 percent less than the reference drug,
- Explanations for prices and price increases, which might include:
    - Cost of research and development,
    - Clinical trial costs paid by the manufacturer,
    - Marketing and advertising costs,
    - Total production costs, and
    - Total sales revenue.
- International Reference rate cost of the medication or lowest list price.[171]
- Advanced notification of anticipated price increases.
- Rebates and other financial incentives provided to pharmacy benefit managers, providers, insurers or consumers.

[170] (NASHP, 2023)
[171] (International Referenced Rate Pricing for Prescription Drugs, 2022; Vargas et al., 2022)

- Financial assistance to consumers.
- Drugs that lost patent exclusivity and the name of generic equivalents.
- Manufacturer contracts with pharmacy benefit managers for exclusion provision of a drug.
- The names of sales representatives.

Each state has established different price increase measures that trigger reporting. California requires manufacturers to report information on all drugs with wholesale acquisition costs greater than $40 a month and/or with specific cumulative price increases over a two-year period. Other states require manufacturers to annually submit information about the top 10, 15 or 25 most frequently prescribed medications, the costliest drugs by total annual spending, and those with the highest year-over-year increase in price or total spending.

Other specific reporting requirements also vary by state. For example, Nevada's first drug transparency law was designed to gather data solely on the price of diabetes medications. Since then, Nevada has expanded the drug transparency laws to cover other pharmaceuticals. States, such as California and Oregon, have passed legislation requiring manufacturers to give 60-day advance notice of anticipated drug price increases over a specified amount.[172] California limits data requests on cost factors to information that is already publicly available while other states ensure confidentiality of trade secret information submitted by manufacturers. In addition, most, but not all, states introduced penalties and fees for non-compliance with the law.

As part of the move to increase transparency, a small number of states now require licensure and registration of Pharmaceutical Sales Representatives.[173] Other states have placed limits or banned gifts from manufacturers to providers to curtail any potential conflicts of interest.[174] The costs to implement laws increasing manufacturer transparency include infrastructure, administrative, and enforcement expenses. States, such as California, have offset costs through civil penalties on manufacturers for non-compliance and other annual fees.[175] A recent environmental scan did not find any federal grants to support increased transparency of drug pricing at the state level.

[172] (NASHP, 2023)
[173] (Relating to Licensing Pharmaceutical Representatives, 2021)
[174] (King & Bearman, 2017)
[175] (Health Care: Prescription Drug Costs., 2017)

Anti-regulatory Litigation:

Pharmaceutical manufacturers have generally opposed state laws to increase drug price transparency on the basis of arguments related to trade secrets and purported violations of the interstate commerce clause of the U.S. Constitution. The Pharmaceutical Researchers and Manufacturers of America (PhRMA) filed a civil lawsuit against Nevada over SB 539, arguing that the new law violated federal and state trade secrecy laws. In response, Nevada amended its trade secrecy laws and allowed manufacturers to request that the state keep data, which meets federal standards of a trade secret, confidential.[176]

In 2017, PhRMA filed suit in the District Court for the Eastern District of California against California's SB-17 law claiming that it violates interstate commerce law, which is the purview of the federal government. PhRMA contended that requiring the 60-day advance notice of price increases would limit or delay their ability to increase prices in other states. PhRMA also argued that the California law violated their First Amendment rights because manufacturers are the only entity in the pharmaceutical supply chain that are required to give advance notice of price increases and the law limits the factors associated with price increases. The case was dismissed. PhRMA appealed to the Ninth Circuit Court of Appeals, which remanded the case without modification due to insufficient evidence.[177] PhRMA has agreed to discontinue the lawsuit with prejudice.

Unintended consequences:

Manufacturers and others claim there are other potential unintended consequences of the state reporting requirements. An analysis of California's SB-17 law highlighted three potential unintended consequences of the new regulations, including the following:

- Manufacturers can spread price increases and adjust rebates to maintain profits.
- Advance notice allows competing manufacturers to increase their price as well.
- Forewarning of price increases encourages pharmacies to stockpile drugs, purchasing at lower prices to sell later at higher prices, possibly creating artificial shortages.[178]

A literature and environmental scan found no direct evidence that these potential unintended

[176] (Gudiksen et al., 2018)
[177] (*Pharmaceutical Research and Manufacturers of America v. Elizabeth Landsberg*, 2022)
[178] (Gudiksen et al., 2018)

consequences occurred after the legislation passed. Manufacturer rebates, however, did increase significantly in at least one state from 2019 to 2021.[179]

Impacts:

Evaluation of state drug transparency laws is limited, with mixed results. Preliminary data suggests that the new laws are having some impact, with states experiencing a decrease in the number of price increases that trigger reporting and a decline in total wholesale acquisition cost increases observed.[180] However, the launch wholesale acquisition cost of new drugs entering the market continues to escalate. The median price increases varied across state reports with generic drugs generally reporting higher percentage increases than brand name drugs.

The impact of the new laws on insulin prices is unclear. The recent insulin price reductions announced by manufacturers are thought to be tied to Congressional pressure and new Medicaid regulations rather than state data reporting requirements.[181]

More pharmaceutical companies are gradually complying with the reporting requirements, yet many fail to provide justification for the price increases or report reference prices paid in other countries as required in some states.[182] For example, between 40-60% of 2021 reports from manufacturers in California did not include any reason for wholesale acquisition cost price increases because the information wasn't already publicly available.[183] The State of Oregon reported that manufacturers even claimed trade secrets on new drugs financed with some public funding.[184] The lack of transparency on the factors associated with price increases remains a barrier to fully understanding the rising cost of pharmaceuticals.

Since the reporting requirements are new and vary across the country, state comparisons are challenging. There is insufficient data available to determine the impact of drug price increases on health insurance premiums in all states with existing transparency laws.[185] Some states, however, have reported that the increased cost of prescription drugs paid by insurers had a significant impact on

[179] (California Department of Managed Health Care, 2021)
[180] (Butler, 2022; Vargas et al., 2022; Vermont Attorney General's Office, 2022)
[181] (Gonzalez, 2023)
[182] (International Referenced Rate Pricing for Prescription Drugs, 2022; Vargas et al., 2022)
[183] (California Department of Health Care Access and Information, 2023)
[184] (Vargas et al., 2022)
[185] (Washington State Health Care Authority, 2022)

premiums. For example, insurers in California paid over $1 billion more for prescription drugs in 2021 than in 2019. Some of that cost was passed on to beneficiaries in higher premiums.[186]

Data uses:

States have used manufacturer data to increase awareness of drug prices and to help contain costs. Different approaches to raise public awareness of drug price increases are noted in the legislation. States, such as California, have made the information publicly available.[187] California regularly posts detailed information about wholesale acquisition cost price increases on their public website. Other states have aggregated the data into annual reports available on their websites.[188] Most, if not all, of these states prohibit disclosing data that could be considered trade secrets under Federal law.[189] Another strategy to raise awareness of drug price increases is to hold an annual public forum to discuss the data with stakeholders. In addition to posting aggregate data publicly, Oregon's drug transparency program conducts an annual public forum to analyze the data and develop policy recommendations.[190]

Some of the states' actions to address transparency issues also incorporate price control incentives or measures. To contain costs, states have used manufacturer data to identify and negotiate supplemental rebates for drugs with total costs exceeding certain thresholds. Manufacturer data on wholesale acquisition cost prices can also be used to set an upper price limit, to compare costs to an international reference price, or to remove the drug from a formulary.[191] These measures generally help states save money but may not impact the cost for the consumer.

Workgroup Discussion:

Workgroup members discussed potential legislation to require price transparency from pharmaceutical manufacturers in New York State without reaching consensus. Some members representing pharmaceutical companies, opposed this type of legislation, while most other members

[186] (California Department of Managed Health Care, 2021)
[187] (Health Care: Prescription Drug Costs., 2017)
[188] (Washington State Health Care Authority, 2022)
[189] (NASHP, 2023)
[190] (Butler, 2022)
[191] (Vargas et al., 2022)

supported this strategy.

Members representing manufacturers stated opposition for the following reasons:

- Manufacturers already report wholesale acquisition cost launch prices and price increases to other states, information which is publicly available.[192] More reporting would be duplicative.
- Manufacturers contend that legislative efforts in other states have not helped contain prices or lower the cost of insulin at the pharmacy.
- Since manufacturers recently lowered the price of insulin, they believe that a new law would likely not trigger reporting of insulin products to the state.

Other members representing advocacy groups, recommended that the state move forward with requiring pricing data from insulin manufacturers for the following reasons:

- Manufacturers voluntarily lowered prices for insulin and advocates of this strategy believe that new legislation would hold drug companies accountable for future rising costs.
- Members, representing patients and advocates, expressed support for the American Diabetes Association recommendations, which call for increased price transparency throughout the full insulin supply chain.[193]
- Some members asserted that advance notice of manufacturer wholesale acquisition cost price increases will allow consumers and employers to prepare for price increases.
- Members suggested that manufacturer data could provide insight into the reasons for rising prices, allowing the state to design targeted approaches to control costs.

Other states' actions to hold manufacturers accountable for drug price increases:

In addition to establishing reporting requirements for manufacturers, states have adopted other strategies to hold manufacturers accountable for drug price increases. Two main strategies discussed in the literature include anti-price gouging laws and Prescription Drug Affordability Boards.

[192] While there may be an opportunity to rely on manufacturer data reported to other states, such as California, the most costly or most prescribed medications may not be the same in each state, which could result in information gaps.
[193] (Cefalu et al., 2018)

Anti-price gouging laws:

The state of Maryland attempted to address the rapidly rising price of pharmaceuticals by implementing the first U.S. price-gouging prohibition law in 2017. The law was specifically crafted to address the increasing prices of generic or off-patent drugs with three or less manufacturers. The law permitted the Maryland Medicaid program to notify the Attorney General of any manufacturer wholesale acquisition cost increase of 50 percent or more in a year for generic or off-patent drugs. From there, the Attorney General could request detailed information from manufacturers justifying the price increase. The law enabled the Attorney General to pursue legal action, with court imposed civil penalties of up to $10,000 for each violation. Under the law, the circuit court could require manufacturers to provide the drug to Maryland state programs at the price prior to the increase.[194] Although the law went into effect on October 1, 2017, it faced significant court challenges and lacked the support of the governor.

The Association for Accessible Medicines sued the state arguing that the law would reduce competition and impact interstate commerce. The lower court allowed the law to be implemented. However, the law was subsequently struck down on appeal. The U.S. Court of Appeals for the 4th Circuit declared the Maryland law unconstitutional, mainly because it would violate the Commerce Clause by regulating drug prices outside of the state.[195] The Maryland Attorney General's office applied for certiorari to the U.S. Supreme Court, which refused to hear the case.[196]

In light of the litigation surrounding the anti-gouging legislation, the National Academy of State Health Policy has developed model legislation to address the legal challenges in the Maryland law. Instead of focusing on wholesale acquisition cost price from manufacturers, the model legislation institutes additional requirements on wholesalers and in-state transactions.[197]

However, most of this model policy would not address the issues of insulin affordability in New York State. The model was designed to control prices of generic and off-patent drugs, and not biosimilars. In addition, it only applies to drugs purchased by state employee health plans, which are not a priority focus area for the Workgroup.

[194] (Greene & Padula, 2017)
[195] (Raymond, Nate, 2018)
[196] (Chung, 2019)
[197] (Staff NASHP, 2020)

State Drug Affordability Boards

A number of states have established Prescription Drug Affordability Boards to act as a watchdog over rising drug prices. In 2019, Maryland became the first state to legislate a Prescription Drug Affordability Board. In general, these state boards have the ability to review drug prices and investigate factors that contribute to rising costs.[198] States use this information to set upper payment limits and/or to harness purchasing power to limit price increases. Legislative action could be taken to place fines on pharmaceutical manufacturers whose drug price increases are unsupported by clinical evidence.

New York State Drug Accountability Board

New York State passed legislation in 2020, authorizing the Department of Financial Services (DFS) to investigate any skyrocketing drug prices and require manufacturers provide justification for the rising costs. The legislation gives the superintendent the ability to investigate prescription drug price increases over 50 percent in a calendar year. The Office of Pharmacy Benefits (OPB), which later merged into the Pharmacy Benefits Bureau, was created to conduct the investigations. The law also created a Drug Accountability Board comprised of a panel of experts to help with the investigations.[199]

Workgroup Discussion:

Workgroup members discussed the role of DFS and the New York State Drug Accountability Board in investigating price hikes in critical prescription drugs, such as insulin. Some members wondered whether the existing policies were sufficient to trigger an investigation of insulin prices and whether trigger points need to be re-evaluated. Other members noted that the 2020 legislation did not address prior notification for impending drug price increases. Most non-pharmaceutical company Workgroup members supported legislation to provide consumers and employers advance notice of price increases. Some Workgroup members also suggested that the New York State Drug Accountability Board give some consideration to the issue around comparative effectiveness and whether drugs are priced disproportionately to their therapeutic value as part of their investigations.

Update: On December 22, 2023, NYS Senate Bill S599A was signed into law, requiring manufacturers to

[198] (Staff NASHP, 2021)
[199] (NYS DFS, 2023c)

provide advance notice of certain drug price increases.

State actions to control price increases in the rest of the pharmaceutical supply chain:

The mandate of the Workgroup is to investigate state actions to hold manufacturers accountable for price increases and transparency in drug pricing. Yet, the pharmaceutical supply chain is complex and opaque, with barriers to price transparency at every link in the chain. States across the country have implemented various laws and strategies to improve transparency and limit price increases throughout the insulin supply chain.

The costs to implement these laws include infrastructure, administrative, and enforcement expenses. New York has already developed a plan to collect application fees from pharmacy benefit managers to limit the cost of its new registration, licensing, and reporting program. A similar format could be used to off-set costs for developing similar programs for wholesalers and insurers. A recent scan of government grants revealed there is no federal funding available to increase transparency of the different links in the pharmaceutical supply chain. The federal government has recently enacted its own regulations to increase transparency of pharmaceutical drug costs, which may impact the availability of information pertinent to the state's efforts in the future.

The following strategies for each link in the supply chain were considered by the Workgroup.

Wholesalers:

Although three wholesalers control 95 percent of the market, only a few states (Maine, Nevada and Virginia) have passed drug price transparency legislation directed at pharmaceutical wholesalers and distributors. So far, only Nevada requires wholesalers to report annually. The statutes in Maine and Virginia allow the states to request the data from manufacturers, but do not impose annual reporting requirements. All three states inflict civil penalties for non-compliance of data requests.[200] Data requested from wholesalers includes the following:

- Wholesale acquisition cost price,
- Volume of units of each drug shipped into the state,

[200] (NASHP, 2023)

- Aggregate amount of rebates negotiated with manufacturers, pharmacies, and pharmacy benefit managers, and
- Aggregate total discounts, dispensing fees, and other fees negotiated with pharmacies.

Impact and New York State legislation:

A recent scan of the literature and state websites found no publicly available information on the impacts of this new legislation directed at improving drug price transparency in the wholesaler/distributor link of the supply chain.

Most states, including New York, have focused more on harnessing the purchasing power of state agencies and plans to negotiate better prices with wholesalers than on data reporting requirements.

Workgroup discussion:

In general, workgroup members support increasing price transparency throughout the full insulin supply chain, including wholesalers, and consider it necessary to support policymaking. Other members maintained that legislation to increase transparency does nothing to lower the cost of insulin at the pharmacy. There were no members representing wholesalers on the Workgroup.

Pharmacy Benefit Managers ("PBMs"):

Many states have taken action to improve pharmacy benefit manager drug price transparency in recent years, implementing laws that require the reporting of various pieces of information to help identify sources of price increases. States have requested pharmacy benefit managers submit the following data annually:

- Rebates received by pharmacy benefit managers, including information on:
    - Aggregate rebates received,
    - The highest, lowest, and mean aggregate retained rebate percentage,
    - Total value of rebates received, and
    - Rebates received and not passed through to the health plan.
- Administrative fees collected.

- De-identified claims level data on drugs.
- Disclosure of any ownership interest the pharmacy benefit manager has in a pharmacy or health plan with which it conducts business.

In addition to the data reports, many states are requiring pharmacy benefit managers to register and be licensed in their jurisdictions. Several states have also passed legislation that prohibits pharmacy benefit managers from implementing non-disclosure agreements with pharmacies and insurers so that they can better inform consumers about drug prices, cost-effective alternatives, and out-of-pocket costs.[201]

Similar to manufacturer drug price transparency laws, the type and form of data requested from pharmacy benefit managers varies from state to state. Currently, fourteen states require pharmacy benefit managers to report rebate information. Most states solicit aggregate information, such as the aggregate amount of rebates received and passed on or retained by the pharmacy benefit manager. Other jurisdictions, like Nevada, obligate pharmacy benefit managers to provide more detailed information, such as the total number of units of each drug that the pharmacy benefit manager has negotiated with the manufacturer for use in the state during the previous year. Likewise, the civil penalties for pharmacy benefit manager reporting non-compliance differ by state, with Minnesota and Washington having the lowest fines, set at $1,000 per day and Maine having the highest ones, set at $30,000 per violation.[202]

Many states have taken additional steps to better understand pharmacy benefit managers' drug pricing practices. For example, California requires pharmacy benefit managers to provide an explanation for the escalation of drug prices. Vermont obligates pharmacy benefit managers to disclose every factor that precipitated the price increase and the percentage of the total cost increase attributed to each factor as well as an explanation of why each factor necessitates a cost increase. Washington requires a statement regarding whether the change or improvement in the drug necessitates the price increase.[203]

In addition to increasing transparency, states are starting to legislate pharmacy benefit manager drug pricing practices. States, such as Colorado, Delaware, Georgia, Kentucky and Michigan,

[201] (NASHP, 2023)
[202] Ibid
[203] (NASHP, 2023)

passed legislation to prohibit pharmacy benefit managers from utilizing spread pricing models for state-regulated or Medicaid plans. Arkansas, West Virginia, and Indiana enacted laws requiring pharmacy benefit managers to pass along rebates to patients and insurers. States, such as Texas and South Carolina, passed legislation forbidding pharmacy benefit managers from steering beneficiaries to pharmacy benefit manager-owned or affiliated pharmacies.[204]

Newer proposed state legislation directed at pharmacy benefit manager pricing strategies includes bills in Louisiana and Maryland. The Maryland bill would prohibit pharmacy benefit managers from charging beneficiaries higher co-pays based on whether they patronize an independent or a pharmacy benefit manager-affiliated pharmacy.[205] Other proposed state legislation prohibits pharmacy benefit managers from reimbursing pharmacies less than the 'acquisition cost of a covered drug' plus a dispensing fee.[206]

Lawsuits:

The Pharmaceutical Care Management Association (PCMA), which represents the eleven largest pharmacy benefit managers in the United States, brought a suit in the Eastern District of Arkansas against the Arkansas Attorney General and Act 900, which regulates pharmacy benefit managers' reimbursement rates to pharmacies for covered medications. Act 900 requires pharmacy benefit managers to reimburse pharmacies at a price equal or higher than the pharmacy's wholesale cost and it also permits pharmacies to refuse to sell a drug if the reimbursement rate is lower than its acquisition cost. The new legislation meant that pharmacy benefit managers had to update their Maximum Allowable Cost (MAC) listings when wholesale prices increased and provide pharmacies with an administrative appeal process to challenge MAC reimbursement rates.

In the lawsuit, the Pharmaceutical Care Management Association argued that Act 900 is preempted by ERISA, claiming that pharmacy benefit managers act as ERISA fiduciaries and, therefore, the Act interferes with ERISA plan administration. The Eastern District agreed with the Pharmaceutical Care Management Association based on a similar case in Iowa. In that case, the Court of Appeals for the Eighth Circuit concluded that the Iowa statute had an "impermissible connection" with an ERISA

[204] (NASHP, 2023; Staff, NCSL, 2022)
[205] (Pharmacy Benefits Managers - Prohibited Actions, 2023)
[206] (Reimbursement Rates of Pharmacy Benefit Managers, 2023)

plan.[207] The Arkansas Attorney General filed a petition with the U.S. Supreme Court to review the case. The court ruled that Act 900's appeal procedure does not govern central matters of plan administration just because it requires administrative participation in a particular process. The court determined Act 900 is not preempted by ERISA because it does not require relationships that would interfere with benefits administration. The statute would be impermissible if it exclusively acted upon ERISA plans; Act 900 regulates pharmacy benefit managers regardless of 'whether or not the plans they service fall within ERISA'.[208] In 2021, the U.S. Court of Appeals for the Eighth Circuit issued a similar ruling in a North Dakota case, *PCMA v. Wehbi*.[209]

These court rulings indicate that a state has some ability to regulate pharmacy benefit manager practices that impact both marketplace and self-funded health plans (ERISA). However, regulations that pertain to ERISA plans must be of a non-central matter of plan administration.

Impacts:

As most of these laws and decisions have been recent, there is minimal impact data available, and the states' reports are not specific for pharmacy benefit manager practices regarding insulin pricing and costs. Some states have reported that pharmacy benefit managers have decreased spread pricing but have retained more income from rebates. For example, Washington State reported a significant decrease (65%) in the dollar amount retained by pharmacy benefit managers from spread pricing between 2019 and 2020, but a quadrupling of the dollar amount of rebates received from manufacturers from 2018 to 2020. Pharmacy benefit managers attributed the increase in rebates received to a larger number of claims processed.[210] On the other hand, data in Maine indicates that pharmacy benefit managers have retained more from payers from spread pricing and administrative fees and also received a greater percentage of the average wholesale acquisition cost amount in rebates from manufacturers between 2019 and 2021 (14% to 26.6%). The beneficiary share of costs remained the same in Maine and increased in Washington, indicating that the pharmacy benefit manager laws have not had a significant impact on consumer costs yet.[211]

[207] (*Rutledge, Attorney General of Arkansas v. Pharmaceutical Care Management Association*, 2018)
[208] (*Rutledge, Attorney General of Arkansas v. PCMA*, 2020)
[209] (*Pharmaceutical Care Management Association v. Nizar Wehbi,* 2021)
[210] (Washington State Health Care Authority, 2022)
[211] (MHDO, 2023; Washington State Health Care Authority, 2022)

More data is needed to assess the longer-term impact of legislation to limit spread pricing and rebate practices of pharmacy benefit managers.

New York State Pharmacy Benefit Manager Legislation:

The New York State Senate Investigation on pharmacy benefit managers in New York State spurred legislation to improve drug price transparency and control unjustified price increases. In 2022, Governor Hochul signed into law, S.3762/A.1396 which requires every operating pharmacy benefit manager to register with the DFS. Pharmacy benefit managers must supply information to DFS on their application about the total number of beneficiaries served by the pharmacy benefit managers nationwide and in New York State; a list of health plans with contracts or agreements with the pharmacy benefit manager; and other items of concern, such as whether they have been subject to bankruptcy proceedings or were found liable in a fraud lawsuit. Licensure requirements are set to begin in January 2024.[212] Once registered and licensed in the state, pharmacy benefit managers must annually report detailed information on various data points, including pricing and fees.

In New York State, in accordance with prescription drug laws, there are limitations on pharmacy benefit manager control. Pharmacy benefit managers cannot prohibit or penalize pharmacies or pharmacists for disclosing the cost of prescription medicine to consumers or disclosing the availability of equivalent alternatives or alternative payment methods.[213]

Workgroup Discussion:

Workgroup discussion of state pharmacy benefit manager policies and legislation revolved primarily around the types of information that the state should require pharmacy benefit managers to report. New York State has already started the process to further regulate pharmacy benefit managers to improve transparency and control costs, and most Workgroup members supports these measures.

Most members voiced the opinion that the annual data collected from pharmacy benefit managers will help inform future policy recommendations.

[212] (NYS DFS, 2023d)
[213] (Licensure for Pharmacy Benefit Managers, 2021)

In a post-meeting survey, some Workgroup members recommended collecting additional information from pharmacy benefit managers on the following:

- All price strategies, including price spreading and broker commissions.
- The number of rebates retained by the pharmacy benefit manager and where the rebates are going.
- The number of generic/biosimilar diabetes drugs that are not covered or not placed on a lower formulary tier.
- Any reimbursement to pharmacies that is less than what the pharmacy benefit managers is getting paid by the insurance company or state.

Some Workgroup members representing advocacy groups, also raised the question of whether it is possible to eliminate the use of pharmacy benefit managers.

Pharmacies:

State actions to increase transparency in the pharmaceutical supply chain directed at pharmacies have mostly been instituted to protect independent, community and rural pharmacies and consumers from unfair pharmacy benefit manager pricing strategies, and are addressed under the Pharmacy Benefit Manager section. One area still considered an issue, at least by the Pharmacist Society of the State of New York, Inc. (PSSNY), is the vertical integration of pharmacy benefit managers, pharmacies, and insurers. PSSNY considers pharmacy benefit manager ownership in pharmacies a direct conflict of interest. To date, there are no laws prohibiting this type of vertical ownership in the pharmaceutical realm.[214]

Workgroup discussion:

The Workgroup discussed the option of requiring pharmacists to report additional price data to the state. In a post-meeting survey, half of Workgroup members supported policies or regulations that required pharmacies to report price data to the state. No members stated opposition to this type of regulation.

[214] (Bertram, 2023)

During Workgroup discussions, members representing pharmacies voiced concern over two other issues not directly related to the task of the Workgroup. Specifically, 1. pharmacy benefit manager and insurer reimbursement practices, which were detailed previously under the pharmacy benefit manager and insurer sections of this report; and 2. the uncompensated time and effort required to assist patients with prescription drug switches, especially if insurers do not include guidance on substitutes, or if it the insurer recommends a substitute that requires the pharmacist to contact the prescriber for guidance.

Insurers:

Over the past five years, States have passed legislation directed at increasing transparency of drug pricing from insurers. The majority of states that adopted these laws are requesting the following drug price information from insurers:

- 25 most frequently prescribed drugs,
- 25 most costly drugs by total annual spending, and
- 25 drugs with the highest year over year cost increases.

States are also trying to better understand how drug prices impact premiums. To get at this question, some states are requiring insurers to report the percent increase in annual net spending for prescription drugs or the portion or percent increase in premiums that are attributable to drug costs. Washington requires insurers to report the rebates received for the 25 most frequently prescribed drugs and Vermont asks for information on pharmacy benefit manager use by insurers.[215]

In 2021, Congress passed the Consolidated Appropriation Act, which obligates insurers and employer-based health plans to submit data on prescription drugs and health care expenses to the U.S. Departments of Health & Human Services, Labor, and the Treasury. In addition to drug price data, payers must submit premium and cost-sharing information. The information is intended to be used to increase transparency, identify factors associated with price hikes, and understand the impact of drug rebates on premiums.[216]

In addition to laws improving drug price transparency, states have passed legislation to ensure that consumers do not bear the brunt of rising drug prices. One strategy floated is to require that

[215] (NASHP, 2023)
[216] (Centers for Medicare & Medicaid Services, 2021a)

insurers pass on all manufacturer rebates to beneficiaries. In 2021, West Virginia became the first state to require pharmacy benefit managers and insurers to pass on rebates to insureds.[217] Colorado passed similar legislation in 2022 directing insurers of individual health benefit plans to pass on all rebates to reduce beneficiaries' out-of-pocket costs and premiums.[218] In 2023, Maine and several other states also introduced legislation that would require insurers to pass on rebates directly to the beneficiary at the pharmacy counter.[219]

Impacts:

Again, the laws are new and the requirements vary by state, limiting both assessment of the impacts and state comparisons. A preliminary review of state reports suggests a few trends in the data. In general, states reported that prices of generic drugs rose at a higher rate than brand name medications. Insurers in these states attributed 20 to 30 percent of premium costs to payments for pharmaceuticals. Specialty drugs were a major driver of increased drug spending by insurers.[220]

Most of the state reports concluded that they had insufficient data to identify correlations between pharmaceutical drug rebates and insurer spending or drug prices and premium costs. In an effort to better understand the relationship between prescription drug prices, insurance premiums, and consumer costs, a number of states have amended their laws and regulations to collect more detailed information from insurers.

New York State Regulations:

In an effort to increase transparency, the New York State Legislature passed bills A02200 and SO 4620, which requires that insurers provide cost data to beneficiaries, their health care provider or a third party.[221] Health Plans already submit data to the Department of Financial Services, as part of the rate plan approval process. Information about premium costs and the estimated aggregate amount of prescription drug rebates is a part of those submissions.

[217] (Update the Regulation of Pharmacy Benefit Managers, 2021)
[218] (Coverage Requirements for Health-Care Products, 2022)
[219] (An Act to Enhance Cost Savings to Consumers of Prescription Drugs, 2023)
[220] (Hawley & Wiseman, 2022; Tran, 2022; Vargas et al., 2022; Washington State Health Care Authority, 2023)
[221] (Provides for Patient Prescription Pricing Transparency, 2023)

Workgroup discussion:

Workgroup members discussed state regulations to collect more data from insurers to increase transparency around drug prices. Members representing insurers recommended identifying what data is already submitted as part of the rate submission process and then reviewing what additional information would be required to improve transparency. In addition, some Workgroup members suggested that the state consider the new federal data reporting requirements before requesting additional data from payers. In a post-meeting survey, a majority of Workgroup members supported additional legislation to require insurers report additional drug information to the state. No specific opposition to this was noted.

Workgroup members also discussed the issue of potentially requiring insurers to pass on rebates to consumers. Some members representing insurers noted that this has been successfully implemented by their companies, with no increase in premiums or overall plan costs. Other members voiced concerns about how the laws requiring insurers to pass on rebates to consumers would work, since a lot of rebates are paid post sale. Members noted that the practical application of the law may be a barrier to implementation and suggested that, in all likelihood, the rebates would benefit all beneficiaries, not just those needing insulin.

Workgroup members raised other cost, access and transparency issues related to insulin and insurers**.** Members representing providers indicated that insurers sometimes change formulary designs which creates stress for the patient and additional uncompensated work for the provider, especially if information about substitute medication is not provided. This practice may cause the patient angst, and disrupting a stable patient is not considered wise medical practice. Members representing health care providers and pharmacists reported that there is frequently no explanation as to why the medication was switched. While New York State recently amended the insurance law to restrict mid-year formulary changes, some members recommended instituting legislation or regulations limiting non-medically switching a stable patient to a different drug at any time and instituting a penalty for non-compliance.

Providers

The majority of states have left legislation to improve transparency in the provider link of the pharmaceutical supply chain up to the federal government. The Physician Payment Sunshine Act provides clear guidelines for transparency of payments from drug manufacturers to providers. The Office of Inspector General of the U.S. Department of Health and Human Services has also developed "A Roadmap for New Physicians" that provides guidance on physician relationships with payers and vendors, such as drug manufacturers.[222] Lack of public awareness of the website is a continued barrier to transparency.

In 2022, California became the first state to pass legislation requiring physicians and surgeons to inform patients of the Open Payments database via electronic and/or written and posted notices.[223]

Impact:

Evaluation data of the impact of the new California law is unavailable as the legislation took effect in January 2023. Research on the impact of disclosure policies on physician prescribing is mixed. Li et al (2022) concluded that the law was effective in reducing prescriptions of brand name statin drugs. A quasi-experimental analysis of physician behavior after the implementation of a 2009 disclosure law in Massachusetts also found that physicians there were less likely to prescribe brand name drugs than physicians in states without public disclosure laws. The authors suggested that the new law prompted providers to self-regulate their behavior.[224]

Little is known about the impact of physician disclosure of potential conflicts of interest on patients' beliefs and behaviors. One study found that after learning of potential conflicts of interests, a patient's perception of trust decreased but not their perception of the physician's competence.[225]

Workgroup discussion:

Workgroup members had limited discussion regarding this strategy to increase transparency in drug prices. Some members voiced support of all efforts to increase transparency throughout the

[222] (Office of Inspector General, 2021)
[223] (Physician Payment Disclosures, 2022)
[224] (Chao & Larkin, 2020)
[225] (Hwong et al., 2017)

pharmaceutical supply chain. However, without more information about the impact of California's new law on physician and/or patient behavior, Workgroup members did not prioritize this strategy for consideration in New York State.

OPTIONS FOR INCREASING AFFORDABILITY AND ACCESS TO INSULIN FOR UNINSURED AND UNDERINSURED INDIVDIUALS

The Workgroup was tasked with investigating options for increasing affordability and access to insulin for both the uninsured and the underinsured. As previously indicated, NYSDOH estimates that 33,000 individuals with diabetes who use insulin in New York State are uninsured. Estimating the number of underinsured individuals with diabetes who use insulin is more challenging. Approximately 96,190 individuals aged 18 to 64 with diabetes who use insulin are covered by private insurance which is not subject to insulin cap laws. Of those, approximately 26,644 reside in households with annual household incomes of less than $50,000.[226] In one retrospective study of Medical Expenditure Panel Survey data, individuals with incomes below $50,000 were at greater risk for catastrophic spending on insulin.[227] Making insulin more affordable for these individuals remains a priority for the Workgroup. The Workgroup investigated a number of options to increase access and affordability for these uninsured and underinsured populations, including the following:

- Insulin and diabetic supplies cap legislation and policies,
- Legislation and policies to exempt insulin from insurance deductibles,
- Emergency safety net programs,
- Patient assistance programs,
- Drug discount and manufacturer discounts,
- Importation of lower cost prescription drugs from Canada, and
- Education to providers/patients on less expensive biosimilar insulin options.

The options explored are not exhaustive or mutually exclusive. Members reached consensus on only one of these strategies, recommending that the state implement legislation similar to Kevin's Law, which is detailed below. For most of the other options discussed, members expressed both strong support and strong dissent. The top four strategies recommended by the majority of Workgroup members as well as the opposition to these options are summarized in the table 7.

[226] (NYS DOH BRFSS, personal communication, Data 2020)
[227] (Bakkila et al., 2022)

Table 7: Options for Increasing Affordability & Access to Insulin				
Strategy	**Patient cost**	**State Cost**	**Pros**	**Cons**
Insulin & Diabetic Supplies Cost Cap or elimination of cost-sharing entirely	Reduces monthly cost of co-pay for all insulin prescriptions for insured individuals.	None	• Standardization with federal rules (Medicare has adopted $35 cap) • Removes or decreases cost barrier at the pharmacy for consumers	• Does not address the root cause of high prices • May shift cost from out-of-pocket to premiums • Does not cover the uninsured or individuals in self-funded ERISA plans, or New Yorkers with out-of-state coverage
Exempt insulin from insurance deductibles	Total monthly cost of insulin would be regulated by the insulin cap	None	• Decreases monthly cost for insured, especially those in HDHPs	• Does not address the root cause of high prices • May shift cost from out-of-pocket to premium. • Does not cover the uninsured or individuals in self-funded ERISA plans, or New Yorkers with out-of-state coverage
Emergency Safety Net Programs	Kevin's law – allows pharmacists to dispense	None	• Allows individuals to gain emergency access to insulin	• None noted
	Alec's Law – provides 30-day emergency supply of insulin	Depends on structure	• Provides life-saving insulin to uninsured individuals who cannot afford it	• Would be duplicative as manufacturers already supply emergency insulin through their PAPs
Patient Assistance Programs ("PAPs")	State-sponsored program would provide insulin and diabetic supplies at no or low-cost to uninsured or underinsured individuals	Estimated costs range from $1.6 to $48 million, depending on eligibility criteria	• Provides life-saving insulin & diabetic supplies to uninsured individuals without means • Strategy doesn't impact insurance premiums or employer costs	• May be duplicative of existing manufacturer patient assistance programs

Insulin and Diabetic Supplies Cap Legislation and Policies

Background:

Big increases in the price of insulin spurred the U.S. Congress and States to adopt policies to rein in costs for consumers. In 2019, Colorado instituted the first law to reduce the out-of-pocket costs of prescription insulin drugs for consumers. Colorado's 2019 "Insulin cap law" limits the out-of-pocket costs individuals pay for a monthly supply of insulin to $100.[228] Since then, 24 other states and the District of Columbia have followed suit, passing similar legislation limiting consumer cost-sharing of prescription insulin to anywhere from $25 to $100 for a 30-day supply of the drug.[229] Currently, Connecticut, Texas, and New Mexico have the lowest cap at $25, and states such as Alabama and New York have the highest cap at $100.[230] Delaware, Connecticut and the District of Columbia have similar "cap" laws for coverage of diabetes supplies, mandating low or no-cost coverage of medically necessary insulin pumps and other supplies to covered individuals in state regulated plans in 2021.[231]

Insulin cap laws primarily apply to fully insured health insurance coverage, including coverage that is available on the state marketplace. Employers that use a self-funding health plan model covered by the federal Employee Retirement Income Security Act of 1974 (ERISA) are exempted from state insulin cap laws. An estimated sixty-five percent of covered workers in the U.S. are enrolled in self-funded plans.[232] In 2020, almost 63 percent of private-sector enrollees were covered by self-funded plans guided by ERISA provisions in New York State without benefit of the new insulin cap laws.[233]

Up until recently, Medicare beneficiaries were also exempt from insulin cap laws. In 2022, the U.S. Congress passed the Inflation Reduction Act, which caps out-of-pocket costs of insulin prescriptions at $35 a month for Medicare Part D enrollees and limits coinsurance for insulin for Medicare Part B beneficiaries.[234] According to estimates, the new law will save Medicare beneficiaries who use insulin millions of dollars, increase medication adherence, and help prevent the negative consequences of rationing.[235] Senators Collins and Shaheen have recently introduced legislation

[228] (Reduce Insulin Prices, 2019)
[229] (American Diabetes Association, 2023a; Ollove, 2023)
[230] (Norris, 2022)
[231] (American Diabetes Association, 2023a; Insurance Coverage of Insulin Pumps, 2021)
[232] (KFF, 2022)
[233] (Percent of Private-Sector Enrollees That Are Enrolled in Self-Insured Plans Table., 2020)
[234] (Cubanski et al., 2023)
[235] (Sayed et al., 2023)

entitled “Improving Needed Safeguards of Users of Lifesaving Insulin Now (INSULIN) Act of 2023”, which would extend the $35 Medicare out-of-pocket cap to individual and group health plans in the commercial sector.[236]

In addition to legislation, health care exchanges in Massachusetts and D.C. have adopted policies to improve health equity by eliminating cost-sharing for certain diabetic medications and/or supplies. These health exchanges are working with insurers to offer no cost-sharing options for individuals with diabetes.[237]

In 2023, insulin manufacturer Eli Lilly announced reductions in the cost of insulin products and out-of-pocket cost caps, a decision that was soon replicated by the two other major manufacturers of insulin in the U.S.[238]

The impact of reducing or eliminating medication cost-sharing:

Research suggests that reducing or eliminating patient costs of pharmaceuticals can help increase medication adherence, improve health outcomes, reduce health disparities and decrease total health care spending.[239] For example, a study in Louisiana demonstrated that a “zero-dollar co-pay” policy instituted by Blue Cross and Blue Shield increased medication adherence while reducing costs, especially among low-income members.[240] In another study, researchers found that providing free medication to post-myocardial infarction patients helped improve medication adherence and decreased the rate of vascular events and health care spending in non-white patients.[241] Research by Express Scripts, a pharmacy benefit manager, found that patients with diabetes on non-insulin treatment enrolled in a Patient Assurance program increased medication adherence and reported fewer outpatient, inpatient and emergency room costs. Based on the positive outcomes of this research, the company instituted a similar insulin cap Patient Assurance program in 2020 for insured individuals with diabetes in participating plans.[242]

Additionally, a systematic review of patient cost-sharing found that higher cost-sharing resulted

[236] (Insulin Act of 2023, 2023)
[237] (Palanker & Gooding, 2022)
[238] (Lovelace Jr., 2023)
[239] (Choudhry et al., 2014; McGilroy, 2022; Mingyan Cong et al., 2021)
[240] (Mingyan Cong et al., 2021)
[241] (Choudhry et al., 2014)
[242] (McGilroy, 2022)

in lower medication adherence and poorer health outcomes.[243] In a retrospective study using data from the Medical Expenditure Panel Survey, researchers found that approximately 14% of insulin users in the U.S. experienced catastrophic spending on insulin, which is "defined as spending more that 40 percent of their subsistence family income on insulin alone". [244] A recent National Center for Health Statistics study found that 8.2 percent of adults aged 18-64 did not take their medication as prescribed due to costs. High out-of-pocket costs, especially for uninsured, underinsured, minority and disabled populations can result in individuals rationing medication such as insulin or choosing between paying for needed medication and other basic needs.[245]

New York State Insulin Cap:

New York State has taken steps to curb the out-of-pocket cost of insulin for individuals with state regulated health coverage, passing legislation in 2020 to address the issue. Current insurance law (Part DDD of Chapter 56 of the Laws of 2020) in New York State caps out-of-pocket insulin costs at $100 per thirty-day supply of insulin regardless of cost-sharing or insulin type prescribed. This does not exempt insulin from cost-sharing, it simply caps the amount an individual can be required to pay out-of-pocket for each prescription.[246]

Similar to other efforts across the country, advocates in New York are pressing the legislature to amend the law and further reduce or eliminate the out-of-pocket costs for total monthly insulin prescriptions.[247] Other advocates are supporting zero-dollar copays for all insulin prescriptions.

Potential costs and fiscal impacts:

While insurers have reported cost savings on zero copay programs, insulin cap laws are fairly new, and evaluation data is limited. One analysis using claims data suggests that at least twenty percent of insulin users will find some financial relief under new insulin cap laws.[248] The Department of Health and Human Services estimated that New York Medicare beneficiaries who use insulin would

[243] (Fusco et al., 2023)
[244] (Bakkila et al., 2022)
[245] (Mykyta & Cohen, 2023)
[246] (NYS DFS, 2023a)
[247] (Insulin Cap Law, 2023)
[248] (Amin et al., 2022)

have saved an annual estimated $483 under the Inflation Reduction Act $35 Insulin Cap in 2020.[249] Other researchers suggest that for the insulin cap to be cost-effective, the price of insulin must also be reduced. Otherwise, insurers may shift the cost and increase premiums, which would impact all beneficiaries.[250],[251]

The fiscal impact to the state due to a new lower insulin cap is unknown. An insulin cap bill currently in the New York State legislature is estimated to have no cost to the state.[252] An independent analysis of a proposed insulin cap law in California estimated that total net expenditures would increase by 0.2 percent due to higher health insurance premiums. These costs are expected to be partially offset by improved health outcomes via better glycemic control. Anticipated cost offsets cited include reduced emergency room visits and a decline in long-term complications due to uncontrolled diabetes.[253] Both the number and the cost of preventable complications, such as kidney disease and amputations, have risen dramatically in the last decade. The U.S. Centers for Disease Control and Prevention estimates that diabetes-related hospitalizations due to amputations doubled from 2009-2019.[254] The cost of these preventable complications is significant to the individuals, the insurer, and the state.[255] Removing cost barriers that help patients improve medication adherence and ultimately glycemic control has the potential to reduce insurer and state costs while improving patient well-being.

Workgroup Discussion:

Workgroup members discussed the option of reducing insulin cost-sharing to $35 a month or lower for all insulin prescriptions and diabetic supplies without reaching consensus. Over half of Workgroup members voiced support for reducing monthly cost-sharing for all insulin prescriptions. One reason espoused by members is that individuals with diabetes who use insulin may need more than 1 type of insulin to achieve optimum glycemic control. There are several types of insulin (rapid, short, intermediate, long, and very long acting) and individuals may regularly need more than one type to control their diabetes. Members noted that some of their patients cannot afford a $15 co-pay let

[249] (Sayed et al., 2023)
[250] (New York Health Plan Association, 2023)
[251] (Shao et al., 2022)
[252] (Insulin Cap Law, 2023)
[253] (California Health Benefits Review Program, 2023)
[254] (Centers for Disease Control and Prevention, 2023)
[255] (McDermott & Jiang, 2020)

alone $100 per insulin prescription. Advocates contend that a reduced insulin cap law would help make insulin more affordable for a larger portion of individuals with diabetes in New York State.

Some Workgroup members representing providers and advocacy groups also suggested that the state consider implementing a zero cost-share/cap on insulin and diabetic supplies, recognizing that people will end up rationing insulin or getting it on the black market if they can't afford to purchase the drug or supplies. Workgroup members stressed that the cost of uncontrolled diabetes for the individual and society is high and that the goal of the Workgroup is to recommend policies to make insulin affordable so that people have access to the resources to help control their diabetes. Members representing advocacy groups stated the opinion that zero cost-sharing together with exempting insulin and diabetic supplies from insurance deductibles (discussed below) would eliminate most cost barriers for individuals covered by these types of policies or laws.

Some members mostly representing health plans indicated opposition to insulin cap laws, stating that in their opinion:

- Insulin caps do not address the factors that contribute to the high cost of insulin.
- The insulin cap does not apply to the uninsured, those covered by self-funded ERISA plans, or New Yorkers with out-of-state coverage.
- Capping or limiting cost-sharing may shift the cost to all insureds and result in higher premiums.
- Higher premiums create a financial burden on all consumers and smaller businesses.[256]
- Payers/insurers may drop lower priced insulin from formularies because they lose out on rebates.
- Manufacturers have voluntarily reduced prices so insulin caps are no longer needed.
- Manufacturers' pharmacy assistance programs are available to help uninsured and uninsured individuals access insulin at an affordable price.
- There are trade-offs to instituting cost caps on medications and supplies for specific illnesses and some workgroup members representing health insurers recommended that actuarial studies be completed to better understand costs.

[256] (New York Health Plan Association, 2023)

Members, advocating for the insulin cap law countered stating that, in their opinion:

- Manufacturer price cuts are voluntary and that laws are required to ensure that insulin remains affordable over the long-term.
- Patients continued to pay high prices for insulin at the pharmacy even after the newly instituted manufacturer price reductions and members hold that laws are needed to ensure compliance.[257]
- The additional bureaucracy of registering for a manufacturer patient assistance program can be a deterrent for patients, especially those who already have health care insurance. Providers and advocates shared their own time-consuming and confusing experiences with patient assistance programs.
- Reducing the out-of-pocket cost at the counter is the easiest solution for patients.
- Out-of-pocket costs caps should be cost-neutral for insurers. Members contend that it is in the plan's best interest to have beneficiaries controlling their diabetes because it will save insurers money.

Legislation and policies to exempt insulin from insurance deductibles

Background:

A recent study found that approximately half of private sector workers in New York State were enrolled in high deductible health plans in 2021.[258] Many individuals and families select high deductible plans because they offer lower monthly premiums. Generally, high deductible health plans' beneficiaries have to pay for the cost of prescription insulin drugs until they meet the minimum yearly deductible amount, which is often unaffordable. Even after meeting the deductible, there may still be cost sharing in the form of copayments and co-insurance.

The Affordable Care Act requires insurers to cover certain preventive services, including some medications, without any patient cost-sharing. Insulin, which is essential to preventing diabetes complications, is not part of the Affordable Care Act requirements of preventive care. In an attempt to administratively alleviate this issue, the Internal Revenue Service expanded the list of pre-deductible

[257] (Sen. Warren et al., 2023)
[258] (DeMarco, 2023)

preventive care benefits high deductible health plans can offer to include insulin.[259]

States have followed suit, implementing legislation to make insulin more affordable by exempting it from insurance deductibles. Rhode Island was one of the first states to institute this type of legislation.[260] In California, legislation has been introduced in the State Senate that would ban insurers from collecting a deductible for prescription insulin drugs.[261] The "Improving Needed Safeguards of Users of Lifesaving Insulin Now (INSULIN) Act of 2023" introduced in the U.S. Senate in 2023 would also exempt insulin from insurance deductibles.

Similar to insulin caps, healthcare exchanges have adopted options or created policies that exempt insulin from insurance deductibles.

Patient costs and financial impact:

Exempting insulin from insurance deductibles may help reduce out-of-pocket costs at the pharmacy counter for insured New Yorkers with diabetes who use insulin. This is particularly true for individuals covered in high deductible or catastrophic health plans. The financial impact to the state is unknown.

Workgroup discussion:

Approximately half of Workgroup members agreed that this was a strategy worth pursuing in New York State either as law or as a NYSOH policy. Other Workgroup members mostly representing insurers noted that this strategy poses some of the same challenges as an insulin cap law. It doesn't directly address the price of insulin and may shift costs for the consumer from the pharmacy counter to the premium.

[259] (Preventable Care under HDHP, 2019)
[260] (State of Rhode Island, 2021)
[261] (Sen. Wiener, 2022)

Emergency Safety Net Programs

Background:

Many states have adopted emergency insulin safety net laws in response to the rising number of preventable deaths related to rationing insulin. One example of this is Kevin's Law, named for Kevin Houdeshell who died at age 36 in Ohio after rationing his insulin because his prescription had expired and he was unable to contact his doctor to renew it. Kevin's Law was signed into law in Ohio in 2015, which expanded emergency dispensing authorization in Ohio up to a 30-day supply for all non-controlled medications. Kevin's Law allows dispensing of chronic maintenance drugs by pharmacists to patients without a prescription if the situation meets the following three criteria: the pharmacist cannot obtain authorization to refill the prescription from the health care provider, the amount dispensed does not exceed the standard quantity, and the pharmacist either has a record of a prescription in that name or has reason to believe refusing the drug to the patient would endanger the patients' health.[262] Kevin's Law does, however, assume payment will come either from patients' insurance or out-of-pocket from patients themselves. Kevin's Law is currently signed into law in eighteen states across the U.S. New York has not passed Kevin's Law legislation.

Another example is Alec's Law, which originated in Minnesota after the death of Alec Smith at age 26, who was rationing insulin after he aged out of his parents' health insurance. The Minnesota Emergency Insulin Safety Net program is two-pronged, providing a 30-day supply of insulin for urgent needs and a pathway to access insulin for a full year for underinsured or uninsured individuals whose income does not exceed 400 percent of the federal poverty level. The Minnesota program connects patients with continuing need with a navigator to help with the application process. Once accepted into the continuing need program, patients can receive a 90-day supply of insulin at a maximum cost of $50, renewable for a year.[263] In 2021, over 1,100 individuals accessed the program, with manufacturers supplying over $6 million worth of insulin to participants.[264]

[262] (TI International, 2023)
[263] (Minnesota Board of Pharmacy, 2023)
[264] (Associated Press, 2022)

Funding Mechanisms:

States have developed a number of creative strategies to fund Emergency Insulin Safety Net programs. Under Alec's law, pharmacists can seek reimbursement or replacement of the dispensed emergency insulin from manufacturers. The Minnesota Health Care Access Fund provides financing to create the program, raise public awareness, provide navigator training, and administer the program.[265] Manufacturers are required by the law to reimburse or replace the insulin dispensed by pharmacists through the Emergency Insulin Safety Net Program. Some states, such as Maine and Colorado, are using the framework of Alec's Law to create similar Emergency Insulin Safety Net programs.[266] At the Federal level, Senator Smith of Minnesota introduced a similar bill, the *Emergency Access to Insulin Act*, to the 118th Congress.[267] Other states are exploring other funding strategies, such as public/private partnerships, state sponsored, or trust funded programs.[268]

Legal challenges to the law:

Alec's Law has been controversial due to its funding strategy. Pharmaceutical Research and Manufacturers of America (PhRMA) filed a lawsuit against the members of the Minnesota Board of Pharmacy, arguing that companies cannot be compelled to give away their private property without compensation. Minnesota Assistant Attorney General Sarah Krans countered that the law's requirements were "not a taking" (in reference to the 5th Amendment to the U.S. Constitution) but rather "requires manufacturers to reduce the nuisance that they caused" by instituting high prices on insulin. The lawsuit was dismissed in March of 2021 by a U.S. District Judge who ruled that PhRMA lacked standing to bring a takings claim. PhRMA then appealed to the U.S. Court of Appeals for the Eighth Circuit,[269] and in April 2023, the Eighth Circuit reversed the district courts' decision. The Eighth Circuit held that PhRMA does have standing to bring their claim and remanded the case. The program has continued to operate regardless of the lawsuit.[270]

[265] (Winter, 2020)
[266] (Colorado Department of Regulatory Agencies, 2022; Insulin Safety Net Program, 2021)
[267] (Emergency Access to Insulin Act of 2023, 2023)
[268] (Establishes Insulin Assistance Program, 2022)
[269] (J. Harris, 2021)
[270] (*Pharmaceutical Research and Manufacturers of America v. Stuart T. Williams;* 2023)

Potential Costs and Financial Impacts:

The cost to patients and the state depends on the type of Emergency Insulin Safety Net program implemented. Kevin's Law maintains the status quo on payments. Costs are born by the patient or insurer, with little or no cost to the state. In contrast, Alec's Law limits patient out-of-pocket costs to $50 per month supply in Minnesota with manufacturers bearing the brunt of the cost. If New York State pursues a public/private partnership to administer and fund an Emergency Safety Net program, the state will likely have to budget for staff to operate it, costs the state may be able to offset by instituting sliding scale fees.

Workgroup Discussion:

Workgroup members discussed the pros and cons of instituting an Emergency Insulin Safety Net law in New York State. Members unanimously agreed that implementing legislation similar to Kevin's Law, which improves access to insulin, makes sense for New York State.

In principle, Workgroup members supported the concept of providing an important safety net for those individuals who cannot afford insulin, through both an emergency and on-going need program. Members, however, did not reach consensus on how to fund or deliver that type of program.

The central point of the discussion focused on the type of program and different funding mechanisms that could or should be implemented in New York State. Members, representing manufacturers, favored pursuing strategies with little or no added cost to the state, utilizing existing manufacturer programs with reimbursement mechanisms already in place. Other members, representing advocacy groups, supported legislation similar to Alec's Law, which requires manufacturers to reimburse or replace the insulin dispensed through the program. Opponents of this funding model reported that Alec's Law is expensive and duplicative, especially since manufacturers already have existing patient assistance programs. Other members supported a private/public option for funding an emergency safety net program.

In a post-meeting online feedback survey, one third of members recommended implementing an Emergency Insulin Safety Net program modeled after Alec's Law with a funding model which requires manufacturers to reimburse or replace the insulin. In general, other options to increase access and affordability of insulin were ranked higher by Workgroup members.

Patient Assistance Programs ("PAPs")

Background:

One strategy that states have adopted to help residents afford needed medication is to implement patient assistance programs. Some of the programs are specific to insulin, diabetes medication and/or supplies, such as in Florida, Delaware, and Utah. Other states, such as North Carolina, have implemented more general patient assistance programs.

The funding and administrative mechanisms along with eligibility criteria adopted by each program is unique. Florida's Insulin Distribution Program is one of the first in the country. It provides insulin free of charge to Florida residents, both insured and uninsured, with incomes at or below 100% of the federal poverty level.[271] Once applications are approved, patients can receive the insulin through their county health department's licensed pharmacy or through the state's Central Pharmacy. Delaware's Emergency Medical Diabetes Fund provides financial support for medication, such as insulin and supplies. However, the program limits the annual allowance to $500 per uninsured client. Patients must go to one of fifteen state service centers to receive assistance through this program. In FY 21-22, the Delaware program served 47 clients at an estimated cost to the state of $6,500.[272] In contrast, Utah's Insulin Savings Program, operates more as a wholesaler. The program, administered by the Public Employees Health Plan, allows uninsured and underinsured individuals to purchase insulin at discounted rates. Insulin is made available to consumers at the post rebate price by using state funds to cover the cost of the rebate until it is paid by the manufacturer through the Pharmacy Benefit Manager. Utahns apply for the card and once approved, Utahns can go to any pharmacy in the state and get insulin at the post-rebate price rather than the pre-rebate/retail price. This is equivalent to a 70 percent savings per prescription. Use of the program in 2022 was in the low hundreds and administrative costs were nominal.[273]

Other states have implemented patient assistance programs that provide medications for a variety of conditions and diagnoses. North Carolina's Med Assist is a statewide non-profit pharmacy that provides medication access to people in need of prescription and over-the-counter medications.

[271] (Florida Department of Health, 2023)
[272] (Delaware Diabetes Prevention and Control Program, 2023)
[273] (Loftis, personal communication, December 12, 2022; PEHP, 2020)

The program is available to residents of North Carolina who meet income eligibility requirements and have no prescription health insurance. Once enrolled in the program, Med Assist fills their prescriptions as the licensed, dispensing pharmacy and mails them directly to the patient's address. The program's operating capital comes from a combination of grants, fund raising, and in-kind donations of medications. Over one-third of the medications dispensed through the program are for diabetes related prescriptions. Insulin for the program is donated from Eli Lilly via their bulk replenishment program. In the 2021-2022 fiscal year, NC Med Assist dispensed insulin to 1,513 patients at a value of $6.1 million. Administrative and operational costs were approximately $200 per patient.[274] For medications other than insulin, North Carolina Med Assist uses The Pharmacy Connection, a web-based software program created by the Virginia Health Care Foundation, to help link patients to pharmaceutical patient assistance programs.

New York State Pharmacy Assistance Programs:

Most states, including New York, have experience with patient assistance programs. Under Part B of the Ryan White HIV/AIDS Program, states provide financial support for health care services and medications for uninsured or underinsured persons living with HIV/AIDS. The program also provides funds to pay for health insurance. In addition to the Ryan White program, NYS DOH offers the Elderly Pharmaceutical Insurance Coverage (EPIC) program which helps income-eligible seniors pay Medicare Part D drug plan premiums and limits out-of-pocket costs for drugs.

Potential Costs and Financial Impacts:

The cost to patients and the financial impact of a state-sponsored patient assistance programs depends on the model and funding mechanism adopted. Table 8 below estimates the state cost of implementing the Delaware and North Carolina models for uninsured and underinsured adults ages 18-64 in New York State with diabetes who use inulin. There may be additional implementation costs not included in these estimates.

[274] (North Carolina Department of Health and Human Services, 2023)

Table 8: New York State adults ages 18-64 with diabetes who use insulin by insurance type		**Delaware Model $500/per year**	**North Carolina Model $200/per year**
No coverage	All = 33,000	$16.5 million	$ 6.6 million
	With immigration status issues = 7,920	$ 3.9 million	$ 1.6 million
Private coverage	All = 96,190	$48.0 million	$19.2 million
	With household income of < than $50,000 = 26,644	$13.3 million	$ 5.3 million

Note: Estimates calculated using NYS BRFSS data 2017 & 2021 and estimated costs from the state programs.

Workgroup Discussion:

Workgroup members discussed the benefits of a state-sponsored patient assistance program without reaching consensus. Members representing advocates, providers, and insurers noted some potential benefits of this type of program, suggesting that:

- A state-sponsored patient assistance program would provide an important safety net for those without affordable options.
- This option would potentially lower costs without increasing the already high cost of health insurance.
- A state-sponsored program could provide assistance for both insulin and diabetes supplies.

Members also discussed several challenges to implementing a successful state-sponsored insulin patient assistance program, including:

- Lack of patient knowledge about programs and how to access them. Some members recommended that the state partner with the pharmaceutical manufacturers to educate consumers about the manufacturer patient assistance programs, the New York State Attorney General price agreements, and how to access low-priced insulin.
- Patient assistance programs and other options to increase access and affordability of insulin only address one aspect of diabetes care. Members advocated for pursuing options that ensure patients receive the suite of care that they need, not just the medicine, to have a better quality of life.
- Workgroup members representing manufacturers questioned the need for a state-sponsored

program since pharmaceutical companies already have patient assistance programs. These members believe that a state program would be duplicative. Members representing manufacturers provided information about how they have worked to simplify and make the patient assistance program application process more accessible. For example, Eli Lilly contracted with a switch company, Relay Health and Change (formerly eRX), to notify pharmacists when an uninsured individual presents with an insulin prescription. Eligible consumers will then be seamlessly connected to the Lilly Insulin Value Program.

- Other Workgroup members countered that, at least in the past, accessing manufacturers' patient assistance programs can be hard to navigate, and that is only if you have the resources (computer, internet, health care literacy, etc.) to navigate them.

In the post-meeting online survey, over forty percent of members favored implementing a state-sponsored insulin patient assistance program to increase access and affordability for those in need. It was one of the top four strategies for increasing access and affordability of insulin for uninsured and underinsured individuals recommended by the Workgroup.

Drug Discount Programs & Manufacturer Discounts

Background:

Most states have implemented drug discount programs that cover specific populations, such as the elderly or disabled. Typically, patients apply and are issued a discount card which they can use directly at the pharmacy. In contrast, manufacturers sometimes provide discounts via coupons and rebates. Approximately 20 percent of brand name prescriptions in commercial plans were found to offer beneficiaries copay coupons.[275]

A recent study found that the use of pharmacy discount cards has increased over the past few years from 3.3% in 2017 to 5.4% in 2021.[276] In this study, utilization of pharmacy discount cards was highest among cash payers, followed by individuals with commercial insurance, and observed deductibles. Not surprisingly, cash payers benefited the most from pharmacy discount cards.

[275] (Karen Van Nuys et al., 2018)
[276] (Adolph et al., 2022)

Discount cards were primarily used for generic drugs. Researchers reported that insured individuals were more likely to use the discount card when cost-sharing is highest. Between 39% and 54% percent of insured individuals first used the pharmacy discount cards after coverage for a medicine was rejected by their policy. Other researchers found that discount cards were mostly used in urban, lower-income areas.[277]

A retrospective analysis of the use of coupons to purchase pharmaceuticals found that individuals were likely to use a coupon for the first fill of a new drug. The researchers found coupon use/availability was associated with market competition. No significant association was reported between neighborhood-level incomes, out of pocket costs, and frequency of coupon use.[278]

Challenges with discount programs:

A number of issues with discount programs and manufacturer coupons have been identified in the literature, including the following:

- Discounts are often not available to individuals with governmental plans,
- Coupons may discourage consumers from trying less costly generic brands,
- Pharmacy benefit managers may eliminate pharmaceuticals with coupons from formularies, and
- Costs may be recovered through other pricing strategies and may ultimately raise drug costs.[279]

New York State RX Card:

The New York State Rx discount card is available to all New York State residents. The program is privately run. Residents can sign up online, download the savings card, and bring it to the pharmacy to receive a discount. The program reportedly provides the guaranteed lowest price logic with discounts on average of 10-20% on brand drugs and 20-70% on generic drugs.[280] New York City has its own Big Apple Rx Discount card that advertises an average of 47% savings on

[277] (Munigala et al., 2019)
[278] (Kang et al., 2019)
[279] (Karen Van Nuys et al., 2018)
[280] (Greene County government, n.d.)

prescription drugs.[281]

Potential costs and financial impacts:

Discount programs and coupons undoubtedly help cash customers cover the out-of-pocket costs at the pharmacy counter. The benefits and unintended consequences of these discount programs are less clear for individuals with coverage.

The discount program is currently available in New York State. Additional promotion of the program would incur minimal cost to the state.

Workgroup discussion:

No meaningful discussion at Workgroup meeting since program is already functional in the state.

Drug Donation Programs

Background:

Another option to increase access to pharmaceuticals for uninsured individuals is to implement drug donation programs, which have the dual purpose of combating drug waste. According to research, two of every three prescriptions in the United States goes unused, with seventeen percent of these being medications for chronic conditions such as diabetes. This results in a two-to-five-billion-dollar cost attributable to annual drug wastage in the U.S.[282] According to a report from the National Academies of Sciences, a main reason for drug waste in the U.S. is that nursing homes, long-term care facilities, and other residential/healthcare organizations discard billions of dollars' worth of prescription drugs that residents no longer require each year.[283]

State Programs:

Approximately 40 states have tackled the issue of drug waste and drug affordability by passing legislation to establish a prescription drug repository and/or drug donation program, with twenty-

[281] (Big Apple RX NYC, 2023)
[282] (Law et al., 2015)
[283] (Committee on Ensuring Patient Access to Affordable Drug Therapies et al., 2018)

seven states moving forward with program implementation. Program administration and operation differ across the country, with states opting to implement one of three types of programs:

1. *State/county operated*: One of the first programs to repurpose unused medications from nursing homes was implemented by the Department of Social Services in Tulsa County, Oklahoma. The medications were redistributed through the county operated clinic and pharmacy.[284] The Wyoming Department of Health also administers and operates the program directly, but partners with other organizations to increase accessibility.[285]
2. *Public/Private partnership*: Other states have opted to create public/private partnerships to implement statewide drug donation/redistribution programs, such as in Iowa with the SafeNetRx program.[286] Vermont is currently considering contracting with Iowa's SafeNetRx to develop a similar type program.[287] Similarly, Georgia has partnered with another non-profit organization, Supporting Initiatives to Redistribute Unused Medicine (SIRUM), to create the state's first pharmacy of donated medicines.[288]
3. *State oversight/Privately operated:* A majority of states, however, have adopted regulations for the collection and redistribution of certain donated prescription drugs, but leave the day-to-day operations to state certified or approved healthcare organizations and third-party intermediaries.[289]

State regulated programs all tend to follow the same basic guidelines. Most states accept donations only from closed systems, which is defined as a healthcare facility or pharmacy where the medication is controlled under the direction of a health care professional and not the patient. However, some states, such as Texas, do accept individual donations. In the case of individual donations, medications which require refrigeration such as insulin are not accepted.[290] States generally prohibit donations of controlled substances, misbranded medications, and expired drugs. Only 14

[284] (Tulsa County Social Services, 2023)
[285] (Wyoming Department of Health, 2023)
[286] (Iowa Department of Health and Human Services, 2023)
[287] (Levine, 2023)
[288] (SIRUM, 2023)
[289] (Staff, NCSL, n.d.)
[290] (Texas Department of State Health Services, 2022)

states permit donations of cancer drugs. The drugs must be unopened in tamper-evident packaging. The statutes generally provide protection from liability both for donors and recipients and products must be checked by pharmacists before being dispensed. Finally, selling or reselling donated prescription drugs is against the law.

In addition to these state programs, non-profits, such as Dispensary of Hope, operate drug donation programs to provide much needed pharmaceuticals to low-income and uninsured patients.[291] Upstate Medical Center in New York has contracted with Dispensary of Hope to provide access to uninsured patients whose income is at or below 300% of Federal Poverty Level. The dispensary at Upstate Medical University is the first in the state located outside of New York City. Upstate Medical University pays a fee every year to receive unlimited access and shipping to the available drugs, including insulin.[292] The Dispensary of Hope at Upstate currently has only insulin from one manufacturer, Eli Lilly, and provides approximately 25 individuals a month with insulin. Insulin for Life USA, is an international non-profit, licensed in Florida to accept and redistribute donations of insulin and diabetic supplies.

Potential Cost and Financial Impact:

The cost of the programs depend on which implementation strategy is adopted by each state. Expenses may include administrative, operational, logistical, and marketing costs. Many of the donations arrive in blister packs which need to be reviewed and re-packaged. The time and personnel required to complete this process can be a barrier to implementation along with liability issues and the lack of storage facilities for donated medications.[293]

Some costs are offset by repository and dispensing fees. Repository fee requirements differ, with most states instituting some type of cap per prescription, ranging from $3 in Colorado to $20 in Ohio, or establishing fees linked to Medicaid co-pays or dispensing fees.[294] Some states have instituted maximum pharmacy dispensing fees or protocols for transferring and repackaging of donated drugs.[295] Redistribution strategies also vary, with some states decreasing barriers to access by implementing

[291] (Dispensary of Hope, 2023)
[292] (Albanese, 2022)
[293] (Briones, 2020)
[294] (Mandell, 2022)
[295] (Staff, NCSL, n.d.)

mail order programs and others requiring patients to present at specific pharmacies and clinics.[296]

The Iowa/SafeNetRx program is estimated to generate over $7 in free medications and supplies for every $1 in administration expenses, with the program costing approximately $600,000 a year to run.[297] Vermont, with a smaller population than Iowa, estimates that the program would cost the state approximately $236,000 per year to operate plus another $40-50,000 in marketing costs.[298]

Access to donated pharmaceuticals via the Dispensary of Hope ranges from $7,500 a year for a non-profit clinic to $12,500 a year for non-profit hospitals or community pharmacies. Fees for multi-site or larger healthcare systems are higher. The cost to patients for insulin via these programs is zero.

Overall, these state programs have helped thousands, filling hundreds of thousands of prescription worth millions of dollars.[299] The American Medical Association has advocated for more state funding to adequately resource donation programs to both eliminate waste and improve access to much needed drugs by low-income populations.[300]

New York State Legislation:

New York State has passed legislation to permit a drug donation/redistribution program. New York State Public Health Law §280-B directs the Commissioner to develop and implement regulations for donation and redistribution of unused prescription drugs. The statute limits donor and recipient entities to manufacturers, wholesalers/distributors, pharmacies, hospitals, and/or third-party intermediaries. Most of the types of donations allowed under New York State law mirror those that have been adopted in other states. In 2018, the DOH issued a request for information to gather input about a potential program and guidelines. Since then, there has been little movement on this issue.

Workgroup Discussion:

Workgroup members discussed the option of implementing a drug donation program in New York State, voicing some quality assurance concerns, particularly related to drug donations from individuals. The integrity of the product, refrigeration requirements, and potential for tampering were

[296] (Briones, 2020)
[297] (Briones, 2020)
[298] (Livingston, 2018)
[299] (Staff, NCSL, n.d.)
[300] (American Medical Association: Council on Science and Public Health, 2018)

of greatest concern. In a follow-up survey, Workgroup members reported additional concerns, such as that donated products could be potentially dangerous or be sub-potent.

Workgroup members responded favorably to drug donation programs which collected unused pharmaceuticals from closed systems, such as clinics and hospitals. One member recommended reviewing the Dispensary of Hope's model for chain of custody to ensure the safety of its products and the well-being of recipients.

Drug Importation

Background:

Another strategy that states are exploring to decrease the cost of pharmaceuticals, in general, is drug importation programs. The United States spends more on prescription drugs than any other country in the world. With the cost of prescription drugs continuing to rise and prescription rates rising, the Kaiser Family Foundation states that 80% of Americans support a plan to import prescription drugs from Canada.[301] With Canadian drugs costing between 28-46% lower than in the in the United States, importation is expected to decrease costs in the United States.[302] With many drugs sold in the US already being made overseas and an estimated 2 million Americans purchasing prescription drugs outside of the U.S. annually, importation seems like a natural next step.[303]

The Department of Health and Human Services has developed two pathways for importation of drugs into the United States. The amended Section 804 of the Food and Drug Cosmetic Act allows importation of drugs from Canada by pharmacists and wholesalers through the Medicare Prescription Drug Improvement and Modernization Act of 2003.[304] Under this law, importation of certain drugs is prohibited. Banned products include controlled substances, biological products, infused drugs, drugs subject to REMS (risk evaluation and mitigation strategy), or drugs that are inhaled or injected.[305] The second pathway, allows manufacturers of Food and Drug Administration-approved pharmaceuticals produced for foreign markets to re-import them into the U.S. instead. The foreign version must be

[301] (The Congressional Digest, 2019)
[302] (Cubanski et al., 2023)
[303] (Galewitz, 2021; Ravitz et al., 2022)
[304] (FDA, Economic Staff, 2020)
[305] (Ravitz et al., 2022)

chemically identical to the version available in the U.S., with appropriate labeling and safeguards.[306]

Development of guidelines for federally approved importation programs stalled until the Trump Administration enacted an executive order in July of 2020 directing the secretary of the Department of Health and Human Services to finalize rulemaking on importation from Canada. Specifically, to take action to allow importation of drugs from other foreign countries, and to allow for insulin products manufactured in the U.S. but sent abroad to be reimported for domestic use.[307]

The first set of guidelines developed focused on importing pharmaceuticals from Canada. The final rules allow states, wholesalers, and pharmacists to sponsor a SIP, or Section 804 Implementation Program for importation from Canada, which requires the SIP sponsor to specify the following:

- The drugs it wants to import,
- The seller in Canada that would purchase the drug from the manufacturer,
- The U.S. importer (wholesaler/distributor) that would buy the drug from the Canadian seller,
- The re-packager of the drug that would ensure it meets U.S. labeling requirements,
- The lab that would test the drug once it has been imported, and
- The steps the program would take to ensure security throughout the supply chain.[308]

The guidelines for Canadian imports allow states, Indian Tribes, wholesalers, and pharmacists to submit importation program demonstration project proposals to the Food and Drug Administration for review and authorization. This also requires that the sponsor explain how they will ensure their program will result in a significant reduction in the cost of covered products to the American consumer. [309]

The second set of guidelines focus on the re-importation of pharmaceuticals, such as insulin. In September 2020, the government issued a request for proposals to develop insulin re-importation programs. No proposals were submitted and in 2021, the request for proposals was rescinded.[310] In 2023, manufacturers of insulin announced voluntary reductions in the price of insulin, mostly negating the need of re-importation programs for insulin products.

[306] (FDA, 2020)
[307] (Freed et al., 2021)
[308] (Freed et al., 2021)
[309] (FDA, 2020)
[310] (FDA, 2021)

State Legislation and Proposals:

While insulin prices have decreased recently, states continue to press forward with legislation to allow imports of other pharmaceuticals, including other diabetes drugs, from Canada. As of February 2023, eight states, Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Vermont, and Wisconsin, have passed legislation permitting drug importation from Canada.[311] The National Academy of State Health Policy has developed model legislation on drug importation designed to produce savings and ensure safety. The model legislation requires that states select only licensed Canadian suppliers who are regulated under Canadian law and select drugs that are already approved for the Canadian market. The drugs would be provided only to distributors, such as pharmacies, who would agree to purchase and reimburse drugs at the import price. They would ensure the imported products are distributed only within their state and monitor the system for compliance, safety, and savings.[312]

At least six states (CO, FL, ME, NH, NM, VT) have submitted proposals to the Department of Health and Human Services to demonstrate how the program would meet safety and cost saving requirements. For any plan to go into effect, the HHS Secretary must certify that it meets safety and cost saving requirements.

Florida submitted its official proposal to Department of Health and Human Services in 2019, before there was a rule for state importation plans. After Florida sued the government for delay in processing the application, the Food and Drug Administration responded that Florida needed to address numerous deficiencies in its plan before moving forward. Likewise, New Hampshire's plan was rejected due to a gap in information. New Mexico's plan is still under review.[313] As of the beginning of 2023, no state plan had been certified.[314]On January 5, 2024, the Food and Drug Administration approved Florida's Canadian Prescription Drug Importation Plan.[315]

Implementation Strategies of Drug Importation Programs:

States adopted different strategies for implementation of their drug importation programs.

[311] (NASHP, 2018; National Conference of State Legislatures, 2023)
[312] (NASHP, 2022)
[313] (Galewitz & Kaiser Health News, 2022)
[314] (Siddiqui, 2023)
[315] (Florida Governor's Office, 2024)

Florida's proposed program is for public use in state agencies, such as prisons, health departments and for the Medicaid population. This program would be overseen by Florida's Agency for HealthCare Administration (AHCA) through a vendor whose role would be to handle program operations and ensure adherence to state and federal laws regarding importation.[316] Colorado's proposed program is for private use. Imported drugs would be distributed to participating pharmacies via a third party. Colorado's plan also hopes to allow health insurance plans within the state to include imported drugs in their benefit designs (Kaiser Health News, 2021). In contrast, Vermont's plan calls for wholesale distributors to import drugs for private and public payers.[317]

Lawsuits & Other Considerations:

Shortly after the government announced plans for drug importation programs, PhRMA (Pharmaceutical Research and Manufacturers of America) responded with a lawsuit based on safety concerns. In May of 2021, HHS filed a motion to dismiss the lawsuit, claiming the plaintiffs cannot prove harm from the final rule or HHS certification. On February 6, 2023, U.S. District Court for the District of Columbia dismissed the lawsuit.[318] PhRMA has also filed Citizen's petitions in various states requesting that the Food and Drug Administration refrain from approving the Section 804 Importation Program (SIP) applications stating that the applications do not have enough information regarding safety and cost to justify approval.

Lawsuits are not the only limitation on drug importation. Other concerns include the difficulty and cost of monitoring safety of the imported drugs, which would cut into cost savings, and the chance that this will result in a reduction in research and development of new drugs in the United States.[319] If the drugs are not properly monitored, the drug supply chain could be compromised with counterfeit or substandard products. There are also concerns that requirements for participation may be burdensome and increase the administrative burden for entities donating and receiving medications. With the small prescription drug market in Canada, it may be hard to find the required Canadian partner for importation. Canada also has raised concerns about the potentially adverse effects on

[316] (Freed et al., 2021)
[317] (*Vermont's Canadian Wholesale Importation Program for Prescription Drugs: Concept Paper*, 2019)
[318] (*Pharmaceutical Research & Manufacturers of America et al., v. Department of Health & Human Services et al.,: Civil Action*, 2020)
[319] (Freed et al., 2021)

Canadian manufacturers and consumers, expressing apprehension about potential prescription drug shortage and/or rising prices.[320]

Potential Costs and Financial Impact:

Importing prescription drugs from Canada or another country is expected to result in cost savings for the U.S and consumers while increasing access and affordability of medications.[321] Florida estimates the program will save the state between eighty and one hundred fifty million dollars during the first year.[322] Officials from Colorado claim their proposal will save state residents and employers an average of sixty-five percent off the cost of medications.[323]

One proposed model in New York State would be funded via a fee charged to the wholesaler.[324] Additional state funds may be required to staff an importation program.

Workgroup discussion:

Workgroup members provided little input on this option, as other options took precedence. With the recent price decreases of insulin, Workgroup members were less likely to select this as a top strategy for the state to pursue.

Educate providers/patients on less expensive biosimilar insulin options

Background:

As noted previously, the price of insulin has increased over the past few decades due to a number of factors, including the absence of competition from lower priced generics and biosimilars. Until recently, the introduction of biosimilar insulin products into the market has been slow. Basaglar was the first biosimilar product approved by the Food and Drug Administration in 2015 via an abbreviated process. Basaglar is not a generic drug. The insulin is similar but not interchangeable with Lantus so providers must individualize the prescription based on patient's needs. Not until 2021, did the first interchangeable biosimilar insulin, Semglee, get approved by the

[320] (FDA, Economic Staff, 2020; Galewitz, 2021)
[321] (FDA, Economic Staff, 2020)
[322] (S. Harris & Copeland, 2020)
[323] (Colorado Department of Health Care Policy & Financing, 2023)
[324] (Relates to Creating a Wholesale Prescription Drug Importation Program, 2023)

Food and Drug Administration. This landmark approval allows patients to purchase the less costly Semglee at the pharmacy without requesting a new prescription from their provider.[325] Since then, other interchangeable biosimilar insulins have been approved by the Food and Drug Administration, including Lilly's Rezvoglar.[326]

One option to make insulin more affordable for patients is to educate and encourage providers to prescribe the lower priced alternatives. A number of options to educate providers exist, from Medical Society and Grand Round webinars to individualized academic detailing and implementation of Electronic Medical Record prompts. As more clinics and community-based providers implement social determinants of health screening, integrating options for accessing lower priced pharmaceuticals seems like a logical next step.

Workgroup Discussion:

Workgroup members generally supported efforts to educate providers and patients on less costly biosimilar options. Members suggested conducting a more in-depth investigation of biosimilar options, specifically in terms of cost savings, cost-effectiveness, and accessibility. Members also voiced concern that pharmacy benefit managers may exclude biosimilar insulins from formularies, making them less accessible to insured individuals with diabetes who use insulin.

[325] (Herman & Kuo, 2021)
[326] (FDA Commissioner, 2022)

OPPORTUNITIES FOR PUBLIC/PRIVATE PARTNERSHIPS TO PROVIDE AFFORDABLE INSULIN DRUGS

Establish a state-based insulin manufacturing facility:

One option states are considering to make insulin more affordable is to develop their own state-funded manufacturing facilities. California lawmakers set aside $100 million in the budget for insulin development, $50 million of which is to be used for the creation of an insulin plant.[327] The Governor of Michigan has also signed an executive directive to explore the option of building its own insulin plant.[328]

Costs and financial impact:

The total cost to manufacture insulin in-state is unknown. PhRMA estimates that a new manufacturing facility can take 5 to 10 years to build and cost up to $2 billion.[329] The California legislature approved $100 million, with the expectation that it will lead to hundreds of millions of dollars in savings for the state and consumers. The American Rescue Plan provided federal funding to regional coalitions for economic development through the Build Back Better Regional Challenge (BBBRC) from the U.S. Economic Development Administration. The program provided $52.9 million in funding to The Advanced Pharmaceutical Manufacturing Coalition to expand the domestic supply chain for essential medicines. While New York applied and received funding from the BBBRC, the projects focus on the acceleration of innovation in new energy storage and the growth of advanced manufacturing. There may by other future opportunities at the federal level to apply for funding for development of essential medicines in the future.[330]

Public/private partnerships:

Another strategy to make insulin more affordable and accessible to constituents is to develop public/private partnerships to manufacturer and/or distribute the drug. California has partnered with

[327] (Beam, 2022)
[328] (Gov. Whitmer, 2022)
[329] (PhRMA, n.d.)
[330] (U.S. Economic Development Administration, 2023)

CivicaRx to manufacture insulin for the state.[331] CivicaRx is a non-profit generic pharmaceutical company created to ensure that essential medicines are available and affordable to patients. California has invested $50 million in Civica for the development and manufacturing of biosimilar insulins for its constituents. The initiative, a collaboration between the State of California's CalRx Biosimilar Insulin program and Civica Rx is anticipated to provide residents with a 30-day supply of insulin at a maximum cost of $30 or $55 for 5 pre-filled pens.

Coordinate with other states/partners to purchase and redistribute low-cost insulin products:

States have long sought out options to contain costs of prescription drugs. State efforts include multi-agency and multi-state initiatives to increase purchasing power to negotiate lower prescription drug costs. One main strategy adopted by states involves collaborating with other states to purchase insulin at discounted prices. Participants can either be purchasers, such as a state hospital that buys and then dispenses the medication directly, or payers, such as an ERISA plan that reimburses the purchaser.[332]

Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) Infuse is a national cooperative group purchasing organization (GPO) established and operated by the State of Minnesota. MMCAP Infuse harnesses the leverage of its 13,000 members to negotiate the best prices for pharmaceuticals and healthcare products for government facilities.[333] MMCAP is the contracted medication GPO for New York State. All eligible New York State entities can use this contract to purchase medication at better pricing. Any facility that is authorized to use the state contract can piggyback on to it. The distributor will apply the discount in the state contract tier. The final price paid may depend on cost of the good and prompt payment discounts.

Full use of the contract in New York State depends on a number of factors, such as how a facility manages medication, drug expiration dates, ability to return medications, and the number of facility locations/addresses. For example, the New York State Office of Mental Health has their own facilities, staffed with pharmacists, who can ensure that the medications are distributed

[331] (Civica, 2023)
[332] (Horvath, 2019)
[333] (MMCAP Infuse, 2023)

correctly and are not expired. On the other hand, the New York State Office of People with Developmental Disabilities does not have staff pharmacists for their residential homes, so they need to use an individual level contract instead of the group one.

Potential costs and financial impact:

Cooperatives with significant leveraging power can provide states and other entities with substantial savings on prescription drug prices, including insulin**.** MMCAP Infuse reports a range of savings for different organizations, with county jails receiving on average greatest overall savings.[334]

The MMCAP contract saves New York State money. An audit of the NYS MMCAP program may help identify if there are additional opportunities to leverage the pricing available via the state contract. The State of Wisconsin conducted a pharmacy cost study to identify differences in drug pricing paid by select agencies and opportunities to effectively implement joint purchasing to lower prices across the state.[335] Likewise, the Minnesota Attorney General's Advisory Task Force on Lowering Pharmaceutical Drug Prices recommended that the state inventory all government entities and providers to identify participation in the MMCAP program and opportunities to expand program participation.[336]

While states may save money, there are currently no laws or regulations that require entities to pass on the savings from MMCAP purchases or other discount programs, such as the 340 B Drug Pricing Program, to patients. States, such as Minnesota and Washington, have considered options to expand the pricing discounts offered by MMCAP to non-governmental purchasers including individual residents.[337]

Workgroup discussion:

Workgroup members discussed the various options for public/private partnerships to provide affordable insulin, reaching consensus on one option. Members advocated for pursuing existing

[334] (MMCAP Infuse, 2023)
[335] (Wisconsin Pharmacy Cost Study Committee, 2020)
[336] (Attorney General Ellison, 2020)
[337] Ibid

options, including leveraging purchasing power, to reduce the price of insulin. In a post-meeting survey, twenty-five percent of Workgroup members selected this as a priority public/partnership strategy for the state to pursue.

Workgroup members recommended investigating all avenues for partnering to procure insulin at a lower cost rather than looking to manufacturer insulin directly. Members representing pharmaceutical companies indicated that the cost of directly manufacturing insulin or producing it through a public private partnership would likely be much higher than the $100 million budgeted by the California legislature for the project. Approximately half of Workgroup members considered it important to explore the option of collaborating with non-profit organizations, such as Civica, to attain or manufacturer low-cost insulin for New York State residents.

CONCLUSION

The Workgroup provided a unique opportunity to bring together a diverse group of health care experts to discuss ways to make insulin more accessible and affordable for uninsured and underinsured individuals in New York State. The diverse opinions of the different stakeholders helped to clarify the costs and benefits of potential strategies the state could implement to help reduce the costs of insulin for consumers. Workgroup members prioritized actions for the state to pursue to increase access and affordability of insulin and identified other longer-term strategies for the state to consider to improve transparency and contain costs throughout the pharmaceutical supply chain. The Workgroup remains a valuable resource for discussing how to improve access and affordability of health care for individuals with diabetes who use insulin. Ensuring that all New Yorkers with diabetes who use insulin have equal access to this life-saving medicine is an essential part of achieving health equity.

APPENDIX A

Insulin Workgroup Members

Elisabeth Ryden Benjamin, MSPH, JD
Vice President, Health Initiatives
Community Service Society of NY

John Croce
President, CPESN NY, LLC / IPA

Stephen Habbe
Vice President, State Government Affairs
American Diabetes Association

George Huntley
Chief Executive Officer
Diabetes Leadership Council

Harold Iselin, JD
Greenberg Traurig, LLP

Alice Lam
Managing Director
Manatt Health

Eric Linzer
President and Chief Executive Officer
New York State Health Plan Association

Esra Mustafa, PharmD, BCACP
Clinical Pharmacist
Community Health Center of Buffalo

Christopher Pernie
Executive Director, Government Affairs
Novo Nordisk

John Steele
Vice President of Corporate Affairs
Lilly Diabetes and Obesity

Insulin Workgroup Members (continued)

Taylor Stimmler
Chapter Leader
T1International

Theresa Talbott, RPh
Director, Pharmacy and Retail Advocacy
CVS Health

Alex Thompson
Director of Advocacy
New York Association on Independent Living

Ruth Weinstock, MD, PhD
Chief of Endocrinology, Joslin Diabetes Center
SUNY Upstate Medical University and University Hospital

APPENDIX B

Data supporting Workgroup discussions:

Navigator program challenges:

- Lack of awareness:

  Further review found that lack of awareness of Navigator programs has been an issue nationally. A 2020 nationally representative survey of adults aged 18-64 found that lack of awareness is a key barrier to obtaining assistance. Survey respondents indicated that other barriers to using a Navigator program included inability to find help close to home, lack of assistance available in Spanish, and difficulty getting an in-person appointment.[338]

- Finding the 33,000 uninsured individuals with diabetes who use insulin:

  A preliminary investigation indicated that there is insufficient data to identify the demographic characteristics or the geographic location of uninsured individuals with diabetes who use insulin in New York State with any certainty. Other data sources provide some insight into geographic locations and populations to prioritize for expanded Navigator programs. Data from the Medical Expenditure Panel Survey indicates that Hispanics utilize insulin for the treatment of diabetes at a higher rate than other racial or ethnic groups.[339] The Office of the Assistant Secretary for Planning and Evaluation (ASPE) reports that 36.2% of uninsured adults in New York State are Hispanic/Latino, almost double the state population rate (19.5%).[340]

  County-level data are available to focus funding for Navigator programs to areas with high rates of uninsured populations and/or diagnosed diabetes. For example, an estimated 60.7% of uninsured adults identify as Latino in the Bronx, a county with one of the highest rates of diagnosed diabetes in the state (15.7%).[341] Queens County has the largest population of uninsured non-elderly adults (177,030), 41.8% of which identify as Latino.[342] This information may help officials direct funding for Navigator programs in high priority underserved locations and populations.

[338] (Pollitz et al., 2020)
[339] (Muhuri & Machlin, 2018)
[340] (ASPE, 2022)
[341] (Bureau of Chronic Disease Evaluation and Research, 2021)
[342] (ASPE, 2022)

APPENDIX C

Potential State Actions to Improve Price Transparency at each link in the Pharmaceutical Chain			
Entity	**Actions**	**Objective**	**Comments**
Manufacturers	Require reporting of the following to the state: • Must notify drug utilization review board of any proposed price increases of wholesale acquisition cost of 16% on drugs $40 or more • Justification for price increases • Require advance notice of price increases	• To better understand factors that influence price increases in the pharmaceutical chain • Provide states with information to better negotiate prices • Hold manufacturers accountable for price increases	• Manufacturers already report data to other states • Duplicative • Impact of legislation on drug prices unknown • Allows consumers and employers to prepare for price increases
	• Provide sales representatives information	• To hold manufacturers accountable. • Potentially require licensing of sales representatives	• Manufacturers report data to other states but this might not include NYS sales representatives
	• Report financial assistance to consumers and rebates to pharmacy benefit manager (PBM)	• To better understand factors that influence price increases in the pharmaceutical chain	• Manufacturers report data to other states, such as CA, but this might not include all data NYS requires (e.g., top 25 drugs might be different for CA than NY)
Wholesalers	Require wholesalers to report the following: • Wholesale acquisition cost Pricing • Amount of rebates negotiated with manufacturers, pharmacies and PBMs • Total discounts, dispensing fees, and other fees negotiated with pharmacies • Volume of units of each drug shipped into the state	• To better understand factors that influence price increases in the pharmaceutical chain • Provide states with information to better negotiate prices & develop policy	• No evaluation data available at this point • Wholesalers dominate 95 percent of the market
Pharmacy Benefit Managers	Require PBMs to report: • All pricing discounts, rebates, inflationary payments, credits, claw backs, grants and reimbursements • Top ten drugs with highest total claims cost • Top ten drugs with the most rebate amounts • Total number of beneficiaries served by the PBM in NYS	• To better understand factors that influence price increases in the pharmaceutical chain • Provide states with information to develop policy to contain costs	• Recent legislation passed in NYS requiring PBMs to license/register and report data annually

	• List of health plans in NYS it provides PBM services • Ownership and pharmacies • Total prescription revenue preferred/non-preferred pharmacies		
	Regulates PBM pricing strategies: • Requires PBMs to use a pass-through pricing model • Prohibits spread pricing	• To reduce pharmacy benefit manager costs and contain drug prices	• Limited available data on the impact of this legislation • Preliminary data suggests when spread pricing prohibited, PBMs retained more in rebates instead
	Regulates PBM pricing strategies: • Relates to reimbursement practices of PBMs. • Law ensures that PBMs do reimbursement pharmacies of an amount less than the cost of procuring the drug	• Seeks to protect small, rural, and independent pharmacies from unfair PBM pricing strategies	• PBM pricing strategies have forced closure of small, rural and independent pharmacies
Insurers	Require insurers to report additional information, such as: • Drug price data • Rebates retained • Percent of premium attributed to drug costs	• To identify the impact of drug prices on premiums • Provide states with information to develop policy to contain costs	• Review data insurers currently report to the state annually to determine what other information would be helpful to better understand drug pricing
	• Requires insurers to certify that most drug rebates are provided to patients at the point of sale	• Seeks to contain drug price out-of-pocket costs for consumer	• Implementation challenges identified since insurers may receive rebates post-sale
Providers	• Require health care providers to inform patients about the Open Data website which provides conflict of interest info	• To ensure that consumers are aware of conflict of interest information	• Significant consumer lack of awareness of the database reported • May help to self-regulate physician COI behavior

REFERENCES

Additional Preventive Care Benefits Permitted to Be Provided by a High Deductible Health Plan Under S223, Pub. L. No. 2019–45, 223 Insurance (2019). https://www.irs.gov/pub/irs-drop/n-19-45.pdf

Adolph, N., Engbers, B., & Kokra, A. (2022). *Pharmacy Discount Card Utilization and Impact* [White Paper]. IQVIA U.S. Market Access Strategy Consulting. https://www.iqvia.com/locations/united-states/library/white-papers/pharmacy-discount-card-utilization-and-impact

Ahmad, N. S., Makmor-Bakry, M., & Hatah, E. (2020). Drug price transparency initiative: A scoping review. *Research in Social and Administrative Pharmacy*, *16*(10), 1359–1369. https://doi.org/10.1016/j.sapharm.2020.01.002

Albanese, J. (2022, July 6). *New prescription drug dispensary at Upstate brings hope to the uninsured and indigent | Upstate News | SUNY Upstate Medical University*. Upstate Medical University. https://www.upstate.edu/news/articles/2022/2022-07-06-hope.php

American Diabetes Association. (2018). Economic Costs of Diabetes in the U.S. in 2017. *Diabetes Care*, *41*(5), 917–928. https://doi.org/10.2337/dci18-0007

American Diabetes Association. (2020). 1. Improving Care and Promoting Health in Populations: *Standards of Medical Care in Diabetes — 2020*. *Diabetes Care*, *43*(Supplement_1), S7–S13. https://doi.org/10.2337/dc20-S001

American Diabetes Association. (2023a). *State Insulin Copay Caps*. https://diabetes.org/tools-support/insulin-affordability/state-insulin-copay-caps

American Diabetes Association. (2023b, August 1). *Health Insurance Aid*. https://diabetes.org/tools-support/health-insurance

American Medical Association: Council on Science and Public Health. (2018). *Prescription Drug Donation* (CSAPH Report 3-A-18). American Medical Association. https://councilreports.ama-assn.org/councilreports/downloadreport?uri=/councilreports/prescription_drug_donation.pdf

Amin, K., Claxton, G., Rae, M., & Cox, C. (2022, March 24). Out-of-pocket spending on insulin among people with private insurance. *KFF*. https://www.kff.org/health-costs/issue-brief/out-of-pocket-spending-on-insulin-among-people-with-private-insurance/

An Act to Amend the Insurance Law, in Relation to Capping Cost Sharing for Insulin, S504, NYS Senate 2023–2024 (2023). https://www.nysenate.gov/legislation/bills/2023/s504

An Act to Amend the Public Health Law, in Relation to Pharmacy Benefit Managers: To Amend the Insurance Law, in Relation to Registration and Licensing of Pharmacy Benefit Managers; and to Repeal Certain Provisions of the Public Health Law Relating Thereto, S3762, the New York State Senate 2021-2022 Legislative Session (2021). https://www.nysenate.gov/legislation/bills/2021/S3762

An Act to Amend the Public Health Law, in Relation to Reimbursement Rates of Pharmacy Benefit Managers, S7110, New York State Senate 2023-2024 Legislative Session, Amd S280-e (2023). https://www.nysenate.gov/legislation/bills/2023/S7110

An Act to Amend Title 18, Title 29, and Title 31 of the Delaware Code Relating to Insurance Coverage of Insulin Pumps, Pub. L. No. Volume 83, Chapter 241 (2021). https://legis.delaware.gov/SessionLaws/Chapter?id=41301

An Act to Enhance Cost Savings to Consumers of Prescription Drugs, LD 1165, State of Maine Legislature 131st (2023). https://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP0737&item=1&snum=131

Artiga, S., & Diaz, M. (2019). *Health Coverage and Care of Undocumented Immigrants* [Issue Brief]. https://files.kff.org/attachment/Issue-Brief-Health-Coverage-and-Care-of-Undocumented-Immigrants

Artiga, S., Tolbert, J., & Rudowitz, R. (2016). *Implementation of the ACA in Kentucky: Lessons Learned to Date and the Potential Effects of Future changes* [Issue Brief]. The Kaiser Commission on Medicaid and the Uninsured. https://files.kff.org/attachment/issue-brief-implementation-of-the-aca-in-kentucky-lessons-learned-to-date-and-the-potential-effects-of-future-changes

ASPE. (2022, November 18). *State and Local Estimates of the Uninsured Population in the U.S. Using the Census Bureau's 2021 American Community Survey* [Official website of the U.S. government]. ASPE. https://aspe.hhs.gov/reports/state-county-local-estimates-uninsured-population

Assistant Secretary for Public Affairs. (2022, August 26). *Biden-Harris Administration Makes Largest Investment Ever in Navigators Ahead of HealthCare.gov Open Enrollment Period* [Text]. HHS.Gov. https://www.hhs.gov/about/news/2022/08/26/biden-harris-administration-makes-largest-investment-ever-in-navigators-ahead-of-healthcare-gov-open-enrollment-period.html

Associated Press. (2022, April 5). Minnesota Insulin Safety Net Funds $6M in Supplies in 2021. *U.S. News & World Report*. https://www.usnews.com/news/best-states/minnesota/articles/2022-04-05/minnesota-insulin-safety-net-funds-6m-in-supplies-in-2021

Attorney General Ellison, K. (2020). *Report of the Minnesota Attorney General's Advisory Task Force on Lowering Pharmaceutical Drug Prices*. The Office of Minnesota Attorney General Keith Ellison. www.ag.state.mn.us/Office/Communications/2020/docs/DPTF_Feb2020Report.pdf

Authorizes Physicians and Pharmacists to Enter into Collaborative Practice Medication Adherence Protocols for Their Patients, S3591A, New York State Senate 2023-2024 Legislative Session, 29-H 2999-ff, S6801-b, EDL amd S5, (2023). https://www.nysenate.gov/legislation/bills/2023/S3591/amendment/A

Bakkila, B. F., Basu, S., & Lipska, K. J. (2022). Catastrophic Spending On Insulin In The United States, 2017–18: Study examines catastrophic spending on insulin in the United States, 2017–18. *Health Affairs*, *41*(7), 1053–1060. https://doi.org/10.1377/hlthaff.2021.01788

Beam, A. (2022, July 9). California aims to make its own insulin brand to lower price. *AP News*. https://apnews.com/article/health-california-diabetes-government-and-politics-f846c58d4cb327578d1c7b3a9495d496

Becker, C. (2022, October 26). *Digging Into Prescription Drug Data: Affordability Boards and Transparency*. National Conference of State Legislatures. https://www.ncsl.org/health/digging-into-prescription-drug-data-affordability-boards-and-transparency

Benjamin, E., Dunker, A., & Orecki, P. (2022). *Narrowing New York's Health Insurance Coverage Gap*. Community Service Society and the Citizen's Budget Commission. https://www.cssny.org/publications/entry/narrowing-new-yorks-health-insurance-coverage-gap

Bertram, A. (2023). *PBM Basics*. Pharmacists Society of the State of New York. https://www.pssny.org/page/PBMBasics

Bhargava, S., Loewenstein, G., & Sydnor, J. (2017). Choose to Lose: Health Plan Choices from a Menu with Dominated Option*. *The Quarterly Journal of Economics*, *132*(3), 1319–1372. https://doi.org/10.1093/qje/qjx011

Big Apple RX NYC. (2023, August). *Big Apple Rx NYC*. Big Apple Rx. https://www.bigapplerx.com/

Biosimilars Council. (2023). *Semglee Launch Tracking*. Association for Accessible Medicines. https://biosimilarscouncil.org/wp-content/uploads/2023/07/Biosimilars-Council-Semglee-Launch-Tracking-2023.pdf

Briones, N. (2020). Current State of Drug Recycling Programs in the United States. *International Program Papers 121*. https://chicagounbound.uchicago.edu/international_immersion_program_papers/121

Bureau of Chronic Disease Evaluation and Research. (2021). *Percentage of adults with diagnosed diabetes, by county, New York State, BRFSS 2018* (2021–01). NYS DOH. www.health.ny.gov/statistics/prevention/injury_prevention/information_for_action/docs/2021-01_ifa_report.pdf

Butler, J. (2022, January 10). Drug Price Transparency Laws Position States to Impact Drug Prices. *National Academy for State Health Policy Blogs*. https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/

California Department of Health Care Access and Information. (2023). *Prescription Drug Wholesale Acquisition Cost Increases* [dataset]. https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases

California Department of Health Care Services. (2022). *Older Adult Expansion* [Government]. CA.Gov. https://www.dhcs.ca.gov/services/medi-cal/eligibility/Pages/OlderAdultExpansion.aspx#:~:text=Beginning%20May%201%2C%202022%2C%20a,immigration%20status%20does%20not%20matter.

California Department of Managed Health Care. (2021). *Prescription Drug Cost Transparency Report—Measurement Year 2021*. California government. https://www.dmhc.ca.gov/Portals/0/Docs/DO/SB172021Report.pdf

California Health Benefits Review Program. (2023). *Key Findings: Analysis of California Senate Bill 90—Health Care Coverage: Insulin Affordability* [Key findings]. California Health Benefits Review Program. ww.chbrp.org/sites/default/files/bill-documents/SB90/SB%2090%20Insulin%20Affordability_Final.pdf

CareSource. (2020). *CareSource Launches Pharmacist Provider Status Pilot*. Caresource.com. https://www.caresource.com/newsroom/press-releases/caresource-launches-pharmacist-provider-status-pilot/

Casagrande, S. S., & Cowie, C. C. (2018). Health Insurance and Diabetes. In C. C. Cowie, S. S. Casagrande, A. Menke, M. A. Cissell, M. S. Eberhardt, J. B. Meigs, E. W. Gregg, W. C. Knowler, E. Barrett-Connor, D. J. Becker, F. L. Brancati, E. J. Boyko, W. H. Herman, B. V. Howard, K. M. V. Narayan, M. Rewers, & J. E. Fradkin (Eds.), *Diabetes in America* (3rd ed.). National Institute of Diabetes and Digestive and Kidney Diseases (US). http://www.ncbi.nlm.nih.gov/books/NBK567967/

Cefalu, W. T., Dawes, D. E., Gavlak, G., Goldman, D., Herman, W. H., Van Nuys, K., Powers, A. C., Taylor, S. I., Yatvin, A. L., & on behalf of the Insulin Access and Affordability Working Group. (2018). Insulin Access and Affordability Working Group: Conclusions and Recommendations. *Diabetes Care*, *41*(6), 1299–1311. https://doi.org/10.2337/dci18-0019

Centers for Disease Control and Prevention. (2023). *Preventing Diabetes-Related Amputations*. CDC. https://www.cdc.gov/diabetes/library/features/amputations.html

Centers for Medicare & Medicaid Services. (2017, January 19). *Medicare Part D – Direct and Indirect Remuneration (DIR) | CMS*. Centers for Medicare & Medicaid Services. https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir

Centers for Medicare & Medicaid Services. (2021a). *Prescription Drug Data Collection (RxDC)*. CMS. https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/prescription-drug-data-collection

Centers for Medicare & Medicaid Services. (2021b). *American Rescue Plan Lowered Health Costs for Millions of Americans Ahead of August 15 Deadline to Get Covered on HealthCare.gov*. CMS.gov. https://www.cms.gov/newsroom/press-releases/american-rescue-plan-lowered-health-costs-millions-americans-ahead-august-15-deadline-get-covered

Centers for Medicare & Medicaid Services. (2023a). *Section 1332: State Innovation Waivers*. CMS.Gov. https://www.cms.gov/cciio/programs-and-initiatives/state-innovation-waivers/section_1332_state_innovation_waivers-

Centers for Medicare & Medicaid Services. (2023b). *Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Initial Guidance*. CMS. www.cms.gov/files/document/inflation-rebate-fact-sheet-february-2023.pdf

Centers for Medicare & Medicaid Services. (2023c, August 6). *Medicare Limited Income NET Program* [Government]. CMS.Gov. https://www.cms.gov/medicare/eligibility-and-enrollment/lowincsubmedicareprescov/medicarelimitedincomenet

Chao, M., & Larkin, I. (2020). Regulating Conflicts of Interest Through Public Disclosure: Evidence From a Physician Payments Sunshine Law. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.3539990

Choudhry, N. K., Bykov, K., Shrank, W. H., Toscano, M., Rawlins, W. S., Reisman, L., Brennan, T. A., & Franklin, J. M. (2014). Eliminating Medication Copayments Reduces Disparities In Cardiovascular Care. *Health Affairs*, *33*(5), 863–870. https://doi.org/10.1377/hlthaff.2013.0654

Chung, A. (2019, February 19). U.S. top court rejects Maryland bid to revive drug price-gouging law. *Reuters*. https://www.reuters.com/article/us-usa-court-pharmaceuticals-idUSKCN1Q81T9

Civica. (2023). *California Selects Civica RX as Its Insulin Manufacturing Parnter*. Civica Rx. https://civicarx.org/california-selects-civica-rx-as-its-insulin-manufacturing-partner/

Colorado Department of Health Care Policy & Financing. (2023). *Implementation of a Canadian Prescription Drug Importation Program*. State of Colorado. https://hcpf.colorado.gov/drug-importation

Colorado Department of Regulatory Access. (n.d.). *OmniSalud | DORA Division of Insurance*. Colorado Department of Re. Retrieved November 27, 2023, from https://doi.colorado.gov/omnisalud

Colorado Department of Regulatory Agencies. (2022, January 1). *Insulin Affordability Program: HB21-1307 & Emergency and 12-Month Insulin Supply*. State of Colorado. https://doi.colorado.gov/prescription-affordability-programs

Committee on Ensuring Patient Access to Affordable Drug Therapies, Board on Health Care Services, Health and Medicine Division, & National Academies of Sciences, Engineering, and Medicine. (2018). *Making Medicines Affordable: A National Imperative* (N. R. Augustine, G. Madhavan, & S. J. Nass, Eds.). National Academies Press. https://doi.org/10.17226/24946

Congressional Research Service. (2020). *The Individual Mandate for Health Insurance Coverage: In Brief* (R44438). https://crsreports.congress.gov/product/pdf/R/R44438

Cousart, C. (2021, February 1). Federal and State Special Enrollment Periods Increase Access to Insurance Coverage. *National Academy For State Health Policy*. https://nashp.org/federal-and-state-special-enrollment-periods-increase-access-to-insurance-coverage/

Coverage Requirements for Health-Care Products, HB22-1370, Colorado 74th General Assembly 2022 Regular Session (2022). https://leg.colorado.gov/bills/hb22-1370

Cox, C., Amin, K., & Ortaliza, J. (2022, August 11). Five Things to Know about the Renewal of Extra Affordable Care Act Subsidies in the Inflation Reduction Act. *KFF*. www.kff.org/policy-watch/five-things-to-know-about-renewal-of-extra-affordable-care-act-subsidies-in-inflation-reduction-act/

Crail, C., & Masterson, L. (2022, August 18). Does Your State Require You to Have Health Insurance? – Forbes Advisor. *Forbes*. https://www.forbes.com/advisor/health-insurance/do-you-have-to-have-health-insurance/

CSSNY. (n.d.). *Child Health Plus—Overview—Benefits Plus*. CSSNY. Retrieved November 28, 2023, from https://bplc.cssny.org/pbm/health-programs/child-health-plus/overview

Cubanski, J., Neuman, T., Freed, M., & Damico, A. (2023). *How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries?* KFF. https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/

Daly, C. J., Quinn, B., Mak, A., & Jacobs, D. M. (2020). Community Pharmacists' Perceptions of Patient Care Services within an Enhanced Service Network. *Pharmacy*, *8*(3), 172. https://doi.org/10.3390/pharmacy8030172

Delaware Diabetes Prevention and Control Program. (2023). *Emergency Medical Diabetes Fund Provides Assistance For Uninsured*. Delaware.Gov. https://www.dhss.delaware.gov/dhss/dph/dpc/diabetesfund.html#:~:text=The%20Delaware%20Emergency%20Medical%20Diabetes,or%20alleviate%20the%20medical%20condition.

DeMarco, J. (2023, January 30). *Rate of Workers Enrolled in High-Deductible Health Plans Jumps for 8th Year in row to Record 55.7%*. Value Penguin.

Department of Homeland Security. (2019). *Inadmissibility on Public Charge Grounds*. National Archives. https://www.federalregister.gov/documents/2019/08/14/2019-17142/inadmissibility-on-public-charge-grounds

Dispensary of Hope. (2023). *Dispensary of Hope*. About Dispensary of Hope. https://www.dispensaryofhope.org/about-us

Dorn, S. (2019). Maryland's Easy Enrollment Health Insurance Program: An Innovative Approach to Covering the Eligible Uninsured. *Health Affairs Forefront*. https://doi.org/10.1377/forefront.20190510.993788

Dorn, S., Capretta, J. C., & Chen, L. J. (2018). *Making Health Insurance Enrollment As Automatic As Possible (Part 1)* [dataset]. https://doi.org/10.1377/forefront.20180501.141197

Dorn, S., Garrett, B., & Epstein, M. (2018). New Risk-Adjustment Policies Reduce But Do Not Eliminate Special Enrollment Period Underpayment. *Health Affairs*, *37*(2), 308–315. https://doi.org/10.1377/hlthaff.2017.0970

Duff-Brown, B. (2019, April 15). An unintended consequence of Open Payments database, which reveals physician payments from drug companies. *Stanford University*. https://healthpolicy.fsi.stanford.edu/news/unintended-consequence-open-payments-physician-records

Eibner, C., & Nowak, S. (2018). *The Effect of Eliminating the Individual Mandate Penalty and the Role of Behavioral Factors*. The Commonwealth Fund. https://www.commonwealthfund.org/publications/fund-reports/2018/jul/eliminating-individual-mandate-penalty-behavioral-factors

Eliason, E. L., & Steenland, M. W. (2023). Association of New York State's Marketplace Special Enrollment Period for Pregnancy With Prenatal Insurance Coverage. *JAMA Health Forum*, *4*(1), e224907. https://doi.org/10.1001/jamahealthforum.2022.4907

Emergency Access to Insulin Act of 2023, S. 1497, U.S. Congress 118th (2023). https://www.congress.gov/bill/118th-congress/senate-bill/1497/text?s=1&r=37

Endocrine Society. (2016, September 26). *Experts Recommend Continuous Glucose Monitors for Adults with Type 1 Diabetes*. Endocrine Society. https://www.endocrine.org/news-and-advocacy/news-room/2016/experts-recommend-continuous-glucose-monitors-for-adults-with-type-1-diabetes

Establishes Insulin Assistance Program, A1875, New Jersey Legislature, 220th 2022 Session (2022). A4155 https://www.njleg.state.nj.us/bill-search/2022/A1875

Families First Coronavirus Response Act, H.R. 6201 116-127 (2020). https://www.congress.gov/bill/116th-congress/house-bill/6201/text

FDA. (2020). *Importation Final Rule*. [Docket No. FDA-2019-N-5711}. https://www.hhs.gov/sites/default/files/importation-final-rule.pdf

FDA. (2021, July 9). *Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation; Withdrawal*. Federal Register. https://www.federalregister.gov/documents/2021/07/09/2021-14637/requests-for-proposals-for-insulin-reimportation-and-personal-prescription-drug-importation

FDA Commissioner, O. of the. (2022, November 18). *FDA Roundup: November 18, 2022*. FDA. https://web.archive.org/web/20221118222015/https://www.fda.gov/news-events/press-announcements/fda-roundup-november-18-2022

FDA, Economic Staff. (2020). *Importation of Prescription Drugs: Regulatory Impact Analysis* (FDA-2019-N-5711). U.S. Department of Health & Human Services, Food & Drug Administration. https://www.fda.gov/media/142408/download

Florida Department of Health. (2023, August 2). *Insulin Distribution Program* [Government]. https://www.floridahealth.gov/diseases-and-conditions/diabetes/Insulin.html

Florida Governor's Office, S. (2024, January 5). *Florida Becomes First in the Nation to Have Canadian Drug Importation Program Approved by FDA* [Government]. https://www.flgov.com/2024/01/05/florida-becomes-first-in-the-nation-to-have-canadian-drug-importation-program-approved-by-fda/

Freed, M., Neuman, T., & Cubanski, J. (2021, July 28). 10 FAQs on Prescription Drug Importation. *KFF*. https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/

Fusco, N., Sils, B., Graff, J. S., Kistler, K., & Ruiz, K. (2023). Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A systematic literature review. *Journal of Managed Care & Specialty Pharmacy*, *29*(1), 4–16. https://doi.org/10.18553/jmcp.2022.21270

Galewitz, P. (2021, January 29). *States Look to Import Prescription Drugs From Canada, Awaiting Biden Plan*. U.S. News. https://www.usnews.com/news/best-states/articles/2021-01-29/states-move-ahead-with-canada-drug-importation-while-awaiting-signal-from-biden

Galewitz, P., & Kaiser Health News. (2022, December 14). *States Seek Permissions to Import Prescription Drugs from Canada*. Route Fifty. https://www.route-fifty.com/health-human-services/2022/12/states-seek-permissions-import-prescription-drugs-canada/380888/

Gonzalez, O. (2023, March 17). Pharma lowers insulin costs to save money. *Axios*. www.axios.com/2023/03/17/sanofi-insulin-price-cap-rebate-medicaid

Gov. Hochul, K. (2023). *Achieving the New York Dream: 2023 State of the State*. NYS Governor's Office. www.governor.ny.gov/sites/default/files/2023-01/2023SOTSBook.pdf

Gov Whitmer, G. (2022). *Whitmer Signs Executive Directive Aimed at Lowering Costs, Manufacturing Insulin in Michigan*. State of Michigan, Office of the Governor. https://www.michigan.gov/whitmer/news/press-releases/2022/10/03/whitmer-signs-executive-directive-aimed-at-lowering-costs#:~:text=Whitmer%20Signs%20Executive%20Directive%20Aimed%20at%20Lowering%2

Greene County government. (n.d.). *Health Insurance and Prescription Drug Programs*. Greene Government. Retrieved August 24, 2023, from https://www.greenegovernment.com/greene-government/insurance-prescription-drug-programs

Greene, J. A., & Padula, W. V. (2017). Targeting Unconscionable Prescription-Drug Prices—Maryland's Anti–Price-Gouging Law. *New England Journal of Medicine*, *377*(2), 101–103. https://doi.org/10.1056/NEJMp1704907

Greene, J. A., & Riggs, K. R. (2015). Why Is There No Generic Insulin? Historical Origins of a Modern Problem. *New England Journal of Medicine*, *372*(12), 1171–1175. https://doi.org/10.1056/NEJMms1411398

Gudiksen, K. L., Brown, T. T., Whaley, C. M., & King, J. S. (2018). California's Drug Transparency Law: Navigating The Boundaries Of State Authority On Drug Pricing. *Health Affairs (Project Hope)*, *37*(9), 1503–1508. https://doi.org/10.1377/hlthaff.2018.0424

Harris, J. (2021, December 15). Minnesota insulin affordability law debated at Eighth Circuit. *Courthouse News*. https://www.courthousenews.com/minnesota-insulin-affordability-law-debated-at-eighth-circuit/

Harris, S., & Copeland, W. (2020). *The State of Florida's Preliminary Section 804 Importation Program (SIP) Proposal for the Importation of Prescription Drugs from Canada*. Agency for Health Care Administration. https://www.safemedicines.org/wp-content/uploads/2019/09/SIP-Proposal-to-HHS-11-23-2020.pdf

Hawley, J. E., & Wiseman, S. (2022). *2022 Utah Pharmacy Premium Impact Report*. State of Utah Insurance Department. https://insurance.utah.gov/wp-content/uploads/2022-Pharmacy-Premium-Impact-Report.pdf

Health Care: Prescription Drug Costs., SB-17, California State Legislature 2017–2081 (2017). https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180SB17

Hellpap, A. (2022, October 19). *Affordable Care Act navigator program boosted insurance enrollment in underserved communities*. UW School of Medicine and Public Health. https://www.med.wisc.edu/news-and-events/2022/october/aca-navigator-program-boosted-insurance-enrollment/

Herity, L. B., Upchurch, G., & Schenck, A. P. (2018). Senior PharmAssist: Less Hospital Use with Enrollment in an Innovative Community-Based Program. *Journal of the American Geriatrics Society*, *66*(12), 2394–2400. https://doi.org/10.1111/jgs.15617

Herman, W. H., & Kuo, S. (2021). 100 years of Insulin: Why is Insulin So Expensive and What Can be Done to Control Its Cost? *Endocrinology and Metabolism Clinics of North America*, *50*(3), e21–e34. https://doi.org/10.1016/j.ecl.2021.09.001

Holom-Trundy, B. (2022, July 21). *The New "Easy Enrollment" Program will Lower Barriers to Affordable Health Care—New Jersey Policy Perspective*. https://www.njpp.org/publications/blog-category/the-new-easy-enrollment-program-will-lower-barriers-to-affordable-health-care/, https://www.njpp.org/publications/blog-category/the-new-easy-

enrollment-program-will-lower-barriers-to-affordable-health-care/
Horvath, J. (2019). *State Initiatives Using Purchasing Power to Achieve Drug Cost Containment*. National Academy for State Health Policy. https://nashp.org/wp-content/uploads/2019/04/Rx-Purchasing-Paper-Jane-Horvath-FINAL-4_9_2019.pdf
Hueston, L. (2023, July 27). *The Pharmacy Connection* [Personal communication].
Hung, A., & Sauvageau, G. (2021). Formulary tiers, medication cost sharing, and transparency in bronze and silver qualified health plans in 2014 vs 2018. *Journal of Managed Care & Specialty Pharmacy*, *27*(10), 1332–1340. https://doi.org/10.18553/jmcp.2021.27.10.1332
Hwong, A. R., Sah, S., & Lehmann, L. S. (2017). The Effects of Public Disclosure of Industry Payments to Physicians on Patient Trust: A Randomized Experiment. *Journal of General Internal Medicine*, *32*(11), 1186–1192. https://doi.org/10.1007/s11606-017-4122-y
Illinois Department of Health and Family Services. (2023, April 23). *Health Benefits For Immigrant Seniors* [Government]. Illinois.Gov. https://hfs.illinois.gov/medicalclients/coverageforimmigrantseniors.html
INSULIN Act of 2023 Improving Needed Safeguards for Users of Lifesaving Insulin Now Act of 2023, S.1269, U.S. Congress 118th (2023). https://legiscan.com/US/bill/SB1269/2023
Insulin Safety Net Program, Pub. L. No. Title 32: Professions and Occupations, 303 Title 32, §13725 (2021). https://legislature.maine.gov/statutes/32/title32sec13725.html
Insulins ValYOU Savings Program. (n.d.). Ademelog. Retrieved November 27, 2023, from https://www.admelog.com/savings
International Referenced Rate Pricing for Prescription Drugs, Pub. L. No. Chapter 606, S.P. 520-LD 1636 (2022). https://legislature.maine.gov/ros/LawsOfMaine/breeze/Law/getDocById/?docId=91828
Iowa Department of Health and Human Services. (2023, August 17). *Rural Health and Primary Care—SafeNetRX Program* [Government]. Official State of Iowa Website. https://hhs.iowa.gov/public-health/rural-health/safenetrx
Iowa Pharmacy Association. (2020, July 13). *How PBMs Are Hurting Patients and Communities*. Iowa Pharmacy Association. http://www.iarx.org/blog_home.asp?Display=81
James, L. (2023a, May 2). *Attorney General James Secures Agreement with Insulin Manufacturers to Cap Insulin Prices for Uninsured New Yorkers*. Office of the New York State Attorney General. https://ag.ny.gov/press-release/2023/attorney-general-james-secures-agreement-insulin-manufacturers-cap-insulin
James, L. (2023b, September 8). *Attorney General James Secures Agreement with Insulin Maker Novo Nordisk to Cap Insulin Prices for Uninsured New Yorkers*. https://ag.ny.gov/press-release/2023/attorney-general-james-secures-agreement-insulin-maker-novo-nordisk-cap-insulin
Kang, S.-Y., Sen, A., Bai, G., & Anderson, G. F. (2019). Financial Eligibility Criteria and Medication Coverage for Independent Charity Patient Assistance Programs. *JAMA*, *322*(5), 422. https://doi.org/10.1001/jama.2019.9943
Karen Van Nuys, P., Geoffrey Joyce, P., Rocio Ribero, P., & Dana Goldman, P. (2018). Prescription Drug Copayment Coupon Landscape. *USC- Health Policy*. https://healthpolicy.usc.edu/research/prescription-drug-copayment-coupon-landscape/
KFF. (2022, October 27). 2022 Employer Health Benefits Survey - Section 10: Plan Funding. *KFF*. https://www.kff.org/report-section/ehbs-2022-section-10-plan-funding/
King, M., & Bearman, P. S. (2017). Gifts and influence: Conflict of interest policies and prescribing of psychotropic medications in the United States. *Social Science & Medicine*, *172*, 153–162. https://doi.org/10.1016/j.socscimed.2016.11.010
Law, A. V., Sakharkar, P., Zargarzadeh, A., Tai, B. W. B., Hess, K., Hata, M., Mireles, R., Ha, C., & Park, T. J. (2015). Taking stock of medication wastage: Unused medications in US households. *Research in Social and Administrative Pharmacy*, *11*(4), 571–578. https://doi.org/10.1016/j.sapharm.2014.10.003
Levine, M. (2023). *Unused Drug Repository Report* [Report to the Legislature]. Vermont Department of Health. https://legislature.vermont.gov/assets/Legislative-Reports/Unused-Drug-Respository-2022-Legislative-Report.Final.pdf
Lilly.com | Eli Lilly and Company. (n.d.). Support for Affordable Insulin Solutions. Retrieved November 27, 2023, from https://www.lilly.com/resources/insulin-affordability
Lin, Y., Shao, H., Fonseca, V., & Shi, L. (2023). Exacerbation of financial burden of insulin and overall glucose-lowing medications among uninsured population with diabetes. *Journal of Diabetes*, *15*(3), 215–223. https://doi.org/10.1111/1753-0407.13360
Livingston, S. (2018). *Unused Drug Repository Report to the Vermont Legislature*. Vermont Agency of Human Services. https://legislature.vermont.gov/assets/Legislative-Reports/Unused-Drug-Respository-2022-Legislative-

Report.Final.pdf
Loftis. (2022, December 12). *Utah Insulin Savings Program* [Personal communication].
Lovelace Jr., B. (2023, March 21). *For many insulin users, new price cuts will be a "lifeline."* NBC News. https://www.nbcnews.com/health/health-news/insulin-users-respond-price-cuts-eli-lilly-novo-nordisk-sanofi-rcna75448
Mandell, T. (2022). *State Prescription Drug Repository Fees*.
Massachusetts Health Connector. (n.d.). Special Enrollment Period. *Massachusetts Health Connector*. Retrieved November 27, 2023, from https://www.mahealthconnector.org/get-started/special-enrollment-period
McDermott, K., & Jiang, H. (2020). *Characteristics and Costs of Potentially Preventable Inpatient Stays, 2017.* (Statistical Brief HCUP Statistical Brief #259). AHRQ. https://hcup-us.ahrq.gov/reports/statbriefs/sb259-Potentially-Preventable-Hospitalizations-2017.jsp
McGilroy, C. (2022, June 15). *Close management of diabetes medications lowers medical costs*. Evernorth Health Services. https://www.evernorth.com/articles/optimizing-diabetes-care-cost-adherence
Medicare Made Clear(r). (2023). *Your pharmacist is a valuable Medicare resource*. United Health Care. https://www.uhc.com/news-articles/medicare-articles/pharmacists-answering-your-medicare-prescription-drug-questions
MHDO. (2023, March 15). *Pricing Component Data*. Maine Health Data Organization. https://mhdo.maine.gov/pharma_data_submitters.htm
Mingyan Cong, P., Janet Chaisson, B. S., Dawn Cantrell, B. A., Brice L. Mohundro, P., Mollie Carby, P., Milam Ford, M. P. H., Miao Liu, M. S., Lisa S. Kemp, P., Jason Ouyang, M. D., Yuan Zhang, P., Heath C. Williams, M. B. A., Benjamin V. Vicidomina, B. S., & Somesh C. Nigam, P. (2021). *Association of Co-pay Elimination With Medication Adherence and Total Cost*. *27*. https://www.ajmc.com/view/association-of-co-pay-elimination-with-medication-adherence-and-total-cost
Minnesota Board of Pharmacy. (2023). *Minnesota Insulin Safety Net Program*. Minnesota Board of Pharmacy. https://mn.gov/boards/pharmacy/public/lowercostmedications/insulinsafetynetprogram.jsp
Minnesota House of Representatives. (2021, March 11). *DFL Caucus—Alec's Law helps 465 Minnesotans access Affordable Insulin*. Minnesota Legislature. https://www.house.leg.state.mn.us/Caucus/View/DFL/31433
MMCAP Infuse. (2023, 17). *MMCAP Infuse* [Government]. State of Minnesota. https://infuse-mn.gov/about/index.jsp
Monahan, C. H., Giovannelli, J., & Lucia, K. (2022). *Update on State Public Option-Style Laws: Getting to More Affordable Coverage*. https://doi.org/10.26099/5FJH-KW48
Muhuri, P. K., & Machlin, S. R. (2018). *Treatment and Monitoring of Adults with Diagnosed Diabetes by Race/Ethnicity, 2015-2015* (Statistical Brief 518; Medical Expenditures Panel Survey). Agency for Healthcare Research and Quality. https://meps.ahrq.gov/data_files/publications/st518/stat518.pdf
Mulcahy, A. W., Whaley, C. M., Gizaw, M., Schwam, D., Edenfield, N., & Becerra-Ornelas, A. U. (2021). *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*. RAND Corporation. https://www.rand.org/pubs/research_reports/RR2956.html
Munigala, S., Brandon, M., Goff, Z. D., Sagall, R., & Hauptman, P. J. (2019). Drug discount cards in an era of higher prescription drug prices: A retrospective population-based study. *Journal of the American Pharmacists Association*, *59*(6), 804-808.e1. https://doi.org/10.1016/j.japh.2019.05.021
Murrin, S. (2022). *Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use* (Report in Brief OEI-05-20-00480; Office of Inspector General). U.S. Department of Health and Human Services. https://oig.hhs.gov/oei/reports/OEI-05-20-00480.pdf
Myerson, R., & Li, H. (2021). *Information Gaps and Health Insurance Enrollment: Evidence from the Affordable Care Act Navigator Programs* (SSRN Scholarly Paper 3966511). https://doi.org/10.2139/ssrn.3966511
MyInsulinRx™ Card Registration Result | Novocare®. (n.d.). Retrieved November 27, 2023, from https://www.novocare.com/diabetes/help-with-costs/help-with-insulin-costs/myinsulinrx/result.html
Mykyta, L., & Cohen, R. (2023). *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*. National Center for Health Statistics (U.S.). https://doi.org/10.15620/cdc:127680
NASHP. (2018, February 6). Four More States Submit Bills to Import Prescription Drugs from Canada. *NASHP*. https://nashp.org/four-more-states-submit-bills-to-import-prescription-drugs-from-canada/
NASHP. (2022, December 16). Model Legislation and Contracts: Prescription Drug Pricing. *NASHP*. https://nashp.org/model-legislation-and-contracts-prescription-drug-pricing/
NASHP. (2023, March 13). *Prescription Drug Pricing Transparency Law Comparison Chart*. National Academy For State

Health Policy. https://nashp.org/prescription-drug-pricing-transparency-law-comparison-chart/
National Conference of State Legislatures. (2023, February 28). State Drug Wholesale Importation Programs. *National Conference of State Legislatures*. https://www.ncsl.org/health/state-drug-wholesale-importation-programs
New York Health Foundation. (2023, March 9). *NYHealth Comments on New York's 1332 State Innovation Waiver Application*. New York Health Foundation. https://nyhealthfoundation.org/2023/03/09/nyhealth-comments-on-new-yorks-1332-state-innovation-waiver-application/
New York Health Plan Association. (2023). *S.504 Limiting Insulin Copay*. New York Health Plan Association. https://nyhpa.org/2023/01/s-504-limiting-insulin-copay/
Norris, L. (2022). *State and Federal Programs to Cap Insulin Out-of-Pocket Costs*. Verywell Health. https://www.verywellhealth.com/programs-to-cap-insulin-costs-5667166
North Carolina Department of Health and Human Services. (2023, April 20). *Medication Assistance Program* [Official website of the State of North Carolina]. NCDHHS. https://www.ncdhhs.gov/divisions/office-rural-health/office-rural-health-programs/medication-assistance-program
NY State of Health. (2020). *2020 Open Enrollment Report* (At a Glance). NY State of Health. https://info.nystateofhealth.ny.gov/sites/default/files/2020%20NY%20State%20of%20Health%20Open%20Enrollment%20Report.pdf
NY State of Health. (2021). *Health Insurance Coverage Update*. NY State of Health. https://info.nystateofhealth.ny.gov/sites/default/files/Health%20Insurance%20Coverage%20Update%20-%20September%202021_0.pdf
NY State of Health. (2023a). *Health Insurance Coverage Update—2023*. NY State of Health. https://info.nystateofhealth.ny.gov/sites/default/files/Health%20Insurance%20Coverage%20Update%20-%20April%202023.pdf
NY State of Health. (2023b). *New York Section 1332 Innovation Waiver Essential Plan Expansion*. New York State. https://info.nystateofhealth.ny.gov/sites/default/files/NY%201332%20Waiver%20Application_5.12.2023.pdf
NY State of Health. (2023c). *Navigator Agency Site Locations*. New York State. https://info.nystateofhealth.ny.gov/sites/default/files/July%202023%20Navigator%20Site%20Schedule.pdf
NY State of Health. (2023d, December 18). *NY State of Health 1332 Waiver Information Page | NY State of Health*. https://info.nystateofhealth.ny.gov/1332
NYS DFS. (2022, May 5). *Pharmacy Benefit Managers Guidance*. Department of Financial Services. https://www.dfs.ny.gov/industry_guidance/industry_letters/il20220505_notice_pbm_2902_2904
NYS DFS. (2023a, May). *Health Insurers FAQs: Insulin Cost-Sharing Limit Q&A Guidance*. Department of Financial Services. https://www.dfs.ny.gov/apps_and_licensing/health_insurers/insulin_cost_sharing_qa_guidance
NYS DFS. (2023b, August). *Insulin Cost-Sharing Limit Q&A Guidance*. Department of Financial Services. https://www.dfs.ny.gov/apps_and_licensing/health_insurers/insulin_cost_sharing_qa_guidance
NYS DFS. (2023c, August). *Investigating Drug Price Spikes*. Department of Financial Services. https://www.dfs.ny.gov/industry_guidance/investigating_drug_price_spikes
NYS DFS. (2023d, August). *Pharmacy Benefit Managers*. Department of Financial Services. https://www.dfs.ny.gov/apps_and_licensing/pharmacy_benefit_managers
NYS DOH. (2022, May 11). *New York State Department of Health Announces Eight New York Pharmacies Receive National Accreditation to Provide Diabetes Self-Management Education and Support Services through Grant Provided by the Department*. https://www.health.ny.gov/press/releases/2022/2022-05-11_accreditation.htm
NYS DOH BRFSS. (2017, Data). *Insulin Use, Adults Age 18-64, NYS* [Personal communication].
NYS DOH BRFSS. (2022). *Diagnosed Diabetes, NYS Adults 2020* (Issue Brief 2022–17). NYS DOH. https://www.health.ny.gov/statistics/brfss/reports/docs/2022-17_brfss_diabetes.pdf
Office of Inspector General. (2021, September 1). *III. Physician Relationships With Vendors*. U.S. Department of Health and Human Services. https://oig.hhs.gov/compliance/physician-education/iii-physician-relationships-with-vendors/
Ollove, M. (2023, January 12). More States Are Doing What They Can to Cap Insulin Costs. *Stateline*. https://stateline.org/2023/01/12/more-states-are-doing-what-they-can-to-cap-insulin-costs/
Palanker, D., & Gooding, N. D. (2022). *What Four States Are Doing to Advance Health Equity in Marketplace Insurance Plans* [Issue Brief]. https://doi.org/10.26099/04cc-ab65
PEHP. (2020). *Utah Insulin Savings Program*. Utahinsulin.Net. https://www.utahinsulin.net/
Percent of private-sector enrollees that are enrolled in self-insured plans table. (Table II.B.2.b.(1)). (2020). [Summary Table]. Agency for Healthcare Research and Quality.

https://meps.ahrq.gov/data_stats/summ_tables/insr/state/series_2/2020/tiib2b1.pdf
Pharmaceutical Care Management Association v. Nizar Wehbi, in His Official Capacity as the State Health Officer of ND; Mark J. Hardy and Tyler Lannoye, in Their Official Capacity on the ND Board of Pharmacy; ; Wayne Stenehjem, in His Official Capacity as the Attorney General of North Dakota, 18-2926 (U.S. Court of Appeals for the Eighth Circuit November 17, 2021). https://ecf.ca8.uscourts.gov/opndir/21/11/182926P.pdf
Pharmaceutical Research & Manufacturers of America et al., v. Department of Health & Human Services et al., : Civil Action, 20-3402 (U.S. District Court for the District of Columbia November 23, 2020). https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2020cv3402-46
Pharmaceutical Research and Manufacturers of America v. Elizabeth Landsberg, 21-16312 (U.S. Court of Appeals for the Ninth Circuit July 25, 2022). https://cases.justia.com/federal/appellate-courts/ca9/21-16312/21-16312-2022-07-25.pdf?ts=1658779237
Pharmaceutical Research and Manufacturers of America v. Stuart T. Williams; Stacey Jassey; Mary Phipps; Andrew Behm; James Bialke; Amy Paradis; Rabih Nahas; Samantha Schirmer; Kendra Metz, All in Their Official Capacities as Members of the Minnesota Board of Pharmacy, 21-1731 (U.S. Court of Appeals for the Eighth Circuit April 3, 2023). https://www.uschamber.com/assets/documents/Opinion20-20PhRMA20v.20Williams2028Eighth20Circuit29.pdf
Pharmacy Benefits Managers - Prohibited Actions, SB0896, Maryland General Assembly 2023 Regular Session (2023). https://mgaleg.maryland.gov/2023RS/bills/sb/sb0896f.pdf
PhRMA. (n.d.). *Setting Up A Pharmaceutical Manufacturing Process and Supply Chain: A Complex & Lengthy Undertaking*. Retrieved June 15, 2023, from ttps://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/S-U/Setting-Up-A-Pharmaceutical-Manufacturing-Process-and-Supply-Chain-A-Complex-and-Lengthy-Undertaking.pdf
Physicians and Surgeons: Payments: Disclosure: Notice., Chapter 750, Statutes of 2022 § 1. Article 6.5, Chapter 1 of Division 2 of the Business & Professions Code (2022). https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=202120220AB1278&showamends=false
Pickett, B., Shin, T. R., & Norton, M. (2023). Utilizing clinical pharmacists and a medication assistance program to improve medication access for indigent and underserved patients in primary care. *Exploratory Research in Clinical and Social Pharmacy*, *9*, 100211. https://doi.org/10.1016/j.rcsop.2022.100211
Pistor, J. (2022, December 19). *Health Care Bills in 2022 Took On Costs, Coverage and Delivery*. National Conference of State Legislatures. https://www.ncsl.org/state-legislatures-news/details/health-care-bills-in-2022-took-on-costs-coverage-and-delivery
Pollitz, K., Tolbert, J., Hamel, L., & Kearney, A. (2020). *Consumer Assistance in Health Insurance: Evidence of Impact and Unmet Need*. KFF. https://www.kff.org/report-section/consumer-assistance-in-health-insurance-evidence-of-impact-and-unmet-need-issue-brief/
Premium Assistance. (n.d.). *Center for Innovation in Social Work & Health*. Retrieved August 26, 2023, from https://ciswh.org/project/the-catalyst-center/financing-strategy/premium-assistance/
Priced Out of A Lifesaving Drug: The Human Impact of Rising Insulin Costs: Hearing on 116–21 before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives 116th Congress (2019). https://www.congress.gov/event/116th-congress/house-event/109299
Provides for Patient Prescription Pricing Transparency, A2200, New York Assembly (2023). https://legiscan.com/NY/bill/A02200/2023
Ravitz, G., Ravitz, J., Hoffmeister, D., Yin, E., Gadiock, P., & Upadhyayula, S. (2022, June 22). *FDA Issues Guidance on Importing Drugs from Canada*. Wilson Sonsini Goodrich & Rosati Professional Corporation. https://www.wsgr.com/en/insights/fda-issues-guidance-on-importing-drugs-from-canada.html
Raymond, Nate. (2018, April 13). U.S. appeals court strikes down Maryland drug price-gouging law. *Reuters*. https://www.reuters.com/article/us-drugs-pricing-maryland/u-s-appeals-court-strikes-down-maryland-drug-price-gouging-law-idUSKBN1HK2FS
Reduce Insulin Prices, HB19-1216, Colorado General Assembly 2019 Regular Session (2019). https://leg.colorado.gov/bills/hb19-1216
Refki, D., Ahmed, R., & Altarriba, J. (2021). Closing the Health Disparity Gap in U.S. Immigrant Communities in the Era of COVID-19: A Narrative Review. *Understanding and Eliminating Minority Health Disparities in a 21st-Century Pandemic: A White Paper Collection*. https://scholarsarchive.library.albany.edu/covid_mhd_nys_white_papers/12
Relates to Creating a Wholesale Prescription Drug Importation Program, S604, New York State Senate 2023-2024 Legislative Session, Art 2-1, Title 2, S280-d (2023). https://www.nysenate.gov/legislation/bills/2023/S604

Relates to Prescribing Insulin and Related Supplies, S4000, New York State Senate 202102022 Legislative, Public Health & Education Law (2021). https://www.nysenate.gov/legislation/bills/2021/S4000

Relating to Licensing Pharmaceutical Representatives, SB 763, Oregon Legislative Assembly, 81st 2021 Regular Session (2021). https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/SB0763/Enrolled

Richardson, E. (2014). The Physician Payments Sunshine Act. *Health Affairs*. https://doi.org/10.1377/hpb20141002.272302

Roberts, D. (2019). The Deadly Costs of Insulin. *AJMC*. https://www.ajmc.com/view/the-deadly-costs-of-insulin

Rodwin, M. (2019). Conflict of Interest in the Pharmaceutical Sector: A Guide for Public Management. *DePaul Journal of Health Care Law*, *21*(1). https://via.library.depaul.edu/jhcl/vol21/iss1/3

Rome, B. N., Feldman, W. B., Desai, R. J., & Kesselheim, A. S. (2021). Correlation Between Changes in Brand-Name Drug Prices and Patient Out-of-Pocket Costs. *JAMA Network Open*, *4*(5), e218816. https://doi.org/10.1001/jamanetworkopen.2021.8816

Rutledge, Attorney General of Arkansas v. PCMA, 18–540 (Supreme Court of the United States December 10, 2020). https://www.supremecourt.gov/opinions/20pdf/18-540_m64o.pdf

Rutledge, Attorney General of Arkansas v. Pharmaceutical Care Management Association, 17-1609, 17-1629 (United States Court of Appeals For the 8th Circuit June 8, 2018). https://caselaw.findlaw.com/court/us-8th-circuit/1898787.html

Sayed, B. A., Finegold, K., Olsen, T. A., De Lew, N., Sheingold, S., Ashok, K., & Sommers, B. D. (2023). *Insulin Affordability and the Inflation Reduction Act: Medicare Beneficiary Savings by State and Demographics* (HP-2023-02). ASPE. https://aspe.hhs.gov/reports/insulin-affordability-ira-data-point

Schwab, R., Corlette, S., & Lucia, K. (2021, January 28). Many States with COVID-19 Special Enrollment Periods See Increase in Younger Enrollees. *The Commonwealth Fund*. https://doi.org/10.26099/xbfq-aw91

Sen. Grassley, C., & Sen. Wyden, R. (2021). *Insulin: Examining The Factors Driving The Rising Cost of a Century Old Drug* (pp. 116–151) [Staff Report]. United States Senate, Committee on Finance. https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf

Sen. Skoufis, J., & Sen. Rivera, G. (2019). *Final Investigative Report: Pharmacy Benefit Managers in New York* [Investigative Report]. NYS Senate. https://www.nysenate.gov/sites/default/files/article/attachment/final_investigatory_report_pharmacy_benefit_managers_in_new_york.pdf

Sen. Warren, E., Sen. Blumenthal, R., & Sen. Warnock, R. (2023). *Unaffordable Insulin: Uninsured Americans Still Face High Costs at the Pharmacy Counter for Eli Lilly's Authorized Generic*. United State Senate. https://www.warren.senate.gov/imo/media/doc/Report%20on%20Insulin%20for%20Uninsured%20Patients%20-%2007.12.2023%20(updated)1.pdf

Sen. Wiener, S. (2022, January 18). *Senator Wiener Introduces Legislation To Cap the Price of Life-Saving Insulin*. Senator Scott Wiener. https://sd11.senate.ca.gov/news/20230118-senator-wiener-introduces-legislation-cap-price-life-saving-insulin

Shao, H., Guan, D., Fonseca, V., Shi, L., Basu, A., Pop-Busui, R., Ali, M. K., & Brown, J. (2022). Economic Evaluation of the $35 Insulin Copay Cap Policy in Medicare and Its Implication for Future Interventions. *Diabetes Care*, *45*(11), e161–e162. https://doi.org/10.2337/dc22-1230

Shepherd, J. (2020). Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs. *Yale Law & Policy Review*. https://openyls.law.yale.edu/bitstream/handle/20.500.13051/17295/auto_convert.pdf?sequence=3&isAllowed=y

Siddiqui, F. (2023, February 13). The Canadian Drug Importation Rule Survives Industry Challenge, But Don't Expect Canadian Drugs at Your Pharmacy Just Yet. *FDA Law Blog*. https://www.thefdalawblog.com/2023/02/the-canadian-drug-importation-rule-survives-industry-challenge-but-dont-expect-canadian-drugs-at-your-pharmacy-just-yet/

SIRUM. (2023, May 23). *SIRUM - Saving Medicine: Saving Lives*. SIRUM. https://sirum.org/impact/

Staff NASHP, N. (2020, July 6). Q&A: A Model Act to Prevent Excessive and Unconscionable Prices for Prescription Drugs. *NASHP*. https://nashp.org/qa-a-model-act-to-prevent-excessive-and-unconscionable-prices-for-prescription-drugs/

Staff NASHP, N. (2021, February 13). States Take Diverse Approaches to Drug Affordability Boards. *NASHP*. https://nashp.org/states-take-diverse-approaches-to-drug-affordability-boards/

Staff, NCSL. (n.d.). *State Prescription Drug Repository Programs*. National Conference of State Legislatures. Retrieved August 24, 2023, from https://www.ncsl.org/health/state-prescription-drug-repository-programs

Staff, NCSL. (2022, March 23). *State Policy Options and Pharmacy Benefit Managers (PBMs)*. National Conference of State Legislatures. https://www.ncsl.org/health/state-policy-options-and-pharmacy-benefit-managers

State of Rhode Island. (2021). *Governor McKee Signs Prescription Drug Affordability Bills*. State of Rhode Island. https://governor.ri.gov/press-releases/governor-mckee-signs-prescription-drug-affordability-bills

Suran, M. (2023). All 3 Major Insulin Manufacturers Are Cutting Their Prices—Here's What the News Means for Patients With Diabetes. *JAMA*, *329*(16), 1337. https://doi.org/10.1001/jama.2022.11688

Texas Department of State Health Services. (2022, December 19). *Prescription Drug Donation Program*. Texas Department of State Health Services. https://www.dshs.texas.gov/sites/default/files/pharmacy/Prescription%20Drug%20Donation%20Program%20Participating%20Provider%20Database.pdf

The Congressional Digest. (2019). Pros & Cons of Drug Imports from Canada: Federal and State Importation Proposals to Lower Drug Costs. *The Congressional Digest*, *98*(10), 31.

The Health Strategies Consultancy LLC. (2005). *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*. KFF. www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf

TI International. (2023). *Kevin's Law Fact Sheet*. TI International. https://www.t1international.com/media/assets/file/Kevins_Law_Fact_Sheet.pdf

Tolbert, J., Diaz, M., Hall, C., & Mengistu, S. (2019). *State Actions to Improve the Affordability of Health Insurance in the Individual Market* [Issue Brief]. KFF. https://www.kff.org/wp-content/uploads/2019/07/Issue-Brief-State-Actions-to-Improve-the-Affordability-of-Health-Insurance-in-the-Individual-Market.pdf

Tran, N. L. (2022). *Prescription Drug Pricing and Cost Transparency in California*. California Research Bureau, California State Library. https://www.library.ca.gov/wp-content/uploads/crb-reports/Prescription_Drug_Pricing_and_Cost_Transparency_in_California-Oct_2022.pdf

Tulsa County Social Services. (2023, August 17). *Tulsa County Social Services* [Government]. Tulsa County Social Services. https://www2.tulsacounty.org/government/departments-offices/social-services/

Upchurch, G. (2022). *Senior PharmAssist Annual Report FY 22*. Senior PharmAssist. https://static1.squarespace.com/static/5dc889428f8a511234bb4dad/t/62f5b8925cba13124674e4ff/1660270738840/FY22+Annual+Report.pdf

Upchurch, G. (2023, June 7). *Senior PharmAssist* [Personal communication].

Update the Regulation of Pharmacy Benefit Managers, Pub. L. No. Chapter 164, Chapter 164 (2021). https://www.wvlegislature.gov/Bill_Status/bills_history.cfm?INPUT=2263&year=2021&sessiontype=RS

Upstate University Hospital. (2023). *Financial Assistance Program, Outpatient Pharmacy*. Upstate University Hospital. https://www.upstate.edu/outpatient-pharmacy/programs/med-assistance.php

U.S. Economic Development Administration. (2023). *American Rescue Plan: Build Back Better Regional Challenge Awardees Fact Sheet*. U.S. Economic Development Administration. https://www.eda.gov/sites/default/files/2022-09/Build-Back-Better-Announcement-Awardee-Fact-Sheet.pdf

Van Nuys, K., Ribero, R., Ryan, M., & Sood, N. (2021). Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018. *JAMA Health Forum*, *2*(11), e213409. https://doi.org/10.1001/jamahealthforum.2021.3409

Vargas, A. R., Soucy, C., Rehfield-Griffith, N., & Parra, S. (2022). *Prescription Drug Price Transparency Results and Recommendations—2022*. Department of Consumer and Business Services. https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2022.pdf

Vermont Attorney General's Office. (2022). *Attorney General's Report on Prescription Drug Cost Transparency*. Vermont Attorney General's Office. https://legislature.vermont.gov/assets/Legislative-Reports/2022-12-1-AGO-Pharma-Cost-Transparency-Report-to-Legislature.pdf

Vermont's Canadian Wholesale Importation Program for Prescription Drugs: Concept Paper. (2019). NASHP.org. https://nashp.org/wp-content/uploads/2019/12/vt-submittal-to-omb-12-3-2019.pdf

Virginia Health Care Foundation. (2023, July 26). *The Pharmacy Connection*. Virginia Health Care Foundation. https://www.vhcf.org/for-those-who-help/the-pharmacy-connection/

Washington Health Plan Finder. (n.d.). *Immigrants*. Washington Health Plan Finder. Retrieved November 27, 2023, from https://www.wahealthplanfinder.org/us/en/health-coverage/who-can-sign-up/immigrants.html

Washington State Health Care Authority. (2022). *Drug Price Transparency (DPT) program—Annual Report 2022* (pp. 1–34) [Annual]. Washington State Health Care Authority. https://www.hca.wa.gov/assets/program/hca-dpt-annual-report-2022.pdf

Washington State Health Care Authority. (2023). *Drug Price Transparency (DPT) program—Annual Report 2023*. Washington State Health Care Authority. https://www.hca.wa.gov/assets/billers-and-providers/drug-price-transparency-annual-report-2023.pdf

Wedenoja, L. (2022, February 28). *Causes of Mortality in New York State – Rockefeller Institute of Government*. https://rockinst.org/blog/causes-of-mortality-in-new-york-state/

Winter, D. (2020, February 26). *House passes bill to create insulin assistance program—Session Daily—Minnesota House of Representatives*. Minnesota Legislature. https://www.house.leg.state.mn.us/SessionDaily/Story/14112

Wisconsin Pharmacy Cost Study Committee. (2020). *Wisconsin Pharmacy Cost Study Committee Report*. Wisconsin.gov. https://rxdrugtaskforce.wi.gov/Documents/WI_Pharmacy_Cost_Study_Committee_Final_Report.pdf

Wyoming Department of Health. (2023). *Wyoming Medication Donation Program*. Wyoming Department of Health. https://health.wyo.gov/healthcarefin/medicationdonation/

Yu, T., Jin, S., Li, C., Chambers, J. D., & Hlávka, J. P. (2023). Factors Associated with Biosimilar Exclusions and Step Therapy Restrictions Among US Commercial Health Plans. *Biodrugs*, *37*(4), 531–540. https://doi.org/10.1007/s40259-023-00593-7