American Diabetes Association®

Barriers to Insulin: Impact of Utilization Management on Access to Insulin

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1. INTRODUCTION

a. Paper Overview

i. Paper Purpose, Objective, and Populations of Focus: Commercial Insurance Beneficiaries

This comprehensive research and analysis project is aimed at illustrating the importance of patient and prescriber choice in insulin treatment and how utilization management undermines choice, using inhaled insulin as an example. To help illustrate this, the paper will highlight patient preferences and health outcome benefits of inhaled insulin. It will also assess prescribing practices, highlighting the key reasons for providers to choose inhaled insulin and the barriers that utilization management processes, including step therapy, pose to patient access in the commercial insurance market. In addition to illustrating the impact of utilization barriers on access to inhaled insulin, the paper will suggest policy changes to elevate patient and prescriber choice in insulin treatment in the commercial market.

ii. About the ADA

The American Diabetes Association® (ADA) is a nationwide nonprofit voluntary health organization founded in 1940. It comprises people with diabetes, health care professionals, research scientists, nearly 350 staff members, and other concerned stakeholders. The ADA's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. The ADA, the largest non-governmental organization that deals with the treatment and impact of diabetes, represents the 136 million individuals living with diabetes or prediabetes in the United States. The ADA also reviews and authors the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes and publishes the most influential professional journals concerning diabetes research and treatment.[1] The ADA also announced that it will be releasing the first *Standards of Care for Obesity* for the management of obesity over the course of this year.

iii. Paper Executive Summary

This white paper examines how utilization management (UM) practices in the commercial insurance market and other barriers impact patient and prescriber access to inhaled insulin (a rapid-acting insulin option for people with diabetes), and the implications for other newer and more expensive types of insulin. The analysis focuses on the experiences of patients and their

[1] The Association publishes five professional journals with widespread circulation: (1) Diabetes (original scientific research about diabetes); (2) Diabetes Care (original human studies about diabetes treatment); (3) Clinical Diabetes (information about state-of-the-art care for people with diabetes); (4) BMJ Open Diabetes Research & Care (clinical research articles regarding type 1 and type 2 diabetes and associated complications); and (5) Diabetes Spectrum (review and original articles on clinical diabetes management).

healthcare providers, how UM or other factors can negatively impact access, how these access barriers can affect a patient's health, and potential reforms that policymakers can consider to address these barriers.

The paper outlines the benefits of inhaled insulin, including its unique delivery method and potential to improve patient adherence and satisfaction, particularly for those who face challenges with injectable insulin. Despite these advantages, inhaled insulin faces significant barriers to access due to restrictive UM tools commonly employed by commercial insurers. Such practices are primarily designed to manage costs but often result in delays, increased administrative burden, and, in many cases, outright denials of coverage for inhaled insulin.

Through a review of prescribing patterns and patient preferences, the paper demonstrates that UM barriers can undermine optimal diabetes management by limiting the availability of clinically appropriate treatment options. The resulting restrictions not only affect health outcomes but also contribute to increased frustration and disease management burden for both patients and providers.

The ADA calls for policy reforms to ensure that commercial insurance beneficiaries have equitable access to all FDA-approved insulin products, including inhaled insulin. Recommendations include limiting the use of restrictive UM tools, ensuring transparent and clinically justified formulary decisions, and otherwise prioritizing patient and provider choice in diabetes care. By addressing these barriers, the ADA believes that health systems can better support individualized diabetes management and improve the overall quality of care for people living with diabetes.

This paper is not intended to endorse any one insulin product, type, or delivery method over another. Instead, this paper focuses on inhaled insulin, as this type of insulin is often subjected to some of the highest UM restrictions, making inhaled insulin an effective case study for understanding the barriers that may impact other newer and more expensive forms of insulin.

The ADA takes the position that there is no single insulin product that will always be the most appropriate option for all patients. Instead, patients and their providers need broad insulin access to select what works best for them. Therefore, this paper does not argue that access to a single and specific insulin product should be improved, but that access *to all insulin therapies should be improved and made more equal*, highlighting the importance of patient and prescriber choice in insulin therapy.

b. Table of Contents

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c. Glossary

i. Regulatory Terminology

- FDA Definition of Insulin: Insulin is the active principle of the pancreas that affects the metabolism of carbohydrates in the body, and which is of value in the treatment of diabetes. The term includes synthetic and biotechnologically derived products that are the same as, or similar to, naturally occurring insulins in structure, use, and intended effect.[i]

ii. Coverage, PBM Formulary, and Utilization Management Terminology

- Formulary/Preferred Drug List (PDL): A list of medications covered by a health insurance plan. A plan formulary outlines the policies on coverage of drugs based on factors such as medical appropriateness, clinical performance, cost, etc.[ii] Formulary goals are often advanced through utilization management tools.

- Utilization Management (UM)/UM Tools: In the context of pharmacy benefits, UM tools are the policies and restrictions health plans use to determine how and whether certain drugs are covered, based on factors such as medical appropriateness, clinical performance, cost, etc. UM tools are regularly used to manage and reduce plan costs but can negatively impact patient access and care. UM tools and other management practices or formulary designs that are commonly used include prior authorization (PA), step therapy, refill-too-soon measures, quantity limits, step edits, drug exclusions, formulary tiering, and therapeutic interchange and mandatory generic substitution.[iii]

    - Prior Authorization (PA): PAs require prescribers to receive pre-approval for certain drugs before plan coverage applies. PAs outline when the use of a medication is appropriate, the health conditions that a patient must have to necessitate coverage,

documentation that needs to be provided, etc.[iv]

- Step Therapy/Step Edits/"Fail First": Step therapy requires patients first try certain lower cost medications (first-line drugs), and only once that initial therapy fails will coverage for the alternative/preferred medication the patient was initially trying to access (second-line drug) be covered. [v]

- Formulary Exclusion List: A list of specific drugs that are not covered by a plan.[vi] If a patient's provider prescribes a medication that is on the exclusion list, they will likely have to pay for the prescribed medication entirely out of pocket unless they can successfully appeal or obtain an exception. A formulary exception request is where a patient or their provider asks for the insurance company to cover the non-formulary drug, often by submitting documentation explaining why the excluded medication is medically necessary.[vii] While it varies from case to case (based on the plan, the specific medical product, and/or other factors), the option of filing an exception request is not always available.

- Formulary Tiering: The practice of organizing drugs into different coverage tiers to establish different levels of coverage and patient out-of-pocket (OOP) costs for various drugs. Generally, lower cost medications are placed into lower tiers (preferred access tiers), while higher cost medications are placed in higher tiers with greater patient OOP cost responsibility.

- Therapeutic Interchange and/or Mandatory Generic Substitution: The practice of substituting a drug (the initial drug ordered by the provider), often with a cheaper but similar alternative drug. [viii] Therapeutic interchange and mandatory generic substitution are both medication substitution practices, with the difference being the degree to which the substitution is chemically and/or biologically the same as the product being substituted. Mandatory generic substitution involves the substitution of one product with a therapeutically equivalent product (e.g., same active drug content/generic drug), whereas therapeutic interchange involves a substitution of one product for another that is understood to have a substantially equivalent therapeutic effect (e.g., different active drug constituents, but understood to have the same effect/within class substitution).[ix]

- Quantity Limits (QLs) and Refill-Too-Soon Edits/Measures/Rejections: The maximum amount of a certain medication the plan is willing to cover over a certain period of time (e.g. a plan restriction specifying that only 30 pills, doses, or a specified number of units of the medication will be covered per month).[x] These rules require a patient to wait a certain amount of time before they can refill a prescription. Individuals who try to fill a prescription before reaching their refill allowance will have their claims rejected under the plan's "refill too soon" measures (or a "refill too soon" rejection, also called a "refill too soon" edit.).[xi]

- Real-Time Prescription Benefit Tools (RTBTs)/Automated Decision Support Tools: RTBTs are electronic clinical decision support tools that provide prescribers with patient-specific medication cost and coverage information at the point of prescribing in real-time. RTBTs can

be used by providers to navigate UM barriers established by a patient's health plan, thereby reducing the risk of prescription abandonment by patients once they reach the pharmacy/dispenser. In particular, RTBTs are well-positioned to streamline the PA process, as RTBTs allow a provider to determine what PA requirements a patient must meet at the time of the clinical visit, rather than at the time of the pharmacy visit.[xii] RTBTs can also be used to help navigate other UM or cost barriers by helping a provider select an alternative medication that is more adequately covered with fewer formulary restrictions.[xiii]

iii. Inhaled Insulin and Traditional Insulin Terminology (Delivery Differences and Terms)

- Types of Insulin: Insulin types (e.g., rapid-acting (inclusive of inhaled insulin), regular/short-acting, intermediate-acting, long-acting, and ultra-long-acting)[xiv] are generally categorized by differences in onset, peak, duration, concentration, and route of delivery.[xv] Inhaled insulin is currently only available in rapid-acting form (fast absorption into the bloodstream), making it a bolus/prandial insulin product.

    - Onset: How fast the insulin product begins to lower blood glucose.
    - Peak: How long it takes for the insulin product to reach its maximum clinical effect.
    - Duration: How long the insulin works to lower blood glucose.
    - Route of Delivery: Whether the insulin product is injected under the skin, given intravenously, inhaled, etc. The primary methods for administering insulin include:

        - Injected Insulin (Subcutaneous Delivery Under the Skin)/Injection:[xvi] Injectable insulin represents the traditional route of insulin delivery used by most people with diabetes in the ambulatory care setting (which includes use of syringes, pens, and insulin pumps).

        - Inhaled Insulin:[xvii] Inhaled insulin is an insulin in powder form that can be inhaled to manage blood glucose.[xviii] Inhaled insulin is administered via an oral inhaler (applied to the mouth and breathed into the lungs).

- Bolus/Prandial Insulin/"Mealtime" Insulin: Insulin products typically administered with meals (e.g., rapid-acting (inclusive of inhaled insulin), and regular/short-acting) that are mainly intended to manage glucose spikes (generally due to eating).[xix] Bolus insulin is commonly taken at or before meals or snacks, and/or for other situations where a "correction dose" is needed to bring elevated blood glucose levels back to the desired target range. Outside of eating, the presence of elevated blood glucose levels (hyperglycemia) may necessitate the use of correction doses of bolus insulin, and may occur due to stress, dehydration, physical inactivity, illness, hormonal fluctuations, medication interactions or side effects, etc.[xx]

- Basal Insulin/"Background" Insulin: Longer acting insulin products (e.g., intermediate-acting, long-acting, and ultra-long-acting) that are primarily used to maintain blood glucose at target levels between meals and overnight (except for mealtime periods when bolus insulin is needed). Basal insulin is commonly taken once or twice per day, depending on the insulin product used.[xxi]

iv. Clinical and Other Terminology

- Blood Glucose: The main source of energy food is turned into that is found in the blood.[xxii] Blood glucose levels are used as a measure of the amount or concentration of glucose present in the blood at a given point in time. Blood glucose levels serve as a key indicator of how well the body regulates sugar. Blood glucose is measured in mmol/L (millimoles per liter) or mg/dL (milligrams per deciliter).

- Hypoglycemia/Low Blood Glucose: Hypoglycemia is a condition where a person's blood glucose level drops below a healthy range (defined as a blood glucose value <70 mg/dL). Hypoglycemia is treated by bringing their blood glucose back to normal ranges using sources of glucose (e.g., glucose tablets or glucose-containing foods) or medication. Hypoglycemia can cause a wide range of negative effects. Mild hypoglycemia can cause shakiness, dizziness, confusion, headache, etc. Severe hypoglycemia can lead to seizures, loss of consciousness, etc.[xxiii]

- A1C/Hemoglobin A1C (A1C)/Glycated Hemoglobin/A1C Test: An A1C test is a blood test that measures a person's average blood glucose level over the preceding two to three months. A1C tests are often used to assess a person's level of glucose management or to diagnose diabetes. Hemoglobin is the part of a red blood cell that carries oxygen to the cells, which joins with glucose in the bloodstream (known as "glycation"). Also called hemoglobin A1C or glycosylated hemoglobin, the test shows the amount of glucose bound to the red blood cell, which is proportional to the amount of glucose in the blood over the preceding two to three months.[xxiv] The following A1C ranges are used to diagnose prediabetes and diabetes:
    - Normal: below 5.7%
    - Prediabetes: 5.7% to 6.4%
    - Diabetes: 6.5% or above[xxv]

- Glucagon: A hormone produced by the alpha cells in the pancreas. It raises blood glucose. Injectable and nasal forms of glucagon, available by prescription, are used to treat severe hypoglycemia.[xxvi]

- Insulin: A hormone produced by the beta cells of the pancreas that helps the body use glucose for energy. Exogenous insulin is used clinically to manage blood glucose in all people with type 1 diabetes and some with type 2 diabetes to manage blood glucose.[xxvii] For the purposes of simplicity, the terms "insulin" and/or "insulin product" will often be used in this paper to refer to the medication (manufactured insulin), rather than the hormone (insulin produced by one's body).

- Lipoatrophy: Loss of fat under the skin, resulting in small dents. Lipoatrophy may be caused by repeated injections of insulin in the same spot.[xxviii]

- Lipodystrophy: Caused by the breaking down or building up of fat below the surface of the skin, resulting in lumps or small dents in the skin surface. Lipodystrophy may be caused by repeated injections of insulin in the same spot.[xxix]

- Lipohypertrophy: Buildup of fat below the surface of the skin, causing lumps. It may be caused by repeated injections of insulin in the same spot.[xxx]

- Disease Management Burden: The challenges that people and those who support them (professional providers, non-professional caregivers, etc.) face when managing a disease, including but not limited to:
    - The time and effort required for diagnosis
    - Treatment and care
    - The level of discomfort
    - Inconvenience
    - Life disruptions caused by the treatment process
    - A broad range of other social, emotional, psychological, and/or financial impacts[xxxi]

- Type 1 Diabetes: A condition characterized by high blood glucose (hyperglycemia) levels caused by a lack of insulin production by beta cells of the pancreas. Type 1 diabetes occurs when the body's immune system attacks the insulin-producing beta cells in the pancreas and destroys them. The pancreas then produces little or no insulin. Type 1 diabetes characteristically develops in young people but can be diagnosed at any age.[xxxii]

- Type 2 Diabetes: A condition characterized by high blood glucose (hyperglycemia) levels caused by the body's inability to use insulin efficiently and/or a lack of insulin production. Type 2 diabetes develops most often in middle-aged and older adults but can appear in young people.[xxxiii]

- Time in Range (TIR): Time in range is the amount of time a person with diabetes spends in the recommended blood glucose range, which is between 70 and 180 mg/dL for most people.[xxxiv]

2. UTILIZATION MANAGEMENT BACKGROUND

a. Utilization Management Explained

Health insurance plans establish their drug coverage policies through formularies. Formulary goals are often advanced through utilization management (UM) tools, as UM is broadly understood to be a major cost management strategy in the context of health care delivery and payment.[xxxv] The application of UM tools in plan formularies has been broadly adopted by managed care organizations (MCOs) such as health plans and pharmacy benefit managers (PBMs).[xxxvi]

In contrast to public insurance programs such as Medicare and Medicaid, where coverage policies are often heavily regulated by the government, commercial plans have relatively broad authority under state and federal law to establish their drug formulary designs and the relevant UM tools applicable to each drug. Although there are some federal laws that curtail a commercial plan's ability to limit access to certain medical products or services (e.g., under the Affordable Care Act, most commercial plans are required to cover certain recommended preventive

services without any patient cost-sharing),[xxxvii] these laws generally do not restrict UM tool utilization outside of the specific types of products or services protected by federal law, such as the ACA's Essential Health Benefits or EHB list, or otherwise apply to or protect insulin access.

As will be explained in a later section, due to the limited level of federal UM regulation of commercial plans, some states have tried to be more proactive in limiting UM tool use for drugs generally and/or for insulin specifically. However, these state actions oftentimes have limited success due to (among other things) preemption under federal law.

The broad use of UM tools by commercial insurance plans is due to how effective these tools are in limiting patient access to certain (often costly) medical resources. In general, the more UM tools applied against a certain drug, the harder it will be for the patient to successfully get the drug covered by their plan, and the less likely they are to gain access to the drug at all. UM tools can operate as a barrier by delaying access, imposing additional justification or documentation requirements, increasing the portion of the cost the patient must bear, etc.

UM tools have existed in one form or another for many decades. Since the 1900s, health care utilization controls initially focused on provider-side activities, with UM tools and prescription drug formularies becoming more common during the later parts of the 1900s. Due to the broader adoption of UM tools and ever-increasing drug costs, prescription drug formularies have steadily evolved to more sophisticated systems incorporating features like step therapy, prior authorization, quantity limits, and complex tiered pricing structures.

Over the last couple of decades, there has been a rapidly growing adoption of UM tools. In response to growing pharmacy spending in Medicaid, most states instituted preferred drug lists (PDLs), PA policies, and/or other pharmacy cost-containment strategies.[xxxviii] For Medicare, between 2011 and 2020, the average percentage of restricted drugs in Part D plans increased from 31.9% to 44.4%.[xxxix] Similar patterns have been seen in commercial insurance plans. One report on coverage policies of certain drugs (including certain diabetes drugs) indicated for use within 12 therapeutic areas (TAs), found that UM tools in the commercial market increased from 2014–2020, and led to reduced patient access.[xl]

b. Utilization Management Impact on Insulin Use and People with Diabetes

UM tools can restrict access and make it more difficult for patients to get the necessary medications they need. This can be harmful for patients with any disease, but the impact can be especially severe on people with diabetes managed with insulin therapy, many of whom cannot safely forgo regular insulin administration.

Improvements to insulin and other glucose-lowering therapies over the past 100 years have largely been aimed at improving three core areas: safety, efficacy, and/or reducing disease management burden. UM tools can negatively impact all three core goals (additional detail is provided in section 4):

- **Safety and Efficacy**: As is often true for other drug classes, not all forms of insulin result in the same clinical effects for people with diabetes. There is no single insulin product or other drug that will always be the most appropriate option for all patients. Instead, patients and their providers need broad drug access to select what works best for them. There is limited public access to UM tool development or plan Pharmacy and

Therapeutics (P&T) Committee meeting decisions, and so it is unclear whether plans are placing costs before patient needs. In practice, UM tools can:
    - Interrupt treatment via delays in access, potentially leading to suboptimal glycemic management
    - Preferentially drive access to less expensive products that might not be the most clinically appropriate for the patient
    - Force a person with diabetes to try different insulin products first to gain coverage to their preferred insulin (step therapy)
    - Etc.
- **Reducing Disease Management Burden**: Newer insulin products can provide added convenience and lifestyle advantages, which can improve patient wellbeing and have a meaningful clinical impact (e.g., increased medication adherence). However, newer brand insulin products are often more expensive than other glucose-lowering agents on plan formularies and are therefore more likely to be restricted through UM tools. Furthermore, UM tools can add to a patient's existing disease burden by creating delays in access, imposing unnecessary documentation or provider appointments, and/or otherwise worsening access and exacerbating patient cost-sharing requirements.

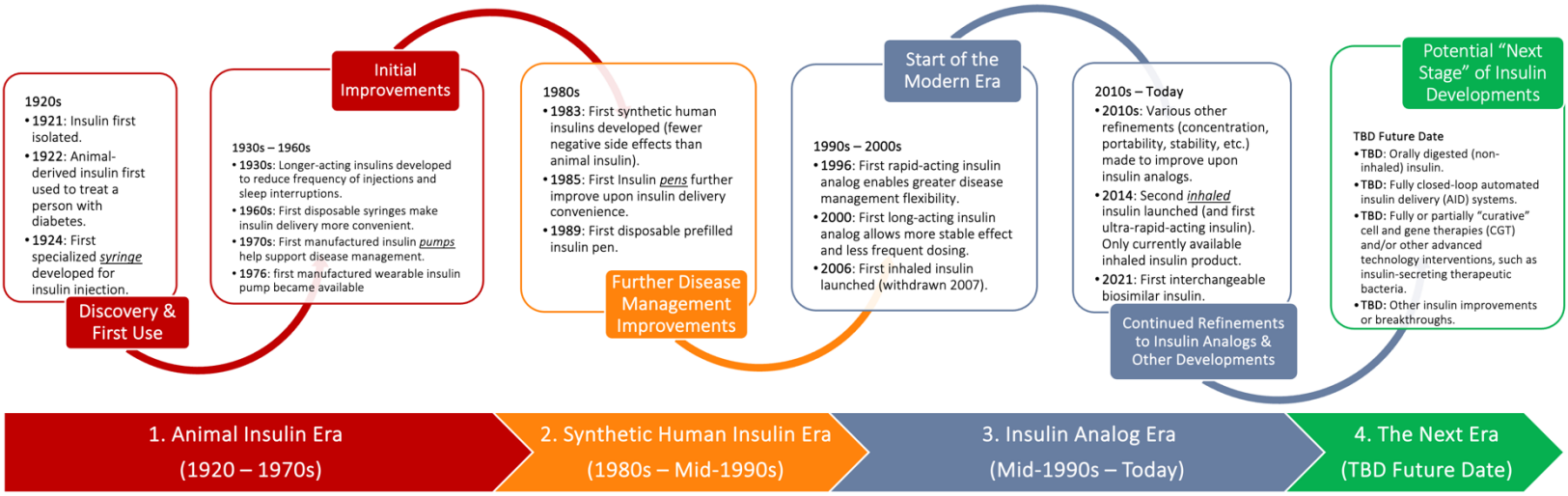
3. INHALED INSULIN BACKGROUND

a. Background and Brief History of Insulin Therapy and Advances Over Time

Insulin, produced in the pancreas, is a hormone that regulates glucose metabolism by promoting the absorption of glucose from the blood into the cells. For all individuals with type 1 and many with type 2 diabetes, insulin replacement therapy is required to maintain health and life. Insulin has been available for the past 100 years. Reducing disease management burden and improving administration convenience has been a major focus of those 100+ years of continuous development and advancement. [xli] Given the many types of insulin products available, they are often categorized by differences in product onset, peak, duration, concentration, and route of delivery (injected under the skin, given intravenously, inhaled, etc.).

Inhaled insulin stands apart from other insulin delivery developments. Unlike insulin syringes, pumps, and pens, which all require the use of a needle for administration, inhaled insulin is delivered via an inhaler and absorbed through the lungs.

Insulin Timeline[xlii]



b. Benefits of Inhaled Insulin

i. Clinical Benefits of Inhaled Insulin

Inhaled insulin, which may be used in place of injectable prandial insulin or correction insulin, has several advantages. Clinically, inhaled insulin is a human insulin that has a fast onset time, fast peak time, and shorter overall duration than other insulins in the same rapid-acting category.

Inhaled insulin has an onset of 12–15 minutes, peaks within 35–45 minutes, and lasts for around 1.5–3 hours. As such, inhaled insulin has been referred to as an "ultra-rapid acting" insulin in relevant literature.[xliii] Studies have shown that ultra-rapid-acting inhaled insulin results in less hypoglycemia in adults with type 1,[xliv] significant decreases in fasting blood glucose levels, and significant weight advantage (when compared to insulin aspart). Other studies have found that ultra-rapid-acting inhaled insulin results in significantly more type 2[xlv] patients achieving A1c target levels, a superior reduction in A1c levels, and reduced postprandial glucose excursions, with no significant difference in the incidence of severe hypoglycemia (when compared to oral therapy alone).[xlvi] In fact, according to the ADA's *Standards of Care in Diabetes* published in the journal *Diabetes Care*®[xlvii], for most adults with type 1 diabetes, insulin analogs (inhaled insulin is included in this category) are preferred over injectable human insulins to minimize hypoglycemia risk.[xlviii] A 2022 systematic review and meta analysis showed similar outcomes, demonstrating that "inhaled insulin is equally effective as subcutaneously administered insulin in patients with type 1 diabetes. The inhaled insulin was found to show less weight gain and fewer hypoglycemic shifts, with a similar effect on the blood glucose level. No significant difference was observed in the incidence of adverse events."[xlix]

In 2024, the manufacturer of the currently available inhaled insulin product released the results of a trial, INHALE 3, on the use of its inhaled insulin in 123 adults with type 1 diabetes across 19 centers in the U.S. The 17-week randomized trial concluded that:

- More participants using the inhaled insulin regimen experienced significant improvements in A1C levels compared to those on usual care. Notably, 21% of those on inhaled insulin had an A1C improvement of greater than 0.5%, while this was seen in only 5% of those receiving usual care.

- Among participants who had an A1C level greater than or equal to 7% at the start of the study, 21% of those on inhaled insulin achieved the A1C goal of less than 7%, while no participants receiving usual care achieved this goal. Nineteen percent of participants who switched from using an automated insulin delivery system to using inhaled insulin plus degludec achieved an A1C improvement greater than 0.5%.[l & li]

- Participants using inhaled insulin achieved a significantly higher time in range (TIR) compared to those on usual care (target A1C of less than 7% was achieved 30% of the time in the inhaled insulin group, compared to only 17% in the usual care group), with around 24% of inhaled insulin users achieving a TIR >70% with no increased hypoglycemia risk (compared to only 13% in the usual care group).[lii]

ii. Practical Considerations: Reducing Needle Anxiety

Practically, with its inhaled route of delivery, inhaled insulin may also alleviate the needle anxiety some people with diabetes experience when taking prandial insulin. Needle-related anxiety is a commonly reported barrier to insulin adherence in adults[liii] and adolescents.[liv] Some studies have recorded intentional insulin omission incidences as being reported by over 50% of study respondents (with regular omission reported by 20% of respondents), with significant risk factors for insulin omission reported including injection site pain, interference with regular daily activities, and embarrassment.[lv] Other studies have added to this, finding that diabetes-related distress contributes to missed insulin doses, with particularly high rates of missed insulin boluses at mealtimes.[lvi] While no medical product can address all diabetes management-related stressors or stigmas, inhaled insulin could address some of these identified concerns (pain, daily schedule interference, and social stigma), thereby potentially enhancing medication adherence and clinical outcomes for some individuals.[lvii] While this practical benefit is useful for adults, inhaled insulin does not completely eliminate the need for insulin injections, except for people with diabetes requiring only prandial insulin coverage. Injection of a basal insulin may still be required.

iii. Additional Reasons Why People with Diabetes and Providers May Want to Use Inhaled Insulin

As outlined in the timeline graphic, there are many types of insulins available to fit the varying needs, lifestyles, and personal preferences of the tens of millions of Americans with diabetes.[lviii] Inhaled insulin is yet another option in the patient-provider toolkit and is well positioned for the following use cases, populations, and situations (within the scope of its approved indication):[lix]

- **1) Both people with type 1 and type 2 diabetes:**
    - **People with type 1 diabetes:** Who take daily basal insulin and prefer to use inhaled prandial insulin (for one or more of the reasons listed below).

    - **People with type 2 diabetes**: Who are not adequately managed on oral glucose-lowering medications alone and prefer to use inhaled insulin (for one or more of the

reasons listed below).

- **2) Reasons why qualifying people with type 1 and type 2 diabetes might prefer to use inhaled insulin**:
    - **Certain health conditions**: As noted above, inhaled insulin has been associated with less weight gain when compared to conventional insulin and can be a useful tool in managing hypoglycemia.[lx] Inhaled insulin can also represent an important option for individuals experiencing other health conditions or intolerances, such as:
        - **Negative skin and injection site reactions with injectable insulin products**: There is a wide range of common skin-related complications associated with subcutaneous insulin injections. This can include minor reactions, such as itching, redness, swelling, bruising, etc., at the injection site, as well as more substantial reactions, including skin abscess formation and scarring, lipoatrophy, lipohypertrophy, lipodystrophy, and induration (hardening or thickening of skin).[lxi] Inhaled insulin bypasses the need for subcutaneous injections, meaning it is an important option for people who experience these side effects and for those with preexisting skin-related conditions that make subcutaneous insulin injection less desirable.[lxii]

        - **Older adults and people with certain types of disabilities**: Inhaled insulin can be an easier-to-administer option for the elderly and/or other individuals with certain types of disabilities that limit their dexterity or mobility.[lxiii]

    - **Flexibility in accommodating lifestyles and disease management regimens, including:**
        - **Those using automated insulin delivery (AID) systems:** Use of inhaled insulin at mealtimes may be an option for those that use AID systems. However, this is not yet standard practice as research into this area is ongoing.[lxiv] This can be important for many individuals as AID system utilization is becoming more common.

        - **More flexible disease management, particularly for those with active lifestyles:** Inhaled insulin has many advantages, including its:
            - Rapid action
            - Short duration
            - Effective postprandial management
            - Convenience
            - Ease of use—no needles or syringes, small and portable system, minimal preparation compared to many other products
            - Flexibility in dosing[lxv]
            - Etc.

Inhaled insulin lends itself toward promoting more flexible disease management for many people. Greater diabetes disease management flexibility is important, as it helps people live their lives the way they want to, rather than having to schedule many of their daily activities (meals, exercise, social activities, stress-related activities, etc.) around their disease. This added

flexibility can be particularly important for the large number of people with physically active lifestyles. Because certain types of exercise can affect blood glucose levels, its "rapid in/rapid out"[lxvi] nature can enable more flexible dosing around exercise periods[lxvii] and help reduce the risk of insulin stacking.[lxviii]

c. Clinical Limitations of Inhaled Insulin

i. Clinical Limitations of Inhaled Insulin

Despite the many clinical and practical advantages of inhaled insulin, it has faced market challenges stemming from several factors. Practical utility considerations related to the route of administration (which reduce patient usability of inhaled insulin), contraindications for a wide range of patients, and potential side effects have all limited the demand for inhaled insulin. Provider skepticism of its route of administration has also played a part in its limited uptake.

ii. Provider Questions and Lack of Familiarity

Concerns about the product's side effects, largely focused on inhaled insulin's possible negative effects on the respiratory system, have made many providers hesitant to recommend inhaled insulin for eligible patients. Furthermore, shifting to a more policy-focused perspective, some policymakers and patient advocacy organizations have reported little interest from constituents in increasing access to inhaled insulin.[lxix] Reasons for limited demand include:

- Some provider skepticism of inhaled insulin as a useful route of administration, who might view inhaled insulin's FDA approved risk profile with more scrutiny than the FDA approved risk profile of other insulin products.
- The need for patient education on the benefits in relation to other types of insulin.
- The adult-only indication—particularly since more adults, compared to children, have the contraindications for inhaled insulin that exclude them as eligible patients.

The adult-only indication misses the pediatric population who may stand to benefit most from a needle-free administration. Needle-related stress and disease management burden are often the highest among pediatric populations. Coupled with the usability considerations and overall lack of familiarity with the product on the market, clinical barriers to the use of inhaled insulin often compete against the clinical benefits associated with its use.

d. Patient-Provider Awareness Considerations for Inhaled Insulin

In addition to the immediate clinical limitations of inhaled insulin, there are other factors that limit its uptake in the commercial market, including low levels of patient-provider awareness of the existence of inhaled insulin, the high cost of the product, and newer alternative therapies to treat diabetes.

i. Low Levels of Patient and Provider Awareness of Inhaled Insulin

When given the choice, patients have reported preferring using an inhaled insulin dosage form over traditional injectable insulin preparations, primarily due to increased convenience, ease of use, and overall satisfaction.[lxx] However, patients are often effectively deprived of this choice because of the low levels of awareness of the availability of inhaled insulin among both patients and providers. The inadequate state of awareness of inhaled insulin takes two primary forms:

1. Simply not being aware that insulin exists in an inhalable form

2. Being aware that inhaled insulin exists, but not having sufficient substantive knowledge about it and who may be a good candidate for use

Robust data is understandably lacking on the specific rates of patient-provider awareness, as it is likely difficult to quantify the absence of knowledge or awareness on a particular subject. However, it does not appear to be in dispute that awareness of inhaled insulin is low.[lxxi] Reports, analyses, articles, and other comments have suggested that:

- There is a general lack of awareness among patients that inhaled insulin exists, meaning that the topic cannot initially be brought up for discussion by patients in the clinic setting (provider's office).[lxxii] For example, one interviewee provided an anecdote where they raised inhaled insulin as an option with a patient unprompted, and the patient adopted its use after expressing frustration and confusion over not having been made aware of it previously.[lxxiii] Other providers added that while inhaled insulin is indeed a more niche product, it can be important for those who can benefit from its advantages.

- A sizable population of health care providers are unaware of the existence of inhaled insulin, its indications, management guidelines, dosing, and prescribing methods.[lxxiv] However, once better educated about inhaled insulin, providers were more likely to be comfortable discussing it with patients in one study.[lxxv]

- Interviewed providers across the spectrum (specialists, general practitioners, and pharmacists) all reported lower levels of knowledge of inhaled insulin when compared to other more common diabetes treatment modalities (e.g., AID systems), including uncertainty about its indication (e.g., whether type 2 diabetes patients can use it) and which patients might benefit from it.[lxxvi] Some interviewees added that there may be a "first mover problem," as many providers may be more hesitant to use newer medications like inhaled insulin until it is adopted by other providers first.[lxxvii]

- Notably, there may have even been low levels of awareness reported among pharmacists, even though they are the health care providers who stock the product on their store shelves.[lxxviii]

Under such circumstances, it's less likely that people with diabetes will request their provider to prescribe them inhaled insulin, nor can providers substantively discuss the merits of the product when asked. Simply put, patient-provider discussions cannot be held on the option of inhaled insulin if there is a lack of awareness and understanding among either party.

4. PATIENT-PROVIDER ACCESS & BARRIERS TO ACCESS WITHIN THE COMMERCIAL MARKET

a. Barriers to Access – Commercial Insurance/PBM Utilization Management Tools

The cost of inhaled insulin on the market is higher in comparison to other insulins. In the absence of high manufacturer rebates for pharmacy benefit managers (PBMs), PBMs and plans are incentivized to cover inhaled insulin only on specialty formulary tiers and are subject to significant utilization management (UM). To this end, commercial plans impose onerous prior authorization and step therapy requirements on inhaled insulin.

- **Prior Authorization (PA):** Many patients seeking to use inhaled insulin must obtain a PA from their prescribers and insurance company, an additional time-consuming obstacle.[lxxix] It has been reported that some plans will void a valid PA after a year has passed, meaning that the person with diabetes will need to obtain a new PA each year.[lxxx]

    - Interviewees reported that PAs were usually the most burdensome of all the UM criteria (both for inhaled insulin and diabetes treatments in general), primarily because:
        - Plan PA requirements can vary widely, meaning that accepted patient conditions and justifications to merit PA approvals are often inconsistent and unclear (e.g., one plan might approve a PA for a patient seeking inhaled insulin due to its advantages in exercise use, while another plan might reject that justification).
        - Managing PAs can take a lot of time and providers generally cannot bill for it—meaning that handling PAs negatively impacts the finances and performance measures of their clinics.[lxxxi]

    - Some interviewees noted that the mere presence of a PA requirement on a certain drug can be enough to discourage many providers from even continuing with the prescription for a medication: “In my experience as a retail pharmacist, prescribers do not like to go through the PA process if they don’t have to, which is kind of the whole point of these utilization management tools. The insurance plans are trying to influence the prescribing patterns of physicians and drive them to lower cost alternatives when available. I’m not sure what the percentage is but over three years of practice, I would say the large majority of prescribers end up changing the prescription to a different drug instead of going through the PA process when contacted by the pharmacy.”[lxxxii]

    - For drugs in general, medical association surveys have found the effects of PAs to be staggering, with a large percentage of physicians reporting numerous negative impacts resulting from PAs, including:
        - PAs leading to adverse events for patients (24%)
        - Negative impact on patient outcomes (93%)
        - Delays in access to care (94%)
        - PA requests often or always get denied (27%)
        - PA requirements leading to higher resource use and unnecessary waste (87%)[lxxxiii]

    - PA requirements negatively impact access and patient outcomes for drugs generally, but these negative factors are exacerbated with respect to chronic

diseases like diabetes, where inadequate access and untimely treatment can lead to rapid and severe disease progression, including hyperglycemia, permanent organ damage, etc.[lxxxiv] One study found that patients who did not receive their requested diabetes medication due to PA issues had worse clinical outcomes. Patients who received their medication after PA (or an alternative medication) showed greater reductions in A1C compared to those who did not receive the requested medication or alternative medicine.[lxxxv] The delays, onerous requirements, and associated confusion can lead to patient abandonment of treatment, which can actually increase costs over time. One study found higher plan-paid health care costs among plan members who requested a type 2 diabetes medication requiring PA but never received it.[lxxxvi] This study found that failure to take physician-recommended treatments resulted in worsened glucose management, worse outcomes, and greater future medical treatment costs, which were not offset by reduced drug costs (the immediate-term lower pharmacy costs obtained by denying access to the medication).[lxxxvii]

- **Step Therapy/Step Edits/"Fail First"**: Some plans subject inhaled insulin to double and sometimes even triple step therapy, effectively requiring that a patient fail first on three separate and similar drugs in succession, with each step therapy period sometimes being as long as 90 days per drug.[lxxxviii] This means that many patients will have to wait six months or more before their insurance will cover inhaled insulin. For those plans that void the initial PA after a year, this can mean the patient will need to restart part of or the entire step therapy process and "re-fail" through the same series of drugs all over again. This can worsen health outcomes by depriving a patient of the medication that works best for them, forcing them into a repeating cycle of having to jump from new medication to new medication each time to "re-fail" through earlier drugs and regain coverage to inhaled insulin. In addition to this administrative and physical burden imposed on patients by this inconsistent treatment plan, providers also noted that what it means for a patient to "fail" on the cheaper step therapy insulin products are often not sufficiently defined by plans, making it unclear what constitutes a valid "failure" (such that the patient can progress towards accessing the newer and more expensive insulin product). In the context of other medications, a patient that "fails" on a certain drug when they don't respond to and/or experience negative side effects. However, in the context of inhaled insulin prescribing, patients often do safety respond to cheaper injected bolus insulins (barring certain negative side effects that some patients may experience with injected insulin, including skin issues such as lipodystrophy), and it may be unclear to providers whether the absence of inhaled insulin's quality of life improvements constitutes a "failure" for that cheaper first-line drug.[lxxxix]

    - Similar to PA requirements, step therapy requirements are likely to have a negative impact on patient outcomes since these serve as another impediment to the specific care recommended by that patient's diabetes care provider. It has been reported that step therapy criteria can be a major time burden on patients and providers, particularly when multi-level step therapy (double or triple step therapy) is involved.[xc]

- More "steps" means a longer delay for a patient to access their recommended medication, during which time the patient's health can worsen. Although some have touted step therapy as an effective cost-utilization tool, others have noted that "one-size-fits-all" step therapy protocols lack sufficient clinical justification as applied to real-world heterogeneous patient populations, where patients and their providers are better suited to make individualized treatment decisions.[xci] For some drugs used to treat chronic conditions, analyses have found that patients faced with step therapy barriers were more likely to experience medication non-adherence or pay out of pocket, with survey results showing that 40% of step-therapy patients stopped taking medicines that did not help, and around 30% stopped treatment due to costs.[xcii] In this survey, patients also reported that they felt step therapy negatively impacted their emotional health (52%), that their overall health declined (20%), and their quality of life declined (36%).[xciii] Of those providers surveyed, 89% of physicians and 78% of pharmacists thought step therapy prevented patients from receiving innovative therapies.[xciv]

- **Formulary Exclusion List**: Nationally, over 30% of commercial insurance plans simply do not cover inhaled insulin, placing the burden of payment entirely on the patient.[xcv] In many cases, this exclusion will mean that the patient and their provider are not even able to initiate an appeal or process with the plan to request coverage.

  - Similar to the other UM criteria on this list, plans are more likely to exclude newer and more expensive forms of insulin (and other expensive drugs in general) from their formularies, including inhaled insulin.[xcvi] However, since there is currently only a single inhaled insulin product on the market, plans that exclude inhaled insulin are effectively excluding an entire modality of insulin delivery to their plan beneficiaries. Between 2014–2025, there has been a massive jump in the number of drugs subject to PBM formulary exclusion lists. In 2014, the largest PBMs excluded around 100 drugs or less, which has since increased to between 600–700 drugs as of 2025.[xcvii] Patients whose insurance currently covers inhaled insulin are subject to the risk of formulary exclusions in one of two main forms:
    1. Their insurance plan initially covers inhaled insulin, but later subjects it to a formulary exclusion

    2. Their insurance plan covers inhaled insulin, but they later change to a new plan (e.g., due to a new job) that subjects inhaled insulin to a formulary exclusion

  - Plans that subject a certain medication to a formulary exclusion will usually offer a cheaper alternative medication, but "one-size-fits-all" treatment regimens do not work for many patients,[xcviii] particularly with respect to inhaled insulin where there are no alternative inhalable options. Patients subject to such exclusions are more likely to face the full brunt of OOP costs and may be forced to discontinue treatment and switch to a less effective alternative treatment covered by the plan. For those that must switch, the time required to restart their search for the optimal insulin and/or to adjust to a new insulin regimen can be disruptive. The associated time, effort, and money involved in follow-up provider visits, lab work, and new

medications may also sometimes outweigh the cost savings expected from switching to the less expensive alternative drug.[xcix] Additionally, some studies acknowledged that while broader insulin formulary access understandably leads to increased drug spending on insulin, health care spending in other areas (e.g., the number of annual outpatient care utilization claims) can decline.[c] PBM exclusion criteria decision making processes have limited transparency, but it appears that such decisions may often be made in the PBM's best financial interest, rather than what is best for patients and providers. As explained in a prior ADA report: "It is clear that [formulary] decisions made from negotiations between stakeholders that affect formulary choice may not be in the best financial or medical interest of the patient.…PBMs often exclude from formularies the insulins made by the manufacturer who offers the lowest rebate…patients with high cost-sharing may be less adherent to recommended medication dosing and administration, resulting in harm to their health…formulary exclusions and frequent formulary changes cause uncertainty, increase financial costs for patients, increase work required by providers, and could be undermining patient health."[ci]

- **Formulary Tiering**: Most major commercial insurance companies and PBMs have included inhaled insulin in coverage tiers 3 or 4 (nonpreferred brands). Medications placed in these tiers have higher copayments compared to their preferred brand name or generic alternatives.[cii]

    - High formulary tiering has also been found to have a negative effect on patients, as higher formulary tiering involves higher OOP costs that many patients may be unable to bear. One study aimed at determining the impact of a Medicare Part D formulary tier change on beneficiaries, found that upward tiering changes were associated with higher OOP costs, a statistically significant decline in insulin adherence, and increases in A1C (when compared to patients with lower OOP costs and/or financial assistance).[ciii] The study emphasized that the A1C increase was significant (at an average increase of 0.9%), and that the number of negative diabetes-related events (e.g., hyperglycemia) also increased.[civ] Other studies have added to this, finding that drugs placed on higher, and therefore more expensive, formulary tiers were associated with reduced likelihood of patient initiation of that therapy, with the opposite being true for drugs on lower tiers.[cv]

- **Quantity Limits (QLs) & Refill-Too-Soon Edits/Measures/Rejections**: QLs are not an inherently problematic tool, as there can be legitimate reasons to limit the amount of medication a patient can have dispensed at a time. However, when QLs are combined with some of the other UM tools outlined above, this can place patients in situations where it is extremely difficult or outright impossible for them to obtain a continuous supply of inhaled insulin.

    - For example, under a 90-day QL, a plan that utilizes triple-step therapy and voids PAs after one year will effectively limit a patient to only being able to access a single 90-day supply of inhaled insulin for an entire year. After the patient completes the three separate 90-day fail-first medications, for a total of 270 days,

the 90-day QL on inhaled insulin will limit the patient to that single dispensing period. This is because the step therapy process may be restarted after the 365-day/one-year mark when the plan voids the prior PA and requires a new PA.[cvi]

Further, the UM barriers on inhaled insulin in turn exacerbate the demand challenges because many prescribers, when faced with burdensome UM, will prescribe alternative therapies with fewer barriers.

5. STATE AND FEDERAL SOLUTIONS TO ADDRESS COMMERCIAL MARKET ACCESS BARRIERS

a. Inhaled Insulin as a Case Study for Other Insulin Access Barriers

Inhaled insulin provides a useful case study on the impact of commercial barriers to access for the following reasons:

- Equity in Access and Choice—Ensuring Every Tool in the Toolkit Is Accessible: The ADA works to ensure all patients, and their providers have access to robust options so patients and providers can choose what is most appropriate. Diabetes management is a personal process based on each person's unique lifestyle, health situation, and personal preferences. There is no "one-size-fits-all" approach to diabetes management, and this extends to one's choice of medication.

- General Trend of Higher Access Barriers for Most Types of Newer and Often More Expensive Insulin Products:
    - As the price tag of a medical product increases, the use of UM tools (both the total number of unique UM barriers and the severity of each barrier) is generally expected to increase, as payors understandably seek to avoid incurring higher costs. The general favoritism of drug formularies towards generics or other lower cost alternatives helps illustrate this.[cvii]

    - While the specific set of UM tools that may be applied to any particular drug inevitably varies across each commercial plan, inhaled insulin is one of the costliest forms of insulin,[cviii] meaning that both the total number of UM tools applied (e.g., 1. PA, 2. Step therapy, etc.) and the extent of each of those applied tools (e.g., 1. PA with large list of requirements, 2. Step therapy protocol that requires the patient to fail multiple drugs first) are both expected to be consistently higher among most plans.

    - This positions inhaled insulin as a useful backdrop/case study into the use of aggressive UM tools for other costly and often more innovative or specialty forms of insulin in general (e.g., UM tools applied to certain expensive and generally newer long- and rapid-acting insulins).[cix]

- Even if UM tools were applied uniformly across all insulin products (regardless of price), UM tools would still be most relevant in the context of newer and more expensive insulin products. This is because the use of UM tools and the resulting coverage denial will necessarily be more impactful on patients for higher cost insulin products (higher OOP cost).

- Risk of Stifling Innovation in the Diabetes Space: Manufacturers recognize this increased trend in UM tool usage for novel and more expensive products and may therefore avoid investing in riskier innovations in the diabetes space.[cx] Furthermore, the impact of access barriers on innovation is not limited to the inhaled insulin space. These barriers could potentially threaten the viability of future insulin delivery and other diabetes management innovations.

b. Insulin Access Barrier Reforms to Date and What Remains to be Done

i. Price and UM Access Barriers Have Historically Made Many Forms of Insulin More Difficult to Obtain

Over the past two decades, the greatest access barriers to insulin products have been the high cost and the correspondingly high level of UM tools applied to such products. These impediments make it exceedingly difficult for many diabetes patients to obtain their necessary insulin supplies. This growing public outcry eventually led to several major changes.

To date, legislative action and other developments have primarily succeeded in lowering insulin cost-sharing.[cxi] This has left UM barriers in place, making UM an area of potential reform that could be implemented quickly to ensure adequate access for all patients across all insulin products. While legislative action to address insulin cost-sharing will continue to remain top of mind for many policymakers, more attention should be directed at UM tools and the role that plans and PBMs play in insulin access.

ii. Developments to Date Have Addressed Price, But Not UM Tools

In terms of insulin access barriers, the high cost of insulin (and correspondingly high patient OOP cost and patient financial burden) has been a major topic of public attention since the early 2000s when insulin list prices started to rapidly increase.[cxii] For most of the past 25 years, insulin prices continued to grow exponentially, and only in roughly the past five years has this trend started to finally adjust.[cxiii] This trend is helped by state-level policies that established insulin copay caps for state-regulated health plans and a $35 insulin copay cap for Medicare.

While insulin has become more affordable for some people with diabetes, access barriers still remain in the form of UM tools, which may deny or delay coverage of an insulin product. Furthermore, barriers may be more acute for new forms of insulin, including inhaled insulin.

- 1) Biosimilar Competition: Biosimilar insulin development is mostly focused on injectable formulations (administered via pens, syringes, and pumps, as that is what most patients use), and there is little interest in biosimilar inhaled insulin.[cxiv] Biosimilar competition will have a limited immediate effect on newer forms of insulin in general since newer biologics are more likely to still be within their exclusivity protection window.[cxv]

- 2) Inflation Reduction Act (IRA) $35 Cap for Medicare Beneficiaries: The IRA caps insulin OOP spending at $35 per month's supply of each insulin product covered under a Medicare Part D plan, but this cap does not apply to formulary exclusions. For example, products not included on a Part D sponsor's formulary are not subject to the copayment cap.[cxvi] For plans that do cover inhaled insulin, the $35 price cap will apply assuming the patient can navigate a plan's inhaled insulin UM barriers.[cxvii] At any rate, this $35 price cap is only applicable to Medicare patients and does not apply to commercially insured patients.

c. State-Level Reform

Outlined below are state-level initiatives specifically intended to improve insulin access, address drug access reform more generally (which also impacts insulin access), and improve drug access that will have limited application for insulin.

- **1) State Insulin-Specific Reforms**:
  - **Price Cap Legislation:** Insulin price cap legislation has been introduced at a growing rate in many states,[cxviii] with many already having some form of insulin price cap law in place.[cxix] While the exact language of these laws varies from state to state, they generally provide a limit on the amount of copay or other cost-sharing that insurance carriers and PBMs can charge the insured for a set supply of insulin (e.g., $100 cap per 30-day supply, $35 cap per 30-day supply, etc.).
    - In crafting such laws, state policymakers should be careful to ensure the definition of "insulin" in such laws is sufficiently broad so as to incorporate all forms of insulin. For example, Colorado's policymakers amended their insulin price cap legislation to include "all covered prescription insulin drugs" regardless of the amount or type of insulin,[cxx] rather than using some narrower or more outdated terminology.[cxxi] This ensured the law's impact was not limited to only certain forms of insulin, which helps patients who may currently be taking "non-traditional" forms of insulin (such as inhaled) and helps future-proof these laws against potential developments in insulin technology.
  - **Insulin Affordability/Safety Net Programs**: Since the insulin price cap laws may have limited application against many types of insurance plans, states should also consider creating insulin affordability programs. For example, Colorado created its insulin affordability program to support people with diabetes who were not covered by the initial insulin cap (and for people who were covered by the price cap but still needed additional assistance). State insulin affordability program laws are somewhat similar to other types of patient assistance programs (PAPs) in that they provide qualifying individuals (e.g., residents of the state in question who have a legitimate financial need for program assistance) with financial assistance to access free or reduced-price insulin.
    - These programs often include both an "urgent/emergency need" component to provide an expedited 30-day supply of insulin and a "longer term/continuing need" component that provides insulin for some longer period (e.g., 90-day supply or reduced-cost insulin over a 12-month

period). These two components can help a patient get access to both immediate and longer-term insulin supplies, thereby reducing the negative impacts that strict plan quantity limit restrictions can have on patients who are unable to obtain a new prescription on time.

- These programs have shown some promise, as a study of Colorado's program found that it was associated with some reductions in OOP spending for insulin, with the mean OOP payment per 30-day supply falling nearly in half (from $62.59 to $35.64). These types of affordability programs can be important for patients on newer and more expensive forms of insulin, which will often have higher levels of plan-imposed patient cost-sharing and/or formulary exclusions.

- **Insulin Step Therapy Limitations**: To date, most states have enacted some form of step therapy law, oftentimes limiting or outright barring the use of step therapy for certain medical services or products where delays in care could cause substantial problems for the patient (e.g., step therapy limitations for stage 4 metastatic cancer).[cxxii] Since delays to a patient's preferred insulin product can similarly cause undue harm, some states have considered legislation that would prohibit plans from imposing step therapy protocols as a prerequisite to authorizing insulin coverage.[cxxiii]

- **2) Broader State Drug Access Reforms that Could Impact Insulin Access**:
  - **State Prior Authorization (PA) Reform**: Measures addressing the prices of drugs are important, but reduced OOP costs will be irrelevant for patients facing UM barriers who cannot even get access to the drug in the first place. States have therefore looked at ways to fix inappropriate UM tool utilization, and a growing number of states have successfully enacted laws to address PAs,[cxxiv] one of the most commonly implicated UM tools due to the harm it can have on both patients and providers.[cxxv] These PA laws include reforms such as:
    - Reducing plans' time to respond to PA requests
    - Requiring that adverse plan determinations be made by adequately qualified medical professionals
    - Increased transparency on an insurer's PA statistics
    - Prohibiting retroactive denials
    - Etc.[cxxvi]

    Some have taken steps to bolster their existing PA legislation to further protect patients and providers. Minnesota recently enacted additional PA protections for chronic conditions like diabetes. PAs do not expire as long as the patient's treatment does not change.[cxxvii] These PA expiry protections can be critical, as many plans sometimes void an existing PA after six months or one year.

- **3) State Drug Access Reforms with Limited Application to Newer and More Expensive Insulin Products (or Insulin in General)**
  - **Group Volume Purchasing Arrangements/Collectives:** State group purchasing arrangements (or cooperative purchasing) authorities are common among states

in one form or another.[cxxviii] These types of programs have demonstrated some success,[cxxix] but the impact of such arrangements may be more limited when applied to newer and more expensive forms of insulin, particularly more niche or specialty products that do not have sufficient widespread use to merit bulk purchasing.

- **Manufacturing/Procurement of Generic Drugs and Biologics Initiatives**: State initiatives similar to California's CalRx initiative (to enter into partnerships to produce or otherwise procure cheaper generic insulin, naloxone, and potentially other drugs)[cxxx] have been considered in other states.[cxxxi] While these state generic/biosimilar manufacturing and procurement initiatives could help reduce drug costs,[cxxxii] this comes with the caveats that such initiatives can be very expensive and take many years to stand up,[cxxxiii] and there will be limited application against newer drugs still under exclusivity protection.

d. Federal-Level Reform

Due to Congress' broad ability to enact reforms, there are a substantial number of possible policies that could improve insulin access.[cxxxiv] This list is not intended to be exhaustive but instead capture general themes and important elements that comprehensive insulin reform could include.

- **1) Federal Insulin-Specific Reforms:**
  - **Price Cap or Other OOP Reduction Legislation (Extension to Commercial Market):** As previously discussed, the IRA created a $35 price cap on insulin for Medicare beneficiaries. Several bills have been introduced to expand upon this progress, including:

    1. The Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act of 2023, which would cap insulin copays at $35 per month for those on private health insurance plans[cxxxv]

    2. The Cap Insulin Prices Act, which would cap insulin prices at $25 or 25% of a plan's negotiated price (whichever is less) for private insurance[cxxxvi]

    Notably, both acts define insulin broadly enough to include all forms of insulin, including inhaled.[cxxxvii] Other bills, such as Matt's Act, would more broadly improve insulin price transparency and otherwise limit patient cost-sharing.[cxxxviii]

  - **Insulin Step Therapy and PA Limitations:** The previously mentioned Cap Insulin Prices Act also addresses UM tool abuses, as it provides that plans shall "not impose any utilization management practices such as prior authorization, step therapy protocols, or other similar conditions on such products, except as clinically justified and as specified by the Secretary." Other bills have also been introduced to prevent inappropriate UM tool utilization of drugs and biologics in general (which would cover insulin, even if not explicitly referencing "insulin" in the bill), including the Safe Step Act, which would require a group health plan to

establish limits and exceptions to medication step therapy protocol in specified cases (which could include diabetes medications such as insulin).[cxxxix]

- **Insulin Affordability/Safety Net Programs:** Safety net programs have also been considered at the federal level, such as the Emergency Access to Insulin Act, which would award grants to states to create insulin card programs to provide uninsured or underinsured individuals with insulin at no cost.[cxl]

- **Biosimilar Insulin Access and Other Insulin Competition:** While states are unable to modify federal IP protections, new biologic exclusivity periods and other matters regarding national insulin market competition, the same is not true for Congress. Many have been introduced to address these and related matters, such as:
  1. The aforementioned Emergency Access to Insulin Act, which would also reduce the marketing exclusivity period for biological drug products from 12 to 7 years[cxli]

  2. The INSULIN Act, which would promote generic and biosimilar competition (and mandate PBMs pass through 100% of insulin rebates and other discounts)[cxlii]

  3. Etc.

- **2) Broader Federal Drug Access Reforms that Could Impact Insulin Access:**
  - **Broader PBM Reform & Overriding Need for Greater PBM Transparency**: PBMs have come under greater scrutiny in recent years, leading to a litany of bills directed at various aspects of PBM activity.[cxliii] These types of packages are often intended to be comprehensive overhauls to how PBMs operate, make money, establish business relationships, and otherwise engage in business. While PBM reform may have a positive effect on insulin access, it is difficult to fully capture the potential impact of these types of reforms, because (among other reasons) a substantial amount of PBM activity is not public.[cxliv] Therefore, while PBM reform legislation has many provisions that could improve insulin access in any given instance (for a particular PBM and insulin product), an overriding component of these bills that could effectuate major change are provisions that increase transparency within PBM operations. Requiring that PBMs engage in more transparent reporting of their activities and dealings could have an overall cooling effect on some PBM practices (whether it be patient steering, spread pricing, UM tool abuses, etc.). A PBM's ability to operate under the cover of confidential business dealings is what allows many of the inappropriate PBM practices to take place.[cxlv] Federal agencies such as the FTC already have substantial authority to regulate unfair and deceptive trade practices, as do state agencies. Enhanced transparency would empower that oversight, as well as any additional PBM restrictions enacted in subsequent federal or state PBM legislation. A PBM's ability to keep most transactional and claims data private makes it more difficult to audit PBMs for compliance with existing laws and any future PBM laws.

6. CONCLUSION – RECOMMENDATIONS FOR INCREASING ACCESS TO INSULIN IN THE COMMERCIAL MARKET

Based on the identified clinical, market, and access barriers to the uptake of inhaled insulin, the following recommendations may serve to increase access to inhaled insulin and other more expensive types of insulin for people with type 1 and 2 diabetes, and/or otherwise address barriers to accessing insulin more broadly:

- UM reform, including prohibiting the use of step therapy for insulin and removing burdensome prior authorization requirements

- State and/or federal legislation to address inappropriate plan and/or PBM activity, including:
    1. Preventing UM tool abuse that unduly limits access to certain higher cost medications
    2. Preventing the ability of PBMs to keep most transactional and claims data private, as lack of transparency makes it more difficult to audit PBMs for compliance with existing PBM transparency laws

- Provider education on the clinical indications of all types of insulin products, and differences in disease management benefits for some patients

- Promoting increased adoption of real-time pharmacy benefit check tools that will enable the physician to see a patient's coverage for the chosen insulin product at the time of prescribing, helping the doctor navigate UM restrictions in less time

- Ensure any efforts to establish copay caps for insulin include inhaled and other newer insulin formulations in the commercial market

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[c] McNamara C, Serna N. The impact of a national formulary expansion on diabetics. Health Econ. 2022 Nov;31(11):2311-2332. doi: 10.1002/hec.4583. Epub 2022 Aug 9. PMID: 35943900. https://pubmed.ncbi.nlm.nih.gov/35943900/. "This paper estimates the causal effect of the expansion of Colombia's national prescription drug formulary to include five new types of insulin on the healthcare utilization and costs of type I diabetics and explores the mechanisms through which outpatient cost reductions are realized. We find that expanded coverage generates an increase in the cost of insulin for type I diabetics equal to 17% of their baseline healthcare costs. *At the same time, their annual outpatient care utilization falls by 1.9 claims*……In column 3, we see that *expanded insulin coverage decreased total non-insulin healthcare utilization by type I diabetics by 2.8 claims.* This decline in overall utilization is driven by reductions in outpatient and non-insulin prescription drug utilization as well as a fall in hospitalization rates. *Outpatient utilization by type I diabetics declined by 1.9 claims, while non-insulin prescription drug utilization fell by 1.3 claims*. The estimates of the two part model for inpatient utilization show that the hospitalization rate for type I diabetics decreased by 3.6% points from a baseline rate of 24.9 as a result of the expanded coverage of insulin. Conditional on a hospitalization, inpatient utilization increased by 0.8 claims. These changes in the rate of hospitalizations and the number inpatient claims incurred conditional on admission together imply an overall decline in inpatient care utilization."
[ci] William T. Cefalu, Daniel E. Dawes, Gina Gavlak, Dana Goldman, William H. Herman, Karen Van Nuys, Alvin C. Powers, Simeon I. Taylor, Alan L. Yatvin, on behalf of the Insulin Access and Affordability Working Group; Insulin Access and Affordability Working Group: Conclusions and Recommendations. *Diabetes Care* 1 June 2018; 41 (6): 1299–1311. https://doi.org/10.2337/dci18-0019. https://diabetesjournals.org/care/article/41/6/1299/36487/Insulin-Access-and-Affordability-Working-Group.
[cii] Oleck, J., Kassam, S., & Goldman, J. D. (2016). Commentary: Why was inhaled insulin a failure in the market? Diabetes Spectrum, 29(3), 180–184. https://doi.org/10.2337/diaspect.29.3.180. Available at: https://diabetesjournals.org/spectrum/article/29/3/180/32800/Commentary-Why-Was-Inhaled-Insulin-a-Failure-in.
[ciii] Nguyen, A. T., Sawant, R. V., Serna, O., Esse, T., & Sansgiry, S. S. (2016). Medicare Part D insulin tiering change: impact on health outcomes. AMERICAN JOURNAL OF PHARMACY BENEFITS, 8(5). https://www.pharmacytimes.com/view/medicare-part-d-insulin-tiering-change-impact-on-health-outcomes.
[civ] Nguyen, A. T., Sawant, R. V., Serna, O., Esse, T., & Sansgiry, S. S. (2016). Medicare Part D insulin tiering change: impact on health outcomes. AMERICAN JOURNAL OF PHARMACY BENEFITS, 8(5). https://www.pharmacytimes.com/view/medicare-part-d-insulin-tiering-change-impact-on-health-outcomes.
[cv] Luo J, Gabriel N, Korytkowski M, Hernandez I, Gellad WF. Association of formulary restrictions and initiation of an SGLT2i or GLP1-RA among Medicare beneficiaries with type 2 diabetes. Diabetes Res Clin Pract. 2022 May;187:109855. doi: 10.1016/j.diabres.2022.109855. Epub 2022 Mar 25. PMID: 35346753; PMCID: PMC10767977. https://pmc.ncbi.nlm.nih.gov/articles/PMC10767977/.
[cvi] Anonymous Interview. Tuesday, January 14, 2025 from 5:05 PM to 5:35 PM EST. Clinical Director and Territory Business Manager of Insulin Company from California.
[cvii] Gavidia Matthew. Employer Utilization Management Prioritizes Health Benefit Cost Over Patient Care, Survey Finds. AJMC. April 13, 2022. Available at: https://www.ajmc.com/view/employer-utilization-management-prioritizes-health-benefit-cost-over-patient-care-survey-finds.; Howell S, Yin PT, Robinson JC. Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients. Health Aff (Millwood). 2021 Aug;40(8):1206-1214. doi: 10.1377/hlthaff.2021.00036.Available at: https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.00036?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed.
[cviii] Marsh Tori. Insulin Costs Plummet: A Decade-Long High Comes to an End. GoodRx. January 15, 2025. Available at: https://www.goodrx.com/healthcare-access/research/how-much-does-insulin-cost-compare-brands; Also see BCBS FEP – FEP Blue Standard™ Formulary.
[cix] Note however that there can be substantial variation between plans and drugs. See: MI BCBS Formulary; FL BCBS Prior Authorization Program Information; KS BCBS Long Acting Insulin Prior Authorization with Quantity Limit Program Summary; Kaiser

Permanente Health oo of Mid-Atlantic States, Inc.Insulins Prior Authorization (PA); AL BCBS Long Acting Insulin Prior Authorization with Quantity Limit Program Summary; etc.

[cx] Howell S, Yin PT, Robinson JC. Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients. Health Aff (Millwood). 2021 Aug;40(8):1206-1214. doi: 10.1377/hlthaff.2021.00036.Available at:.

[cxi] Feldman, W. B., & Rome, B. N. (2023). The rise and fall of the insulin pricing bubble. *JAMA Network Open, 6*(6), e2318074. https://doi.org/10.1001/jamanetworkopen.2023.18074. Available at: https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2806020.

[cxii] Aubrey Allison, Inskeep Steve. Insulin costs increased 600% over the last 20 years. States aim to curb the price. NPR. September 12, 2022. Available at: https://www.npr.org/2022/09/12/1122311443/insulin-costs-increased-600-over-the-last-20-years-states-aim-to-curb-the-price.

[cxiii] Aubrey Allison, Inskeep Steve. Insulin costs increased 600% over the last 20 years. States aim to curb the price. NPR. September 12, 2022. Available at: https://www.npr.org/2022/09/12/1122311443/insulin-costs-increased-600-over-the-last-20-years-states-aim-to-curb-the-price.

[cxiv] Research and Markets. Growth Trends in the Insulin Biosimilar Market, Forecast to 2034. December 5, 2024. Available at: https://www.globenewswire.com/news-release/2024/12/05/2992475/0/en/Growth-Trends-in-the-Insulin-Biosimilar-Market-Forecast-to-2034.html.

[cxv] Kim, A. P., & Bindler, R. J. (2016). The future of biosimilar insulins. *Diabetes Spectrum, 29*(3), 161–166. https://doi.org/10.2337/diaspect.29.3.161. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC5001215/.

[cxvi] Centers for Medicare & Medicaid Services. Frequently Asked Questions about Medicare Insulin Cost-Sharing Changes in the Prescription Drug Law (Updated January 2023). Available at: https://www.cms.gov/files/document/frequently-asked-questions-medicare-part-d-insulin-benefit.pdf.

[cxvii] Hopcroft April. Afrezza Inhaled Insulin for Adults with Type 1 Diabetes. DiaTribe. June 23, 2024. Available at: https://diatribe.org/diabetes-medications/afrezza-inhaled-insulin-adults-type-1-diabetes.; Humana. Does Medicare Cover Insulin?. January 9, 2025. Available at: https://www.humana.com/medicare/medicare-resources/does-medicare-cover-insulin**.;** SEC. 11406. of IRA states: "'(C) COVERED INSULIN PRODUCT.—In this paragraph, the term 'covered insulin product' means an insulin product that is a *covered part D drug covered under the prescription drug plan or MA–PD plan* that is *approved* under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act and marketed pursuant to such approval or licensure, including any covered insulin product that has been deemed to be licensed under section 351 of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such section."

[cxviii] National Academy For State Health Policy. 2024 State Legislation to Lower Prescription Drug Costs. January 7, 2025. Available at: https://nashp.org/state-tracker/2024-state-legislation-to-lower-pharmaceutical-costs/.

[cxix] American Diabetes Association. State Insulin Copay Caps. Available at: https://diabetes.org/tools-resources/affordable-insulin/state-insulin-copay-caps.**;** For trends in adoption of state copay caps from 2019-2022, see CSG. State Legislation Provides Hope for Rising Insulin Costs. The Council of State Governments. March 31, 2023. Available at: https://www.csg.org/2023/03/31/state-legislation-provides-hope-for-rising-insulin-costs/.

[cxx] 3 Colo. Code Regs. § 702-4-2-68-5. Section 3 CCR 702-4-2-68-5 - Cost-Sharing Requirements and Limitations: "Carriers that provide coverage for prescription insulin drugs shall cap the total amount that an individual is required to pay for all covered prescription insulin drugs at an amount not to exceed $100 for the individual's entire thirty (30) day supply, regardless of the amount or type of insulin needed to fill the covered person's prescription or the number of insulin prescriptions."

[cxxi] Healio. How Colorado's Insulin Cap Law Evolved. May 18, 2023. Available at: https://www.healio.com/news/endocrinology/20230510/how-colorados-insulin-cap-law-evolved.

[cxxii] AHIP. Step Therapy Laws Chart: Summary of State Requirements. August 23, 2021. Available at: https://ahiporg-production.s3.amazonaws.com/documents/State-Law-Charts/ahip_chart_step_therapy_laws_august_2021.pdf ; Step Therapy. Step Therapy Legislation by State. September 2024. Available at: https://steptherapy.com/step-therapy-legislation-by-state/.

[cxxiii] CA SB-40 Health care coverage: insulin. **"**On and after January 1, 2026, the bill would prohibit a health care service plan or disability insurer *from imposing step therapy protocols as a prerequisite to authorizing coverage of insulin*. Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program……..
(e) Consistent with this section, on and after January 1, 2026, a health care service plan shall not impose step therapy protocols as a prerequisite to authorizing coverage of insulin. For purposes of this section, "*step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified condition, including self-administered drugs and physician-administered drugs, are medically appropriate for a particular enrollee and are covered under a health care service plan contract*."

[cxxiv] Mcauliff Michael. Prior Authorization targeted by more and more states. Modern Healthcare. August 27, 2024. Available at: https://www.modernhealthcare.com/politics-policy/prior-authorization-state-legislation-congress-medicare-medicaid ;Triage Cancer. Health Insurance State Laws: Prior Authorizations. Available at: https://triagecancer.org/state-laws/health-insurance-prior-authorization. "This chart highlights the state laws related to prior authorizations, including if the state has a consumer protection law, if there is pending legislation, and more. Check back often, as this chart is updated frequently…..*If you have a self-funded plan, certain state laws may not apply*."

[cxxv] American Hospital Association. AMA Survey Shows physicians, patients heavily burdened by prior authorization. June 20, 2024. Available at: https://www.aha.org/news/headline/2024-06-20-ama-survey-shows-physicians-patients-heavily-burdened-prior-authorization.

[cxxvi] Henry Albert Tanya. 9 states pass bulls to fix prior authorization. American Medical Association. March 8, 2024. Available at: https://www.ama-assn.org/practice-management/prior-authorization/9-states-pass-bills-fix-prior-authorization.
[cxxvii] Henry Albert Tanya. 9 states pass bulls to fix prior authorization. American Medical Association. March 8, 2024. Available at: https://www.ama-assn.org/practice-management/prior-authorization/9-states-pass-bills-fix-prior-authorization.
[cxxviii] Eqaulis Group. State Legal Authorities. Available at: https://equalisgroup.org/state-legal-authorities/.
[cxxix] Waldrop Thomas, Calsyn Maura. State Policy Options To Reduce Prescription Drug Spending. February 13, 2020. Available at: https://www.americanprogress.org/article/state-policy-options-reduce-prescription-drug-spending/ "Another example of non-Medicaid bulk purchasing is the Minnesota Multistate Contracting Alliance for Pharmacy. The organization was founded in 1985 to purchase prescription drugs for government facilities that provide health care services, such as correctional facilities, departments of health, and public schools and universities. Every state except for Massachusetts participates in the program.[78] The program accrues significant savings for its members, even compared with other group purchasing collectives. An evaluation of the program found that its prices were between 2.8 and 4.4 percent lower than prices for the same drugs purchased by other group purchasing organizations, and its average prices paid were comparable to Medicaid's best price."
[cxxx] California. Medi-Cal Rx. Available at: https://www.medi-calrx.dhcs.ca.gov/home/.
[cxxxi] NY Senate Bill S4786A. "Enacts the "New York affordable drug manufacturing act"……Enacts the "New York affordable drug manufacturing act" to direct the commissioner of health to enter into partnerships to increase competition, lower prices, and address shortages in the market for generic prescription drugs, to reduce the cost of prescription drugs for public and private purchasers, taxpayers, and consumers, and to increase patient access to affordable drugs. "
[cxxxii] Bonavitacola Julia, In-State Insulin Manufacturing Will Benefit Californians With Diabetes, Commentary States. AJMC. November 14, 2022. Available at: https://www.ajmc.com/view/in-state-insulin-manufacturing-will-benefit-californians-with-diabetes-commentary-states
[cxxxiii]Bonavitacola Julia, In-State Insulin Manufacturing Will Benefit Californians With Diabetes, Commentary States. AJMC. November 14, 2022. Available at: https://www.ajmc.com/view/in-state-insulin-manufacturing-will-benefit-californians-with-diabetes-commentary-states.
[cxxxiv] Socal, M. P., & Bai, G. (2021). Bipartisan federal legislation to address insulin access and affordability. Diabetes Spectrum, 34(4), 394-398. https://doi.org/10.2337/ds21-0008. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC8603115/ . "Insulin access and affordability affect the well-being of millions of Americans. In the 116th Congress (2019–2020), seven bipartisan bills were introduced to address this issue. In this article, the authors group the seven bills into *five categories (enhancing price transparency, limiting cost-sharing, changing biosimilar regulations, certifying prices, and permitting importation),* summarize the main content of these bills, and discuss their implications. Understanding the bipartisan insulin pricing policy proposals can facilitate the development of a feasible legislative agenda to improve insulin access and affordability."
[cxxxv] Congresswoman Angie Craig. U.S. Reps. Craig, Kildee and McBath Reintroduce Legislation to Cap Insulin Copays at $35 per Month. House Rep Angie Craig. March 9, 2023. Available at: https://craig.house.gov/media/press-releases/us-reps-craig-kildee-and-mcbath-reintroduce-legislation-cap-insulin-copays-35.
[cxxxvi] DeBeer Ellie. Sen. Josh Hawley introduces bill to reduce insulin prices. KOMU 8. January 30, 2023. Available at: https://www.komu.com/news/nationworld/sen-josh-hawley-introduces-bill-to-reduce-insulin-prices/article_d027eed0-a0b3-11ed-a601-273b3cc3ac64.html.
[cxxxvii] S.146 - Cap Insulin Prices Act. "(1) SELECTED INSULIN PRODUCTS.—The term 'selected insulin products' means at least one of each dosage form (such as vial, pump, or *inhaler dosage forms*) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting, and premixed) of insulin (as defined below), when available, as selected by the group health plan or health insurance issuer."; **S.954 - Affordable Insulin Now Act of 2023.** This uses the same definition – "(1) SELECTED INSULIN PRODUCTS.—The term 'selected insulin products' means at least one of each dosage form (such as vial, pump, or *inhaler dosage forms*) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting, and premixed) of insulin (as defined below), when available, as selected by the group health plan or health insurance issuer."
[cxxxviii] H.R.4813 - Matt's Act.
[cxxxix] Senator Maggie Hassan. Senator Hassan and Colleagues Reintroduce Bipartisan Bill to Ensure That Patients Can Get the Medication They Need. Senator Maggie Hassan. March 10, 2023. Available at: https://www.hassan.senate.gov/news/press-releases/senator-hassan-and-colleagues-reintroduce-bipartisan-bill-to-ensure-that-patients-can-get-the-medication-they-need; S.652 - Safe Step Act. "the plan or coverage shall— "(1) implement a clear and transparent process for a participant or beneficiary (or the prescribing health care provider on behalf of the participant or beneficiary) *to request an exception* to such medication step therapy protocol, pursuant to subsection (b)…….. (b) Circumstances for exception approval……. *(2) Delay of effective treatment would lead to severe or irreversible consequences*…… 4) Any treatment otherwise required under the protocol has prevented, will prevent, or is *likely to prevent a participant or beneficiary from achieving or maintaining reasonable and safe functional ability*……. *(6) Other circumstances, as determined by the Secretary*."
[cxl] H.R.3134 - Emergency Access to Insulin Act of 2023.
[cxli] H.R.3134 - Emergency Access to Insulin Act of 2023.
[cxlii] Collins Susan. Senators Collins, Shaheen Introduce Bipartisan INSULIN Act to Cut Insulin Costs for Millions More Americans. Susan Collins. April 21, 2023. Available at: https://www.collins.senate.gov/newsroom/senators-collins-shaheen-introduce-bipartisan-insulin-act-to-cut-insulin-costs-for-millions-more-americans.
[cxliii] Powel-Woodson Dorthula, DeLoatch Brooke, Ross Jordan. Proposed State and Federal PBM Legislation: Is There Reason for Action Now? Wiley. May 1, 2024. Available at: https://www.wiley.law/alert-Proposed-State-and-Federal-PBM-Legislation-Is-There-Reason-for-Action-Now. "Common themes found across the proposed legislation include: (i) eliminating spread pricing; (ii) expanding

reporting obligations; (iii) reshaping the relationship between PBMs and their affiliated pharmacies; and (iv) redefining and constricting PBMs' outlets for remuneration. While it is not clear whether any of these bills will pass, it does seem clear that exposing PBMs' opaque business practices and imposing regulatory constraints will remain a top priority for regulators. Evaluating various legislative proposals provides insight into regulators' current priorities and offers potential opportunities for action vis-à-vis your current (as well as future) PBM contract."

[cxliv] Mattingly TJ, Hyman DA, Bai G. Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy. *JAMA Health Forum.* 2023;4(11):e233804. doi:10.1001/jamahealthforum.2023.3804. Available at: https://jamanetwork.com/journals/jama-health-forum/fullarticle/2811344. "Findings:….The PBM provides 5 key functions: formulary design, utilization management, price negotiation, pharmacy network formation, and mail order pharmacy services. Criticism of the PBM industry centers around the lack of competition, pricing, agency problems, and lack of transparency. *Legislation to address these concerns has been introduced at the state and federal levels, but the potential for these policies to address concerns about PBMs is unknown and may be eclipsed by private sector responses*."

[cxlv] NASHP. New PBM Laws Reflect States' Targeted Approaches to Curb Prescription Drug Costs. August 12, 2019. Available at: https://nashp.org/new-pbm-laws-reflect-states%C2%92-targeted-approaches-to-curb-prescription-drug-costs/. Example language indicating that PBM transparency will improve oversight in various ways: "Access to a PBM's financial information will allow health plans in New York to monitor their contracted PBMs for fraudulent activity and deceptive acts."