A STUDY OF NEW JERSEY ASSEMBLY BILL 2839

REQUIRES HEALTH INSURERS TO LIMIT COST SHARING FOR INSULIN, EPINEPHRINE AUTO-INJECTORS AND ASTHMA INHALERS

Report to the New Jersey Assembly

May 18, 2022

Mandated Health Benefits Advisory Commission

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INTRODUCTION

The Mandated Health Benefits Advisory Commission (MHBAC) has been asked to review A-2839 (see Appendix I), a bill requiring coverage for and limiting the out-of-pocket costs for epinephrine auto-injector devices (EAs), prescription asthma inhalers and insulin for a 30-day supply. Specifically, A-2839 supplements various parts of statutory law by providing that the benefits for insulin, asthma inhalers, and EAs shall not be subject to any deductible, and that the copayment or coinsurance shall be limited as follows: $35 for a 30-day supply of insulin, $50 for a 30-day supply of an asthma inhaler, and $25 for a 30-day supply of EAs. The bill was referred to the MHBAC on March 14, 2022 by Assembly Financial Institutions and Insurance Committee Chairman John F. McKeon.

That part of the bill, mandating a specific level of cost-sharing, is the main focus of this report. This mandated benefit applies to hospital, medical and health service corporations, commercial group insurers and health maintenance organizations. The bill also applies to health benefits plans issued pursuant to the Individual Health Coverage Program, the Small Employer Health Benefits Program, the State Health Benefits Program and the School Employees' Health Benefits Program. The bill does not apply to Medicaid, Medicare Supplement, Medicare Advantage, Medicare, self-funded plans, multiple employer welfare arrangements, and other coverage not regulated by the New Jersey Department of Banking and Insurance (DOBI). The MHBAC estimates that the mandate would impact approximately 2,088,708 people, or roughly 22.5% of people covered under New Jersey-regulated plans.

The Mandated Health Benefits Advisory Commission Act (N.J.S.A. 17B:27D-1 *et seq.*) tasks the Commission with providing an independent analysis of the social, medical, and financial impact of proposed legislation referred to it for review. The Act does not ask the Commission to recommend whether or not to enact the legislation, and the Commission does not do so here.[i] The MHBAC prepared this report using its own resources, including staff from the New Jersey Department of Banking and Insurance. Commission members contributed their professional expertise, on a voluntary basis, in helping to shape the presentation of this report, analyzing published research, and drafting and editing its various sections. The MHBAC has sought to include information from a number of reputable sources that it found credible, but recognizes that opinions and analyses may differ.

LEGISLATIVE HISTORY

A-2839 was introduced on February 28, 2022 and referred to the Assembly Financial Institutions and Insurance Committee. It was reported out of Committee on March 24, 2022 and second referenced to the Assembly Health Committee. The Committee statement notes that "[t]his Assembly Bill No. 2839, as reported by this committee, is identical to Senate Bill No.1614." The Committee statement noted the following key elements of the legislation:

1. "This bill places a flat cap on the out-of-pocket contribution for any covered person prescribed insulin, an epinephrine auto-injector device, or a prescription asthma inhaler across insurance providers. Coverage for these items may not be subject to any deductible, and copayments or coinsurance are capped at $35 per 30-day supply of insulin, $25 for epinephrine auto-injector devices per 30-day supply, and $50 for prescription asthma inhalers per 30-day supply."
2. "These coverage standards apply to individual or group hospital service corporations, medical service corporations, and health service corporations as well as individual and group health insurance policies and health maintenance organizations. Additionally, the bill extends these coverage standards to individual and small employer health benefits plans and require that the State Health Benefits Commission and the School Employee's Health Benefits Commission ensure that their contracts comply with the coverage standards."

In the Senate, S-1614, was introduced on February 14, 2022 and was referred to the Senate Commerce Committee. The bill was reported out of committee on March 14, 2022 and the bill was referred to the Senate Budget and Appropriations Committee. This bill is identical to A-2839.

As of the writing of this report, the bill has not been heard in Assembly Health Committee nor Senate Budget and Appropriations Committee, and it has not been amended in either house from its original introduced text.

While A-2839 is new legislation for the 2022-23 Legislative Session, the Legislature has considered similar legislation in the past. ACS-954 from the 2020-21 Legislative Session sought to limit cost-sharing for consumers on insulin only. The MHBAC issued a report on June 12, 2020. A-2839 limits the cost-sharing for insulin as well, but also mandates out-of-pocket limits for asthma inhalers and epinephrine auto-injector devices.

ACS-954, and its Senate counterpart S-526, was not signed into law and while the Senate passed the bill on November 16, 2020, the bill was amended in the Assembly Appropriations Committee on February 24, 2021. As a result, the versions in the Assembly and the Senate did not match. The primary different between the two versions was the inclusion of Section 12 in ACS-954, which required reporting and disclosure from insulin manufacturers. The Senate version of the bill was first to include the reporting requirements via amendment on January 27, 2020; that reporting requirement was later removed in the Senate via committee amendments on November 9, 2020. With differences in the content of the bill and the passage in only one house, the bill was not presented to the Governor before the end of the session.

On March 18, 2020 the Office of Legislative Services (OLS) published a fiscal note on ACS-954. It found that the bill will increase by an indeterminate amount annual State and local costs incurred through the State Health Benefits Program (SHBP) and the School Employees' Health

Benefits Program (SEHBP). The Fiscal Note went on to say that the OLS does not have access to information about the number of plan members requiring insulin, the frequency with which it is purchased, or the prices for insulin currently paid to arrive at a cost estimate for the bill.

These estimates are limited to the impact on two public employee programs, the State Health Benefits Program and the School Employees' Health Benefits Program, which do not cover all public employees, nor do they apply to the commercial large or small group markets.[ii]

The fiscal note also found:

- "For active and retired plan members, the prescription drug copayments for retail generic, retail preferred brand, mail generic, and mail preferred brand prescriptions are below the $50 copayment ceiling imposed by the bill. The copayments that could exceed the $50 threshold are the prescriptions for the following types of insulin: retail non-preferred brand, mail non-preferred brand, and brand name with generic available. This is because either the current established member copayment under these categories is greater than $50, or the member is required to pay the difference in the price between the brand name drug and the generic drug, leaving open the potential for the copayment to exceed $50."

- "Informal information from the Division of Pensions and Benefits indicates that the bill could cost the State as much as $20 million. However, information regarding how the division arrived at its estimate and the data used were not provided. Information regarding pricing, the price differential, and an estimate of the number of prescriptions that would be written for the brand drugs with generic equivalents and non-preferred brand drugs, is not available to the OLS in order to determine an estimate independently."

A fiscal note for A-2839 has not yet been produced by OLS. However, because A-2839 is a similar bill, the fiscal note on ACS-954 is relevant for this analysis when exploring the financial impacts to the state of the bill.

The MHBAC enabling statute requires an analysis of "the demand for the proposed mandated health benefit from the public and the source and extent of opposition to mandating the health benefit." Stakeholders' positions of support or opposition for the cost-sharing cap bills A-2839 and S-1614, as expressed through legislative slips and lobbying activities, are presented in Table 1.

Table 1. Stakeholders' Positions on A-2839 and S-1614

Organization	Position (In Favor/Opposed/Seeks Amendment)	Comment
Chemistry Council of New Jersey	Seeks Amendment	
Prime Therapeutics LLC	Opposed	
Lilly	In Favor	
New Jersey Association of Health Plans	Opposed	Bill does not require manufacturers to address affordability; recommends cost reporting requirements on manufacturers as set forth in Section 12 of ACS-954 from last session.
Independence Blue Cross	Opposed	
New Jersey Citizen Action	In Favor	Calls for requirements for greater accountability on pharmaceutical companies to address systemic causes of price increases.
Pharmaceutical Care Management Association	Seeks Amendment	Bill fails to address rising manufacturer prices; calls for incorporating annual price reporting by manufacturers of insulin products, asthma inhalers, and epi pens as set forth in Section 12 of ACS-954 from the last session.
New Jersey Pharmacists Association and Garden State Pharmacy Owners	In Favor	

Independent Pharmacy Alliance and Omega Pharmacy Group	In Favor	
Sanofi	In Favor	
Novartis Services, Inc.	Partly In Favor/Partly Opposed	

Source: Testimony and witness slips submitted to the Assembly Financial Institutions and Insurance Committee and the Senate Commerce Committee at its meeting on A-2839/S-1614, March 14, 2022.

Source: ELEC Lobbying Activity Report. Accessed 5/9/22. (https://www3-elec.mwg.state.nj.us/ELEC_AGAA/LobbyingActivitySearch.aspx)

SOCIAL IMPACT AND MEDICAL EVIDENCE -- ASTHMA

Asthma in the United States

Approximately 25 million Americans have been diagnosed with asthma-1 in 13, representing 8% of adults, and 7% of children. States with the highest prevalence of asthma among adults include Maine (11.8%), Vermont (11.6%), West Virginia (11.5%) and Washington, D.C. (11.4%).[iii] The highest prevalence of asthma in the world, exists in Puerto Rico (14.2% of the population), and has been attributed to endemic viral respiratory illness in early childhood, on the island.[iv]

Cost of Asthma

Asthma is an expensive illness: between 2008-2013, the annual economic cost was estimated to be $81.9 billion, including medical costs, and loss of work and school days. The estimates were $3 billion in losses due to missed work/school days, $29 billion due to asthma related mortality, and $50.3 billion due to medical costs.[v]

Racial Disparities

Racial and ethnic disparities in asthma diagnosis exist in America, and parallel the effects of poverty, including poorer housing, exposure to poorer air quality and indoor allergens, and reduced access to health care. Black children have three times the asthma rate of white children. Black women have the highest fatality rate due to asthma. At 100% of the poverty level, 11.8%

of Americans have asthma, whereas at 450% of the poverty level, only 5.9% of Americans have asthma.[vi]

Prevalence of Asthma in New Jersey

In New Jersey, 9% of adults and 7% of children are estimated to have asthma. The number of women with asthma in New Jersey is double the rate of men, and more boys have asthma than girls. Asthma can affect anyone but in New Jersey, blacks, Hispanics and those in poorer, urban areas are more likely to carry the diagnosis than those in wealthier, suburban areas.[vii] However, nationwide, asthma is diagnosed most often in areas with higher levels of poverty, regardless of geography, and that holds true in New Jersey, where asthma patients are the most likely to be hospitalized if they come from Cumberland County, New Jersey's poorest. 10.7% of Cumberland Country residents describe a lack of health insurance compared to 8.7%, statewide; 22% of Cumberland County residents report being smokers, compared to 15%, statewide.[viii] [ix]

Medical Evidence

Asthma is used to describe a constellation of symptoms that include wheezing, breathlessness, chest tightness, and sometimes, cough.[x]

Asthma is a disease of the large and small airways of the lungs. In response to sensitizing agents, including but not limited to environmental allergens, airborne or occupational irritants, physical factors –heat, cold or exercise, the smooth muscles of the airways of the lungs contract and the airways become constricted; as part of an inflammatory reaction, excess mucus production occurs, further narrowing the airways. When untreated or inadequately treated, asthma can lead to permanent thickening and remodeling of the airways, chronic inflammation, and ultimately, respiratory arrest.[xi] [xii]

Asthma Treatment

Asthma treatment works by expanding the airways and decreasing mucus production, improving breathing capacity as well as oxygen exchange.[xiii]

Types of Inhalers Used in Asthma Treatment: [xiv]

Rescue Inhalers:

- Short-acting beta-agonists, like albuterol, levalbuterol to expand airways
- Anti-cholinergics like ipratropium to decrease mucus and help open airways
- Combination medications with both beta-agonists and anti-cholinergics

Preventive, Long-Term Inhalers:

- Inhaled corticosteroids like beclamethasone, budenoside, fluticasone
- Long-acting beta-agonists like formoterol, salmeterol
- Combination inhalers that include inhaled corticosteroids, along with a beta-agonist, like Advair (fluticasone/salmeterol) Breo (fluticasone/vilanterol), Symbicort (budesonide/formoterol).
- Long-acting muscarinic antagonists, that relax the airways like Spiriva (tiotropium).

These long-acting medications generate the greatest costs for consumers and payers, but their use results in the greatest reductions in emergency department care and hospitalizations.[xv]

Frequency of Inhaler Use Linked to Cost

The frequency with which an asthmatic patient uses an asthma inhaler depends upon a number of factors including disease severity, access to a health care provider for diagnosis and prescription-writing, and adequate health insurance (and/or money) to purchase the medication, as prescribed. Patients with more severe asthma must often use several inhalers, several times a day. Stories abound of patients incapable of securing a written prescription for an asthma inhaler from the pharmacy because: they had no drug coverage in their insurance plan, they had a high deductible insurance plan and were first required to pay the full cost of the drug, or the co-pay was higher than they could afford.[xvi] The cost of asthma inhalers in 2021 is presented in Table 2.

Table 2. Average Cost Without Insurance of Brand Name Asthma Inhalers vs. Generic Brands, 2021

Brand Name Inhaler	**Cost of 1 Inhaler w/out Insurance**	**Generic Medication**	**Cost of 1 Inhaler w/out Insurance**
Advair	$471.75	Fluticasone/salmeterol	$319.47
Alvesco	$138.30	None on the market	N/A
Asmanex Twisthaler	$302.13	None on the market	N/A
Flovent	$271.56	None on the market	N/A
Pulmicort	$252.40	Budesonide	$227.19

Qvar	$244.51	None on the market	N/A
Serevent	$522.43	None on the market	N/A
Symbicort	$358.75	Budesonide/formoterol	$322.30
Ventolin	$74.32	Salbutamol[xvii]	$54.34

Source: https://www.talktomira.com/post/asthma-inhalers-cost-without-insurance-in-2021 [xviii]

Individuals with asthma who are either untreated or incompletely or ineffectively treated when they cannot afford prescribed inhalers, are likely, as symptoms become more severe, to seek care in emergency rooms, or to require hospitalization for their treatment, driving up the economic costs of this condition.[xix]

SOCIAL IMPACT AND MEDICAL EVIDENCE -- DIABETES

Diabetes in the United States

According to the Center for Disease Control and Prevention (CDC), 37. 3 million Americans of all ages had been diagnosed with diabetes mellitus (DM) in 2022, or 11.3% of the U.S. population.[xx] The highest ethnic prevalence is in American Indians (14.5%), followed by non-Hispanic blacks (12.1%) Hispanics (11.8%), non-Hispanic Asian people (9.5%) and non-Hispanic whites (7.4%). Although fewer adults over the age of 18 were diagnosed with DM between 2008-2018, compared to the prior decade, there was an increasing rate of diagnosis in youths, below age 18, particularly among non-Hispanic blacks.[xxi] In 2019, Diabetes was the 7th leading cause of death in the United States.[xxii]

In 2018, 1.4 million adults, 20 years of age or older, reported having Type I Diabetes Mellitus, and using insulin; additionally, 187,000 children, below 20 years of age, are diagnosed with Type 1 Diabetes Mellitus, requiring the use of insulin.[xxiii] According to Hanefeld, the majority of individuals with Type 2 DM will require insulin therapy within the first decade after their diagnosis.[xxiv] The CDC reports that 2-8% of pregnant American women may experience gestational diabetes and that these women have as high as a 50% chance of developing Type II DM during their lifetime.[xxv] Overall, it is estimated that 7.4 million Americans with diabetes use one or more types of insulin.[xxvi]

Diabetes in New Jersey

As of January 2022, 10.5% of the New Jersey population had been diagnosed with diabetes. It is estimated that every year, 64,094 individuals in New Jersey are diagnosed with diabetes. Those with diabetes incur nearly 2.5 times the direct medical costs as those without the disease. The total direct medical costs of diabetes in New Jersey were estimated to be $6.7 billion in 2017, whereas another $2.5 billion was attributed to indirect medical costs. [xxvii]

In 2018, the New Jersey age-adjusted rate of adults diagnosed with diabetes was: 9.6% of non-Hispanic Blacks; 10.1% of Hispanics and 7.2% of Asians and non-Hispanic whites.[xxviii]

The highest prevalence of diabetes in New Jersey (15.3%) is reported in Cumberland Country, which is also New Jersey's poorest county. In 2018, New Jersey and the United States shared approximately the same prevalence of diabetes (9.6% and 10.4%, respectively).[xxix]

Although 10.8% of New Jersey's population described being told by a health care provider that they had diabetes in 2019, mortality rates related to diabetes were then lower in New Jersey than in all other states except Colorado, suggesting that many diabetics were abiding by treatment guidelines.[xxx,xxxi] Uncontrolled hyperglycemia in untreated diabetics results in vascular disease that can be manifested, overtime, in neural damage, blindness, limb amputations, chronic kidney disease, heart attacks, and death.[xxxii] Treatment compliance in New Jersey as across the United States, is being challenged by the rising cost of insulin, which has tripled in price between 2002 and 2013.[xxxiii] Patients who have high-deductible health insurance plans, no insurance, or are in the Medicare Part D donut hole, may be forced to pay close to the manufacturer's list price for insulin, causing some to seek alternative means of obtaining their insulin that can result in increased health risks. Some examples that have been reported as methods of reducing costs for insulin include driving across borders to purchase the same medication at lower cost or a strategy of rationing doses -- an extremely risky choice that may result in hospitalization or loss of life. Even diabetic patients with generous prescription plans have experienced increased out-of-pocket costs due to the increase in the manufacturer's list price for insulin and limited availability of insulin choices in the current pharmaceutical market.[xxxiv,xxxv,xxxvi]

Cost pressures and the lack of choice have even led one state, California, to pass legislation creating a state-sponsored generic drug label,[xxxvii,xxxviii] and later announce, as part of the state's latest budget, that California would seek to contract for and manufacture its own insulin.[xxxix] Similarly, the Blue Cross Blue Shield Association has launched an initiative with Civica, a nonprofit enterprise designed to reduce chronic generic drug shortages and high pricing, to manufacture and distribute generic drugs, including insulin.[xl]

Between 2003 and 2013 the mean price of insulin approximately tripled, rising from $4.34 per milliliter to $12.92 per milliliter.[xli] From 2012 to 2016 the price of insulin nearly doubled. The average cost of insulin per diabetes patient per year rose from $2864 in 2012 to $5705 in 2016.[xlii] Over the past decade, out-of-pocket costs for insulin have also doubled. A study of health care claims for patients with Type 1 diabetes concluded that the doubling of gross spending on insulin in that same period, "were primarily driven by increases in insulin prices, and to a lesser extent, a

shift towards use of more expensive products."[xliii] High costs for insulin can contribute to nonadherence and less effective glycemic control for patients.[xliv]

A 2017 survey, for instance, found that 25.5% of the respondents reported cost-related insulin underuse.[xlv] This underuse included using less insulin than prescribed, stretching out insulin supplies over longer periods, stopping the use of insulin altogether, not filling a prescription for insulin, or not starting the use of insulin due to cost. Furthermore, more than one-third of those who reported cost-related underuse also reported not discussing their affordability issues with their clinicians.[xlvi]

There are profound healthcare cost implications if diabetics do not regulate their blood sugar levels effectively. Poor glycemic control can result in higher rates of blindness, kidney failure, heart disease, stroke, amputations of toes, feet, and legs, and hospitalizations.[xlvii] If a lower and predictable price improves their access to insulin, it is reasonable to expect that diabetics will find that their health improves, they require less medical care, and their overall healthcare costs decline.[xlviii]

There are three primary drivers causing these dramatic insulin price rises. First, only three manufacturers make the overwhelming majority of the world's insulin supply (*i.e.*, Sanofi, Novo Nordisk, and Eli Lilly). Second, the rules and costs for bringing a generic version of insulin to market make it difficult and cost-prohibitive.[xlix] Finally, there are multiple pathways that can determine the price paid by the person with diabetes at the point-of-sale. Insulin manufacturers, pharmaceutical wholesalers, PBMs, pharmacies, pharmacy services administrative organizations, health plans, and employers are all parts of the payer system that affects the ultimate out-of-pocket costs for patients. Patient costs are determined by a combination of list prices, rebates, and fees negotiated among these stakeholders.[l] Pricing power can be concentrated in a small number of stakeholders in this chain. This concentration may reduce the incentives for manufacturers, wholesalers, and PBMs to compete on drug prices.

To address the pressure created by rapid price increases, some insurance companies, pharmacy benefits managers, and drug manufacturers have created programs to lower insulin costs for select patient groups. Some of these programs are offered through existing health insurance plans, while others are tailored to low income patients or those who pay directly for their insulin, rather than using a prescription plan.[li] Cigna and Express Scripts, for example, cap monthly out-of-pocket insulin costs at $25 for diabetics whose employers opt into their programs. Drug maker Sanofi offers a program for patients paying cash for their insulin. The company provides 10 vials of insulin or 10 insulin pens, roughly a 30-day supply, for $99. Eli Lilly is offering a generic version of its expensive insulin drug Humalog for half the price of its non-generic version, at $137.35 per vial.

The purpose of these programs is to reduce patients' out-of-pocket costs, so that they do not pay the full cost-sharing amounts. Some of these programs involve manufacturer's coupons or

savings cards. Novo Nordisk, for instance, offers a NovoLog Savings Card that makes its NovoLog insulin product available to patients covered by commercial insurance for as little as $25 per 30-day supply.[lii] Eli Lilly offers a BASALGAR Savings Card, also for diabetics with commercial insurance coverage. The savings card permits users of the BASALGAR insulin product to pay as little as $5 per month out-of-pocket for their prescriptions.[liii] Both of these savings cards are limited to 24 months or 24 prescriptions.

The impact of these manufacturers' programs to reduce out-of-pocket costs is limited to specific insurance market segments for specific insulin products. As the BASALGAR Savings Card webpage states, "This offer is invalid for patients without commercial drug insurance or those whose prescription claims are eligible to be reimbursed…by…Medicaid, Medicare, Medicare Part D, Medigap, DOD, VA, TRICARE/CHAMPUS, or any state patient or pharmaceutical assistance program."[liv] Indeed, under federal anti-kickback law, it's illegal for drug manufacturers to offer any type of drug coupon for federally regulated coverage. Moreover, drug coupons have come under greater scrutiny as a cost-driver in health care as a recent Kaiser Health News article, "Is My Drug Copay Coupon a Form of Charity – Or a Bribe?" noted.[lv]

Medical Evidence -- Diabetes

Diabetes Mellitus (DM) is a metabolic disease involving the body's production and utilization of the pancreas-secreting hormone, commonly known as insulin. In Type 1 DM, damaged beta cells of the islets of Langerhans in the pancreas fail to secrete insulin, or enough insulin, for glucose transport into cells, resulting in hyperglycemia. Type 2 DM, is characterized by both diminished insulin production and increased cell resistance to insulin, eventually also leading to hyperglycemia.[lvi] Gestational Diabetes (GD), first diagnosed in the second or third trimester of pregnancy, is associated with a higher risk for maternal birth complications associated with macrosomia, intrauterine fetal death, and neonatal hypoglycemia.[lvii,lviii] Other, rare forms of diabetes exist, related to genetic disorders, diseases of the pancreas, endocrinopathies and pancreatic damage from drugs or chemicals.

Type 1 Diabetes

Classified as an autoimmune disorder, Type 1 DM is theorized to result from lymphocytic destruction of the insulin-producing cells of the pancreas after a viral illness in a genetically susceptible individual. Type 1 DM, called juvenile-onset diabetes in the past, has a peak incidence of onset of 11-13 years of age, but 50% of patients experience an onset after 20 years of age. After an initial diagnosis, the disease may go into a brief remission, but ultimately everyone with Type 1 DM will require exogenous insulin. Type 1 DM occurs most often in non-Hispanic whites, particularly those of northern European origin, and is more common in men than women.[lix,lx,lxi] The disease is life-altering and labor-intensive, requiring strict attention to dietary control, multiple daily blood sugar measurements, multiple daily insulin injections or management of an insulin pump, and close monitoring of blood sugar levels in response to exercise, stress and illness.

Type 2 Diabetes

Type 2 diabetics comprise 90-95% of those diagnosed with the disease.[lxii] Risk factors for Type 2 DM include: being over 45 years of age, obesity, family history of the disease, ethnicity (African American, Alaska Native, American Indian, Asian American, Hispanic/Latino, Native Hawaiian, or Pacific Islander), sedentary lifestyle, hypertension, dyslipidemia, history of gestational diabetes and diagnosis of polycystic ovarian syndrome.[lxiii] As noted in the Social Impact discussion above, the fastest rising incidence of Type 2 diabetes is in non-Hispanic black children and youths, below age 18.[lxiv] Some individuals with Type 2 DM will successfully arrest the advance of the disease with weight loss, dietary changes and increased exercise; most will require oral medications to decrease insulin resistance and/or increase pancreatic secretion of insulin and many will eventually require treatment with insulin. Early transient insulin therapy in clinically appropriate individuals has been shown to preserve beta cell functioning and to reduce macrovascular changes which lead to coronary heart disease and strokes.[lxv]

A recent observational study of patients hospitalized with COVID-19 found that those with diabetes or uncontrolled hyperglycemia had longer hospital stays and higher mortality rates.[lxvi]

Insulin used to treat diabetes

Prior to the discovery and successful clinical treatment of a patient by Banting, Best, MacLeod, and Collip at the University of Toronto between 1921 and 1922, Type 1 diabetes was an inevitably fatal disease within two years of diagnosis.[lxvii] Type 1 diabetes (and when necessary, Type 2 DM and GD) is treated with a combination of insulin formulations based on their onset of action, peak of action, and duration of action, with dosages and scheduling of doses designed to control blood sugar both between meals and at night, and after post meal blood sugar surges. With the exception of Afrezza, which is inhaled, all insulin must be injected and cannot be taken orally. Sensitive to heat and light, the insulin in a vial begins to deteriorate after 28 days, and care in storage and handling is necessary to reduce the need to discard and replace insulin before it is administered. Individual patients with Type 1 diabetes may need to inject as many as 5 doses of insulin/day, requiring multiple syringes.[lxviii] Those using insulin pumps are faced with the functional challenges and costs of that technology. A chart of insulin types available in the US and their characteristics is presented in Table 3.

Table 3. Insulin Chart (Available in US)

Insulin Type	Onset of Action	Peak	Duration of Action
Afrezza	<15 minutes	Approx. 50 minutes	2-3 hours
Lispro U-100 (Humalog)	Approx. 15 minutes	1-2 hours	3-6 hours
Lispro U-200 (Humalog 200)	Approx. 15 minutes	1-2 hours	3-6 hours
Aspart (Novolog)	Approx. 15 minutes	1-2 hours	3-6 hours
Glulisine (Apidra)	Approx. 20 minutes	1-2 hours	3-6 hours

Regular U-100 (Novolin R, Humulin R)	30-60 minutes	2-4 hours	6-10 hours
Humulin R Regular U-500	30-60 minutes	2-4 hours	Up to 24 hours
NPH (Novolin N, Humulin N, ReliOn)	2-4 hours	4-8 hours	10-18 hours
Glargine U-100 (Lantus)	1-2 hours	Minimal	Up to 24 hours
Glargine U-100 (Basaglar)	1-2 hours	Minimal	Up to 24 hours
Glargine U-300 (Toujeo)	6 hours	No significant peak	24-36 hours
Detemir (Levemir)	1-2 hours	Minimal	Up to 24 hours
Degludec U-100 & U-200 (Tresiba)	1-4 hours	No significant peak	About 42 hours

Adapted from Bennett, J. Insulin Chart: dLife. 8/17/17. **https://dlife.com/insulin-chart/**

The use of human insulin (Regular, NPH) has been increasingly supplanted by insulin analogs (like Glargine, Lispro, Aspart, Detemir) which Lipska describes as no more effective in achieving glycemic control or reducing severe hypoglycemic episodes, but significantly more expensive.[lxix] A Cochrane analysis of 9 studies found slight improvement in glycemic control with the use of insulin analogs compared to regular insulin, but no differences in the incidence of hypoglycemia or quality of life.[lxx] In contrast, some diabetes experts as well as patient advocates recommend the use of insulin analogs describing their greater prandial rapidity of action, sustained basal action, need for fewer injections, self-reports of less nocturnal hypoglycemia (and fear of same), less weight gain and improved quality of life.[lxxi,lxxii]

SOCIAL IMPACT AND MEDICAL EVIDENCE – EPINEPHRINE AUTO-INJECTORS (EAs)

EpiPen is a brand name for one of a number of epinephrine auto-injector devices used by patients suffering from a potentially life-threatening allergic reaction called anaphylaxis.[lxxiii] Epinephrine Auto-Injector (EA) will be used as the common name for all such devices throughout this related section of the report.

Approximately 2 million prescriptions were written for EAs in 2019, for approximately 1.5 million patients.[lxxiv] Patients may purchase more than one device to carry with them or to store for immediate access (home; school; boat; car).

More than 50 million Americans experience allergic reactions each year. Allergies are the 6th leading cause of chronic illness in the United States. [lxxv] It is common for individuals to be allergic to more than one trigger, the most common being: trees, grass, weed pollen, mold spores, dust mites, cockroaches, and cat, dog, and rodent dander. In 2021 adults experienced allergies to varying triggers with the following frequency:[lxxvi]

-Drug allergies: 15%
-Mold allergies: 14%
-Pet allergies: 12%
-Food allergies: 11%
-Insect allergies: 7%
-Latex allergies: 5%
-Other triggers: 3%

Approximately 26 million adults (10.8%) and about 5.6 million children have food allergies (7.6%) in the US. [lxxvii] [lxxviii] Milk is the most common food allergen in children, followed by eggs, and peanuts. The most common food allergen among adults is shellfish, followed by peanuts and then tree nuts.[lxxix]

Anaphylaxis, the life-threatening response to allergens necessitating the use of an EA, occurs most frequently in response to medicine, food and then insect stings.[lxxx]
Medication-related anaphylaxis is the most common cause of death. Black Americans and older Americans are the most likely to die from anaphylaxis due to medications, food or an unknown allergen.[lxxxi]

Medical Evidence -- EAs

Anaphylaxis is a severe allergic reaction to a triggering agent like a medication, food or insect sting. It can occur immediately after exposure to an allergen, or it can occur several hours later. It involves a full body response which may include local swelling, swelling of the lips, mouth and throat, bronchoconstriction (resulting in narrowed airways), rapidly falling blood pressure, nausea, loss of consciousness and cardiac arrest. If not immediately treated with intramuscular epinephrine, which reverses vasodilation and bronchoconstriction, anaphylaxis can result in death.[lxxxii]

Symptoms of Anaphylaxis

Symptoms of anaphylaxis may include:
• Breathing: wheezing, shortness of breath, throat tightness, cough, hoarse voice, chest pain/tightness, trouble swallowing, itchy mouth/throat, nasal stuffiness/congestion

• Circulation: pale/blue color, low pulse, dizziness, lightheadedness/passing out, low blood pressure, shock, loss of consciousness
• Skin: hives, swelling, itch, warmth, redness, rash
• Stomach: nausea, pain/cramps, vomiting, diarrhea
• Other: anxiety, feeling of impending doom, itchy/red/watery eyes, headache, cramping of the uterus[lxxxiii].

Because anaphylaxis can occur to an individual at any time and in any setting, having immediate access to an injectable form of epinephrine is essential. Based on nationwide random-digit-dial surveys, Wood and colleagues estimate the prevalence of anaphylaxis in the U.S. population to be at least 1.6%. Among those who had experienced anaphylaxis in their large sample (many more than once), 52% did not have a prescription for an EA.[lxxxiv]

Injected epinephrine is the only immediate, emergency treatment for anaphylaxis, and it is very effective. Among 13 children experiencing anaphylaxis in response to a food allergen, 6 of 7 children treated within 30 minutes of ingestion of the allergen with intramuscular epinephrine, survived.[lxxxv]

Use of Epinephrine Auto-Injectors in Relation to Cost

EpiPens have been on the market since 1977. In 2009, Mylan purchased the pharmaceutical company that manufactured the EpiPen. At that time, EpiPens sold for about $57 apiece.[lxxxvi] In 2010 federal guidelines recommended that EpiPens be sold in pairs, because a small, but significant, percentage of children requiring epinephrine needed more than one dose. Mylan began selling only twin-packs, at a higher unit price. Other changes in federal law and the difficulties in bringing effective competitive products to the market, left Mylan free to raise its prices even more. By May 2016, a twin-pack of EpiPens cost more than $600, an inflation-adjusted rise of more than 450% since 2004.

The current costs of EpiPens and generic versions, from two data sources, reflected in black and red, are presented in Table 4.

Table 4. Average Cost of Epinephrine Auto-injectors, 2022

Pharmacy	**Cost of Brand Name EpiPen (2-pack)**	**Cost of Generic Version (2-pack)**
CVS	$650 ($649.99)	$340 ($340.84)
Walgreens	$735 ($735.08)	$341 ($376.12)

Stop n Shop	$696	$662
Rite Aid	$696 ($732.99)	$530 ($489.85)
Walmart	$684	$320
Duane Reade	$696	$341
Wegmans	$696	$418
Kroger	$730 ($730.49)	$389 ($572.33)
Target	$649.99	$340
Safeway	$671.43	$470.04

Source: https://www.talktomira/post/how-much-does-an-epipen-cost [lxxxix]

Source: https://costaide.com/epipen-price/ [xc]

These prices may put EAs out of reach for individuals or parents without a prescription drug component in their health care plan, with a high-deductible plan, or with a high copay for prescription drugs, particularly in the face of severe allergies where there is a need to have more than one EA at any one time (e.g., at home, school, work, etc.).

OTHER STATES COST-SHARING CAPS LEGISLATION AND FINANCIAL IMPACT

Cost-Sharing Legislation and Financial Impact -- Asthma Inhalers

Only one state, Rhode Island, has introduced legislation to limit cost-sharing exclusively for prescription asthma inhalers. RI H7878 would require any health plan that provides coverage for prescription asthma inhalers to cap the total amount a covered person must pay at $50 for a 30-day supply. That proposed cost-sharing cap would not be subject to any deductible.[xci] The Rhode Island House Health and Human Services Committee recommended that H7878 be held for further study, and no fiscal note was attached to the bill. H7878 was the only bill identified that contained a stand-alone cost-sharing cap on prescription asthma inhalers.

Cost-Sharing Legislation and Financial Impact -- Insulin

To date, twenty states and the District of Columbia have passed legislation capping cost-sharing for 30-day insulin supplies (see Table 5).

Table 5. States That Have Passed an Insulin Price Cap

State	Legislation	Effective Date
Alabama	$100 cap for 30-day supply	10/1/21
Colorado	$100 cap for 30-day supply	1/1/20
Connecticut	$25 cap for 30-day supply; $100 cap for 30-days' worth of devices and supplies	1/1/22
Delaware	$100 cap for 30-day supply	1/1/21
District of Columbia	$30 cap for 30-day supply and "collective" family cap of $100	1/1/22
Illinois	$100 cap for 30-day supply	1/1/21
Kentucky	$30 co-pay, no matter the quantity or insulin type	1/1/22
Maine	$35 cap for 30-day supply	1/1/21
Minnesota	$35 cap for 1x per year emergency 30-day supply; $50 cap for 90-day supply	7/1/20
New Hampshire	$30 cap for 30-day supply	9/14/20

New Mexico	$25 cap for 30-day supply	1/1/21
New York	$100 cap for 30-day supply (for state-regulated commercial plans)	1/1/21
Oklahoma	$30 cap for 30-day supply	11/1/21
Oregon	$75 cap for 30-day supply	1/1/22
Rhode Island	$40 cap for 30-day supply	1/1/22
Texas	$25 cap for 30-day supply	9/1/21
Utah	$30 cap for 30-day supply	1/1/21
Vermont	$100 collective cap for 30-day supply	1/1/22
Virginia	$50 cap for 30-day supply	1/1/21
Washington	$100 cap for 30-day supply	1/1/21
West Virginia	$100 collective cap for 30-day supply	7/1/20

Source: American Diabetes Association, "Insulin Co-pay Cap Laws," September 15, 2021.

Colorado was the first state to pass insulin price cap legislation, when its law went into effect in 2020. Colorado's law permits insurers to charge patients $100 per insulin prescription per month. The cost-sharing limits are based on a per prescription basis, not as a monthly cap on out-of-pocket costs for the patient. For diabetics who take two types of insulin -- such as a basal insulin and a mealtime insulin or a short-acting insulin and a long-acting insulin -- therefore, the new law leaves them with potential copays of $200 per month for both insulin prescriptions.[xcii] The laws passed in Colorado, Illinois, and New Mexico require the states to produce reports on insulin pricing practices and suggest public policy options to improve insulin affordability.[xciii]

Financial Impact - Insulin

The only empirical evidence of the impact of insulin cost-sharing caps on insurance premium rates comes from Colorado. Before its first-in-the-nation law went into effect, The Colorado Sun examined the documents that 21 health plans submitted to the state's Division of Insurance to justify their proposed premium rates in the individual and small group markets. The Colorado Sun reported that most plans did not mention the insulin cost-sharing caps as being a factor in their pricing calculations; the plans that did reference the cost-sharing requirements described the law's impact with words like "negligible." Kaiser Permanente in its filing to the state, for example, stated, "It is expected that the cost sharing caps will have a *de minimis* impact on rates."[xciv]

Colorado's Legislative Council Staff produced a fiscal note on the state's proposed $100 insulin copayment cap bill before it became law. The analysis found that the proposed bill would increase state expenditures and General Fund diversions on an ongoing basis.[xcv] The expenditures were estimated at $32,078 in the first fiscal year and $16,040 in the second fiscal year. The expenditures would be realized as diversions of insurance premium tax revenue from the General Fund to the Division of Insurance in Colorado's Department of Regulatory Agencies. The revenue diverted to the Division of Insurance would fund the personnel requirements to cover additional rate and form reviews and complaints, estimated as a 0.4 full time equivalent (FTE) employee in fiscal year 1 and a 0.2 FTE employee in fiscal year 2.[xcvi]

Before passing its copayment cap on insulin at $25 per month into law, New Mexico issued a Fiscal Impact Report on the proposed legislation. This analysis found that the estimated impact on the state's operating budget would be $14,000 in the first fiscal year, $42,000 in the second fiscal year, and $0 in the third fiscal year, for a three-year total cost of $56,000, to be drawn from the state's General Fund.[xcvii] The analysis reported that amendments that established a preferred formulary of prescription insulin products dropped the cost estimates of the legislation dramatically. The analysis also found that negotiations with the state's pharmacy benefit manager, Express Scripts, reduced the fiscal impact of the proposed $25 insulin copay cap to zero, "at least for General Services Department, and probably for the entire suite of state-provided insurance products."[xcviii] The analysis emphasized the importance of negotiating insulin prices with the state plans' PBM in reducing the law's fiscal impact essentially to zero.

Washington capped its cost-sharing requirement at $100 for a 30-day supply of insulin. When the legislation was under consideration, the Office of the Insurance Commissioner issued a fiscal note on the estimated costs of the bill. It reported that the new law would require less than one FTE employee, to establish new filing procedures and review new forms and rates.[xcix] The analysis estimated FY 2021 costs at $46,406, calendar year costs from 2021 to 2023 at $38,616, and no costs for calendar years 2023 to 2025.[c] These estimated operating expenditures would be spent from the Insurance Commissioner's Regulatory Account.

Utah's State Legislature produced a fiscal note when it was considering a bill for a $30 cost-sharing cap on a 30-day supply of insulin. The fiscal note estimated total costs of the legislation as $45,900 for FY 2021 and $32,000 for FY 2022.[ci] The cost of the legislation to the Public Employees Health Program was estimated at $25,000 for FY 2021 and annually thereafter.[cii] The estimated cost to the Department of Insurance was $19,200 in FY 2021 (including first-year expenditures) and $7,200 annually thereafter.[ciii] The tiny difference in projections was made up by an increase in annual revenue to the Department of Commerce Service Fund, which would be used to pay for the insulin cost-sharing cap.

Maine's Health Coverage, Insurance and Financial Services Committee produced a fiscal note estimating the impact of its proposed legislation to cap cost-sharing for a 30-day supply of insulin at $35. The analysis reported that the Maine State Employee Health Plan did not anticipate a significant cost increase as a result of the cost-sharing limit.[civ] The fiscal note concluded, "Any costs, which are expected to be minor, would likely be reflected through increased premium amounts in future fiscal years."[cv]

The Florida Senate considered a bill to cap cost-sharing for a 30-day supply of insulin at $100. In an analysis, based on current health plans' insulin claims volume and the low enrollment in the state's high deductible health plans, the Department of Management Services estimated that the implementation of the proposed $100 insulin copay cap would result in a fiscal impact in the range of $14,000 to $17,500 per year to the State Group Insurance program.[cvi]

Virginia's State Corporation Commission also issued a fiscal impact statement on its proposed $50 per 30-day insulin supply cost-sharing cap. That fiscal impact statement reported that the proposed copayment limit would have no fiscal impact and no fiscal implications for the State Corporation Commission, Bureau of Insurance.[cvii]

An Illinois report on insulin pricing to its General Assembly examined the impact of a mandated $100 cap on copayments for a 30-day supply of insulin. The report looked at the impact of the mandate on premiums for 17 Affordable Care Act-compliant insurers. In the analysis, those 17 insurers were divided into 13 insurers that would experience no impact or a negligible impact on their premiums, and 4 insurers that would experience some measurable impact. [*N.B.,* the report noted that two of these four insurers have large market shares.] The analysis found that the first insurer would see a premium increase of $0.25 per member per month, the second insurer would see premiums rise by 0.20%, the third insurer would see a premium increase of $0.39 (PMPM), and the fourth insurer would see premiums rise by 0.0-0.-17%.[cviii]

The Kentucky Department of Insurance issued a Financial Impact Statement of the proposed bill mandating that cost-sharing for a covered insulin prescription not exceed $30 for a 30-day supply. The bill excluded members covered by Medicaid and the state employee health plans. The analysis estimated that the proposed bill would increase health benefit plan premiums approximately $0.00 to $0.80 PMPM, representing an increase of roughly 0.0% to 0.1%. The Kentucky financial impact

statement also reported that the mandate was not expected "to materially increase administrative expenses of insurers," based upon the analysis of the proposed mandate and the Department's "experience with similar health insurance benefits."[cix]

It should be noted that the fiscal notes generally measure the difference between a current benefit available under a state's public employee program and the coverage as modified by the proposed legislation in that state. To the extent that coverage under state public programs is relatively rich, the cost impact would be lower. In states with less rich pharmacy benefits, the cost impact would be greater. Also, the size of the state's public employee program has an impact on the overall cost to the state.

Finally, a 2019 Milliman study, commissioned by drug manufacturer Eli Lilly, examined the impact on premiums of reducing patient cost-sharing for insulin purchases to $0 in integrated high deductible plans. The investigators concluded that eliminating all cost-sharing would result in an estimated 51% of insulin users saving over $250 on total out-of-pocket costs per year, while an estimated 69% of insulin users would save over $500 on insulin out-of-pocket costs per year.[cx] Premiums for all members of the high deductible plans would increase an estimated $5.12 per member per year, as a result of eliminating cost-sharing for insulin users.[cxi]

Cost-Sharing Legislation and Financial Impact -- Epinephrine Auto-injectors

A small number of states have attempted to address the related issues of rising costs and limited availability of EAs and name-brand EpiPens by passing targeted legislation in the last few years. None of these bills affecting EA affordability and accessibility were accompanied by fiscal notes or financial impact analyses.

Idaho, for example, attempted to streamline the process by which patients obtain EAs by amending the 2019 Idaho Code to permit pharmacists to prescribe and dispense them.[cxii] Idaho pharmacists were granted this new authority without physician oversight or protocol arrangement.

On January 7, 2019 Ohio's Governor signed into law House Bill 101, the Epinephrine Accessibility Act. That law contained two provisions intended to reduce the cost of and increase accessibility to EAs. The first provision permitted Ohio pharmacists to substitute a pharmaceutically-equivalent EA for a prescribed brand-name EA, with the patient's consent. The second provision enabled Ohio pharmacists to dispense EAs to patients age 18 and above without an additional prescription, once the patient had established that s/he had received an initial EA prescription.[cxiv] The Ohio law placed no cost-sharing caps on EA prices, but relied on free market competition and a greater utilization of generic alternatives to reduce patient costs.

A fiscal note on HB 101 anticipated no discernible ongoing costs for the State Board of Pharmacy or local boards of health to implement and enforce the new law.[cxv]

Illinois added a new section to its Insurance Code requiring all group and individual health insurance policies or managed care plans issued or amended after January 1, 2020 to "provide coverage for medically necessary epinephrine injectors for persons 18 years of age or under.[cxvi] This addition to the Illinois Insurance Code did not include cost-sharing caps, such as limitations on copayments, deductibles, coinsurance, or other out-of-pocket expenses to the patient, or limitations on the prices manufacturers can charge.

Maine attempted to reduce the cost and expand access to EAs by expanding the definition of epinephrine pen and epinephrine auto-injector to include new epinephrine delivery methods approved by the United States Food and Drug Administration. This law, LD 1972 (also SP 674), passed in 2020 and effective immediately, sought to broaden the availability and affordability of epinephrine by broadening the definition of EAs beyond EpiPens.[cxviii] The specific language of the law replaced "epinephrine pen" with "epinephrine autoinjector."[cxix]

DISCUSSION

Attempts in other states to address the impact of rising drug costs on affordability and accessibility through legislation have focused primarily on insulin. The Legislatures of New Jersey and Minnesota are considering expanding the potential benefits of capping cost-sharing for more chronically ill consumers by introducing legislation to limit cost-sharing for drugs used to treat asthma, diabetes, and allergies in the same bill. There are some segments of the New Jersey population, however, whose drug costs would be unaffected by the proposed cost-sharing limitation bill.

A-2839, for example, would have no impact on New Jerseyans covered under Medicaid, Medicare, self-funded plans, or those with no health insurance. Approximately 15.5% of New Jersey's population is covered by Medicaid.[cxx] It should be noted, however, that Medicaid generally has no cost-sharing prescription drugs for most beneficiaries, and very modest cost-sharing for others. Most residents enrolled in Medicaid/CHIP, do not have any cost-sharing for covered medications.[cxxi] Another 14.6% of New Jersey's population is covered under Medicare.[cxxii] The cost of drugs for Medicare recipients depends upon the plan they have chosen through either traditional Medicare Part D or a supplemental drug coverage plan, whether or not they have met an income-dependent annual deductible, whether or not they qualify for a low income subsidy, and upon the designated tier of the drug prescribed.[cxxiii] Medicare products are generally regulated at the federal level and the provisions of A-2839 would not apply to individuals covered by Medicare. Approximately 36% of New Jersey residents are covered under self-funded plans that are regulated at the federal level; they would not be impacted by this bill. Finally, approximately 6.4% of New Jerseyans are not covered under any health

insurance.[cxxiv] None of the New Jersey residents in these groups would see their prescription cost-sharing expenses for EAs, insulin, or asthma inhalers affected by A-2839.

Another concern is that cost-sharing limit laws do not bring down the rising drug manufacturer list prices that keep driving up costs for those who are not directly affected by such legislation. Cost-sharing limit laws could attempt to address the opacity of drug pricing methodologies by requiring annual reports on price movements from drug manufacturers. Perhaps the greatest criticism, however, is that cost-sharing cap laws do nothing to encourage competition among drug manufacturers, pharmaceutical wholesalers, pharmacy benefit managers (PBMs), and other market forces that have an impact on drug prices.[cxxv]

A final consideration in measuring the cost impact of A-2839 relates to the scope of the bill's limitation on cost-sharing for consumers – does the bill require that all FDA-approved drugs, regardless of the formulary, be covered subject to the bill's caps, or does it allow the payer to use a formulary to promote the use of lower-cost alternatives? The bill is clear that for both the State Health Benefits Program and the School Employees' Health Benefits Program, a formulary may be used. For example, section 25 of the bill provides, "Nothing in this section shall prevent the State Health Benefits Commission from reducing an enrollee's cost-sharing requirement by an amount greater than the amount specified in this section or prevent the commission from utilizing formulary management, including a mandatory generic policy, to promote the use of lower-cost alternative generic drugs that are the therapeutic equivalent of the brand-name drug, which could result in the member's copay being higher than set forth in this section." However, the sections governing the DOBI-regulated commercial markets do not contain such language. As noted above in the description of Nevada's insulin cost-sharing legislation and below in the actuarial analyses from health insurance carriers, allowing the use of a formulary of preferred prescription products reduces the cost estimates of the legislation dramatically.

To the extent that the legislation allows for consumers to be directed to generic versions or preferred brands of insulin, asthma inhalers, and EAs, the more potential leverage and the less impact on costs to the state or to the premium payers. If, on the other hand, laws mandating cost-sharing limitations are written to require that all FDA-approved drugs in the class must be covered with the same cost-sharing cap, then the incentives for consumers to utilize less expensive options first is eliminated, with a greater corresponding pressure for insurance premium increases to cover the difference. It should be noted that current federal legislation, H.R. 6833, capping insulin costs, clearly allows the use of a formulary. That bill provides, "For plan years beginning on or after January 1, 2023, a group health plan or health insurance issuer offering group or individual health insurance coverage shall provide **coverage of selected insulin products.…**" [emphasis added].[cxxvi] Alignment of potential federal standards that would apply to ERISA plans in New Jersey with state standards could help limit confusion among consumers, providers, and payers.

As we consider access to needed medications, one key existing consumer protection should be part of the discussion. In the event that a drug is not on a carrier's formulary, New Jersey already requires an exception process set forth in N.J.A.C. 11:22-5.9(b)6. The process allows a consumer to obtain coverage for a non-preferred drug at the same cost-sharing level as a preferred drug when there is a certification of medical necessity from a health care provider.

Lastly, one other consideration on overall cost is the impact of the bill's requirements on the "actuarial value' of the plan, especially in the individual and small employer markets, which must meet certain standards. The "actuarial value" of a plan is a measurement of the percentage of total average costs for covered benefits that a plan will cover. For example, if a plan has an actuarial value of 70%, a consumer generally would be responsible for 30% of the costs of all covered benefits. However, a member could be responsible for a higher or lower percentage of the total costs of covered services for the year, depending on his or her actual health care needs and the terms of the insurance policy. The ACA specifies that the value of the plans offered to small employers and individuals must be at one of four actuarial value levels: 60% (a bronze plan), 70% (a silver plan), 80% (a gold plan), and 90% (a platinum plan). Some cost-sharing caps could cause a material change in the actuarial value of a plan, so a decrease in one covered service could require an increase in the cost-sharing for another service to maintain the plan's same overall actuarial value. As discussed below, the input from carrier actuaries has produced some differences of opinion.

COST-SHARING LEGISLATION AND FINANCIAL IMPACT -- INSULIN, ASTHMA INHALERS, AND EPINEPHRINE AUTO-INJECTORS

New Jersey and Minnesota are the only states that have introduced legislation to cap cost-sharing for insulin, prescription asthma inhalers, and EAs in a single bill. In two, related bills (i.e., HF 3592/SF 3367 and HF 2056), the Minnesota legislature has introduced legislation to cap cost-sharing for State-regulated health plans for insulin, asthma inhalers, and epinephrine auto-injectors at $25 per month. The bills would also cap cost-sharing for related medical supplies, such as glucose monitors and insulin pumps, at $50 per month.[cxxvii] The substance of these bills has been folded into an omnibus bill, HF 4706, Article 6, Section 41.

Minnesota Management and Budget (MMB) issued a detailed fiscal note on the impact of HF 2056 on state government.[cxxix] The analysis reported that MMB administers the State Employee Group Insurance Program (SEGIP), including self-funded health and pharmacy benefits through the Minnesota Advantage Health Plan. SEGIP contracts with three health plan administrators for medical benefits and one Pharmacy Benefit Manager (PBM) for its prescription drug benefits, so the cost analysis was based on current data for the state's approximately 131,000 members.

HF 2056 requires SEGIP to pay member cost-sharing above $25 per month for each covered prescription drug and cost-sharing above $50 for all related medical supplies to treat diabetes,

asthma, and allergies where use of an EA is necessary.[cxxx] SEGIP's health plan administrators estimated SEGIP would pay roughly $141,480 a year for member cost-sharing for related medical supplies beyond the $50 cap in the bill. To arrive at this estimate, the plan administrators reviewed member claims with a diagnosis of diabetes, asthma, or allergies and their cost-sharing for related medical supplies between 2019 and 2021, assuming any cost-sharing above the $50 cap would be paid by the Advantage Plan. Each of the 3 health plan administrators provided a PMPM cost estimate that SEGIP used to arrive at an average of $0.09 PMPM.

SEGIP's PBM estimated that SEGIP would pay roughly $40,000 a year to cover member cost-sharing above the cap of $25 per month for each covered medication for diabetes, asthma, and allergies under HF 2056. SEGIP's PBM looked at claims for 2021 to generate this estimate. Dividing the $40,000 estimate by the 131,000 covered members over 12 months, SEGIP came to $0.03 PMPM. To generate an estimate of the total cost impact of the bill on SEGIP, the analysts summed $0.09 PMPM for the covered medical supplies capped at $50 per month and the $0.03 PMPM for the covered prescription drugs capped at $25 per medication per month for a total of $0.12 PMPM.[cxxxii] Assuming 5% inflation and a full 12 months experience if the bill comes into effect on January 1, 2023, the FY24 impact of HF 2056 on the State Employee Group Insurance Program medical and pharmacy costs is estimated at $198,072.

Turning to A-2839, actuaries for four New Jersey health insurance carriers have provided to the MHBAC their estimates of the impacts of A-2839 on their health benefit plans' costs and premium structures, and potential impacts on the calculations of their plans' Actuarial Value given changes in some cost-sharing elements necessitated by the bill. The actuaries were asked to provide estimates under two different assumptions: 1) that the health benefit plan design assumed a closed formulary, with a limited number of drug choices and a preference for generic and lower-cost options; and 2) an open formulary, in which all FDA-approved insulins, prescription asthma inhalers, and EAs were covered under the A-2839's cost-sharing limits.

The first New Jersey actuary limited his/her response to the cost and premium impacts assuming that existing formulary lists were maintained under the bill's provisions. Given that scenario, the actuary reported that A-2839 would have "*de minimis*" impact on the carrier's costs.[cxxxiii] For the carrier's fully insured market segments combined, and assuming no changes to the existing plan formularies, the actuary estimated that the impact of the bill's proposed $35 per month cost-sharing cap on insulin would increase carrier costs by $221,000 per year, resulting in an estimated premium increase of 0.02%. The actuary estimated the bill's proposed per month cost-sharing cap of $25 on EAs would increase carrier costs by $55,000 per year, resulting in a 0.00% premium increase. Finally, the actuary reported that A-2839's proposed monthly cost-sharing cap of $50 on asthma inhalers would have no measurable impact on carrier costs, resulting in no corresponding premium increase. The actuary also estimated that the *de minimis* cost impacts of A-2839, assuming no changes to existing drug formularies, would not warrant any changes to the Actuarial Value calculations of its health benefit plans.

A second New Jersey actuary providing estimates of cost and premium impacts for another carrier offered a detailed analysis incorporating a number of assumptions and scenarios. This actuary estimated that the bill's cost-sharing caps taken together would increase plan costs by 0.2% in the carrier's commercial fully insured lines of business. The actuary estimated that the cost-sharing caps would increase the carrier's 2024 costs by $8.4 million, and result in a corresponding premium increase of 0.2%.[cxxxv] The actuary also reported that the same 0.2% increase in carrier costs and projected premium could be estimated for the carrier's self-insured lines of business, if the cost-sharing provisions of A-2839 were incorporated into their plan designs. All of these estimated cost and premium increases assumed that existing plan drug formularies remained unaltered under A-2839.

If the actuarial assumption changes to permit an open formulary, so that all insulins, EA devices, and prescription asthma inhalers are available with the cost-sharing caps, the actuary estimates that carrier costs and premiums would increase by an additional 1.4%.[cxxxvii] The actuary explains that there are two aspects to the significantly higher costs of an open formulary. First, the carriers receive rebates from pharmaceutical manufacturers if the carriers place the manufacturers' drugs in their formularies or on preferred drug lists. An open formulary would eliminate the incentive for manufacturers to pay these rebates to the carriers. Second, if cost-sharing is capped no matter which drug the member selects, there is no incentive for the member to choose a generic or lower cost alternative, even if the drug provides effective treatment, since there is no difference in the out-of-pocket costs for the member. The actuary asserts that the carrier is left with no means to encourage the member to select a lower cost, but effective, option. The combination of members selecting more expenses insulins, EAs, and asthma inhalers and carriers losing pharmaceutical manufacturer rebates results in the significantly higher cost and premium impacts of an open formulary.

Finally, the second actuary posits that the incorporation of an open formulary under A-2839 would also require changes in the Actuarial Valuation Calculations for ACA-compliant qualified health plans. The ACA mandates overall cost-sharing parameters for each of its metallic levels (i.e., bronze, silver, gold, platinum) in the individual and small group markets. If cost-sharing arrangements change significantly for some plan benefits, then other cost-sharing arrangements must also change to put the overall set of plan benefits back in balance. In this example, the actuary asserts that if cost-sharing is limited for insulin, EAs, and asthma inhalers with an open formulary under A-2839, it will necessitate an increase in cost-sharing for other plan benefits to restore the Actuarial Value calculation of the overall cost-sharing level of all plan benefits, as required under ACA.[cxxxix]

The third New Jersey actuary provided cost estimates assuming both a preferred drug list (*i.e.*, established formulary) and an open formulary including all FDA-approved drugs in each of the categories. Beginning with the assumption that health plans would be designed with preferred drug lists for prescription asthma inhalers, insulin, and EAs, the third actuary estimated that the cost-sharing limits in A-2839 would raise asthma inhaler costs to the carrier by $40,000 per year,

would raise prescription costs by 0.03% per year, and would have no impact (i.e., 0.0%) on overall premiums.[cxl] The impact of A-2839's cost-sharing limits on insulin, assuming a preferred drug list, would be an increase in costs to the carrier of $66,500 per year, a rise in prescription costs of 0.05%, and an increase in overall premiums of 0.01%.[cxli] The third actuary estimated that A-2839's impact would increase the carrier's costs for EAs by $43,500 per year, increase prescription expenses by 0.03% per year, and lead to an increase of 0.01% in overall premiums, if a preferred drug list were incorporated into plan design. Taking these projected numbers together, the third actuary estimated that, under plan design incorporating preferred drug lists, A-2839 would increase overall costs to the carrier by $150,000 per year, would raise prescription costs by 0.12%, and would lead to premium increases of 0.02%. That actuary stated, "We believe there is **NO IMPACT** [actuary's emphasis] to the actuarial value of the plan as measured by the CMS actuarial value calculator proposed for CY2023."

The third New Jersey actuary also provided cost estimates assuming that all FDA-approved drugs in each category would be covered with the same cost-sharing limitations under A-2839. Under the open formulary assumption, the actuary estimated that the cost-sharing limits in A-2839 would raise asthma inhaler costs to the carrier by $102,000 per year, would raise prescription costs by 0.08% per year, and would raise overall premiums by 0.01%.[cxliii] The estimated impact of A-2839's cost-sharing limits on insulin, assuming an open formulary, would be an increase in costs to the carrier of $128,000 per year, a rise in prescription costs of 0.10%, and an increase in overall premiums of 0.02%. The third actuary estimated that A-2839's impact would increase the carrier's costs for EAs by $102,00 per year, increase prescription expenses by 0.08% per year, and lead to an increase of 0.01% in overall premiums, if an open formulary were incorporated into plan design. Taking these projected numbers together, the third actuary estimated that A-2839, under an open formulary, would increase overall costs to the carrier by $215,000 per year, would raise prescription costs by 0.17%, and would lead to premium increases of 0.03%. Even under the open formulary assumption, however, the third actuary estimated there would be no impact on the plans' actuarial value for CY2023, as measured by the CMS calculator.[cxlv]

The fourth New Jersey actuary provided cost estimates of the impact of A-2839 assuming plan designs with both the continuation of the carrier's existing formularies and with open formularies. Beginning with the cost impacts assuming current formulary design, the fourth actuary estimates that the cost-sharing limit on insulin will raise payer costs approximately $0.60 PMPM, resulting in roughly a 0.1% increase in average premiums.[cxlvi] The cost-sharing limit on EAs would increase payer costs $0.04 PMPM on average, having no impact on average premiums. The cost-sharing limit on prescription asthma inhalers would increase payer costs by approximately $0.15 PMPM, having no significant impact on average premiums. Taken together, then, adding the cost impacts of the cost-sharing caps for these three categories of medications, assuming plan designs with existing formularies, the fourth actuary estimates that A-2839 would increase payer costs by roughly $0.79 PMPM and raise average premiums on the

order of 0.1%-0.15%. This actuary stressed that the cost impacts, even assuming current formulary design, would vary widely, with copayment plans seeing "small to no change," and high deductible plans seeing much larger impacts.[cxlvii] The fourth actuary estimated, for example, that the insulin cost-sharing limit alone could increase costs for high deductible plans by as much as $2 PMPM.

The fourth actuary provided very broad estimates for cost impacts assuming open formularies. The actuary writes, "If customers are afforded the same cost share caps on drugs off of our formularies….we believe that covering non-formulary drugs could increase the costs by at least 2 to 3 times the estimated averages" for costs assuming plan designs with existing formularies.[cxlviii] Finally, the fourth actuary pointed out that while his/her carrier does not use the CMS actuarial value calculator for its New Jersey commercial lines of business, "[W]e do believe these changes will impact the actuarial value of the plan and could have spillover effects into Mental Health Parity compliance."

CONCLUSION

Balancing Social Impact, Medical Evidence, and Financial Impact

Diabetes and asthma are chronic diseases with life-threatening potential that impact an estimated 10% of New Jersey's 9.4 million residents. Additionally, it is estimated that 1 in 20 Americans, including those in New Jersey, experience anaphylaxis, annually. Limiting the out-of-pocket cost for the medications necessary to manage diabetes, asthma or anaphylaxis is likely to make them more accessible to patients diagnosed with these conditions, resulting in better disease control and fewer instances of costly hospitalizations and emergency room visits.

However, these cost-savings must be balanced against rises in health insurance costs, as carriers increase premiums to cover their increased burden of cost-sharing for the relevant medications.

As this report shows, if A-2839 allows carriers to use existing formulary structures or preferred drug lists to design plans with limits on patient cost-sharing for insulin, prescription asthma inhalers, and epinephrine auto-injectors, the estimates of all four New Jersey carrier actuaries agree the bill will have a minimal impact on health care premiums, except for one actuary's concerns that any limits on cost-sharing for these drugs could have significant impacts on the costs of high deductible plans. In New Jersey, the Department of Banking and Insurance has a process in place that permits patients, denied a particular medication because of formulary restrictions, to gain access to that drug at the same cost-sharing level as the generic/preferred drug. All four actuarial opinions also found that the use of formularies or preferred drug lists in plan designs under the cost-sharing limits of A-2839 would not necessitate changes in the cost-sharing formulas in the actuarial value calculations of their plans, except in the case of high deductible plans, as noted above.

Should the bill mandate the use of an open formulary, however, where an insured can choose any form of an FDA-approved prescribed medication, generic or brand-name, there was a difference of actuarial opinion on the cost implications. Two New Jersey actuaries found that the cost to carriers could be significant and necessitate substantial changes in other cost-sharing elements of their plans, in order to maintain the overall calculated actuarial values of their plans under A-2839. One of the other New Jersey actuarial reports estimated that even if the plans were designed with open formularies, this would not result in meaningful increases in premium levels and would not necessitate adjustments to overall cost-sharing formulas to maintain actuarial value calculations. The remaining New Jersey actuary did not provide an estimate of the impact of an open formulary on plan premiums or the calculations of actuarial values with altered cost-sharing elements under A-2839.

Because cost-sharing limitation laws for asthma inhalers and epinephrine auto-injectors are new to the legislative process, the most relevant information available about their potential impact must come from experience with laws limiting insulin cost-sharing.

The empirical evidence from Colorado's first year of rate filings after passing cost-sharing limits on insulin suggested that the state's healthcare plans did not anticipate having to raise insurance premiums much, if at all, in response to the new cost-sharing caps. It also remains to be seen how these out-of-pocket cost limits, particularly those in which there is no adjacent requirement for drug manufacturers to report pricing changes and the rationale for such change, will impact the manufacturer list price, which has a significant impact on overall cost to the patient and the health plan.

Further, the primary criticisms of insulin cost-sharing cap laws are that they do not address the lack of price competition at the various levels at which the drug's price is determined and they only impact the individuals covered by the select insurance market segments affected by the laws enacted in each state.

Programs, such as discount coupons and savings cards, offered by manufacturers, PBMs, and insurance carriers, have tended to be focused on specific products, on patients in narrowly-defined market segments, or for limited durations. Legislation compelling greater competition among medication manufacturers, pharmaceutical wholesalers, PBMs, and pharmacies is a much tougher political and regulatory challenge at the state level.

Similarly, cost-sharing caps on insulin, asthma inhalers and epinephrine auto-injectors for all diabetics, asthmatics, and allergy patients with a history of anaphylaxis, insured or uninsured, and those covered by Medicaid and Medicare, would also require a national commitment. With those criticisms in mind, a cost-sharing cap on a 30-day supply does have the potential to improve affordability for patients who use insulin, asthmatic inhalers, and EAs, and will benefit those who have insurance coverage under the affected plans.

Finally, adding an annual reporting requirement for the manufacturers of EAs, insulin, and asthma inhalers, as was done with the previous bill, ACS-954, might provide an effective means

of monitoring changes in retail prices of the drug types affected by A-2839. It would also address some of the concerns of stakeholders who opposed the bill at its earlier hearing.

ENDNOTES

[i] Sections 8 and 9 of ACS-954 created new sections applying the bill's cost-sharing restrictions to the state's individual and small employer markets. The existing diabetes mandate, P.L. 1995, c. 331, did not amend the laws governing the individual and small employer markets. However, the standardized individual and small employer market health benefits plans, promulgated as regulations, included the benefits set forth in that law. So, while this appeared as a new section, mandated diabetes benefits are not new to those markets.

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[cxii] 2019 Idaho Code, Title 54 – Professions, Vocations, and Businesses, Chapter 17 – Pharmacists, Section 54-1733C – Epinephrine Auto-Injectors – Emergency Administration. (https://law.justia.com/codes/idaho/2019/title-54/chapter-17/section-54-1733c/)

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[cxiv] *Ibid.*

[cxv] Ohio Legislative Service Commission, Fiscal Note & Local Impact Statement, H.B. 101 of the 132nd G.A. January 7, 2019.

[cxvi] Illinois General Assembly, Public Act 101-0281. Accessed 4/26/22. (https://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=101-0281)

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[cxxvi] "Affordable Insulin Now Act," H.R. 6833, 117th Congress, section 2799A-11, 2022. Accessed 5/12/22. (https://www.congress.gov/bill/117th-congress/house-bill/6833/text)

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[cxxxii] *Ibid.*

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[cxxxiv] *Ibid.*

[cxxxv] Private correspondence with the Executive Director of the New Jersey Mandated Health Benefits Advisory Commission, April 25, 2022.

[cxxxvi] *Ibid.*

[cxxxvii] *Ibid.*

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[cxli] *Ibid.*

[cxlii] *Ibid.*

[cxliii] *Ibid.*

[cxliv] *Ibid.*

[cxlv] *Ibid.*

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[cxlvii] *Ibid.*

[cxlviii] *Ibid.*

[cxlix] *Ibid.*

Appendix I (text of bill A-2839)

Appendix II (referral letter from Chairman McKeon)

ASSEMBLY, No. 2839

STATE OF NEW JERSEY

220th LEGISLATURE

INTRODUCED FEBRUARY 28, 2022

Sponsored by:
Assemblyman JOHN F. MCKEON
District 27 (Essex and Morris)
Assemblyman ROBERT J. KARABINCHAK
District 18 (Middlesex)
Assemblywoman ANNETTE QUIJANO
District 20 (Union)
Assemblyman PAUL D. MORIARTY
District 4 (Camden and Gloucester)

Co-Sponsored by:
Assemblyman Benson, Assemblywomen Mosquera, Reynolds-Jackson, McKnight, Assemblyman Danielsen, Assemblywomen Park, Murphy, Assemblyman Schaer, Assemblywomen Carter and Jimenez

SYNOPSIS

Requires health insurance carriers to provide coverage for epinephrine auto-injector devices and asthma inhalers; limits cost sharing for health insurance coverage of insulin.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 5/9/2022)

AN ACT concerning cost sharing for certain prescription drugs, amending P.L.1995, c.331, and supplementing various parts of the statutory law.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. Section 1 of P.L.1995, c.331 (C.17:48-6n) is amended to read as follows:

1. a. Every individual or group hospital service corporation contract providing hospital or medical expense benefits that is delivered, issued, executed or renewed in this State pursuant to P.L.1938, c.366 (C.17:48-1 et seq.) or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of this act shall provide benefits to any subscriber or other person covered thereunder for expenses incurred for the following equipment and supplies for the treatment of diabetes, if recommended or prescribed by a physician or nurse practitioner/clinical nurse specialist: blood glucose monitors and blood glucose monitors for the legally blind; test strips for glucose monitors and visual reading and urine testing strips; insulin; injection aids; cartridges for the legally blind; syringes; insulin pumps and appurtenances thereto; insulin infusion devices; and oral agents for controlling blood sugar. Coverage for the purchase of insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed $35 per 30-day supply. The provisions of this subsection shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this subsection shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

b. Each individual or group hospital service corporation contract shall also provide benefits for expenses incurred for diabetes self-management education to ensure that a person with diabetes is educated as to the proper self-management and treatment of their diabetic condition, including information on proper diet. Benefits provided for self-management education and education relating to diet shall be limited to visits medically necessary upon the diagnosis of diabetes; upon diagnosis by a physician or nurse practitioner/clinical nurse specialist of a significant change in the

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

subscriber's or other covered person's symptoms or conditions which necessitate changes in that person's self-management; and upon determination of a physician or nurse practitioner/clinical nurse specialist that reeducation or refresher education is necessary. Diabetes self-management education shall be provided by a dietitian registered by a nationally recognized professional association of dietitians or a health care professional recognized as a Certified Diabetes Educator by the American Association of Diabetes Educators or a registered pharmacist in the State qualified with regard to management education for diabetes by any institution recognized by the board of pharmacy of the State of New Jersey.

c. The benefits required by this section shall be provided to the same extent as for any other sickness under the contract.

d. This section shall apply to all hospital service corporation contracts in which the hospital service corporation has reserved the right to change the premium.

e. The provisions of this section shall not apply to a health benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A-2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

f. The Commissioner of <u>Banking and</u> Insurance may, in consultation with the Commissioner of Health, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), promulgate and periodically update a list of additional diabetes equipment and related supplies that are medically necessary for the treatment of diabetes and for which benefits shall be provided according to the provisions of this section.

(cf: P.L.1995, c.331, s.1)

2. (New section) An individual or group hospital service corporation contract providing hospital or medical expense benefits that is delivered, issued, executed, or renewed in this State pursuant to P.L.1938, c.366 (C.17:48-1 et seq.) or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) shall provide coverage for at least one epinephrine auto-injector device, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of an epinephrine auto-injector device shall not be subject to any deductible, and no copayment or coinsurance for the purchase of an epinephrine auto-injector device shall exceed $25 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply

to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a hospital service corporation from reducing a subscriber's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

3. (New section) An individual or group hospital service corporation contract providing hospital or medical expense benefits that is delivered, issued, executed, or renewed in this State pursuant to P.L.1938, c.366 (C.17:48-1 et seq.) or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) shall provide benefits to a subscriber or other person covered thereunder for expenses incurred for a prescription asthma inhaler, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of a covered prescription asthma inhaler shall not be subject to any deductible, and no copayment or coinsurance for the purchase of a covered prescription asthma inhaler shall exceed $50 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a hospital service corporation from reducing a subscriber's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

4. Section 2 of P.L.1995, c.331 (C.17:48A-7l) is amended to read as follows:

2. a. Every individual or group medical service corporation contract providing hospital or medical expense benefits that is delivered, issued, executed or renewed in this State pursuant to P.L.1940, c.74 (C.17:48A-1 et seq.) or approved for issuance or renewal in this State by the Commissioner of <u>Banking and</u> Insurance on or after the effective date of this act shall provide benefits to any subscriber or other person covered thereunder for expenses incurred for the following equipment and supplies for the treatment of diabetes, if recommended or prescribed by a physician

or nurse practitioner/clinical nurse specialist: blood glucose monitors and blood glucose monitors for the legally blind; test strips for glucose monitors and visual reading and urine testing strips; insulin; injection aids; cartridges for the legally blind; syringes; insulin pumps and appurtenances thereto; insulin infusion devices; and oral agents for controlling blood sugar. Coverage for the purchase of insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed $35 per 30-day supply. The provisions of this subsection shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this subsection shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

b. Each individual or group medical service corporation contract shall also provide benefits for expenses incurred for diabetes self-management education to ensure that a person with diabetes is educated as to the proper self-management and treatment of their diabetic condition, including information on proper diet. Benefits provided for self-management education and education relating to diet shall be limited to visits medically necessary upon the diagnosis of diabetes; upon diagnosis by a physician or nurse practitioner/clinical nurse specialist of a significant change in the subscriber's or other covered person's symptoms or conditions which necessitate changes in that person's self-management; and upon determination of a physician or nurse practitioner/clinical nurse specialist that reeducation or refresher education is necessary. Diabetes self-management education shall be provided by a dietitian registered by a nationally recognized professional association of dietitians or a health care professional recognized as a Certified Diabetes Educator by the American Association of Diabetes Educators or a registered pharmacist in the State qualified with regard to management education for diabetes by any institution recognized by the board of pharmacy of the State of New Jersey.

c. The benefits required by this section shall be provided to the same extent as for any other sickness under the contract.

d. This section shall apply to all medical service corporation contracts in which the medical service corporation has reserved the right to change the premium.

e. The provisions of this section shall not apply to a health benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A-2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

f. The Commissioner of Banking and Insurance may, in consultation with the Commissioner of Health, pursuant to the

"Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), promulgate and periodically update a list of additional diabetes equipment and related supplies that are medically necessary for the treatment of diabetes and for which benefits shall be provided according to the provisions of this section.
(cf: P.L.1995, c.331, s.2)

5. (New section) An individual or group medical service corporation contract providing hospital or medical expense benefits that is delivered, issued, executed, or renewed in this State pursuant to P.L.1940, c.74 (C.17:48A-1 et seq.) or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) shall provide coverage for at least one epinephrine auto-injector device, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of an epinephrine auto-injector device shall not be subject to any deductible, and no copayment or coinsurance for the purchase of an epinephrine auto-injector device shall exceed $25 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a medical service corporation from reducing a subscriber's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

6. (New section) An individual or group medical service corporation contract providing hospital or medical expense benefits that is delivered, issued, executed, or renewed in this State pursuant to P.L.1940, c.74 (C.17:48A-1 et seq.) or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) shall provide benefits to a subscriber or other person covered thereunder for expenses incurred for a prescription asthma inhaler, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of a covered prescription asthma inhaler shall not be subject to any deductible, and no copayment or coinsurance for the purchase of a

covered prescription asthma inhaler shall exceed $50 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a medical service corporation from reducing a subscriber's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

7. Section 3 of P.L.1995, c.331 (C.17:48E-35.11) is amended to read as follows:

3. a. Every individual or group health service corporation contract providing hospital or medical expense benefits that is delivered, issued, executed or renewed in this State pursuant to P.L.1985, c.236 (C.17:48E-1 et seq.) or approved for issuance or renewal in this State by the Commissioner of <u>Banking and</u> Insurance on or after the effective date of this act shall provide benefits to any subscriber or other person covered thereunder for expenses incurred for the following equipment and supplies for the treatment of diabetes, if recommended or prescribed by a physician or nurse practitioner/clinical nurse specialist: blood glucose monitors and blood glucose monitors for the legally blind; test strips for glucose monitors and visual reading and urine testing strips; insulin; injection aids; cartridges for the legally blind; syringes; insulin pumps and appurtenances thereto; insulin infusion devices; and oral agents for controlling blood sugar. <u>Coverage for the purchase of insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed $35 per 30-day supply. The provisions of this subsection shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this subsection shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.</u>

b. Each individual or group health service corporation contract shall also provide benefits for expenses incurred for diabetes self-management education to ensure that a person with diabetes is

educated as to the proper self-management and treatment of their diabetic condition, including information on proper diet. Benefits provided for self-management education and education relating to diet shall be limited to visits medically necessary upon the diagnosis of diabetes; upon the diagnosis by a physician or nurse practitioner/clinical nurse specialist of a significant change in the subscriber's or other covered person's symptoms or conditions which necessitate changes in that person's self-management; and upon determination of a physician or nurse practitioner/clinical nurse specialist that reeducation or refresher education is necessary. Diabetes self-management education shall be provided by a dietitian registered by a nationally recognized professional association of dietitians or a health care professional recognized as a Certified Diabetes Educator by the American Association of Diabetes Educators or a registered pharmacist in the State qualified with regard to management education for diabetes by any institution recognized by the board of pharmacy of the State of New Jersey.

c. The benefits required by this section shall be provided to the same extent as for any other sickness under the contract.

d. This section shall apply to all health service corporation contracts in which the health service corporation has reserved the right to change the premium.

e. The provisions of this section shall not apply to a health benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A-2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

f. The Commissioner of <u>Banking and</u> Insurance may, in consultation with the Commissioner of Health, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), promulgate and periodically update a list of additional diabetes equipment and related supplies that are medically necessary for the treatment of diabetes and for which benefits shall be provided according to the provisions of this section.

(cf: P.L.1995, c.331, s.3)

8. (New section) An individual or group health service corporation contract providing hospital or medical expense benefits that is delivered, issued, executed, or renewed in this State pursuant to P.L.1985, c.236 (C.17:48E-1 et seq.) or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) shall provide coverage for at least one epinephrine auto-injector device, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of an epinephrine auto-injector device shall not be subject to any deductible, and no copayment or coinsurance for the purchase of an epinephrine auto-injector device shall exceed $25 per 30-day supply. The provisions of this section shall apply to a high

deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a health service corporation from reducing a subscriber's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

9. (New section) An individual or group health service corporation contract providing hospital or medical expense benefits that is delivered, issued, executed, or renewed in this State pursuant to P.L.1985, c.236 (C.17:48E-1 et seq.) or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) shall provide benefits to a subscriber or other person covered thereunder for expenses incurred for a prescription asthma inhaler, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of a covered prescription asthma inhaler shall not be subject to any deductible, and no copayment or coinsurance for the purchase of a covered prescription asthma inhaler shall exceed $50 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a health service corporation contract from reducing a subscriber's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

10. Section 4 of P.L.1995, c.331 (C.17B:26-2.1l) is amended to read as follows:

4. a. Every individual health insurance policy providing hospital or medical expense benefits that is delivered, issued, executed or renewed in this State pursuant to Chapter 26 of Title

17B of the New Jersey Statutes or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of this act shall provide benefits to any person covered thereunder for expenses incurred for the following equipment and supplies for the treatment of diabetes, if recommended or prescribed by a physician or nurse practitioner/clinical nurse specialist: blood glucose monitors and blood glucose monitors for the legally blind; test strips for glucose monitors and visual reading and urine testing strips; insulin; injection aids; cartridges for the legally blind; syringes; insulin pumps and appurtenances thereto; insulin infusion devices; and oral agents for controlling blood sugar. Coverage for the purchase of insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed $35 per 30-day supply. The provisions of this subsection shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this subsection shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

b. Each individual health insurance policy shall also provide benefits for expenses incurred for diabetes self-management education to ensure that a person with diabetes is educated as to the proper self-management and treatment of their diabetic condition, including information on proper diet. Benefits provided for self-management education and education relating to diet shall be limited to visits medically necessary upon the diagnosis of diabetes; upon diagnosis by a physician or nurse practitioner/clinical nurse specialist of a significant change in the covered person's symptoms or conditions which necessitate changes in that person's self-management; and upon determination of a physician or nurse practitioner/clinical nurse specialist that reeducation or refresher education is necessary. Diabetes self-management education shall be provided by a dietitian registered by a nationally recognized professional association of dietitians or a health care professional recognized as a Certified Diabetes Educator by the American Association of Diabetes Educators or a registered pharmacist in the State qualified with regard to management education for diabetes by any institution recognized by the board of pharmacy of the State of New Jersey.

c. The benefits required by this section shall be provided to the same extent as for any other sickness under the policy.

d. This section shall apply to all individual health insurance policies in which the insurer has reserved the right to change the premium.

e. The provisions of this section shall not apply to a health benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A-2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

f. The Commissioner of Banking and Insurance may, in consultation with the Commissioner of Health, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), promulgate and periodically update a list of additional diabetes equipment and related supplies that are medically necessary for the treatment of diabetes and for which benefits shall be provided according to the provisions of this section.

(cf: P.L.1995, c.331, s.4)

11. (New section) An individual health insurance policy providing hospital or medical expense benefits that is delivered, issued, executed, or renewed in this State pursuant to Chapter 26 of Title 17B of the New Jersey Statutes or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) shall provide coverage for at least one epinephrine auto-injector device, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of an epinephrine auto-injector device shall not be subject to any deductible, and no copayment or coinsurance for the purchase of an epinephrine auto-injector device shall exceed $25 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent an individual health insurer from reducing a covered person’s cost-sharing requirement by an amount greater than the amount specified in this section.

12. (New section) An individual health insurance policy providing hospital or medical expense benefits that is delivered, issued, executed, or renewed in this State pursuant to Chapter 26 of Title 17B of the New Jersey Statutes or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of P.L. , c. (C.)

(pending before the Legislature as this bill) shall provide benefits to a person covered thereunder for expenses incurred for a prescription asthma inhaler, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of a covered prescription asthma inhaler shall not be subject to any deductible, and no copayment or coinsurance for the purchase of a covered prescription asthma inhaler shall exceed $50 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent an individual health insurer from reducing a covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

13. Section 5 of P.L.1995, c.331 (C.17B:27-46.1m) is amended to read as follows:

5. a. Every group health insurance policy providing hospital or medical expense benefits that is delivered, issued, executed or renewed in this State pursuant to Chapter 27 of Title 17B of the New Jersey Statutes or approved for issuance or renewal in this State by the Commissioner of <u>Banking and</u> Insurance on or after the effective date of this act shall provide benefits to any person covered thereunder for expenses incurred for the following equipment and supplies for the treatment of diabetes, if recommended or prescribed by a physician or nurse practitioner/clinical nurse specialist: blood glucose monitors and blood glucose monitors for the legally blind; test strips for glucose monitors and visual reading and urine testing strips; insulin; injection aids; cartridges for the legally blind; syringes; insulin pumps and appurtenances thereto; insulin infusion devices; and oral agents for controlling blood sugar. <u>Coverage for the purchase of insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed $35 per 30-day supply. The provisions of this subsection shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this subsection shall</u>

apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

b. Each group health insurance policy shall also provide benefits for expenses incurred for diabetes self-management education to ensure that a person with diabetes is educated as to the proper self-management and treatment of their diabetic condition, including information on proper diet. Benefits provided for self-management education and education relating to diet shall be limited to visits medically necessary upon the diagnosis of diabetes; upon diagnosis by a physician or nurse practitioner/clinical nurse specialist of a significant change in the covered person's symptoms or conditions which necessitate changes in that person's self-management; and upon determination of a physician or nurse practitioner/clinical nurse specialist that reeducation or refresher education is necessary. Diabetes self-management education shall be provided by a dietitian registered by a nationally recognized professional association of dietitians or a health care professional recognized as a Certified Diabetes Educator by the American Association of Diabetes Educators or a registered pharmacist in the State qualified with regard to management education for diabetes by any institution recognized by the board of pharmacy of the State of New Jersey.

c. The benefits required by this section shall be provided to the same extent as for any other sickness under the policy.

d. This section shall apply to all group health insurance policies in which the insurer has reserved the right to change the premium.

e. The provisions of this section shall not apply to a health benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A-2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

f. The Commissioner of Banking and Insurance may, in consultation with the Commissioner of Health, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), promulgate and periodically update a list of additional diabetes equipment and related supplies that are medically necessary for the treatment of diabetes and for which benefits shall be provided according to the provisions of this section.

(cf: P.L.1995, c.331, s.5)

14. (New section) A group health insurance policy providing hospital or medical expense benefits that is delivered, issued, executed, or renewed in this State pursuant to Chapter 27 of Title 17B of the New Jersey Statutes or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) shall provide coverage for at least one epinephrine auto-injector device, if recommended or prescribed by

a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of an epinephrine auto-injector device shall not be subject to any deductible, and no copayment or coinsurance for the purchase of an epinephrine auto-injector device shall exceed $25 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a group health insurer from reducing a covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

15. (New section) A group health insurance policy providing hospital or medical expense benefits that is delivered, issued, executed, or renewed in this State pursuant to Chapter 27 of Title 17B of the New Jersey Statutes or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) shall provide benefits to a person covered thereunder for expenses incurred for a prescription asthma inhaler, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of a covered prescription asthma inhaler shall not be subject to any deductible, and no copayment or coinsurance for the purchase of a covered prescription asthma inhaler shall exceed $50 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a group health insurer from reducing a covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

16. Section 6 of P.L.1995, c.331 (C.26:2J-4.11) is amended to read as follows:

6. a. Every contract for health care services that is delivered, issued, executed or renewed in this State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or approved for issuance or renewal in this State on or after the effective date of this act shall provide health care services to any enrollee or other person covered thereunder for the following equipment and supplies for the treatment of diabetes, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist: blood glucose monitors and blood glucose monitors for the legally blind; test strips for glucose monitors and visual reading and urine testing strips; insulin; injection aids; cartridges for the legally blind; syringes; insulin pumps and appurtenances thereto; insulin infusion devices; and oral agents for controlling blood sugar. Coverage for the purchase of insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed $35 per 30-day supply. The provisions of this subsection shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this subsection shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

b. Each contract shall also provide health care services for diabetes self-management education to ensure that a person with diabetes is educated as to the proper self-management and treatment of their diabetic condition, including information on proper diet. Health care services provided for self-management education and education relating to diet shall be limited to visits medically necessary upon the diagnosis of diabetes; upon diagnosis by a participating physician or participating nurse practitioner/clinical nurse specialist of a significant change in the enrollee's or other covered person's symptoms or conditions which necessitate changes in that person's self-management; and upon determination of a participating physician or participating nurse practitioner/clinical nurse specialist that reeducation or refresher education is necessary. Diabetes self-management education shall be provided by a participating dietitian registered by a nationally recognized professional association of dietitians or a health care professional recognized as a Certified Diabetes Educator by the American Association of Diabetes Educators or, pursuant to section 6 of P.L.1993, c.378 (C.26:2J-4.7), a registered pharmacist in the State qualified with regard to management education for diabetes by any institution recognized by the board of pharmacy of the State of New Jersey.

c. The health care services required by this section shall be provided to the same extent as for any other sickness under the contract.

d. This section shall apply to all contracts in which the health maintenance organization has reserved the right to change the schedule of charges.

e. The provisions of this section shall not apply to a health benefits plan subject to the provisions of P.L.1992, c.161 (C.17B:27A-2 et seq.) or P.L.1992, c.162 (C.17B:27A-17 et seq.).

f. The Commissioner of Banking and Insurance may, in consultation with the Commissioner of Health, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), promulgate and periodically update a list of additional diabetes equipment and related supplies that are medically necessary for the treatment of diabetes and for which benefits shall be provided according to the provisions of this section.

(cf: P.L.1995, c.331, s.6)

17. (New section) A contract for health care services that is delivered, issued, executed, or renewed in this State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or approved for issuance or renewal in this State on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) shall provide coverage for at least one epinephrine auto-injector device, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of an epinephrine auto-injector device shall not be subject to any deductible, and no copayment or coinsurance for the purchase of an epinephrine auto-injector device shall exceed $25 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a health maintenance organization from reducing an enrollee's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

18. (New section) A contract for health care services that is delivered, issued, executed, or renewed in this State pursuant to P.L.1973, c.337 (C.26:2J-1 et seq.) or approved for issuance or renewal in this State on or after the effective date of P.L. , c.

(C.) (pending before the Legislature as this bill) shall provide benefits to an enrollee or other person covered thereunder for expenses incurred for a prescription asthma inhaler, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of a covered prescription asthma inhaler shall not be subject to any deductible, and no copayment or coinsurance for the purchase of a covered prescription asthma inhaler shall exceed $50 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a health maintenance organization from reducing an enrollee's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

19. (New section) An individual health benefits plan that provides hospital and medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1992, c.161 (C.17B:27A-2 et al.), on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage to an enrollee or other person covered thereunder for insulin for the treatment of diabetes, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed $35 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

The benefits shall be provided to the same extent as for any other condition under the health benefits plan.

This section shall apply to those health benefits plans in which the carrier has reserved the right to change the premium.

20. (New section) An individual health benefits plan that provides hospital and medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1992, c.161 (C.17B:27A-2 et al.), on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for at least one epinephrine auto-injector device, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of an epinephrine auto-injector device shall not be subject to any deductible, and no copayment or coinsurance for the purchase of an epinephrine auto-injector device shall exceed $25 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a carrier from reducing an enrollee's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

21. (New section) An individual health benefits plan that provides hospital and medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1992, c.161 (C.17B:27A-2 et al.), on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide benefits to an enrollee or other person covered thereunder for expenses incurred for a prescription asthma inhaler, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of a covered prescription asthma inhaler shall not be subject to any deductible, and no copayment or coinsurance for the purchase of a covered prescription asthma inhaler shall exceed $50 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a carrier from reducing an enrollee's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

22. (New section) A small employer health benefits plan that provides hospital and medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1992, c.162 (C.17B:27A-17 et seq.), on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage to an enrollee or other person covered thereunder for insulin for the treatment of diabetes, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed $35 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

The benefits shall be provided to the same extent as for any other condition under the health benefits plan.

This section shall apply to those health benefits plans in which the carrier has reserved the right to change the premium.

23. (New section) A small employer health benefits plan that provides hospital and medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1992, c.162 (C.17B:27A-17 et seq.), on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for at least one epinephrine auto-injector device, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of an epinephrine auto-injector device shall not be subject to any deductible, and no copayment or coinsurance for the purchase of an epinephrine auto-injector device shall exceed $25 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this

section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a carrier from reducing an enrollee's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

The benefits shall be provided to the same extent as for any other condition under the health benefits plan.

This section shall apply to those health benefits plans in which the carrier has reserved the right to change the premium.

24. (New section) A small employer health benefits plan that provides hospital and medical expense benefits and is delivered, issued, executed, or renewed in this State pursuant to P.L.1992, c.162 (C.17B:27A-17 et seq.), on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide benefits to an enrollee or other person covered thereunder for expenses incurred for a prescription asthma inhaler, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of a covered prescription asthma inhaler shall not be subject to any deductible, and no copayment or coinsurance for the purchase of a covered prescription asthma inhaler shall exceed $50 per 30-day supply. The provisions of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if the plan is used to establish a medical savings account pursuant to section 220 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.220) or a health savings account pursuant to section 223 of the federal Internal Revenue Code of 1986 (26 U.S.C. s.223). The provisions of this section shall apply to the plan to the maximum extent that is permitted by federal law and does not disqualify the account for the deduction allowed under section 220 or 223, as applicable.

Nothing in this section shall prevent a carrier from reducing an enrollee's or other covered person's cost-sharing requirement by an amount greater than the amount specified in this section.

The benefits shall be provided to the same extent as for any other condition under the health benefits plan.

This section shall apply to those health benefits plans in which the carrier has reserved the right to change the premium.

25. (New section) The State Health Benefits Commission shall ensure that every contract purchased or renewed by the commission on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for health care services to a person covered thereunder for insulin for the treatment of diabetes, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical

nurse specialist. Coverage for the purchase of insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed $35 per 30-day supply, except a contract provided by the State Health Benefits Commission that qualifies as a high deductible health plan shall provide coverage for the purchase of insulin at the lowest deductible and other cost-sharing requirement permitted for a high deductible health plan under section 223(c)(2)(A) of the federal Internal Revenue Code (26 U.S.C. s.223 (c)(2)(A)).

Nothing in this section shall prevent the State Health Benefits Commission from reducing an enrollee's cost-sharing requirement by an amount greater than the amount specified in this section or prevent the commission from utilizing formulary management, including a mandatory generic policy, to promote the use of lower-cost alternative generic drugs that are the therapeutic equivalent of the brand-name drug, which could result in the member's copay being higher than set forth in this section.

26. (New section) The State Health Benefits Commission shall ensure that every contract purchased or renewed by the commission on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for at least one epinephrine auto-injector device, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of an epinephrine auto-injector device shall not be subject to any deductible, and no copayment or coinsurance for the purchase of an epinephrine auto-injector device shall exceed $25 per 30-day supply, except a contract provided by the State Health Benefits Commission that qualifies as a high deductible health plan shall provide coverage for the purchase of an epinephrine auto-injector device at the lowest deductible and other cost-sharing requirement permitted for a high deductible health plan under section 223(c)(2)(A) of the federal Internal Revenue Code (26 U.S.C. s.223 (c)(2)(A)).

Nothing in this section shall prevent the State Health Benefits Commission from reducing a covered person's cost-sharing requirement by an amount greater than the amount specified in this section or prevent the commission from utilizing formulary management, including a mandatory generic policy, to promote the use of lower-cost alternative generic drugs that are the therapeutic equivalent of the brand-name drug, which could result in the member's copay being higher than set forth in this section. .

27. (New section) The State Health Benefits Commission shall ensure that every contract purchased or renewed by the commission on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide benefits to a person

covered thereunder for expenses incurred for a prescription asthma inhaler, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of a covered prescription asthma inhaler shall not be subject to any deductible, and no copayment or coinsurance for the purchase of a covered prescription asthma inhaler shall exceed $50 per 30-day supply, except a contract provided by the State Health Benefits Commission that qualifies as a high deductible health plan shall provide coverage for the purchase of a covered prescription asthma inhaler at the lowest deductible and other cost-sharing requirement permitted for a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code (26 U.S.C. s.223). Nothing in this section shall prevent the State Health Benefits Commission from reducing a covered person’s cost-sharing requirement by an amount greater than the amount specified in this section or prevent the commission from utilizing formulary management, including a mandatory generic policy, to promote the use of lower-cost alternative generic drugs that are the therapeutic equivalent of the brand-name drug, which could result in the member’s copay being higher than set forth in this section.

28. (New section) The School Employees' Health Benefits Commission shall ensure that every contract purchased by the commission on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill) that provides hospital and medical expense benefits shall provide health care services to a person covered thereunder for insulin for the treatment of diabetes, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of insulin shall not be subject to any deductible, and no copayment or coinsurance for the purchase of insulin shall exceed $35 per 30-day supply, except a contract provided by the School Employees’ Health Benefits Commission that qualifies as a high deductible health plan shall provide coverage for the purchase of insulin at the lowest deductible and other cost-sharing requirement permitted for a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code (26 U.S.C. s.223 (c)(2)(A)).

Nothing in this section shall prevent the School Employees’ Health Benefits Commission from reducing an enrollee's cost-sharing requirement by an amount greater than the amount specified in this section or prevent the commission from utilizing formulary management, including a mandatory generic policy, to promote the use of lower-cost alternative generic drugs that are the therapeutic equivalent of the brand-name drug, which could result in the member’s copay being higher than set forth in this section.

29. (New section) The School Employees' Health Benefits Commission shall ensure that every contract purchased or renewed by the commission on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide coverage for at least one epinephrine auto-injector device, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of an epinephrine auto-injector device shall not be subject to any deductible, and no copayment or coinsurance for the purchase of an epinephrine auto-injector device shall exceed $25 per 30-day supply, except a contract provided by the School Employees' Health Benefits Commission that qualifies as a high deductible health plan shall provide coverage for the purchase of an epinephrine auto-injector device at the lowest deductible and other cost-sharing requirement permitted for a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code (26 U.S.C. s.223 (c)(2)(A)).

Nothing in this section shall prevent the School Employees' Health Benefits Commission from reducing an enrollee's cost-sharing requirement by an amount greater than the amount specified in this section or prevent the commission from utilizing formulary management, including a mandatory generic policy, to promote the use of lower-cost alternative generic drugs that are the therapeutic equivalent of the brand-name drug, which could result in the member’s copay being higher than set forth in this section.

30. (New section) The School Employees' Health Benefits Commission shall ensure that every contract purchased or renewed by the commission on or after the effective date of P.L. , c. (C.) (pending before the Legislature as this bill), shall provide benefits to a person covered thereunder for expenses incurred for a prescription asthma inhaler, if recommended or prescribed by a participating physician or participating nurse practitioner/clinical nurse specialist. Coverage for the purchase of a covered prescription asthma inhaler shall not be subject to any deductible, and no copayment or coinsurance for the purchase of a covered prescription asthma inhaler shall exceed $50 per 30-day supply, except a contract provided by the School Employees' Health Benefits Commission that qualifies as a high deductible health plan shall provide coverage for the purchase of a covered prescription asthma inhaler at the lowest deductible and other cost-sharing requirement permitted for a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code (26 U.S.C. s.223 (c)(2)(A)).

Nothing in this section shall prevent the School Employees' Health Benefits Commission from reducing a covered person’s cost-sharing requirement by an amount greater than the amount specified in this section or prevent the commission from utilizing

formulary management, including a mandatory generic policy, to promote the use of lower-cost alternative generic drugs that are the therapeutic equivalent of the brand-name drug, which could result in the member's copay being higher than set forth in this section.

31. This act shall take effect on the first day of the seventh month next following the date of enactment and shall apply to plans issued or renewed on or after January 1 of the next calendar year, but the Commissioner of the Department of Banking and Insurance may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of the act.

STATEMENT

This bill places a flat cap on the out-of-pocket contribution for any covered person prescribed insulin, an epinephrine auto-injector device, or a prescription asthma inhaler across insurance providers. Coverage for these items may not be subject to any deductible, and copayments or coinsurance are capped at $35 per 30-day supply of insulin, $25 for epinephrine auto-injector devices per 30-day supply, and $50 for prescription asthma inhalers per 30-day supply.

These coverage standards apply to individual or group hospital service corporations, medical service corporations, and health service corporations as well as individual and group health insurance policies and health maintenance organizations. Additionally, the bill extends these coverage standards to individual and small employer health benefits plans and require that the State Health Benefits Commission and the School Employee's Health Benefits Commission ensure that their contracts comply with the coverage standards.

Appendix II

NEW JERSEY GENERAL ASSEMBLY

JOHN F. MCKEON
ASSEMBLYMAN, 27TH DISTRICT
ESSEX & MORRIS COUNTIES
221 MAIN STREET
MADISON, NJ 07940
PHONE: (973) 377-1606
FAX: (973) 377-0391
AsmMcKeon@njleg.org

COMMITTEES
MEMBER
FINANCIAL INSTITUTIONS AND INSURANCE, CHAIR
APPROPRIATIONS
ENVIRONMENT AND SOLID WASTE
INTERGOVERNMENTAL RELATIONS COMMISSION

March 14, 2022

New Jersey Mandated Health Benefits Advisory Commission
P.O. Box 325
Trenton, NJ 08625

Dear Members of the Commission:

As the Chairman of the Assembly Financial Institutions and Insurance Committee, I respectfully request the Commission to review and prepare a written report of A2839 which requires health insurance carriers to provide coverage for epinephrine auto-injector devices and asthma inhalers and limits cost sharing for health insurance coverage of insulin.

If you have any questions, please do not hesitate to contact Mark Iaconelli, Jr., Esq., Deputy General Counsel, at 609-847-3500. Thank you for your immediate attention to this matter.

Sincerely,

John F. McKeon

John F. McKeon

CC: Mark Iaconelli, Jr., Esq.
Deputy General Counsel
Assembly Majority Office