A STUDY OF NEW JERSEY ASSEMBLY COMMITTEE SUBSTITUTE BILL 954

REQUIRES HEALTH INSURERS TO LIMIT COPAYMENTS FOR INSULIN

Report to the New Jersey Assembly

June 15, 2020

Mandated Health Benefits Advisory Commission

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INTRODUCTION

The Mandated Health Benefits Advisory Commission (MHBAC) has been asked to review ACS-954 (see Appendix I). In addition to legislative findings regarding the high cost of insulin, this bill builds upon the state's existing mandated benefits for equipment and supplies for the treatment of diabetes by limiting consumer cost-sharing for insulin.

Specifically, ACS-954 supplements various parts of statutory law by providing that the benefits for insulin shall not be subject to any deductible, and that the copayment or coinsurance for the purchase of insulin shall not exceed $50 per 30-day supply. 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 bill also requires every manufacturer of an insulin product to submit, on an annual basis, a report to the Commissioner of Banking and Insurance containing certain information about its insulin products.

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-954 was introduced on January 14, 2020 and referred to the Assembly Financial Institutions and Insurance Committee. It was reported out of Committee with a committee substitute on February 13, 2020 for A-954, A-653 and A-1669. The Committee statement notes that "[t]his Assembly Committee Substitute for Assembly Bill Nos. 954, 653, and 1669, as adopted and reported by this committee, is identical to Senate Bill No. 526(1R)." The Committee statement noted the following key elements of the legislation:

1. "This committee substitute makes certain findings and declarations concerning the rising cost of insulin and requires health benefits plans issued pursuant to the New Jersey Individual Health Coverage and Small Employer Health Benefits Programs, the State Health Benefits Program, and the School Employees' Health Benefits Program, to provide coverage for insulin for the treatment of diabetes." [This section was new to the Assembly legislation.]
2. "The bill further requires health insurers (health, hospital and medical service corporations, commercial individual and group health insurers, and health maintenance organizations) and health benefits plans issued pursuant to the New Jersey Individual Health Coverage and Small Employer Health Benefits Programs, the State Health Benefits Program, and the School Employees' Health Benefits Program to provide coverage for the purchase of insulin that is not subject to any deductible and to limit the copayment or coinsurance that may be required for an insulin prescription to $50 per 30 day supply of insulin." [ACS-954 lowered the cost-sharing from previous versions of the bill to $50 and clarified that included all forms of consumer cost-sharing. The introduced versions of A-954 and A-1669 provided that "No copayment for the purchase of insulin shall exceed $100 per 30 day supply," while A-653 provided that "….a carrier shall not require a covered person to pay, for a covered prescription insulin drug, an amount exceeding $100 per 30 day supply of insulin, regardless of the amount or type of insulin needed to fill the covered person's prescription."]
3. "Lastly, the bill requires insulin manufacturers to submit an annual report to the Commissioner of Banking and Insurance containing certain information concerning the manufacture, pricing, and sales of insulin products." [This section was new to the Assembly legislation.]

In the Senate, S526, a bill limiting cost-sharing for insulin, was introduced on January 14, 2020 was referred to the Senate Commerce Committee. The bill was reported out of committee with amendments on January 27, 2020 and the bill was referred to the Senate Budget and Appropriations Committee. The committee statement noted that the amendments did the following:

(1) provide that the purchase of insulin shall not be subject to any deductible and require health insurers to limit the copayment or coinsurance that may be required for an insulin prescription to $50 per 30-day supply of insulin;

(2) add findings and declarations concerning the rising cost of insulin prices;

(3) require insulin manufacturers to submit an annual report to the Commissioner of Banking and Insurance containing certain information concerning the manufacture, pricing, and sales of insulin products; and

(4) make certain technical changes.

As of the issuance of this report, the Senate Budget and Appropriations Committee has not considered the bill.

On March 18, 2020 the Office of Legislative Services (OLS) published a fiscal note on the bill. 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."

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 opposition or support for the related insulin copayment cap bills S-526, A-954, ACS-954, and A-1669, as expressed through legislative slips, are presented in Table 1.

Table 1. Stakeholders' Positions on S-526 and A-954, ACS-954, and A-1669 (Limiting Copayments for Insulin and Requiring Insulin Cost Reporting)

Organization	**Position and Comment on Insulin Copay Limit and Insulin Price Reporting Requirements**
New Jersey Association of Health Plans	Neutral (Reviewing amendments)
Medical Society of New Jersey	In Favor
New Jersey Education Association	Oppose (Bill mandates a benefit in the School Employees Health Benefits Plan without going through the Plan Design Committee)
American Diabetes Association	In favor of copay cap, neutral to the insulin price reporting requirement for not going far enough
Pharmaceutical Care Management Association	Neutral
New Jersey Business and Industry Association	Seeking amendments
Independent Pharmacy Alliance/Omega Pharmacy Group	In favor
PhRMA	Oppose reporting requirements
Health Care Institute of New Jersey	Oppose reporting requirements
Chemistry Council of New Jersey	Oppose
New Jersey Hospital Association	In favor
New Jersey Association of Osteopathic Physicians	In favor
New Jersey Pharmacists Association	In favor
AARP NJ	In favor

Source: Witness slips and testimony submitted to the Senate Commerce Committee at its meeting on January 27, 2020 and to the Assembly Financial Institutions and Insurance Committee at its meeting on February 13, 2020.

SOCIAL IMPACT

Diabetes in the United States

According to the Center for Disease Control and Prevention (CDC), 26.9 million Americans of all ages had been diagnosed with diabetes mellitus (DM) in 2018, or 8.2% of the U.S. population. The highest incidence of the disease is in adults over the age of 65. The highest ethnic prevalence is in American Indians, followed by Hispanics, non-Hispanic blacks, and non-Hispanic whites. 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. 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.[iii] According to Hanefeld, the majority of individuals with Type 2 DM will require insulin therapy within the first decade after their diagnosis.[iv] 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.[v] Overall, it is estimated that 7.4 million Americans with diabetes use one or more types of insulin.[vi]

Diabetes in New Jersey

Although 10.8% of New Jersey's population of 8.88 million people described being told by a health care provider that they had diabetes in 2019, mortality rates related to diabetes are lower in New Jersey than in all other states except Colorado, suggesting that many diabetics were abiding by treatment guidelines.[vii,viii] 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.[ix] 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.[x] 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.[xi,xii,xiii]

Legislation to Reduce Insulin Co-payments

Legislatures in 8 states have now passed legislation to help reduce patient out-of-pocket costs for insulin, by limiting cost-sharing on 30-day supplies of the drug; these states include New York, Maine, Washington, West Virginia, Colorado, New Mexico, Utah and Illinois. Required co-payments in these states range from a low of $25/30-day supply in New Mexico to $100/30-day supply in New York and Washington.[xiv]

ACS-954 would provide first dollar coverage and would limit the cost-sharing for a 30-day supply of insulin to diabetics in New Jersey's state regulated insurance market to $50.[xv] The legislation would have no impact on those individuals covered under Medicaid, Medicare or with no health insurance.

New Jersey's Medicaid enrollment increased by 32 percent, or more than 400,000 people, between the fall of 2013 and spring of 2019, after New Jersey had adopted the Federal Medicaid expansion program. By September 2019, 1.7 million New Jersey residents were enrolled in Medicaid/CHIP.[xvi] For New Jersey residents enrolled in Medicaid/CHIP, most do not have any cost-sharing for covered medications.[xvii] The bill does not apply to Medicaid or NJ FamilyCare.

As of September, 2019, 1.6 million New Jersey residents were enrolled in Medicare.[xviii] 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 the new low income subsidy, and finally upon the designated tier of the drug prescribed.[xix] Medicare products are generally regulated at the federal level and the bill does not apply to Medicare.

In 2018, 7.4% of the New Jersey population was not covered by some form of health insurance.[xx] These were people, not eligible for employer-based plans, Medicaid/FamilyCare or Medicare, who could not afford or did not seek coverage under individual plans. In accordance with P.L. 2018, c.31, the New Jersey Health Insurance Market Preservation Act, families who are uninsured for all of 2020, must pay a charge of $695 per adult ($347.50 per child) up to a household maximum of $2,085 or 2.5% of household income above the tax filing threshold, whichever is greater; the maximum penalty is equivalent to the cost of a bronze plan in New Jersey.[xxi] Individuals without insurance bear the highest cost burden for insulin, paying at or close to the list price of the manufacturer.[xxii]

On January 21, 2020, Governor Murphy signed A-2431 (P.L. 2019, c.472), which limits out-of-pocket costs for drugs covered by plans on the state insurance market to $150-$250 per 30-day supply of medication, depending upon the plan.[xxiii] The law applies to individuals covered under health plans regulated by the Department of Banking and Insurance, the State Health Benefits Program, and the School Employees Health Benefits Program, which is the same scope of impact of ACS-954 being considered for this report. It provides no cost-relief for individuals either not enrolled in those plans or without health insurance.

Lastly, individuals covered by qualified High Deductible Health Plans (HDHP) generally may establish and deduct contributions to a Health Savings Account (HAS), as long as they have qualifying health coverage. To qualify as a HDHP, a health benefits plan generally may not provide benefits for any year until the minimum deductible for that year is satisfied. However, an HDHP is not required to have a deductible for preventive care (as defined for purposes of the HDHP/HSA rules). In July of 2019, the Internal Revenue Service issued Notice 2019-45, which added care for a range of chronic conditions to the list of preventive care benefits that may be provided by a high deductible health plan (HDHP). Insulin and other glucose lowering agents are included on that list.

While the MHBAC is charged with consideration only of this bill, the proposed legislation raises the issue of why there should be special cost-sharing treatment for one type of drug/disease state.

We note that there are special circumstances with respect to the treatment of diabetes and coverage for insulin that warrant different cost-sharing treatment. The factors set forth in the IRS's decision in NOTICE 2019-45 to classify some services as preventive services for purposes of HDHPs, including insulin coverage, reflect the same kind of considerations that might warrant different cost-sharing limits for insulin. We further note that should additional governmental interventions regulating consumer cost-sharing lead to separate cost-sharing caps for different drugs, it could be difficult for a consumer to understand his or her benefit package and challenging for a carrier to administer cost-sharing caps on an *ad hoc* basis.

MEDICAL EVIDENCE

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.[xxiv] 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.[xxv,xxvi] 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.[xxvii,xxviii,xxix] 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

In Type 2 DM, some combination of reduced peripheral uptake of insulin as a result of tissue resistance to insulin, chronic hypersecretion of insulin by the liver, and decreased production of insulin by the pancreas in response to increased carbohydrate intake, produces a state of relative hyperglycemia.[xxx] Type 2 diabetics comprise 90-95% of those diagnosed with the disease.[xxxi] 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 life style, hypertension, dyslipidemia, history of gestational diabetes and diagnosis of polycystic ovarian syndrome.[xxxii] 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.[xxxiii] 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.[xxxiv] In order to prevent complications and to preserve the highest quality of life, many Type 1 and Type 2 diabetics will also require management of hypertension and dyslipidemia, meaning that other medications, like anti-hypertensives and statins will add to the cost burden of their disease.

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.[xxxv]

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.[xxxvi] 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.[xxxvii] Those using insulin pumps are faced with the functional challenges and costs of that technology. See Table 2 for Insulin types available in the US.

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.[xxxviii] 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.[xxxix] 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.[xl,xli] Davidson argues that differences in outcomes regarding glycemic control, episodes of hypoglycemia or quality of life are not sufficiently significant to justify the far higher costs of analog over human insulin, with two exceptions: in the case of Type 1 diabetics who require 24 hour coverage with basal insulin and in the case of Type 2 diabetics who experience nocturnal hypoglycemia despite a bedtime snack.[xlii]

Table 2. 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/**

OTHER STATES

To date, eight states have passed legislation capping cost-sharing for 30-day insulin supplies (see Table 3). Five more states have advanced legislation capping insulin copays.

Table 3. States That Have Passed an Insulin Price Cap

State	Legislation	Date Effective	Date Signed
Colorado	$100 cap for 30-day supply	January 1, 2020	May 22, 2019
Illinois	$100 cap for 30-day supply	January 1, 2021	January 2020
Maine	$35 cap for 30-day supply	January 1, 2021	March 31, 2020
New Mexico	$25 cap for 30-day supply	January 1, 2021	March 4, 2020
New York	$100 cap for 30-day supply (for state-regulated commercial plans)	January 1, 2021	April 3, 2020
Utah	$30 cap for 30-day supply	January 1, 2021	March 30, 2020
Washington	$100 cap for 30-day supply	January 1, 2021	March 31, 2020
West Virginia	$100 cap for 30-day supply	July 1, 2021	March 6, 2020

Source: The diaTribe Foundation, https://diatribe.org/foundation/about-us/dialogue/eight-states-pass-legislation-place-caps-insulin-price-five-more-await-ruling#main-content

Colorado was the first state to pass insulin price cap legislation, and it is the only state with its law in effect in 2020. The other seven states' laws will become effective in 2021. 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.[xliii]

New Mexico's insulin cost-sharing cap is the lowest of the eight states, at $25 for a 30-day supply. Utah's insulin copay cap is the next lowest of the eight states, at $30 for a 30-day supply. Utah's law also permits pharmacists to refill expired insulin prescriptions on an emergency basis, thereby eliminating a potential cause of disrupted diabetic care. Maine's law mirrors that of Utah, with an insulin copay cap of $35 per month and a provision allowing emergency refills on insulin for patients with a previous prescription.[xliv] 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.[xlv]

Five additional states have advanced insulin cap bills. The bills advancing in Florida, Kentucky, Tennessee, and Virginia feature insulin cost-sharing caps of $100 for a 30-day supply, while Connecticut's bill limits out-of-pocket insulin expenses to $50 per month.[xlvi]

The Federal government has also recently announced a pilot program to be offered to some of the 3.3 million Medicare beneficiaries who take at least one of the common forms of insulin. The pilot program, which will begin in January 2021, will limit the cost of 30-day supplies of insulin to $35 per prescription. The program will be offered to beneficiaries with enhanced Medicare drug plans, those with more generous drug coverage and higher premiums. The pilot program is estimated to save participants an average of $446 a year on insulin costs.[xlvii] The pilot program received support from all three insulin manufacturers, Sanofi, Eli Lilly, and Novo Nordisk. This begins to address the needs of the more than one-third of Medicare beneficiaries who have reported that drug costs have had an impact on their purchases of insulin.[xlviii]

DISCUSSION

ACS-954 includes findings that describe the rising cost of insulin and note that the "the rising cost of insulin has created an affordability crisis that threatens the health and financial well-being of many diabetes patients." Concerns regarding the effectiveness of this legislation reflect that while capping cost-sharing helps certain diabetics lower their monthly insulin costs, such caps fail to address deeper problems with insulin pricing. First, copay caps only affect the market segments covered by the new laws, having no impact on other groups of insured diabetics or those who are uninsured.[xlix] High out-of-pocket costs are particularly harmful to low income diabetics, even if they have insurance coverage, as the same out-of-pocket cost is a much greater burden to a lower income person. Furthermore, cost-sharing caps do not bring down rising insulin manufacturer list prices that keep driving up costs for those who are not directly affected by such legislation. Cost-sharing cap laws in some states, including ACS-954, are attempting to address the opacity of insulin drug pricing methodology by requiring annual reports from insulin manufacturers on price movements. Perhaps the greatest criticism, however, is that cost-sharing cap laws do nothing to encourage competition among insulin manufacturers, pharmaceutical

wholesalers, pharmacy benefit managers (PBMs), and other market forces that have an impact on insulin prices.[l]

FINANCIAL IMPACT

Between 2003 and 2013 the mean price of insulin approximately tripled, rising from $4.34 per milliliter to $12.92 per milliliter.[li] 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.[lii] 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."[liii] High costs for insulin can contribute to nonadherence and less effective glycemic control for patients.[liv]

A 2017 survey, for instance, found that 25.5% of the respondents reported cost-related insulin underuse.[lv] 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.[lvi]

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.[lvii] 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.[lviii]

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.[lix] 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, 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.[lx] 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.[lxi] 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.[lxii] 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.[lxiii] 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 by their purpose, namely to lower direct costs to consumers in 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."[lxiv] Indeed, under federal anti-kickback law, it's illegal for drug manufacturers to offer any type of drug coupon for federally regulated coverage.

The American Diabetes Association (ADA) has reported that the medical expenses of diabetics are approximately 2.3 times higher than the medical costs of non-diabetics.[lxv] In a fact sheet focusing on New Jersey, the ADA estimated that direct medical expenses for diagnosed and undiagnosed diabetes, prediabetes, and gestational diabetes in the state was $7.5 billion in 2012. The ADA estimated that another $2.8 billion was spent on indirect costs from lost productivity due to diabetes in New Jersey in that same year.[lxvi] In an effort to begin to address the rising cost of insulin and the healthcare cost implications of diabetics being unable to afford insulin or underusing insulin, a flurry of states has passed legislation to cap cost-sharing expenses to diabetics.

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 minimus* impact on rates."[lxvii]

Colorado's Legislative Council Staff produced a fiscal note on the state's proposed $100 insulin copay 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.[lxviii] 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.[lxix]

Before passing its copay 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.[lxx] 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."[lxxi] 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.[lxxii] 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.[lxxiii] 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.[lxxiv] The cost of the legislation to the Public Employees Health Program was estimated at $25,000 for FY 2021 and annually thereafter.[lxxv] The estimated cost to the Department of Insurance was $19,200 in FY 2021 (including first-year

expenditures) and $7,200 annually thereafter.[lxxvi] 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.[lxxvii] The fiscal note concluded, "Any costs, which are expected to be minor, would likely be reflected through increased premium amounts in future fiscal years."[lxxviii]

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.[lxxix]

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 copay cap would have no fiscal impact and no fiscal implications for the State Corporation Commission, Bureau of Insurance.[lxxx]

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.

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.[lxxxi] 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.[lxxxii]

CONCLUSION

Balancing Social Impact, Medical Evidence, and Financial Impact

Diabetes is a leading cause of morbidity and mortality, contributing significantly to overall healthcare costs. The high and rising cost of insulin results in less than optimal utilization of the

medication for a significant proportion of diabetics. The resulting diminished glycemic control for patients who struggle to afford their insulin causes additional serious health complications, with concomitant cost and productivity implications.

One way to address the rising cost of insulin for diabetics is to lower and limit their cost-sharing expenses when they purchase the medication. Eight states have passed such cost-sharing limitation laws, ranging from a low of $25 to a high of $100 per 30-day supply of insulin. These cost-sharing caps promise at least some assistance to the diabetes patients covered by the new laws. Some of the new cost-sharing cap laws allow pharmacists to refill expired insulin prescriptions on an emergency basis, ensuring that patients' insulin use is uninterrupted. Several of the new insulin cost-sharing cap laws also include requirements that the states produce reports on annual movements of insulin prices. It is hoped that these annual reports will permit policymakers and consumers to better track changes in insulin prices, and that this increased monitoring will slow future price increases.

According to the fiscal analyses conducted by a number of states, there does not appear to be a compelling case that the costs of implementing a cost-sharing limit on a 30-day supply of insulin would be prohibitive, either in terms of insurance premium increases or in significantly higher regulatory costs. That was true whether the states were estimating the costs of a $100 cost-sharing cap or a cap as low as $25 for a month's supply of insulin. Most states estimated the expense would run in the tens of thousands of dollars, some for only the first few years of the new cost-sharing arrangement. New Jersey's fiscal note cited a possible cost impact to the State of $20 million for certain public employee coverage, but as we noted, "information regarding how the division arrived at its estimate and the data used were not provided."

The empirical evidence from Colorado's first year of rate filings also 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. However, it is important to note that long-term cost implications on premiums have yet to be realized, as the law that has been in effect the longest has yet to see a full benefits year of claims data to show the true impacts on costs. 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 insulin products, patients in narrowly-defined market segments, or for limited durations. Legislation compelling greater competition among insulin manufacturers, pharmaceutical wholesalers, PBMs, and pharmacies is a much tougher political and regulatory challenge at the state level. Encouraging the development of generic insulin, for example, might require national legislation or regulatory changes. Similarly, cost-sharing caps on insulin for all diabetics, 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 diabetics who use insulin and will benefit diabetics who have insurance coverage under the affected plans.

ENDNOTES

[i] Sections 8 and 9 of ACS-954 create 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 appears as a new section, mandated diabetes benefits are not new to those markets.

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ASSEMBLY COMMITTEE SUBSTITUTE FOR

ASSEMBLY, Nos. 954, 653, and 1669

STATE OF NEW JERSEY

219th LEGISLATURE

ADOPTED FEBRUARY 13, 2020

Sponsored by:
Assemblyman ROBERT J. KARABINCHAK
District 18 (Middlesex)
Assemblyman JOHN ARMATO
District 2 (Atlantic)
Assemblywoman ANNETTE QUIJANO
District 20 (Union)

Co-Sponsored by:
Assemblywoman Lampitt, Assemblymen Mazzeo, Freiman, Assemblywomen Vainieri Huttle, Timberlake, Assemblyman Benson and Assemblywoman Downey

SYNOPSIS

Provides that purchase of insulin is not subject to deductible; requires health insurers to limit copayments and coinsurance for insulin; requires insulin manufacturers to submit report to Commissioner of Banking and Insurance.

CURRENT VERSION OF TEXT

Substitute as adopted by the Assembly Financial Institutions and Insurance Committee.

AN ACT concerning cost sharing for insulin, 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. (New section) The Legislature finds and declares that:

a. The rising cost of insulin has created an affordability crisis that threatens the health and financial well-being of many diabetes patients.

b. Research by the non-partisan Health Care Cost Institute found that prices for insulin nearly doubled over the five year period from 2012 to 2016 and other studies show that prices for insulin have increased by 700% over the past two decades.

c. The lack of competition, transparency, and accountability in the prescription drug market has allowed manufacturers of insulin to exert extraordinary pricing power.

d. While insulin products have been on the market for almost a century, there is limited competition from lower-cost generics, in part due to aggressive efforts by brand name drug manufacturers to block the entry of generic insulin products into the market.

e. Even consumers with health insurance may face a lack of access to insulin due to the plan design of some health insurance policies.

f. For consumers without insurance, or with insurance coverage not subject to New Jersey State law, access to current and reliable cost information may be helpful to consumers and researchers trying to better understand the true cost of insulin.

g. It is, therefore, in the public interest to protect consumers by mandating insurance coverage cost sharing maximums in New Jersey to improve consumer access to insulin, and to provide for transparency and publication of drug company pricing of insulin.

2. 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 $50 per 30 day supply.

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 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 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.1)

3. 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 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 $50 per 30 day supply.

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)

4. 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 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 $50 per 30 day supply.

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 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.3)

5. 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 $50 per 30 day supply.

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)

6. 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 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 $50 per 30 day supply.

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)

7. 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 $50 per 30 day supply.

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)

8. (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 any 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 $50 per 30 day supply.

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.

9. (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 any 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 $50 per 30 day supply.

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.

10. (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 any 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 $50 per 30 day supply.

11. (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 any 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 $50 per 30 day supply.

12. (New section) Every manufacturer of an insulin product shall submit, not later than January 1, 2021, and annually thereafter, a report to the Commissioner of Banking and Insurance containing the following information:

a. name of the insulin products currently manufactured;

b. identification of whether the insulin products are brand name or generic drug products;

c. total sales of insulin products to New Jersey consumers quantified in total units and total revenue;

d. the effective date and amounts of any changes in the wholesale acquisition cost or other list prices for insulin during the prior calendar year;

e. aggregate, company-level research and development costs for insulin over the prior calendar year;

f. the name of each of the manufacturer's insulin products that were approved by the federal Food and Drug Administration in the previous five calendar years;

g. the name of each of the manufacturer's insulin products that lost patent exclusivity in the United States in the previous five calendar years; and

h. a statement of rationale regarding the factor or factors that caused the increase in the wholesale acquisition cost or list price increase for insulin.

13. Sections 2 through 4, 6, and 7 of this act shall take effect on the 180th day next following the date of enactment and shall apply to plans issued or renewed on or after January 1 of the next calendar year; sections 5, 8, and 9 shall take effect on the 270th day next following the date of enactment and shall apply to plans issued or renewed after January 1 of the next calendar year; sections 10 and 11 shall take effect on the 90th day next following the date of enactment and shall apply to contracts purchased on or after that date; and section 12 shall take place immediately.

Appendix II

NEW JERSEY GENERAL ASSEMBLY

JOHN J. BURZICHELLI
ASSEMBLYMAN, DISTRICT 3
DEPUTY SPEAKER
EMAIL: AsmBurzichelli@njleg.org

CHAIR, ASSEMBLY APPROPRIATIONS COMMITTEE
VICE-CHAIR, ASSEMBLY BUDGET COMMITTEE
LEGISLATIVE SERVICES COMMISSION
JOINT BUDGET OVERSIGHT COMMITTEE

February 19, 2020

RECEIVED

FEB 28 2020

OFFICE OF LIFE & HEALTH
DIVISION OF INSURANCE

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 Appropriations Committee, I respectfully request the Commission to review and prepare a written report of A-954, sponsored by Assemblyman Robert Karabinchak. The bill would provide limit copayments and coinsurance for insulin and require insulin manufacturers to submit report to Commissioner of Banking and Insurance.

If you have any questions, please do not hesitate to contact, Mark Iaconelli, Associate General Counsel for the Assembly Majority Office, at 609-847-3500. Thank you for your immediate attention to this matter.

Sincerely,

John J. Burzichelli
Deputy Speaker

Enclosure
CC: Hon. Robert Karabinchak, Assemblyman
Mark Iaconelli, Jr., Esq., Associate General Counsel

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