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RETAIL • COMMUNITY • COMPOUNDING • HEALTH SYSTEM
DISASTER MANAGEMENT • CONSULTANT • INDUSTRY • ACADEMIA
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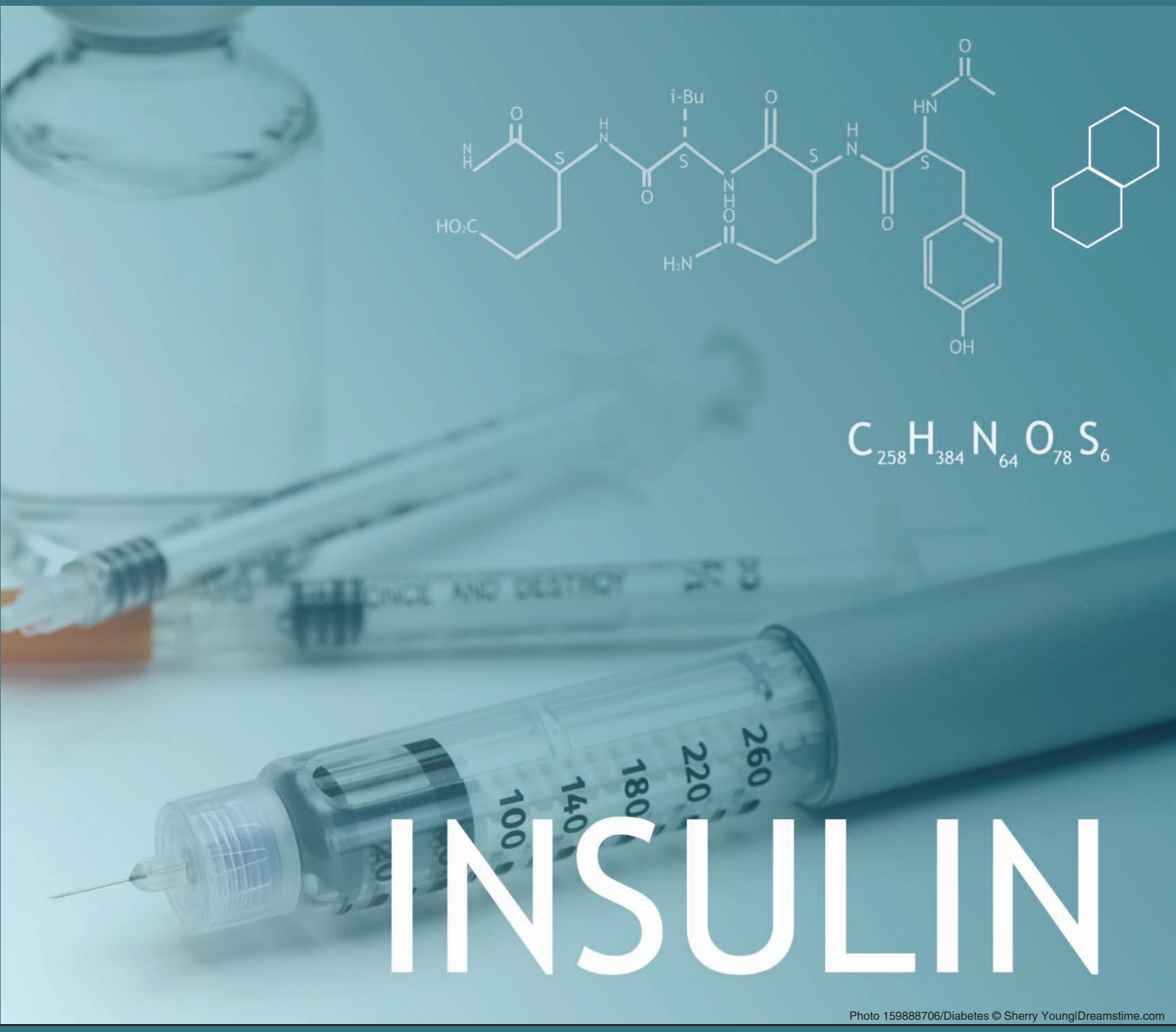

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Peer Reviewed

SCRIPT YOUR FUTURE

NEW JERSEY PHARMACISTS ASSOCIATION
152ND ANNUAL MEETING & CONVENTION

LIVE: OCT. 22; VIRTUAL EVENINGS: OCT 25 & NOV 2

PRELIMINARY SCHEDULE

SATURDAY, October 22; Princeton Marriott at Forrestal	
Registration Open	7:30 AM – 12:00 PM
BREAKFAST	7:30 AM – 8:30 AM
Morning CE Programs	8:00 AM – 10:00 AM
Morning Networking Break with Exhibitors	10:00 AM – 10:45 AM
KEYNOTE Address	10:45 AM – 11:15 AM
Morning CE program	11:15 AM – 12:15 PM
Annual Meeting	12:15 PM – 12:45 PM
Poster Session	12:15 PM – 1:30 PM
LUNCH with Exhibitors	12:15 PM – 2:00 PM
The Legislative Hearing Process	2:00 PM – 3:30 PM
Afternoon Networking Break with Exhibitors	3:30 PM – 4:00 PM
Student Pharmacist Self-Care Championship	4:00 PM – 5:30 PM
EVENING RECEPTION with Awards Presentation & Installation of Officers	5:30 PM – 7:30 PM

Student Activities
10:00AM–6:00PM

- √ Orientation
- √ Round Table Discussions
- √ Networking breaks
- √ Poster Session
- √ Legislative Hearing
- √ Student Championship
- √ Evening Reception

SCRIPT YOUR FUTURE

Schedule is subject to change

VIRTUAL SESSIONS

TUESDAY, Oct. 25	
CE Program	6:30 PM
WEDNESDAY, Nov 2	
CE Program	6:30 PM

The New Jersey Pharmacists Association

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Stay Connected with NJPhA

Mission Statement:

To advance the profession of pharmacy, enabling our members to provide optimal care to those they serve.

President's Letter

Hello,

I would like to extend my thanks to the teams of member volunteers that worked on recent NJPhA projects, such as the health policy paper on access to insulins that is the subject of this issue.

George Crabtree, PharmD, RPh, and Grace Earl, PharmD, BCACP, with assistance from Kirollos E. Daoud, PharmD, Mina Michael, PharmD, and Peter Yakoub, PharmD who assisted while students at Long Island University.

In addition, a recently completed series of manuscripts on Medication Therapy Management by Antonia Carbone, PharmD, BCACP, Grace Earl, PharmD, BCACP, Antonia Carbone, PharmD, BCACP, Lindsay Haimowitz, PharmD, CCP, Nicole Skyer-Brandwene, PharmD, MS, BCPS, CCP and Carmela Silvestri, PharmD, CCP, FASHP is being published as Disease Management and Prevention Resource Guide through a grant received from the New Jersey Department of Health by the Pharmacist Institute of New Jersey, our related foundation.

Additional assistance was provided by PharmD candidate students Paul Castellano, Antonio DeAgresta, Mackenzie Doherty, Sydney Macuray, Kim McArdle, Jorge Nunez, Reina Puri, Ashley Singh, Victoria Spivak, and Ashley Taneja.

I also want to thank Elise Barry, NJPhA CEO, on a successful renewal of NJPHA's ACPE accreditation.

I acknowledge the contributions of Jessica Chmielewski and Lisa Hong, our new Journal committee co-chairs. Their tireless work ensures the publication of the NJPhA journal.

I encourage all our members to get more involved with NJPhA as supporting our profession is not possible without everyone's contributions.

Thank you,
Aakash Gandhi

Message from the Chair of the Board of Trustees

This journal's message is continuing the theme of recognizing individuals who are instrumental in delivering the New Jersey Pharmacists Association professional training certificate programs. Elise Barry, CEO, assisted me in identifying our trainers. The New Jersey Pharmacists Association responded to the COVID19 pandemic by offering the APHA Pharmacy-Based Immunization Delivery Certificate Training for pharmacists and the new pharmacy technician immunization course. NJPHA has also provided the Medication Therapy Management (MTM) Certificate Training and Patient-Centered Diabetes Care Training. We appreciate the efforts of these individuals who led the courses: Mary Bridgeman, Rupal Mansukhani, Pooja Shah, Anita Siu, Margaret Sluglocki, Lucio Volino, Anita Siu and Sneha Srivastava. If you are interested in taking a certificate course, please look on our website: https://njpharmacists.org/certificate-training-programs/ If you are interested in being a trainer for NJPHA and have a NJ license and a train-the-trainer certificate, please reach out to us at njpha@njpharma.org.

The news media and government leaders focused on the COVID19 health crises affecting vulnerable patients in long-term care facilities. Consultant Pharmacists are important health professionals who provide their expertise in this population. We offer the NJPhA certificate program "Preparing for a Consultant Pharmacist Career" at least once a year, based on demand. Thank you to Carmela Silvestri, Penny Applegate, and Ed Rucki for facilitating this course in the past.

Do you routinely call your state legislator – either a member of the assembly or senate? Did you know that NJPhA routinely screens new bills which are introduced for legislative business? Thanks to the leadership of the Government Affairs committee chairs we engage our members in professional advocacy: George Crabtree (2022), Harold Bobrow (2021) and Loretta Brickman (2021). (Both Harold and Loretta are past NJPHA Presidents)

Our 2021 Visioning Event, facilitated by Carrie Corboy, was incredibly helpful as we heard from members who supported this focus area for engaging members. Please look for announcements in the fall 2022 inviting you to join a task force which will develop modules fostering skills for calling or writing to legislators or attending legislative events.

Grace Earl, PharmD, BCACP
Chair, New Jersey Pharmacists Association

From The Editors' Desks...

Dear colleagues,

Thank you for your continued support for *The New Jersey Journal of Pharmacy* – the official peer-reviewed journal of the New Jersey Pharmacists Association. It is our sincere hope that you enjoy the spring edition of our journal. This issue's CE article centers around a diabetes health policy report.

We welcome submissions for the next issue of The New Jersey Journal of Pharmacy. If you are interested in submitting a manuscript for publication consideration or serving as a peer reviewer, please email the Journal Committee at njpharmacists@gmail.com.

Jessica Chmielewski, PharmD, MHS, RPh
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Health Policy Promoting Insulin Affordability

George Crabtree, PharmD, RPh[1], Kirollos E. Daoud[2], Mina Michael[2], Peter Yakoub[2], Grace Earl, PharmD, BCACP[3]

Acknowledgement: Edited by Grace Earl; Reviewed by Elise Barry, Laurie Clark

Abstract

The profession of pharmacy embraces accountability for optimizing the patient's medication therapy and subsequent health outcomes. In the United States, the prevalence of diabetes is increasing and rising drug prices affecting insulin pose a health barrier. A task force assembled by the New Jersey Pharmacists Association developed an overview of the landscape of health policies affecting medications used for diabetes mellitus, including insulins. The paper describes innovative policymaking impacting copay limits for insured patients, emergency refill laws and regulations, and Insulin Access Programs. Additional policies have an effect upstream on the pharmaceutical manufacturing supply chain through fostering consumer costs transparency, manufacturer pricing, and creating a regulatory climate which promotes greater opportunities to manufacture drugs. A major component influencing medication prices relates to pharmacy benefit managers (PBM), an intermediary of insurance companies or health plans. These policy solutions are designed to make insulin more accessible and affordable.

Introduction

Prescription medication price increases are currently under the scrutiny of the public and policymakers. Rising drug prices affects many people in the United States (US). This leads to substantial cost burden for people requiring injectable insulin.[1] A cost analysis performed by Kaiser Family Foundation (KFF) has shown that between 2007 and 2016, average Part D spending per insulin user increased 358% from $862 to $3,949.[2] This translates to a nearly doubling of average out-of-pocket (OOP) costs for insulin for Part D enrollees who do not meet low-income eligibility subsidy limits.

The steady rise of insulin prices leaves some people with diabetes limited choices and some resort to solutions placing their health at risk. For example, patients delayed their appropriate prescription refills to save money. The Yale Diabetes Center surveyed 354 patients with type 1 or type 2 diabetes on whether they resort to **skipping insulin doses** or **underdosing insulin.**[3] Twenty-five percent of patients admitted to underdosing insulin due to inability to pay for the insulin.[3] Uncontrolled diabetes is associated with significant acute and long-term complications. For example, difficulties with adherence are associated with increasing overall disease risk and hospitalization for diabetic ketoacidosis (DKA). DKA, a serious complication of diabetes, leads to increased healthcare costs and negative health outcomes including death.[4] Additionally, low socioeconomic class is associated with a greater risk for DKA. Insulin prices are especially important to this asset-limited population as their health depends on access to life-saving medication.

For these reasons, it is important to make insulin affordable and accessible to all patients with diabetes. Health policy is one of the potential tools to make diabetes medications more affordable and accessible. Health policies including proposed and approved laws and regulations to enhance access to life-saving drug therapy are summarized in **Table 1**.

Figure 1 provides an overview of the landscape of health policy in the space of diabetes care. Health policies may directly **Enhance Access to Insulins** and directly impact pharmacists and pharmacy practice. There are several examples of innovations in policymaking which impact the **Pharmaceutical Manufacturer Supply Chain**. These policies have an effect upstream in the drug supply chain through fostering transparency of consumer costs and manufacturer pricing and creating a regulatory climate which promotes greater opportunities to manufacture drugs. A major component influencing medication pricing relates to **Prescription Benefit Managers** (PBM), an intermediary of insurance companies or health plans. These short-term and long-term solutions for making insulin more accessible and affordable are described in this paper.

Emergency Insulin Refills

Laws allowing pharmacists to dispense an **emergency refill** avoid emergency situations. Financial pressures influence patients' decision-making regarding access to medications and healthcare, especially in emergency situations. If a patient uses their last dose of insulin on a weekend and they cannot reach their doctor, they may avoid going to the emergency department (ED) or urgent care center to avoid extra medical bills. This poses an immediate danger to the patient due to an inadequate number of insulin vials on-hand and/or injecting a lower insulin dose to extend the supply, referred to as **rationing insulin**. Alternatively, pharmacists often assist patients who are traveling for business or vacation who inadvertently leave home without their insulin vials and request an emergency refill or **early fill**.

Several states have enacted laws that allow pharmacists to prescribe **emergency refills** for patients when they run out of insulin and are unable to reach their doctor. The State of Ohio, for example, has **Kevin's law**, named after Kevin Houdshell, a patient with diabetes who lost his life to diabetic ketoacidosis in 2013 (Ohio Legislature, HB-188, 2016).[5] Kevin's story was shared with various state legislatures. After his request for renewing his insulin prescription went unanswered for 3 days, Kevin had to resort to rationing his insulin.[6] Insulin rationing may lead to deadly consequences for patients. Since the law passed in Ohio, 19 states have followed with similar laws allowing pharmacists to prescribe a limited day supply of insulin to last until they speak with their physician or prescriber.[7] Each law varies by state, but laws are enacted allowing pharmacists to prescribe and fill

Table 1. Policy Fostering Drug Access

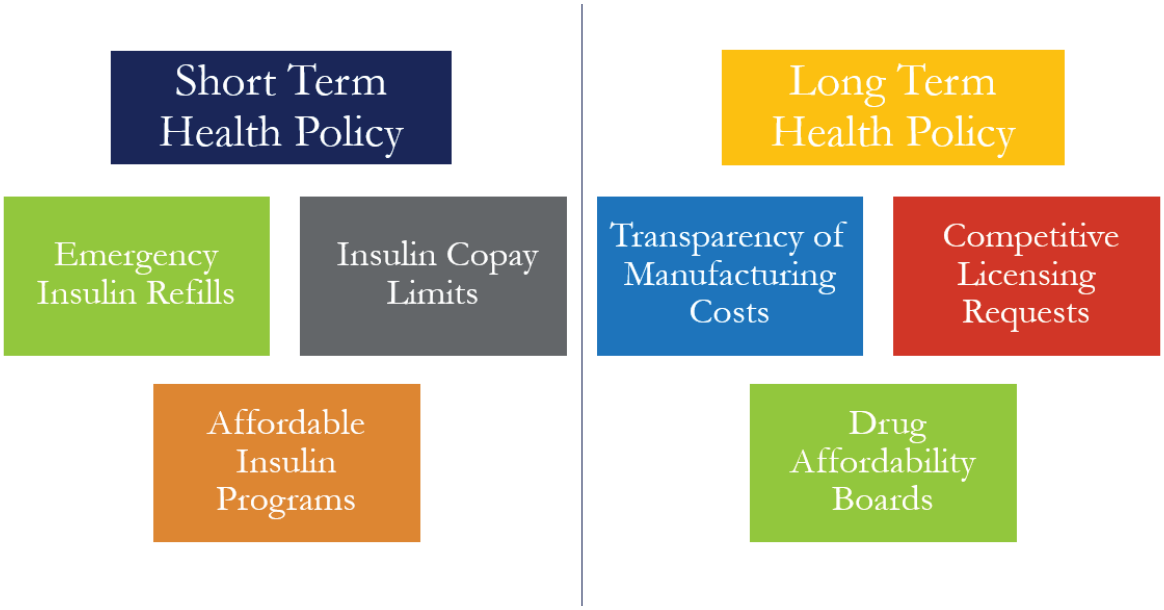
	Impact to Drug Access	Description	Comments	NJ Law/Regulation	Federal Law
1	Emergency refills	NJ Pharmacists may dispense 72-hour emergency supply of chronic maintenance medication	NJ laws/regulations not specific for insulin products. Does not address insurance coverage.	Yes (N.J.A.C. 13:39-7.4)	No
2	Copay limits	Limits OOP monetary costs per insulin prescription	NJ Bill introduced to eliminate deductible and limit copays (S1614)	No (Bills Introduced: S1614, S301, A553)	Yes*
3	Pricing capping of supplies	Limit copays for testing supplies, glucometers, syringes	In some states	No	No
4	Affordable insulin programs	Safety net and cost-control programs for extended duration (i.e. 12 months)	Patients must meet eligibility criteria.	No (Bill introduced, S1614)	No
	IMPACT to MFG & PBM				
5	MFG & PBM Transparency	MFG Reporting requirements and explanations for price increases; Reporting costs for R&D, marketing, pricing strategies & profits PBM reports negotiated prices, administrative fees, rebates, and DIR fees	Fines imposed for failing to comply; may be subject to transfer of technology, data, raw material.	No (Bill introduced, S1615)	No**
6	Drug affordability boards	Establish state-level boards to establish targets for pricing to promote transparency	Legislation introduced Prescription Drug Review Commission	No (Bill introduced, S329)	No
	Competitive licensing requests				
7	MFG licensing drug products to external partners or states	Used to streamline manufacturing of non-biologic generics or insulin	Law could include manufacturing of insulin products	No	Yes. H.R. 1046; 28 Code 1498

DIR: direct and indirect remuneration; MFG: manufacturer; OOP: Out-of-pocket; NJ: New Jersey; PBM: pharmacy benefit manager.

* Limits on co-pays applies to Medicare and Medicaid; CMS Savings Model implemented for 2022 limits OOP expenses to $35 per insulin vial; Build Back Better federal act which is pending proposes an Insulin OOP cap.

** Build Back Better federal legislation which is pending proposes requiring reporting to examine drug pricing transparency

Figure 1. Summary of health policy approach



a supply of insulin up to a 1-month emergency supply (Ohio Legislature, HB-188, 2016).[5]

In Minnesota, the "**Alec Smith Affordability Act"** allows an **emergency fill** of insulin for 30-days at a cost not exceeding $35 (HF 3100).[8] Eligible patients can receive a second month's supply if they meet eligibility criteria listed in the act that includes Minnesota residency. In addition, the patient is not enrolled in MinnesotaCare, or other medical programs and they may not be enrolled in a prescription drug coverage plan that has a co-pay, deductible, or coinsurance limit; nor received an urgently needed supply of insulin through this program. The pharmacy submits a claim for the emergency fill to the manufacturer's vendor unless the manufacturer agrees to replace the insulin dispensed.

If a patient has less than a 7-day supply of insulin, a Connecticut law allows pharmacists to use their professional judgement to dispense an **emergency fill** of a 30-day supply of medication and supplies, after consulting the state's emergency drug monitoring program.[9,10]

State of New Jersey

Currently, federal law exempts short- and intermediate-acting types of insulin from prescription status and these insulins may be purchased over the counter without a prescription.[11] This includes short-acting regular insulin, intermediate-acting NPH insulin and mixed NPH/regular insulins. New Jersey law requires a prescription to dispense newer insulin analogues or other insulin combinations (ex. Insulin lispro, aspart and others). New Jersey pharmacists may dispense some medications without a prescription in emergency situations. **Emergency Dispensing** of a medication or device, if used for chronic maintenance treatment of a condition (N.J.A.C. 13:39-7.4), authorizes pharmacists to apply their professional judgement to assess the patient's health and welfare without the medication. ref12 A 72-hour supply of medication may be dispensed if the pharmacist ascertains if the medication or device was prescribed by order of a practitioner and obtain proper identification from the patient or caregiver. Based on the New Jersey emergency dispensing law, an example of a chronic maintenance medication occurs with a patient who is taking insulin on a chronic basis. Barriers limiting optimal implementation of the New Jersey law relate to insurance coverage and dispensing practices. The Division of Banking and Insurance could mandate coverage for emergency dispensing, emergency refills or early fills for insulin or other medications for insured patients independent of whether the deductible or coinsurance limit is met. Furthermore, new laws and regulations could make it feasible to dispense a **standard unit of dispensing** of a multiple-dose form. For example, a multiple dose vial of injectable insulin, the standard unit of dispensing, may contain a quantity greater than a 72-hour supply. Because insulins are supplied in ready-to-use multiple-dose vials or other delivery forms, it may not be feasible to dispense manufactured injectable insulins. An alternative solution, for example, is from the Ohio code which states, "if the standard unit of dispensing for the drug exceeds a 30-day supply, the amount of drug dispensed or sold does not exceed the standard unit of dispensing."[3]

Copay Limits

To combat the high cost and variation of insulin copays, the **Centers for Medicare and Medicaid Services** (CMS), in collaboration with the Executive Branch, have implemented Part D Senior Savings Model in order lower patient insulin costs.[14] States including Illinois, New York, Utah, Washington State, New Mexico, and Maine passed laws to limit out-of-pocket (OOP) copays on insulin.[15-19] Many insured patients will pay OOP copays, coinsurance or deductibles for prescription medications. These OOP payments will go to the pharmacy to pay for the list price of the medication as well as the pharmacists' dispensing fee. Plus, the health plan, will establish amounts paid by

the patient referred to as **cost-sharing**. Cost-sharing may be in the form of copayments (also known as **copays)**, deductibles and co-insurance. which are set as various dollar amounts.[20] A glossary of terms is available from other sources.[20]

A **deductible** is a set amount of money determined by the health plan that is the financial responsibility of the patient. To establish pharmacy reimbursement, the adjudicated amount of a claim is reduced by the amount of the deductible paid by the patient. The patient pays the deductible, as an OOP drug cost until the deductible, copayments or co-insurance is satisfied. Thereafter, a percentage of the OOP drug costs are paid with each prescription medication as a deductible, copay or coinsurance. According to the Health Care Cost Institute, the **average copay for insulin** at the beginning of 2017, was $105 and gradually decreased to $48 in December 2017 as patients met their deductible.[21] The average New Jersey copay for insulin for individuals enrolled in **consumer-directed health plans** (CDHP) averaged from $296 in January 2017 to $77 in December 2017.[21] **New Jersey copays were higher than the national average for CDHP enrollees** whose out-of-pocket spending on insulin averaged $258 in January and $59 in December.[21] Consumers choosing high-deductible plan deposit funds into a healthcare account to pay for OOP expenses.

Federal Insulin Copay Limits

The Part D Senior Savings Model started as a voluntary model on January 1,2021 and will continue for five years through December 31, 2025. All participating prescription drug plans will offer lower insulin copays from the beginning of the year through the Part D coverage gap. The insulin savings model will cover insulin pen and vial dosage forms for rapid-acting, short-acting, intermediate-acting, and long-acting formulations. On January 1, 2022, CMS announced that a total of 2,159 Part D prescription drug plans and Medicare Advantage plans would provide access to a broad set of insulins at a maximum of $35 copay for a one-month supply for the 2022 plan year.[14] Participating pharmaceutical manufacturers will pay the 70 percent discount in the coverage gap for the Part D insulins they market, but those manufacturer discount payments would now be calculated before the application of supplemental benefits under the Model. These benefit design changes lead to an average saving of $446 per year on insulin costs for Medicare patients.[14]

The federal **Build Back Better Act (BBBA)**, proposed in 2022, included provisions to reduce prescription drug costs and lower insulin prices to lower cost sharing for seniors. A standard unit of insulin product would be capped at $35. The Part D OOP costs for seniors would be capped at $2000 annually. The **Build Back Better Act** also proposed that Medicare could negotiate directly with manufacturers over drug pricing. (BBB, https://www.whitehouse.gov/build-back-better/). The **Build Back Better Act** is no longer in consideration; however, the insulin provision may be included in a future bill.

State Insulin Copay Limits

Many states have passed laws to lower OOP insulin costs by capping insulin copays. Colorado became the first state to cap the soaring insulin prices. The OOP copay for insulin is $100 per 30-day supply for insured individuals began in January 2020.[22] Soon afterward, other states have followed Colorado's initiative to cap insulin copay costs. Colorado's insulin copay law translates to a $200 OOP maximum cost for those taking basal and bolus insulin.[22] However, the Colorado law excludes certain insurance plans, rendering plan enrollees with diabetes ineligible for assistance under this current law.

The New Mexico law of 2021 limits monthly insulin copays (House Bill 292) to $25 for insured patients, noted as the lowest copay for insulin in the nation. This controlled price expands access to affordable medication.[23]

Maine passed "**An Act to Save Lives by Capping the Out-of-pocket Cost of Certain Medications**" bill which was signed into law in 2020.[24] The law mandates that health insurance carriers provide coverage for prescription insulin drugs with a maximum $35 OOP cost for a 30-day supply.[24] The law has been enacted and applied to state-regulated commercial insurance policies issued or renewed on or after January 1, 2021. In addition, the law authorizes pharmacists to dispense emergency refills of insulin and related supplies by an individual standing order for a maximum of 30-day supply or the smallest available package size.[24]

The State of Washington requires health plans to limit OOP costs and a prescription copay cap applies regardless of whether a patient is meeting their deductible. Any cost sharing paid by the patient will be applied toward the deductible. The law expires on January 1, 2023.[17]

Proposed Copay Legislation in New Jersey

New Jersey is taking steps to ensure affordability for patients in need of life-saving insulin. New Jersey bills S301(Vitale; Pou) and A553(Karabinchak; Quiajano; Calabrese) were introduced in the current legislative session that began in January 2022, to eliminate the deductible and require health insurers to limit insulin copays to $50 per 30-day supply.[25] Legislation that provides predictable insulin copays will benefit patients and reduce the need to ration medication or choose between filling or refilling a prescription and paying the rent.

Task Force Recommendation:

The NJPhA Task Force applauds the bills proposed sponsored by Senators Vitale and Pou, and Assembly members Karabinchak, Quijano and Calabrese, to eliminate deductibles and limit copays for insulin to assist New Jersey patients in achieving better health outcomes and recommends that coverage for diabetes supplies be added to the bill

Capping of Diabetes Supplies Prices

Connecticut has taken a different approach by addressing the rising cost of diabetes supplies.[9,26] Many patients with

Type 1 and 2 diabetes monitor their blood glucose levels at home as part of self-management activities. Blood glucose monitoring involves a blood collection test strip and a glucose meter (also called a glucometer) to interpret the concentration of glucose in the blood. The Connecticut law includes glucose meters (glucometers), glucose test strips, and syringes to $100 each for a 30-day supply.[9] Drawing insulin products from a glass vial requires a plastic barrel syringe with measurement markers and a needle. The law took effect on January 1, 2022.[9,27]

Affordable Insulin Programs

States have enacted laws to create **safety net** and **cost-control programs**. These programs endeavor to meet the longer term needs of individuals facing barriers to affordable medications. **Affordable Insulin Programs** target the needs of uninsured individuals.

In Minnesota, the "**Alec Smith Affordability Act**", referenced in the Emergency Insulin Refill section above, allows pharmacists to provide an emergency fill of medications and it allows patients to have access to the 12-month continuing **safety net program** (HF 3100).[8] In addition, the law supports patient access to insulin at a cost not to exceed $50 for a 90-day supply.[8] Patients submits a completed application to the pharmacy. If the eligibility criteria are met, patients have access to the **safety net program**. The eligibility criteria for participating in the safety net programs includes individuals or families with incomes equal to or less than 400 percent of federal poverty guidelines. An individual is ineligible if they receive healthcare through a federally funded program or receive prescription drug benefits through the Department of Veterans Affairs.

In New Jersey, Senate bill 1614 was recently introduced in 2022 to establish an **Insulin Assistance Program.**[28] The bill has been referred to the Assembly Financial Institutions and Insurance Committee. Income eligibility criteria, for those individuals who are uninsured and unable to afford the cost of insulin, is included in the Assembly bill. At the present time, a companion bill has not been introduced in the Senate.

Manufacturer and PBM Transparency: Federal and State Responses

Insulin prices have been growing exponentially over the past decades. In the 1940s, the price of short-acting insulins was 20 cents per 100 units without insurance. That is equivalent to $3 today.[29] In 2019, the cash price for 100 units of short-acting insulin is now $18 per 100 units.[29] Until recently, Pharmacy Benefit Managers (PBMs) and pharmaceutical manufacturers were not obligated to reveal the factors affecting drug price such as discounts and rebates.

An investigation into PBM practices was launched on the federal level in January 2021. Senate Finance Committee Chairman Chuck Grassley (R-Iowa) and Ranking Member Ron Wyden (D-Ore.) released a report of their findings concerning the rising price of insulin.[30,31] Their report examined the expenses, negotiations, and price increases of primary insulin manufacturers (Eli Lilly and Company, Sanofi, and Novo Nordisk), and studied their dealings with Pharmacy Benefit Managers (PBMs). The PBM acts as an intermediary between the drug manufacturers and health insurance plans, and they build formularies for each plan that meets each unique plan design. PBMs receive administrative fees and rebate dollars from manufacturers related to drug placement on formularies. The more advantageous the insulin is placed on formulary; this will cause higher potential revenue for a PBM. However, PBM practices obligate insulin drug manufacturers to pay rebates which places them at a financial disadvantage.

The Senate Committee on Finance reported that PBMs used their size and threatened to exclude drugs from formularies to secure more generous rebates and administrative fees from insulin manufacturers.[30,31] The investigation discovered that Eli Lilly and Company, Sanofi, and Novo Nordisk engaged in pricing collusion. In 2015, the Novo Nordisk Board of Directors struck down a proposal to decrease the price of insulin because of potential financial backlash from PBMs and payers. [30,31] The Senate Finance report uncovered business practices that are keeping insulin prices at elevated levels.[30] Since 2013, the rebates for insulin have grown from single digits to nearly 60.[30] Likewise, the PBM administrative fees have grown to 5% of a drug's list price. The price of a given insulin product covered by insurance is based on the price negotiated between the PBM and the manufacturer and PBM administrative fees. The lack of drug pricing transparency between drug manufacturers and PBMs has a negative effect on pharmacies and patients.

Among many states, (NY, CO, IL, ME, NM, UT, WA, and WV) that tried to shed some light on these mysterious business arrangements, Nevada passed Nevada Diabetes Drug Transparency Bill in 2017 and it was signed into law (SB 539).[32] This law obligates diabetes drug manufacturers to release marketing and development costs of drugs and associated rebates for each drug (both insulin and biguanides per the 2019 revision). Under this law, PBMs will also need to disclose **price negotiations** made with manufacturers and any **rebates** received by the PBM

In addition, the transparency law requires drug manufacturers to disclose diabetes drug price increases in a 1–2-year period and state the reason for the price increase (SB 539).[32] Failure to comply with this results in a fine up to $5000 per day (SB 539).[32] After the release of the Nevada law, the 2019 report on diabetes drug prices showed that the 2018 drug prices increases were less that the 2017 increases.[33] Out of 695 reported National Drug Codes (NDCs) in the 2019 diabetes drug price report of, 536 drugs (77.6%) had no significant price increase. In the most recent report released in 2020, 117 drugs (18.5%) had a significant price increase in a 1–2-year period and 514 drugs (81.5%) had no significant price increase.[34] The most common diabetes drug classes to increase in 2019 and 2020 were Sodium Glucose Transport inhibitors and Dipeptidyl-Peptidase Type 4 inhibitors, respectively. Insulin prices increased by 17% in 2019 and again by 13% in 2020.

In both the 2019 and the 2020 Nevada reports, it was noted that insulin prices continue to rise, accounting for 65% of Medicaid spending on essential drugs.[34]

Task Force Recommendation
The New Jersey Legislature is poised to vote on very aggressive PBM package (S1614, S1615, S1616) (Table 2). The task force applauds these efforts to address the high cost of pharmaceuticals through policies aimed at improving PBM transparency.

Drug Affordability Boards
Policy makers recognize the rising incidents of diabetes in the population, and they are focused on adopting policies fostering fair insulin pricing.[2] **Drug Affordability Boards** have the ability to set annual drug spending targets, establish upper payment limits for public purchasers, set upper limits on drug prices and call for required reporting from manufacturers and payers under the purview of the board, or negotiate supplemental rebate agreements for drugs that meet certain total cost or cost increase triggers.[35]

The components of drug affordability board policy include establishing the purpose, membership, and powers of the board.[36] There exists variability among state legislation when it comes to drug affordability boards, and the role of a **Drug Affordability Board** may differ by state.

Currently, there are six states that have enacted legislation to create an affordability board or commission (ME, MD, MA, NH, NY and OH). Among these states, there are different approaches to reducing prescription drug prices.[35] The most common method is the establishment of upper payment limits. The second most common method is negotiating supplemental rebates from the manufacturer.

In 2020, there were 17 states that either implemented state drug affordability boards or were exploring legislation to create a board.[35] This illustrates there is a large interest in using drug affordability boards to reduce prescription drug spending. However, questions on the legal authority and ability of drug affordability boards remain.

In July 2019, the State of Maryland became the first state to implement a Prescription Drug Affordability Board (PDAB).[37] The PDAB studies the entire pharmaceutical delivery and payment process. Upon review of pricing and utilization data, the board makes recommendations to the Maryland General Assembly to pursue upper payment limits to make drugs affordable.[37] One challenge for the PDAB has been securing a permanent source of funding. Governor Larry Hogan vetoed Senate Bill 669 and House Bill 1095 in 2020, which would have authorized the PDAB to assess and collect a fee from drug manufacturers, wholesalers, PBMs and insurers as a source of funding.[38,39] Both the Maryland Senate and House of Delegates overrode the veto. As of February 11, 2021, SB 669 became law per Maryland Constitution, Chapter 4 of 2021.[38] With funding secured, the PDAB began studying the pharmaceutical process to develop regulations.

State of New Jersey
The State of New Jersey has several pending bills, sponsored by Senator Troy Singleton and Assemblyman John McKeon, which address a drug affordability board, pricing disclosures, and state bulk purchasing, for example, which promote drug cost transparency. These bills (S323, S320, S334, S781, S788, S1030, S1614, S1615, S1616) focus on various pricing disclosures and savings (**Table 2**). Bill S1615 and companion bill A2840 seeks to establish drug supply chain data reporting to a Prescription Drug Review Commission and require the Division of Consumer Affairs to publish an annual pricing report (**Table 2**) One of the goals for this commission involves determining a list of critical prescription drugs based on substantial public interest for inclusion in the annual pricing report. The drug manufacturer would report information related to costs of production, research and development, and marketing. In addition, manufacturers would report prices charged to purchasers outside the United States and prices charged to New Jersey health plans.

Competitive Licensing Agreements
Brand insulin products have been on the market for decades and despite being an established drug, insulin prices have risen. When manufacturers periodically introduce any formulation changes, it provides opportunity to extend their patent on the branded drug and its inactive ingredients.[7] A real solution to this problem would be to streamline the process of generic insulins/biosimilars entering the market. Insulin generics are difficult to produce, requiring extensive and costly work to make copies of biologics. The resulting products, for drugs like insulin, are known as biosimilars. Biosimilar manufacturers adhere to strict standards and validation methods that assure that their copycat insulin has the same efficacy as the originator, brand name, product. The complexity of the regulations surrounding biosimilars challenges companies to compete for a license to make insulin.[7]

Until recently, CMS was prohibited from negotiating with drug manufacturers to lower drug prices. The Medicare Negotiation and Competitive Licensing Act of 2021 was introduced in the 117th Congress to amend the Social Security Act to require the Secretary of Health and Human Services to negotiate the prices of drugs furnished under the Medicare Part D program and gives CMS the ability to issue competitive licenses to other manufacturers to use exclusive patent, clinical trial and other exclusive information to develop a competitor product if the original drug manufacturer does not agree to a fair price.[40] The Medicare Negotiation and Competitive Licensing Act of 2021 is no longer in consideration; however, these provisions may be included in a future bill.[40]

Table 2. New Jersey Legislature Bills for 2022-2023

Bill number and Title	Link
S323: Establishes prescription drug pricing disclosure requirements and measures to reduce prescription drug costs (Identical bill to A3245)	https://www.njleg.state.nj.us/bill-search/2022/S323
S329: Establishes Prescription Drug Affordability Board; appropriates $1 million (Identical bill to A1747)	https://www.njleg.state.nj.us/bill-search/2022/S329
S334: Requires carriers to pass prescription drug savings to consumers (Identical Bill to A1745)	https://www.njleg.state.nj.us/bill-search/2022/S334
S781: Establishes requirements for State entities to enter into bulk purchasing arrangements for pharmaceutical products.	https://www.njleg.state.nj.us/bill-search/2022/S781
S788: Removes exception of self-insured health benefits plans from law concerning pharmacy benefits managers (Identical Bill to A1763	https://www.njleg.state.nj.us/bill-search/2022/S788
S1030: Permits certain managed care organizations to consider cost-effectiveness when placing prescription drug on formulary.	https://www.njleg.state.nj.us/bill-search/2022/S1030
S1614: Requires health insurance carriers to provide coverage for epinephrine auto-injector devices and asthma inhalers; limits cost sharing for healthcare coverage of insulin (Identical bill to A2839)	https://www.njleg.state.nj.us/bill-search/2022/S1614
S1615: Establishes certain data reporting requirements for prescription drug supply chain; requires Division of Consumer Affairs to issue annual report on emerging trends in prescription drug pricing; appropriates $900,000 (Identical Bill to A2840)	https://www.njleg.state.nj.us/bill-search/2022/S1615
S1616: Establishes new transparency standards for pharmacy benefits manager business practices (Identical to A536 & A2841).	https://www.njleg.state.nj.us/bill-search/2022/S1616

A: Assembly; S: Senate

Government Manufactured Insulin

There is precedent for government manufactured prescription drugs. Into the 1990s, Michigan and Massachusetts had state-run vaccine manufacturing.[41] This history leads to an interesting approach to reduce the cost of insulin for patients. The U.S. Congress Affordable Drug Manufacturing Act was introduced in Congress in 2018, 2019 and 2020 with the goal to establish an Office of Drug Manufacturing within the Department of Health and Human Services.[42] Had this act been enacted, the Office of Drug Manufacturing would begin public production of insulin, naloxone, and antibiotics within one year. These products would then be sold to the public at a reasonable price after covering the cost of manufacturing.

The Office of Drug Manufacturing may produce medications based on set criteria which includes[42]

1. Drugs not marketed in the U.S.
2. Drugs marketed by fewer than 3 drug manufacturers
3. Drugs with wholesale acquisition costs that have increased at a rate greater than the consumer price index
4. Drugs included on the drug shortage list under the Federal Food, Drug, and Cosmetic Act
5. Drugs with an average wholesale acquisition cost (WAC) that has been determined to be a barrier to patient access
6. Drugs listed by the World Health Organization as essential medicines

Conclusion

Due to the rising costs of medications, patients often make difficult healthcare decisions. These decisions may include rationing their insulin dose or paying a household bill instead. There is pressure building for policymakers to act on the issue of rising insulin costs.[2] Many states are introducing legislation that targets the cost for diabetes care. As policymakers continue their effort to look at controlling the cost of healthcare, there will be new and interesting health policies championed at the state and federal level. This paper covers a wide range of health policy options for policymakers to consider as part of a comprehensive approach to increase insulin access.

The work of the NJPhA Diabetes Task Force, herein, offers summaries of state actions, and recommendations for New Jersey healthcare professionals and policymakers to consider. Laws, as outlined in sections above, attempt to help the most vulnerable patients in the state. In fact, there are 692,000 uninsured New Jersey residents and 9.2% of state residents are under the poverty line according to the 2019 New Jersey Census Report.[43]

It is important to clearly delineate how to shift the cost burden away from the patient without moving the cost to pharmacies or the state. The lack of drug pricing transparency is a key factor in the rising costs of medications, including insulin, affecting the ability to understand why and how insulin prices rise substantially each year. The "Insulin Access and Affordability Working Group", convened by the American Diabetes Association (ADA), concluded that current pricing strategies and rebates promote higher list prices for insulins.[20] The insulin supply chain includes the pharmaceutical manufacturers, PBMs and health plans, wholesalers, and **pharmacy services administrative organizations** (PSAOs) before the drug gets to the pharmacies.[20] The ADA Working Group recommends solutions aimed at addressing the overall lack of transparency in the patient burden that result because of the construction of the health plan formulary, the secrecy surrounding the rebates, discounts, and fees paid across the supply chain.[20]

Pharmacies are subjected to below-cost reimbursement or zero reimbursement terms in many PBM contacts required to provide services to Medicare patients, for example.[44] As the severity of the drug prices and pharmacy contracting escalate, patients, who live within five miles of a pharmacy in every state in America, may have nowhere to go.

Summary/Taskforce Recommendations

- **Insulin emergency fills:** While there is no federal law requiring emergency dispensing of insulin and related supplies in all states, many states have developed processes to meet patient needs. Amending the current New Jersey law that permits emergency dispensing of chronic medications for a 72-hour period when a physician or prescriber is unavailable to extend the covered period to 30 days including supplies. This would allow pharmacists to use their professional judgement to address the patients' health needs for diabetes medication and supplies (e.g., lancets, test strips). Furthermore, laws and regulations should be written to make it feasible to dispense a **standard unit of dispensing** of a multiple-dose form (ex. Insulin in vials or pens).

- **Insulin copay caps:** In New Jersey, S301 was reintroduced in the new legislative session and referred to the Senate Commerce Committee because of a fiscal note.[24] The bill removes patient deductible, copayment, and coinsurance stipulations and limits the cost of insulin to $50 per 30-day supply. Health insurers include health benefit plans issued as individual health coverage and small employer health benefit programs, state health benefit programs and school employees' health benefit programs. We recommend this effort as this bill covers all insurance companies and a large range of insulins. Insulin copay limits will help reduce out-of-pocket cost for diabetic patients and will expand the affordability of treatment.

- **Insulin affordability programs:** A bill "**Establishes Insulin Assistance Program**" introduced into the assembly (A1875) in 2022 is a promising effort to address the needs of uninsured individuals who are unable to afford insulin (Table 2). We recommend efforts to provide a safety-net for individuals with diabetes who require injectable insulins.

- **Drug Affordability Boards and Drug Pricing Transparency:** The State of New Jersey proposes a drug affordability board (S329) to curb the rising costs of prescription drug products including brand and generic drugs, biological products, and interchangeable biosimilar products (Table 2). Pharmacies and pharmacists will be prohibited from serving on the board. Bill S1615 (Table 2) establishes data reporting requirements for the prescription supply chain. In addition, the Division of Consumer Affairs will compile an annual report on prescription drug pricing.

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Health Policy Promoting Insulin Affordability

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Learning Objectives:
After participating in this activity by reading the Health Promoting Insulin Affordability, the pharmacist shall be able to:

Pharmacists:
1. Explain the impact to the patient when barriers limit the affordability of insulin and other medications for diabetes.
2. Identify types of out-of-pocket costs that patients will pay to prescription benefit managers or health plans.
3. Describe terms which reflect patients' behaviors when they face barriers that limit access to insulin and other medications for diabetes
4. Explain different types of health policies aimed at improving access to medications.
5. Define the term "transparency" and explain how this is important to understand costs that factor into drug affordability.
6. Identify and describe types of fees in the pharmacy supply chain that include pharmaceutical manufacturers, prescription benefits managers, and pharmacies
7. Define the term "monetary claw back" and explain the flow of money in the pharmacy supply chain.
8. Identify legal strategies for policymakers or the government to increase patient access to medications, especially in health crises situations.
9. List types of health policies that could increase access to medications for insured versus uninsured patients.
10. Compare state data versus national data examining consumer copay costs to identify which states have higher prescription copay costs.

Pharmacy Technicians:
At the completion of this activity, the participant will be able to:
1. Identify examples of the term out-of-pocket costs
2. List risk factors associated with poor health outcomes in patients wit diabetes mellitus
3. Outline patient behaviors when they face barriers that limit access to insulin and other medications for diabetes
4. List different types of health policies aimed at improving access to medications
5. Explain the role of the health plan in establishing policies for patients

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ABSTRACT

The profession of pharmacy embraces accountability for optimizing the patient's medication therapy and subsequent health outcomes. In the United States, the prevalence of diabetes is increasing and rising drug prices affecting insulin pose a health barrier. A task force assembled by the New Jersey Pharmacists Association developed an overview of the landscape of health policies affecting medications used for diabetes mellitus, including insulins. The paper describes innovative policymaking impacting copay limits for insured patients, emergency refill laws and regulations, and Insulin Access Programs. Additional policies have an effect upstream on the pharmaceutical manufacturing supply chain through fostering consumer costs transparency, manufacturer pricing, and creating a regulatory climate which promotes greater opportunities to manufacture drugs. A major component influencing medication prices relates to pharmacy benefit managers (PBM), an intermediary of insurance companies or health plans. These policy solutions are designed to make insulin more accessible and affordable.

INTRODUCTION

This needs assessment is based on expert opinion, research articles, and federal government reports.

Pharmacy practice leaders and educators have called to

make pharmacists aware of "Health in Public Policy" and expand the role of pharmacists in legislative advocacy (Maine LL, 2012); Matzke GR, 2016). Pharmacists delivering patient-centered care in the community, ambulatory care, health-systems, long-term care, and many other practice settings are recognized as an important member of the healthcare workforce in addressing individual and public health. Important global aims of pharmacy practice address promoting the quality of care and access to care. The specific elements at the nexus of pharmaceutical care quality and access to care involves promoting cost-effective medication therapy and integration of social determinants of health by ensuring health equity (Dalton K, 2017). Pharmacists have a covenantal responsibility to patients to encourage utilization of cost-effective drug therapy. The New Jersey Pharmacist Association (NJPhA), a member of the National Alliance of State Pharmacy Associations, engages a legislative consultant to represent the pharmacist voice in the New Jersey legislature. Given the increasing incidence of people with diabetes in the state and rising costs of insulin and other medications, the NJPhA members created a task force to examine state polices across the United States that are favorable for people diagnosed with Diabetes (NASPA, 2018; U.S. Senate Committee on Finance, 2021a and 2021b). The paper "Health Policy Promoting Insulin Affordability" was developed by the NJPhA task force in order to consider patient-factors leading to negative health outcomes when patients are rationing medications. The paper defines key health policy terms and explains current policy barriers as well as legislative solutions to ease the economic burden of prescription costs. Through the NJPhA task force paper, the members of NJPhA are raising the bar to help educate pharmacists and promote a state and national legislative advocacy agenda to increase access to insulins through health policy.

***Learners must read the content of this issue titled *Health Policy Promoting Insulin Affordability* in its entirety before proceeding to the test and evaluation to meet the continuing education activity requirements**

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*Positions at time of writing

The New Jersey Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Test and Evaluation Information:
Please enter this URL into your browser to access the home study test - http://njpharmacists.org/continuing-education/home-study and scroll to the title of the home study activity. Members sign in, and non-members register for the activity. You will receive a confirmation email with the test link for pharmacists or pharmacy technicians.

NJPhA 2022 ANNUAL CONVENTION POSTER CALL

Join the 10th Annual Poster Session:

October 22 Live, In-Person at the Princeton Marriott

It's a *new format*, but the same great opportunity to share your research. We will be using the "Better Poster' process explained below.

Encores Welcome!

The 2022 Poster Session is offered to our convention attendees for credit when they engage with presenters at designated times during the day.

Posters submitted for consideration in 2022 must fall within the theme of "**Advancing Pharmacy through Research"** and meet the pharmacist and pharmacy technician objectives listed on page 2. This year our poster session will coincide with program breaks and lunch hour. Spots are limited.

Logistics: Presenters of accepted posters will discuss their research during breaks and lunch. The Better Poster format will be used this year. For more information about the "Better Poster" design, please watch the YouTube video found here: https://www.youtube.com/watch?v=1RwJbhkCA58

Submission Deadline & Details: Poster applications will be accepted until September 30th, 2021. Accepted poster applicants will be notified on or about October 4th after review.

Journal Publication: Titles, abstracts and presenters for all accepted posters will be listed in an issue of *The New Jersey Journal of Pharmacy.*

See you there!

Rupal Mansukhani, PharmD, CTTS, FAPhA

NJPhA President-elect & Convention Committee Chair

SCRIPT YOUR FUTURE

2022 Poster Theme: *Advancing Pharmacy through Research*

To submit, ensure your poster falls within specified guidelines, complete the attached form and email with a PDF of your poster by September 30, 2021.

Poster presentations will be included in the live, in-person Convention on October 22

NEW JERSEY PHARMACISTS ASSOCIATION