

JOINT STATE GOVERNMENT COMMISSION

General Assembly of the Commonwealth of Pennsylvania

DIABETES IN PENNSYLVANIA:

PREVENTION AND
MAINTENANCE PROGRAMS

Fourth Biennial Report

September 2019



*Serving the General Assembly of the
Commonwealth of Pennsylvania Since 1937*

REPORT

Diabetes In Pennsylvania:
Prevention and Maintenance Programs

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The Joint State Government Commission was created in 1937 as the primary and central non-partisan, bicameral research and policy development agency for the General Assembly of Pennsylvania.¹

A fourteen-member Executive Committee comprised of the leadership of both the House of Representatives and the Senate oversees the Commission. The seven Executive Committee members from the House of Representatives are the Speaker, the Majority and Minority Leaders, the Majority and Minority Whips, and the Majority and Minority Caucus Chairs. The seven Executive Committee members from the Senate are the President Pro Tempore, the Majority and Minority Leaders, the Majority and Minority Whips, and the Majority and Minority Caucus Chairs. By statute, the Executive Committee selects a chairman of the Commission from among the members of the General Assembly. Historically, the Executive Committee has also selected a Vice-Chair or Treasurer, or both, for the Commission.

The studies conducted by the Commission are authorized by statute or by a simple or joint resolution. In general, the Commission has the power to conduct investigations, study issues, and gather information as directed by the General Assembly. The Commission provides in-depth research on a variety of topics, crafts recommendations to improve public policy and statutory law, and works closely with legislators and their staff.

A Commission study may involve the appointment of a legislative task force, composed of a specified number of legislators from the House of Representatives or the Senate, or both, as set forth in the enabling statute or resolution. In addition to following the progress of a particular study, the principal role of a task force is to determine whether to authorize the publication of any report resulting from the study and the introduction of any proposed legislation contained in the report. However, task force authorization does not necessarily reflect endorsement of all the findings and recommendations contained in a report.

Some studies involve an appointed advisory committee of professionals or interested parties from across the Commonwealth with expertise in a particular topic; others are managed exclusively by Commission staff with the informal involvement of representatives of those entities that can provide insight and information regarding the particular topic. When a study involves an advisory committee, the Commission seeks consensus among the members.² Although an advisory committee member may represent a particular department, agency, association, or group, such representation does not necessarily reflect the endorsement of the department, agency, association, or group of all the findings and recommendations contained in a study report.

¹ Act of July 1, 1937 (P.L.2460, No.459); 46 P.S. §§ 65 – 69.

² Consensus does not necessarily reflect unanimity among the advisory committee members on each individual policy or legislative recommendation. At a minimum, it reflects the views of a substantial majority of the advisory committee, gained after lengthy review and discussion.

Over the years, nearly one thousand individuals from across the Commonwealth have served as members of the Commission's numerous advisory committees or have assisted the Commission with its studies. Members of advisory committees bring a wide range of knowledge and experience to deliberations involving a particular study. Individuals from countless backgrounds have contributed to the work of the Commission, such as attorneys, judges, professors and other educators, state and local officials, physicians and other health care professionals, business and community leaders, service providers, administrators and other professionals, law enforcement personnel, and concerned citizens. In addition, members of advisory committees donate their time to serve the public good; they are not compensated for their service as members. Consequently, the Commonwealth of Pennsylvania receives the financial benefit of such volunteerism, along with their shared expertise in developing statutory language and public policy recommendations to improve the law in Pennsylvania.

The Commission periodically reports its findings and recommendations, along with any proposed legislation, to the General Assembly. Certain studies have specific timelines for the publication of a report, as in the case of a discrete or timely topic; other studies, given their complex or considerable nature, are ongoing and involve the publication of periodic reports. Completion of a study, or a particular aspect of an ongoing study, generally results in the publication of a report setting forth background material, policy recommendations, and proposed legislation. However, the release of a report by the Commission does not necessarily reflect the endorsement by the members of the Executive Committee, or the Chair or Vice-Chair of the Commission, of all the findings, recommendations, or conclusions contained in the report. A report containing proposed legislation may also contain official comments, which may be used in determining the intent of the General Assembly.³

Since its inception, the Commission has published more than 350 reports on a sweeping range of topics, including administrative law and procedure; agriculture; athletics and sports; banks and banking; commerce and trade; the commercial code; crimes and offenses; decedents, estates, and fiduciaries; detectives and private police; domestic relations; education; elections; eminent domain; environmental resources; escheats; fish; forests, waters, and state parks; game; health and safety; historical sites and museums; insolvency and assignments; insurance; the judiciary and judicial procedure; labor; law and justice; the legislature; liquor; mechanics' liens; mental health; military affairs; mines and mining; municipalities; prisons and parole; procurement; state-licensed professions and occupations; public utilities; public welfare; real and personal property; state government; taxation and fiscal affairs; transportation; vehicles; and workers' compensation.

Following the completion of a report, subsequent action on the part of the Commission may be required, and, as necessary, the Commission will draft legislation and statutory amendments, update research, track legislation through the legislative process, attend hearings, and answer questions from legislators, legislative staff, interest groups, and constituents.

³ 1 Pa.C.S. § 1939 (“The comments or report of the commission . . . which drafted a statute may be consulted in the construction or application of the original provisions of the statute if such comments or report were published or otherwise generally available prior to the consideration of the statute by the General Assembly”).



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September 25, 2019

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To the Members of the General Assembly:

This is the fourth in a series of reports by the Joint State Government Commission in response to the mandate of 2014 House Resolution 936 (Pr.'s No. 4098), which provides for an ongoing study of the public health problem posed by diabetes in Pennsylvania. The Commission's task is to describe, evaluate, and make recommendations to improve the Commonwealth's response. This report focuses on the relevant programs of the Commonwealth agencies, chiefly the Departments of Health and Aging. The recent significant increase in the price of insulin and the response by the medical community and advocates is also addressed.

As discussed in the pages that follow, diabetes education remains a vital part of the strategy to help people prevent and manage the disease through lifestyle changes. Self-management and, when necessary, preventive measures, monitoring, and therapeutic interventions are key components in the fight against this disease. We hope these reports will assist the Commonwealth in mounting a vigorous and effective response to this serious and growing public health problem.

Respectfully submitted,

Glenn J. Pasewicz
Executive Director

TABLE OF CONTENTS

INTRODUCTION	1
Prevalence in Pennsylvania	1
Economic Costs of Diabetes in the United States and Pennsylvania	4
DIAGNOSIS AND CLASSIFICATION OF DIABETES MELLITUS	15
Definition and Description	15
Classification	15
NEW DEVELOPMENTS IN DIABETES RESEARCH AND THERAPEUTIC APPROACHES	19
The ADA/EASD Consensus Report	19
The ADA Standards of Medical Care in Diabetes – 2019	21
Recent Successes and Current Challenges	27
DEPARTMENT OF HEALTH	29
Diabetes Prevention Program (DPP)	29
Diabetes Self-Management and Support Program (DSMES)	36
Juvenile Diabetes Cure Research Check-off Program	42
DEPARTMENT OF AGING	43
Health & Wellness Program	43
Chronic Disease Self-Management Program	44
Diabetes Self-Management Program	46
PACE	48
DEPARTMENT OF HUMAN SERVICES	51
Medical Assistance (Medicaid)	51
Office of Long-Term Living (OLTL)	53
YMCA’S DIABETES PREVENTION PROGRAM	55
RECOMMENDATIONS	59
APPENDICES	61
Appendix A House Resolution No. 936 of 2014	63
Appendix B Senate Resolution No. 484 of 2018	69
Appendix C State Drug Utilization Data (Pennsylvania)	71

INTRODUCTION

This is the fourth in a series of reports by the Joint State Government Commission (JSGC) written in response to House Resolution No. 936 of 2014. HR 936 provides for an ongoing study of the public health problem posed by diabetes in Pennsylvania and directs the JSGC, in collaboration with certain other state departments and agencies, to describe, evaluate, and make recommendations for the Commonwealth's response. This report describes the relevant programs run by the entities charged with implementing public health policy and with assisting persons with diabetes. The broad purposes of public health policies aimed at controlling diabetes and preventing the disease are "to reduce the incidence of diabetes, improve diabetes care, and control complications associated with diabetes."⁴

In 2018, Pennsylvania legislators demonstrated their continued focus on diabetes by adopting Senate Resolution No. 484, which recognized November 2018 as "National Diabetes Month" in Pennsylvania.⁵ The resolution was unanimously adopted by the Senate on October 17. During the month of November, advocates nationwide join together "to raise awareness, promote ongoing diabetes education and support those living with diabetes."⁶ The theme for the 2018 National Diabetes Month was "Everyday Reality"; it highlighted daily impacts of diabetes on those who have it and their families. This year's theme is gestational diabetes.

Prevalence in Pennsylvania

The United Health Foundation, in its review of the public health impact of diabetes, lists percentages of people in each state who have been told by a health care professional that they have diabetes; those with prediabetes and gestational diabetes are excluded. The overall United States value is 10.5 percent, with the healthiest state, Utah, at 7.1 percent and the least-healthy state, West Virginia, at 15.2 percent. Prevalence of diabetes in Pennsylvania is very close to the national level – 10.6 percent in 2017.⁷ The latest available data indicate slightly higher rate for Pennsylvania – 11.4 percent in 2018.⁸ The chart below clearly illustrates how close the numbers and the trends are when you compare the Commonwealth and the national data:

⁴ HR No. 936 of 2014.

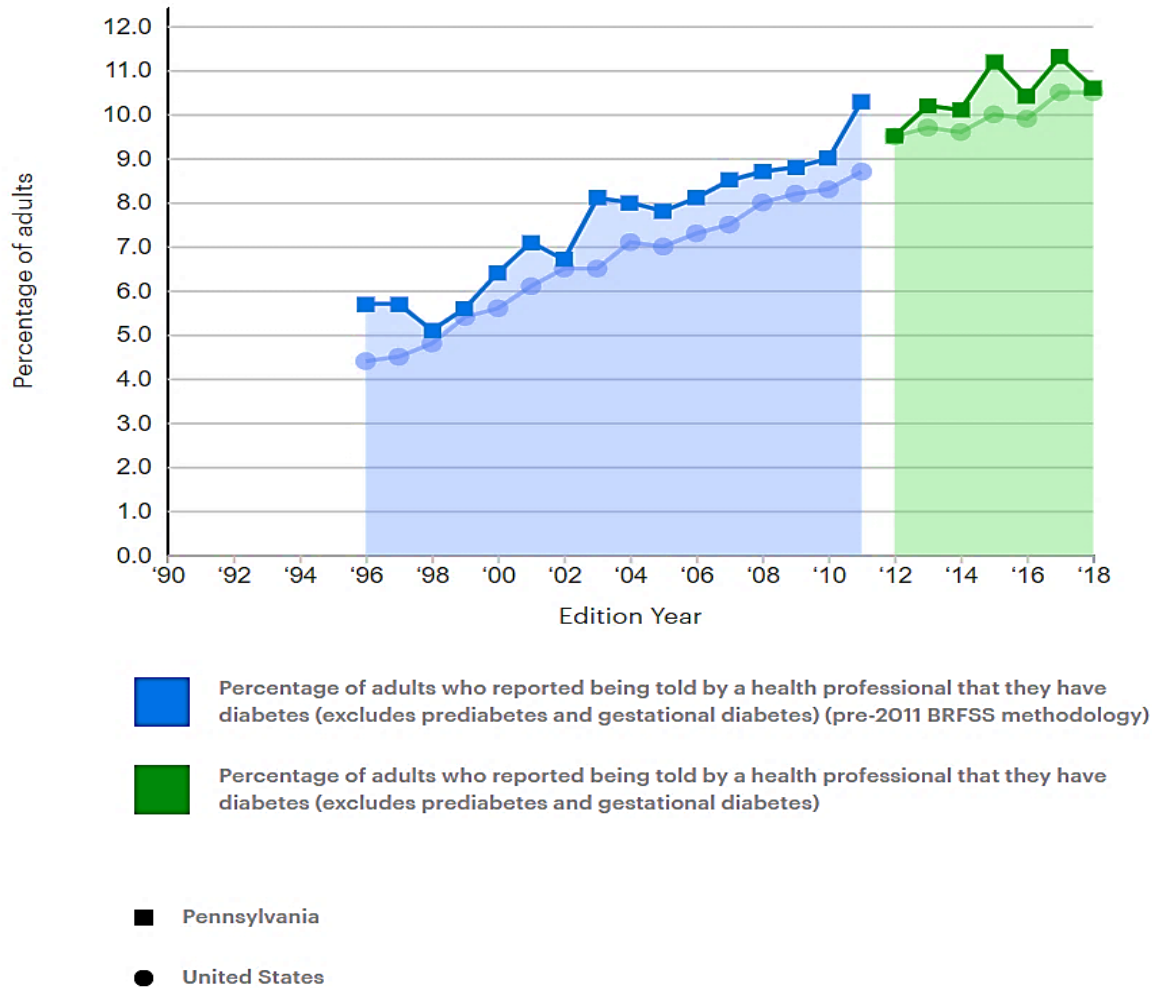
⁵ SR No. 484 of 2018.

⁶ Ibid.

⁷ United Health Foundation. *America's Health Rankings Analysis of CDC Behavioral Risk Factor Surveillance System*, <https://www.americashealthrankings.org/explore/annual/measure/Diabetes/state/PA> (accessed June 4, 2019).

⁸ Robert Wood Johnson Foundation. *The State of Obesity in Pennsylvania*, <https://www.stateofobesity.org/states/pa> (accessed September 20, 2019).

Trend: Diabetes, Pennsylvania, United States



Source: CDC, Behavioral Risk Factor Surveillance System

A closer look at subpopulations reveals further similarities. Prevalence of diabetes among females in Pennsylvania (9.9 percent) is slightly lower than in the U.S. in general (10.5 percent) while prevalence of diabetes among males in Pennsylvania is marginally higher than in the U.S. in general (11.3 percent and 11.2 percent, respectively). When the numbers are subdivided by race/ethnicity, Pennsylvania numbers are very close to those of the U.S. in general among black and white adults, but noticeably lower among Hispanics living in Pennsylvania than in the U.S. Hispanic population in general (9.5 percent and 11.3 percent, respectively).⁹ Subdivided by age and urbanicity, the Commonwealth numbers are very close to the national values.

⁹ United Health Foundation. *America's Health Rankings Analysis of CDC Behavioral Risk Factor Surveillance System*, <https://www.americashealthrankings.org/explore/annual/measure/Diabetes/state/PA> (accessed June 4, 2019).

Obesity is often associated with type 2 diabetes in adults and increased risk of impaired glucose tolerance, insulin resistance, and type 2 diabetes in children. Pennsylvania has the 25th highest adult obesity rate in the nation, and the 14th highest obesity rate for youth ages 10 to 17. Pennsylvania’s adult obesity rate is currently over 30 percent – almost one-third of adult population (30.9 percent in 2018), showing significant increases over the past two decades, up from 20.3 percent in 2000 and from 13.7 percent in 1990.¹⁰

Obesity among children and adolescents has been gaining growing attention from researchers and health care providers. Nationwide, in 2013-2016, the prevalence among youth aged from 2 to 19 was 17.8 percent for obesity and 5.8 percent for severe obesity.¹¹ An extensive cross-sectional study of obesity among children and adolescents established that “in 2013-2016, there were differences in the prevalence of obesity and severe obesity by age, race and Hispanic origin, and household education, and severe obesity was inversely associated with urbanization.”¹² According to the study findings, “in adjusted analyses, obesity and severe obesity significantly increased with greater age and lower education of household head, and severe obesity increased with lower level of urbanization. Compared with non-Hispanic white youth, obesity and severe obesity prevalence were significantly higher among non-Hispanic black and Hispanic youth.”¹³ Understanding and addressing obesity among children and youth is especially important as while it is well-known that overweight children are at increased risk for developing type 2 diabetes as adults, there are indications that the course can be reversed. A study of over 60,000 of men whose weights and heights had been measured at ages 7 and 13 revealed an impressive result: “In those who were overweight at age 7 but who had dropped to a normal weight by age 13, the risk for developing type 2 diabetes by age 60 was no different than for those who had never been overweight.”¹⁴ These findings highlight the importance of early intervention though losing weight in young adulthood – ages 17 to 26 – also reduced the risk compared with maintaining excess weight the entire time.

Currently, the CDC estimates the prevalence of childhood obesity at 18.5 percent (13.9 percent among 2- to 5-year-olds, 18.4 percent among 6- to 11-year-olds, and 20.6 percent among 12- to 19-year-olds.)¹⁵ Obesity rate among Pennsylvania children aged from 10 to 17 years old was 16.8 percent in 2016-2017, and among Pennsylvania high students, it was 13.7 percent in 2017.¹⁶ Decreasing the prevalence of obesity among children and adolescents may be an effective tool to decrease the incidence of diabetes in the Commonwealth in years to come.

¹⁰ Robert Wood Johnson Foundation. *The State of Obesity in Pennsylvania*, <https://www.stateofobesity.org/states/pa> (accessed September 20, 2019).

¹¹ Ogden, Cynthia L. et al. “Differences in Obesity Prevalence by Demographics and Urbanization in US Children and Adolescents, 2013-2016.” *JAMA*. Vol. 319. No. 23. June 2018, doi: 10.1001/jama.2018.5158.

¹² Ibid.

¹³ Ibid.

¹⁴ Tucker, Miriam E. “Reversing Course.” *Diabetes Forecast*. September/October 2018. P.18.

¹⁵ Centers for Disease Control and Prevention. *Prevalence of Childhood Obesity in the United States*, <https://www.cdc.gov/obesity/data/childhood.html#Prevalence> (accessed September 20, 2019).

¹⁶ Robert Wood Johnson Foundation. *The State of Obesity in Pennsylvania*, <https://www.stateofobesity.org/states/pa> (accessed September 20, 2019).

Economic Costs of Diabetes in the United States and in Pennsylvania

Diabetes remains a significant economic burden, with continuously increasing costs.

The study prepared under the direction of the American Diabetes Association (ADA) estimated the total cost of diagnosed diabetes in 2017 at \$327 billion, including \$237 billion in direct medical costs and \$90 billion in reduced productivity.¹⁷ According to the authors' calculations, for cost categories analyzed, "care for people with diagnosed diabetes accounts for 1 in 4 health care dollars in the U.S., and more than half of that expenditure is directly attributable to diabetes."¹⁸ People with diagnosed diabetes incur average medical expenditures of approximately \$16,750 per year, of which about \$9,600 is attributed to diabetes. People with diagnosed diabetes, on average, have medical expenditures approximately 2.3 times higher than what expenditures would be in the absence of diabetes.¹⁹ Indirect costs were calculated by incorporating absenteeism and reduced productivity while at work for the employed population, reduced productivity for those not in the labor force, inability to work because of disease-related disability, and lost productivity due to premature deaths attributed to diabetes.

Based on their analysis, the authors conclude that "after adjusting for inflation, economic costs of diabetes increased by 26% from 2012 to 2017 due to the increased prevalence of diabetes and the increased cost per person with diabetes."²⁰ They note, in particular, that the growth in diabetes prevalence and medical costs is primarily among the population aged 65 years and older, which contributes to a growing economic cost to the Medicare program. The estimates in the ADA report highlight "the substantial financial burden that diabetes imposes on society, in addition to intangible costs from pain and suffering, resources from care provided by unpaid caregivers, and costs associated with undiagnosed diabetes."²¹

The number of people diagnosed with diabetes has continued to grow, by approximately 700,000 annually between 2012 and 2015, and prevalence is projected to keep rising over time as the population grows and ages. Furthermore, the ADA report draws attention to "changes in the demographics of the population with diabetes, health care use and delivery patterns, technology, medical costs, insurance coverage, and economic conditions that affect the economic burden associated with diabetes."²²

¹⁷ American Diabetes Association. "Economic Costs of Diabetes in the U.S. in 2017." *Diabetes Care*. Vol. 41, May 2018, <https://doi.org/10.2337/dci18-0007>.

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Ibid.

²¹ Ibid.

²² Ibid.

The ADA table of state-level estimates of diabetes prevalence and costs in 2017 provides the following numbers for Pennsylvania:

- Prevalence - 7.8 percent
- Population with diabetes – 1,006,000
- Costs (billions \$) – 9.34 (medical), 3.54 (indirect), 12.88 (total).²³

In its detailed analysis of the estimated national cost of diabetes, the authors find it “particularly noteworthy” that “excess costs associated with medications constitute 43% of the total direct medical burden. This includes nearly \$15 billion for insulin, \$15.9 billion for other antidiabetic agents, and \$71.2 billion in excess use of other prescription medications attributed to higher disease prevalence associated with diabetes.”²⁴

The costs of insulin and other medications have increased sharply in the past few years. According to the ADA study, “after adjusting for inflation, the total cost of insulin and other medications to control blood glucose increased by 45% from 2012 to 2017, to a total of \$31 billion. The inflation-adjusted cost of insulin increased by 110% during the same period.” The authors note that “these increases are attributable to both an increase in the number of people using these medications and the cost of the medications themselves.”²⁵

A nationally representative survey indicates that the mean price of insulin nearly tripled between 2002 and 2013: it increased from \$4.34 per milliliter in 2002 to \$12.92 in 2013.²⁶ In 2013, the estimated expenditure per patient for insulin in the United States was greater than all other antihyperglycemic medications combined.²⁷

A special study focused on Medicaid reimbursements for insulin found that “between 1991 and 2014, there was a near-exponential upward trend in Medicaid payments on a per-unit basis for a wide variety of insulin products regardless of formulation, duration of action, and whether the product was patented.”²⁸ Although reimbursements for newer, patent-protected insulin analogs increased at a faster rate than reimbursements for older insulins, payments increased for all products examined in the study. The authors noted that “their findings suggest a lack of price competition in the United States for this class of medications” and cautioned that if reimbursements for many commonly used insulin products continue to increase “at a dramatic rate, <...> patients, physicians, and public and private insurers will find it increasingly difficult to pay for this specialized class of essential medicines.”²⁹

²³ Ibid.

²⁴ Ibid.

²⁵ Ibid.

²⁶ Hua, Xinyang et al. “Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013.” *JAMA*. Vol. 315. No. 13. April 5, 2016, doi: 10.1001/jama2016.0126.

²⁷ Ibid.

²⁸ Luo, Jin; Avorn, Jerry and Aaron S. Kesselheim. “Trends in Medicaid Reimbursements for Insulin From 1991 Through 2014.” *JAMA Internal Medicine*. Vol. 175. No. 10. 2015, doi: 10.1001/jamaimternmed.2015.4338.

²⁹ Ibid.

According to the data collected by the Center for Medicaid and CHIP Services (CMCS), in 2018, the Commonwealth of Pennsylvania spent \$233,302,309.86 on insulin alone.³⁰

The Health Care Cost Institute (HCCI) conducted a study based on health care claims data to investigate trends in total health care spending on individuals with type 1 diabetes between 2012 and 2016. HCCI found “a rapid increase in total health care spending, driven primarily by gross spending on insulin that doubled over the period.”³¹ The HCCI researchers note that “during that time insulin use rose only modestly” and “while the composition of insulins use shifted, the price of all types of insulin and insulin products increased, with point-of-sale prices roughly doubling on average between 2012 and 2016,” and the authors make an unequivocal final statement: “We conclude that increases in insulin spending were primarily driven by increases in insulin prices, and to a lesser extent, a shift towards use of more expensive products.”³²

The HCCI examination of gross per-person spending by type of service – inpatient, outpatient, professional procedure, insulin, and non-insulin pharmacy – over 2012 to 2016 brought the following results:

- In 2016, individuals with type 1 diabetes spent \$5,705 per-person on insulin.
 - Gross spending on insulin accounted for 31% of the \$18,494 in total per-person spending.
 - Per-person spending on non-insulin pharmacy services was \$4,119 (22%), which includes diabetic supplies, as well as other prescription drugs.
- Between 2012 and 2016, gross insulin spending per-person increased by \$2,841.
 - The increase in gross spending on insulin accounted for 47% of the \$6,027 increase in total per-person spending over the period.
 - The increase in gross spending on insulin was larger than any other category, nearly doubling between 2012 and 2016.
 - Non-insulin prescription drug and outpatient spending per-person had the next largest increases rising \$1,097 and \$1,014, respectively.³³

Putting the findings of their study in plain words, Jean Fuglesten Biniek, a senior researcher at HCCI who co-authored the report, said in an interview: “It’s not that individuals are using more insulin or that new products are particularly innovative or provide immense benefits... Use is pretty flat, and the price changes are occurring in both older and newer products... The exact same products are costing double.”³⁴ HCCI CEO Niall Brennan said, “You literally have a captive, near helpless customer base when it comes to Type 1 diabetics and insulin... There are few if any

³⁰ Center for Medicaid and CHIP Services. *State Drug Utilization Data* (updated July 23, 2019), <https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html> (accessed August 23, 2019). Detailed data can be found in Appendix C.

³¹ Fuglesten Biniek, Jean and William Johnson. *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices: HCCI BRIEF January 2019*, https://healthcostinstitute.org/images/easyblog_articles/267/HCCI-Insulin-Use-and-Spending-Trends-Brief-01.22.19.pdf.

³² Ibid.

³³ Ibid.

³⁴ Advisory Board. *Insulin Costs Per Patient Nearly Doubled Over 5 Years, Study Reveals*, <https://www.advisory.com/daily-briefing/2019/01/25/insulin>.

segments of the American economy where a manufacturer could raise prices by 92% and have people consume the same quantity of that product.”³⁵

“Captive” and “helpless” are well-chosen words to describe the position individuals who have to take insulin to manage diabetes find themselves in when insulin prices sharply increase. Insulin-dependent patients with diabetes (either type 1 or type 2) need to take insulin to maintain safe glycemic control. If they cannot afford the necessary doses of insulin or start rationing their insulin because they cannot afford it, they risk serious complications or, in some cases, even death. High insulin prices lead to nonadherence, which, in its turn, results in poor glycemic control. Yale researchers found that one in four ((25.5 percent) patients with type 1 or 2 diabetes had reported using less insulin than prescribed due to high costs (the authors remind their audience that “over the past decade, insulin prices have tripled in the United States, while out-of-pocket costs per prescription doubled”).³⁶ The results were based on a survey of nearly 200 patients at the Yale Diabetes Center, who were asked to respond to clinical and sociodemographic questions. In her presentation of the study results, one of the co-authors, Darby Herkert, made a strong statement, “Insulin is a life-saving medication... It has been listed as an essential medicine by the World Health Organization and its use has been associated with lower rates of hospitalization and emergency department utilization. However, the high cost of medication has been shown to be associated with reduced adherence.”³⁷ One of the Yale study findings was that patients with type 1 or type 2 diabetes who indicated they used less insulin than prescribed due to cost concerns were much more likely to have poor glycemic control compared with those who report regular insulin use (43 percent versus 28 percent).³⁸ Herkert said that “in multivariable analyses, researchers found that patients also had threefold higher odds of having an HbA1c of at least 9% vs. patients who did not report insulin underuse ($P = .03$).”³⁹ The Yale study authors’ conclusion was unequivocal: “Access to more affordable insulin is urgently needed, and we need greater transparency with regards to the way insulin is priced and greater advocacy for those patients who are unable to afford their prescriptions.”⁴⁰

In June 2018, the Institute for Patient Access (IFPA) released a white paper “Protecting Access to Diabetes Care,” prepared by the Diabetes Therapy Access group. The paper outlines several access challenges faced by people with diabetes in their effort to cope with the disease. While acknowledging that educating patients about self-management techniques can have a significant impact on their ability to control symptoms and avoid complications, the authors underscore that “progress is limited if health plan policies do not adequately cover the therapies

³⁵ Ibid.

³⁶ Herkert, Darby; Vijayakumar, Pavithra; Luo, Jing; et al. “Cost-Related Insulin Underuse Among Patients With Diabetes.” *JAMA Internal Medicine*. 2019, Vol. 179. No. 1 (January), doi:10.1001/jamainternmed.2018.5008.

³⁷ *Cost-related Insulin Underuse Raises Risk for Poor Glycemic Control*, <https://www.healio.com/endocrinology/diabetes/news/online/%7Bfd952a00-75e1-476a-b3dd-aae95c878799%7D/cost-related-insulin-underuse-raises-risk-for-poor-glycemic-control>.

³⁸ Herkert, Darby; Vijayakumar, Pavithra; Luo, Jing; et al. “Cost-Related Insulin Underuse Among Patients With Diabetes.” *JAMA Internal Medicine*. 2019, Vol. 179. No. 1 (January), doi:10.1001/jamainternmed.2018.5008.

³⁹ *Cost-related Insulin Underuse Raises Risk for Poor Glycemic Control*, <https://www.healio.com/endocrinology/diabetes/news/online/%7Bfd952a00-75e1-476a-b3dd-aae95c878799%7D/cost-related-insulin-underuse-raises-risk-for-poor-glycemic-control>.

⁴⁰ Ibid.

that physicians recommend.”⁴¹ They comment on specific insurance company policies and cost issues that become an obstacle to successful treatment. The IFPA white paper contains a strong statement: “Diabetes’ impact and prevalence demand policies that allow people to access appropriate medications and effective health care.”⁴²

In the past few years, as the steep increase in the insulin costs has emerged as a major concern, there is increased public awareness, and medical professionals are urging that there be better access and affordability. Multiple newspapers and magazines published disturbing articles with titles like “Life, Death and Insulin,” relating shocking stories of individuals losing their lives as a result of attempts to ration their insulin, share it with others, or skip doses due to sharply rising prices.⁴³

Noting that that “the average list price of insulin has skyrocketed in recent years, nearly tripling between 2002 and 2013,” the ADA Board of Directors convened an Insulin Access and Affordability Working Group to ascertain the full scope of the insulin problem and to advise the ADA on the execution of strategies to address the problem.⁴⁴ The working group was created in the spring of 2017 and presented its findings and recommendations a year later. The working group assembled existing public information about insulin prices and patient cost-sharing, conversed with researchers studying insulin pricing at the national and global levels, and convened a series of meetings with stakeholders throughout the insulin supply chain to find out how each entity impacts the cost of insulin for the consumer. The stakeholders interviewed by the group included representatives of pharmaceutical manufacturers, wholesalers, pharmacy benefit managers (PBMs), pharmacies, pharmacists, distributors, health plans, employers, and people with diabetes and caregivers.

A thorough analysis of the average U.S. list price of the four insulin categories (short-acting insulin vials, rapid-acting insulin vials, rapid-acting insulin pens, and long-acting insulin pens/vials) performed by the working group experts revealed that this price increased by 15 percent to 17 percent per year from 2012 to 2016. Over the same period, the price pharmacies paid to purchase insulin increased at similar rates. Spending on insulins by Medicare Part D has also shown an increasing and accelerating trend, as did patients’ out-of-pocket costs.⁴⁵ All these increases considerably exceed overall inflation during this time, medical care service costs, and spending for other prescription drugs.

⁴¹ Institute for Patient Access. *Protecting Access to Diabetes Care, If* http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2018/05/IFPA_Protecting-Access-to-Diabetes-Care_June-2018.pdf. tecting-Access-to-Diabetes-Care_June-2018.pdf

⁴² Ibid.

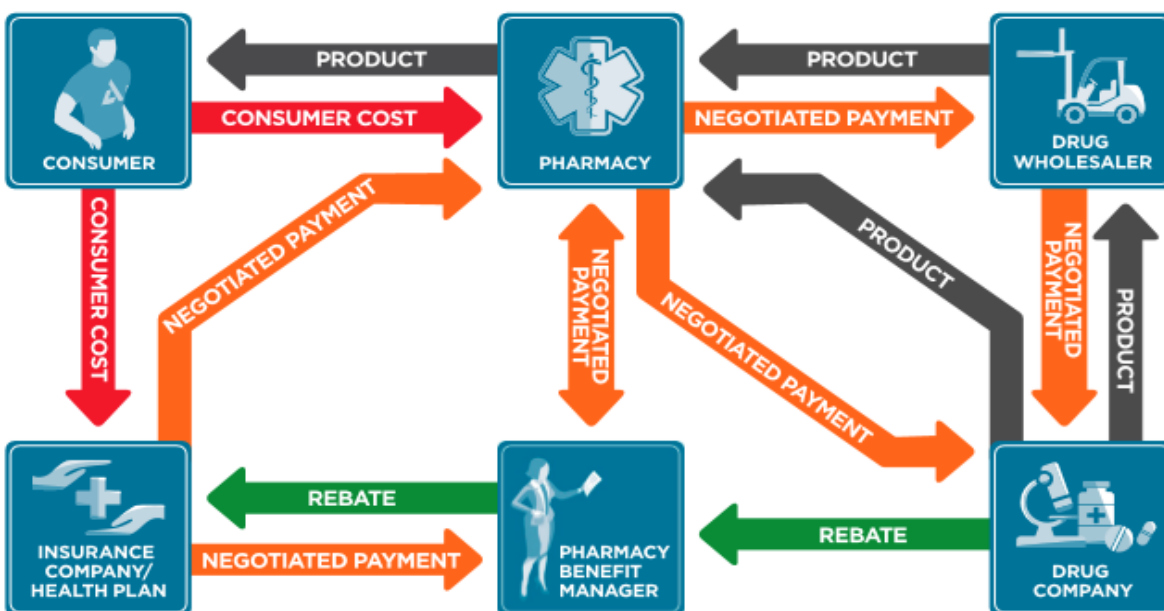
⁴³ Stanley, Tiffany. “Life, Death and Insulin.” *The Washington Post Magazine*. January 7, 2019, <https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/>. See also: Rosenthal, Elisabeth. “When High Prices Mean Needless Death.” *JAMA Internal Medicine*. 2019. Vol. 179. No. 1 (January), doi:10.1001/jamainternmed.2018.5007. and Olivo, Antonio. “Diabetic, 27, Dies After Taking Cheaper Insulin as He Lost Private Health Insurance.” *The Independent*. August 5, 2019, <https://www.independent.co.uk/news/world/americas/diabetes-josh-wilkerson-death-age-counter-insulin-cost-lost-private-health-insurance-american-doctor-a9039656.html>.

⁴⁴ Cefalu, William T. et al. on behalf of the Insulin Access and Affordability Group. “Insulin Access and Affordability Group: Conclusions and Recommendations.” *Diabetes Care*. May 8, 2018, <https://doi.org/10.2337/dci18-0019>.

⁴⁵ Ibid.

One of the highlights of the working group’s findings is the complexity and opacity of the insulin supply chain and pricing mechanisms. The price ultimately paid by the person with diabetes at the point of sale results from the prices, fees, and rebates negotiated among the stakeholders, who have varying degrees of negotiating power. The ADA working group included an overview of insulin supply chain dynamics, acknowledging that even after its numerous conversations with multiple stakeholders, it remains concerned by the complexity of the system and the lack of transparency.

Insulin Supply Chain: A Complex System



The first link in the insulin production and supply chain is, obviously, the manufacturer. There are only three insulin manufacturers serving the U.S. market: Eli Lilly, Novo Nordisk, and Sanofi. The same three large corporations dominate the global insulin market. The price manufacturers set for their product is known as the list price. Average list prices of insulin over the past two decades have been growing rapidly. Along with yearly increases, the published data suggest that “when one insulin manufacturer increases the price for a given insulin formulation, the other insulin manufacturers often increase their prices by a similar amount shortly thereafter.”⁴⁶

Manufacturers like to remind that the price they set for their medication, the list price, is not what they receive for their products, which is known as the net price. The net price manufacturers receive is the list price minus any fees paid to wholesalers, any discounts paid to pharmacies, and any rebates paid to pharmacy benefit managers (PBMs) or health plans. The net price to the insulin manufacturers has grown at a slower rate than the list price.⁴⁷ The

⁴⁶ Ibid.

⁴⁷ Cefalu, William T. et al. on behalf of the Insulin Access and Affordability Group. “Insulin Access and Affordability Group: Conclusions and Recommendations.” *Diabetes Care*. May 8, 2018, <https://doi.org/10.2337/dci18-0019>.

manufacturers offer patient assistance programs, which bring relief to the individuals who have access to them, but the impact of these programs is very limited and cannot be considered a solution to the problem.⁴⁸

Once the ADA working group discovered greater increases in list prices than net prices, it embarked on its search of other parties who benefited from the substantial increase in insulin prices over the last decade. One of such beneficiaries is a pharmacy benefit manager (PBM). The working group experts concluded that “the widening gap between the net and list price of insulin in recent years appears to be the result of increasing rebates and discounts negotiated between stakeholders.”⁴⁹ Drug manufacturers negotiate with a PBM for discounts from the list price to have their medications placed on a lower cost-sharing tier and/or to avoid constraints on utilization on the PBM’s client formulary. In this process, manufacturers agree to fees and price concessions paid to the PBM after health plan enrollees receive the manufacturer’s medication. It was established that the rate of increase in these retroactive discounts or rebates had accelerated to approach approximately half of the list price of insulin.⁵⁰ PBMs also negotiate with pharmacies to determine how much participating pharmacies will be paid for medications dispensed to enrollees in the PBMs client’s health plan. At the same time, PBMs design the formulary for their clients, which allows them to have a significant input into placing medications on the formulary and at a particular tier, thus, setting the parameters for patient access to and cost-sharing for insulin and other drugs. Nationally, PBMs administer the prescription benefit for more than 266 million Americans, with the three major PBMs (CVS Caremark, Express Scripts, and OptumRx) managing about 70 percent of all prescription claims.⁵¹ All this gives PBMs considerable leverage in any rebate/discount negotiations with other parties. In addition, in most cases, these negotiations are hidden: even PBM clients do not know the net price obtained by the PBM for insulins.

Moreover, PBMs as well as health plans have an incentive to select medications for their formularies that offer a higher rebate. At the same time, the need to offer higher rebates in order to achieve preferential formulary positioning from PBMs creates an incentive for manufacturers to raise the list price. Commonly, manufacturer rebates are not directly passed on to people with diabetes. The working group revealed incentives throughout the insulin supply chain for high list prices. It also revealed the lack of transparency throughout the chain.

See also: Langreth, Robert; Keller, Michael and Christopher Cannon. *Decoding Big Pharma’s Secret Drug Pricing Practices* [article online]. Bloomberg, June 19, 2016, <https://www.bloomberg.com/graphics/2016-drug-prices/> (accessed August 13, 2019).

⁴⁸ The American Association of Diabetes Educators’ (AADE) Insulin Affordability Task Force compiled an *Insulin Cost Saving Resource Guide* and posted it in an open AADE Forum. The guide contains information on manufacturer patient assistance program and allows patients, their families, and diabetes educators see what kind of financial resources may be available to them.

⁴⁹ Cefalu, William T. et al. on behalf of the Insulin Access and Affordability Group. “Insulin Access and Affordability Group: Conclusions and Recommendations.” *Diabetes Care*. May 8, 2018, <https://doi.org/10.2337/dci18-0019>.

⁵⁰ Ibid.

⁵¹ Ibid.

The ADA working group came to a disconcerting conclusion that “decisions made from negotiations between stakeholders that affect formulary may not be in the best financial or medical interest of the patient” and expressed serious “concern about the increased burden on people with diabetes and reduced adherence to effective management strategies.”⁵²

After their research and their conversations with an extensive group of stakeholders, the working group experts remained concerned about the complexity and opacity of the insulin delivery system. It was the consensus of the working group that “incentives throughout the insulin supply chain facilitate and may even promote high list prices.”⁵³

The main conclusions of the ADA Insulin Access and Affordability Working Group are as follows:

- List prices of insulin have risen precipitously in recent years. Between 2002 and 2013, the average price of insulin nearly tripled.
- The current pricing and rebate system encourages high list prices.
- There is a lack of transparency throughout the insulin supply chain. It is unclear precisely how the dollars flow and how much each intermediary profits.
- PBMs have substantial market power.
- People with diabetes are financially harmed by high list prices and high out-of-pocket costs.
- Patients’ medical care can be adversely affected by formulary decisions.
- The regulatory framework for development and approval of biosimilar insulins is burdensome to manufacturers.
- Prescribing patterns have favored newer, more expensive insulins.⁵⁴

Based on its findings, the working group developed a number of important recommendations:

- Providers, pharmacies, and health plans should discuss the cost of insulin preparations with people with diabetes to help understand the advantages, disadvantages, and financial implications of potential insulin preparations.
- Providers should prescribe the lowest-price insulin required to effectively and safely achieve treatment goals.
- Cost-sharing for insured people with diabetes should be based on the lowest price available.
- Uninsured people with diabetes should have access to high-quality, low-cost insulins.
- Researchers should study the comparative effectiveness and cost-effectiveness of the various insulins.
- List price for insulins should more closely reflect net price, and rebates based on list price should be minimized. The current payment system should rely less on rebates, discounts, and fees based on the price.

⁵² Ibid.

⁵³ Ibid.

⁵⁴ Ibid.

- Health plans should ensure that people with diabetes can access their insulin without undue administrative burden or excessive cost. In particular, payers, insurers, manufacturers, and PBMs should design pharmacy formularies that include a full range of insulin preparations, including human insulin and insulin analogs, in the lowest cost-sharing tier.
- PBMs and payers should use rebates to lower costs for insulin at the point of sale for people with diabetes.
- There needs to be more transparency throughout the insulin supply chain.
- Payers, insurers, manufacturers, PBMs, and people with diabetes should encourage innovation in the development of more effective insulin preparations.
- The FDA should continue to streamline the process to bring biosimilar insulins to market.
- Organizations such as the ADA should advocate for access to affordable and evidence-based insulin preparations for all people with diabetes; ensure that health care providers receive ongoing medical education on how to prescribe all insulin preparations, including human insulins, based on scientific and medical evidence; and make information about the advantages, disadvantages, and financial implications of all insulin preparations easily available to people with diabetes.⁵⁵

In May 2018, the U.S. Senate Special Committee on Aging held a public hearing “Insulin Access and Affordability: The Rising Cost of Treatment.” In July 2019, a bipartisan bill was filed to incentivize a significant reduction in the list price of leading brands of insulin. Known as the Insulin Price Reduction Act, the bill seeks to provide patient protections with respect to the cost of insulin.⁵⁶

Recent changes in the U.S. Treasury Department and IRS rules should benefit a comparatively narrow but highly vulnerable group of patients – those participating in high-deductible health plans.⁵⁷ The Treasury Department and IRS added “treatments for a range of chronic conditions to the list of preventive-care benefits for which a high-deductible plan (HDHP) can pay – even if a plan enrollee’s health care spending hasn’t surpassed the plan deductible – without running afoul of the rules allowing pretax contributions to health savings accounts (HSAs).”⁵⁸ Insulin and other glucose-lowering agents as well as retinopathy screening, glucometer and Hemoglobin A1c testing are now listed as preventive care for individuals diagnosed with diabetes.⁵⁹ Though plans will not be required to pay 100 percent for the treatments on this list, expanding coverage of preventive products and services for managing chronic conditions is, however, a welcome development, expected to improve adherence to medication and

⁵⁵ Ibid.

⁵⁶ Insulin Price Reduction Act, S. 2199, 116th Cong. (as referred to S. Comm. on Finance, July 22, 2019).

⁵⁷ *Notice 2019-45. Additional Preventive Care Benefits Permitted to Be Provided by a High Deductible Health Plan Under § 223*, <https://www.irs.gov/pub/irs-drop/n-19-45.pdf>.

⁵⁸ Miller, Stephen. *IRS Allows Health Plans to Cover More Treatments Before Deductible Is Met*, <https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/irs-allows-hdhp-to-cover-more-treatments-before-deductible-is-met.aspx>.

⁵⁹ *Notice 2019-45. Additional Preventive Care Benefits Permitted to Be Provided by a High Deductible Health Plan Under § 223*, <https://www.irs.gov/pub/irs-drop/n-19-45.pdf>.

recommended screening, reduce costs for consumers, and, ultimately, improve health outcomes for this group of patients.

At the state level, in his recent special report “Bringing Transparency and Accountability to Drug Pricing: Are Rebates Inflating the Price of Your Prescription?” Pennsylvania Auditor General Eugene DePasquale offered specific recommendations to the Pennsylvania General Assembly as well as to Congress regarding the role of rebates.⁶⁰ Along with recommendations from his earlier report “Bringing Transparency and Accountability to Drug Pricing: A Special Report on the Role of Pharmacy Benefit Managers,” issued in December 2018,⁶¹ these recommendations outline specific steps the General Assembly can take to regulate PBMs’ practices and significantly increase transparency in their actions and in pharmacists’ communication with patients.

⁶⁰ Pennsylvania Auditor General Eugene A. DePasquale. *Bringing Transparency and Accountability to Drug Pricing: Are Rebates Inflating the Price of Your Prescription?*
https://www.paauditor.gov/Media/Default/Reports/RPT_PBM_rebates_022819_final.pdf.

⁶¹ Pennsylvania Auditor General Eugene A. DePasquale. *Bringing Transparency and Accountability to Drug Pricing: A Special Report on the Role of Pharmacy Benefit Managers*,
https://www.paauditor.gov/Media/Default/Reports/RPT_PBM_FINAL.pdf.

DIAGNOSIS AND CLASSIFICATION OF DIABETES MELLITUS

Definition and Description

Diabetes mellitus is defined as “a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both.”⁶²

Diabetes develops as a result of several pathogenic processes, ranging from autoimmune destruction of the beta-cells of the pancreas with consequent insulin deficiency to abnormalities that result in resistance to insulin action. “Deficient insulin action results from inadequate insulin secretion and/or diminished tissue responses to insulin at one or more points in the complex pathways of hormone action. Impairment of insulin secretion and defects in insulin action frequently coexist in the same patient, and it is often unclear which abnormality, if either alone, is the primary cause of the hyperglycemia.”⁶³

Acute, life-threatening consequences of uncontrolled diabetes are hyperglycemia with ketoacidosis or the nonketonic hyperosmolar syndrome.⁶⁴ Hypoglycemia (abnormally low level of blood sugar), which is often associated with diabetes and its treatment, can also lead to severe consequences and can sometimes be life-threatening as it is a potential cause of acute cardiovascular events.

The chronic hyperglycemia of diabetes (abnormally high level of blood sugar) is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels. Long-term complications of diabetes include retinopathy with potential loss of vision; nephropathy leading to renal failure; peripheral neuropathy with risk of foot ulcers and amputations; and autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms and sexual dysfunction. Patients with diabetes have an increased incidence of atherosclerotic cardiovascular, peripheral arterial, and cerebrovascular disease.⁶⁵

Classification

Diabetes is currently classified into the following general categories:

1. Type 1 diabetes (due to autoimmune β -cell destruction, usually leading to absolute insulin deficiency)

⁶² American Diabetes Association. *Diagnosis and Classification of Diabetes Mellitus*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2797383>.

⁶³ Ibid.

⁶⁴ Ibid.

⁶⁵ Ibid.

2. Type 2 diabetes (due to a progressive loss of β -cell insulin secretion frequently on the background of insulin resistance)
3. Gestational diabetes mellitus (GDM) (diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation)
4. Specific types of diabetes due to other causes, for example, monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young [MODY]), diseases of the exocrine pancreas (such as cystic fibrosis) and drug- or chemical-induced diabetes (such as with glucocorticoid use, in the treatment of HIV/AIDS, or after organ transplantation)⁶⁶

Most common forms of diabetes are type 1 diabetes and type 2 diabetes. Ongoing research has recognized that clinical presentation and progression of these heterogeneous diseases vary significantly; it has also led to reconsideration of certain traditional paradigms and suggested a new framework for future studies and regulatory decision making. One of the recent developments is the acknowledgement that “the traditional paradigms of type 2 diabetes only in adults and type 1 diabetes only in children are no longer accurate, as both diseases occur in both cohorts.”⁶⁷

Type 1 diabetes, previously called “insulin-dependent diabetes” or “juvenile-onset diabetes,” accounts for 5-10 percent of diabetes and is due to cellular mediated-autoimmune destruction of the pancreatic β -cells; it is identified by the presence of one or more specific autoimmune markers.⁶⁸ This form of diabetes commonly occurs in childhood and adolescence, but, as has been recently acknowledged, it may occur at any age. The SEARCH for Diabetes in Youth (SEARCH) study, initiated in 2000, revealed a significant increase of over 20 percent in prevalence of type 1 diabetes in youth in most racial/ethnic and age groups in the first decade of the twenty-first century.⁶⁹ It can be expected that antibody testing in relatives of those with type 1 diabetes, combined with education about diabetes symptoms and close follow-up, may enable earlier identification of type 1 diabetes onset.⁷⁰ That would be beneficial as patients with this form of diabetes are often diagnosed only when they already have acute symptoms of the disease, significantly elevated blood glucose level, and in many cases, life-threatening ketoacidosis. Antibody testing for risk assessment in the setting of a clinical research study can be considered for individuals who have relatives with type 1 diabetes. Presently, various methods of preventing type 1 diabetes in people with evidence of autoimmunity are being tested in numerous clinical studies.⁷¹

Type 2 diabetes, previously referred to as “noninsulin-dependent diabetes” or “adult-onset diabetes,” accounts for 90-95 percent of all diabetes; this form “encompasses individuals who have relative (rather than absolute) insulin deficiency and have peripheral insulin resistance.”⁷² There

⁶⁶ American Diabetes Association. “Classification and Diagnosis of Diabetes.” *Diabetes Care*, Vol. 40 (Supplement 1), January 2017, <https://doi.org/10.2337/dc17-S005>.

⁶⁷ Ibid.

⁶⁸ Ibid.

⁶⁹ Hamman, Richard F. et al. “The SEARCH for Diabetes in Youth Study: Rationale, Findings, and Future Directions.” *Diabetes Care*, Vol. 37, December 2014, <https://doi.org/10.2337/dc-0574> (accessed January 11, 2018).

⁷⁰ American Diabetes Association. “Classification and Diagnosis of Diabetes.” *Diabetes Care*, Vol. 40 (Supplement 1), January 2017, <https://doi.org/10.2337/dc17-S005> (accessed December 18, 2017).

⁷¹ Ibid.

⁷² Ibid.

are various causes of type 2 diabetes. It is often associated with a strong genetic predisposition, and the risk of developing this form of diabetes increases with age, obesity, and lack of physical activity. There are also other known risk factors. Type 2 diabetes often remains undiagnosed for many years because hyperglycemia develops gradually and, at earlier stages, is not severe enough for the patient to recognize the classic diabetes symptoms. As “even undiagnosed patients are at increased risk of developing macrovascular and microvascular complications” and as the “duration of glycemic burden is a strong predictor of adverse outcomes,” the American Diabetes Association strongly recommends early detection and early intervention, underscoring the availability of simple tests to detect preclinical disease and the existence of effective interventions that prevent progression from prediabetes to diabetes and reduce the risk of diabetes complications.⁷³ To fortify its recommendations for the early detection and treatment of type 2 diabetes, the ADA cites computer simulation model studies suggesting that “major benefits are likely to accrue from the early diagnosis and treatment of hyperglycemia and cardiovascular risk factors in type 2 diabetes,” and, “moreover, screening, beginning at age 30 or 45 years and independent of risk factors, may be cost-effective (<\$11,000 per quality-adjusted life-year gained).”⁷⁴

One of the current trends in understanding diabetes and approaches to treatment is the acknowledgement of significant overlap across the spectrum of diabetes. Today’s consensus in the diabetes research community is that the progressive loss of β -cell mass and/or function that clinically manifests as hyperglycemia can be driven by a variety of genetic and environmental factors; however, once hyperglycemia occurs, people with all forms of diabetes are at risk for developing the same complications, though rates of progression may differ. The importance of early diagnosis/intervention and good management in early stages of the disease has been demonstrated by multiple international studies.

Healthy People 2020, that summarizes goals and objectives developed by the Office of Disease Prevention and Health Promotion (ODPHP) and includes reducing the disease burden of diabetes and improving the quality of life for all persons who have, or are at risk for, diabetes as one of the nation’s health improvement priorities, identifies four “transition points” in the natural history of diabetes health care that provide opportunities to reduce the health and economic burden of diabetes mellitus:

- Primary prevention: Movement from no diabetes to diabetes
- Testing and early diagnosis: Movement from unrecognized to recognized diabetes
- Access to care for all persons with diabetes: Movement from no diabetes care to access to appropriate diabetes care
- Improved quality of care: Movement from inadequate to adequate care.⁷⁵

⁷³ Ibid.

⁷⁴ Ibid.

⁷⁵ *Healthy People 2020. Diabetes*, <https://www.healthypeople.gov/2020/topics-objectives/topic/diabetes> (accessed January 29, 2018).

NEW DEVELOPMENTS IN DIABETES RESEARCH AND THERAPEUTIC APPROACHES

The ADA/EASD Consensus Report

In 2018, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) released a consensus report reflecting the results of the work of the panel they had convened to update the earlier position statements, published in 2012 and 2015, on the management of type 2 diabetes in adults. The panel conducted a systematic evaluation of studies published between January 2014 and February 2018, including randomized clinical trials, systematic reviews, and meta-analyses, and developed new recommendations based on the review of the new evidence. New recommendations embrace additional focus on lifestyle management and diabetes self-management education and support.

The goals of treatment for type 2 diabetes are to prevent and delay complications and maintain quality of life. Treatment requires control of glycemia, cardiovascular risk factor management, regular follow-up, and, as the panel underlined, a patient-centered approach to enhance patient engagement in self-care activities. The authors continuously remind physicians that “careful consideration of patient factors and preferences must inform the process of individualizing treatment goals and strategies.”⁷⁶

The consensus report canvasses the rationale, importance, and context of glucose-lowering treatment, various approaches to glucose management and glucose monitoring, and optimal principals of care. It identifies “lifestyle management, including medical nutrition therapy (MNT), physical activity, weight loss, counseling for smoking cessation, and psychological support, often delivered in the context of diabetes self-management education and support (DSMES)” as fundamental aspects of diabetes care.⁷⁷ As “the expanding number of glucose-lowering treatments – from behavioral interventions to medications and surgery – and growing information about their benefits and risks provides more options for people with diabetes and providers, but can complicate decision making,” ADA and EASD in their consensus statement strive to lay out an approach that summarizes a large body of recent evidence for practitioners in the United States and Europe.

⁷⁶ Davis, Melanie J. et al. “Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD).” *Diabetes Care*. Vol. 41, 2018, <https://doi.org/10.2337/dci18-0033>.

⁷⁷ Ibid.

Based on the newly accumulated evidence, the authors offer several consensus recommendations:

- Providers and health care systems should prioritize the delivery of patient-centered care. Providing patient-centered care that is respectful of and responsive to individual patient preferences and barriers, including the differential costs of therapies, is essential to effective diabetes management. Providers should evaluate the impact of any suggested intervention, including self-care regimens, in the context of cognitive impairment, limited literacy, distinct cultural beliefs, and individual fears or health concerns given their impact on treatment efficacy.
- All people with type 2 diabetes should be offered access to ongoing DSMES programs. DSMES is a key intervention to enable people with diabetes to make informed decisions and to assume responsibility for day-to-day diabetes management. In type 2 diabetes, high-quality evidence has consistently shown that DSMES is a cost-effective intervention in the health care systems studied. DSMES significantly improves clinical and psychological outcomes, improves glycemic control, reduces hospital admissions, improves patient knowledge, and reduces the risk of all-cause mortality.
- Facilitating medication adherence should be specifically considered when selecting glucose-lowering medications. Suboptimal adherence, including poor persistence, to therapy affects almost half of people with diabetes, leading to suboptimal glycemic and cardiovascular disease risk factor control as well as increased risk of diabetes complications, mortality, hospital admissions, and health care costs. Multiple factors contribute to inconsistent medication use and treatment discontinuation, including patient-perceived lack of medication efficacy, fear of hypoglycemia, lack of access to medication, and adverse effects of medication. Ultimately, patient preference is a major factor driving the choice of medication.⁷⁸

In addition to the above-listed general care management recommendations, the ADA/EASD consensus report contains a detailed description of the entire decision cycle for patient-centered glycemic management in type 2 diabetes as well as the overall approach to selecting glucose-lowering medications in type 2 diabetes and preferred medications in various specific circumstances, illustrated with vivid, easy-to-use charts and tables. A wide range of medications available for lowering glucose and strategies for implementation are discussed in detail.

The ADA and EASD express their concern about “huge disparities in the cost of new and old glucose-lowering medications in some countries, limiting access to the full range of diabetes therapies in large segments of the population.” They make a grave statement: “Since glycemic management remains a cornerstone of the prevention of diabetes complications, these disparities raise questions of fairness, equality, and overall public health.”⁷⁹

⁷⁸ Ibid.

⁷⁹ Ibid.

The authors consider the full range of therapeutic options, including lifestyle management, medication, and obesity management. As lifestyle interventions, including medical nutrition therapy and physical activity, are effective and safe for improving glucose control in type 2 diabetes, they are recommended as first-line therapies from the time of diagnosis and as cotherapy for patients who also require glucose-lowering medications or metabolic surgery. In fact, one of the consensus recommendations is to offer an individualized program of medical nutrition therapy to all patients. Eschewing one single ration of carbohydrate, proteins, and fat intake that would be optimal for every person with type 2 diabetes, the ADA/EASD guideline, instead, involves “individually selected eating patterns that emphasize foods of demonstrated health benefit, that minimize foods of demonstrated harm, and that accommodate patient preference and metabolic needs, with the goal of identifying healthy dietary habits that are feasible and sustainable.”⁸⁰ The effect of the Mediterranean eating pattern appears to be the greatest. The report confirms that “increasing physical activity improves glycemic control and should be encouraged in people with type 2 diabetes.”⁸¹ The combination of dietary change for weight reduction and physical exercise has been shown to improve hyperglycemia and reduce cardiovascular risk factors more than dietary interventions or physical activity alone.

The ADA/EASD writing group concludes its report with admitting that “despite over 200 years of research on lifestyle management of diabetes and more than 50 years of comparative-effectiveness research in diabetes, innumerable unanswered questions regarding the management of type 2 diabetes remain.”⁸² The authors outline existing gaps and evolving areas of current investigation. In particular, they highlight “a huge gap between the knowledge gained from clinical trials and application of that information in clinical practice” and encourage pragmatic studies that would fill this gap.⁸³

The authors observe that “the management of hyperglycemia in type 2 diabetes has become extraordinarily complex with the number of glucose-lowering medications now available.” They remind the providers that “patient-centered decision making and support and consistent efforts to improve diet and exercise remain the foundation of all glycemic management” and that addition of glucose-lowering medications should be based on patient comorbidities and concerns.⁸⁴

The ADA Standards of Medical Care in Diabetes – 2019

The American Diabetes Association updates its *Standards of Care* on an annual basis to incorporate new developments in diabetes research and care in order “to ensure that clinicians, health plans, and policy makers can continue to rely on them as the most authoritative and current guidelines for diabetes care.”⁸⁵ The recommendations include screening, diagnostic, and

⁸⁰ Ibid.

⁸¹ Ibid.

⁸² Ibid.

⁸³ Ibid.

⁸⁴ Ibid.

⁸⁵ American Diabetes Association. “Standards of Medical Care in Diabetes – 2019.” *Diabetes Care*. Vol. 42 (Suppl. 1). January 2019, http://care.diabetesjournals.org/content/diacare/suppl/2018/12/17/42.Supplement_1.DC1/DC_42_S1_2019_UPDAT ED.pdf (accessed June 12, 2019).

therapeutic actions that are known or believed to favorably affect health outcomes of patients with diabetes; many of these interventions have also been shown to be cost-effective. To facilitate access, the ADA made its *Standards of Care* available through its new interactive app, along with tools and calculators that can help guide patient care. The ADA also issued an abridged version of the 2019 *Standards* intended for primary care providers and containing the evidence-based recommendations most pertinent to primary care.⁸⁶ The ADA developed a classification system to grade the quality of scientific evidence supporting its recommendations and assigns appropriate ratings to each of its recommendations depending on the quality of evidence. The ADA reminds physicians that evidence should be only one component of their decision-making and all guidelines must be interpreted with the individual patient in mind. “Clinicians care for patients, not populations,” ADA states, and it encourages doctors to always consider individual circumstances, such as their patients’ coexisting diseases, age, education, disability, and, above all, their values and preferences.⁸⁷

Standards of Medical Care in Diabetes are regularly reviewed and updated by the Professional Practice Committee (PPC) of the American Diabetes Association. The PPC is a multidisciplinary committee comprised of physicians, diabetes educators, and others who have expertise in a range of areas, including adult and pediatric endocrinology, public health, epidemiology, hypertension, lipid research, and pregnancy care.

The field of diabetes care keeps changing with the emergence of new research, technology and treatments that have the potential of improving the health and well-being of people with diabetes, and the ADA’s annual updates reflect these new developments. Each annual edition of *Standards of Medical Care in Diabetes* includes a section summarizing the current revisions. The main revisions in the 2019 update include the following:

- A dedicated section on diabetes technology, which contains preexisting material that was previously in other sections and has been consolidated, as well as new recommendations.
- Additional information on the financial costs of diabetes to individuals and society.
- Discussion on the use of telemedicine to facilitate remote delivery of health-related services and clinical information to patients with diabetes.
- Changes in the criteria for the diagnosis of diabetes.
- Nutrition section update to highlight the importance of weight loss for those at high risk for developing type 2 diabetes who have overweight or obesity.
- A new table listing factors that increase risk of treatment-associated hypoglycemia.
- Additional discussion about the importance of macronutrient distribution based on an individualized assessment of current eating patterns, preferences, and metabolic goals.
- Advice to decrease consumption of both sugar-sweetened and nonnutritive-sweetened beverages and use other alternatives, with an emphasis on water intake.

⁸⁶ American Diabetes Association. *Standards of Medical Care in Diabetes – 2019 Abridged for Primary Care Providers*, <https://doi.org/10.2337/cd18-0105>.

⁸⁷ American Diabetes Association. “Standards of Medical Care in Diabetes – 2019.” *Diabetes Care*. Vol. 42 (Suppl. 1). January 2019, http://care.diabetesjournals.org/content/diacare/suppl/2018/12/17/42.Supplement_1.DC1/DC_42_S1_2019_UPDAT_ED.pdf (accessed June 12, 2019).

- Highlighting the centrality of A1C testing in glycemic management.
- Emphasizing that the risks and benefits of glycemic targets can change as diabetes progresses and patients age and that glycemic targets should be reevaluated over time.
- Significant changes to the section on the pharmacological treatment of type 2 diabetes, including consideration of key patient factors such as important comorbidities, hypoglycemia risk, effects in body weight, and patient preferences.
- A new section and recommendation on lifestyle management to address the unique nutritional and physical activity needs and considerations for older adults.
- A new table to help guide providers considering medication regimen simplification and deintensification/deprescribing in older adults with diabetes.
- An expanded section on type 2 diabetes in children and adolescents, with recommendations in a number of areas, including screening and diagnosis, life management, pharmacological management, transition of care to adult providers, glycemic targets, metabolic surgery, psychosocial factors, and others.
- New recommendations for management of diabetes in pregnancy.
- New recommendations for diabetes care in the hospital.
- ADA statement based on the conclusions and recommendations of the Insulin and Affordability Working Group.

The ADA’s broad recommendations with regard to diabetes and population health are the following:

- Ensure treatment decisions that are timely, rely on evidence-based guidelines, and are made collaboratively with patients based on individual preferences, prognoses, and comorbidities.
- Align approaches to diabetes management with the Chronic Care Model, emphasizing productive interactions between a prepared proactive care team and an informed activated patient.
- Care systems should facilitate team-based care, patient registries, decision support tools, and community involvement to meet patient needs.
- Efforts to assess the quality of diabetes care and create quality improvement strategies should incorporate reliable data metrics, to promote improved processes of care and health outcomes, with simultaneous emphasis on costs.⁸⁸

With the realization that clinical practice recommendations for health care providers are “tools that can ultimately improve health care across populations” but “for optimal outcomes, diabetes care must also be individualized for each patient,” the ADA puts heavy emphasis on “*patient-centered care*, defined as care that is respectful of and supportive to individual patient preferences, needs, and values and that ensures that patient values guide all clinical decisions.”⁸⁹

⁸⁸ Ibid.

⁸⁹ Ibid.

Noting certain positive developments, such as the increased proportion of patients with diabetes who achieve recommended A1C, blood pressure, and LDL cholesterol levels, and improvements in cardiovascular outcomes and substantial reductions in end-stage microvascular complications, the ADA, however, attests the need for substantial system-level improvements. As many experts and practitioners believe that “the major barrier to optimal care is a delivery system that is often fragmented, lacks clinical information capabilities, duplicates services, and is poorly designed for the coordinated delivery of chronic care,” the ADA endorses the Chronic Care Model (CCM) as an effective framework for improving the quality of diabetes care. Intended to optimize the care of patients with chronic disease, the Chronic Care Model includes six core elements:

1. Delivery system design (moving from a *reactive* to a *proactive* care delivery system where planned visits are coordinated through a team-based approach)
2. Self-management support
3. Decision support (basing care on evidence-based, effective care guidelines)
4. Clinical information systems (using registries that can provide patient-specific and patient-based support to the care team)
5. Community resources and policies (identifying or developing resources to support healthy lifestyles)
6. Health systems (to create a quality-oriented culture).⁹⁰

The ADA latest edition of *Standards of Care* confirms that high-quality diabetes self-management education and support (DSMES) has been shown “to improve patient self-management, satisfaction, and glucose outcomes.”⁹¹

As in almost a quarter of cases, uncontrolled A1C, blood pressure, or lipids were associated with poor medication-taking behaviors (“medication adherence”), the ADA paid special attention to a variety of barriers to medication taking and ways to overcome these barriers. Barriers to medication adherence may include patient factors (financial limitations, remembering to obtain or take medications, fear, depression, or health beliefs), medication factors (complexity, multiple daily dosing, cost, or side effects), and system factors (inadequate follow-up or support). The ADA’s Professional Practice Committee believes that success in overcoming these barriers may be achieved if the patient and provider agree on a targeted approach for a specific barrier. The ADA encourages providers to assess social context, including potential food insecurity, housing stability, and financial barriers, and apply that information to treatment decisions; to refer patients to local community resources when available; and to arrange self-management support for their patients from lay health coaches, navigators, or community health workers when available.

Social determinants of health, defined as the economic, environmental, political, and social conditions in which people live, have been gaining growing attention in the discussion of diabetes care. They are highlighted in the ADA guidelines, and health care providers are encouraged to raise these issues with their patients. The National Health Interview Survey (NHIS) revealed that “half of the adults with diabetes perceived financial stress, and one-fifth reported financial

⁹⁰ Ibid.

⁹¹ Ibid.

insecurity with health care and food insecurity.”⁹² Twice as many adults with diabetes than without diabetes reported cost-related non-adherence (14 percent versus 7 percent).⁹³ It is well known that cost-related non-adherence (CRN) can have significant negative health consequences for individuals with diabetes. According to a study examining health and non-health-related pressures and the use of cost-reducing strategies among the U.S. population with and without diabetes based on the NHIS data, cost-related non-adherence is associated with worse glycemic control and declines in functioning.⁹⁴ Similar findings were presented in several other studies in various states. One of those studies, based on a randomized trial evaluating a diabetes intervention in primary care clinics, demonstrated that food insecurity was “significantly associated” with self-care behaviors including less adherence to a general diet, less physical activity, and with a greater occurrence of medical non-adherence; food insecurity was also associated with worse glycemic control.⁹⁵

In addition to paying for medications and sugar-checking supplies, people with diabetes need to be careful in their food choices, which often incurs more expense. As researchers point out, “dietary regimens are common therapeutic strategies integral to prevention and effective management of chronic disease, yet also vulnerable to CRN.”⁹⁶ The National Health Interview Survey data have shown that “1 in 3 chronically ill adults report that they are unable to afford food, medication, or both, and CRN is more common among those with food insecurity.”⁹⁷ Rates of food insecurity are even higher among certain population groups such as older adults and ethnic minorities. Some studies indicate that over a half of lower-income older adults (54 percent) report food insecurity; according to one study, “57% of food insecure participants were nonadherent to oral hypoglycemics.”⁹⁸ Based on these results, the authors conclude that “underlying basic needs must be addressed to improve diabetes management in this population.”⁹⁹

The NHIS-based study, which was the first study to examine the influence of both health-related and non-health related perceived stressors and potential cost-reducing strategies on CRN in a nationally representative sample of adults with diabetes, demonstrated that perceived financial stress and perceived financial insecurity with health care and food “were associated with a significant increase in CRN behaviors regardless of age, income, and insurance status.”¹⁰⁰ Based

⁹² Patel, M.R. et al. “Social Determinants of Health, Cost-related Nonadherence, and Cost-reducing Behaviors Among Adults with Diabetes: Findings From the National Health Interview Survey.” *Medical Care*. Vol. 54. No. 8. August 2016, doi:10.1097/MLR.0000000000000565.

⁹³ Ibid.

⁹⁴ Ibid.

⁹⁵ Heerman, W.J. et al. “Food Insecurity is Associated with Diabetes Self-Care Behaviors and Glycaemic Control.” *Diabetic Medicine*. Vol. 33. No. 6. June 2016, doi: 10.1111/dme.12896.

⁹⁶ Patel, M.R. et al. “Social Determinants of Health, Cost-related Nonadherence, and Cost-reducing Behaviors Among Adults with Diabetes: Findings From the National Health Interview Survey.” *Medical Care*. Vol. 54. No. 8. August 2016, doi:10.1097/MLR.0000000000000565.

⁹⁷ Ibid.

⁹⁸ Sattler, E.L., Lee, J.S., and V. Bhargava. “Food Insecurity and Medication Adherence in Low-Income Older Medicare Beneficiaries with Type 2 Diabetes.” *Journal of Nutrition in Gerontology and Geriatrics*. Vol. 33. No. 4. 2014, doi: 1080/21551197.2014.959680.

⁹⁹ Ibid.

¹⁰⁰ Patel, M.R. et al. “Social Determinants of Health, Cost-related Nonadherence, and Cost-reducing Behaviors Among Adults with Diabetes: Findings From the National Health Interview Survey.” *Medical Care*. Vol. 54. No. 8. August 2016, doi:10.1097/MLR.0000000000000565.

on their findings, the authors highlight important implications for behavioral interventions, clinical practice, and policy. They recommend enhancing screening practices and improving communication with the health care provider to identify cost-related nonadherence: “Increased communication and transparency of factors affecting adherence may ... safeguard patients from the health consequences of cutting back on treatment and care, and move the needle towards improved diabetes outcomes.”¹⁰¹

The Hospital and Healthsystem Association of Pennsylvania (HAP) has recently undertaken new steps to investigate and address the impact of social factors on Pennsylvanians’ health in various regions of the Commonwealth. In his presentation at the Diabetes Network Association (DAN) meeting, Mr. Robert Shipp, HAP Vice-President responsible for Quality and Population Health, listed several HAP-supported initiatives in 2019:

- Identification of measures and strategies to address social determinants of health
 - Housing
 - Food insecurity
- Population Health Dashboards
- Collaborative Opportunities to Advance Community Health (COACH)
- HealthyMePa.¹⁰²

One of the HAP-supported initiatives, the Healthy Food Access Pilot in Southeast Pennsylvania, may be particularly important for diabetes management and prevention: this program screens patients for food insecurity using a research-validated two-question screening tool and connects patients who are food-insecure to healthy food resources and programs. The Healthy Food Access Pilot is an example of how hospitals, through collaboration with community partners, can impact care in non-traditional ways.

Some Pennsylvania hospitals take their own steps to help their patients address their health-related social needs. For example, the Children’s Hospital of Philadelphia (CHOP) is partnering with a software company to generate a resource map of potentially helpful community services in the Philadelphia area so its “patient families and providers have at their fingertips a curated list of food pantries, counseling and housing services, and other resources.”¹⁰³

Nationwide, health management systems have shown growing awareness of the impact of social determinants of health on patients’ outcomes and payers’ expenses. A recent publication by HMS states that “individuals who report they are food insecure have a higher incidence of diabetes and hypertension.”¹⁰⁴ The HMS white paper references results of a study by *Population Health*

¹⁰¹ Ibid.

See also Davidson, Karina W. and Thomas McGinn. “Screening for Social Determinants of Health: The Known and Unknown.” *JAMA*. Published online August 29, 2019, doi:10.1001/jama.2019.10915.

¹⁰² Shipp, Robert G., III. *Social Determinants of Health*: Presentation at the Diabetes Network Association meeting on July 10, 2019.

¹⁰³ Rubin, David. “How Much Should Physicians Be Responsible for Addressing Social Risks to Their Patients?” *The Philadelphia Inquirer*. July 1, 2019, <https://www.inquirer.com/health/doctors-social-determinants-of-health-responsibility-food-housing-employment-20190701.html>.

¹⁰⁴ Health Management Systems (HMS). *Social Determinants of Health: The Impact on Members, Health Outcomes and the Bottom Line*, <https://s3-prod.modernhealthcare.com/201903/>

Management, indicating that “for health plan members who successfully connected with social services, their healthcare costs reduced by 10 percent or \$2,443 annually per member.”¹⁰⁵ HMS encourages managed care organizations (MCOs) to identify members who have concerns about life necessities and to support them by connecting them with helpful resources.

Reflecting the growing awareness of the importance of social determinants of health, the *ADA Standards of Care – 2019* include detailed discussion of specific negative impacts food insecurity and homelessness may have on diabetes self-management and call upon providers to consider these factors when making treatment decisions for patients with diabetes who experience food insecurity or are homeless and to seek local resources that might help their patients to address these additional challenges, thus, improving diabetes care.

Recent Successes and Current Challenges

Diabetes treatment and management is a constantly developing field. New research leads to a better understanding of the disease. New classes of medications and innovative technology allow for safer and more effective treatment. The improved long-term outlook for adults diagnosed with diabetes is justifiably considered “one of the most important clinical and public health successes in recent decades.”¹⁰⁶ Researchers remind that during the early 1990s, individuals with diabetes had reductions in lifespan of 7 to 10 years and a significantly increased risk of lower-extremity amputation (LEA) versus those without diabetes (58 versus 3 cases per 10 000 persons/year respectively) and kidney failure (28 versus 2 cases per 10 000 persons/year). Risk of cardiovascular events also was higher among patients with diabetes versus those without diabetes (141 versus 38 hospitalizations for acute myocardial infarction [AMI] per 10 000 persons/year). Through “multifaceted improvements in diabetes care, risk factor management, self-management education and support, and better integration of care, these risk differences were reduced by 28% to 68% across a range of complications between 1990 and 2010, with gains most notable for reductions in AMI, stroke, and death due to hyperglycemia.”¹⁰⁷ Health care professionals felt that “although the excess morbidity risk remained too high and the reduction in cardiovascular disease mortality led to new types of complications and causes of death,” the prospects for reducing the overall public health burden caused by diabetes seemed promising.¹⁰⁸

However, close attention to some recent developments revealed unexpected alarming trends. Public health experts point out that “in an unanticipated new challenge to these improvements, a resurgence of diabetes complications has appeared in national statistics and in the epidemiology literature.”¹⁰⁹ They refer to such facts as an increase in diabetes-related lower-extremity amputations that occurred in the United States between 2010 and 2015, reversing more than one-third of the 20-year decline in only 5 years; an almost double number of annual emergency department visits for hyperglycemic crisis between 2009 and 2015 (from 16.2 to 29.4

HMS%20Social%20Determinants%20of%20Health%20White%20Paper.pdf.

¹⁰⁵ Ibid.

¹⁰⁶ Gregg, Edward W.; Hora, Israel; and Stephen R. Benoit. “Resurgence in Diabetes-Related Complications.” *JAMA*. Published online April 15, 2019, doi:10.1001.2019.3471.

¹⁰⁷ Ibid.

¹⁰⁸ Ibid.

¹⁰⁹ Ibid.

per 1000); an increase of hospitalizations by 73 percent (from 15.3 to 26.6 per 1000); and an increase in deaths by 55 percent (from 15.7 to 24.2 per 1000).¹¹⁰ Researchers also note that for end-stage kidney disease, acute myocardial infarction, and stroke, the long-term improvements stalled after 2010, and they are concerned that “the recent increase in complication rates is occurring in young and middle-aged adults, among whom the risk of hyperglycemic crisis, AMI, stroke, and LEAs each increased by more than 25% during only 5 years.”¹¹¹ At the same time, among older adults, the long-term reductions in rates have reached a plateau. Analysts acknowledge that changes in cardiovascular outcomes may not be limited to patients with diabetes as these changes are similar to the trends observed in the general population. Explaining these trends is difficult due to a range of potential factors in preventive care, patient characteristics, and tracking procedures. The authors of a thought-provoking article on the resurgence in diabetes-related complications indicate four key plausible sources of these changes, believing that these sources “warrant examination because understanding the modifiable etiology of this resurgence could be helpful in developing an effective response:”

1. There may be increasing heterogeneity or a changing profile for the population of new diabetes cases.
2. There may be stagnation in preventive care, again most prominent among young adults.
3. Some broader policy-level factors may be driving the access to preventive care and influencing the risk for complications.
4. Broader social and economic factors may be affecting vulnerable populations that drive trends in outcomes.¹¹²

Concerning trends that have emerged, along with positive developments, require improved monitoring, further expert analysis, and continued attention on the part of policymakers because multiple broader socioeconomic factors can contribute to various adverse complications of diabetes and, as the authors point out, “the future direction of diabetes complications has enormous collective implications for health and costs.”¹¹³

¹¹⁰ Ibid.

¹¹¹ Ibid.

¹¹² Ibid.

¹¹³ Ibid.

DEPARTMENT OF HEALTH

The Pennsylvania Department of Health (PADOH) is the leading agency in supervising programs aimed at prevention and management of diabetes. Most of the Commonwealth's diabetes programs are centralized within PADOH to ensure that statewide efforts are coordinated. PADOH works through Pennsylvania's healthcare system and coordinates its work with the other state departments, in particular the Office of Administration, to ensure diabetes prevention and management programs' coverage by the Pennsylvania Employees Benefit Trust Fund (PEBTF); the Department of Human Services Office of Medical Assistance Programs (OMAP) and Medicaid Managed Care Organizations, to collaborate on the Diabetes Self-Management Education Program (DSMES) and to achieve Medicaid coverage for the Diabetes Prevention Program (DPP); with the Department of Aging, to promote awareness of prediabetes and participation in DPP among older Pennsylvanians; and with the Department of Education, to offer recommendations and resources for the School Nurses Program.

This report will focus on two major programs currently administered by PADOH: Diabetes Prevention Program (DPP) and Diabetes Self-Management Education Program (DSMES). A brief update on the Juvenile Diabetes Cure Research Tax Check-off Program is also included; the program is currently in transition.

Diabetes Prevention Program (DPP)

The Diabetes Prevention Program (DPP) is an evidence-based lifestyle change intervention program for preventing or delaying type 2 diabetes among people at high risk. It is a long-term, structured program. Participants, who have prediabetes or are at risk of developing type 2 diabetes, meet in groups with a specially trained lifestyle coach once a week for 6 months (core phase) and then once or twice a month for 6 months (post-core maintenance period) to learn ways to incorporate healthier eating and moderate physical activity as well as problem-solving and coping skills into their daily lives. In order to accommodate various lifestyles, to respond to various clients' preferences, and to improve attrition, DPP has lately utilized four delivery modes: in-person, online, distance learning, and a combination of these. The goals are to decrease each participant's weight by five to seven percent and to increase physical activity to 150 minutes per week.

Lifestyle changes have been shown to lower the risk of developing diabetes. The National Institute of Diabetes and Digestive and Kidney Diseases encourages people who have a high chance of developing type 2 diabetes to take steps to prevent or delay the onset of the disease by "losing a modest amount of weight by following a reduced-calorie eating plan and being physically active most days of the week."¹¹⁴ A 15-year follow-up in the Diabetes Prevention Program

¹¹⁴ National Institute of Diabetes and Digestive and Kidney Diseases. *Preventing Type 2 Diabetes*,

Outcomes Study has confirmed that “lifestyle interventions or metformin significantly reduced diabetes development over 15 years”; specifically, during a mean follow-up of 15 years, diabetes incidence was reduced by 27 percent in the lifestyle intervention group and by 18 percent in the metformin group, compared with the placebo group, with declining between-group difference over time.¹¹⁵ The result, thus, unequivocally supports the importance of diabetes prevention.

CDC’s Division of Diabetes Translation (DDT) funds state and local health departments to support programs and activities aimed at preventing or delaying the onset of type 2 diabetes and improving health outcomes for people diagnosed with diabetes. CDC’s funding and activities are part of two multi-program cooperative agreements: Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (CDC-RFA-DP18-1815), and Diabetes and Heart Disease and Stroke Prevent Programs-Innovative State and Local Public Health Strategies to Prevent and Manage Diabetes and Heart Disease and Stroke (CDC-RFA-DP18-1817). The Pennsylvania Department of Health secured only the first of these grants – 1815.¹¹⁶

The Pennsylvania Department of Health is supporting the implementation of the CDC National Diabetes Prevention Program by facilitating applications submissions and working to increase the number of CDC-recognized lifestyle change programs available for adults with prediabetes or at risk for developing type 2 diabetes in Pennsylvania.¹¹⁷

Diabetes Prevention Program (DPP) work in the Commonwealth is completed under three funding sources:

- Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (CDC-RFA-DP18-1815)
- Preventative Health and Health Services Block Grant, also referred to as Block Grant
- State Funding.

<https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-type-2-diabetes> (accessed January 26, 2018).

¹¹⁵ Diabetes Prevention Program Research Group. “Long-Term Effects of Lifestyle Intervention or Metformin on Diabetes Development and Microvascular Complications over 15-year Follow-up: The Diabetes Prevention Program Outcomes Study.” *The Lancet Diabetes & Endocrinology*. Vol. 3. No. 11. November 2015, DOI: [http://dx.doi.org/10.1016/S2213-8587\(15\)00291-0](http://dx.doi.org/10.1016/S2213-8587(15)00291-0) (accessed January 26, 2018).

¹¹⁶ Centers for Disease Prevention and Control. *Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke*, <https://www.cdc.gov/RFA-DP18-1815/> (accessed August 21, 2019).

¹¹⁷ The following section of the report is largely based on the information provided to the Joint State Government Commission by the Department of Health in the personal e-mails from Ms. Barbara Orwan and Ms. Camelia Rivera, Public Health Program Administrators, PADOH Bureau of Health Promotion and Risk Reduction, on August 15, 2019.

Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (CDC-RFA-DP18-1815)

Funding for DPP-SFY 2018-2019 -- \$417,553.

This is a five-year grant that ends in June 2023. This grant is provided by the CDC's Division of Diabetes Translation and Division for Heart Disease and Stroke Prevention. The purpose of this CDC grant to "support state investments in implementing and evaluating evidence-based strategies to prevent and manage cardiovascular disease (CVD) and diabetes in high-burden populations/communities within each state and the District of Columbia, contributing to improved health outcomes."¹¹⁸ CDC defines high-burden populations as "those affected disproportionately by high blood pressure, high blood cholesterol, diabetes, or prediabetes due to socioeconomic or other characteristics, including inadequate access to care, poor quality of care, or low income."¹¹⁹

This grant supports Healthy People 2020 objective D-16: Increase prevention behaviors in persons at high risk for diabetes with prediabetes, and its three subobjectives: increase the proportion of persons at high risk for diabetes with prediabetes who report increasing their levels of physical activity (D-16.1), trying to lose weight (D-16.2), and reducing the amount of fat or calories in their diet (D-16.2).

Category A strategies supported by the 1815 grant focus on diabetes management and type 2 diabetes prevention. DPP activities funded by this grant are grouped under three strategies:

- Strategy A.4. Assist health care organizations in implementing systems to identify people with prediabetes and refer them to CDC-recognized lifestyle change programs for type 2 diabetes prevention.
- Strategy A.5. Collaborate with payers and relevant public and private sector organizations within the state to expand availability of the National DPP as a covered benefit for one or more of the following groups: Medicaid beneficiaries; state/public employees; employees of private sector organizations.
- Strategy A.6. Implement strategies to increase enrollment in CDC-recognized lifestyle change programs.

During SFY 2018-2019, the Pennsylvania Department of Health engaged multiple stakeholders including Tobacco Regional Primary Contractors (RPCs), Pennsylvania Pharmacists Association (PPA), Harrisburg Area Young Men's Christian Associations (YMCAs), and DPP providers. These stakeholders focused their efforts on improving access to DPP and conducted outreach to prospective sites across the Commonwealth.

¹¹⁸ Centers for Disease Prevention and Control. *Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke*, <https://www.cdc.gov/RFA-DP18-1815/> (accessed August 21, 2019).

¹¹⁹ Ibid.

In 2018, Quality Insights (QI) reengaged 85 healthcare practices, to assist them with implementing systems to identify people with prediabetes and refer them to DPP, such as creating electronic health records (EHR) reports to identify patients that qualify for DPP and add clinical decisions support (CDS) rules to EHR reminding providers to refer patients with prediabetes to DPP, sending those patients identified through EHR reports an introduction letter from their physician to encourage them enroll in DPP, and educating clinicians to screen for abnormal blood glucose for those patients who are overweight or obese, and to initiate prediabetes conversations with patients at risk for type 2 diabetes.

Through partnership with the Health Promotion Council (HPC), in SFY 2018 PADOH delivered free trainings of almost 60 lifestyle coaches at existing and new program sites across the state, developed an online community of lifestyle coaches housed on LiveHealthyPA website, and monitored the implementation of the DPP Action Plan drafted at the DPP Statewide Engagement Meeting in August 2017 and released in its final form in June 2018. The DPP Action Plan's main goal is to decrease the new cases of diabetes among people with prediabetes and those at highest risk, by increasing enrollment in CDC-recognized lifestyle change programs by 5 percent. To meet the goal, strategies are organized in the Action Plan according to four DPP pillars:

- Awareness of prediabetes;
- Availability of and enrollment in CDC-recognized lifestyle change programs;
- Referral, which includes clinical screening, testing, and referral to CDC-recognized lifestyle change programs under the National DPP; and,
- Coverage for the National DPP's lifestyle change program.

Metrics, resources and leadership for the completion of each strategy were identified, and in 2018 the pillar workgroup members were reconvened for three of the four pillars to monitor progress towards achieving the priorities of each pillar. There was no convening of the Coverage Pillar, due to Department's focus on separate opportunities towards achieving DPP coverage in Pennsylvania. One of these opportunities is a technical assistance grant from the National Association of Chronic Disease Directors (NACDD) to facilitate state Medicaid and public health implementation of the Centers for Disease Control and Prevention's (CDC) 6|18 Initiative to expand access to the national DPP to Medicaid recipients in Pennsylvania. The CDC's 6|18 Initiative promotes the adoption of evidence-based interventions that can improve health and control costs related to six high-burden, high-cost health conditions — tobacco use, high blood pressure, inappropriate antibiotic use, asthma, unintended pregnancies, and type 2 diabetes. Another opportunity is coverage, on a pilot basis, for state employees in Harrisburg and Philadelphia, with the main goal of demonstrating the benefits of covering the National DPP for Pennsylvania State Employees. Under this opportunity, the Commonwealth of Pennsylvania and the PA System of Higher Education had staff trained as lifestyle coaches to offer classes at no cost for state employees.

Preventive Health and Health Services Block Grant (PHHS Block Grant)

Funding for DPP-SFY 2018-2019 - \$834,411

The PHHS Block Grant allows states, territories, and tribes to

- Address emerging health issues and gaps
- Decrease premature death and disabilities by focusing on the leading preventable risk factors
- Work to achieve health equity and eliminate health disparities by addressing the social determinants of health
- Support local programs to achieve healthy communities
- Establish data and surveillance systems to monitor the health status of targeted populations.¹²⁰

The block grant is issued in two-year increments; activities it is utilized for must support Healthy People 2020 objectives.

Healthy People 2020 enjoins the National Diabetes Prevention Program that has been established to implement the lifestyle intervention nationwide as lifestyle change has been proven effective in preventing or delaying the onset of type 2 diabetes in high-risk individuals and as the DPP research has demonstrated that “lifestyle intervention has its greatest impact in older adults and was effective in all racial and ethnic groups.”¹²¹ In addition, Healthy People 2020 states that translational studies of this work have also shown that delivery of the lifestyle intervention in group settings at the community level is also effective at reducing type 2 diabetes risk.¹²²

DPP activities funded by the Preventive Health and Health Services Block Grant in the Commonwealth are tracked by the quarterly evaluation reports prepared by the Research and Evaluation Group (R&E Group) at the Public Health Management Corporation (PHMC). R&E Group is collecting quarterly information from each Regional Primary Contractor (RPC) regarding progress toward pending and full CDC DPRP recognition, technical assistance provided by RPCs, PPA and Harrisburg Area YMCA, DPP sessions conducted, participant success stories reported, and progress towards reaching sustainability goals.¹²³

¹²⁰ Centers for Disease, Prevention and Control. *The Preventive Health and Health Services Block Grant*, <https://www.cdc.gov/phhsblockgrant/about.htm> (accessed August 28, 2019).

¹²¹ *Healthy People 2020. Diabetes*, <https://www.healthypeople.gov/2020/topics-objectives/topic/diabetes> (accessed January 29, 2018).

¹²² Ibid.

¹²³ The Research and Evaluation Group, PHMC. *Diabetes Prevention Program (DPP) Evaluation Quarterly Report. SFY18-19. Quarter 3*. April 2019.

The PHMC report issued in April 2019 lists the following Regional Primary Contractors in Pennsylvania:

- Northeast – American Lung Association (ALA)
- Northcentral – American Lung Association (ALA)
- Northwest – Erie County Department of Health
- Southeast – Health Promotion Council (HPC)
- South Central – American Lung Association (ALA)
- Southwest – Adagio Health.¹²⁴

These RPCs are identifying and assisting partner organizations to establish new DPP sites in identified counties.

PADOH continues to utilize existing partner infrastructure to increase DPP access across the state. By March 2019, there were 70 PADOH-partner DPP sites in Pennsylvania located in 45 of Pennsylvania's 67 counties. In 2018, there were 1,691 enrolled DPP participants at PADOH-partner sites. RPCs have reported collaborations between DPP programs and tobacco cessation programs, asthma education, women's health programs, and WIC/nutrition services.

In 2017, PADOH established a new partnership with PPA to implement DPP at pharmacy locations across the state, and by December 2018 twelve pharmacies have received pending recognition from CDC to deliver the program at their sites.

As of the third quarter SFY 2018-2019, there are 214 DPP Lifestyle Coaches and 5 active Master Trainers.¹²⁵

All RPCs provide technical assistance on a regular basis via phone calls or e-mail with lifestyle coaches. DPP coordinators assisted sites with data collection, budget support, recruitment, and retention. Continuing education opportunities regarding the program are shared with the service providers. In some regions, sites are visited and feedback is offered to lifestyle coaches. As needed, sites are also given assistance in applying for the DPRP recognition program; they are provided guidance regarding participant recruitment and various incentives that can be used to encourage participants to stay on track to meet CDC standards. Several DPP coordinators reported continuing challenges recruiting eligible participants in rural areas.

Important areas of DPP activities are outreach efforts, collaboration with other local organizations, and participant recruitment.

Media campaigns, advertisements at various public locations, and announcements in local hospitals and physicians' offices are utilized to spur participant recruitment. Most sites promoted classes through flyers; newspaper, newsletter, and radio ads; social media posts; meeting with providers; and recruiting eligible participants using electronic health records. Geisinger class

¹²⁴ Ibid.

¹²⁵ Ibid.

coordinators reported attending local medical home meetings, advertising classes on their website, and targeted e-mails to employees within the BMI and blood glucose ranges for prediabetes. Sometimes, successful recruitment came through referrals from former participants. To increase participant motivation and retention, most sites provided prizes such as lunch bags with portion-size containers, blenders, measuring cups, food scales, body scales, water bottles, healthy snacks, grocery gift cards, recipe pocket calendars, and weight management guides.¹²⁶

State Funding

Funding for DPP-SFY 2018-2019 - \$100,000

The Pennsylvania Department of Health, through its partner Harrisburg Area YMCA, worked to reduce the incidence of diabetes through the implementation of DPP pilots for state employees at three new sites: two in Harrisburg and one in Philadelphia. Data will be evaluated at the conclusion of this project from the perspective of providing program insurance coverage for state employees.

In October 2018, the Pennsylvania Department of Health and the Pennsylvania Department of Human Services began participating in a technical assistance opportunity to adopt evidence-based prevention strategies under the Centers for Disease Control and Prevention's (CDC) 6|18 Initiative. This initiative supports state/territorial Medicaid agencies and public health departments in establishing or strengthening cross-agency partnerships to accelerate implementation of prevention strategies in Medicaid – with the ultimate goal of improving health outcomes and controlling costs. Under this initiative, the Pennsylvania Department of Health and the Pennsylvania Department of Human Services received technical assistance from NACDD and Leavitt Partners to work towards coverage of the National DPP lifestyle change program as a Medicaid benefit. As a result, the Department of Human Services published a Medical Assistance Bulletin effective July 1, 2019, stating that DPP providers may enroll in the Medical Assistance (MA) Program to allow them to participate as network providers in the MA managed care plans. Pennsylvania has applied and was approved for continued intensive technical assistance and funding from NACDD and Leavitt Partners for the period August 2019 – July 2020, to further its efforts in enrolling CDC-recognized DPP providers for participation in its Medicaid program.

Most of the DPP sites in Pennsylvania are supported with budget funding by PADOH – 68 of 86, which is the total number of CDC-recognized organizations in the Commonwealth as of August 2019.¹²⁷

¹²⁶ Ibid.

¹²⁷ Centers for Disease, Control and Prevention. *National Diabetes Prevention Program: Registry of All Recognized Organizations*, https://nccd.cdc.gov/DDT_DPRP/Registry.aspx (accessed August 16, 2019).

Diabetes Self-Management and Support Program (DSMES)

DSMES ensures that people who have diabetes receive AADE-accredited and/or ADA-recognized diabetes self-management education. DSMES is a collaborative process through which people with diabetes gain the knowledge and skills needed to modify their behavior and successfully self-manage the disease and its related conditions. This process incorporates the needs, goals, and life experiences of the person with diabetes and is guided by evidence-based standards. DSMES has been shown to improve outcomes.

A joint position statement of the American Diabetes Association, the American Association of Diabetes Educators (AADE), and the Academy of Nutrition and Dietetics established the key parameters of DSMES and outlined a diabetes education algorithm that defines when, what, and how DSMES should be provided for adults with type 2 diabetes. The goals of the position statement are “to improve the patient experience of care and education, the health of individuals and populations, and to reduce diabetes-associated per capita health care costs.”¹²⁸ The position statement references studies showing DSMES to be cost-effective by reducing hospital admissions and readmissions, as well as estimated lifetime health care costs related to a lower risk for complications. Various studies have indicated that DSMES helps patients achieve significant reduction in unhealthy sugar levels. It has also been shown to reduce the onset and/or advancement of diabetes complications, to improve quality of life and lifestyle behaviors such as having a more healthful eating pattern and engaging in regular physical activity, to enhance self-efficacy and empowerment, to increase healthy coping, and to decrease diabetes-related distress and depression.¹²⁹

ADA and AADE endorse a personalized and comprehensive approach, where collaboration and effective communication are perceived to be the route to patient engagement. Through this approach, patients are better able to explore options, choose their own course of action, and make informed self-management decisions.

The DSMES algorithm of care relies on five guiding principles:

- patient engagement,
- information sharing,
- psychosocial and behavioral support,
- integration with other therapies, and
- coordinated care.¹³⁰

Diabetes self-management education and support process should be ongoing; it should be assessed, provided and adjusted at critical times such as at first diagnosis, with the emergence of new complicating factors or transitions in care; annual assessment is recommended.

¹²⁸ Powers, Margaret A. et al. “Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics.” *The Diabetes Educator*. 2015. DOI: 10.1177/0145721715588904 (accessed January 30, 2018).

¹²⁹ Ibid.

¹³⁰ Ibid.

Compliance with the National Standards for DSMES is intended to guarantee the adequate quality of the programs offered to people who have diabetes nationwide. To ensure that the standards align with current evidence-based practices and utilization trends, the National Standards for Diabetes Self-Management and Care were updated in 2017, with additional focus on the support element, reflected in the modified name of the program. The ten standards cover the following areas:

1. Internal Structure
2. Stakeholder Input
3. Evaluation of Population Served
4. Quality Coordinator Overseeing DSMES Services
5. DSMES Team
6. Curriculum
7. Individualization
8. Ongoing Support
9. Participant Progress
10. Quality Improvement.¹³¹

The updated National Standards reaffirm that quality DSMES continues to be a critical element of care for all people with diabetes. The Standards underscore that the DSMES services “must be individualized and guided by the concerns, preferences, and needs of the person affected by diabetes.”¹³² The Standards reference numerous studies that have shown the benefits of DSMES, including improved clinical outcomes and quality of life, along with reducing hospitalizations and health care costs. DSMES, however, remains underutilized. In the past few years, technology has been changing the way DSMES is delivered and implemented with positive outcomes. Based on the current evidence, the new Standards endorse “person-centered services that embrace the ever-increasing technological engagement platforms and systems.”¹³³

The updated Standards’ focus on the individual with diabetes as the center of the care team underlies specific revisions. The Standards urge health care teams to consider the burden of treatment placed on those living with diabetes (the “work of being a patient”) and consider all decisions within the lens of the individual’s capacity: “The minimally disruptive model of care defines a goal of maximizing particular outcomes with the minimal amount of work required by the person with diabetes to help simplify diabetes management and not add complexity.”¹³⁴

The Standards remind that ensuring quality is an essential component of the chronic care model and that person-centered health care is associated with improved outcomes and better relationships between referring practitioners, individuals with diabetes, and teams. Continuous emphasis on individualization determines the choice of recommendations for DSMES curriculum and structure, which should offer significant flexibility to accommodate each participant’s needs.

¹³¹ *2017 National Standards for Diabetes Self-Management Education and Support*, https://www.diabeteseducator.org/docs/default-source/practice/deap/standards/nationalstandards_2017.pdf?sfvrsn=2 (accessed August 26, 2019).

¹³² *Ibid.*

¹³³ *Ibid.*

¹³⁴ *Ibid.*

With regard to DSMES curriculum, the Standards include a strong statement: “It is crucial that the content be tailored to match individuals’ needs and be adapted as necessary for age, developmental stage, type of diabetes, cultural factors, health literacy and numeracy, and comorbidities.”¹³⁵

Another highlight of the revised Standards is ongoing support. Research indicates that initial improvements in metabolic and other outcomes tend to diminish after six months; it means that to maintain behavior at the level needed to effectively self-manage diabetes, program participants need resources that will help them implement and sustain the skills, knowledge, and behavior changes necessary for managing their condition. “The vital point” is that the participant selects the resource or activity that best suits his or her self-management needs.¹³⁶ The Standards suggest a variety of strategies available for engaging in ongoing support both within and outside DSMES services.

Effective DSMES, based on a personalized and comprehensive approach, becomes a significant contributor to clinical improvement and long-term positive health outcomes.

In Pennsylvania, Diabetes Self-Management Education (DSMES) work is currently completed under two funding sources:

- Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (CDC-RFA-DP18-1815).
- Preventive Health and Health Services Block Grant.

The State Public Health Actions to Prevent and Control Diabetes, Heart Disease, Obesity and Associated Risk Factors and Promote School Health (DP13-1305), also known as the LiveHealthyPa Grant has concluded; after a three-month extension, it ended September 29, 2018. The new Centers for Disease Control and Prevention grant is titled “Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke” (DP18-1815). This grant ends June 29, 2023.

Total diabetes funds under this grant, so far, are as follows:

September 30, 2018 - June 29, 2019 -- \$958,821

June 30, 2019 - June 29, 2020 -- \$1,171,893

¹³⁵ Ibid.

¹³⁶ Ibid.

Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (CDC-RFA-DP18-1815)

This is a 4.75-year grant, beginning September 30, 2018 and ending June 29, 2023.

Funding for DSMES contractors:

- SFY 2018-2019 (9 months) - \$238,088
- SFY 2019-2020 - \$290,000
- Remaining years are unknown.

Contractors for DSMES are the following:

- Health Promotion Council (HPC)
- Pennsylvania Pharmacists Association (PPA)
- Quality Insights (QI)
- Funding also supports a portion of 1815 evaluation efforts provided by the Evaluation Institute for Public Health, University of Pittsburgh and Behavioral Risk Factor Surveillance System (BRFSS) Diabetes Questions.

PADOH is implementing evidence-based strategies to contribute to the management of diabetes in high-burden populations in Pennsylvania. Strategies improve care and management of people with diabetes by increasing access to and use of diabetes self-management education and support (DSMES) programs and medication management processes.

Through the Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke (1 NU58DP006541-01-00) (1815) cooperative agreement from the CDC, the DPCP is working, in partnership with the Cardiovascular Disease Program, to improve access to and participation in American Diabetes Association (ADA)-recognized and American Association of Diabetes Educators (AADE)-accredited DSMES programs in underserved areas and increase engagement of pharmacists in the provision of medication management or DSMES for people with diabetes.

PADOH is collaborating with the HPC and the PPA to increase access to recognized/accredited DSMES programs, by providing technical assistance to programs seeking to achieve recognition or accreditation. Additional technical assistance will be provided to support program sustainability. PADOH is also working with PPA to identify how to incorporate medication management for people with diabetes into pharmacists' patient care process collaborations and best practice protocols.

Through work with QI, PADOH will increase participation in recognized/accredited DSMES programs by educating providers, promoting DSMES within communities, and improving referral processes and networks. QI will engage health systems, independent practices, and electronic health record (EHR) vendors to assist in completing this work.

PADOH is exploring how to increase access and participation of disparate populations, such as people with disabilities or people with limited health literacy, by initiating information gathering meetings with stakeholders to inform next steps. By increasing access to and participation in recognized/accredited DSMES programs, PADOH will decrease the proportion of people with diabetes with an A1C>9.

Preventive Health and Health Services Block Grant (PHHS Block Grant)

Funding for DSMES Activities:

- SFY 2018-2019 – \$202,000
- SFY 2019-2020 – \$178,550

Contractors for DSMES:

- SFY 2018-2019 – Bureau of Community Health Systems (BCHS)
- SFY 2019-2020-
 - Pennsylvania Pharmacists Association (PPA)
 - Erie County Department of Health/Multi-Cultural Health Evaluation & Delivery System
 - Special Olympics Pennsylvania

Activities:

- SFY 2018-2019 - Bureau of Community Health Systems

With funding from the Preventive Health and Health Services Block Grant, the Bureau of Community Health Systems in collaboration with the Bureau of Health Promotion and Disease Prevention developed a strategy to identify individuals with diabetes and empower them to join a Diabetes Self-Management Education and Support program in their community.

The Bureau of Community Health Systems developed a toolkit containing educational materials supporting participation of people with diabetes in recognized and accredited DSMES programs. The toolkit was made available to 80 Community Health Nurses statewide which assisted in their ability to educate individuals about the severity of diabetes and promote program participation. 123 Community Health Nurses were trained on DSMES and techniques that would assist in uncovering objections that individuals had about enrolling in a program.

Community Health Nurses established relationships with local DSMES programs to understand the scope of their services and challenges they face with recruitment of people with diabetes. Community Health Nurses identified local community groups such as faith-based organizations, schools, community centers, libraries, and others, to provide education to people with diabetes and raise awareness of DSMES programs existing in their communities. They scheduled community presentations around the start date of the DSMES programs offered in the area and provided potential participants with resources about DSMES. Between January 2019 and

May 2019, 132 presentations were provided to 3,963 participants across 33 counties in the state of Pennsylvania.

- SFY 2019-2020-

Funding from the Preventive Health and Health Services Block Grant (PHHS Block Grant) will support a comprehensive approach, integrating community-level efforts to strengthen foundational activities from 1815.

- PPA - PADOH is building on work in 1815 to increase access to DSMES by supporting pharmacist-led DSMES program sustainability. Through the Pennsylvania Pharmacists Association (PPA), PADOH will provide educational workshop opportunities to a cohort of pharmacists who provide recognized/accredited DSMES. A new workshop will be developed to address barriers identified through the 1815 mentoring group, such as recruitment, retention, and billing. Additionally, PPA will increase the number of allowed attendees for existing and new workshops and will provide support to pharmacists to assist with billing platforms.
- Erie County Department of Health/Multi-Cultural Health Evaluation & Delivery System - 2019 PHHSBG funds will pilot a new approach, delivering enhanced DSMES classes to targeted refugee populations. The Erie County Department of Health (ECDH) and the Multi-Cultural Health Evaluation and Delivery System (MHEDS), primary care center, will provide DSMES with two additional sessions, grocery shopping and cooking lessons, with assistance of cultural navigators. The pilot will support four sets of classes: two for Asian (Bhutanese/Nepali/Burmese) and two for Middle-Eastern (Iraqi/Syrian) refugees with diabetes.
- Special Olympics Pennsylvania - PADOH will work with Special Olympics Pennsylvania to increase awareness of DSMES and to provide outreach to adult athletes in the Special Olympics program who also have diabetes. The purpose of this activity is to increase participation in DSMES for people with both diabetes and intellectual disabilities and to improve health outcomes for this disparate population.

Juvenile Diabetes Cure Research Check-off Program

The Juvenile Diabetes Cure Research Check-off Program was established pursuant to Act 133 of 2004.¹³⁷ The act created a state income tax check-off option for individuals to contribute a portion of their state tax refund to be donated directly to the Pennsylvania Department of Health to support research for type 1 diabetes. The department publishes an annual report to the Pennsylvania General Assembly, which provides an update in activities and contributions to the program, as well as guidelines for distribution of collected funds. The program funds research grants focused on restoring normal glucose blood levels, addressing complications of the disease, and preventing type 1 diabetes.

Type 1 diabetes, previously known as insulin-dependent diabetes mellitus, or juvenile-onset diabetes, used to be called that way because it usually appears in children and young adults though its onset may occur at an older age as well. Risk factors may be autoimmune, genetic, or environmental, but the exact cause of type 1 diabetes remains unknown. There is no known way to prevent it, and there is no cure. Research centered on type 1 diabetes strives to detect its causes and to find a cure.

Between 2004 and 2018, the PADOH Bureau of Health Promotion and Risk Reduction had been administering the requirements of the Juvenile Diabetes Research Fund (JDRF). In December 2018, the PADOH Health Research Office received the responsibility of managing Act 2004-133 and the JDRF. A Request for Application (RFA) issued by the Bureau of Health Promotion and Risk Reduction in January 2018 did not receive any bids. Once the Health Research Office assumed responsibility for the JDRF, it started reviewing options for distributing the funds to institutions that meet the statutory requirements. The Health Research Office has developed policies and procedures for the distribution of funds and is planning to pilot them in 2020.¹³⁸

The fund amount received based on donations in the first five months of 2019 is \$10,309.43.¹³⁹ The balance for the Juvenile Diabetes Fund as of July 2019 is \$155,985.68.¹⁴⁰

¹³⁷ This legislation added § 315.7 to the Tax Reform Code of 1971.

¹³⁸ Information provided to the Joint State Government Commission by Ms. Penny E. Harris, Director of the PADOH Health Research Office, in the personal e-mail on July 29, 2019.

¹³⁹ Information provided to the Joint State Government Commission by Ms. Penny E. Harris, Director of the PADOH Health Research Office, in the personal e-mail on June 4, 2019.

¹⁴⁰ Information provided to the Joint State Government Commission by Mr. Christopher Albright, Administrative Officer of the PADOH Health Research Office, in the personal e-mail on July 29, 2019.

DEPARTMENT OF AGING

The mission of the Pennsylvania Department of Aging (PDA) is to “enhance the quality of life of older Pennsylvanians by empowering diverse communities, the family, and the individual.” It is the foundation of PDA to “prevent instability of health and wellness by enabling citizens to age in place with dignity and protect the most vulnerable from abuse, neglect, abandonment, and exploitation.”¹⁴¹

Health & Wellness Program

The Health & Wellness Program operates under the auspices of the PDA’s Education and Outreach Office (EEO). The Education and Outreach Office oversees health and consumer education programs initiated by PDA, including the Health Insurance Information Counseling and Assistance Program, also known as APPRISE, and the Health & Wellness Program.¹⁴²

The role of PDA’s Health & Wellness Program is to

- Research and interpret federal guidelines regarding the Older Americans Act (OAA) Title IIID funding for disease prevention and health promotion services;
- Coordinate efforts among community resources;
- Act as a catalyst for the Area Agencies of Aging (AAA) and PDA’s Health & Wellness initiatives;
- Provide training, technical assistance, and materials, as appropriate, for any of the PDA-endorsed evidence-based programs.

The goals of PDA’s Health & Wellness program are to

- Abolish the myth that inevitable functional decline comes with age;
- Empower older adults with the information they need to age well;
- Support older adults in making lifestyle changes to improve their overall health;
- Reduce the utilization of the healthcare system.

¹⁴¹ Pennsylvania Department of Aging. 2016-2020 State Plan, https://www.aging.pa.gov/publications/state-plan-on-aging/Documents/2016-2020State_Plan_on_Aging.pdf.

¹⁴² The information regarding the Health & Wellness Program, its role, goals and funding sources, was provided to the Joint State Government Commission by the Pennsylvania Department of Aging in the personal e-mail from Ms. Katrina Kyle, Health & Wellness Program Specialist of the Department of Aging Education and Outreach Office, on July 31, 2019.

PDA receives federal funding from the Administration for Community Living (ACL), through the OAA Reauthorization 2016 Title IIID, to provide disease prevention and health promotion services through the Health & Wellness Program. Under Title IIID of the OAA, funding has been provided since 1987 to states and territories based on their share of the population aged 60 and over the programs that support healthy lifestyles and promote healthy behaviors.

Effective October 1, 2016, ACL required Title IIID funds to be used only for evidence-based programs, as defined by ACL. In response to this mandate, PDA issued Aging Program Directive (APD)# 16-04-01: Older Americans Act Title IIID Funding for Evidence-Based Programs and Health & Wellness Program on October 1, 2016. APD# 16-04-01 outlines the roles, responsibilities, and directives between PDA's Health & Wellness Program and the 52 AAA's Health & Wellness Programs serving Pennsylvania's 67 counties.

Chronic Disease Self-Management Program (CDSMP) and Diabetes Self-Management Program (DSMP) are two of the PDA-endorsed evidence-based programs that the AAAs may choose to conduct in their service areas that address diabetes.

Chronic Disease Self-Management Program

The Chronic Disease Self-Management Program (CDSMP) was developed by the Stanford University Patient Education Research Center as a collaborative research project with the Northern California Kaiser Permanente Medical Care Program. This program teaches older adults practical skills for managing chronic health conditions such as diabetes, hypertension, heart disease, and stroke. The objective is for participants to gain the confidence and motivation needed to manage the challenges of living with chronic health conditions. Certified CDSMP Lay Leaders or CDSMP Master Trainers conduct workshops, which consist of 2.5-hour weekly sessions held over six weeks. Workshops are held at senior community centers, senior housing facilities, faith-based organizations, libraries, health centers, and various other community sites.

Beginning in 2010, PDA purchased a multi-agency license for CDSMP from Stanford University. Since 2010, PDA has supported the delivery of CDSMP to over 7,000 Pennsylvania residents.

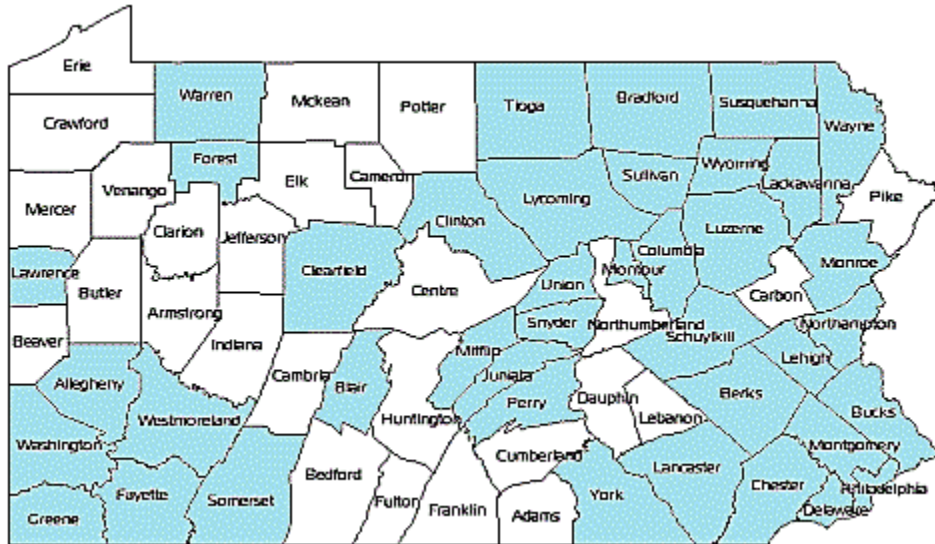
The licensing entity of CDSMP has since moved from Stanford University to the Self-Management Resource Center (SMRC). Under PDA's license with the Self-Management Resource Center, as of July 1, 2019, there are 32 CDSMP Master Trainers and 162 CDSMP Lay Leaders trained to conduct CDSMP workshops reaching Pennsylvanians in 46 counties.¹⁴³

In state fiscal year 2017-2018, there were 561 CDSMP participants across 40 counties in 29 AAA service areas. Of these 561 CDSMP participants, 34 percent reported they had been diagnosed with diabetes.¹⁴⁴

¹⁴³ Data on CDSMP in Pennsylvania were provided to the Joint State Government Commission by the Pennsylvania Department of Aging on July 31, 2019.

¹⁴⁴ Data on CDSMP in Pennsylvania were provided to the Joint State Government Commission by the Pennsylvania Department of Aging on July 31, 2019.

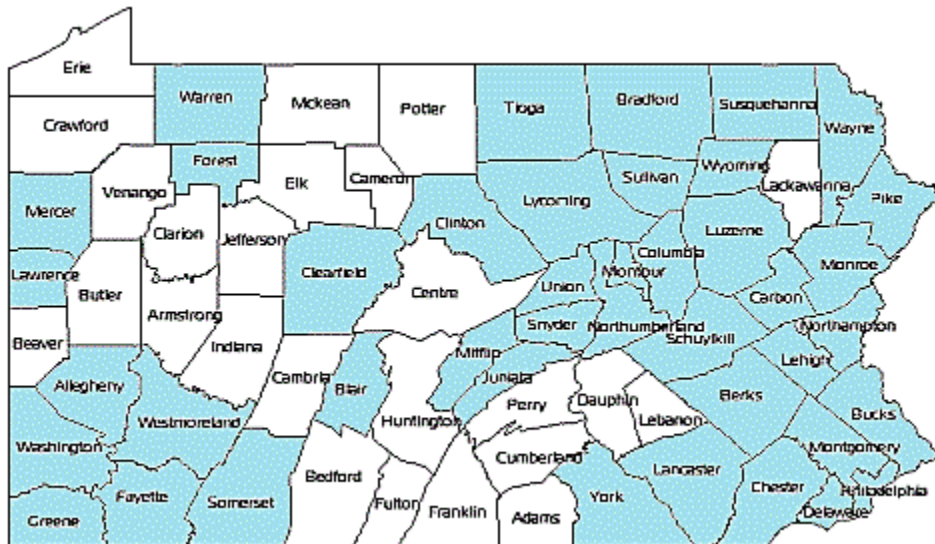
SFY 2017-2018 CDSMP Workshops in Pennsylvania



Map provided by Pennsylvania Department of Aging.

In state fiscal year 2018-2019, AAAs planned to serve CDSMP 858 participants, across 42 counties in 31 AAA service areas.¹⁴⁵

SFY 2018-2019 CDSMP Workshops in Pennsylvania



Map provided by Pennsylvania Department of Aging.

¹⁴⁵ Data on CDSMP in Pennsylvania were provided to the Joint State Government Commission by the Pennsylvania Department of Aging on July 31, 2019.

CDSMP has received favorable reviews nationwide and in other countries and is available in many different languages. According to the National Council on Aging, a study found that participants who took the program demonstrated:

- A 3 percent reduction in hospital admissions;
- A 5 percent reduction in Emergency Room utilization; and
- An average of \$368 in healthcare savings per participant minus the cost of the program.¹⁴⁶

Diabetes Self-Management Program

The Diabetes Self-Management Program (DSMP) was developed by Stanford University as a complement to the CDSMP. Similar to CDSMP, DSMP uses certified Lay Leaders or Master Trainers to conduct workshops to teach older adults who have diabetes how to manage their condition. Workshops take place in senior community centers, senior housing facilities, faith-based organizations, libraries, health centers, and various other community sites.

In October 2015, Health Promotion Council of Pennsylvania, Inc. (HPC) was awarded a two-year Prevention and Public Health Fund (PPHF-2015) grant from the Administration on Community Living to expand DSMP in Pennsylvania. With the funding award, DSMP was added to PDA's SMRC license, and HPC was able to provide DSMP training for existing and new PDA Master Trainers and Lay Leaders as well as initial DSMP supplies. Once PDA Master Trainers were cross-trained in DSMP, they were able to train new DSMP Lay Leaders. As of July 1, 2019, there are 19 DSMP active Master Trainers and 99 DSMP Lay Leaders serving approximately 30 counties.¹⁴⁷

In state fiscal year 2017-2018, there were 483 DSMP participants across 22 counties in 19 AAA service areas. Of these 483 DSMP participants, 46 percent reported they had been diagnosed with hypertension and over 31 percent reported obesity as a health care concern.¹⁴⁸

¹⁴⁶ National Council on Aging. *Improving Quality of Life and Health Care Outcomes through CDSME Programs*, July 17, 2019, <https://www.ncoa.org/healthy-aging/chronic-disease/>.

¹⁴⁷ Data on DSMP in Pennsylvania were provided to the Joint State Government Commission by the Pennsylvania Department of Aging on July 31, 2019.

¹⁴⁸ Data on DSMP in Pennsylvania were provided to the Joint State Government Commission by the Pennsylvania Department of Aging on July 31, 2019.

In addition to CDSMP and DSMP, the AAA network utilizes approximately 24 other evidence-based programs that address areas such as injury and disease prevention, exercise, chronic conditions, nutrition, mental health, medication management, and substance abuse.¹⁵⁰ These programs are provided at no charge to those 60 years old and older.

PACE

Along with facilitating health and wellness programs which teach older adults practical skills that can help in maintaining good health, preventing illness and injury, and successfully managing their chronic conditions, the Department of Aging is also responsible for programs assisting eligible older Pennsylvanians in paying for their prescription medications. Taking the necessary medications is an essential part of disease management. It is especially critical for chronic conditions, such as diabetes.

The Pharmaceutical Assistance Contract for the Elderly (PACE) program and the PACE Needs Enhancement Tier (PACENET) program assist qualified older adults age 65 years or older in paying for their prescription medications. “PACE covers all medications requiring a prescription in the Commonwealth, as well as insulin, insulin syringes, and insulin needles, unless a manufacturer does not participate in the Manufacturers’ Rebate Program.”¹⁵¹ PACE pays the cost of prescription drugs and insulin supplies over a copay. PACENET pays the cost of prescription drugs and insulin supplies after a cardholder meets the premium requirement and pays a copayment. The PACEPlus Medicare Program pays Medicare premiums for Part D for PACE and PACENET cardholders. PACENET cardholders repay the Part D premiums. With the goal of providing seamless coverage, the PACE and PACENET programs provide benefits when Medicare Part D does not. For example, benefits are paid during the deductible and the coverage gap, for drugs excluded by Part D or for drugs not in a plan’s formulary, and for copayment differentials between the Part D plan coverage and the PACE and PACENET copayments. In 2018, 258,000 older adults were enrolled in the PACE and PACENET programs, 45,100 of whom received antidiabetic pharmaceutical assistance.¹⁵²

The Pennsylvania Patient Assistance Program Clearinghouse (PA PAP) provides the expertise necessary to determine eligibility for persons of all ages who seeking assistance from manufacturers’ medication programs. In 2018, 14,000 people received medication assistance by contacting the Clearinghouse. PA PAP connects persons with other social service resources, initiates any new programs that are the result of Attorney General Lawsuit settlements, and assists Medicare Part D-enrolled cardholders with obtaining the Low-Income Subsidy benefit.

¹⁵⁰ Information provided to the Joint State Government Commission by the Pennsylvania Department of Aging on July 31, 2019.

¹⁵¹ Pennsylvania Department of Aging, *PACE (Pharmaceutical Assistance Contract for the Elderly) Annual Report to the General Assembly, January 1 – December 31, 2018*, <https://www.aging.pa.gov/publications/annual-reports/Documents/2018%20PACE%20Annual%20Report.pdf>.

¹⁵² Information provided to the Joint State Government Commission by the Department of Aging on July 31, 2019.

In 2019, PACE, through the Department of Health, received funds under the Preventive Health and Health Services Block Grant. This short-term project (January – June 2019) promoted awareness of prediabetes and the Diabetes Prevention Program to older Pennsylvanians by distributing information to prescribing clinicians. The PACE Academic Detailing Program developed a teaching tool to educate 500 clinicians, who care for PACE patients, about screening, testing and referring their eligible patients to local, no or low-cost Diabetes Prevention Programs.

An important component of the PACE program is updating physicians about changing therapies in complicated disease states. Type 2 diabetes is a common chronic condition with projected increases in prevalence for Pennsylvania that will continue to challenge health care providers. In April 2016, the program released an updated diabetes education module as part of its long-standing physician education program. Clinical educators completed 737 physician office visits in 2016-2018 on this topic. In April 2019, the diabetes module was updated again to reflect the new clinical trials and treatment guidelines that led to changes in diabetes medication utilization. The 2019 module includes:

- Written evidence reports (print monograph)
- Summary document of top 4-5 key messages
- Academic detailing education sessions in physicians' offices delivered by trained outreach educators (pharmacists, nurses, physicians) who present the material face-to-face
- Reference cards for easy access to key materials
- Patient education brochures and tear-off sheets

The goals for the diabetes educational program are to help practitioners

- Choose an appropriate target HbA1C based on a patient's health status and response to treatments, with a goal of 7% for most patients with diabetes.
- Select metformin as first-line treatment for all patients with type 2 diabetes who require drug treatment, unless contraindicated.
- Choose appropriate additional therapeutic interventions for patients not controlled on metformin based on patient characteristics.
- Regularly recommend a healthy diet and regular exercise and assess adherence to medications before titrating doses.
- Select insulin as the agent of choice to be initiated promptly when non-insulin agents are not sufficient to achieve HbA1C target.
- Manage hypertension and hyperlipidemia aggressively to prevent type 2 diabetes-related complications.

Educational modules are found at www.alosahealth.org, under Our Solutions. PACE Academic Detailing Modules are designated for *AMA PRA Category 1 Credits* by the Harvard Medical School.¹⁵³

To evaluate the effectiveness of its academic detailing, the program conducted a collaborative research and evaluation project with Wilkes University. This program evaluation study specifically examined prescribing patterns before and after prescribers participated in the program's 2013 diabetes management module. The module provided information on the comparative effectiveness and safety of diabetes medications, presented evidence regarding appropriate therapy strategies, and weighed the benefits, risks, and value of treatment options with the intent to improve the quality of prescribing and patient care. This interrupted time series evaluation focused on the third diabetes educational outreach intervention that was presented to 704 prescribers in 2013-14. In addition to the group of prescribers who received the diabetes management training, the evaluation analysis also includes a comparison group of prescribers who did not receive the training.

The quality metrics identified for this study included:

- Prescribing metformin in older patients with diabetes
- Prescribing of HMG-CoA reductase inhibitors (statins) in diabetic patients
- Prescribing of either an angiotensin-converting-enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB) for patients who have both diabetes and hypertension
- Avoidance of long-acting sulfonylureas (chlorpropamide, glyburide) in older patients with diabetes

The results did not demonstrate differences between the intervention and comparison groups with respect to the four metrics. However, most prescribers in the detailed group had been exposed to more than one wave of diabetes training since 2007, and the quality metrics have become the standard of care. The findings are consistent with a ceiling effect in the measured metrics, suggesting that most prescribers were following treatment guidelines during the evaluation period. These results have been accepted for publication in *American Health & Drug Benefits* in 2019.

¹⁵³ Information provided to the Joint State Government Commission by the Department of Aging on July 31, 2019.

DEPARTMENT OF HUMAN SERVICES

Medical Assistance (Medicaid)

In state fiscal year 2017-18 – the latest period for which data are available – there were 235,450 total Medicaid recipients with diabetes.¹⁵⁴

The Department of Human Services' (DHS) Office of Medical Assistance Programs oversees the Physical Health component of the HealthChoices Program. The HealthChoices Program is the name of Pennsylvania's mandatory managed care program for Medical Assistance (MA, or Medicaid) recipients. Medicaid recipients gain access to medical care and appropriate physical health services through physical health managed care organizations (MCOs).

Regular screenings are a key to successful diabetes management, to prevention, early detection, and prompt treatment of dangerous and expensive complications. As reflected in the table below, the number of these critically important screenings for Medicaid patients in the Commonwealth has been growing consistently or remaining constant in recent years though 2018 showed a slight decrease in three categories.

HealthChoices Performance Areas Medical Assistance Recipients with Diabetes Average Annual Screenings by Type, 2016-2018			
Type of Screening or Exam	Percentages of Recipients		
	2016	2017	2018
BP Control (<140/90 mmHg)	67.1%	67.9%	69.2%
Eye	59.2	59.4	59.0
A1C	86.2	87.5	87.2
Nephropathy	90.0	89.9	89.6

¹⁵⁴ This section of the report is largely based on the information provided to the Joint State Government Commission by the Department of Human Services on July 26, July 29, and September 4, 2019.

The numbers of screenings for Medicaid patients in the Commonwealth are close to the results nationwide, with the number of eye exams slightly higher (comp. to 57.2 percent in 2017) and monitoring nephropathy slightly lower (comp. to 90.1 percent in 2017).¹⁵⁵

Education and outreach are an important part of improving diabetes control and maintenance. All of the HealthChoices MCOs offer diabetes-related education and outreach to both providers and members. Some of the information offered to providers describes best practices, ways of coding to identify diabetic members, and home lab testing and re-testing protocols for members with high results. Examples of member education offered are diabetes disease specific education, instructions for obtaining screening and follow-up testing, and medication adherence coaching. Examples of member outreach include Diabetes Trac phone text messages, tele-monitoring, tele-retinal in-home screening, and community events, which offer Hemoglobin A1C screenings and diabetic eye exams.

The MCOs have implemented a community-based care management (CBCM) model of care to meet members in the community. The CBCM team may consist of licensed and non-licensed staff such as registered nurses, social workers, community health workers, or pharmacists depending on the need of the MCO's population. CBCM staff meet diabetic members face-to-face in their community or home to assist with filling out health care forms, making calls to the member's doctor's office to schedule an appointment, arranging transportation to the doctor's office, or obtaining a referral for a specialist. To assist high-volume practices with their diabetic Medicaid members, MCOs have embedded community health workers, pharmacists, diabetic navigators, and/or social workers to assist with members who require higher-touch interactions to ensure medical services that are needed are obtained. Diabetic navigators alert providers about their members who are due or overdue for testing. These navigators also educate members on diabetes, screenings and re-testing, medication adherence, scheduling appointments and ensuring appointments are kept, and assisting with any barriers that the member may have. These interactions are mostly face-to-face; however, they can also occur telephonically.

Another community-based initiative the MCOs have implemented is medication therapy management (MTM). MTM involves a pharmacist who interacts with an MCO's diabetic member at the pharmacy to review the types, amounts, and duration of medications prescribed by the member's physician. Registered nurses or community health workers will also conduct home visits and review medications with the pharmacists by phone to ensure the member has the correct prescriptions and is taking them as prescribed. An additional CBCM initiative the MCOs implemented is tele-monitoring. Tele-monitoring involves a health professional conducting a home visit when a member can't make it into a physician's office. This community-based initiative is convenient and beneficial for diabetic members because it brings health services to the home and can decrease emergency room and inpatient visits.

In addition, some of the MCOs offer Food as Medicine programs through partnerships with the Metropolitan Area Neighborhood Nutrition Alliance (MANNA) in Philadelphia, Geisinger's Fresh Food Farmacy (FFF), and Family Food (FF) programs. These programs provide diabetes education, along with meals for the member and his or her family.

¹⁵⁵ National Committee for Quality Insurance. *Comprehensive Diabetes Care (CDC)*, <https://www.ncqa.org/hedis/measures/comprehensive-diabetes-care/> (accessed September 4, 2019).

In October 2018, the Department of Human Services and the Department of Health began participation in the Centers for Disease Control and Prevention (CDC) 6118 Initiative to implement the coverage of CDC-recognized Diabetes Prevention Programs (DPP) in the MA program. Starting in calendar year 2019, the MCOs were contractually required to implement a DPP pilot consistent with the CDC's DPP guidelines. DPP is an evidence-based lifestyle change program designed for individuals 18 years or older who have prediabetes or are at-risk for type 2 diabetes, but who do not already have diabetes. The year-long program is delivered in-person, online, or through a combination approach using group support. The goal of the program is to increase prediabetic individuals' knowledge of proper nutrition and eating habits, which can lead to weight loss, decreased Hemoglobin A1C levels, and decreased likelihood of becoming a type 2 insulin-dependent diabetic in the future. DPP is described in detail in an earlier section of this report.¹⁵⁶ On July 1, 2019, DHS began enrolling CDC-recognized DPP providers in the MA program so that they could begin to contract with the MCOs as in-network providers. As MCO network providers, these DPP providers will play an integral role in the MCOs' Diabetes Prevention Programs required within their community-based care management programs.

Lastly, two of the MCOs report that they are currently participating with the Health Promotion Council (HPC) and Pennsylvania Community Living Initiative (PA CLI) Leadership Sustainability Group and the National Diabetes Prevention Program Virtual Learning Collaborative Statewide Engagement surrounding diabetes prevention programs.¹⁵⁷

Office of Long-Term Living (OLTL)

The Office of Long-Term Living administers a new mandatory managed care program for dually eligible individuals (Medicare and Medical Assistance), older adults, and individuals with physical disabilities, called the Community HealthChoices (CHC). The program is referenced nationally as a managed long-term services and supports program (MLTSS). Eligible individuals enroll with a managed care organization (MCO), and the MCO manages and coordinates the individual's services and benefits. CHC will be phased in across the state over three years using the five geographic HealthChoices zones. The program took effect in 14 counties in the Southwest on January 1, 2018, and in 5 counties of the Southeast region on January 1, 2019. The third and final phase of the program will expand CHC to the remaining 48 counties effective January 1, 2020.

The Standards of Care set forth for the CHC program include the following:

- a) Maintenance of participants' blood sugars and Hemoglobin A1c levels within ADA guidelines both as inpatients and outpatients;
- b) Maintaining appropriate diabetic diets and medications.

¹⁵⁶ See page 29.

¹⁵⁷ Information on HealthChoices education and outreach was reported to DHS by each individual MCO in June 2019.

Some perceived challenges include

- a) Consistent monitoring of patients' blood sugar level and also their A1c level, especially as they transition from settings such as hospitals and nursing facilities to a home- and community-based setting;
- b) Maintaining diabetic dietary compliance;
- c) Specific challenges involved in the CHC population who carry a diagnosis of schizophrenia as this group is noted to have a high prevalence of diabetes.

Strategies to address the above-mentioned challenges include the following steps:

- a) All CHC MCOs have developed individual person-centered service plans for every participant deemed nursing facility clinically eligible (NFCE), and these plans address diabetic education, monitoring, and medication usage and compliance.
- b) All CHC MCOs are reporting to both DHS and NCQA, annually, on the number of participants who are getting appropriate blood sugar and Hemoglobin A1c checks.

New initiatives include

- a) Several Dual Eligible Special Needs Plans (D-SNPs) and two of the three CHC plans have contracted with MANNA (Food is Medicine) to provide their participants with diabetes-appropriate meals as they transition from hospital to community settings.
- b) Each CHC MCO has begun to implement performance improvement projects which have clear strategies to improve care coordination and nursing facility transitions. These strategies include dietary education as well as compiling a problem list (diabetes to be listed) and medication reconciliation (diabetic medications in particular) by health plan medical directors or teams.
- c) For the participants who have a diagnosis of schizophrenia, the Office of Long-Term Living (OLTL) and the Office of Mental Health and Substance Abuse Services (OMHSAS) are developing a strategy to require all CHC-MCOs and behavioral health MCOs (BHMCOs) to report on the number of participants who have their A1c checked at appropriate intervals.

YMCA'S DIABETES PREVENTION PROGRAM

YMCAs play an important part in chronic disease prevention. Pennsylvania Ys, in particular, strive to increase awareness of type 2 diabetes and prediabetes and to offer people tools to reduce their risk for developing this disease.

The YMCA's Diabetes Prevention Program uses a CDC-approved curriculum and is part of the CDC-led National Diabetes Prevention Program. This is a long-term program that encourages healthier eating habits and increasing social activity; it is described in detail in an earlier section of this report.¹⁵⁸ The YMCA's Diabetes Prevention Program is available to all qualifying individuals regardless of their insurance status and their Y membership or lack thereof.

In the past two years, the YMCA's Diabetes Prevention Program has been growing in Pennsylvania, with more Ys in various parts of the Commonwealth offering it and more people taking advantage of it.

In 2018-2019, the following Pennsylvania YMCAs have offered DPP:

- Berwick Area YMCA
- Carbondale YMCA
- Franklin/Grove City YMCA
- Greater Philadelphia YMCA
- Greater Scranton YMCA
- Greater Valley YMCA
- Harrisburg Area Metropolitan YMCA
- Lancaster Family YMCA
- North Penn YMCA
- Richard G. Snyder YMCA
- Uniontown YMCA
- Valley Points Family YMCA
- Wilkes-Barre YMCA
- YMCA of Greater Brandywine
- YMCA of Greater Erie
- YMCA of Greater Pittsburgh
- YMCA of York and York County.¹⁵⁹

¹⁵⁸ See Page 29.

¹⁵⁹ Data provided to the Joint State Government Commission by Ms. Megan Maurer, Program Director of Healthy Living, Harrisburg Area YMCA, in the personal e-mails of August 6 and August 7, 2019.

The following graph presents data from the YMCA's DPP, with the exception of Uniontown Y, which is new to the program and had not started it in time to be included.

It is worth noting the high average retention rate for the YMCA's DPP program – over 86 percent.

Some YMCAs gave DPP participants a free membership to the YMCA to encourage visits to the center and physical activity. At some sites, Lifestyle Coaches provided trackers at each session with positive comments to increase participants' motivation.¹⁶⁰

Several other Pennsylvania YMCAs are currently offering DPP separately from the YMCA Diabetes Prevention Program:

- Blair Regional YMCA
- Butler YMCA
- Chambersburg Memorial YMCA
- Meadville YMCA
- New Castle Community YMCA
- Shenango Valley YMCA.¹⁶¹

¹⁶⁰ The Research and Evaluation Group, PHMC. *Diabetes Prevention Program (DPP) Evaluation Quarterly Report. SFY18-19. Quarter 3.* April 2019.

¹⁶¹ Ibid.



Technical Advisor

Associations

Clear All Filters

State

Total Enrolled

All

Pennsylvania

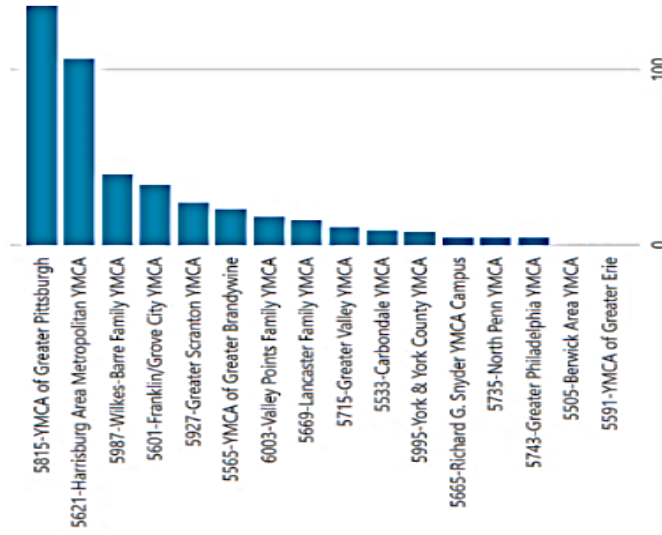
24

427

YMCA

All

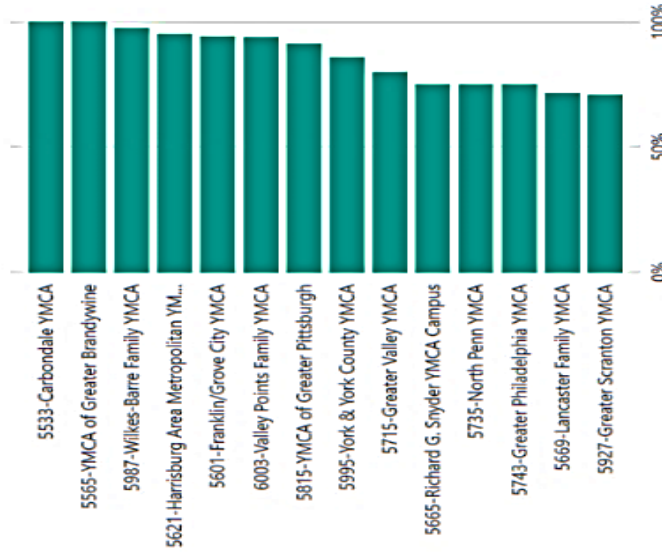
Participants Enrolled



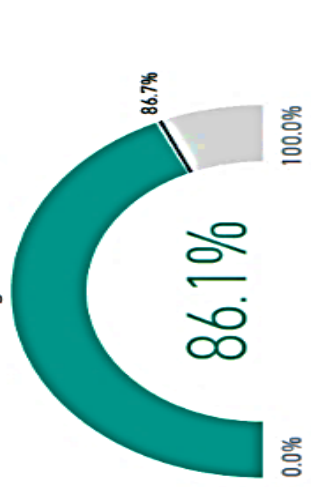
Average Participants



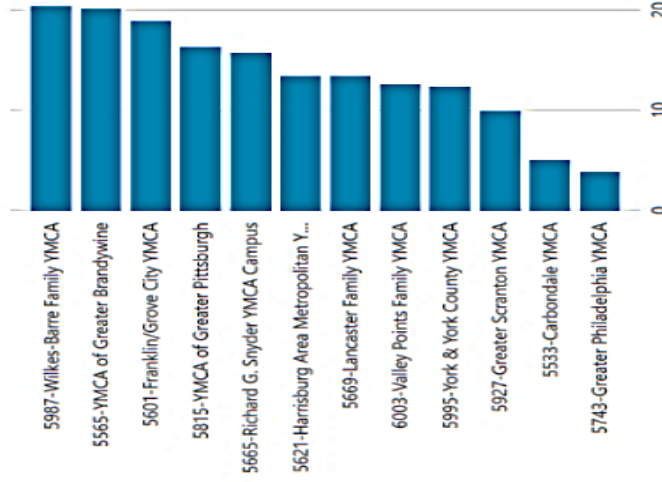
Retention



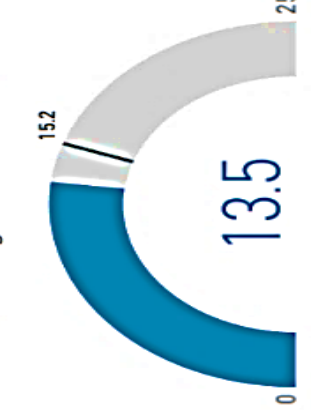
Average Retention



Attendance



Average Attendance



RECOMMENDATIONS

General Assembly Responses

Institute policies that respect the physician-patient relationship's role in quality care and acknowledge the individual health care needs of people with diabetes.

- Adopt step therapy regulations for patients with diabetes and other chronic diseases mandating that health plan policies should rely on current clinical data, be transparent, and offer clear and concise exceptions to step therapy protocols based on medical necessity.
- Pass legislation addressing non-medical switching.

Take steps to improve affordability of insulin and other essential medications. Disincentivize price increases for insulin and other essential medications.

- Mandate that pharmacy benefit managers (PBMs) receive a flat fee for service for providing administration of each prescription drug claim, regardless of the drug price, rather than being paid a percentage of the drug price as a rebate.
- Pass legislation that increases transparency into PBM pricing practices.
- Consider other measures that would curtail PBMs' power in the drug supply chain.
- Pass legislation banning all "gag rules" and allow pharmacists to tell all patients if they could be paying less for their medications.
- Mandate that PBMs and health plans use rebates to lower costs for insulin and other essential medications at the point of sale for people with diabetes.

Other Recommendations

Medical and educational institutions, social service agencies, and the media should continue their diabetes awareness campaign.

Providers and health care systems should prioritize the delivery of patient-centered care.

Doctors should make treatment decisions that are timely, rely on evidence-based guidelines, and are made collaboratively with patients, taking into account their individual preferences, prognoses, and comorbidities.

All people with type 2 diabetes should be offered access to ongoing Diabetes Self-Management Education and Support Programs (DSMES).

Approaches to diabetes should be aligned with the Chronic Care Model, emphasizing productive interactions between a prepared proactive care team and an informed activated patient.

APPENDICES

APPENDIX A
House Resolution No. 936 of 2014

PRIOR PRINTER'S NO. 3907

PRINTER'S NO. 4098

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 936 Session of
2014

INTRODUCED BY OBERLANDER, LONGIETTI, BAKER, BOBACK, V. BROWN,
CALTAGIRONE, CAUSER, COHEN, D. COSTA, DONATUCCI, FLECK,
GIBBONS, GINGRICH, GODSHALL, GRELL, GROVE, HARHART, HEFFLEY,
KAUFFMAN, KILLION, KIRKLAND, KOTIK, KULA, LUCAS, MAJOR,
MENTZER, MILLARD, MURT, MUSTIO, O'BRIEN, READSHAW, SONNEY,
SWANGER, TALLMAN, THOMAS, TOBASH, WHITE, YOUNGBLOOD, SCHLEGEL
CULVER, JAMES, BENNINGHOFF, BRIGGS, PICKETT, WATSON,
McCARTER, PYLE AND QUINN, JULY 1, 2014

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES,
AS AMENDED, SEPTEMBER 17, 2014

A RESOLUTION

1 Directing the Joint State Government Commission, in
2 collaboration with certain other State departments and
3 agencies, to develop a report on diabetes and to issue the
4 report to the House of Representatives.

5 WHEREAS, More than 990,000 adults in this Commonwealth have
6 been diagnosed with diabetes; and

7 WHEREAS, An estimated 517,000 Pennsylvanians are undiagnosed;
8 and

9 WHEREAS, An estimated 3.27 million Pennsylvanians are at risk
10 of developing diabetes; and

11 WHEREAS, Diabetes and its complications are the seventh
12 leading cause of death in this Commonwealth; and

13 WHEREAS, Diabetes will cost Pennsylvanians an estimated ~~\$1.7~~ <--
14 \$14.7 billion in 2015 and an estimated \$18.4 billion by the year <--
15 2025; and

1 WHEREAS, Statistics show that with appropriate management and
2 early identification, costs related to diabetes can be
3 significantly reduced; therefore be it

4 RESOLVED, That the House of Representatives direct the Joint
5 State Government Commission to submit a report on diabetes that
6 identifies goals and benchmarks and includes plans to reduce the
7 incidence of diabetes, improve diabetes care and control
8 complications associated with diabetes; and be it further

9 RESOLVED, That the Joint State Government Commission develop
10 the report on diabetes in collaboration with all of the
11 following:

- 12 (1) The Department of Health.
- 13 (2) The Department of Public Welfare.
- 14 (3) The Department of Education.
- 15 (4) The State Employees' Retirement System.
- 16 (5) The Health Care Containment Council.
- 17 (6) Any additional State departments or agencies the
18 commission deems appropriate to develop, research and prepare
19 the report;

20 and be it further

21 RESOLVED, That the Joint State Government Commission assess
22 the financial impact and reach diabetes has on the residents of
23 this Commonwealth and the State departments and agencies
24 collaborating on the report, and that the assessment include all
25 of the following:

- 26 (1) The number of individuals with diabetes impacted or
27 covered by the State department or agency.
- 28 (2) The number of individuals with diabetes and family
29 members impacted by prevention and diabetes control programs
30 implemented by the State department or agency.

1 (3) The financial toll or impact diabetes and its
2 complications placed on State department or agency programs.

3 (4) The financial toll or impact diabetes and its
4 complications placed on the State department or agency
5 programs in comparison to other chronic diseases and
6 conditions;

7 and be it further

8 RESOLVED, That the Joint State Government Commission conduct
9 an assessment of the benefits of implemented programs and
10 activities aimed at controlling diabetes and preventing the
11 disease, and that the assessment include the amount and source
12 for any funding from the Federal Government and the General
13 Assembly for programs and activities aimed at reaching those
14 with diabetes; and be it further

15 RESOLVED, That the Joint State Government Commission provide
16 a description of the level of coordination existing between
17 State departments and agencies on activities, programmatic
18 activities and messaging on managing, treating or preventing all
19 forms of diabetes and its complications; and be it further

20 RESOLVED, That the Joint State Government Commission provide
21 detailed plans and recommendations for the control and
22 prevention of diabetes for consideration by the General
23 Assembly, and that the plans and recommendations do all of the
24 following:

25 (1) Identify proposed action steps to reduce the impact
26 of diabetes, pre-diabetes and related diabetes complications.

27 (2) Identify expected outcomes of the action steps
28 proposed in the following biennium.

29 (3) Establish benchmarks for controlling and preventing
30 relevant forms of diabetes; and be it further

1 RESOLVED, That the Joint State Government Commission develop
2 a detailed budget blueprint identifying needs, costs and
3 resources required to implement the plans and recommendations of
4 each department or agency, and that the blueprint include a
5 budget range for all options presented in the recommendations
6 identified by each department or agency for consideration by the
7 General Assembly; and be it further

8 RESOLVED, That the Joint State Government Commission provide
9 the initial report on the estimated number of individuals with
10 diabetes, pre-diabetes or related diabetes ~~within~~ WHO ARE SERVED <--
11 BY each department or agency and any additional information the
12 commission deems appropriate to the General Assembly by March 1,
13 2015; and be it further

14 RESOLVED, That the Joint State Government Commission submit a
15 ~~final~~ COMPREHENSIVE report on the items listed in this <--
16 resolution to the Diabetes Caucus of the House of
17 Representatives and the Human Services Committee AND THE HEALTH <--
18 COMMITTEE of the House of Representatives by September 15, 2015,
19 and by September 15 of each odd-numbered year thereafter
20 following the release of the initial report.

1 WHEREAS, 3.5 million people in Pennsylvania have prediabetes
2 with blood glucose levels higher than normal but not yet high
3 enough to be diagnosed as diabetes; and

4 WHEREAS, Every year an estimated 71,000 individuals are
5 diagnosed in this Commonwealth with diabetes, including a
6 dramatic increase in the incidence of type 1 diabetes; and

7 WHEREAS, Diabetes is the seventh leading cause of death in
8 this Commonwealth; and

9 WHEREAS, Approximately 1.25 million American children and
10 adults have type 1 diabetes; and

11 WHEREAS, Type 1 diabetes, previously known as juvenile
12 diabetes, can be diagnosed at any age; and

13 WHEREAS, Approximately 5% of people with diabetes have type 1
14 diabetes; and

15 WHEREAS, Children and adults can learn to manage type 1
16 diabetes with the help of insulin therapy and other treatments
17 and live long, healthy lives; and

18 WHEREAS, In an effort to focus the nation's attention on this
19 ever-growing disease, November has been recognized as "National
20 Diabetes Month"; and

21 WHEREAS, This year's theme is "Everyday Reality," because for
22 those who've been diagnosed, diabetes impacts nearly every
23 decision they make daily, from what they'll eat, wear and do and
24 how they'll take care of themselves, the 24/7 burden of diabetes
25 management often being misunderstood; and

26 WHEREAS, This awareness campaign is intended to demonstrate
27 the everyday reality of diabetes from the point of view of
28 people living with diabetes or caring for someone with diabetes;
29 and

30 WHEREAS, Advocates nationwide join together as a united

1 community during this month to raise awareness, promote ongoing
2 diabetes education and support those living with diabetes; and

3 WHEREAS, Continuing advocacy and healthy disease management
4 promotes the vision of a life free of diabetes and all of its
5 burdens; therefore be it

6 RESOLVED, That the Senate recognize the month of November
7 2018 as "National Diabetes Month" in Pennsylvania and join the
8 movement to stop diabetes.

APPENDIX C
State Drug Utilization Data (Pennsylvania)

State Drug Utilization Data (Pennsylvania) 2018		
Product Name	Units Reimbursed	Medicaid Amount Reimbursed
ADMELOG SO	308,464	\$9,150,366.62
ADMELOG VI	138,506	3,162,774.11
APIDRA 10M	78,000	2,070,954.88
APIDRA 3ML	188,109	6,481,916.43
BASAGLAR	2,064,789	43,946,456.10
FIASP FLEX	741	14,927.80
FIASP VIAL	2,950	50,252.40
HUMALOG	1,088,020	25,898,372.64
HUMALOG KW	1,227,326	42,692,029.05
HUMALOG MI	293,664	9,776,840.21
HUMULIN 70	222,763	4,435,442.45
HUMULIN N	116,286	2,256,346.53
HUMULIN R	118,272	5,394,352.08
LANTUS 10M	265,412	6,534,511.68
LANTUS 3ML	756,316	18,866,943.38
LANTUS NOV	--	--
LANTUS SOL	--	--
NOVOLIN 70	66,710	728,801.97
NOVOLIN N	28,810	311,407.76
NOVOLIN R	12,592	121,340.59
NOVOLOG 10	628,029	12,217,093.46
NOVOLOG MI	107,314	3,495,623.62
NOVOLOG PE	572,814	17,536,827.50
TOUJEO MAX	2,318	190,299.55
TOUJEO SOL	180,121	14,400,508.91
TRESIBA FL	89,865	3,567,920.14
Total	8,558,190	\$233,302,309.86
Center for Medicaid and CHIP Services. <i>State Drug Utilization Data</i> (updated July 23, 2019), https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html (accessed August 23, 2019).		