

# POLICY BRIEF

## Obesity and Type 2 Diabetes:

Prevention and Treatment Together Remain Critical Priorities to Protect the Health of Americans and Sustain Long-Term Affordability of Health Care



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## Support

NEHI wishes to acknowledge **Novo Nordisk** for providing financial support that made NEHI's research and report possible.

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NEHI consults with its broad membership, and conducts independent, objective research and convenings, to accelerate these innovations and bring about changes within health care and in public policy.

# Introduction

About 40 percent of American adults have obesity. By some estimates at least 50 percent of Americans will have obesity by 2030. Obesity-related disease and disability is now thought to be a major factor in the unprecedented decline of life expectancy among Americans.<sup>1</sup> The medical costs of treating obesity-related conditions range around \$1,900 per every person in the U.S. (2014 dollars), although some estimates range much higher.<sup>2</sup>

The rising rate of obesity has pulled up rates of type 2 diabetes in its wake. While not all persons with obesity will develop type 2 diabetes, about 85 percent of persons with type 2 diabetes have obesity. Approximately 30 million Americans, over 9.3 percent of the U.S. population, now have diabetes. The American Diabetes Association estimates that as much as 25 percent of all U.S. health care spending can be attributed to diabetes-related causes. These costs grew by over 26 percent in just five years, 2012-2017.<sup>3</sup>

Now it appears that rising rates of obesity and type 2 diabetes may be claiming more lives and driving up health care costs by reversing some of the most hard-fought gains in U.S. public health, the long-term gains against heart disease, stroke, and other cardiovascular diseases. One recent analysis suggests that improvements in cardiovascular health are some of the few long-term trends in public health and medicine that have exerted downward pressure on Medicare and other U.S. health care spending.<sup>4</sup> But clinicians now see an “alarming resurgence” in cardiovascular conditions that may be attributable to rising rates of obesity and type 2 diabetes among younger adults.<sup>5</sup>

The news is not all bad. While the percentage of Americans with obesity is growing, the percentage of Americans regarded as overweight, but without obesity is not.<sup>6</sup> The Centers for Disease Control and Prevention (CDC) recently reported that the annual count of newly-diagnosed cases of diabetes has fallen 35 percent since 2009, a drop that may reflect greater awareness and treatment of diabetes, boosted by expanded health insurance coverage under the Affordable Care Act (ACA).<sup>7</sup> A new generation of non-insulin diabetes medications are now known to reduce risks of cardiovascular disease, and may reduce obesity as well.

Yet the CDC estimates that over 84 million Americans now live in a state of “pre-diabetes” that can progress into full-blown diabetes within five years of onset.<sup>8</sup> Expanded Medicaid and private health insurance expansions extended under the Affordable Care Act remain under threat, while Americans consistently rate costs of health insurance and out-of-pocket costs of medications as among the single most important issues facing the country. Medications for type 2 diabetes and related conditions are among the most heavily prescribed drugs in U.S. health care.

Media attention to obesity prevention, nutrition and fitness may have crested in the early years of ACA implementation with new policies such as mandated calorie counts on fast food menus and initiatives such as the Obama White House’s “Let’s Move” campaign. But it is clearer than ever that more aggressive national action on obesity prevention and treatment, including access to evidence-based prevention and treatment for persons at risk from type 2 diabetes, is a critical priority for both public health and for the success of health care reform.

# Six Key Developments for Public-Policy Makers

## 1 | The obesity health crisis, which began 40 years ago, is now a global phenomenon.

In the mid-1970s obesity rates that had ranged below 20 percent for decades began to climb at a distinctly higher rate and are now double the rate seen in 1980.<sup>9</sup> Modern science suggests that around 50 percent of an individual's susceptibility to obesity may be genetic in origin but activated by interaction with the individual's environment.<sup>10</sup> It is unlikely that the human genome has evolved towards obesity in only 40 years; research suggests that the environment itself has become more "obesogenic" instead. Factors that may have rendered the environment more obesogenic include the radically increased prevalence of highly-processed, energy-dense foods (such as fast food) and sugary drinks that represent the most affordable food sources for many people, and reduced opportunities for safe, regular physical activity. These factors could explain why obesity has risen markedly among all socioeconomic and racial/ethnic groups in the U.S. but driven significant health disparities among low-income and historically-marginalized groups such as African Americans and Latinos.<sup>11</sup>

Leading analysts now consider obesity not only as a pervasive health risk (a pandemic), but part of a global "syndemic" that will be continuous and self-reinforcing throughout the world unless radical action is taken to reverse it. The obesity syndemic is a product of the increased reliance on energy-dense food of poor nutritional value (under-nutrition), climate change, and obesity itself, since obesity reinforces pressure to produce cheap, low-nutrition foods, the production of which stresses the environment while also reducing acreage for the growth of more nutritious food sources.<sup>12</sup>

## 2 | "Chemistry, not character"<sup>13</sup>: Despite growing evidence on the genetic and environmental drivers of obesity, the social stigma of obesity remains a major impediment to action.

Public health initiatives to prevent and reduce unhealthy weight have engendered serious political opposition that is often justified on the grounds that obesity is a lifestyle choice, a product of the individual's free will.<sup>14</sup> Yet biological research suggests that obesity is predominantly a product of "chemistry, not character." Research suggests that even when people commit themselves to serious dieting or weight-loss measures, powerful biological processes kick-in to pull an individual back towards higher levels of weight. From an evolutionary standpoint, the human body seems to have adapted itself to avoid starvation by hoarding energy, not to maintain a precise body weight.<sup>15</sup>

The stigma of obesity has also been shown to be a source of bias that inhibits physicians and other health care providers from offering evidence-based help to individuals at risk for or from obesity and inhibits greater insurance coverage and utilization of evidence-based obesity medicine.<sup>16</sup>

For these reasons the American Medical Association voted in 2013 to declare obesity a disease, as have the American Association of Clinical Endocrinologists, the Endocrine Society, and the American College of Cardiology.<sup>17</sup> Each of these societies now views obesity as a chronic, treatable disease in which the goal of treatment is to improve health and reduce the risk of health complications, and not to achieve obesity reduction for a cosmetic effect, (i.e. “look thin.”). Scientific evidence suggests that safe and appropriate weight loss achieves good health outcomes in a “dose-related” manner. For example, even modest weight losses of just 5 percent of body weight can slow or avert the progression of type 2 diabetes.<sup>18</sup>

**3** | **There is strong consensus that addressing social determinants of health is key to achieving and sustaining healthy weight among individuals at risk. But whether this is financed through public health programs or from within the health care system is still an open question.**

Obesity researchers have catalogued a vast number of factors that influence an individual’s ability to prevent unhealthy weight gain, or to achieve and sustain healthy weight loss over time and thus overcome biological factors that may induce a recurrence of weight gain.<sup>19</sup> These factors are primarily located outside the confines of a physician’s office or health care clinic, or what the American Association of Clinical Endocrinologists has described as the “overwhelming socioeconomic contextualization” of obesity.<sup>20</sup> Key factors include: the cost and ease of accessing nutritious food in a neighborhood and workplace, and the opportunities for safe, reliable physical activity throughout the day, such as the ability to walk to and from work or to and from schools.

Fundamental U.S. health care reforms are grounded in these insights. Both public and private sector health care payers in the U.S. continue to move health care payments away from traditional fee-for-service reimbursement and towards value-based models that reward measurable improvements in patient health. About 60 percent of all provider payments are now linked in some way to a quality-based measure.<sup>21</sup> Payment models such as Medicare’s Accountable Care programs and similar private-sector models push health care providers towards population health management in which improvements across all patients with a specific condition – diabetes especially – are targeted and measured. The front-line practitioners in population health management are primary care physicians and primary care teams organized and often accredited as patient-centered medical homes (PCMH). The PCMH model is in turn based in large part on a seminal clinical care model of practice known as the Chronic Care Model.<sup>22</sup> Under the Chronic Care Model each patient’s care is closely coordinated by primary care teams, tailored to address key personal and socioeconomic characteristics of the patient, and coordinated with community-based services outside the confines of the physician office or clinic.

In the view of the American Academy of Clinical Endocrinologists, optimal, evidence-based care for persons with diabetes is grounded in a diabetes-specific version of the Chronic Care Model, the model of care that has proven to be a foundation for such innovations in care delivery as the patient-centered medical home (PCMH). The diabetes chronic care model encompasses a broad spectrum of tools for treatment and prevention, including tools for patient-self-care and for accessing services in the community. In July 2019 the Academy elaborated on this standard in greater detail by defining principles of “transcultural” diabetes care to address socioeconomic and cultural factors that are shaped by differing biological characteristics among African

Americans, Latinos, Asian-Americans and Native Americans, as well as the impact of culture and bias.<sup>23</sup>

Achieving this optimal standard of care depends crucially on health insurance that supports and reimburses team-based care. It also depends crucially on the existence of effective, evidence-based and community-based services to which clinicians can refer patients at risk for obesity and type 2 diabetes. Here there is promising news, but much work to be done.

Extensive research sponsored by the CDC has demonstrated that intensive lifestyle interventions in support of good nutrition and physical activity can prevent or delay progression of type 2 diabetes among as many as 58 percent of people otherwise at risk from the disease.<sup>24</sup> A resulting model, the Diabetes Prevention Program (DPP), was successfully tested in YMCAs across the country and achieved a significant milestone in early 2018 when the Medicare program approved coverage of certified DPP programs as a Medicare benefit under the Medicare Part B program.

With Medicare coverage now in place, local YMCAs and some other would-be providers of Medicare DPP have been faced with new tasks: learning to operationalize the DPP by achieving National DPP recognition and qualifying as Medicare suppliers and managing the requisite documentation and billing processes. As Medicare DPP suppliers emerge around the country, gaps are appearing, as few suppliers come forward in rural communities and some other areas where obesity and type 2 diabetes rates are high.

Additionally, online, virtual delivery of the Medicare DPP is not covered by Medicare at this point in time, even though the CDC does recognize virtual DPP providers. This has prompted the president of the American Medical Association to call on CMS to extend Medicare coverage to virtual DPP services.<sup>25</sup> And although some private payers, public employee health plans and a handful of state Medicaid programs now provide coverage for the National DPP, many payers do not.<sup>26</sup> This uneven coverage presents an added challenge to sustaining DPP programs and ensuring access for individuals with prediabetes.

Whether these efforts will be commensurate with the sheer scale of challenges associated with the growing prevalence of obesity and the rising cost of treating type 2 diabetes is an open question. Some health care provider groups openly question whether funding diverted from medical services will ever be sufficient to effectively address social determinants of health among their at-risk patients.<sup>27</sup> Federal funding for public health and many community-based services has fallen below historical levels and is expected to decline further over the next decade. Federal non-defense discretionary spending is currently at about 3.2 percent of U.S. Gross Domestic Product (GDP), below the 50-year average of 3.8 percent, and the Congressional Budget Office projects it will fall to 2.5 percent of GDP by 2029.<sup>28</sup> Federal programs specifically directed at low-income persons address many of the social determinants of health, including education, housing and food assistance. Federal spending on non-health programs for low-income persons has declined below the levels reached in the Great Recession (2007-2009) and is projected to fall below 40-year averages by 2029. Declines in federal spending for low-income programs have more than offset spending increases on health programs for low-income people.<sup>29</sup>

Supportive public policy faces a similar challenge. In the last decade numerous state and local public health agencies launched initiatives and policies on healthy eating and physical activity, initiatives that required relatively little in public spending but complemented the movement towards population health management in the health care system.

These include initiatives to promote healthy nutrition and physical activity, such as stronger standards for school breakfast, lunch and snacks, urban agriculture, adoption of “complete street” plans that facilitate walking and bicycling, and other measures. Other public health initiatives have aimed to help individuals utilize SNAP food assistance at local farmers’ markets. New federal policies requiring the posting of calorie counts on restaurant menus, were enacted as part of the Affordable Care Act. The same law established the Prevention and Public Health Fund which enabled the federal government to provide new resources to support these and other state and local initiatives. However, as The Trust for America’s Health and the Robert Wood Johnson Foundation noted in their most recent State of Obesity in the United States report, “Some of these efforts (have since been) delayed or weakened, preventing full implementation and thus denying researchers the ability to effectively study which efforts best help people maintain a healthy weight.”<sup>30</sup> Congress has diverted funds from the Prevention and Public Health Fund, and legislation has been introduced and considered that would eliminate it altogether. Congress and most recently the Department of Agriculture have acted to delay or weaken nutritional standards for school meals, related to the use of whole grains, low-fat milk, and sodium content. The beverage industry has sought to rollback local sugar-sweetened beverage taxes and have achieved some limited success.<sup>31</sup>

## 4 | Clinical experts are making a stronger case for medical treatment of obesity among patients at high-risk.

As science continues to strengthen the case that obesity is a disease, the case for treating obesity with medications has grown stronger. Recommendations issued by the nation’s endocrinology and cardiology specialty societies, as well as recommendations from the American Diabetes Association and American Heart Association, now point more strongly towards use of appropriate medications among individuals with obesity who cannot achieve or sustain a meaningful weight loss with diet and physical activity interventions alone. Diet and physical activity are still recommended for nearly all patients, but medications, when used appropriately and under physician supervision, can help patients with obesity who are at risk for diabetes avoid or delay a progression to diabetes, and help patients with diabetes avoid or delay a progression that necessitates intensified treatment, including a progression to use of insulin. Insulin treatment induces a weight gain among many patients, creating a “vicious circle .... requiring more intensive diabetes medication treatment, which then contributes to further weight gain and worsening of diabetes.”<sup>32</sup>

Medications for weight loss generally produce modest reductions in weight, but as noted above, modest reductions have been shown to yield meaningful reductions in risks for diabetes and for cardiovascular disease.<sup>33</sup>

Five medications are FDA-approved for the treatment of obesity, including one (liraglutide) first approved in 2010 for treatment of type 2 diabetes. Liraglutide is a so-called GLP-1 (glucagon-like peptide 1 receptor agonist) medication, a non-insulin pharmaceutical. Several GLP-1 medications, manufactured by several companies and offered in varying formulations (some combined with insulins), are now on the market as treatments for type 2 diabetes; all of them are subjects of active clinical research for approval as weight loss medications. A second class of non-insulin medications approved for treatment of type 2 diabetes, the so-called SGLT2 (sodium glucose co-transporter) medications, also have weight loss effects and are under investigation for approval as weight loss agents as well. Metformin, a generic, oral medication often prescribed

as the first anti-diabetes medication for newly diagnosed patients, also appears to cause weight loss, although it is not FDA-approved as a weight loss medication.<sup>34</sup>

Despite growing evidence to support use of medications to reduce obesity, many physicians remain reluctant to prescribe these medications. Their reluctance may stem from the memory of unsafe and ineffective “diet pills” such as amphetamines, in use 20 or more years ago, and the lingering belief that obesity is the responsibility of the patient, not the provider.<sup>35</sup>

Weight loss medications are also poorly covered in many Medicaid and state-level ACA exchange health insurance plans and excluded from coverage altogether under Medicare Part D.<sup>36</sup> The GLP-1 and SGLT2 medications are exceptions, in that they are covered as treatments for type 2 diabetes, but access to both types of medication may be subject to limitations, such as prior authorization by health insurers.

## **5 Emerging clinical practice also favors greater use of non-insulin medications among persons with type 2 diabetes because these medications do not induce weight gain, and they reduce risks of cardiovascular disease.**

In a separate but related development to new clinical recommendations on treatment of obesity, clinical recommendations on treatment of type 2 diabetes are embracing broader and more intensive use of non-insulin medications as treatments that reduce cardiovascular risk. Evidence emerging from clinical trials shows that patients with diabetes who use these medications are more able to maintain and sometimes lose weight in the process.

Two classes of non-insulin medication, the GLP-1 and SGLT2 medications, reduce risks of cardiovascular disease among patients with type 2 diabetes. Large scale clinical trials originally ordered by the FDA to identify if these drugs created greater risks of heart attack and stroke have proven an opposite effect among patients with type 2 diabetes when the drugs are appropriately prescribed. Studies have shown a significant impact on patient outcomes, including reduced hospitalizations and reduced patient mortality. As a result, clinical recommendations for the treatment of type 2 diabetes now favor broader and more aggressive use of the GLP-1 and SGLT2 medications both among obese patients at risk for developing type 2 diabetes or at risk for intensified treatment, and among patients with type 2 diabetes who are at high risk for heart attack, stroke and related cardiovascular conditions. Updated and more aggressive clinical practice advice among endocrinologists and cardiologists now call for “a paradigm shift” in the treatment of cardiovascular risks among patients with type 2 diabetes and greater reliance on the use of the GLP-1 and SGLT2 medications.<sup>37</sup>

## **6 New tools and techniques of population health management could offset the costs associated with more intensive prevention and treatment of obesity and type 2 diabetes. Active experimentation is needed to demonstrate how to target new spending towards individuals at highest risk.**

Many of the prevention and treatment recommendations summarized above will require new investment and new spending at a time when the health care system is under ever-growing pressure to control costs. In many ways this is a dilemma that the health care system cannot avoid, since ignoring the prevention and treatment challenge will only contribute to a build-up of more cost (and more illness). The recent history of bariatric surgery offers some context. Bariatric surgery is now generally accepted as a guideline-based intervention that not only reduces severe obesity but can reduce the intensity of treatment among patients with obesity and type 2 diabetes, and even eliminate the need for use of insulin altogether among some patients. Current clinical practice guidelines not only recommend bariatric surgery among patients with Class III (high-risk) obesity, but among patients with Class II (moderate risk) and even Class I (low risk) obesity, if standard medical treatment and lifestyle interventions are not sufficient to control hyperglycemia.<sup>38</sup> Nearly 230,000 bariatric surgeries were performed in the U.S. in 2017, an increase of 44 percent in only 6 years (2011-2017), according to the American Society for Metabolic and Bariatric Surgery.<sup>39</sup> Earlier access to evidence-based prevention interventions such as the Diabetes Prevention Program, and earlier and broader use of appropriate medications, may prove more cost effective as obesity becomes more prevalent and larger and larger numbers of patients are recommended for surgery or suffer high-risk conditions such as heart attack, stroke or kidney disease.

Nevertheless, broader use of new tools and techniques could ensure that intensive prevention and treatment is directed towards those individuals at highest risk for the development or progression of obesity and type 2 diabetes and resulting risks such as cardiovascular disease. Among the leading tools and techniques:



**Risk stratification:** Risk stratification is a common practice among health care providers operating under payment models that reward population health management goals, reimburse providers for achieving overall budget targets, or both. Mature Accountable Care Organizations (ACOs) have demonstrated a variety of approaches for risk-stratifying or segmenting their patient populations in order to target the intensity of services according to the level of need or health risk among patients.<sup>40</sup>



**Digital health tools:** A new generation of small, wearable and minimally intrusive continuous glucose monitors (CGM devices) are rapidly transforming care for persons with type 1 diabetes and making rapid inroads among patients with type 2 diabetes as well.<sup>41</sup> The new CGM devices reduce or eliminate the need for patients to test their blood glucose levels by finger stick, and can generate alerts on the patient's glucose levels that allow the patient to take action to avert hypoglycemia or hyperglycemia. The CGM devices can be configured to transmit data directly from a smartphone to an Internet cloud, and display data to both the patient and caregivers. The devices now offer the possibility of better, more personalized diabetes management for patients that could result in long-term reduction of complications.



**Value-based payment arrangements:** Thus far, a handful of health insurers and pharmaceutical manufacturers have executed contracts that link part of reimbursement to measurable improvements in patient outcomes or reduction of health risks with use of GLP-1 and SGLT2 medications. Greater adoption of value-based arrangements by payers and manufacturers likely depends in part on changes in federal policy.<sup>42</sup> New capabilities to transmit CGM data to providers may render value-based contracts more feasible by reducing the cost of monitoring patient health; a recent contract executed by Blue Cross Blue Shield of Minnesota covers the purchase of a CGM device itself with a value-based arrangement linked to improved patient diabetes self-management.<sup>43</sup>

# Conclusion

## Re-energizing the National Agenda on Prevention and Treatment of Obesity and Type 2 Diabetes

To address growing obesity rates and to prevent or delay progression to type 2 diabetes, action will be needed to:

- Address obesogenic nutritional and physical activity patterns through public health regulation and programming;
- Broaden access to structured intensive lifestyle interventions in clinical practice; for the 84 million Americans with prediabetes, this can start with dramatically broader screening, referral and participation in the Diabetes Prevention Program (DPP) or similar programs;
- Support appropriate use of obesity medication, in conjunction with lifestyle interventions, to manage obesity and to reduce progression to type 2 diabetes;
- Support appropriate use of non-insulin medications to manage type 2 diabetes among individuals at risk for heart disease, stroke and other cardiovascular diseases.

Several federal agency initiatives and pending legislative opportunities in Congress and the states offer potential levers for promoting action on obesity and type 2 diabetes in the months ahead. They include:

1

### **Extend coverage of the Diabetes Prevention Program**

While Medicare now covers the Diabetes Prevention Program, to date only 12 state Medicaid programs provide or are moving to provide coverage. New action is needed to extend coverage of the DPP in Medicaid, among state employee plans and under commercial insurance plans.

2

### **Expand Medicare coverage of Intensive Behavioral Therapy (IBT) and coverage of obesity medications**

Intensive Behavioral Therapy (IBT) consists of measurement of Body Mass Index (BMI), dietary and nutritional assessments and intensive behavioral counseling that promotes sustained weight loss through high intensity (i.e. regular and frequent) diet and exercise interventions. While Medicare now covers IBT among primary care providers it does not cover IBT as delivered by dietitians, endocrinologists and other providers with special training. The Medicare Part D drug insurance program is also prohibited from covering “weight loss drugs,” as there were no widely-accepted and FDA-approved drugs for weight loss when the program was first enacted.

Bipartisan sponsors in both the U.S. Senate and House have filed the Treat and Reduce Obesity Act (TROA), which would allow for Medicare coverage of drugs approved by the FDA for weight loss and authorize qualified professionals to provide evidence-based intensive behavioral therapy for obesity.

3

### **Extend coverage of Medicare Advantage benefits addressing social determinants of health**

The CHRONIC Care Act of 2018 directs the Centers for Medicare and Medicaid Services to authorize supplemental Medicare benefits that help treat patients' medical needs through services that address social determinants of health. CMS recently re-defined and expanded the scope of these benefits.<sup>44</sup> Expanded benefits that address social determinants of health more directly could spur further innovation and competition among Medicare Advantage health plans.<sup>45</sup>

4

### **Leverage the National Clinical Care Commission**

The Commission operates under terms of bipartisan legislation enacted in 2017 and is mandated to report to the Secretary of HHS and to Congress in 2021 on a government-wide plan to leverage federal programs “related to complex metabolic or autoimmune diseases that result from insulin-related issues and represent a significant disease burden in the United States, including complications due to such diseases.”<sup>46</sup> The Commission is a vehicle that could re-frame and streamline the federal government’s commitment to addressing the crisis of obesity and type 2 diabetes. Stakeholder groups from outside the federal government are invited to make this case to the Commission as the Commission meets throughout 2019-2021.

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