

January 17, 2019

U.S. Department of Health and Human Services
Office of Disease Prevention and Health Promotion
Don Wright, MD, MPH
Director, Office of Disease Prevention and Health Promotion
Rockville, MD 20852

Dear Dr. Wright:

The members of the <u>Diabetes Advocacy Alliance</u>[™] (DAA) are pleased to submit comments to the Office of Disease Prevention and Health Promotion (ODPHP), U.S. Department of Health and Human Services, with respect to the proposed set of Healthy People 2030 objectives for diabetes and other objective areas that mention diabetes.

The DAA is a coalition of twenty-four diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked to increase awareness of, and action on, the diabetes epidemic among legislators and policymakers. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat diabetes.

As you may know, over 30 million Americans have diabetes and an additional 84 million adults are at risk of developing the disease. In addition, the annual cost of this public health emergency has skyrocketed to \$322 billion and will continue to rise unless something is done. Both the human and economic toll of this disease is devastating.

The DAA is proud of its six-year relationship with ODPHP in support of Healthy People 2020 diabetes objectives related to diabetes prevention, education, and care. For example, in 2017 and 2018, our partnership with ODPHP focused on new opportunities to reach underserved populations and eliminate persisting disparities through education and changing Medicare rules (See a Healthy People 2020 blog post from November 13, 2018). The DAA values this partnership and looks forward to our continued work with ODPHP around the Healthy People 2020 diabetes objectives.

Comments on Healthy People 2030 Draft Objectives for Diabetes

To help inform its review of ODPHP's Healthy People 2030 objectives for diabetes, the DAA prepared a crosswalk of the existing Healthy People 2020 objectives with the proposed Healthy People 2030 objectives (Please see Attachment A).

Overall, the DAA is appreciative that Healthy People 2030 includes a number of objectives that are focused on improving the prevention, detection and management of diabetes.

The DAA **supports** many of the below Healthy People 2030 proposed objectives for diabetes as Core Objectives in their current form, and offers questions and suggestions for others. In our comments, we frequently cite the American Diabetes Association's (ADA) <u>Standards of Medical Care in Diabetes—2019</u>. The Standards of Care is intended to provide healthcare professionals, patients, researchers, payers and other interested individuals with the components of diabetes care, general treatment goals, and tools to evaluate the quality of care. The ADA has historically released updated Standards on an annual basis and now updates their Standards in real-time as new science and evidence becomes available. The ADA Standards of Care are viewed as the global standard for diabetes care.

D-01 Reduce the annual number of new cases of diagnosed diabetes in the population.

The DAA recognizes the intent of this objective is to reduce new cases of diabetes overall and we support that goal. However, by including the word "diagnosed" the objective inadvertently discourages screening and diagnosis of type 2 diabetes. 7.2 million people are currently living with undiagnosed diabetes. The DAA recommends that objective D-01 be adjusted to read "Reduce the incidence of diabetes in the population."

D-02 Reduce the rate of all-cause mortality among adults with diagnosed diabetes

D-03 Reduce the rate of lower extremity amputations in adults with diagnosed diabetes

D-04 Reduce the proportion of adults with diagnosed diabetes with an A1c value greater than 9 percent.

The DAA is concerned with the use of 9 percent and is interested in the rationale for 9 percent, versus 8 percent, or 7 percent, for example. The DAA notes that the National Committee for Quality Assurance, in its measures for comprehensive diabetes care, lists three separate measures in this area: HbA1c poor control (> 9.0 percent), HbA1c control (< 8.0 percent), and HbA1c control (< 7.0 percent) for a selected population.

The DAA also notes that the National Quality Forum (NQF) lists a <u>related diabetes</u> <u>quality measure</u> (updated in 2014) as follows: "The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) whose most recent HbA1c level is <8.0% during the measurement year." The NQF cites the National Committee for Quality Assurance as the steward for this measure. The DAA is interested in the thinking that supports proposed diabetes objective D-04 as currently written.

The DAA strongly supports appropriate, clinically based standards, as are represented by these measures, but notes that in order to alleviate burden on physicians, the thresholds adopted in Healthy People 2030 should be same as the standards by which physician performance and quality are measured.

D-05 Increase the proportion of adults with diabetes who have an annual eye exam.

The DAA is concerned about the elimination from the parallel Healthy People 2020 objective of the word "dilated" to describe the annual eye exam, as dilation is critical to detecting diabetic retinopathy. See page S-36; 40 – Table 4.4 (or pages 44; 48 of the PDF) in the American Diabetes Association's <u>Standards of Medical Care in Diabetes</u>— 2019. Also, note that the National Committee for Quality Assurance, in its list of <u>measures for comprehensive diabetes care</u>, uses this language for a relevant measure: Eye exam (retinal) performed.

D-06 Increase the proportion of adults with known diabetes who receive an annual urinary albumin test.

The DAA seeks clarification as to why this wording change was made to the parallel Healthy People 2020 objective — "diagnosed diabetes" was changed to "known diabetes." The DAA supports this change: "annual urinary microalbumin measurement" to "annual urinary albumin test," as the American Diabetes Association calls for urinary albumin to be assessed at least once a year (see page S-124 or page 132 of the PDF) in its Standards of Medical Care in Diabetes—2019. This language is also consistent with the 2012 National Kidney Foundation Kidney Outcomes Quality Initiative (KDOQI) U.S. Commentary on the Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Evaluation and Management of CKD.

D-07 Increase the proportion of adults with diabetes using insulin who perform self-monitoring of blood glucose at least once daily.

The DAA supports the addition of the phrase "using insulin" as compared with the parallel Healthy People 2020 objective, as this recommendation is aligned with the rationale provided by the American Diabetes Association in its <u>Standards of Medical Care in Diabetes—2019</u>. See page S-5 or page 13 in the PDF, and page S-73 or page 81 in the PDF.

The DAA supports the goal of this objective and recommends a slight modification to account for individuals with diabetes who use continuous blood glucose monitors (CGMs). We recommend objective D-07 be modified to read "Increase the proportion of adults with diabetes using insulin who monitor blood glucose daily."

D-08 Increase the proportion of persons with diagnosed diabetes who ever receive formal diabetes education.

The DAA seeks clarification as to why the word "ever" was added to this objective as compared with the parallel Healthy People 2020 objective.

D-09 Reduce the proportion of adults with undiagnosed prediabetes.

The DAA recommends editing this objective to add a phrase, as follows: "Reduce the proportions of adults with undiagnosed diabetes and prediabetes." The blood tests that can identify prediabetes are the same as those that can identify diabetes, and the risk factors for undiagnosed prediabetes are the same as those for undiagnosed diabetes. If the public health and medical communities aim to reduce undiagnosed prediabetes through testing, they will simultaneously identify adults with undiagnosed diabetes. See page S-14 (or page 22 of the PDF) in the American Diabetes Association's Standards of Medical Care in Diabetes—2019.

D-D01 (Developmental) Increase the proportion of eligible individuals completing CDC-recognized lifestyle change programs.

This objective aligns with DAA priorities and also the rationale provided by the American Diabetes Association for the value of diabetes prevention through lifestyle change programs in its Standards of Medical Care in Diabetes—2019. See page S-30 (or page 38 of the PDF).

The DAA Supports Additional Healthy People 2030 Objectives That Mention Diabetes

OA-2030-05 Reduce the rate of hospital admissions for diabetes among older adults.

The DAA supports OA-2030-05; however, we recommend a modification to the language so that OA-2030-5 states "Reduce the rate of hospital admissions for hypoglycemia and hyperglycemia for older adults with diabetes."

Additional Comments on Healthy People 2030 Proposed Objectives for Diabetes

People with diabetes are at high risk of chronic kidney disease (CKD) and cardiovascular disease and its complications. These conditions are also interconnected. The DAA appreciates and supports all the CKD metrics. However, we question why CKD-2030-04 (Increase the proportion of Medicare beneficiaries aged 65 years or older with chronic kidney disease who receive medical evaluation with serum creatinine, lipids and urine albumin tests), has been limited to people 65 or older. This evaluation is recommended for all adults in the KDIGO and National Kidney Foundation KDOQI clinical practice guidelines for the evaluation and management of CKD.

The DAA also believes it is important that Healthy People 2030 encourage, in some manner, the public health and clinical care communities to promote awareness of the need for people with diabetes to manage and reduce their risk for cardiovascular disease. Healthy People 2020 included two objectives related to diabetes and cardiovascular disease:

D-6 Improve lipid control among persons with diagnosed diabetes.

D-7 Increase the proportion of persons with diagnosed diabetes whose blood pressure is under control.

The DAA seeks clarification as to why objectives D-6 and D-7 were eliminated from consideration for Healthy People 2030. The DAA understands ODPHP's desire to reduce the total number of objectives in Healthy People overall, so the DAA asks if data supporting the measurement of these two objectives is captured in Healthy People 2030 objectives for Heart Disease and Stroke (HDS):

HDS-2030-06 Increase the proportion of adults with hypertension whose blood pressure is under control.

HDS-2030-09 Increase the treatment of blood cholesterol among eligible adults.

The DAA recommends that ODPHP introduce sub-objectives to HDS-2030-06 and HDS-2030-09, such that data on hypertension control and blood cholesterol treatment among adults with diabetes are captured, and the sub-objectives appear and be promoted as part of the final set of Healthy People 2030 objectives.

In support of a diabetes sub-objective for HDS-2030-06, the DAA notes that the National Quality Forum lists a <u>relevant measure for controlling hypertension in diabetes</u> (updated 2012): "The percentage of patients 18 to 85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure (BP) was adequately controlled (<140/90) during the measurement year." The NQF cites the National Committee for Quality Assurance as the steward for this measure.

Additional Health and Complication Areas Related to Diabetes

The DAA noticed that the following diabetes objectives from Healthy People 2020 had been eliminated in the proposed set of diabetes objectives for Healthy People 2030:

D-3: Reduce the diabetes death rate.

D-8: Increase the proportion of persons with diagnosed diabetes who have at least an annual dental examination.

D-9: Increase the proportion of adults with diabetes who have at least an annual foot examination.

D-11: Increase the proportion of adults with diabetes who have a glycosylated hemoglobin measurement at least twice a year.

Again, the DAA understands ODPHP's desire to reduce the total number of objectives in Healthy People overall.

- We agree with the elimination of Healthy People 2020 objective D-3.
- We seek clarification on why D-8 on annual dental exams was eliminated.
- While the DAA believes annual foot exams for people with diabetes are important, we believe it is reasonable to eliminate objective D-9 in an effort to reduce the overall number of objectives in HP2030. There are many things that can be done to reduce amputations in people with diabetes and the DAA believes prioritizing the D-03 objective related to reduced amputations is appropriate.
- Similarly, given the low level of evidence for glycosylated hemoglobin measurement at least twice a year, the DAA believes it is reasonable to eliminate objective D-11.

The DAA is pleased to provide this set of comments to ODPHP and looks forward to our continuing partnership with Healthy People.

Sincerely,

Academy of Nutrition and Dietetics
American Association of Clinical Endocrinologists
American Association of Diabetes Educators
American Diabetes Association
American Medical Association
American Optometric Association
American Podiatric Medical Association
Diabetes Patient Advocacy Coalition
Endocrine Society
Healthcare Leadership Council
National Kidney Foundation
Novo Nordisk, Inc.
Omada Health
WW International (formerly Weight Watchers)

Attachment A – Crosswalk of Healthy People 2020 and 2030 Objectives

(Words highlighted in yellow show differences in wording in similar objectives.)

2020 #	HP 2020 Objective	2030 #	HP 2030 Objective
	*		
D-1	Reduce the annual number of new cases	D-01	Reduce the annual number of new cases
	of diagnosed diabetes in the population		of diagnosed diabetes in the population
D-2	(Developmental) Reduce the death rate		
	among persons with diabetes		
	D-2.1 (Developmental) Reduce the rate	D-02	Reduce the rate of all-cause mortality
	of all-cause mortality among persons		among adults with diagnosed diabetes
	with diabetes		
	D-2.2 (Developmental) Reduce the rate		
	of cardiovascular disease deaths in		
	persons with diagnosed diabetes		
D-3	Reduce the diabetes death rate		
D-4	Reduce the rate of lower extremity	D-03	Reduce the rate of lower extremity
	amputations in persons with diagnosed		amputations in adults with diagnosed
	diabetes		diabetes
D-5	Improve glycemic control among		
	persons with diabetes		
	D-5.1 Reduce the proportion of persons	D-04	Reduce the proportion of adults with
	with diabetes with an A1c value greater		diagnosed diabetes with an A1c value
	than 9 percent		greater than 9 percent
	D-5.2 Proportion of the diabetic		
	population with an A1c value less than		
	7 percent		
D-6	Improve lipid control among persons		
	with diagnosed diabetes		
D-7	Increase the proportion of persons with		
	diagnosed diabetes whose blood		
	pressure is under control		

D-8	Increase the proportion of persons with		
	diagnosed diabetes who have at least an		
	annual dental examination		
D-9	Increase the proportion of adults with		
	diabetes who have at least an annual		
D 10	foot examination	7.07	
D-10	Increase the proportion of adults with	D-05	Increase the proportion of adults with
	diabetes who have an annual dilated eye		diabetes who have an annual eye exam
D-11	examination Increase the proportion of adults with		
D-11	diabetes who have a glycosylated		
	hemoglobin measurement at least twice		
	a year		
D-12	Increase the proportion of persons with	D-06	Increase the proportion of adults with
	diagnosed diabetes who obtain an		known diabetes who receive an annual
	annual urinary microalbumin		urinary albumin test
	measurement		
D-13	Increase the proportion of adults with	D-07	Increase the proportion of adults with
	diabetes who perform self-blood		diabetes using insulin who perform self-
	glucose-monitoring at least once daily		monitoring of blood glucose at least
D 14	T	D 00	once daily
D-14	Increase the proportion of persons with	D-08	Increase the proportion of persons with
	diagnosed diabetes who receive formal diabetes education		diagnosed diabetes who ever receive formal diabetes education
D-15	Increase the proportion of persons with		Tormar diabetes education
D-13	diabetes whose condition has been		
	diagnosed		
D-16	Increase prevention behaviors in		
	persons at high risk for diabetes with		
	prediabetes		
	D-16.1 Increase the proportion of		
	persons at high risk for diabetes with		
	prediabetes who report increasing their		
	levels of physical activity		
	D-16.2 Increase the proportion of persons at high risk for diabetes with		
	prediabetes who report trying to lose		
	weight		
	D-16.3 Increase the proportion of		
	persons at high risk for diabetes with		
	prediabetes who report reducing the		
	amount of fat or calories in their diet		
		D-09	Reduce the proportion of adults with
			undiagnosed prediabetes
		D-DO1	(Developmental) Increase the
			proportion of eligible individuals
			completing CDC-recognized lifestyle
		1	change programs