



January 31, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9898-NC
P.O. Box 8016, Baltimore, MD 21244-8016.

Dear Administrator Brooks-LaSure:

The Obesity Care Advocacy Network (OCAN) appreciates the opportunity to provide comments in response to the Department of Health and Human Services and Centers for Medicare & Medicaid Services (CMS) Request for information (RFI) regarding issues related to the Essential Health Benefits (EHB) under the Patient Protection and Affordable Care Act (ACA). OCAN is pleased that CMS is seeking public input on what appears to be a very broad examination of how our nation defines essential health care under the ACA and whether this care is being provided equally and equitably across the country.

Founded in 2015, OCAN is a diverse group of organizations focused on changing how we perceive and approach obesity in the United States. OCAN works to increase access to evidence-based obesity treatments by uniting key stakeholders and the broader obesity community around significant education, policy and legislative efforts. We aim to fundamentally change how the U.S. healthcare system treats obesity, and to shift the cultural mindset on obesity so that policymakers and the public address obesity as a serious chronic disease.

REVIEW OF EHB

Obesity advocates have argued – both during the congressional development of the ACA and the continuing federal regulatory and state implementation of the health care reform law – that, as a chronic disease, treatments for obesity should be viewed as “essential” under the ACA’s mandated 10 EHB categories. For example, metabolic and bariatric surgery should be covered under the “hospitalization” category; Food & Drug Administration (FDA) approved anti-obesity medications (AOMs) should be covered under the “prescription drug” category; and behavioral health and counseling services should fall under the broad “preventive and wellness services and chronic disease management” category pursuant to the relevant USPSTF recommendations.

The obesity community’s justification for this argument was based on the fact that numerous agencies of the federal government had already categorized obesity as a disease far ahead of the passage of the ACA – starting in 1998 when the National Institutes of Health published Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults that stated, “Obesity is a complex multifactorial chronic disease.” In early 2002, the

Internal Revenue Service issued a ruling that expenses for obesity treatment would qualify as deductible medical expenses. Later in 2002, the Social Security Administration (SSA) published an evaluation of obesity stating that “Obesity is a complex, chronic disease characterized by excessive accumulation of body fat.” This determination explicitly stated that obesity is a valid medical source of impairment for the purpose of evaluating Social Security disability claims.

Soon after the ACA was passed, the American Medical Association (AMA) adopted formal policy recognizing obesity as a complex and chronic disease and “supporting patient access to the full continuum of care of evidence-based obesity treatment modalities such as behavioral, pharmaceutical, psychosocial, nutritional, and surgical interventions.” AMA’s recognition of obesity as a disease in 2013 was the catalyst behind numerous other organizations coming out in support for ensuring patient access to obesity care, such as the National Council of Insurance Legislators, National Lieutenant Governors Association, National Hispanic Caucus of State Legislators, and the National Black Caucus of State Legislators (See “Timeline of Guidance and Policy Statements Supporting Patient Access to Obesity Care”).

Most recently, in 2022, the Office of Personnel Management (OPM) took a major step forward in addressing adult obesity care. OPM offers over 200 health plans across the U.S. and manages the health insurance benefits for more than eight million federal employees, retirees, and their families. Based on the U.S. adult obesity rates, we estimate that over 3 million people with obesity receive these federal health benefits. In 2014, OPM encouraged federal health benefit plans to cover AOMs. Their guidance also prohibited federal employee health plans from excluding coverage based on the belief that obesity is a lifestyle condition or that such treatment is cosmetic. Despite this guidance from OPM, many plans continued to exclude or carve out coverage for AOMs.

In guidance released in March 2022, in the form of a carrier letter that spelled out OPM’s expectations for the health benefits in 2023, OPM stated that health plan carriers are not allowed to exclude anti-obesity medications from coverage “based on a benefit exclusion or a carve out.” In rolling out this new guidance, OPM is quite clear — emphasizing that “obesity has long been recognized as a disease in the US that impacts children and adults”... and that “obesity is a complex, multifactorial, common, serious, relapsing, and costly chronic disease that serves as a major risk factor for developing conditions such as heart disease, stroke, type 2 diabetes, renal disease, non-alcoholic steatohepatitis, and certain types of cancer.”

Clearly, many national, federal and state organizations now recognize obesity as a complex and chronic disease and worthy of coverage for comprehensive evidence-based treatment avenues. OCAN believes that CMS should issue guidance that follows the numerous agencies of the federal government that have already categorized obesity as a disease and mirrors the coverage language surrounding obesity care issued by OPM in 2022.

BENEFIT DESCRIPTIONS IN EHB-BENCHMARK PLAN DOCUMENTS

The obesity community continues to be extremely concerned regarding CMS's failure to prohibit discriminatory benefit design regarding obesity treatment in EHB plans. While we have taken every opportunity (numerous face-to-face meetings with CMS and HHS and submission of formal comments on the EHB proposed regulations, and comments regarding federal oversight of State EHB benchmark plan selection) to secure federal guidance specific to this issue, HHS has not acted to address our concerns regarding clear discriminatory practices that are being employed by qualified health plans. No example is more glaring than the blatant failure of state EHB benchmark plans to include clear coverage language specific to ACA-mandated preventive health services for obesity.

Intensive Behavioral Therapy Services for Obesity

Under Section 2713 of the Affordable Care Act (ACA), private health plans must cover evidence-based preventive care services for adults that have a rating of "A" or "B" in the current recommendations of the USPSTF. Current USPSTF recommendations state that clinicians screen for obesity in adults and in children and adolescents 6 years and older and offer or refer them to intensive, multicomponent behavioral interventions.

We also note that the recently released American Academy of Pediatrics (AAP) evidence-based recommendations on medical care for those age 2 and older as part of its new "[Clinical Practice Guideline \(CPG\) for the Evaluation and Treatment of Children and Adolescents with Obesity](#)." The CPG discusses multicomponent behavioral interventions and states these services "are more effective with greater contact hours; the most effective treatments include 26 or more hours of face-to-face, family-based, multicomponent treatment over a 3- to 12-month period." These services "should include nutrition, physical activity, and behavioral change support and should be delivered by pediatricians or other PHCPs and their teams in collaboration with pediatric obesity specialists, allied health providers, and community partners."

The Public Health Service (PHS) Act and federal regulations also allow plans to use "reasonable medical management" techniques to determine the frequency, method, treatment, or setting for a preventive item or service to the extent it is not specified in a recommendation or guideline. While there is no formal regulatory definition or parameters for "reasonable medical management," this is typically operationalized by plans imposing limits on number of visits or tests if unspecified by a recommendation, covering only generics or selected brands of pharmaceuticals, or requiring prior authorization for certain services, tests, or medications.

The combination of these caveats and limitations has resulted in many questions about how plans should implement the preventive services policy. In particular, questions have arisen about the frequency, range of methods that can be used for certain services, and the types of providers that are subject to the policy. For these reasons, the Tri-Agencies issued the October 23, 2015, FAQ advising against coverage exclusions for weight management services as part of the implementation of the ACA. As part of that FAQ, the Tri-Agencies highlighted how the 2012

USPSTF recommendation “specifies that intensive, multicomponent behavioral interventions include, for example, the following:

- Group and individual sessions of high intensity (12 to 26 sessions in a year),
- Behavioral management activities, such as weight-loss goals,
- Improving diet or nutrition and increasing physical activity,
- Addressing barriers to change,
- Self-monitoring, and
- Strategizing how to maintain lifestyle changes.”

In late 2016, OCAN conducted an analysis of obesity treatment coverage language contained in EHB benchmark plan submissions for each of the 50 states and the District of Columbia for 2017. The study focused on coverage language specific to obesity screening and referral for intensive, multicomponent behavioral interventions for weight management. The study also evaluated coverage language pertaining to other evidence-based obesity treatment services such as anti-obesity medications and bariatric surgery to evaluate any or all treatment options for those individuals that are diagnosed with obesity through the screening benefit.

When looking at each state’s certificate of coverage in 2016 regarding weight management services under both the “excluded services” and “covered preventive health services” sections, the study found that **24 states (AK, AR, CO, DE, FL, HI, IA, ID, KS, KY, LA, ME, MS, MT, NE, NJ, NV, NY, OR, SC, SD, WI, WV and WY)** excluded coverage for weight/obesity management services and made NO MENTION of obesity screening and counseling services under the USPSTF covered preventive services section of the document.

The study also found that 24 states and the District of Columbia performed slightly better regarding coverage of these USPSTF recommended obesity-related services. **Eleven states (AL, IL, IN, MO, NH, OH, OK, TN, UT, VA and VT)** clearly indicated that weight loss programs were not covered under their EHB plan summary document; contained fairly blanket exclusions on weight/obesity management services in their certificate of coverage; but made some mention of obesity screening and possibly counseling services under the covered preventive services section of the certificate of coverage. **Five states (AZ, CT, GA, PA and WA)** provided tangential coverage information regarding obesity screening or counseling services — often under nutritional guidance/dietary adjustment for a chronic disease state.

Eight states (CA, MD, MN, NC, ND, NM, RI and TX) and the District of Columbia indicated some coverage for obesity screening or counseling services within their certificate of coverage despite stating that weight loss programs are not covered services under their EHB plan summary document. Only **two states (MA and MI)** indicated coverage for obesity/weight management services across all relevant documents.

While this study is now more than six years old, it is still relevant given that the EHB benchmark plan documents for all 50 states and the District of Columbia on the Center for Consumer Information and Insurance Oversight’s (CCIIO) website remain unchanged – with the exception

of IL, SD, MI, NM, OR, CO, and VT. These seven states utilized the Final 2019 HHS Notice of Benefits and Payment Parameters, which established new standards for States to update their EHB-benchmark plans. In evaluating the updated coverage documents for these seven states, we continue to find discriminatory benefit design language surrounding obesity treatment services – including language that is contrary to the USPSTF’s updated 2018 recommendations stating that “clinicians offer or refer adults with a body mass index (BMI) of 30 or higher to intensive, multicomponent behavioral interventions.” See Table 1.

Given CMS’ specific request for public comment as to “what extent States may require additional guidance on how to ensure that plans are interpreting the EHB-benchmark plan documents in a manner that provides EHB coverage to consumers, consistent with applicable requirements,” OCAN urges CMS to issue formal guidance that mirrors the Tri-Agencies October 23, 2015 FAQ guidance on weight management services to ensure that these critical preventive care services are being adequately covered to encompass both the appropriate frequency and intensity of the benefit.

Anti-Obesity Medications

There has been tremendous advancement in both the understanding of obesity and the effectiveness and durability of treatment services since passage of the ACA. For example, the FDA has approved several AOMs throughout the last decade – with each new medication showing greater promise and results for adults and children. As highlighted above, the new AAP’s Clinical Practice Guideline evidenced by the American Academy of Pediatrics (AAP), which recently released its evidence-based recommendations on medical care for those age 2 and older as part of its new [“Clinical Practice Guideline \(CPG\) for the Evaluation and Treatment of Children and Adolescents with Obesity.”](#)

The AAP guidelines contain key action statements, which represent evidence-based recommendations for evaluating and treating children with overweight and obesity and related health concerns. These recommendations include motivational interviewing, intensive health behavior and lifestyle treatment, pharmacotherapy and metabolic and bariatric surgery. The approach considers the child’s health status, family system, community context, and resources. The comprehensive evidence-based recommendations included in the CPG reflect just how far the understanding and care of childhood obesity has come. The CPG is extraordinarily detailed with respect to diagnosis, assessment of comorbidities, and recommending proactive management and treatment of childhood obesity.

On October 20, 2022, the Institute for Clinical and Economic Review (ICER), an independent non-profit research institute that produces reports analyzing the evidence on the effectiveness and value of drugs and other medical services, released its final policy recommendations surrounding treatments for obesity management. Many OCAN member groups participated in this ICER review and were supportive of the recommendations.

In releasing these recommendations, ICER’s Chief Medical Officer, David Rind, MD stated that:

“The vast majority of people with obesity cannot achieve sustained weight loss through diet and exercise alone. As such, obesity, and its resulting physical health, mental health, and social burdens is not a choice or failing, but a medical condition. The development of safe and effective medications for the treatment of obesity has long been a goal of medical research that now appears to be coming to fruition. With a condition affecting more than 40% of adults in the US, the focus should be on assuring that these medications are priced in alignment with their benefits so that they are accessible and affordable across US society.”

The following statements represent the major policy priorities that ICER included in its final report:

- All stakeholders have an important role to play in ensuring that people living with obesity have access to effective medications as a core benefit of health care insurance coverage.
- Manufacturers should set the price for new treatments for obesity in proportion to their demonstrated benefit to patients and society, with adjustments for residual uncertainty about long-term benefits and the large size of the potential population of people to be treated. Similarly, payers should ensure that pharmaceutical benefit designs developed in conjunction with employers and other plan sponsors ensure access to approved therapies among individuals with obesity.
- All stakeholders should take steps that make effective treatment options for people living with obesity available in a way that will help reduce health inequities.
- Manufacturers should develop patient assistance programs at a level commensurate with other chronic disease conditions to support access to medications among racial and ethnic groups where the burden of obesity is increased, payer coverage is low, and inability to afford out-of-pocket payments is common. Likewise, payers should design coverage criteria that are sensitive to racial and ethnic variability in the clinical applicability of BMI thresholds.

We are pleased that CMS is recognizing these scientific advancements in AOMs and urge the agency to support utilization of the United States Pharmacopeia Drug Classification (USP-DC) as the standard for determining covered drug classes within state EHB benchmark plans. We also appreciate CMS highlighting the Part D exclusion of drugs for anorexia, weight loss or weight gain as a prime example of the many problems associated with utilizing the Medicare Model Guidelines outside of the Medicare program and its population. Obesity advocates and OCAN have been working with the USP Healthcare Quality Expert Committee throughout the last decade and are extremely pleased that the USP-DC has included a new class for anti-obesity agents as well as recognition of new combination agents (Naltrexone/Bupropion and Phentermine/Topiramate) since release of the USP-DC in 2018.

Metabolic and Bariatric Surgery

Metabolic and bariatric surgery is already widely covered by Medicare, TRICARE, the Federal Employees Health Benefits program, and nearly every State Medicaid and State employee plan. Despite this broad coverage and the significant evidence surrounding the effectiveness and safety of this treatment avenue, less than half of state EHB benchmark plans cover treatment for bariatric surgery. This is especially frustrating given the evolving science behind new populations for whom surgical intervention could be beneficial.

For example, the American Society for Metabolic and Bariatric Surgery (ASMBS) and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) issued new *Guidelines on Indications for Metabolic and Bariatric Surgery* in 2022. The new ASMBS/IFSO guidelines are meant to replace a consensus statement developed by National Institutes of Health (NIH) more than 30 years ago that set standards most insurers and doctors still rely upon to make decisions about who should get weight-loss surgery, what kind they should get, and when they should get it.

The ASMBS/IFSO Guidelines now recommend metabolic and bariatric surgery for individuals with a BMI of 35 or more “regardless of presence, absence, or severity of obesity-related conditions” and that it be considered for people with a BMI 30-34.9 and metabolic disease and in “appropriately selected children and adolescents.” But even without metabolic disease, the guidelines say weight-loss surgery should be considered starting at BMI 30 for people who do not achieve substantial or durable weight loss or obesity disease-related improvement using nonsurgical methods.

The ASMBS/IFSO Guidelines are just the latest in a series of new recommendations from medical groups calling for expanded use of metabolic surgery. In 2016, 45 professional societies, including the American Diabetes Association (ADA), issued a joint statement that metabolic surgery should be considered for patients with type 2 diabetes and a BMI 30.0–34.9 if hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable medications. This recommendation is also included in the ADA’s “Standards of Medical Care in Diabetes – 2022.”

For those benchmark plans that do cover bariatric surgery, many insurance carriers employ discriminatory patient requirements, despite limited or no clinical evidence to support such requirements, including mandated preoperative weight loss, a required specific number of visits with a dietitian, documented prior weight loss attempts, no weight gain while in a bariatric program, presence of severe obesity for a predetermined duration, and uncontrolled co-morbid conditions despite maximal medical treatment. Moreover, requirements vary from carrier to carrier and are often contradictory; some require preapproval weight loss, others demand a documented failure to lose weight despite best efforts, and others will deny coverage for patients who successfully lose some amount of weight. Furthermore, insurance carriers can take a “one and done” approach and refuse to cover revisional weight loss surgery or refuse to cover operative complications if the index operation was paid for by the patient.

The obvious consequence of such restrictions is denial of insurance coverage and access to care for seemingly arbitrary reasons. In addition, the effect of these constraints can lead to patient discouragement and attrition, with resultant progression of disease. Meanwhile, patients with other chronic diseases, such as coronary heart disease or diabetes, are not subject to similar restrictions. Indeed, it would be considered ethically unacceptable and socially intolerable for insurance carriers to impose demands that are not evidence-based before approving coverage of treatment for patients with such chronic conditions or to impose limitations or a punitive schema after treatment is initiated. (Surgery for Obesity and Related Diseases 15 (2019) 814–821 [ASMBS position statement on weight bias and stigma](#))

Sample Summary of Benefits and Coverage Template

Finally, OCAN strongly urges CMS to prohibit health plans from including the terms “weight loss programs” or “bariatric surgery” as excluded services, or benefits that may be limited in scope, as part of the ACA-mandated Summary of Benefits and Coverage (SBC) form. In 2011, [the obesity community strongly objected](#) when CMS proposed the sample SBC template because advocates knew that plans would utilize the sample language as a convenient excuse for employing discriminatory benefit design language against those affected by obesity. These concerns are clearly illustrated by OCAN’s analysis of EHB benchmark plans highlighted above.

SUMMARY

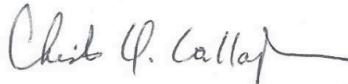
OCAN appreciates the opportunity to provide comments on the proposed rule regarding Essential Health Benefits under the ACA. In closing, we urge you to recognize obesity as a complex and chronic disease and require EHB plans to cover all evidence-based treatment services under the appropriate EHB categories. We also encourage you to provide guidance to state EHB plans that mirrors the OPM language to Federal Employee Health Benefit (FEHB) which ensures coverage of FDA approved anti-obesity medications. We also ask that you address the discriminatory benefit design language surrounding obesity preventative care services, and to utilize the United States Pharmacopeia (USP) drug classification as the standard for determining drug classes within state EHB benchmark plans.

We stand ready to provide more information and are available to discuss if you have any questions about our comments. Please feel free to reach out to us if we can provide further assistance. Thank you again for the opportunity to comment on this important issue.

Sincerely,



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APPENDIX

Table 1

State – Effective Plan Year	WLP Coverage in Plan Summary	WLP/Obesity Treatment Coverage Language in Certificate of Coverage	Mention of Obesity Screening/Counseling under Preventive Services in Certificate of Coverage
IL - 2020	Not Covered	Drugs prescribed and dispensed for the treatment of obesity or for use in any program of weight reduction, weight loss, or dietary control are excluded.	Under Preventive Care Services section, plan covers “obesity screening and counseling” for adults and children
SD - 2021	Not Covered	Your benefits do not include coverage for weight reduction programs or supplies (including dietary supplements, foods, equipment, lab testing, examinations, and prescription drugs), whether or not weight reduction is medically appropriate.	While plan states coverage for “Items or services with an “A” or “B” rating in the current recommendations of the United States Preventive Services Task Force (USPSTF),” the plan makes no mention of obesity screening or counseling services.

MI - 2022	Covered per page 20 of plan document	“Physician-supervised weight loss programs as outlined in our medical policies” are covered.	Plan document states that “obesity screening and counseling are covered for adults and children of all ages.”
NM - 2022	Covered	“Dietary evaluations and counseling for the medical management of morbid obesity and obesity are covered. Prescription drugs medically necessary for the treatment of obesity and morbid obesity are also covered.	While plan does state that screening for obesity is covered, it does not specifically state that counseling services are available for obesity: “Preventive screening services including screening for depression, diabetes, cholesterol, obesity, various cancers, HIV and sexually transmitted infections, as well as counseling for drug and tobacco use, healthy eating and other common health concerns.”
OR - 2022	Not Covered	Obesity (including all categories) or weight control treatment or surgery, even if there are other medical reasons for you to control your weight are excluded. Food supplementation programs, behavior modification and self-help programs, and other services and supplies for weight loss are also excluded from coverage.	While plan document does include language and a link to USPSTF website for more information on preventive care services, it does not contain any language specific to obesity screening or counseling services under preventive care services section.
CO - 2023	Not Covered	Plan specifically excludes coverage for “weight loss programs” and “drugs for the treatment of weight control” and “services received in a weight management facility.”	While the plan document enumerates several covered preventive care services, it makes no specific mention of obesity screening or counseling services.
VT - 2024	Not Covered	“Treatment of obesity, except surgical treatment when determined Medically Necessary” is excluded.	While plan document does state that “Preventative Services are covered with no cost-sharing for Covered Persons to the extent required by 42 U.S.C. § 300gg–13,” the document makes no mention of obesity screening or counseling services.

TIMELINE OF POLICY GUIDANCE AND STATEMENTS SUPPORTING PATIENT ACCESS TO OBESITY CARE

AMA's recognition of obesity as a disease in 2013 was the catalyst behind numerous other calls for ensuring patient access to obesity care.

- In 2013, Senator Tom Carper introduced the Treat and Reduce Obesity Act (TROA) – legislation that aims to effectively treat and reduce obesity in older Americans by enhancing Medicare beneficiaries' access to healthcare providers that are best suited to provide intensive behavioral therapy (IBT) and by allowing Medicare Part D to cover FDA-approved obesity drugs.
- In 2014, the federal Office of Personnel Management (OPM) issued specific guidance to Federal Employee Health Benefit (FEHB) Program carriers regarding obesity treatment services – stating that the agency will no longer tolerate plans excluding obesity treatment coverage on the basis that obesity is a "lifestyle" condition or that treatment is "cosmetic."
- In 2015, the Departments of HHS, Treasury and Labor issued an FAQ advising against coverage exclusions for weight management services as part of the implementation of the ACA.
- In 2015, the National Council of Insurance Legislators that represents legislators who chair Insurance Committees in state legislatures across the country adopted its first ever disease-specific policy statement – urging Medicaid, state employee and state health exchange plans to update their benefit structures “to improve access to, and coverage of treatments for obesity such as pharmacotherapy and bariatric surgery.”
- In 2018, the National Lieutenant Governors Association went on record supporting efforts to reduce obesity stigma and support access to obesity treatment options for state employees and other publicly funded healthcare programs.
- In 2020, the National Hispanic Caucus of State Legislators and National Black Caucus of State Legislators adopted formal policy recognizing that “health inequities in communities of color have led to a disproportionate impact of COVID-19 and that states must address the high rates of obesity to improve the health of racial minorities and prepare for the next public health epidemic.....and ensure that their constituents, including those using Medicaid, have access to the full continuum of treatment options for obesity.”
- In 2020, Congress included report language in the Consolidated Appropriations Act for FY 2021, which "encourages CMS to work to ensure beneficiary access to the full continuum of care for obesity, including access to FDA-approved anti-obesity medications under Medicare Part D... and that CMS reexamine its Medicare Part B national coverage decision for intensive behavioral therapy for obesity considering current USPSTF recommendations.”

· In 2022, OPM issued follow-up guidance to its 2014 carrier letter -- "clarifying that FEHB Carriers are not allowed to exclude anti-obesity medications from coverage based on a benefit exclusion or a carve out..." and that "FEHB Carriers must have adequate coverage of FDA approved anti-obesity medications (AOMs) on the formulary to meet patient needs and must include their exception process within their proposal." In rolling out this new guidance, OPM is quite clear — emphasizing that "obesity has long been recognized as a disease in the US that impacts children and adults" ... and that "obesity is a complex, multifactorial, common, serious, relapsing, and costly chronic disease that serves as a major risk factor for developing conditions such as heart disease, stroke, type 2 diabetes, renal disease, non-alcoholic steatohepatitis, and certain types of cancer."

· In 2022, AMA's Board of Trustees announced new policy —stating that AMA "will: (a) assume a leadership role in collaborating with other interested organizations, including national medical specialty societies, the American Public Health Association, the Center for Science in the Public Interest, and the AMA Alliance, to discuss ways to finance a comprehensive national program for the study, prevention, and treatment of obesity, as well as public health and medical programs that serve vulnerable populations; (b) encourage state medical societies to collaborate with interested state and local organizations to discuss ways to finance a comprehensive program for the study, prevention, and treatment of obesity, as well as public health and medical programs that serve vulnerable populations; and (c) continue to monitor and support state and national policies and regulations that encourage healthy lifestyles and promote obesity prevention."