

Title III – Improving the Health of the American People

Subtitle A – Modernizing Disease Prevention of Public Health Systems

Sec. 301. National Prevention, Health Promotion and Public Health Council

Current Law

Nothing strictly applicable.

Proposed Law

This proposal would require the President to establish a National Prevention, Health Promotion and Public Health Council (“Council”), composed of secretaries, chairmen, and directors of Federal departments, boards and agencies (as specified), and appoint a chairperson. The Council would be required to provide Federal coordination and leadership with respect to prevention, wellness, and health promotion practices; develop, within one year of enactment, a national prevention, health promotion, public health, and integrative health care strategy; and other activities as specified. The Council would meet at the call of the chairperson. The Council would be required, not later than July 1, 2010, and annually thereafter through January 1, 2015, to report to the President and Congress on activities under the strategy, and progress toward identified goals. The chairperson would be required to annually request an opportunity to testify before Congress regarding activities under the strategy, the amount and source of applicable Federal funds, and the results of program evaluations.

Sec. 302. Prevention and Public Health Investment Fund

Current Law

Nothing strictly applicable.

Proposed Law

The stated purpose of this section is to establish a Prevention and Public Health Investment Fund (“Fund”) to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. The Fund would be established in the U.S. Treasury, with amounts appropriated or credited to it to remain available until expended. The proposal would appropriate to the Fund \$10 billion for each of fiscal years 2010 through 2019; and for FY2020 and each fiscal year thereafter, an amount that is not less than the amount appropriated for FY2019. Amounts in the Fund would be permitted to be appropriated to increase funding, over the FY2008 level, for programs authorized by the Public Health Service Act (PHS Act) for prevention, wellness, and public health activities, including prevention research and health screenings. Amounts so appropriated,

and outlays flowing from such appropriations, would not be taken into account for purposes of any budget enforcement procedures. The Subcommittees on Labor, Health and Human Services, Education, and Related Agencies of the Committees on Appropriations of the House of Representatives and the Senate would be able to provide for the transfer of funds appropriated from the Fund among eligible activities authorized by the PHS Act for prevention, wellness, and public health activities, including prevention research and health screenings.

Sec. 303. Clinical and Community Preventive Services

Current Law

The U.S. Preventive Services Task Force (USPSTF) is established in Section 915(a) of the PHS Act. Current authority requires the USPSTF to “review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations.” The section also requires AHRQ to provide administrative, research, and technical support to the USPSTF, and exempts the USPSTF from requirements of the Federal Advisory Committee Act (FACA).

The Task Force on Community Preventive Services (TFCPS) is a non-governmental panel of public health and prevention experts whose members are appointed by the CDC Director. It conducts systematic reviews of evidence, similar to the process carried out by the USPSTF, but applied to population-based, rather than clinical, interventions. Its recommendations are published in the Guide to Community Preventive Services. The TFCPS is not explicitly authorized; rather, it is conducted under general authorities of the Secretary in Title III of the PHS Act.

Proposed Law

The first subsection of this proposal would strike and replace the existing authority for the USPSTF with language requiring the AHRQ Director to convene an independent Preventive Services Task Force (“Clinical Task Force”), composed of individuals with appropriate expertise. The Clinical Task Force would be required to review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services, for individuals and organizations delivering clinical services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, Congress and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives.

Duties of the Clinical Task Force would include: (1) development of additional topic areas for review, including interventions for specific populations and age groups; (2)

review and revision of existing recommendations at least once every five years; (3) improved integration with Federal government health objectives and related target setting for health improvement; (4) the enhanced dissemination of recommendations; (5) the provision of technical assistance to health care professionals, agencies and organizations that request help in implementing the recommendations; and (6) the submission of yearly reports to Congress and related agencies identifying gaps in research and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

AHRQ would be required to provide administrative, research, and technical support for Clinical Task Force operations, including support for the dissemination of recommendations, and assistance to organizations in their implementation.

The Clinical Task Force would be required to coordinate its work with the Community Preventive Services Task Force (authorized in the next subsection) and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community. The proposal would appear to exempt the Clinical Task Force from FACA requirements. There would be authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Clinical Task Force.

The next subsection of this proposal would create a new Section 399S of the PHS Act, that requires the CDC Director to establish a Community Preventive Services Task Force ("Community Task Force") composed of individuals with appropriate expertise, to review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services, for individuals and organizations delivering population-based services. These would include primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, medical groups, Congress, and other policy-makers. Community preventive services include any policies, programs, processes, or activities designed to affect or otherwise affecting health at the population level.

Duties of the Community Task Force would include: (1) development of additional topic areas for review, including interventions for specific populations and age groups, and other specified topics; (2) review and revision of existing recommendations at least once every five years; (3) improved integration with Federal government health objectives and related target setting for health improvement; (4) the enhanced dissemination of recommendations; (5) the provision of technical assistance to health care professionals, agencies and organizations that request help in implementing the recommendations; and (6) the submission of yearly reports to Congress and related agencies identifying gaps in research and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

The CDC Director would be required to provide administrative, research, and technical support for Clinical Task Force operations, including support for the dissemination of recommendations, and assistance to organizations in their implementation.

The Community Task Force would be required to coordinate its work with the Clinical Task Force (authorized in the prior subsection) and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community. The Community Task Force would appear to be exempt from FACA requirements. There would be authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Community Task Force.

Sec. 304. Education and Outreach Campaign Regarding Preventive Benefits

Current Law

Nothing strictly applicable. The Secretary has general authority to conduct public health education campaigns under Titles II and III of the PHS Act, among other authorities.

Proposed Law

This proposal would require the Secretary, in consultation with the Institute of Medicine, to plan and implement a national public-private partnership for a prevention and health promotion outreach and education campaign. The purpose of the campaign would be to raise public awareness of health improvement across the life span, to include the dissemination of information that, among other things, describes the benefits of preventive services and healthy lifestyles, and describes the preventive services covered under health plans offered through a Gateway. There would be authorized to be appropriated such sums as may be necessary to carry out this section.

Subtitle B – Increasing Access to Clinical Preventive Services

Sec. 311. Right Choices Program

Current Law

Several Federal programs that are authorized in current law pay for certain screening or preventive services for low-income individuals who are not eligible for Medicaid, CHIP, or other Federal health care financing programs. Some examples include: (1) The CDC National Breast and Cervical Cancer Early Detection Program (Title XV of the PHS Act), funded through annual discretionary appropriations. (2) The Vaccines for Children (VFC) program (Section 1928 of the SSA), funded through the Medicaid appropriation. VFC provides recommended pediatric vaccines to certain uninsured and underinsured children. VFC is operated by CDC. Medicaid-eligible children are also eligible for VFC-funded vaccines; (3) Community Health Centers (Section 330 of the PHS Act), which provide a

number of specified primary care and preventive health services to medically underserved populations.

Medicare and Medicaid each cover health assessments for certain beneficiaries. Medicare Part B covers a one-time initial preventive physical examination (IPPE) to identify diseases and risk factors, and to provide education, counseling, and referral for covered screening and other preventive services. (Sections 1833, 1861, and 1862 of the SSA) States are required, under Medicaid, to cover a package of “well-child” and preventive service benefits for most eligible children under the age of 21, called Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services. (Section 1905 of the SSA)

The “Gateways” referred to in the proposal are not currently authorized.

Proposed Law

Beginning upon enactment, the Secretary would be required to provide annual grants to each State to establish a “Right Choices” program, which the State could administer through its Medicaid program or a comparable program. Under this program, States would be required to conduct outreach to the uninsured, and provide a “Right Choices” card to eligible individuals. Eligible individuals would be citizens and legal immigrants without private insurance coverage for the six months prior to the date of determination of eligibility; who have a family income at or below 350% of the Federal poverty level; and who are not eligible for Medicare, Medicaid, CHIP, armed services, or veterans health benefits.

An eligible individual would receive a one-time health risk appraisal and a risk-stratified care plan from a primary care physician participating in Medicare or Medicaid, or with a State or Federal safety net provider (such as a community care team, community health center, rural clinic, mobile clinic, or others, as identified by the State). The care plan would include recommendations for lifestyle changes and referrals to community-based resources. Care plans would also include referrals for age- and gender-appropriate immunizations and screenings as identified by the Secretary, in consultation with CDC, AHRQ, HRSA, SAMHSA, and other appropriate sources. To the extent feasible, care plans would also include referrals to Federal and State programs for which they may be eligible. A program participant diagnosed with a chronic illness would be referred for treatment to existing State or Federal safety net providers/facilities, as appropriate (such as public hospitals, community health centers, and rural clinics).

Program providers would be paid by the States, with reimbursement based upon Medicaid rates, and not to exceed Medicare rates. States would have to require individuals with family incomes above 200% of the Federal poverty level to contribute a portion of the cost of their care, on a sliding scale determined by the Secretary.

Grants would be distributed to States in amounts according to the percentage of uninsured adults and children, and the prevalence of the most common costly chronic diseases (in each case as compared to all States), as determined by the Secretary. The

Secretary would be required to determine what amount of the grant could be used for State administration of the program. The Secretary would be allowed to set aside not more than 20% of the funds appropriated to the program to allocate to other programs that would fund the treatment of participating individuals. The Secretary would be required to determine how payments would be made to States on a prospective basis, to enable them to provide program participants with access to items and services until Federal or State Gateways were available. The Secretary would be prohibited from obligating more than \$5 billion per fiscal year to the program.

For the purposes of this section, a “State” would be defined as each of the several States; the District of Columbia; each of the U.S. territories; and Indian tribes and tribal organizations (as such terms are defined in Sections 4(b) and 4(c) of the Indian Self-Determination and Education Assistance Act). The Secretary would be required to conduct an annual evaluation of the effectiveness of the pilot program under this section. The program would sunset on the date on which Federal or State Gateways were available, or on a date determined by the Secretary.

Sec. 312. School-Based Health Clinics

Current Law

School-based health clinics (SBHCs) are not explicitly authorized, but have been established pursuant to the general authority to establish community health centers, under Section 330 of the PHS Act. Explicit authorities for school-based health services are limited to authorities in the PHS Act for certain dentistry and mental health/substance abuse services.

Proposed Law

This proposal would add a new Section 399Z-1 to the PHS Act, which would define “comprehensive primary health services,” “medically underserved children and adolescents,” “school-based health clinic,” and other terms. The new section would also require the Secretary to prescribe criteria for determining the specific shortages of personal health services for medically underserved children and adolescents, considering input from State and local officials, and taking into account specified matters regarding access to health care services in the area.

The Secretary would be required to award grants for the operation of SBHCs. An eligible SBHC would be one that submitted a timely application to the Secretary with information regarding (1) evidence of need; (2) evidence that the criteria developed above are met; (3) assurances regarding compliance with Federal, State and local laws regarding parental or guardian consent, and regarding privacy of patient and student records; collaboration with neighboring providers; availability of services; and responsibility for facility administration; and (4) other information required by the Secretary. The Secretary would be authorized to give preference to applicants who demonstrate ability to serve communities with specified barriers to access.

The Secretary would be authorized to waive certain requirements of an SBHC for up to two years; and to waive the requirement that the SBHC provide all required comprehensive primary health services for a designated period of time, as determined by the Secretary.

An SBHC would be authorized to use grant funds provided under this section for (1) acquiring and leasing equipment; (2) certain training; (3) management and operation of center programs; and (4) salaries for physicians, nurses, and other SBHC personnel. The Secretary would be authorized to award grants which could be used to pay construction costs associated with expanding and modernizing existing buildings for use as an SBHC, including purchase of trailers or manufactured buildings to install on the school property. The Secretary would be authorized to determine the amount of an award to an SBHC based on financial need; State, local, or other funding provided to the SBHC; and other factors as determined appropriate by the Secretary. Entities that receive a grant under this section would be required to match 20% of the grant amount from non-Federal sources. The Secretary would be allowed to waive all or part of the matching requirement for any fiscal year if he/she determines that applying the matching requirement would result in serious hardship or an inability to carry out the purposes of this section. Grantees would have to use funds provided to supplement, not supplant, other Federal or State funds.

The Secretary would be required to establish programs to: provide specified technical assistances to grantees; and evaluate SBHCs and monitor grantee quality performance. There would be authorized to be appropriated such sums as may be necessary to carry out this section for FY2010 through FY2014.

Sec. 313. Oral Healthcare Prevention Activities

Current Law

Nothing strictly applicable. The PHS Act currently authorizes certain activities focused specifically on oral health, including community water fluoridation activities, and a school-based dental sealant program in underserved areas (both in Section 317M); a program to improve oral health among children under six years of age who are eligible for services under a Federal health care program (Section 320A); programs to bolster the dental health workforce (Sections 340F, 340G, and 768); and the National Institute of Dental Research at NIH (Section 453).

Proposed Law

This proposal would establish a new Part S in the PHS Act, titled “Oral Healthcare Prevention Activities.” It would include a new Section 399GG in the PHS Act, requiring the Secretary, acting through the CDC Director, to establish a five-year national, public education campaign focused on oral health care prevention and education, including prevention of oral disease such as early childhood and other carries, periodontal disease, and oral cancer. In establishing the program, the Secretary is to ensure that activities

targeted toward specific populations are provided in a culturally and linguistically appropriate manner; and that science-based strategies are used to convey messages including, but not limited to, community water fluoridation and dental sealants. The Secretary would be required to begin implementation within two years of enactment, and to begin planning activities upon enactment.

This proposal would also establish a new Section 399GG-1 in the PHS Act, requiring the Secretary, acting through the CDC Director, to award grants to eligible entities to demonstrate the effectiveness of research-based dental caries disease management activities. Eligible entities would be community-based providers of dental services (as defined by the Secretary), including Federally-qualified Health Centers, clinics of a State-owned hospital; State or local departments of health; private providers of dental services; medical, dental, public health, nursing, or nutrition educational institutions; or national organizations involved in improving children's oral health. Entities would have to apply to the Secretary, providing such information in such manner as the Secretary prescribes. Grantees would be required to use amounts received under a grant under this section to demonstrate the effectiveness of research-based dental caries disease management activities. The Secretary would be required to utilize information generated from grantees under this section in planning and implementing the public education campaign under Section 399GG, as established in this Act.

There would be authorized to be appropriated such sums as may be necessary to carry out this Part.

Sec. 314. Oral Health Improvement

Current Law

The PHS Act currently authorizes a school-based dental sealant program for underserved areas, under which the Secretary may award grants to States and Indian tribes to develop programs to improve children's access to sealants. (Section 317M(c)) The program's authorization of appropriations expired at the end of FY2005.

The proposal for CDC cooperative agreements with States to establish oral health programs is not explicitly authorized, but could be carried out under broad authorities of the Secretary in Title III of the PHS Act.

Four national surveys or surveillance systems referenced in the proposal are authorized in broad authorities in the PHS Act. They are (1) the Pregnancy Risk Assessment Monitoring System (PRAMS), administered by CDC (general authorities in Title III, among others); (2) the National Health and Nutrition Examination Survey (NHANES), administered by CDC (Section 306, among others); (3) the Medical Expenditures Panel Survey (MEPS), administered by AHRQ (Title IX); and (4) the National Oral Health Surveillance System (NOHSS), administered by CDC (general authorities in Title III, among others).

Proposed Law

This proposal would make the school-based dental sealant program mandatory, amending PHS Act Section 317M(c) to require the Secretary to award grants for the dental sealant program to each of the 50 States and territories and to Indians, Indian tribes, tribal organizations and urban Indian organizations (as such terms are defined in Section 4 of the Indian Health Care Improvement Act).

This proposal would also reorder and add a new subsection (d) to PHS Act Section 317M, requiring the Secretary, acting through the CDC Director, to enter into cooperative agreements with State, territorial, and tribal units of government to establish oral health leadership programs, including data collection and interpretation, (to include determinants of poor oral health among vulnerable populations), a multi-dimensional delivery system for oral health, and implementation of science-based programs (including dental sealants and community water fluoridation) to improve oral health. There would be authorized to be appropriated such sums as may be necessary to carry out this subsection for fiscal years 2010 through 2014.

This proposal would also require the Secretary to implement oral health components in four national health surveys and surveillance systems. (1) For PRAMS, State grantees would be required, within five years of enactment, and every five years thereafter, to report to the Secretary regarding oral health care measurement. There would authorized to be appropriated to carry out this paragraph such [sums] as may be necessary. (2) For NHANES, the Secretary would be required to develop oral health care survey components, to include tooth-level surveillance. Such components would have to be updated at least every six years. (3) For MEPS, the Secretary would be required to include the verification of dental utilization, expenditure, and coverage findings through conduct of a look-back analysis. (4) For NOHSS, there would be authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014 to increase participation from 16 States to all 50 States, territories, and District of Columbia. The Secretary would be required to ensure that the NOHSS system includes the measurement of early childhood caries.

Subtitle C – Creating Healthier Communities

Sec. 321. Community Transformation Grants

Current Law

Nothing strictly comparable. Several sections in Title III of the PHS Act provide broad authority that could be used to support grants for community preventive health activities. Title XVII requires the Secretary to establish goals, support research, provide technical and other assistance, and use other authorities as applicable to support disease prevention and health promotion purposes.

Proposed Law

The Secretary, acting through the CDC Director, would be required to award competitive grants to State and local governmental agencies and community-based organizations for the implementation, evaluation, and dissemination of proven evidence-based community preventive health activities in order to reduce chronic disease rates, address health disparities, and develop a stronger evidence base of effective prevention programming.

Sec. 322. Healthy Aging, Living Well*Current Law*

Nothing strictly applicable. There is at least one example of an explicitly authorized Federal program that pays for screening services for low-income individuals who are not eligible for Medicaid, CHIP, or other Federal health care financing programs, and then provides a mechanism to finance treatment services for those individuals whose screenings indicate the need for it. The National Breast and Cervical Cancer Early Detection Program (Title XV of the PHS Act) is administered by CDC and funded through annual discretionary appropriations. Women who are found to have breast or cervical cancer through the program then become eligible for coverage under Medicaid for the duration of their treatment. (Section 1902 of the SSA)

Community Health Centers (Section 330 of the PHS Act) provide a number of specified primary care and preventive health services to medically underserved populations.

Proposed Law

This section would require the Secretary, acting through the CDC Director, to award grants to State and local health departments for five-year pilot programs to provide public health community interventions, screenings, and, where necessary, clinical referrals, for individuals who are between 55 and 64 years of age. Grant applicants would be required to submit such information and in such a manner as required by the Secretary, including demonstration of the capacity, if funded, to develop relationships with health agencies, providers, and insurers, as needed, and identification of a community-based clinical partner such as a community health center or rural health clinic.

Grantees would be required to collaborate with CDC, the Administration on Aging, and relevant local agencies and organizations and use the funds awarded to deliver interventions to the target population to, among other things, improve nutrition, increase physical activity, reduce tobacco use and substance abuse, improve mental health, and promote healthy lifestyles. Grantees would also be required to conduct ongoing health screenings to identify risk factors for cardiovascular disease, stroke, and diabetes. Such screening activities could include: mental health/behavioral health; physical activity, smoking, and nutrition; and any other measures deemed appropriate by the Secretary. Grantees would be required to maintain records of screening results to establish baseline data for monitoring the target population. Grantees would further be required to use funds

to assure that individuals found to have chronic disease risk factors received clinical referral/treatment for follow-up services to reduce such risk.

For individuals found to have risk factors for chronic disease under this program, grantees would be required to determine whether such individuals have a source of health insurance coverage. Covered individuals would be referred to providers participating in their plans. For uninsured individuals, the grantee's community-based clinical partner would be required to assist the individual in determining eligibility for available public coverage options and identify other appropriate community health care resources and assistance programs. A grantee would be required to use amounts received under this program to assist in the referral of at-risk patients for clinical follow-up, and to help determine eligibility for other public programs.

Grantees would be required to use funds provided under this program to measure changes in the prevalence of chronic disease risk factors among participants. The Secretary would be required to conduct an annual evaluation of the effectiveness of this program, by examining changes in the prevalence of uncontrolled chronic disease risk factors among new Medicare enrollees (or individuals nearing enrollment, including those who are 63 and 64 years of age) who reside in States or localities receiving grants under this section as compared with national and historical data for those States and localities for the same population. There would be authorized to be appropriated such sums as may be necessary for FY2010 through FY2014 to carry out this section.

Sec. 323. Wellness for Individuals with Disabilities

Current Law

Section 502 of the Rehabilitation Act established the Architectural and Transportation Barriers Compliance Board to develop design standards for, and to assure compliance by, facilities designed, built, altered, or leased with Federal funds, in order to improve access for people with disabilities.

Proposed Law

This proposal would amend Title V of the Rehabilitation Act by adding a new Section 510, requiring the Architectural and Transportation Barriers Compliance Board to issue standards for minimal technical criteria for medical diagnostic equipment (as defined) used in medical settings. The standards must ensure that individuals with disabilities can use, enter, and exit such equipment independently, to the maximum extent possible. The Board would be required periodically to review the standards and amend them as necessary.

Sec. 324. Immunizations

Current Law

Section 317 of the PHS Act authorizes the Secretary to make grants to States for prevention programs, including immunization programs. A portion of awarded funds may be used by States to purchase vaccines.

Proposed Law

This provision would amend Section 317 of the PHS Act to provide explicit authority to the Secretary to negotiate and enter into contracts with manufacturers for the purchase of vaccines for adults, and for States to purchase such vaccines at the prices negotiated by the Secretary.

This provision would also add a new subsection 317(m), which would require the Secretary, acting through the CDC Director, to conduct a demonstration program of grants to States to improve immunization coverage of children, adolescents, and adults, using evidence-based, population-based interventions for high-risk populations. To be eligible, States would have to submit an appropriate plan to the Secretary. States would be required to use funds provided to implement recommendations of the Task Force on Community Preventive Services (administered by CDC), or other evidence-based interventions, regarding the use of recalls and reminders; patient and provider education and outreach approaches; ways to decrease out-of-pocket costs; use of home visits; and other approaches as specified, alone or in combination. In awarding grants under this subsection, the Secretary would be required to consider any reviews or recommendations of the Task Force on Community Preventive Services.

Within three years of receiving a grant, a State would be required to report to the Secretary regarding an evaluation of progress in improving immunization rates in high-risk populations. Within five years of enactment, the Secretary would be required to report to Congress regarding the effectiveness of the demonstration program, and recommendations regarding whether it should be extended or expanded. There would be authorized to be appropriated such sums as may be necessary for FY2010 through FY2014 to carry out this subsection.

This section would also reauthorize the program of immunization grants to States by striking the dates in current law in PHS Act Section 317(j), in effect making the authorization of appropriations for the program permanent.

Sec. 325. Nutrition Labeling of Standard Menu Items at Chain Restaurants and of Articles of Food Sold at Vending Machines

Current Law

Section 301(a) of the Federal Food, Drug and Cosmetic Act (FFDCA) prohibits the introduction or delivery for introduction into interstate commerce of any food that is misbranded. FFDCA Section 403 list the circumstances that would cause a food to be deemed misbranded, including failure to adhere to the Act's nutrition labeling requirements. Certain food is exempt from those requirements, including: (i) food that is

served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments; and (ii) food which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.

FFDCA Section 403A prohibits States and localities from requiring their own nutrition labeling that is not identical to the FFDCA's labeling requirements. This prohibition does not apply to food that is exempt from FFDCA's labeling requirements, discussed in the paragraph above.

Proposed Law

This proposal would modify the nutrition labeling exemption for food served in certain restaurants and similar retail food establishments. Failure to comply with the new requirements would deem a food misbranded under FFDCA Section 403. For such food, the proposal would require labeling of standard menu items offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items. Such establishments would be required, for standard menu items, to disclose, in a clear and conspicuous manner on the menu, and on a menu board (as defined, including a drive-through menu board), in addition to other information required: (1) the number of calories contained in the item, as it is usually prepared and offered for sale; and (2) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu, according to additional specifications. Such establishments would also be required to make the above information, in written form, available at the premises upon request. Existing law regarding insignificant amounts of nutrients would apply.

Except where inapplicable as described below, a restaurant or similar retail food establishment offering food for sale at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display and that is visible to customers, would be required to place adjacent to each food offered a sign that lists calories per displayed food item or per serving.

An establishment would be required to have a reasonable basis for its nutrient content disclosures, including use of nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in 21 CFR 101.10 (or any successor regulation), or in a related FDA guidance.

The Secretary would be required to establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks,

ice cream, pizza, doughnuts, or children's combination meals, through means determined by the Secretary, including ranges, averages, or other methods.

If the Secretary determines that a nutrient (other than a nutrient whose disclosure is already required) should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary would be permitted to require, by regulation, disclosure of such nutrient in written form. For such regulations, existing law regarding insignificant amounts of nutrients would apply. (FFDCA Section 403(q)(5)(C)).

The requirements above would not apply to items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use); daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, or custom orders; or such other food that is part of a customary market test appearing on the menu for less than 90 days, under terms and conditions established by the Secretary.

In the case of an article of food sold from a vending machine that (a) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and (b) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines, the vending machine operator would be required to provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.

An authorized official of any restaurant or similar retail food establishment or vending machine operator not subject to the requirements of this provision would be permitted to elect to be subject to such requirements by voluntarily registering, biannually, the name and address of such restaurant or similar retail food establishment or vending machine operator with the Secretary, as specified by the Secretary by regulation. Within 120 days of enactment, the Secretary would be required to publish a notice in the Federal Register specifying the terms and conditions for implementation of such voluntary election, pending promulgation of regulations. Nothing in this provision would authorize the Secretary to require, in order to voluntarily register, an application, review, or licensing process.

Not later than 1 year after the date of enactment, the Secretary would be required to promulgate proposed regulations to carry out this proposal. In promulgating regulations, the Secretary would be required to (a) consider standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors, as the Secretary determines; and (b) specify the format and manner of the nutrient disclosure requirements. The Secretary would be required to provide quarterly reports to Congress that describe the Secretary's progress toward promulgating final regulations.

This proposal would also amend FFDCA 403A, narrowing the scope of what states and their political subdivisions could regulate regarding foods served in restaurants, retail food establishments, and vending machines. The new parameters would prohibit such state regulation except for food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items.

Nothing in the amendments made by this proposal would: (1) preempt any provision of state or local law except regarding nutrient content disclosures of the type required under provisions in this bill and expressly preempted under them; (2) apply to any state or local requirement about safety warnings on food labels; or (3) (except as provided regarding the voluntary provision of nutrition information) apply to any restaurant or similar retail food establishment other than those described in this proposal, regarding general requirements for restaurants and similar retail food establishments.

Subtitle D - Support for Prevention and Public Health Information

Sec. 331. Research on Optimizing the Delivery of Public Health Services

Current Law

Nothing strictly applicable. The Secretary has general authority to conduct public health research under several sections in Title III of the PHS Act.

Proposed Law

This proposal would require the Secretary, acting through the CDC Director, to provide funding for research on the following: (1) examining evidence-based practices relating to prevention, focused on high-priority areas as identified by the Secretary in the National Prevention Strategy or Healthy People 2020, including comparing community-based public health interventions in terms of their effectiveness and cost; (2) analyzing the translation of interventions from academic to real-world settings; (3) identifying effective strategies for organizing, financing, or delivering public health services in community settings, including comparing State and local health department structures and systems in terms of their effectiveness and cost; and (4) collecting and disseminating specified information about the public health workforce.

The Secretary would be required to coordinate research efforts with the Community Preventive Services Task Force, and make use of existing partnerships and initiatives within the Federal government, with State and local governments, and with the private sector. The Secretary would be required, annually, to report to Congress concerning the activities and findings of research supported under this section.

Sec. 332. Understanding Health Disparities: Data Collection and Analysis

Current Law

While federal data collection efforts assemble a broad range of data for measuring disparities in the quality of and access to health care, there are no statutory requirements to ensure that a sample size is large enough to generate reliable, statistically significant estimates for various racial and ethnic groups.

Since 1999 HHS has required, as a matter of policy, that all HHS-funded and sponsored data collection systems require the inclusion of information on race and ethnicity, according to OMB standards. OMB Directive 15, “Standards for the Classification of Federal Data on Race and Ethnicity,” outlines standards for the collection of race and ethnicity data in federally-sponsored surveys, forms, and other records (e.g., school applications or mortgage lending applications). The directive does not mandate collection of such data. However, it requires: (1) when race data are collected, that a minimum of five racial categories (White, Black or African American, American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander) be used; and (2) when ethnicity data are collected, that a dichotomous question “Hispanic or Latino” or “not Hispanic or Latino” be used. (Data collection instruments may include additional ethnicity categories, under specified conditions). When individuals are asked to self-identify (OMB’s preferred method), the directive also requires that they be given the opportunity to report multiple races in response to a single question. Including “multiracial” is not a permitted option. Requirements to use OMB Directive 15 may be waived if an organization can demonstrate that it is unreasonable to use the categories in a particular situation, or if it can be shown that race and ethnicity data are not critical to the administration of the program seeking this information.

OMB standards do not apply to state and local public health departments or to Medicaid. While the standards do apply to the CHIP program, they are not binding on states that opt to use CHIP funding to finance a Medicaid expansion, or that use a hybrid approach.

OMB standards do not address data on primary or preferred language. However, CMS requires that this information be reported for Medicaid beneficiaries. CMS does not require the collection of primary language data for CHIP enrollees and their parents.

The recently enacted Health Information Technology for Economic and Clinical Health (HITECH) Act (P.L. 111-5) instructed the new HIT Policy Committee to recommend standards to ensure that HIT systems collect patient demographic data, including, at a minimum, race, ethnicity, primary language, and gender.

There is no current law that requires the Secretary to share health disparities measures, data, and analyses with other HHS agencies. Section 903 of the PHS Act requires the Director of AHRQ to conduct and support research on health disparities, and to produce and publish an annual report on the matter, to describe prevailing disparities in health care delivery as it relates to racial and socioeconomic factors in priority populations.

The health information privacy rule, promulgated under the 1996 Health Insurance Portability and Accountability Act (HIPAA), places certain restrictions on the use and disclosure of individually identifiable health information that is created and maintained by health plans, health care providers, and their business associates.

Proposed Law

This proposal would establish a new Title XXXIII in the PHS Act, regarding “Data Collection, Analysis, and Quality.” Section 3301 would require the Secretary, within one year of enactment, to assure that any ongoing or federally conducted or supported health care or public health program, activity or survey meets certain standards regarding the collection and reporting of data. All such activities would be required to collect and report the following data for applicants, recipients or beneficiaries: (A) race and ethnicity; (B) gender, geographic location, socioeconomic status (including education, employment or income), primary language, and disability status; (C) the smallest geographic level if such data can be aggregated; and (D) if practicable, racial and ethnic subgroups, using statistical oversamples if needed.

The Secretary (or designee) would be required to develop data standards for the above requirements. In so doing, the Secretary would be required to: (A) use OMB standards, at a minimum, for race and ethnicity measures; (B) develop standards for measures of gender, geographic location, socioeconomic status, primary language, and disability; and (C) develop standards [regarding data that are] self-reported by the applicant, recipient, or beneficiary; [and/or] from a parent or legal guardian if such person is a minor or legally incapacitated. The Secretary would also be required, acting through the National Coordinator for Health Information Technology, to develop national standards for the management of data collected, and interoperability and security systems for data management.

The Secretary would be required to: analyze the data collected as above to detect and monitor trends in health disparities (as defined in section 485E of the PHS Act) at the Federal and State levels; make such analyses available to specified agencies in HHS and other agencies and entities as the Secretary determines; report such data and analyses through public Internet sites and other appropriate mechanisms; and make such data available for additional research, analysis, and dissemination to other Federal agencies, non-governmental entities, and the public.

The proposal states that nothing in the new Section 3301 should be construed to permit the use of information collected under this new section in a manner that would adversely affect any individual. The Secretary would be required to ensure, through regulation or otherwise, that all data collected as above would be: (1) covered by privacy safeguards that are at least as protective as the HIPAA privacy rule; and (2) protected from all inappropriate internal use by any entity that collects, stores, or receives the data, including use of such data in determinations of eligibility (or continued eligibility) in health plans, and from other inappropriate uses, as defined by the Secretary.

There would be authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.

Sec. 333. Health Impact Assessments

Current Law

Nothing strictly applicable. The proposed activity would be authorized under general authorities of the Secretary in Title III of the PHS Act.

Proposed Law

The purpose of this provision is to facilitate the use of health impact assessments as a means to assess the effect of the built environment on health outcomes. Built environment is defined as “an environment consisting of building, spaces, and products that are created or modified by individuals and entities, including homes, schools, workplaces, greenways, business areas, transportation systems, and parks and recreation areas, electrical transmission lines, waste disposal sites, and land-use planning and policies that impact urban, rural and suburban communities.” Health impact assessment is defined as “a combination of procedures, methods, and tools by which a regulation, program, or other project is assessed as to its potential effects on the health of a population, and the distribution of those effects within the population.”

The proposal would require the Secretary, in coordination with the Administrator of the Environmental Protection Agency, to establish a program at the National Center for Environmental Health at CDC to foster advances and provide technical support in the field of health impact assessment. The Secretary would be required to collect and disseminate evidence-based practices; to provide grants for technical assistance and training; and to provide guidance for implementation and program evaluation. There would be authorized to be appropriated sums as may be necessary for each of fiscal years 2010 through 2014 to carry out this section.

Sec. 334. CDC and Employer-based Wellness Programs

Current Law

Nothing strictly applicable. Workplace wellness programs are increasingly common. Under HIPAA non-discrimination requirements in Section 702 of the Employee Retirement Income Security Act (ERISA), employers are permitted to reward participation in such programs, subject to certain conditions. Final regulations are at 29 CFR 2590.702.

Proposed Law

This provision would amend the PHS Act, adding several new sections. A new PHS Act Section 399HH would require the CDC Director, in consultation with others, to conduct targeted educational campaigns to: (1) make employers, employer groups, and other interested parties aware of the benefits of employer-based wellness programs; (2) establish a culture of health by emphasizing health promotion and disease prevention; (3) emphasize an integrated and coordinated approach to workplace wellness; and (4) ensure informed decisions through high quality information to organizational leaders.

A new PHS Act Section 399HH-1 would require the CDC Director to provide employers with technical assistance and other resources to evaluate workplace wellness programs, including measuring employee participation; developing standardized measures of factors that have a positive effect on health behaviors, outcomes, and expenditures; and evaluating the effect of programs on health outcomes, absenteeism, productivity, workplace injury rates, and medical costs. The Director would also be required to build evaluation capacity among workplace staff by providing resources, technical assistance, and consultation through Web portals, call centers, or other means.

A new PHS Act Section 399HH-2 would require the CDC Director, within two years of enactment and at regular intervals thereafter (as determined by the Director), to conduct a national survey to assess employer-based health policies and programs, and to report to Congress on survey findings and recommendations for the implementation of effective employer-based health policies and programs.

A new PHS Act Section 399HH-3 would require the CDC Director, in collaboration with academic institutions and employers, to institute workplace demonstration projects across small, medium, and large employers. Projects should be designed to determine best practices for achieving effective and sustainable workplace wellness interventions. The Director would be required to report to Congress on findings of the demonstrations, including recommendations of the Director for the implementation of effective employer-based health policies and programs.