



Nutrition Labeling of Restaurant Menus

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Summary

Rising rates of obesity and the resulting effects on citizens' health and health care costs have prompted federal, state, and local policymakers to consider a number of policy options to reduce obesity levels in the United States, such as exercise promotion, nutrition education, and taxation of certain foods. Labeling of the nutritional content of foods purchased and consumed outside the home has been recommended by researchers and policymakers as one tool to address rising obesity rates.

The Federal Food, Drug, and Cosmetic Act (FFDCA, P.L. 75-717, as amended) authorizes the Food and Drug Administration (FDA) to regulate labeling of most foods other than meat and poultry. Section 4205 of the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) amended the FDA's nutrition labeling authorities under the FFDCA to require nutrition labeling of foods sold in some chain restaurants and vending machines, both of which were previously exempt from the FDA's nutrition labeling regulations. While the ACA provided general requirements for restaurant menu nutrition labeling, it required the FDA to promulgate regulations specifying the scope of entities affected by the law, the scope of food covered by the law, and certain details regarding how the required calorie and nutrition information is conveyed to consumers.

The FDA's proposed rule on nutrition labeling in restaurants and similar retail food establishments (SRFE), published in April 2011, proposed definitions for a number of terms that are not defined in law. It proposed two options for determining the entities affected by the rule, set requirements for covered restaurants and SRFE to implement the rule, provided details for voluntary registration of establishments that are not covered by the rule but that elect to be subject to the requirements of the rule, proposed an effective date, and outlined enforcement mechanisms for establishments that fail to comply. The comment period on the proposed rule ended on July 5, 2011. The FDA is currently finalizing the rule, and the agency has indicated that it expects to issue the final rule in November 2012.

Several potential concerns for Congress have been emphasized regarding implementation of the proposed rule. First is the scope of the entities affected by the rule. The second is the food that will require calorie and nutrient information under the rule. Other related concerns include the presentation of calorie and nutrient information and the amount of time businesses will have to implement the rule. Some Members of Congress are concerned that the FDA's proposed rule reaches beyond congressional intent and the agency's authority, and have introduced legislation that would limit the scope of the FDA's proposed rule.

This report provides a brief overview of the FDA's authority to regulate nutrition labeling, modifications to these authorities under the ACA, and a discussion of selected aspects of the proposed rule. Concerns regarding the proposed rule raised by industry, Congress, and the public are also discussed.

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Introduction

As public concern with rising obesity rates has grown, and as individuals consume an increasing proportion of their food outside the home, public health stakeholders have successfully advocated for policies on restaurant menu nutrition labeling at the state and local level.¹ These efforts have resulted in state and local variability of laws and regulations. Businesses that must comply with these laws and regulations have grown supportive of a consistent national policy on restaurant menu labeling requirements.

Section 4205 of the Patient Protection and Affordable Care Act (ACA)² amended the FDA's nutrition labeling requirements in the Federal Food, Drug, and Cosmetic Act (FFDCA),³ which were established by the Nutrition Labeling and Education Act of 1990 (NLEA).⁴ The ACA provision required nutrition labeling for foods sold in chain restaurants and vending machines. Both were previously exempt from the FDA's nutrition labeling authority. The provision also has a section on federal preemption of state and local laws regarding nutrition labeling in restaurants and SRFE.

This report provides a discussion of the role of nutrition labeling in combating obesity, an overview of the FDA's authority to regulate nutrition labeling under the FFDCA, the restaurant menu labeling provision in Section 4205 of the ACA, and the proposed rule implementing this provision. The report also identifies issues that have generated industry and congressional interest regarding the FDA's interpretation of this provision in the proposed rule.

Background on Restaurant Menu Labeling and Obesity

Obesity rates have risen substantially in recent decades, from 13% of the adult population in the 1960s to 36% in 2009-2010.⁵ Although many factors contribute to an individual's weight, the basic cause of weight gain is an excess of energy intake over energy expenditure. At the population level, this has been reflected in indicators of decreased physical activity and increased calorie consumption. In adults, obesity is associated with a number of other health problems,

¹ For state-specific information on menu labeling legislation, see the National Conference of State Legislatures: <http://www.ncsl.org/issues-research/health/trans-fat-and-menu-labeling-legislation.aspx>.

² ACA was signed into law on March 23, 2010 (P.L. 111-148). A week later, on March 30, 2010, the President signed the Health Care and Education Reconciliation Act (HCERA; P.L. 111-152), which amended multiple health care and revenue provisions in ACA. Several other bills that were subsequently enacted during the 111th and 112th Congresses made more targeted changes to specific ACA provisions. All references to ACA in this report refer to the law as amended. Note that previous CRS reports on the Patient Protection and Affordable Care Act used the acronym PPACA to refer to the law. CRS is now using the more common acronym ACA.

³ P.L. 75-717, as amended.

⁴ P.L. 101-535, codified at 21 U.S.C. §343(q); 21 U.S.C. §343(r).

⁵ C Ogden and M Carroll, "Prevalence of Overweight, Obesity, and Extreme Obesity in Adults: United States, Trends 1960-1962 through 2007-2008," *NCHS Health E-Stat*, June 2010.

including diabetes and high blood pressure.⁶ These health issues disproportionately affect low-income individuals and certain minorities.⁷

The federal government has sought to address these health concerns using a variety of approaches, including programs (e.g., the “Let’s Move” campaign)⁸ and legislation (e.g., the Healthy, Hunger Free Kids Act)⁹ that promote nutrition, healthy weight, and physical activity.¹⁰ At the state and local level, lawmakers have also proposed a variety of approaches, including taxation and prohibition of high-calorie items, and requiring calorie labeling of restaurant food.

Studies have shown that the number of calories consumed by individuals in the United States has risen concurrent with rising rates of obesity.¹¹ The number of overall calories consumed has increased from a daily average of 1,875 calories during 1977-1978 to 2,067 calories during 2005-2008. Increasingly, these calories are consumed outside the home. Recent data from the National Health and Nutrition Examination Survey (NHANES) show that 32% of Americans’ calorie intake from 2005-2008 came from foods consumed outside the home, including foods consumed in restaurants and school cafeterias.¹²

Consumers tend to underestimate the number of calories in restaurant meals. In one study, lunchtime customers at a fast food restaurant underestimated the calorie content of their lunch by 23%.¹³ Calorie labeling on menus has been adopted as one approach to making consumers aware of the amount of calories they are consuming. Calorie labeling on menus has been shown to change consumer behavior—for example, in one study, consumers were less likely to choose higher-calorie items when provided with calorie information on the restaurant menu.¹⁴

Restaurant menu labeling as a policy option for obesity prevention has garnered broad support from the public health community. The Centers for Disease Control and Prevention have deemed menu labeling a “winnable battle,”¹⁵ and the approach is supported by the American Heart Association,¹⁶ the American Medical Association,¹⁷ and others. Additionally, this approach has

⁶ Trust for America's Health, *F as in Fat: How Obesity Threatens Americans' Future*, Washington, DC, September 2012, <http://healthyamericans.org/assets/files/TFAH2012FasInFatFnlRv.pdf>.

⁷ *Ibid.*

⁸ See <http://www.letsmove.gov/>.

⁹ P.L. 111-296.

¹⁰ For additional examples of congressional and executive branch activities in these areas, see: CRS Report R41420, *Childhood Overweight and Obesity: Data Brief*, by (name redacted) ; CRS Report R41354, *Child Nutrition and WIC Reauthorization: P.L. 111-296*, by (name redacted); White House Task Force on Childhood Obesity, *Solving the Problem of Childhood Obesity Within a Generation*, Report to the President, Washington, DC, May 2010, http://www.letsmove.gov/sites/letsmove.gov/files/TaskForce_on_Childhood_Obesity_May2010_FullReport.pdf.

¹¹ L Young and M Nestle, "The Contribution of Expanding Portion Sizes to the U.S. Obesity Epidemic," *American Journal of Public Health*, vol. 92, no. 2 (February 2002), pp. 246-249.

¹² B Lin and R Morrison, "Food and Nutrient Intake Data: Taking a Look at the Nutritional Quality of Foods Eaten at Home and Away From Home," *Amber Waves*, Economic Research Service, vol. 10, no. 2 (June 2012).

¹³ B Wansink and P Chandon, "Meal Size, Not Body Size, Explains Errors in Estimating the Calorie Content of Meals," *Annals of Internal Medicine*, vol. 145, no. 5 (September 5, 2006), pp. 326-332.

¹⁴ S Burton, E Creyer, and J Kees, "Attacking the Obesity Epidemic: The Potential Health Benefits of Providing Nutrition Information in Restaurants," *American Journal of Public Health*, vol. 96, no. 9 (September 2006), pp. 1669-1675.

¹⁵ Centers for Disease Control and Prevention, Menu Labeling: http://www.cdc.gov/phlp/winnable/menu_labeling.html.

¹⁶ American Heart Association, *Position Statement on Menu Labeling*, <http://www.heart.org/idc/groups/heart-> (continued...)

gained popularity with policymakers at the state and local level. Menu labeling laws have been enacted in New York City, California, and several other jurisdictions.¹⁸

For the restaurant industry, state and local regulations have resulted in variable and sometimes conflicting requirements. For example, the California menu labeling law,²² enacted in 2008, requires restaurants with 20 or more locations *in the state* to post caloric content, carbohydrates, saturated fat, trans fat, and sodium content. The New Jersey menu labeling law, enacted in 2010, requires chain restaurants with 20 or more locations *nationally* to display calorie content for all items sold on all drive-thru and indoor menu boards.²³ New York City, perhaps the most widely publicized example, enacted legislation in 2008 to require restaurants that are part of a chain with 15 or more locations nationally to post calorie content.²⁴ While these differences may seem subtle to policy makers, the restaurant industry has made it clear that complying with varying local laws and regulations is more burdensome than complying with uniform national standards would be.

New research on nutrition labeling of menus and menu boards suggests this approach may be successful in helping consumers lower their overall calorie intake. In one study in New York City, one in six fast food consumers reported using the posted calorie information, and those

Focus on Restaurant Menu Labeling in New York City

In 2006, the New York City Board of Health voted to require restaurants that already made calorie information publicly available to consumers to publish the calorie information on menus and menu boards.¹⁹ The regulation was to take effect on July 1, 2007, but it was challenged in federal court by the New York State Restaurant Association.

A federal district court held that the regulation as adopted was preempted by the NLEA (21 U.S.C. 343-1[a][5]). Since restaurants that voluntarily disclosed calorie information were required by the regulation to post the information on menus and menu boards, the regulation directly impacted the NLEA provision regarding nutrient content claims.²⁰ However, the law was revised to address the preemption concern, and redrafted to mandate calorie posting in all restaurants that are part of a chain of 15 or more restaurants. The law was implemented in January 2008 and survived preemption and First Amendment challenges.²¹

The NYC regulation differs from the FFDC requirements for menu labeling and the FDA's proposed interpretation of the law in a number of ways. It applies to chain restaurants with 15 or more locations; only calorie information is required—providing additional nutrition information is optional; a calorie range is required for custom and combination items; alcoholic beverages are included; it does not apply to grocery or convenience stores, movie theaters, etc.

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public/@wcm/@adv/documents/downloadable/ucm_428424.pdf.

¹⁷ "AMA Calls for Menu Labeling," *Nation's Restaurant News*, June 27, 2007.

¹⁸ For state-specific information on menu labeling legislation, see the National Conference of State Legislatures: <http://www.ncsl.org/issues-research/health/trans-fat-and-menu-labeling-legislation.aspx>.

¹⁹ *N.Y. State Restaurant Ass'n v. NYC Board of Health*, 509 F.Supp.2d.351, 352 (S.D.N.Y. 2007).

²⁰ *Id.* at 362.

²¹ *N.Y. State Restaurant Ass'n v. NYC Board of Health*, 556 F.3d.114 (2nd Cir.2009); see also New York City Law Department, Office of the Corporation Counsel, "Federal Appeals Court Upholds New York City's Landmark Health Code Provision Requiring Certain Chain Restaurants to Post Calorie Information on Menus and Menu Boards," press release, February 17, 2009, http://www.nyc.gov/html/law/downloads/pdf/Calorie_Case%20_%20Appeals_Win.pdf.

²² CA SB 1420, Chapter 600, Statutes of 2008.

²³ NJ SB 3905, Chapter No. 2009-306.

²⁴ See New York City Law Department, Office of the Corporation Counsel, "Federal Appeals Court Upholds New York City's Landmark Health Code Provision Requiring Certain Chain Restaurants to Post Calorie Information on Menus and Menu Boards," press release, February 17, 2009, http://www.nyc.gov/html/law/downloads/pdf/Calorie_Case%20_%20Appeals_Win.pdf.

customers also purchased 106 fewer calories of food than those who did not use the posted calorie information.²⁵ In King County, Washington, researchers found that the nutrition labeling law affected restaurants' behavior as well. They found that calorie content, saturated fat, and sodium were lower in entrees at chain restaurants within 18 months of implementation of a county-wide nutrition labeling regulation.²⁶ However, because these laws and regulations are fairly recent, the long-term impact of state and local menu labeling regulations on population level obesity rates has not been widely studied.

One indirect consequence of variable state and local regulations regarding restaurant menu labeling is the advent of restaurant industry support for a national menu labeling policy. Major industry groups such as the National Restaurant Association supported inclusion of a restaurant menu labeling provision in the ACA.²⁷

In advance of the FDA's final rule on the national menu labeling law, some establishments have moved forward with menu nutrition labeling. McDonald's, the largest fast food company in the United States, announced in September 2012 that it would list calorie information on all restaurant and drive-thru menu boards.²⁸

FDA's Authority to Regulate Nutrition Labeling

Federal responsibility for food safety and food labeling rests primarily with the FDA and the Department of Agriculture (USDA).²⁹ The FDA is responsible for ensuring that all domestic and imported food products, except for most meats and poultry, are safe, nutritious, and accurately labeled.

The 1938 Federal Food, Drug, and Cosmetic Act (FFDCA) granted FDA the authority to regulate food products and their ingredients.³⁰ FDA's authority over nutrition labeling of those products was created by the Nutrition Labeling and Education Act (NLEA),³¹ which amended Section 403 of the FFDCA (to provide the FDA with the authority to require and regulate nutrition labeling), and added a new Section 403A (to preempt state and local nutrition labeling regulations). The ACA further amended these sections to provide FDA the authority to regulate nutrition labeling of

²⁵ T Dumanovsky et al., "Changes in Energy Content of Lunchtime Purchases from Fast Food Restaurants After Introduction of Calorie Labeling: Cross Sectional Customer Surveys," *British Medical Journal*, vol. 343 (July 26, 2011).

²⁶ B Bruemmer et al., "Energy, Saturated Fat, and Sodium Were Lower in Entrees at Chain Restaurants at 18 Months Compared with 6 Months Following the Implementation of Mandatory Menu Labeling in King County, Washington," *Journal of the Academy of Nutrition and Dietetics*, vol. 112, no. 8 (August 2012), pp. 1169-1176.

²⁷ Letter from Dawn Sweeney, President and CEO, National Restaurant Association, to The Honorable Margaret A. Hamburg, M.D., Commissioner, U.S. Food and Drug Administration, July 5, 2011, http://www.restaurant.org/pdfs/advocacy/20110705_ml_fda_sweeney.pdf.

²⁸ McDonald's USA, "McDonald's USA Adding Calorie Counts to Menu Boards, Innovating with Recommended Food Groups, Publishes Nutrition Progress Report," press release, September 12, 2012, <http://www.aboutmcdonalds.com/content/dam/AboutMcDonalds/Newsroom/Electronic%20Press%20Kits/Nutrition%20EPK/McDonalds%20USA%20Adding%20Calorie%20Counts%20to%20Menu%20Boards.pdf>.

²⁹ For more information on the food safety responsibilities of federal agencies, see CRS Report RS22600, *The Federal Food Safety System: A Primer*, by (name redacted).

³⁰ FFDCA §401 *et seq.*; 21 U.S.C. 301 *et seq.*

³¹ P.L. 101-535, codified at 21 U.S.C. §343(q); 21 U.S.C. §343(r).

restaurants, similar retail food establishments (SRFE), and vending machine operators that are part of a chain of 20 or more.³² This section provides an overview of the statutory authorities of the FDA that are relevant to this issue, and how those authorities were amended by the ACA.

The FDA is authorized to create nutrition labeling requirements for most foods, and to regulate nutrient content claims and health claims on food labels. Under the FFDCA, FDA may deem foods misbranded unless health and nutrition claims are made according to FDA regulations.³³ Introduction of misbranded food into commerce, misbranding of food that is in commerce, or receipt and delivery of misbranded food in commerce are prohibited.³⁴ There are a number of conditions under which a food would be deemed misbranded, including if its label is “false or misleading.”³⁵

Generally, the FDA relies on food companies to voluntarily recall misbranded products, either on their own initiative or upon regulators' request.³⁶ However, the agency does have the authority to pursue other enforcement actions against regulated firms, individuals, and products that fail to comply with the FFDCA. These actions include warning letters, seizures, injunctions, civil monetary penalties, and prosecution.³⁷

The FFDCA requires all food regulated by the FDA to bear labeling with the serving size, total calories per serving, total calories per serving derived from fat, and the amount of various nutrients.³⁸ It also provides the Secretary the authority to remove or otherwise change nutrient information requirements by regulation. The FDA has the authority to further specify requirements for the layout and design of the label to assist consumers. The FFDCA has provisions regarding its preemption of state and local nutrition labeling laws.³⁹

The FFDCA provides several exemptions from nutrition labeling requirements. Infant formula and medical foods, which are subject to other labeling requirements,⁴⁰ are exempt from the nutrition labeling requirements. Foods in packaging that is too small to comply with the required information, food that contains insignificant amounts of all the nutrients required to be listed, and foods offered by an individual who has grossed less than \$500,000 from food sales (or who grosses less than \$50,000 annually in food sales) unless the individual makes a health or nutrition claim for that food are also exempt.⁴¹ Foods with insignificant amounts of more than one-half the required nutrients may use a simplified labeling format.

³²The vending machine provision applies to an article of food sold from a vending machine that does not permit a purchaser to examine the nutritional information before purchase and is operated by a person owning or operating 20 or more vending machines. 21 U.S.C. §343(q)(5)(H)(viii).

³³ FFDCA §403; 21 U.S.C. §343.

³⁴ FFDCA §301; 21 U.S.C. §331.

³⁵ FFDCA §403; 21 U.S.C. §343(a).

³⁶ A provision in the Food Safety and Modernization Act (FSMA, P.L. 111-353) provides the FDA with limited authority to order a mandatory recall of foods that are misbranded due to allergen labeling.

³⁷ FFDCA §301-310; 21 U.S.C. §331-337.

³⁸ These are: fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein per serving; and vitamin and other nutrient content as determined by the Secretary of HHS. 21 U.S.C. §343(q)(1).

³⁹ FFDCA §403A; 21 U.S.C. §343-1

⁴⁰ FFDCA §413; 21 U.S.C. §350a; and Section 5(b) of the Orphan Drug Act, P.L. 97-414; 21 U.S.C. §360ee(b)(3).

⁴¹ FFDCA §403; 21 U.S.C. §343(q)(5)(B), (C), and (D).

Prior to passage of the ACA, two other categories of food were also exempt from nutrition labeling requirements. These categories were (1) food “which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or used in such establishments,” and (2) food “which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is the type described” in (1) and “which is offered for sale to consumers but not for immediate consumption in such establishment and which is not offered for sale outside such establishment.”⁴²

Nutrition Labeling of Restaurant Menus

As noted, prior to passage of the ACA, restaurant-type food and food from vending machines were exempt from nutrition labeling authorities in the FFDCA. The ACA amended the FDA’s authorities to require certain restaurants, SRFE, and vending machine operators to provide calorie and other nutrient information.⁴³ Current law also allows restaurants, SRFE, and vending machine operators who are not subject to the requirements of the law to voluntarily register to be subject to these requirements.

Section 4205 of the ACA amended Section 403(q) of the FFDCA, regarding nutrition labeling requirements, and Section 403A of the FFDCA, regarding federal preemption of state and local food labeling requirements. It amended the FFDCA to newly require nutrition labeling for standard menu items offered for sale in chain restaurants or SRFE⁴⁴ with 20 or more locations, doing business under the same name regardless of the type of ownership of the locations, and that offer substantially the same menu items. Under the amended law, restaurants and SRFE are required to disclose the number of calories in each item “as usually prepared and offered for sale,” and provide a statement on suggested total daily caloric intake “in a clear and conspicuous manner” on menus and menu boards. Additionally, the law requires restaurants and SRFE to make other specified nutrition information available to consumers in writing upon request,⁴⁵ and to provide a prominent, clear, and conspicuous statement on the menu or menu board regarding the availability of this information. The law also requires restaurants and SRFE to provide calorie information adjacent to self-service food (i.e., salad bars, buffet lines, and cafeteria lines).

Section 4205 required that nutrient content disclosures have a “reasonable basis,” such as nutrient databases, cookbooks, or laboratory analyses. The law requires HHS to establish standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but are listed as a single menu item (i.e., “combo meals”). Foods exempted from the law include items not listed on a menu or menu board (such as condiments and items for general use); daily specials and other temporary menu items,⁴⁶ custom orders; and food items that are being market-tested.⁴⁷ The provision also has a section on federal

⁴² FFDCA §403; 21 U.S.C. §343(q)(5)(A), prior to amendment by the ACA.

⁴³ The FFDCA, as amended by ACA Section 4205, requires vending machine operators that own or operate 20 or more vending machines to provide signs “in close proximity” disclosing the number of calories contained in each article of food, so that the information is accessible to consumers before they make their purchases.

⁴⁴ The term similar retail food establishment (SRFE) is not defined in the FFDCA.

⁴⁵ This information is specified in 21 U.S.C. §343(q)(1)(C) and (D) as: total number of calories derived from any source; total number of calories derived from fat; total fat; saturated fat; cholesterol; sodium; total carbohydrates; complex carbohydrates; sugars; dietary fiber; and total protein contained in each serving size or other unit of measure.

⁴⁶ Limited to items that appear on the menu for less than 60 days per year.

⁴⁷ Limited to items that appear on the menu for less than 90 days per year.

preemption of state and local laws regarding nutrition labeling in restaurants and SRFE. The ACA required the FDA to promulgate regulations to carry out this new section of the FFDCa within one year of enactment, and to provide the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce with quarterly reports on the agency's progress toward promulgating these regulations. The law specifically required the FDA to promulgate regulations for the following issues:

- standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, that are listed as a single menu item;
- any other nutrient that may be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices;
- rules for registration of establishments that are not otherwise subject to the law's requirements to voluntarily provide nutrition information; and
- the format and manner of the nutrient content disclosure requirement.

The FDA was further instructed to consider certain factors in rulemaking, including the standardization of recipes and preparation methods; variation in ingredients, serving size, and formulation of menu items; space on menus and menu boards; and human components including worker training and the possibility of human error.

FDA Rulemaking on Nutrition Labeling of Standard Menu Items in Restaurants

The FDA published the preliminary regulatory impact analyses (PRIA) for restaurant menu nutrition labeling and vending machine calorie labeling⁴⁸ in March 2011 and the proposed rules for restaurant nutrition labeling⁴⁹ and for calorie labeling of articles of food in vending machines⁵⁰ in April 2011. The PRIA for restaurant menu labeling analyzed the possible regulatory and economic impact of Section 4205 and proposed options for approaches to the regulations. The PRIA and proposed rules generated hundreds of comments from industry, Members of Congress, and the public.

Overview of the Proposed Rule

Introductory material for the proposed rule on nutrition labeling in restaurants and similar retail food establishments provided background information on food consumption outside the home, current nutrition labeling requirements as they apply to packaged foods, and the historic

⁴⁸ Center for Food Safety and Applied Nutrition, *Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments*, Food and Drug Administration, Notice of Proposed Rulemaking, March 2011; and Center for Food Safety and Applied Nutrition, *Food Labeling: Calorie Labeling of Articles of Food in Vending Machines*, Food and Drug Administration, Notice of Proposed Rulemaking, March 2011.

⁴⁹ Food and Drug Administration, "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Proposed Rule," *76 Federal Register* 19192, April 6, 2011.

⁵⁰ Food and Drug Administration, "Food Labeling; Calorie Labeling of Articles of Food in Vending Machines; Proposed Rule," *76 Federal Register* 66, April 6, 2011.

exemption for restaurants and SRFE under NLEA. It also listed the requirements of Section 4205 of the ACA, and the proposed rule included definitions for a number of terms that were not defined in the law. The proposed rule set requirements for covered restaurants and SRFE to implement the rule, provided detail for voluntary registration of establishments that are not covered by the law but that elect to be subject to the requirements of the law, set an effective date, and outlined enforcement mechanisms for establishments that fail to comply. The proposed rule was available for public comment through July 5, 2011, and a final rule is expected by the end of 2012.

The following sections of the report describe the components of the proposed rule that have invoked concern or debate, and the policy implications of the rulemaking process.

Selected Aspects of the Proposed Rule

The following sections present many of the terms that were defined in the statute and the proposed rule, and then provide a discussion of the issues raised regarding these terms. While some definitions are clear and straightforward, others have generated debate, including the FDA's determination of the scope of covered establishments, variation among establishments, the cost of providing the required information, and the accessibility of calorie and nutrition information to consumers. All of these factors could influence the impact on affected restaurants and SRFE. Specific concerns regarding the impact of the proposed rule, and the industry and congressional response, are also discussed in this section.

Covered establishments

Under the ACA, restaurants and similar retail food establishments (SRFE) that are part of a chain of 20 or more (regardless of the type of ownership of the locations) and establishments that voluntarily register with the FDA to become subject to the requirements of Section 4205 of the ACA are subject to certain provisions of the FFDCFA and respective regulations regarding nutrition labeling. The meaning of SRFE was not defined in the ACA.

FDA's Proposed Rule

The FDA has proposed two options for the definition of "restaurants or similar retail food establishments" to be covered by the rule. Each definition would impact different segments of the food industry. One proposed interpretation of restaurants and SRFE (see Option 1 in **Table 1**) would generally exempt movie theaters, amusement parks, general merchandise stores with in-house concession stands, hotels, and transportation carriers such as trains and airplanes. The alternate definition (see Option 2 in **Table 1**) would also generally exempt these entities, as well as grocery and convenience stores. Other restaurants and SRFE that are not regulated under the proposed definitions may voluntarily register with an "authorized official"⁵¹ to be subject to the requirements of this regulation and would also be considered "covered establishments."

⁵¹ "Authorized official" is proposed to mean the "owner, operator, agent in charge, or any other person authorized by the owner, operator, or agent in charge" of a restaurant or SRFE not subject to the requirements of Section 4205.

Table 1. Covered Establishments Under the Proposed Rule

ACA Section 4205	Proposed Rule
<p>Restaurants or similar retail food establishments that are</p> <p>(1) part of a chain with 20 or more locations (regardless of the type of ownership of the locations);</p> <p>(2) doing business under the same name; and</p> <p>(3) offering for sale substantially the same menu items.</p>	<p>“Restaurant or similar retail food establishment” means a retail establishment that offers for sale restaurant or restaurant-type food, where the sale of food is the primary business activity of that establishment.</p> <p>Option 1: (1) the establishment presents or has presented itself publicly as a restaurant, or (2) a total of more than 50% of a retail establishment’s gross floor area is used for the preparation, purchase, service, consumption, or storage of <i>food</i> (or 50% of the establishment’s revenues are derived from <i>food</i>).</p> <p>Option 2: (1) the establishment presents or has presented itself publicly as a restaurant, or (2) a total of more than 50% of a retail establishment’s gross floor area is used for the preparation, purchase, service, consumption, or storage of <i>restaurant or restaurant-type food or its ingredients</i>.</p> <p>“Doing business under the same name” means sharing a name that is either the same or a slight variation due to region, location, or size.</p> <p>“Offering for sale substantially the same menu items” means offering for sale menu items that use the same general recipe and are prepared in the same way with the same components, even if the name varies.</p>

Source: Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments," *76 Federal Register* 19192, April 6, 2011.

Discussion of Covered Establishments Under the Proposed Rule

Specifically in the context of the proposed rule, the possible inclusion of supermarkets and convenience stores under the definition of SRFE has generated debate. This has provoked some Members of Congress to propose legislation⁵² directing the FDA to narrowly interpret the law by excluding primarily retail entities, because the perceived burden of including those entities outweighs the perceived potential benefits.

At issue is the scope of covered establishments. Some have argued that Option 1, as described in **Table 1**, is too broad and that grocery and convenience stores should not be covered by the rule. Others have argued that Option 2 is too narrow, and that congressional intent was to encompass grocery and convenience stores, as well as entities such as movie theaters, bowling alleys, bookstore cafes, and all establishments that sell restaurant-like food to consumers. Some Members of Congress, with support from the grocery industry, have expressed concern over Option 1, and have introduced legislation that would define SRFE as establishments that derive more than 50% of their revenue from restaurant-type food, similar to the proposed Option 2 in **Table 1**.⁵³

⁵² H.R. 6174, The Common Sense Nutrition Disclosure Act.

⁵³ H.Rept. 112-101 (June 3, 2011); also see H.R. 6174, The Common Sense Nutrition Disclosure Act.

Members of Congress who advocate for a broader definition of SRFE note that Congress intended the law to apply to “restaurants as well as other retail food establishments that sell food to consumers, regardless of the percentage of floor space devoted to food and regardless of whether food sales constitute a large or small portion of the establishments’ total business.” This would include food outlets such as movie theaters, bowling alleys, and other entertainment venues, as well as grocery and convenience stores.⁵⁴

Those who argue for the narrower version, including industry groups such as the Food Marketing Institute, feel that the FDA has overstepped its statutory authority and that grocery stores should not be included in the rule for a number of reasons, including disproportionate burden on grocery stores and questions about whether this is outside of the scope of the agency’s authority to regulate supermarkets.⁵⁵ They have argued for the narrower definition of the term that does not include supermarkets as SRFE, which the FDA has acknowledged as less burdensome.

The state and local menu labeling regulations that have been enacted in the United States generally do not apply to grocery stores. Some have argued that congressional intent in drafting the provision that was eventually enacted as part of the ACA was not to broaden the scope of those laws. The original sponsors of the bill disagree.⁵⁶ However, as many grocers and other business owners have increased their share of the market in sales of restaurant-type food, one question for policymakers is whether the inclusion of supermarkets and convenience stores is instrumental to the effectiveness of the menu labeling law. If congressional intent was to regulate all restaurant-type food, regardless of location, so that consumers have full information, then restaurant-type food from convenience stores, supermarkets, and movie theaters could generally be included.

In anticipation of the final rule, some establishments have moved forward with menu labeling. McDonald’s, the largest fast food company in the United States, announced in September 2012 that it would list calorie information on all restaurant and drive-thru menu boards.⁵⁷

Covered Food

Under the ACA, covered establishments are required to provide calorie and nutrition information for “food that is a standard menu item.” These items include combination meals, variable menu items, self-service food, and food on display.

⁵⁴ Letter from Senator Tom Harkin and Representative Rosa DeLauro to Dr. Margaret Hamburg, Commissioner, Food and Drug Administration, June 17, 2011.

⁵⁵ Food Marketing Institute, *Comments on Proposed FDA Menu Labeling Rule*, Arlington, VA, July 5, 2011, <http://www.fmi.org/docs/newsletters-comments/fda-proposed-menu-labeling-rule-%28fda-2011-f-0172%29.pdf?sfvrsn=2>.

⁵⁶ Letter from Senator Tom Harkin and Representative Rosa DeLauro to Dr. Margaret Hamburg, Commissioner, Food and Drug Administration, June 17, 2011; also see S. 1048 (111th Congress), The M.E.A.L. Act.

⁵⁷ McDonald’s USA, “McDonald’s USA Adding Calorie Counts to Menu Boards, Innovating with Recommended Food Groups, Publishes Nutrition Progress Report,” press release, September 12, 2012, <http://www.aboutmcdonalds.com/content/dam/AboutMcDonalds/Newsroom/Electronic%20Press%20Kits/Nutrition%20EPK/McDonalds%20USA%20Adding%20Calorie%20Counts%20to%20Menu%20Boards.pdf>.

FDA's Proposed Rule

Under ACA Section 4205, now FFDCFA Section 403(q)(5)(H), foods that do not require labeling in restaurants and SRFE are

- custom orders, which are prepared in a specific manner at the customer's request;
- daily specials—foods that are not routinely listed on the menu;
- temporary menu items, which appear on a menu or menu board for less than 60 days per calendar year;
- part of a customary market test—foods that are offered for fewer than 90 consecutive days to test consumer acceptance; and
- condiments available for general use, such as salt, pepper, and ketchup, that every customer has access to.

The proposed rule further specifies the foods that would require labeling and food that would be exempt under the proposed rule are listed in **Table 2**. Its proposed definitions for restaurant food and restaurant-type food, standard menu items, and combination meals. Under its proposed rule, the FDA also tentatively concluded that the new menu labeling requirements do not apply to alcoholic beverages.

Table 2. Food That is Covered and Food That is Exempt Under the Proposed Rule

Covered Food	Proposed Interpretation
Restaurant food	Food that is served in restaurants or other establishments in which food is served for immediate human consumption, that is, to be consumed either on the premises where the food is purchased or while walking away, or that is sold for sale or use in such establishment.
Restaurant-type food	Food that is ready for human consumption, offered for sale to consumers but not for immediate consumption, processed and prepared primarily in a retail establishment, and not offered for sale outside of that establishment.
Standard menu item	A restaurant or restaurant-type food that is routinely offered as a self-service food or food on display, to include multiple serving foods that are routinely included on a menu or other primary writing or routinely offered as a self-service food or food on display.
Combination meal	A standard menu item that consists of more than one food item (i.e., a meal consisting of a sandwich, side item, and drink).
Exempt Food	Proposed Interpretation
Variable menu item	A standard menu item that comes in different flavors, varieties, or combinations, and is listed as a single menu item.
Self-service food	Restaurant or restaurant-type food that that is offered for sale at a salad bar, buffet line, cafeteria line, or similar self-service facility, and self-service beverages.
Food on display	Restaurant or restaurant-type food that is visible to the customer before the customer makes a selection, so long as there is not an ordinary expectation of further preparation by the consumer before consumption.

Source: Department of Health and Human Services, Food and Drug Administration, "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments," *76 Federal Register* 19192, April 6, 2011.

Discussion of Covered and Exempt Foods Under the Proposed Rule

The proposed definition of restaurant-type food would mean that grab-and-go items, such as sandwiches or meals prepared in a restaurant or SRFE, would also be regulated. The grocery industry disagrees with this definition. Additionally, the interpretation of “variable menu items” has raised grocers’ concern because certain prepared items, such as fruit or vegetable platters, vary in composition according to seasonality, altering the calorie and nutrient content. Composition of other products may also vary according to brand and ingredient availability.

The FDA has estimated that grocery stores and supermarkets have approximately one-half of the number of restaurant-type food menu items that a restaurant has that would be covered by the proposed rule. That would be approximately 40 items requiring nutrition labeling in supermarkets and grocery stores, versus approximately 80 items requiring nutrition labeling in restaurants.⁵⁸ The grocery industry argues that this estimate is inaccurate, and that many more items at grocery stores would be affected by the adoption of Option 1 in the final rule, due to the inclusion of self-service food and food on display, which are prevalent in grocery stores and supermarkets. Grocers argue that the FDA’s estimate would be accurate if the rule only applied to restaurant food; however, if it applies to restaurant-type food, which would include many self-serve and deli items, then the affected number of items would be closer to 500 to 15,000 items, according to the Food Marketing Institute (FMI).⁵⁹

Menus and Menu Boards

The proposed rule includes clarification of several concepts that were noted but not defined in the ACA, including the medium (i.e., menu, table tent, place mat), placement, and layout of the information provided to consumers. Under the law, covered establishments must provide calorie information on menus and menu boards, and must provide other nutrition information upon request for standard menu items.

FDA’s Proposed Rule

According to the proposed rule, calorie information must be provided adjacent to the name of the menu item so that it is clearly associated with that item. Establishments can choose to implement this requirement by including a column on the menu or menu board (including drive-through menu boards) with the heading “Calories” or “Cal” or they may list the number of calories and “Calories” or “Cal” next to each item.

⁵⁸ Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments," 76 *Federal Register* 19192, April 6, 2011.

⁵⁹ Food Marketing Institute, *Comments on Proposed FDA Menu Labeling Rule*, Arlington, VA, July 5, 2011, <http://www.fmi.org/docs/newsletters-comments/fda-proposed-menu-labeling-rule-%28fda-2011-f-0172%29.pdf?sfvrsn=2>.

Table 3. “Menu and Menu Boards” Under the Proposed Rule

ACA Section 4205	Proposed Interpretation
“Menu or menu boards” means “the primary writing of the restaurant or SRFE from which a consumer makes an order selection.”	“Menu” or “menu board” includes any writing that is the primary writing from which a customer makes an order selection, including, but not limited to, breakfast, lunch, and dinner menus; dessert menus; beverage menus; children’s menus; other specialty menus, electronic menus, and menus on the Internet. The menus may be in different forms, for example, booklets, pamphlets, or single sheets of paper. Menu boards include those inside a restaurant or similar retail food establishment as well as drive-through menu boards at restaurants or similar retail food establishments.

Source: Department of Health and Human Services, Food and Drug Administration, “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments,” *76 Federal Register* 19192, April 6, 2011.

Menu boards must also have a prominent, clear, and conspicuous statement on menus and menu boards regarding the availability of written nutrition information for menu items. The written nutrition information must include the same nutrition information that is currently required by law on food package labeling.⁶⁰

The FDA further proposes that the term “primary writing” be interpreted from a customer’s vantage point. This would include drive-through menus, take-out and delivery menus, and information posted on the Internet by the covered establishment that a customer would use as the primary writing for placing an order by telephone, fax, or online. Advertisements would not be considered primary writing, but a menu sent through the mail might be, if customers routinely order from it.

Discussion of Menus and Menu Boards

There has been some concern with the FDA’s interpretation of “primary writing.”⁶¹ The nature and use of primary writing may vary depending on the type of restaurant or SRFE. For example, pizza companies have argued against in-store menu and menu board labeling, as 90% of their business is driven by phone and online ordering. On the other hand, grocery stores have argued that posting calorie and other nutrition information on the Internet should be voluntary, because their customers would be unlikely to look up this information prior to going to the store. Expecting all entities to comply in the same manner could impose the highest burden, as opposed to allowing flexibility based on the context.

The FDA and industry also differ on the estimated cost burden of providing the required information on menus and menu boards. Notably, the FDA estimates the cost of a menu board at \$550. Industry estimates range as high as \$1,500 per menu board.⁶²

⁶⁰ FFDC 403; 21 U.S.C. §343(q)(1)(C) and (D).

⁶¹ Letter from M. Scott Vinson, Vice President, National Council of Chain Restaurants, and Scott DeFife, Executive Vice President, National Restaurant Association, to Division of Dockets Management, Food and Drug Administration, July 5, 2011, http://www.restaurant.org/pdfs/advocacy/20110705_ml_fda_jointindustry.pdf.

⁶² Food Marketing Institute, *Comments on Proposed FDA Menu Labeling Rule*, Arlington, VA, July 5, 2011, [http://www.fmi.org/docs/newsletters-comments/fda-proposed-menu-labeling-rule-%28fda-2011-f-\(continued...\)](http://www.fmi.org/docs/newsletters-comments/fda-proposed-menu-labeling-rule-%28fda-2011-f-(continued...))

Calorie and Other Nutrition Information

Section 4205 of the ACA required covered establishments to disclose the number of calories contained in standard menu items as usually prepared and offered for sale. Calorie information must have a “reasonable basis” and be displayed adjacent to the name of the standard menu item on all menus and menu boards. The restaurant or SRFE must also provide a statement concerning daily recommended caloric intake, presented in a manner that enables the public to understand the significance of each item in the context of a total daily diet, and a statement indicating that additional nutrition information is available upon request.

FDA’s Proposed Rule

To fulfill the requirement that covered entities post a succinct statement concerning daily recommended calorie intake on menus and menu boards, FDA proposes the following statement:

A 2,000 calorie diet daily diet is used as the basis for general nutrition advice; however, individual calorie needs may vary.

The proposed rule would require that covered establishments declare calories on menus and menu boards to the nearest 5-calorie increment up to and including 50 calories, and to the nearest 10-calorie increment for foods above 50 calories. The FDA proposes use of the “80-120 rule” that is currently the standard for prepackaged food.⁶³

In the proposed rule, the FDA requested comment and consumer research on five different options for disclosing the calorie and nutrient content for standard menu items that come in different flavors, varieties, or combinations: using an average or median value; using an average or a range; using slashes to separate calorie disclosure when there are only two varieties; and either a range or an average if there are more varieties.

Discussion of Calorie and Nutrition Information Under the Proposed Rule

The law requires that all nutrient content disclosures must have a reasonable basis. However, estimates of the per item cost of determining nutrition information vary widely, and some Members of Congress and the restaurant industry have asserted that the FDA has misinterpreted the “reasonable basis” that restaurants and SRFE must have for nutrient disclosures in the proposed rule.⁶⁴ According to the law, the required nutritional information could be determined using nutrient databases, cookbooks, laboratory analyses, labels on packaged foods, or “any other

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⁶³ The proposed rule references the reasonable basis standard for packaged food set forth in 21 C.F.R. §101.9(g). The 80-120 rule is the common name for the standard tolerances on the accuracy of nutrition labeling that is referenced in 21 C.F.R. §101.9(g). For any nutrient whose consumption is encouraged (i.e., protein), the actual level in food must be 80% or more of the declared value; for any nutrient to be avoided in excess (i.e., sodium), actual level in food must be 120% or less of declared value.

⁶⁴ Letter from Senator Tom Harkin and Representative Rosa DeLauro to Dr. Margaret Hamburg, Commissioner, Food and Drug Administration, June 17, 2011.

reasonable means.”⁶⁵ The FDA estimates a cost of \$269 per item to determine this information, while some industry groups have determined it will cost as much as \$500 to \$1,000 per item.⁶⁶

In the proposed rule, the FDA proposes use of the “80-120 rule,” which permits a narrow deviation between the posted calorie value for a particular item and the actual calorie content of the item. This rule is currently applied to pre-packaged food, where preparation is largely mechanized. However, some note that restaurant food preparation is generally done by human hands, and thereby subject to greater variation in preparation, making it more challenging to adhere to the 80-120 rule.⁶⁷ Further, critics note that wide variation due to individual order preparation was one of the reasons the FDA exempted restaurant food from the NLEA regulations promulgated in 1993. The restaurant industry has argued that adhering to a stricter standard of “reasonable basis” may discourage smaller independent operators from participating voluntarily in the menu labeling program, simply because their food presentation is not standardized.⁶⁸

Calorie counts may also be difficult to determine due to varying portion sizes. In grocery stores, foods that are “packaged and prepared for immediate consumption” are not always pre-portioned (e.g., deli items), which means that these items will not be served in standardized portions. Additionally, certain items in restaurants, SRFE, and other establishments, are served as a whole (e.g., pizza, buckets of fried chicken) and some feel that these should be labeled as per portion, rather than whole item. Pizza companies have argued against “whole pie” labeling, because they feel it is not an accurate representation of what an individual would typically eat in one sitting.

Compliance and Enforcement

FDA does not have mandatory recall authority for food that is deemed misbranded due to nutrition labeling.⁶⁹ Although the FDA was allowed to enforce certain provisions in Section 4205 upon enactment of the ACA, it has proposed to refrain from enforcement until it has completed rulemaking.

FDA's Proposed Rule

As noted earlier in this report, the FDA has the authority to deem foods misbranded⁷⁰ unless health and nutrition claims are made according to regulations promulgated by the Secretary. The

⁶⁵ FFDC §403; 21 U.S.C. 343(q)(5)(H).

⁶⁶ Regulatory Counsel, Food Marketing Institute, *Menu Labeling: Did FDA Overreach?*, Food and Drug Policy Forum, Vol. 2 (13), Washington, DC, July 11, 2012, <http://www.fdi.org/resources/resources-order-box-detail-view/menu-labeling-did-fda-overreach->.

⁶⁷ Letter from M. Scott Vinson, Vice President, National Council of Chain Restaurants of the National Retail Federation, and Scott DeFife, Executive Vice President, Policy and Government Affairs, National Restaurant Association, to Division of Dockets Management, Food and Drug Administration, July 5, 2011, http://www.restaurant.org/pdfs/advocacy/20110705_ml_fda_jointindustry.pdf.

⁶⁸ Letter from Dawn Sweeney, President and CEO, National Restaurant Association, to The Honorable Margaret A. Hamburg, M.D., Commissioner, U.S. Food and Drug Administration, July 5, 2011, http://www.restaurant.org/pdfs/advocacy/20110705_ml_fda_sweeney.pdf.

⁶⁹ Mandatory recall authority for misbranded food is limited to food deemed misbranded under 21 U.S.C. §343(w), pertaining to major food allergen labeling.

⁷⁰ FFDC §403 [21 U.S.C. §343] defines a number of conditions under which a food would be deemed to be misbranded, beginning with a broad provision in paragraph (a) saying that a food is deemed misbranded if its label "is false or misleading in any particular." Similar to the definition of adulteration, numerous specific types of misbranding (continued...)

FDA generally does not have the authority to order a recall of a misbranded food, unless it is deemed misbranded under allergen labeling regulations. Rather, the agency relies on food companies to voluntarily recall adulterated, misbranded, or otherwise unsafe products, either on their own initiative or upon regulators' request.

In the proposed rule, the FDA provides a six-month window for restaurants and SRFE to comply with the final rule, once published. Industry representatives have requested a longer timeline of one year for full compliance.⁷¹ Failure to comply with the regulations, once finalized, will render the food misbranded. If the language regarding the 80-120 rule is included in the final rule, the accuracy of restaurant calorie information would be determined using the same standards as packaged foods.

Discussion of Compliance and Enforcement Under the Proposed Rule

The restaurant industry has argued that the six-month window for compliance is not enough time for their constituents to fully comply. Faced with the possibility of budget cuts, it is unclear if the FDA will have the funding to enforce a strict interpretation of the accuracy of calorie and other nutrition information.

Costs and Benefit Considerations for the Proposed Rule

The FDA's final determination on these definitions and the timeline for compliance and enforcement activities will affect the regulation's scope and cost. As noted in the previous sections, concerns about the cost of implementing this rule were raised before, during, and after the proposed rule was published. These include the cost and burden imposed on businesses implementing the rule. However, the eventual public health benefit to society may also be weighed; quantification of this benefit can be challenging.

The FDA's PRIA points to three elements of cost for this rule: (1) collecting and managing nutritional analysis records; (2) revising or replacing existing menus and menu boards; and (3) employee training.⁷² Cost estimates for implementation of the proposed rule provided by the FDA and industry vary widely, with the FDA estimating the initial cost of compliance at \$315 million and ongoing annual cost of the provision at \$44 million, and industry estimating the cost will exceed \$1 billion in the first year.⁷³ FDA also notes that the potential cost to industry of complying with an increasing number of state and local regulations (in the absence of a uniform national policy) could have been much greater.⁷⁴ Additionally, FDA estimated that 27% of chain

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are also defined. *FFDCA §301(a) - (c) provide that introducing misbranded food into commerce, misbranding food that is in commerce, or the receipt and delivery of misbranded food in commerce is prohibited.*

⁷¹ National Restaurant Association, "National Restaurant Association Files Menu Labeling Comments," press release, July 5, 2011, <http://www.restaurant.org/pressroom/pressrelease/?ID=2134>.

⁷² Center for Food Safety and Applied Nutrition, *Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments*, Food and Drug Administration, Notice of Proposed Rulemaking, March 2011, p. 11.

⁷³ Ibid; and FMI comments to FDA on proposed menu labeling rule. July 5, 2011. See: <http://fmi.org/news-room/news-archive/view/2011/07/08/fmi-comments-on-fda-proposed-menu-labeling-rule>.

⁷⁴ Ibid, p. 17.

restaurants have already obtained nutrition information to comply with those state and local regulations.

The Office of Management (OMB) is to review the regulations promulgated under the law to ensure, among other considerations, that they are consistent with Executive Orders 12866 and 13563, which require agencies to promulgate rules only after determining that the benefits of a regulation justify its costs. Furthermore, these executive orders require agencies to tailor their regulations to impose the least burden on society and to select approaches that maximize net benefits.⁷⁵

The economic burden of obesity is projected to continue rising. Researchers have projected that more than half of Americans will be obese by 2030.⁷⁶ Increases in weight are linked to increased risk of type 2 diabetes, cardiovascular diseases, osteoarthritis, and several forms of cancer. Additionally, it has been documented that obesity leads to decreased productivity, in terms of increased absenteeism as well as what researchers deem “presenteeism” (decreased outputs while at work).⁷⁷

The estimated societal cost of obesity has been estimated in multiple studies; however, these estimates are not precise. Obesity burdens the health care system, and many of those costs fall to government. Obesity accounts for approximately 1% to 10% of a country’s total health care costs, and obese individuals have medical costs that are 30% higher than individuals of normal weight.⁷⁸ A recent study by the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Disease Control and Prevention (CDC), estimated that the annual medical cost of obesity was as high as \$78.5 billion in 1998, or about 10% of medical spending.⁷⁹ Of that amount, roughly half of the cost was financed by Medicare and Medicaid. The authors estimated that cost may have risen to as much as \$147 billion in 2008.

The true cost and savings from any obesity prevention policy is challenging to determine—just as the factors that contribute to obesity are complex, researchers cannot isolate the effect of one specific policy relative to other interventions. In order to determine the effectiveness of an intervention such as menu labeling, researchers and policy makers may review the impact of these policies on individuals’ behavior and monitor changes in the obesity rate over time, while taking into account other factors that may also account for those changes, including the time needed for weight loss and obesity prevention programs to yield an effect, particularly on chronic disease costs.

⁷⁵ A broader discussion of cost-benefit and other analysis requirements in the rulemaking process are addressed in CRS Report R41974, *Cost-Benefit and Other Analysis Requirements in the Rulemaking Process*, by (name redacted).

⁷⁶ C Wang et al., "Health and Economic Burden of the Projected Obesity Trends in the USA and the UK," *Lancet*, vol. 378 (August 2011), pp. 815-825.

⁷⁷ R Hammond and R Levine, "The Economic Impact of Obesity in the United States," *Diabetes, Metabolic Syndrome, and Obesity: Targets and Therapy*, vol. 3 (August 17, 2010), pp. 285-295.

⁷⁸ D Withrow and D Alter, "The Economic Burden of Obesity Worldwide: a Systematic Review of the Direct costs of Obesity," *Obes Rev*, vol. 12 (2011), pp. 131-141.

⁷⁹ E Finkelstein et al., "Annual Medical Spending Attributable to Obesity: Payer and Service-Specific Estimates," *Health Affairs*, vol. 28, no. 5 (July 2009), pp. 822-831.

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