

# Health Policy Brief

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## The FDA's Menu-Labeling Rule. Many restaurants will soon be required to list the calorie count of the food they sell.

### WHAT'S THE ISSUE?

The Affordable Care Act (ACA) mandated that many chain restaurants and other “similar” food establishments list the calorie count of the food they sell. The requirement will take effect nationwide in December 2016, more than six and a half years after the ACA became law.

The regulations, promulgated by the Food and Drug Administration (FDA) in a [final rule](#) released December 1, 2014, affect only “standard menu items” sold in restaurants and other places that sell ready-to-eat food and are part of chains with at least twenty stores. The requirements are threefold: Each menu item must have a clearly visible calorie count, and each food establishment must post two statements, one noting that the average daily intake is 2,000 calories and another letting customers know that detailed nutritional information about each menu item is available on request.

There are exceptions: Daily specials and items sold by food trucks or on airplanes or trains are exempt from the labeling requirements, as are many alcoholic drinks. But made-to-order sandwiches, take-out food and salad bar items in restaurants and grocery stores, and food sold in movie theatres must all meet the new requirements.

New York City began mandating calorie counts of chain restaurant food in 2007. The new national rules were backed by the restaurant industry's trade association, the National Restaurant Association, in an effort to achieve uniformity nationwide and to avoid a growing patchwork of separate state and municipal regulations.

So far, most studies, including a 2015 [meta-analysis](#), show that providing menu nutrition labeling results in virtually no statistically significant change in calorie consumption.

### WHAT'S THE BACKGROUND?

The last major federal government action involving nutrition labeling was the [Labeling and Education Act of 1990](#), which took effect in 1994 and required nutrition labeling and serving size to be clearly displayed on most packaged foods. But it specifically exempted restaurant fare and other ready-to-eat food. In March 2014 the FDA issued a [proposed rule](#) to update the nutrition-facts label on packaged foods to include added sugar and to dramatically increase the size of the calorie label typeface. As of June 2015 there was no word yet on a final release date, according to an FDA spokesperson.

Meanwhile, the United States is in the midst of an obesity epidemic: A little more than one in three adults are obese, and an additional

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one in three are overweight. At the same time, the percentage of total food calories consumed in restaurants has almost doubled, from about 18 percent in the 1970s to about 33 percent today. Restaurant food, according to the FDA's November 2014 [regulatory analysis](#) of the new rule, typically has larger portions, more fat, more calories, and less fiber than food prepared at home.

The ACA's most widely discussed provisions involved expanding insurance coverage and reforming the health insurance market. But the law also aims to move the US health care system away from one simply focused on treating sick people toward one aimed at keeping people healthy. Requiring restaurants to give consumers nutritional and calorie information “in a direct and accessible manner” so that they can make “informed and healthful dietary choices”—the language of the FDA's final rule—is designed to serve this aim.

The FDA published a [proposed](#) menu-labeling rule on April 6, 2011, and accepted comments for three months. Three and a half years later, on December 1, 2014, the FDA issued its final rule.

Despite pushback for exemptions from the pizza and grocery store lobby, among others, the final rule was in fact stronger than the proposed regulation and was widely praised by consumer advocates.

“The new rules around menu labeling are terrific,” the Center for Science in the Public Interest's Margo Wootan, a frequent and vociferous critic of government food policy, told National Public Radio the day the new rules were released.

Nevertheless, on July 9, 2015, the FDA yielded to industry pressure, announcing that it would push back the rule's effective date by one year, from December 1, 2015, to December 1, 2016.

#### WHAT'S IN THE LAW?

The nutrition-labeling requirement is part of the ACA's Title IV: “Prevention of Chronic Disease and Improving Public Health.”

The language of the law, which amends the Federal Food, Drug, and Cosmetic Act of 1938, is simple: It requires restaurants and “similar” retail food establishments that are “part of a chain with 20 or more locations doing business under the same name” to “disclose in a

clear and conspicuous manner” a “nutrition disclosure statement,” a “suggested daily calorie intake,” and “the number of calories contained in the standard menu item.” Standard menu items do not include such things as daily specials, but they do apply to “food on display” and “self-service food.”

The menu-label requirements apply not only to restaurants but also to foods purchased at drive-through windows, take-out food such as pizza, made-to-order sandwiches that are listed on a menu board at a deli or grocery store, muffins from a coffee shop, hot dogs and other fast food prepared on site at a convenience store, and certain alcoholic beverages listed on a menu.

The law also applies to vending machines that are part of an operating or ownership group of twenty vending machines or more.

The law will cost businesses to implement, which is one reason it excludes traditional mom-and-pop restaurants—which generally don't have twenty or more locations—as well as the odd vending machine that is not part of a larger group. The National Restaurant Association says that about 215,000 restaurants will be affected, or some 36 percent of the 600,000 eating and drinking establishments in the United States.

According to the FDA's 133-page final regulatory analysis, released in November 2014, a total of some 300,000 establishments, including non-restaurants such as grocery stores that sell meal items to go, will be covered under the law.

Given the high cost of obesity in the health care system, the FDA estimates that despite the cost of adding nutritional information to the menus, the new requirement will produce a “stream of benefits” of anywhere from \$3.7 billion to \$10.4 billion over the next twenty years. That wide range between the lower and upper bounds of potential benefits is because of the difficulty estimating several factors, including the number of consumers who will actually use the nutrition labels to reduce their caloric intake. Ultimately, any net benefit, says the FDA in its analysis, is mostly attributable to the lower probabilities of mortality that come from eating healthier food.

One goal of the labeling requirement, according to the FDA's final rule, is not just to focus on food served in restaurants but to level the playing field between restaurants and non-

# 33%

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restaurant establishments that nonetheless serve items “most like” restaurant food that is eaten either on the premises, “while walking away, or soon after arriving at another location,” a definition that covers food from a grocery store salad bar to a convenience store.

The rule pertains only to “standard menu items,” so it doesn’t include condiments or daily specials or bottles of liquor behind a bar used to prepare mixed drinks. The requirements also do not include items such as nuts or dried fruits purchased in bulk from grocery stores; food that is to be eaten over several days, such as a loaf of bread; food that needs additional preparation before being eaten; and food sold by weight that is not self-serve, such as deli salads that are either prepacked or put in a container at the consumer’s request.

The law also does not apply to food served by establishments without a fixed location, such as airplanes, food trucks, or trains.

The FDA rule also preempts any local or state nutrition-labeling requirements, including any stronger provisions, which will no longer be allowed. The rule also allows restaurants that are not part of a chain to voluntarily opt in to the requirements.

#### WHAT'S THE DEBATE?

The law might seem relatively straightforward, but a close reading of the final rule makes clear that virtually every word in section 4205 of the ACA—the statutory basis for the FDA rule—was carefully parsed and subject to vigorous debate.

Former FDA commissioner Margaret Hamburg [said](#) nearly two years before the final rule was released that writing it had “gotten extremely thorny.” The FDA received more than 1,100 comments, and in its final rule it specifically lists 161 comments and the agency’s response.

For example, the initial description of which establishments were covered by the rule had been based on the size of the floor space used for the sale of food. But the National Restaurant Association, which supported the labeling requirement, [argued](#) that this definition excluded locations such as movie theaters and grocery stores that still sold lots of “restaurant-like” food. So the final definition of “similar retail food establishments”—the actual statutory language — specifically includes grocery stores, convenience stores,

and food-service areas inside “entertainment venues.”

In fact, the supermarket industry had argued strongly that it did not fit under the definition of “similar retail food establishments” but was instead made up of “food retailers.” If Congress had intended supermarkets to be covered, lawmakers would have used that term, which is the statutory language in the section of the US code that covers “misbranded food,” [wrote](#) the Food Marketing Institute’s Erik Lieberman in a September 7, 2010, letter to the FDA, citing language from the 1979 Supreme Court case, *Cannon v. University of Chicago*. “It is always appropriate to assume that Congress knows the law,” he added. The FDA disagreed.

Cost was also a hotly debated factor. The supermarket industry had [said](#) it might have to spend up to a billion dollars to implement the new labeling requirements; the restaurant industry said that number was a gross exaggeration. But a [fact sheet](#) prepared by the Center for Science in the Public Interest, which backed the rule, says its analysis shows that the average cost to a grocery store chain would come to just \$22,500.

A larger, existential question is whether calorie and other nutrition labeling actually makes a difference in how many calories people consume. A meta-analysis in the May 2015 issue of the *American Journal of Public Health* found no significant impact in the relationship between calorie labeling and what consumers actually order.

Still, a small reduction in calorie intake can go a long way. A March 2015 [study](#) in the same journal concluded that among all consumers, there is a decrease of ten to twenty calories per meal, although that figure is heavily skewed toward a much smaller subset of people who actually pay attention to calorie levels and change their ordering habits as a result. The FDA [notes](#) that given the drastic impact of obesity on the health care system and other health risks, if there is a reduction in just 100 calories a week by 0.6 percent of the obese adult population, then that would result in a net benefit from the menu-labeling requirement at least as great as the costs.

What people eat, and how they make those decisions, is extremely complex and depends on far more than a calorie count. Indeed, many people make choices about what and how

**300,000**  
**establishments**

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much to eat for reasons that have nothing to do with nutrition.

Perhaps the strongest public policy justification for menu-nutrition labeling is the widely held assumption that more information is better than less information. “People can clearly benefit by knowing more, and the new FDA rules will help to do just that,” FDA commissioner Hamburg [wrote](#) on a blog post when the final rules were announced.

Still, some contend that industry support for the right to know is not as benign nor as altruistic as it may appear. George Loewenstein, a behavioral economist at Carnegie Mellon University, [argued](#) in a 2011 *American Journal of Clinical Nutrition* editorial that calorie labeling had wide industry support because it was preferable to more onerous but far more effective obesity-reduction policies—in particular—taxing the sugar content of food.

“Consumers have not grown fat because they have stopped paying attention to what they eat; they have grown fat because processed food has become cheaper...whereas

fresh food has become more expensive,” wrote Loewenstein.

## WHAT'S NEXT?

One of the major unresolved issues involving the new rules is determining who will enforce them. States, cities, or counties that pass laws identical to the federal regulations can use their own local inspectors to enforce the rules, or the FDA can possibly contract out local officials to do the inspections even if there is no corresponding local law. The FDA also has its own team of inspectors who check food manufacturing facilities, and who could be used to visit establishments with potential menu-labeling violations.

For now, the FDA continues to issue advice on how the final rule should be implemented, including a thirty-four-page [“small entity compliance guide”](#) it released in March 2015 that restates the requirements “in plain language.” The one-year extension before the rule finally takes effect in December 2016 should give reluctant businesses the additional time they need to prepare. ■

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## RESOURCES

Sara Bleich, Julia Wolfson, and Marian Jarlenski, [“Indirect Effects from Menu Labeling Can Improve the Public’s Health,”](#) *Health Affairs* Blog, February 24, 2015.

Center for Food Safety and Applied Nutrition, [“Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments: Final Regulatory Impact Analysis”](#) (Washington, DC: Food and Drug Administration, November 2014). Report No. FDA-2011-F-0172.

Center for Food Safety and Applied Nutrition, [“Guidance for Industry: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments: Small Entity Compliance Guide”](#) (Washington, DC: Food and Drug Administration, March 2015).

Roxana Chen, Michael Smyser, Nadine Chan, Mydud Ta, Brian E. Saelens, and James Krieger, [“Changes in Awareness and Use of Calorie Information after Mandatory Menu Labeling in Restaurants in King County, Washington,”](#) *American Journal of Public Health* 105, no. 3 (2015):546–53.

Larry Cohen and Juliet Sims, [“How Menu Labeling Could Spark Change Beyond the Menu Board,”](#) *Health Affairs* Blog, February 24, 2015.

Brian Elbel, Rogan Kersh, Victoria L. Brescoll, and L. Beth Dixon, [“Calorie Labeling and Food Choices: A First Look at the Effects on Low-Income People in New York City,”](#) *Health Affairs* 28, no. 6 (2009):1110–21.

Food and Drug Administration, [“Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Calorie Labeling of Articles of Food in Vending Machines; Final Rule,”](#) *Federal Register* 79, no. 230 (2014):71156–259.

George Loewenstein, Cass R. Sunstein, and Russell Golman, [“Disclosure: Psychology Changes Everything,”](#) (Cambridge, MA: Harvard Public Law, August 18, 2013). Working Paper No. 13-30.

Michael W. Long, Deirdre K. Tobias, Angie L. Craddock, Holly Batchelder, and Steven L. Gortmaker, [“Systematic Review and Meta-Analysis of the Impact of Restaurant Menu Calorie Labeling,”](#) *American Journal of Public Health* 105, no. 5 (2015):e11–24.