FDA Closer to Implementing Menu Labeling Provisions of PPACA

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Last month, the U.S. Food and Drug Administration (FDA) issued draft guidance documents associated with the implementation of section 4205 of the Patient Protection and Affordable Care Act (PPACA),1 which requires certain chain restaurants and vending machine operators to disclose nutrition and related information of the food items sold to consumers. Under § 4205, certain retail food establishments and vending machine operators must display “in a clear and conspicuous manner” the nutrient content associated with each menu item, the item’s number of calories, as well as other health-related information.2 Additionally, establishments must display a statement from the Secretary of the U.S. Department of Health and Human Services (DHHS) related to suggested daily caloric intake for an individual, provide written nutrition information to consumers upon request, and include caloric disclosures next to food items on a buffet or for other self-service foods.3 Some provisions of the law took effect on the date the PPACA was signed into law, March 23, 2010. Other provisions related to the menu labeling law will require regulations promulgated by the FDA. The FDA’s recently released guidance documents related to § 4205 outline how the agency plans to enforce the law as well as offers affected food establishments and vending machine operators some insight on what the agency considers to be important.

Background

Americans’ waistlines continue to expand year after year, with obesity rates reaching 30 percent or more in nine states4 last year.5 Nearly 2.4 million more individuals became obese from 2007 to 2009, bringing the total to 72.5 million or 26.7 percent of the country’s population.6 Researchers at the Centers for Disease Control and Prevention cite the recurring problems of lack of exercise and eating too many high-calorie foods as culprits for the skyrocketing obesity rates.7 With more Americans reaching the status of “obese,” rising health problems, as well as health care costs, also mount, including coronary heart disease, type-2 diabetes, stroke and certain forms of cancer.8 Included within PPACA is § 4205 which amends § 403(q)(5)(A) of the Federal Food, Drug, and

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2 Id. at § 4205(b)(i)-(iii).
4 Alabama, Arkansas, Kentucky, Louisiana, Mississippi, Missouri, Oklahoma, Tennessee, and West Virginia. Mississippi is the most obese state, with 34.4 percent of the state’s population.
6 Id.
7 Id.
Cosmetic Act (FDCA)\(^9\) to require retail food establishments and vending machine operators with more than 20 locations doing business under the same name and offering substantially the same menu to provide calorie information for “standard menu items” in an effort to assist consumers in making more informed dining decisions.

Some provisions of § 4205 went into effect on the date PPACA was signed into law, March 23, 2010. These provisions require establishments to:

1. disclose the number of calories in each standard menu item on menus and menu boards;
2. make additional written nutrition information available to consumers upon request;
3. provide a statement on menus and menu boards about the availability of the additional written nutrition information; and
4. provide calorie information (per serving or per food item) for most self-service items and food on display, on a sign adjacent to each food item.\(^{10}\)

Additionally, chain vending machine operators are required to immediately disclose, in a clear and conspicuous manner, “calories for articles of food that do not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or do not otherwise provide visible nutrition information at the point of purchase.”\(^{11}\)

Other aspects related to § 4205 cannot be enforced until final regulations are issued for specific § 4205 requirements, including:

- a statement on the food establishment’s menu or menu board that puts the calorie information in the context of a total daily caloric intake; and
- 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.\(^{12}\)

FDA Guidance Documents

The FDA’s recently-released, non-binding, draft guidance documents regarding § 4205 “do not establish legally enforceable responsibilities.”\(^{13}\) Instead, the documents describe


\(^{11}\) Id.


\(^{13}\) Id.
the federal agency’s “current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.”

One question posed to the FDA was the effect § 4205 may have on state and local nutrition labeling laws for restaurants and other establishments. In other words, would § 4205 of PPACA preempt similar state laws? In its guidance on the issue, the FDA noted:

State and local governments cannot directly or indirectly impose any nutrition labeling requirements that are different from, or not imposed by (or contained in) section 4205, or the related implementing regulations. State and local laws that are “identical to” the federal requirements are not preempted by section 4205. Nutrition labeling for restaurants or similar retail food establishments that are not “chain retail food establishments”…will continue to be governed by State and local regulation, if applicable, unless those establishments elect to participate exclusively in the federal regulatory program…

Despite the fairly strong message from the FDA, it was quick to point out that any State or locality that had nutrition disclosure laws in place prior to the enactment of PPACA may petition the FDA for an exemption from preemption.

The other draft guidance document included much more specific questions and answers related to the implementation of § 4205. For example, one question requested examples of restaurants or other similar retail food establishments that would be covered under the law. In response, the FDA cited the following extremely broad categories of entities that could be subject to § 4205, including:

- table service restaurants;
- quick service restaurants;
- coffee shops;
- delicatessens;
- food take out and/or delivery establishments (e.g., pizza take out and delivery);
- convenience stores;
- movie theaters;
- cafeterias;
- bakeries/retail confectioners;
- food service vendors (e.g. lunch wagons, ice cream shops, mall cookie counters, and sidewalk carts);
- transportation carriers (e.g. airlines and trains); and
- grocery stores that have cafes or food courts.

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14 Id.
15 Id.
16 See 21 C.F.R. Pt. 100.1.
Additionally, the FDA said that an Internet menu or a take-out menu may be considered a “menu” subject to § 4205 compliance “if it can be used as the primary writing from which a consumer makes a selection… For example, if the establishment’s take-out menu is posted on the Internet and it serves as a primary writing from which a customer makes selections over the phone or Internet for take-out, deliver, or dine-in service, then it is a menu under § 4205 and, therefore, requires calorie disclosure.” 18

A notice that a consumer may request “additional nutrition information” will also be required to be easily seen on an establishment’s menu board, including menus on drive-throughs and in a type size at least as large as the name or the price of a menu item with the same prominence, i.e., the same color and contrasting background as the calorie disclosures themselves. 19 The “additional nutrition information” consumers may request will likely be required to include:

- the total number of calories derived from any source;
- the total number of calories derived from the total fat;
- total fat content;
- saturated fat content;
- cholesterol;
- sodium content;
- total carbohydrates;
- total sugars;
- dietary fiber content; and
- total protein. 20

Conclusion

With its understanding that most food establishments affected by § 4205 may need time to establish compliance with the section, the FDA made a note that it will not begin enforcing the menu labeling law until “after a time period established in the final guidance” which is expected to be issued in December 2010. 21

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18 Id.
19 Id.
20 Id.
21 Id.
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