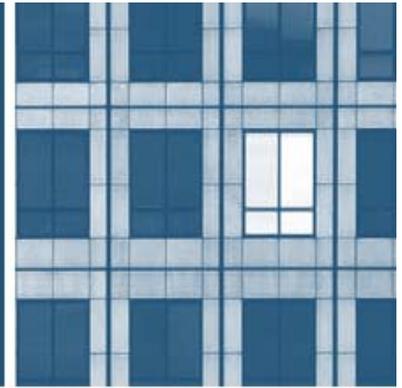


On the Subject



Health Industry Advisory

August 27, 2010

New health legislation and FDA guidance immediately affect chain restaurants, convenience and grocery stores, commercial caterers, hotels, airlines, railroads, vending machine operators and others with more than 20 outlets.

New Menu Labeling Requirements Affect Broad Range of Food Establishments

On August 24, 2010, the U.S. Food and Drug Administration (FDA) published two draft guidance documents outlining the agency's current thinking on new federal nutritional disclosure requirements applicable to chain restaurants and retail food establishments of 20 or more and to operators of vending machines. The agency has taken an aggressive position aimed at rapid implementation of the new mandates.

The FDA actions are authorized by a section of comprehensive health care legislation signed into law earlier this year. In July and August 2010, the FDA published four notices and two guidance documents. Many details remain for the FDA to address in further guidance, but a few key points should help affected industry members begin developing compliance plans:

- The federal statute calls for calorie disclosures by chain restaurants and similar retail food establishments (RFEs) with 20 or more outlets, as well as operators of 20 or more vending machines. More detailed nutritional information about regular menu items must also be available to consumers on request.
- The FDA has asserted the disclosure requirements in the new law are essentially self-executing and became effective immediately upon enactment of the statute (March 23, 2010). However, the August 24 guidance indicates the "FDA expects to refrain from initiating enforcement action until after a time period established in the final guidance.

- Chain restaurants and RFEs are broadly defined to include virtually every conceivable type of restaurant, convenience and grocery store selling ready-to-eat products, airlines, railroads, certain commercial caterers, food and beverage carts, and various self-service facilities.
- The second FDA guidance document issued on August 24 addresses federal preemption of state and local menu disclosure laws.

Process and Timing

Comments will be accepted on the draft guidance issued on August 24 for an indefinite period of time. The guidance documents are not binding, although they offer important insights on the FDA's basic understanding of the law. Principles in the documents could ultimately be incorporated into agency regulations or formal policies.

The FDA also published two separate notices on implementation of the nutritional disclosure requirements. A July 7 notice seeks comments on practical issues related to menu disclosures, such as variations in serving sizes, human factors related to food preparation, space available on menus and the format of nutrient disclosures. (Comments in response to that notice are due by September 7, 2010.) Additionally, a July 23 notice addressed registration for food establishments that are not covered by the mandatory disclosure requirements, but that wish to participate voluntarily.

A list of FDA Federal Register notices and guidance documents related to menu labeling can be found at <http://www.mwe.com/info/news/ots0810k.pdf>.

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