LAW360

Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Delayed FDA Menu Labeling Rules Face Bumpy Road

By **Natalie Rodriguez**

Law360, New York (August 08, 2014, 5:35 PM ET) -- The U.S. Food and Drug Administration's final Affordable Care Act-mandated rules to have restaurants and other food retailers post certain nutritional information have not yet dropped, but experts are forecasting a slate of challenges — particularly if the final version is perceived as unfair to convenience stores, pizzerias and other food sellers.

Already well past due, the FDA's guidelines on the proposed rule — known as "nutrition labeling of standard menu items in restaurants and similar retail food establishments" — could come out any day, as they are currently with the Office of Management and Budget for review. But once they do, it is unlikely to be the end of the story, as the rule will likely face challenges from certain food retailers that have been lobbying against being covered because of the costly burdens that compliance will mean for them, experts note.

“Whatever the shape of the final version of the rule, I expect to see retailer petitions to the FDA for extensions of the compliance deadline, such as we saw with the gluten-free labeling rule,” said Kristen E. Polovoy, an attorney with Montgomery McCracken Walker & Rhoads LLP.

And perhaps more significantly, there are also two federal bills waiting in the wings that could challenge the FDA rule's intent if it has not been tweaked to be more favorable toward convenience stores and certain other food retailers, according to experts.

The bill — H.R. 1249, known as the Common Sense Nutrition Disclosure Act of 2013 — as well as companion legislation in the Senate would limit nutrition disclosure requirements to establishments that get more than half of their revenue from prepared food and would also give establishments more flexibility with labeling.

The legislation is intended to help chains of convenience stores, grocery stores and other operations that do sell some prepared food but which some argue were not intended to be ensnared in the ACA-mandated rule that covers chains of 20 or more stores.

While there has not been much movement with the bills, congressional backers of the legislation have indicated that they are ready to press forward if the final FDA rule has not been sufficiently modified, said Lyle Beckwith, the National Association of Convenience Stores' senior vice president of government relations

“I have to believe that the presence of this legislation, waiting to move, has to be weighing on them,”

Beckwith said.

He and others, however, do note that the FDA's delays are likely due — at least in part — to the agency's struggles to grapple with how to follow the intent of the ACA mandate while not putting undue burdens on certain food sellers.

“The fact that these rules have been over four years in the rule-making process and have now exceeded the 90-day OMB review time — although this is frequently exceeded — signals what a difficult issue this is and that there may still be potential for changes,” said Kristi L. Wolff of Kelley Drye & Warren LLP.

She also noted that the New York court's recent ruling tossing out the state's soda ban for being applied arbitrarily to some drinks or locations and not others could be weighing on the agency.

“It probably caused them to take a second look and [ask], 'Is something that we have here ... arbitrary?'” Wolff said.

At the heart of the boiling tensions over the menu labeling rule is the ACA's mandate to cover restaurants and “similar food service establishments.”

In the proposed version of its rule, the FDA took a broad definition for food service establishments and essentially said that any establishment that has 50 percent or more of its square footage dedicated to food — that also is part of a larger chain — must comply with providing calorie information on any menu materials and must be able to provide other nutritional information if requested by a customer.

The broad scope has riled restaurants such as pizzerias that often do made-to-order dishes that are hard to give precise calorie and nutritional information for, as well as convenience stores and supermarkets that sell some prepared food — like hot dogs or salads — alongside mostly packaged items, such as cans of soup or bags of chips.

While most big restaurant chains have already begun the nutritional labeling required, pizzerias, convenience stores and other food establishments contend that they already run on slim margins and will be unduly burdened if they have to take on the same kind of costly nutritional testing, as well as revamping their menus and marketing materials, according to experts.

“The fast-food chains, they send their limited menu for testing. But in the convenience store and supermarket setting, we don't have limited menus like that. We have very regionalized offerings,” Beckwith said, also noting that the square-footage requirement can be far too subjective, as it's unclear whether aisle space is meant to be part of that measurement.

The NACS and several other organizations have fallen behind the proposal to make the definition based on gross sales receipts for prepared food, as is suggested in the federal bills. Proponents of this method argue that the ACA mandate was meant to only cover restaurants and not these other food establishments that do not primarily make their money from preparing food.

“We're hopeful they listen to the concerns and keep it targeted to where it was intended to be targeted,” Beckwith said.

But the FDA is also facing pressures to stay on the more conservative side of making sure that the ACA mandate is fully followed through, experts note.

“With the ACA’s intent, with growing national statistics on the costs to this country of obesity and other food-related conditions, and with Michelle Obama’s well-publicized initiatives for childhood nutrition, it's hard to imagine the FDA not taking these strong policy pushes into consideration in rendering their final menu labeling rule,” Polovoy said.

Because the final rule has not dropped yet, experts can only speculate as to what track the agency will ultimately take.

“The FDA could interpret 'or similar retail food establishment' to exclude businesses whose primary purpose is food sales but where the vast majority would be grocery items, which would include convenience stores. The concern that they likely have about that is that it would also exclude other businesses that the agency thinks should be covered,” Wolff said.

It's also not above the realm of possibility that the FDA might lengthen the review period, as it did with its guidance on the use of the term “evaporated cane juice,” which had its comment period reopened nearly five years after it had originally closed, Polovoy noted.

“The FDA has head from the affected parties and from Congress, and we have to wait and see ... if they somewhat scale it back or not,” Beckwith said.

--Editing by Jeremy Barker and Philip Shea.
