Insight

FDA forgoes up to $585 million in savings with menu labeling guidance

DAN BOSCH | NOVEMBER 17, 2017

The Food and Drug Administration (FDA) announced recently that it would make no further changes to its rule requiring the posting of calorie information on displays, menus, and menu boards in covered restaurants and prepared food establishments with 20 or more locations. The decision signals the end of a series of delays and extensions of the compliance date since the rule was finalized in 2014. The decision also signals that regulators often bow to practical realities, even when faced with expectations to cut regulatory costs.

Under Executive Order 13,771, agencies are expected to cut regulatory costs as a key element of the Trump Administration's regulatory policy. Total costs of the menu labeling rule, when finalized, were just under $1.2 billion. The most recent delay of the compliance date to May 2018 trimmed just $8 million off that price tag. Using cost estimates developed by the FDA in the 2014 final rule, it appears the agency left approximately $585 million in additional savings on the table.

Let me explain. To obtain additional cost savings FDA would have to propose changes to the 2014 final rule. Instead, it issued a draft guidance document that offers businesses flexible compliance options consistent with the concerns raised in the public comment period. While this guidance offers additional flexibility on how businesses can satisfy the calorie posting requirements (albeit with no calculated cost savings) it also means that, at any point, FDA could modify or withdraw the document.

It is difficult to know exactly what costs savings could be realized with a proposed rule prescribing the same adjustments allowed in the guidance document. However, in its final regulatory impact analysis from the 2014 rule, FDA estimated the costs if it chose an option that regulated 67,400 fewer establishments, which the agency said would have met the requirements of the Affordable Care Act (ACA). The costs of that option were $614.8 million.

Why would FDA decide against revising the rule if it meant forgoing potential savings of $585 million? Based on FDA's announcement, the reason is that the agency believes the guidance strikes the appropriate balance between providing flexibility and complying with the ACA mandate. This may be true. Another possibility is that many businesses have already taken substantial steps, and incurred significant expenses, in anticipation of a rule that has been delayed three times. Therefore, there would likely be little actual cost savings from revising the rule to a less costly option. On top of that, FDA would likely face another year or more of regulatory process working to finalize changes.

Implications of FDA's Decision

FDA's announcement demonstrates that even when given a mandate to cut costs from existing rules, regulators still must weigh practical realities versus reductions. If anything, this situation shows that trying to cut costs after a rule has been finalized is often difficult. This is an important consideration when it comes to examining

possible cost reductions under Executive Order 13,771.

If Congress wants to prevent excessive regulatory costs, there are some options.

One is to pass legislation after a rule is finalized that addresses an agency's failure to cut costs. An example in this case is the Common Sense Nutrition Disclosure Act (of which there are variations in the House and the Senate). However, this option makes things tricky for businesses that have prepared to comply with a final regulation -– particularly at such a late stage.

A better way would be to pass legislation requiring agencies to adopt the most cost-effective regulatory option. Holding agencies to this standard on the front end of a rulemaking would improve the outcome. One example of legislation that would require this, the Regulatory Accountability Act, has already passed the House this Congress.

A final option would be for Congress to write more prescriptive language in legislation authorizing new regulatory activity to limit agency discretion. Although at its current rate of legislative production, Congress passing more precise, exacting bills seems unlikely.

FDA's decision makes one thing clear – substantially reducing costs from existing rules can be very difficult.