

State and Local Authority to Establish Tobacco Product Standards

Federal Regulation of Tobacco: Impact on State and Local Authority
July 2009

Background

On June 22, 2009, President Barack Obama signed into law the Family Smoking Prevention and Tobacco Control Act, giving the U.S. Food and Drug Administration (FDA) comprehensive authority to regulate the manufacturing, marketing, and sale of tobacco products. The new law represents the most sweeping action taken to date to reduce what remains the leading preventable cause of death in the United States.

Before enactment of the new law, tobacco products were largely exempt from regulation under the nation's federal health and safety laws, including the Food, Drug, and Cosmetic Act. The FDA has regulated food, drugs and cosmetics for many decades, but not tobacco products, except in those rare circumstances when manufacturers made explicit health claims.

What the New Law Does

The Family Smoking Prevention and Tobacco Control Act adds a new Chapter IX to the Food, Drug, and Cosmetic Act, establishing and governing the regulation of tobacco products. A new Center for Tobacco Products is created within the FDA to establish tobacco product standards, among other things. Chapter IX vests the FDA with jurisdiction to regulate both current and new tobacco products and restrict tobacco product marketing, while also directly implementing measures to restrict tobacco product marketing and advertising, strengthen cigarette and smokeless tobacco warning labels, reduce federal preemption of certain state cigarette advertising restrictions, and increase nationwide efforts to block tobacco product sales to youth.

The new law gives the FDA exclusive authority to establish tobacco product standards, which are regulations affecting the design or safety of a product. The FDA is also authorized to prohibit adulterated or misbranded tobacco products, establish labeling requirements, and regulate manufacturing standards and modified-risk tobacco products, thereby generally preempting previously existing state authority in those areas. Similarly, the law preempts states from separately licensing tobacco manufacturers and suppliers specifically and exclusively for tobacco product regulation purposes.

While the new law thus limits state and local authority to regulate tobacco product standards, it leaves in the hands of the states an array of options to restrict or eliminate the sale, distribution, and possession of certain types of tobacco products and non-tobacco products that contain nicotine. Indeed, states retain significant regulatory authority in the area of tobacco product standards.

The new law's product standard section directly prohibits any cigarettes with a characterizing flavor other than tobacco or menthol, but it does not mandate similar changes in other tobacco products. States retain their existing authority to ban any or all categories of tobacco products as a function of states' jurisdiction over sales and distribution. States and localities could, for example, outlaw all classes of tobacco products (e.g. cigarettes or smokeless tobacco).

The law also preserves state and local governments' authority to implement fire-safe cigarette laws that regulate the ignition propensity of tobacco products, and permits states and localities to impose additional reporting requirements, including ingredient disclosures, on tobacco product manufacturers in the event states identify any information that has not already been obtained or shared by the FDA. Nor does the law appear to change states' ability to require licenses and permits from manufacturers or other tobacco industry entities for purposes other than tobacco regulation.

A fundamental feature of the new law is that it requires FDA review and approval of all new tobacco products before they can be introduced to the market. While the FDA will have the responsibility to regulate—or, if it deems appropriate, prohibit—novel or new products, including their marketing, sale and distribution, states and localities retain the power to take enforcement actions to ensure that any new products approved by the FDA are marketed and sold in compliance with federal law and do not hamper state tobacco control efforts.

States also retain the authority to prohibit the sale of non-tobacco products containing nicotine that have not been approved by the FDA, and to tax or restrict the sale, distribution, or marketing of unapproved non-tobacco products containing nicotine. Advocates and lawmakers should be alert to the fact that many state laws contain definitions of "cigarette," "smokeless tobacco," and "tobacco product" that may not be sufficiently broad to cover new types of tobacco products for taxation and other purposes. States are well-advised to modify such definitions to close potential gaps or loopholes.

To learn more about FDA regulation of tobacco, visit www.tclconline.org.

The Tobacco Control Legal Consortium provides information and technical assistance on issues related to tobacco and public health, but does not provide legal representation or advice. This fact sheet should not be considered legal advice or a substitute for obtaining legal advice from an attorney who can represent you. If you have specific legal questions, we recommend that you consult with an attorney familiar with the laws of your jurisdiction.