NEWLY DEEMED TOBACCO PRODUCTS:

In 2009, the Family Smoking Prevention and Tobacco Control Act (TCA) gave the U.S. Food and Drug Administration (FDA) authority to regulate all tobacco products but only required the FDA to regulate cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco. To regulate other tobacco products the FDA was required to issue an additional rule that would “deem” these products to be under its authority.

In May 2016, the FDA did just that by issuing a final rule that extends its authority to regulate all tobacco products that meet the statutory definition of tobacco products in the TCA. This definition states a tobacco product is “any product that is made or derived from tobacco and is intended for human consumption”. This does not include any item classified as a drug under the Federal Food, Drug and Cosmetic Act. (e.g., FDA-approved nicotine replacement therapies)

The tobacco products that are covered as of August 8, 2016 include:

- all types of cigars (including premium, little cigars and cigarillos),
- e-cigarettes and other electronic nicotine delivery systems (ENDS),
- hookahs,
- pipe tobacco,
- dissolvable tobacco products, and
- any future products that meet the statutory definition of a tobacco product.

WHAT ARE THE RESTRICTIONS?

The newly deemed products will be subject to some of the same provisions and requirements as cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco. These include:

- Minimum sales age of 18, both in-person or online
- Age verification using a photo ID of anyone under the age of 27 to purchase
- Free sample distribution is prohibited
- Vending machine sales are prohibited except in adult only venues
- Manufacturers are required to provide FDA with a listing of ingredients including harmful and potentially harmful constituents
- FDA can request additional documents from the manufacturers related to health effects, research and marketing of the products
- The sale of these products with misleading modified risk descriptions (e.g., light, low, and mild) is prohibited
- Enforcement action can be taken against those who adulterate or misbrand these products
Additional provisions with separate effective dates include:

- Vape shops and e-cigarette stores that mix or prepare e-liquids or create or modify ENDS for direct sale to customers are considered tobacco manufacturers and must register with and provide a list of ingredients to the FDA.
- A pre-market review by FDA is required for all newly deemed tobacco products that came on the market after February 15, 2007. Timeframes depend on the type of product to be reviewed.
- Health warning labels are required on newly deemed tobacco product packaging and advertisements (effective 24 months after publication of final rule)

**NOT ALL PROVISIONS APPLY**

Not all of the provisions of the TCA were extended to the newly deemed products with this new rule. Provisions that are not currently required for the new products include:

- Ban on flavoring in tobacco products (only applies to cigarettes)
- Prohibition on self-service displays in retail outlets (e.g., products placed out of reach of the customer-only applies to cigarettes and smokeless tobacco)
- Minimum packaging size requirements
- Prohibition of breaking up packages to sell single or smaller numbers of the product
- Ban on sponsorships of sports or music events
- Ban on distributing non-tobacco merchandise branded with tobacco product logos

The FDA has indicated its intent to issue a rule to extend the ban on flavors (except menthol and tobacco flavor) to cigars in the future. This would not address ENDS or other flavored tobacco products.

**NEXT STEPS**

The new rule is a step in the right direction towards supporting tobacco use prevention and control initiatives. In addition, the TCA specifically states that each state, local and tribal government may regulate tobacco products more strictly than the federal law requires. This could include regulations that prohibit the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age.

Research and experience has documented that the following strategies help to decrease tobacco use in local communities and protect additional citizens:

- limiting tobacco advertising in the community,
- limiting the number of tobacco retail outlets in an area,
- creating tobacco free outdoor spaces,
- increasing the minimum age to purchase,
- banning tobacco industry sponsorships of events in the community,
- banning flavored tobacco products,
- prohibiting self service of other tobacco products,
- required posting of health warnings and quit information in establishments where tobacco is sold

Stay tuned for the September 2016 edition of Talking Tobacco when we further discuss policies and strategies that help protect communities.

*Information Source: U.S. Food and Drug Administration, Center for Tobacco Products*