The Division of Insurance ("Division") has issued Bulletin 2016-01 to remind carriers of certain benefit requirements for tobacco cessation aids provided for under the federal Patient Protection and Affordable Care Act ("ACA") and clarified through guidance from the federal Department for Health and Human Services ("HHS") The Division expects carriers to be in compliance with the requirements outlined in Bulletin 2016-01 as well as with any subsequent revisions and clarifications clarified through guidance from HHS.

The ACA requires coverage, with no cost-sharing, for certain evidence-based preventive items and services given a rating of "A" or "B" by the U.S. Preventive Services Task Force ("USPSTF"). Among its recommendations, the USPSTF indicate that clinicians should screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco. It appears clear that such screening and tobacco interventions are required to be covered without cost-sharing and that plan benefits should not include any blanket benefit exclusions or limitations that apply to tobacco cessation items or services.

The Centers for Medicare and Medicaid Services ("CMS") has also promulgated regulations that clarify that carriers may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for the recommended item or service when those elements are not made clear in the USPSTF recommendations.

## **Tobacco Cessation Products**

HHS has issued guidance that identifies the following types of tobacco cessation products as items that it believes are appropriate for smoking cessation:

- 1. Nicotine chewing gum
- 2. Nicotine skin patches
- 3. Nicotine lozenges
- 4. Nicotrol nasal spray
- 5. Nicotine inhaler
- 6. Zyban (buproprion hydrochloride)
- 7. Chantix (varenicline tartrate)<sup>1</sup>

The Division would consider a health plan to be in compliance with the preventive care requirements of the ACA relative to tobacco cessation products if the health plan's drug benefit includes at least one product within each of the above-noted tobacco cessation product types without cost-sharing (e.g., the health plan's drug benefit includes coverage, without cost sharing, for at least one nicotine gum, one nicotine patch, one nicotine lozenge, etc.). Coverage requirements pertain to both over-the-counter and prescription products.

Carriers are permitted to employ reasonable managed care techniques to determine the frequency, method, treatment, or setting for the recommended item or service, provided that covered persons are always given access to at least one of the tobacco cessation products without prior authorization and the managed care methods are consistent with all state and federal laws. Whenever carriers make an adverse determination that denies or limits access to a requested product based on medical necessity criteria, they must provide all necessary notifications to patients and providers and follow all appropriate procedures for internal and external appeals.

Carriers should amend policies, evidences of coverage, formularies and/or drug brochures, or riders as necessary to ensure that insureds are given complete information about the coverage of and the cost sharing for tobacco cessation items and services.

If you have any questions about this Bulletin, please consider contacting Kevin Beagan at 617-521-7323 or Kevin.beagan@state.ma.us.

HHS FAQ 19, issued May 2, 2014, available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca\_implementation\_faqs19.html, expects coverage of all Food and Drug Administration ("FDA")-approved tobacco cessation products, including both prescription and over-the-counter medications. The FDA has approved as smoking cessation products the five tobacco replacement products and two non-nicotine medications listed.