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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

December 26, 2018

Submitted electronically via: www.uspreventiveservicestaskforce.org

USPSTF Coordinator
c/o USPSTF
5600 Fishers Lane
Mail Stop 06E53A
Rockville, MD 20857

**Re: Draft Recommendation Statement Prevention of Human Immunodeficiency Virus (HIV)
Infection: Pre-Exposure Prophylaxis, 2019**

Dear Sir or Madam:

The National Business Group on Health (the “Business Group” or NBGH) is pleased to comment on the U.S. Preventive Services Task Force’s (USPSTF’s) recommendation that clinicians offer pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.

The Business Group represents 435 primarily large employers, including 74 of the Fortune 100, who voluntarily provide health benefits and other health programs to over 55 million American employees, retirees, and their families.

The Business Group supports the goal of encouraging clinicians to provide and plan participants to regularly receive evidence-based preventive care. To assure that employees and their families receive it, employers, as group health plan sponsors, generally offer coverage of preventive services beyond those recommended by the USPSTF and other government agencies when clinical and medical evidence warrants such coverage. Our members know that preventive care can dramatically reduce the incidence, health care demands, and long-term cost burdens of chronic conditions, acute illness, and injuries and can help to keep people healthier, longer. Moreover, it also contributes to employee morale and productivity.

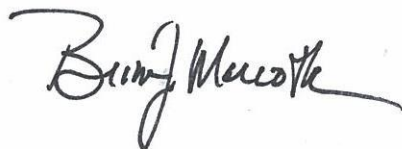
While we understand that the USPSTF primarily weighs clinical evidence in making its recommendations, we have previously advocated for some additional process at HHS, similar to what it has in place for Medicare, before A and B recommendations automatically become benefit mandates for employer plans. Because of the weight and impact of USPSTF A and B recommendations since the passage of the ACA, the Business Group recommends the consideration of certain factors, beyond clinical evidence, as the taskforce makes its recommendations. Specific to the current recommendation, we offer the following:

- **Impact on financial sustainability.** The Large Employers' 2019 Health Care Strategy and Plan Design Survey found employers project the total cost of providing medical and pharmacy benefits will rise 5% for the sixth consecutive year in 2019. Including premiums and out-of-pocket costs for employees and dependents, the total cost of health care is estimated to be \$14,099 per employee this year, and projected to rise to an average of \$14,800 in 2019. Employers will cover roughly 70% of those costs; employees will bear about 30%. The annual cost of the medication for PrEP alone is currently higher than the average cost of health care per employee and will add to the inflationary pressure on per capita costs.
- **No competition.** Currently, there is only one approved PrEP product – a combination of two HIV medicines (tenofovir and emtricitabine), sold under the name Truvada, which reportedly costs approximately \$2,000 per month. Given current pharmaceutical supply chain deficiencies, we are concerned that this recommendation may substantially increase the price of this product.
- **Adherence and efficacy.** While the effectiveness of Truvada at preventing HIV contraction has been shown to be extraordinarily high (92-96%, depending on the study), medication adherence has also been cited as a key driver in overall effectiveness. However, despite high medication adherence being critical to PrEP efficacy, adherence has not been shown to be uniformly achieved by various drug trial participants.
- **Ability to forecast.** Because PrEP is indicated for people without HIV who are at very high risk for getting it from sex or injection drug use, through self-reporting, there are little to no means by which an employer plan may be able to anticipate the number of covered lives eligible for this product, thus making it difficult to project the potential impact to pharmacy costs.

In making these recommendations, our goal is not to reduce coverage for needed preventive care, but to emphasize that coverage decisions should consider multiple factors, including the potential impact on the financial sustainability for payers and patients, whether or not there is a competitive market to serve the recommendation, how adherence and efficacy factor into the recommendation's effect on population health, and how private payers can best plan to absorb the financial impact of the recommendation.

Thank you for considering these comments and recommendations to enhance the process by which USPSTF recommendations are translated into coverage. If you would like more information or wish to discuss this issue further, please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy at (202) 558-3012.

Sincerely,



Brian Marcotte
President and CEO