LAB
LABORATORY ACCESS & BENEFITS COALITION

IMPROVING ACCESS TO AFFORDABLE DIAGNOSTIC TESTING

ISSUE

Laboratories are not allowed to participate in value-based arrangements because they were excluded from the Anti-Kickback Statute safe harbor.

The Fall 2020 OIG Final Rule adding safe harbors for certain-value based arrangements under AKS, Stark and CMP, which went into effect in January 2021, **specifically carved out clinical laboratories and pharmaceutical manufacturers from participating in VBAs under AKS.**

STATUS

Laboratories and providers are not allowed to work together on value-based plan design for testing, including complex tests for things like cancer, and patients get less as a result. Exclusion from the safe harbor creates a chilling effect where laboratories are not allowed to pursue innovative coverage models because of the law.

Excluding labs from value-based care models creates a significant gap in care coordination. Laboratory testing is an essential service for patients when receiving a diagnosis or treatment. This is especially true in cases of genetic testing, cancer care, and pediatrics. These populations often spend years navigating the healthcare system before receiving an accurate diagnosis. Value-based arrangements would increase access and reduce the time to diagnosis.

SOLUTION

Simple legislation adding labs to the value-based arrangement safe harbor will allow testing to be a part of value-based plan design.

Laboratory professionals have the necessary expertise to ensure clinicians are ordering and receiving only the appropriate testing for their patients, and are therefore instrumental in reducing costs and improving value. Despite only representing three percent of healthcare spending, diagnostic testing is an invaluable piece of the healthcare system and laboratories are active participants in a variety of value-based arrangements.

Allow laboratories to participate in value-based arrangements to increase access to tests, shorten time to diagnosis, and decrease costs

Case Studies: Access to Genetic Testing

- Genetic testing and early detection of breast cancer alone could save up to $50 million each year.[1]
- Access to genome sequencing in pediatrics has been shown to lead to diagnosis in 20% of newborns and modification in treatment of more than 65% of newborns.[2]

1. Georgetown University, Lombardi Comprehensive Care Center. https://lombardi.georgetown.edu/news-release/genetic-testing-in-women-diagnosed-with-breast-cancer-decreases-cost-of-care-nationwide/#
2. *Intensive Care Medicine* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6483967/