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CARE DELIVERY AND REGULATORY POLICY

The validity of VALID act: Cost modeling cancer diagnostics regulation by the FDA.

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Abstract Disclosures

Abstract

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Background: VALID Act is a bipartisan draft legislation proposing to ensure the quality and safety of diagnostic tests through direct FDA

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oversight. Currently, FDA exercises enforcement discretion and exempts from premarket review tests that are developed and used in the same clinical laboratory. Many stakeholders have pointed out that the lack of direct FDA oversight has led to erroneous results that have serious patient consequences. However, the maintenance cost after the implementation of the Act is unknown. Thus, we estimate the additional financial burden of genotyping all new late stage cancer patients under a fully implemented VALID Act precertification framework. **Methods:** Based on our laboratory with 36 high-complexity clinical assays, we modeled the cost increase by dividing the total anticipated cost for annual FDA precertification by our 2019 patient volume. To model the stringency of complying with the Act, we calculated either 3, 6, or 9 assays as representative of the laboratory's test complexity. To make the estimated additional annual national healthcare cost relatable, we expressed the increase as a distributed cost per newly diagnosed late stage cancer patient in 2019 (NCI SEER) or per employed person in 2019 (Bureau of Labor Statistics). **Results:** FDA precertification for 3 assays was estimated at $638,310.13, or when divided by our annual late stage patient volume (n = 10,232), an increased cost of $62.38/patient. Precertification for 6 or 9 assays costs $684,751.60 (+$66.92/patient) or $1,253,717.25 (+$122.53/patient), respectively. If only 1 cancer center per state/DC/PR got precertified (n = 52), multiplied by the cost of precertifying 3 assays, then the annual national healthcare cost would increase by $33,192,126.50, or +$42.37/new late stage patient (n = 783,476) or +$0.21/employed (n = 158,803,000). Precertification for 52 centers for 6 or 9 assays would cost $35,607,083.20 (+$45.45/patient, +$0.22/employed) or $65,193,297.00 (+$83.21/patient, +$0.41/employed), respectively. Nationally, there are ~886 centers and the increased cost was estimated at < $7/employed. Even though

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the VALID Act will affect more than late stage cancer patients, thus costs will vary, our data show how a specific change of the Act will impact oncology practice. **Conclusions:** We provided a concrete cost model for late stage cancer patients under the proposed VALID Act. Cost modeling is important in informing the balanced legislative language needed to ensure patient access to validated cancer diagnostics, while supporting continued innovation by clinical laboratories.

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