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Updates on the VALID Act

Earlier this year, it looked as though the Verifying Leading-edge IVCT Development (VALID) Act had a good chance of passing into law. Recently, however, momentum has shifted against this legislation.

The VALID Act seeks to move oversight of laboratory developed tests (LDTs) to the Food and Drug Administration (FDA). Though many pathology and laboratory associations are opposed to this legislation, the College of American Pathologists (CAP) has taken a more even-handed approach by openly acknowledging aspects of the bill they support and identifying areas that could use improvement.

In its current form, the VALID Act would:

- Implement a risk-based system of tiers to direct FDA oversight
- Exempt existing LTDs from FDA pre-market review
- Use various metrics (e.g., performance testing) to place LTDs in lower tiers of regulation
- Require public hearings for LTD oversight by the FDA
- Avoid the FDA infringing on the practice of medicine
- Prohibit duplicative regulation under CLIA
- Outline a negotiation process between the agency and industry to determine user fees

There is some concern that user fees may have a negative impact on the development of LTDs, but any user fee decisions would need to be approved by Congress in future legislation.

The effective date of the VALID Act would be five years after passage, although certain aspects (including the registration and listing requirements when made available by the FDA) are able to begin implementation as early as October, 2024.

APS will continue to monitor progress on this important bill. Please reach out to your Practice Manager with any questions.

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