SIDLEY

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What Should Clinical Laboratories Expect in 2017?

This is the second in a two-part series.

As discussed in our first installment, clinical laboratories were subject to significant changes in law and policy as the result of the Obama Administration, and they face continued changes and challenges in the Trump Administration. Here, we continue to discuss how Congress and the current Administration may affect clinical laboratories.

The CURES Act and the Precision Medicine Initiative

Despite the threat of cutbacks, opportunities exist for clinical laboratories to carve out a stake in the pool of funding and institutional support created by the 21st Century Cures Act (CURES Act) recently enacted by Congress. In contrast to the Patient Protection and Affordable Care Act of 2010 (ACA), the Precision Medicine Initiative (PMI) and the Cancer Moonshot initiative have received less public scrutiny from the President. They have even received support from some of his key nominees, such as U.S. Department of Health and Human Services (HHS) Secretary Tom Price, R-Ga. It is likely that President Donald Trump's focus on repealing the ACA will take precedence over cutbacks on other health spending programs, especially given the bipartisan nature of the CURES Act, from which the PMI, Cancer Moonshot and National Institutes of Health (NIH) will draw significant funding. Still, the President has yet to nominate an individual to head NIH (temporarily leaving Dr. Francis Collins as head), which creates uncertainty regarding the future direction and priorities of the agency.

Reimbursement

Under the Protecting Access to Medicare Act of 2014 (PAMA), "applicable laboratories" are required to begin reporting certain private payor lab test prices and volumes to the Centers for Medicare & Medicaid Services (CMS) during the January 1 – March 31 window. New Medicare payment rates derived from this reported "market-based" data take effect in January 2018. Under CMS estimates, payments to clinical laboratories are generally expected to decrease as a result of PAMA, although reductions will phase in over several years under transition provisions of the new law. CMS has offered no clear sense of, among other things, the

number of applicable laboratories that exist (with particular uncertainty with respect to how many and which hospital laboratories will report), and CMS has indicated that it will not carefully police whether all laboratories that are required to report actually do so. Accordingly, the integrity of the resulting data that will set the initial market-based Medicare prices is somewhat unclear, as is the full impact of the new payment methodology on the industry (given that, historically, Medicare rates have driven Medicaid and private payor rates). President Trump has not yet indicated his intention to address PAMA.

Other Potential Concerns

The HHS Office of Inspector General has been increasing its activity in the clinical laboratory area. It issued a Special Fraud Alert in June 2014 restricting payment of specimen collection and bioregistry fees to referring physicians and entering various high-profile settlements with laboratories for alleged violations of anti-kickback, reimbursement and civil monetary penalty laws. HHS has also focused on data sharing through, for example, (i) an HHS rule promulgated under the Health Insurance Portability and Accountability Act of 1996 and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) giving patients direct access to their laboratory test results, (ii) the NIH Genomic Data-Sharing Policy requiring sharing of genomic data when research involves federal funding and (iii) various proposed or final revisions to clinical research rules that require enhanced reporting of clinical research results.

In addition, the Food and Drug Administration (FDA) announced in November 2016 that it would not issue its long-awaited final guidance on regulation of laboratory-developed tests (LDTs) during the Obama Administration. However, on January 13, 2017, in the final week of the Obama Administration, FDA issued a Discussion Paper on Laboratory Developed Tests that provided one possible approach to LDT oversight. FDA clarified that this proposal represented an effort to "advance the public discussion" even though it was not enforceable. As a result, regulation of LDTs remains in the purview of the CLIA program and applicable state laws. President Trump has not expressed policy positions in these areas.

Stay Tuned

Clinical laboratories should closely watch legislative and regulatory actions in these key areas. Significant opportunities will exist for laboratories to affect policy as it develops. We will be closely monitoring developments and would be happy to address your questions or concerns as they arise.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work or

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