

National Update: PAMA, EKRA, NCDs/NGS, FDA/LDTs

Alan Mertz

Director of Government Affairs

June 13, 2019

NYSCLA Annual Meeting



Environment for Health Legislation in DC

- Divided Government, Divided Congress + 2020 Election Year Mean Make for Difficult Environment To Pass Most Legislation
- Exception Is “Must Pass” Bills Such as Medicare Extenders
- Passing Almost Any Health Care Bill Requires “Hitching a Ride” on Medicare Extender or other “Must Pass”
- Unlikely: Drug Pricing Reform, Patent Reform, Fixing Obamacare...
- Any Policy Changes More Likely CMS, Courts....

PAMA

- 2019 is 2nd Year of First Round
- First Round Cuts Capped at 10-10-10, 2018-2020
- Second Round of Surveys:
 - Jan 1, 2019-June 30, 2019 Labs Collect Data
 - Jan 1, 2020-March 31, 2020 Labs Report Data
 - Jan 1, 2021-Dec 31, 2023 New Rates Go Into Effect
- The Key Problems With PAMA Were:
 - CMS Interpretation of “Applicable Labs” to Report Rates Left Hospitals Out of Data (Only 1% of Labs Reported)
 - Congress Used “Median” Commercial Rates versus “Mean”

PAMA

- Lab Industry Attempts To Fix/Mitigate:
 - Lawsuit (ACLA v Azar)
 - Comments on CMS Rulemaking
 - Legislation
- CMS Nov 2018 Final Rule Only Partially Addressed Problems
 - Laboratories to Report Now Include Labs that Receive at Least \$12,500 of Medicare CLFS Revenue & Use CMS 1450 14X bill Type (Used by Some Hospital Outreach Labs)
 - AHA Reports Only 12% of Hospital Outreach Claims use 14X
 - Few of Even These Hosp Labs Aware of This Requirement

PAMA

- Status of ACLA v. Azar Lawsuit
- Legislative to be Introduced
 - Bill to be Introduced In House That Would
 - Suspend Reporting Private Sector Payment Rates for One Year from 2020 to 2021
 - Require a Study & Report by the National Academy of Medicine on:
 - How Best to Implement the Least Burdensome Data Collection Process, more Representative and valid data sample of private market rates from all lab market segments, ensure sustainable patient access
 - Sponsors:
 - Rep Scott Peters (D-CA), Rep Pascrell (D-NJ), Rep Bilirakis (R-FL), Rep Holding (R-NC), Rep Hudson (R-NC), Rep Schrader (D-OR)

“EKRA” Raises Confusion Over Anti-Kickback Laws For Labs

- “Eliminating Kickbacks in Recovery Act” (EKRA)
Enacted Oct 2018 Part of Opioid Legislation
- **Calls Into Question Whether Safe Harbors That Long-Allowed Labs to Pay Sales Commissions, GPO’s, Phlebotomists Can Continue**
- Two Sentence Legislative Amendment Needed
- Under Review at Department of Justice
- Hospitals and Labs Trying to Get Legislation Passed

CMS National Coverage Decision (NCD) on NGS

- In Surprise “National Coverage Decision” (NCD), CMS Appeared to Instruct MACs that NGS Germline and Somatic Testing Would be Non-Covered for Early Stage Cancer
- Strong Pushback from 63 Organizations, Including Most Lab Groups
- CMS Announced in March They Would Reconsider
- Under Review Now

Laboratory Developed Tests & FDA

- FDA Commissioner Gottlieb Resigns
- Multiyear Effort to Arrive at Consensus for Legislation Creating New Pathway for LDT Oversight
- Many Lab Organizations, Manufacturers & Patient Groups Agreed on Draft Bill “DAIA” (DX Coalition)
- FDA Responds with “VALID” Act
- DX Coalition Working With FDA & Congress To Move the Issue Forward in Congress



Thank You! Questions ?