



## What Is NILA?

The **National Independent Laboratory Association (NILA)** is a trade association for community, regional, and health system clinical laboratories. NILA serves as a platform for laboratory owners and senior executives (CEO, COO, President, Vice-President, etc.) to share business expertise, focus on legislative and regulatory issues, work together to address industry concerns, and to improve the operations of NILA's member laboratories.

## What Is NILA Working On?

- **Implementation of the Protecting Access to Medicare Act (PAMA).** Final rules were released on June 17, 2016. Laboratories were to report private payor data no later than March 31, 2017, which, due to NILA's advocacy, was delayed until **May 30, 2017**. NILA is seeking inclusion of all private payor data, including hospital outreach testing, in CMS's calculations for the 2018 Clinical Laboratory Fee Schedule (CLFS). Without these changes, **Medicare payments for the highest volume CLFS tests could be cut by 10% on January 1, 2018; another 10% on January 1, 2019; and an additional 10% on January 1, 2020.** Additional 15% annual cuts could occur in 2021, 2022, and 2023.
- **FDA Oversight of Laboratory Developed Tests (LDTs)** – The FDA was expected to finalize its Draft Guidances published October 3, 2014, by the end of 2016, but the FDA announced on November 18, 2016, that it will instead work with Congress and the Trump Administration to develop a regulatory system for LDTs. NILA continues to work with other laboratory and health care organizations to find alternatives to the FDA Guidances.
- **On July 18, 2016, the PAMA Clinical Diagnostic Laboratory Tests (CDLT) Advisory Panel voted in favor of NILA's proposal to reprice definitive drug testing codes G0480-G0483.** Subsequently, CMS proposed to increase payments for these four codes by up to 47%. On November 21, 2016, CMS finalized the increased payment rates, which became effective January 1, 2017. NILA is seeking clarification on a new payment code (G0659) introduced by CMS but not made available for public comment.
- **Navigating the dramatic changes** in the U.S. Health Care System, including the exclusion of community and regional laboratories from restrictive managed care contracts, and anticipated changes to the Affordable Care Act (Obamacare) under the Trump Administration.

### NILA Membership Benefits

- **Networking** with fellow laboratory owners and senior executives to share information and address issues concerning your laboratory and the laboratory industry.
- **Representing your laboratory's interests** before federal, state and local lawmaking bodies and regulatory agencies, including participation in **NILA's Capitol Hill Day**.
- **Participating in periodic "Capitol Hill Insider" conference calls** with NILA's Washington representatives.
- **Receiving "Alerts" and "Updates"** on important legislative, regulatory and laboratory industry issues.
- **Access** to NILA's mid-winter "Laboratory Leaders Forum."
- **Discounts** on NILA meeting registration fees.
- **FREE** subscriptions to the *AAB Bulletin* and AAB's Proficiency Testing Service (PTS) *News Clips*.
- **2 individual laboratory executive members** (CEO, COO, President, Vice President, etc.).

### NILA's Advocacy Achievements on Behalf of Community and Regional Laboratories

- 60-day delay (until May 30, 2017) of the March 31, 2017, deadline for reporting private payor data to CMS (**2017**).
- A letter to CMS signed by 88 Members of the U.S. House of Representatives expressing concern about the implementation of Section 216 of PAMA requiring the reporting of private payor payment rates (**2016**).
- CMS agreeing to NILA's request to reprice definitive drug testing codes G0480-G0483 (**2016**).
- The withdrawal of the FDA's October 3, 2014, Draft Guidances regulating LDTs (**2016**).
- No Laboratory Fee Schedule cuts in the permanent "Doc Fix" (SGR) legislation (**2015**).
- A \$2 increase in specimen collection fees for SNF/homebound patients (**2014**).
- Winning several lawsuits that forced the New York State Health Department to refund over \$23 million in Permit Fee/Overcharges to New York licensed laboratories (**2013**).
- Repealing a CMS Requirement for physician signatures on all Part B clinical laboratory requisitions (**2011**).
- Blocking CMS's Competitive Bidding Demonstration Project for Part B CLFS payments (**2007**).
- Defeating a Congressional proposal to reinstitute a 20% copayment on Part B Clinical Laboratory Fee Schedule (CLFS) payments (**2003**).