A Report from Julie Scott Allen, NILA Washington Representative, on the July 18, 2016, Annual Laboratory Public Meeting and Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

The Annual Laboratory Public Meeting and PAMA Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLTs) commenced on Monday, July 18, 2016, at the Centers for Medicare and Medicaid Services (CMS) in Baltimore, MD. At issue were several new laboratory codes for 2017 and reconsideration of definitive drugs of abuse test codes G0480-G0483. Reconsideration was accepted by CMS following the submission of formal requests from NILA and NILA member Aegis Laboratories and a direct follow up request by NILA to ensure the agency reconsidered all definitive drug test codes. CMS initially denied inclusion of G0480 under reconsideration, but changed its decision after NILA's appeal.

Laboratory stakeholders were provided the opportunity to register to present at the meeting to CMS and to the PAMA panel members. NILA was represented by Mr. Lance Benedict of Industry Lab Diagnostic Partners, LLC, who presented on behalf of NILA with recommendations for adjusting the pricing of definitive drug test codes (NILA Request for Consideration) (June 29, 2016, NILA letter to CMS). Mr. Benedict explained that the current rates set by CMS for definitive drug testing by drug class do not cover the cost of the many tests performed under the current drug classes. He discussed the inappropriateness of setting rates at such low levels prior to PAMA implementation and with no consideration of the impact such pricing has on the small and mid-size laboratory market and access to needed testing services.

Several other presenters supported the recommendations offered by NILA, showing an industry aligned in recommendations as it relates specifically to definitive drug testing payment rates.

Following stakeholder presentations, PAMA panel members deliberated on all of the recommendations provided, including reconsideration of definitive drug test payment rates. Dr. Bryan Loy of Humana, who is a PAMA panel member, questioned the need to change the rates to the levels indicated by NILA and others, expressing concern about whether or not the recommended delta increments between the codes had taken into account the economies of scale that might be recognized by the higher rates in each drug class.

Ms. Gail Marcus, formerly with Calloway Labs and another PAMA panelist, was vocally supportive of the suggested changes raised by NILA, noting that some economies of scale may be recognized, but those would be mostly in instances where presumptive testing was being done and not definitive testing. Her insights were supported by fellow panelist William Clarke, Ph.D., of Johns Hopkins. Dr. Steve Phurrough, CMS Medical Officer and chair of the PAMA Advisory Panel, noted that in no instance did any testimony offered differ from the others with respect to recommended changes to the pricing for the definitive drug testing code set.

The PAMA Advisory Panel voted on the recommended rate adjustments raised by NILA, with the following results:

Toxicology Code/Tier	Results of PAMA Advisory Panel Vote
G0480 (Tier 1)	8 in favor of NILA's proposed increase 2 in favor of increasing the price, but at a different rate than NILA's recommendation 1 in favor of "gapfilling"
G0481 (Tier 2)	8 in favor of NILA's proposed increase 1 in favor of increasing pricing, but at a different rate than NILA's recommendation 1 in favor of "gapfilling"
G0482 (Tier 3)	10 in favor of NILA's proposed increase 1 in favor of increasing pricing, but at a different rate than NILA's recommendation
G0483 (Tier 4)	10 in favor of NILA's proposed increase 1 in favor of increasing pricing, but at a different rate than NILA's recommendation

CMS will accept written comments on the reconsidered codes and new test codes until 5:00 p.m., August 8, 2016. The agency will then review the PAMA recommendations and issue proposed decisions in September for stakeholder comment with final decisions issued in November 2016.

View the proceedings of the meeting via YouTube:

July 18, 2016, Clinical Laboratory Public Meeting (Morning Session – 3:29:10)
NILA Testimony: 45:28 - 54:36

July 18, 2016, Clinical Laboratory Public Meeting (Afternoon Session – 1:39:21)
Panel Discussion: 1:43:42
Reporting of Vote: 2:13:00