

**Statement on behalf of the National Independent Laboratory
Association (NILA) to the PAMA Advisory Panel
September 12, 2016**

- Good Morning. I am Anne McGarrett and I work with Shiel Medical Laboratory, a Division of Fresenius Medical Care. I am here today representing the National Independent Laboratory Association – NILA.
- NILA welcomes the opportunity to provide information on the billing and reimbursement of AMA CPT Panels and chemistry tests and the complexity inherent across all laboratory providers and commercial payors.
- I will say at the onset this is an extremely complex issue and it is critically important that CMS not rush to establish a one-size fits-all approach to addressing it in order to meet a January 1 PAMA reporting cycle. This issue requires careful evaluation and surveying across the laboratory market and not quick deliberation and judgement following today's public meeting. The consequences of moving forward with a strategy that does not accurately capture market rates would result in volumes of junk data from which the stakeholder community fears the Clinical Laboratory Fee Schedule would be rebased.
- In my brief comments today, I would like to highlight some examples to help the PAMA Panel and CMS understand the inconsistency in reimbursement across commercial payors and even within particular plans those payors offer, as to how AMA CPT Panels and chemistry tests are billed by and reimbursed to clinical laboratory providers. I have brought copies of the examples I plan to illustrate and would be happy to provide these to CMS and the panel.
- Likewise, I also hope to help you understand that there is no consistency in how laboratories, particularly the small community and mid-size regional labs NILA represents, submit claims from their data systems or apply payments once received. Many of Shiel's laboratory claims are submitted to payors with rules we have developed in our system which align with AMA CPT4 guidelines but which also take into account a particular payor's history of reimbursement when their reimbursement is typically inconsistent with existing AMA CPT4 guidelines.
- Shiel Medical Laboratory is a large regional lab with testing facilities in Brooklyn, NY and Rockleigh, NJ. We perform anatomic pathology and clinical testing for private physicians, group practices, hospitals, long-term care facilities, union and industrial clients, homecare agencies, drugs of abuse rehab centers and for clinical trials.
- Shiel's billing system has been programmed based upon AMA CPT4 Guidelines – and I want to explain what this means.
- Shiel offers clients options for how they order tests: they can order tests individually, order approved AMA CPT Panels, or order client-specific custom panels for which Shiel maintains a legal authorization from the client disclosing components of the custom panel and Medicare reimbursement for each test contained in the custom panel.

- Most clients will order an approved AMA CPT panel and at times, additional individual tests based upon a patient's clinical condition.
- When billing, if a client has ordered 10 individual tests, but the components would equal an approved AMA CPT Panel, Shiel's billing system automatically bundles, per AMA CPT4 Guidelines, those individual tests into the AMA CPT Panel composed of those tests ordered individually. For example, if a client ordered a Carbon Dioxide, Chloride, Potassium, and a Sodium, our billing system is programmed to automatically rebundle this order into an Electrolyte Panel, CPT 80051. If a client orders a CMP, TSH and CBC/Diff/Plt, the system rebundles into an 80050, General Health Panel.
- As another example, if a client orders only 7 of the 8 tests contained in a BMP, the system will seek a panel that accommodates most of the tests ordered and then bill the remaining CPT codes individually. In this instance, our system would bill an Electrolyte Panel and the additional three tests by their CPT codes. This ensures the claim submitted is aligned with AMA CPT4 Guidelines.
- In another example, if a client orders both a CMP (CPT 80053) and a Hepatic Panel (CPT 80076) – two panels which share six components, Shiel's system automatically bills a CMP (CPT 80053) and a Bilirubin Direct (CPT 82248), the only test that is different between the two panels.
- Issues arise when commercial payors reimburse claims in a manner different than how the claims were filed. Carriers may have varying payment plans within their own network, and also from other commercial payors. This makes it challenging for a laboratory's billing department.
- In Shiel's experience, one carrier routinely bundles claims filed with CPT codes 80053 (CMP) and 84443 (TSH) into 80050, General Health Panel, even when clients did not order a CBC/Diff/Plt on the same requisition. Another carrier routinely reimburses us for an 80050 General Health Panel when only a TSH is ordered. A third provider rebundled 84443 TSH and CBC/Diff/Plt into a General Health Panel and then didn't reimburse on two separate tests ordered, the AMA Hepatic Panel and Amylase.
- It is not unusual for Shiel to see commercial carriers decide to pay for an AMA CPT Panel, even if the client order excludes tests that are included in the panel. It is likewise not unusual for Shiel to see commercial carriers bundle tests for payment purposes and in a manner different from how they were billed and then fail to reimburse a test that was included on the claim.
- These examples persist throughout the clinical laboratory market. Equally as inconsistent is how laboratories respond to such payment oddities when applying payments to their individual and unique billing systems. No two labs do this exactly the same, as we have all chosen different billing systems with which to process claims.
- How do we handle this? Every laboratory programs their system to best accommodate these payment anomalies to properly credit payments and close the invoice. Shiel's system prorates payments based upon tests not paid and the ratio of expected payment. Dependent upon what is ordered, the reimbursement from one provider may appear 10 different ways or more, across a six month period.

- The HCPCS coding list for PAMA reporting released on August 24th is not feasible as outlined.
- The PAMA final rule and subsequent guidance requires laboratories to report final payment rates for the HCPCS codes CMS outlined. This is impossible, given the way carriers pay laboratories today. As illustrated in the examples I have provided, many labs are forced to prorate test payment rates because carriers are not accurately paying per AMA CPT4 Guidelines, but rather by their own internal rules.
- In addition, in the PAMA HCPCS List, CMS is asking that laboratories report individually the components of lipid, hepatic, and general health panels. Our systems have no way of retroactively capturing that data as we have only billed for the approved CPT panels in accordance with AMA CPT4 Guidelines.
- The CMS final PAMA rule and the HCPCS PAMA code list released do not align. CMS stated in the final PAMA rule that when private payors group test-level payments into a claim-level payment, instead of by individual HCPCS codes, those rates are not applicable information and are not to be reported. But, with the release of the HCPCS PAMA code list, you are asking us to do just that.
- NILA's members are confused and significantly concerned about how they can appropriately meet reporting requirements given the inconsistency in how carriers pay and in how labs capture the data, especially when dealing with retroactive data and a small window before reporting begins.
- In the absence of their being standardization across the payor community, and with carriers that do not always adhere to the AMA CPT4 Guidelines when reimbursing providers, it is impossible to see how CMS can include such data in any data reporting process going forward, especially one set to begin less than four months from today.
- NILA encourages CMS to develop a better understanding of how frequently payors adhere to or amend the chemistry test panels they issue payment on. CMS must also reconsider its request that specific AMA panels be reported under individual test codes when they haven't been itemized as such in laboratory billing systems.
- How will PAMA properly evaluate market-based payment reform with so many anomalies in the system? CMS and clinical laboratories do not have the authority to require insurance carriers to adhere to AMA's CPT4 Guidelines.
- NILA first asks that CMS not deviate from the terms outlined in the final rule and subsequent regulatory guidance that state when private payors group test-level payments into claim-level payments not aligned with individual HCPCS codes, these rates are not considered applicable information under PAMA and therefore not to be reported.
- NILA then asks that CMS recognize that laboratories do not have this data parceled out within their billing systems. To figure out a mechanism for accurately reporting retroactive data outside of these anomalies will require more time than the short three and a half months remaining before PAMA reporting is set to begin.

- It is not conceivable that laboratories can accomplish this, let alone address any further adjustments CMS plans to make in regard to automated test panels following this meeting. More time is needed to address these complicated issues and ensure accurate information will be reported that provides an apples-to-apples comparison across the industry.
- I cannot emphasize enough that PAMA reporting must not be forced to begin January 1. More time is needed to get this right.
- NILA looks forward to working with the PAMA Panel and CMS to address these issues further. Thank you, and I'm happy to answer questions.