August 8, 2016

Ms. Carol Blackford
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments to Support Reconsideration for Final Payment Determinations for HCPCS Codes G0480, G0481, G0482, and G0483 - Definitive Drug Testing

Dear Ms. Blackford:

In follow up to the Clinical Laboratory Fee Schedule (CLFS) Annual Laboratory Public Meeting on July 18, 2016, and public comments the Association delivered at the meeting, the National Independent Laboratory Association (NILA) respectfully submits the following comments in support of reconsideration of the Centers for Medicare and Medicaid Services' (CMS) final payment determinations for HCPCS Codes G0480, G0481, G0482, and G0483 for definitive drug testing (tiers 1-4). These comments follow submission of NILA's formal reconsideration request in January 2016 and again in June 2016.

Reconsideration Request – G0480, G0481, G0482, G0483

Background

NILA formally requests reconsideration of the 2016 definitive drug testing final payment rates issued by CMS for HCPCS Codes G0480-G0483 (tiers 1-4) as the revised rates currently in place by CMS are significantly below the fixed costs of performing these tests, including specimen preparation, reagents, allocated instrument capital costs, and testing labor.

CMS' current pricing decision is centered around 37 drug classes in an effort to mirror the AMA CPT Manual. However, when making its decision, CMS did not take into consideration that there are hundreds of medications and/or illicit substances that are tested under each of the 37 drug classes. Based on the coding structure and significantly low pricing of the final determinations, it appears that CMS based its decision on the false belief that testing done using Liquid Chromatography/Mass Spectrometry (LC-MS/MS) always produces results for multiple medications and/or illicit substance with one analyte and/or aliquot. This is simply an incorrect view of the technology and the testing process. Depending on the referring provider's order, toxicology laboratories may prepare and run multiple analyte or aliquots for medications/illicit drugs within one drug class. This frequently requires several separate runs on the testing instrument given that different drugs or drug groups require different analytical reagents and instrument set ups due to variability in the chemical structure of particular drug classes. Also,

many different drug or drug groups will necessitate different sample preparation and specimen adjustment. Sample preparation will vary depending on what drugs and/or metabolite is being tested. As a specimen is tested for a higher number of drugs, per a physician's order, additional specimen preparation will likely be necessary, and as a result, additional runs on the LC/MS-MS instrument will be required. Additional runs on the instrumentation following complex sample preparation cost the laboratory more to conduct as they utilize additional resources, more staff time, and toxicologist expertise to conduct the testing and assess results. The current payment rates for G0480-G0483 grossly misrepresent the time, work, expertise, and expense to perform drug testing and are unfortunately established to pay per drug class without understanding the operations of toxicology testing and the number of tests that are often needed for review within a given drug class. The following illustrates an example of the number of drugs that can often be tested under each of the drug classes and estimated number of analytes and/or aliquots prepared for the purpose of performing the testing under G0480:

G0480 – Up to 7 drug classes

Drug Class	**Medications and Illicit Drugs**	**Estimated Number of Analytes and/or Aliquots**
Amphetamine	Methamphetamine, Amphetamine	3
Barbiturates	Butalbital, Phenobarbital	3
Synthetic Stimulants		20
Cannabinoids, synthetic	JWH-018 4,5-Hydroxypentyl	6
	JWH-019 5,6-Hydroxyhexyl	
	JWH-122 4,5-Hydroxypentyl	
	JWH-210 4,5-Hydroxypentyl	
	JWH-250 4,5-Hydroxypentyl	
	JWH-073 3,4-Hydroxybutyl	
Cocaine	Cocaine, Benzoylecgonine	2
Oxycodone	Oxycodone, Noroxycodone	2
Fentanyl	Fentanyl, Norfentanyl	2

When making reimbursement decisions, it is important that CMS understand the differences in the technology used and expertise and time needed to conduct high complexity LC-MS/MS testing for drug analysis in comparison to moderate complexity Immunoassay (IA) technology and further in comparison to IA testing done through desktop analyzers. The following provides a quick breakdown of some of the significant differences, which highlight the resource and cost needs of performing LC-MS/MS testing:

- IA requires BS level technologists versus MS, PhD level scientists frequently utilized for LC-MS/MS. Salaries and staff required for LC-MS/MS are three-to-five times what are required for IA.
- LC-MS/MS instruments costs are five times the cost of IA instrumentation.

- The technical time required to produce LC-MS/MS results is significantly longer than the time needed to produce results through IA testing.
- Facility space requirements to perform LC-MS/MS testing are significantly larger than IA space needs.
- Overall costs of LC-MS/MS testing are approximately five times that of IA testing.
- IA testing through desk top analyzer technology is designed to be operated in the physician office with little, or no, direct lab oversight or expertise and virtually no space requirements.

The attached process diagrams detail what is involved in the two central testing processes – LC-MS/MS and IA testing. The IA process is simple and mechanical. Laboratory reagents are pre-made commercially and the computer assists in reporting the tests with some but little technical intervention. Technical expertise is at the Associate or Bachelor level. Staffing is minimal with a single technologist able to perform the workload of one IA instrument. Instrument cost is in the $70,000 range. Production (the number of tests or panels that can be reported) is approximately 400 tests per hour or about 500 IA panels per day. Facility space needed is about 13 square feet for the instrument and another 100 square feet for associated functions. Associated facility costs are low.

LC-MS/MS testing, depending on the toxicology being performed (therapeutic drug monitoring, addiction monitoring, forensic) has different levels of complexity. The attached LC-MS/MS process diagram shows addiction monitoring drug testing. The first observation is the staff requirement for the technical steps. Bachelor, Master, level expertise is needed to run the test, but Masters or Doctoral level expertise is required to develop, validate and troubleshoot the test and equipment. The number of staff required far exceeds the minimal staff required for IA testing. Instrument cost is in the $350,000 range and in addiction monitoring, three instruments are needed to produce the required ordered drug panel. Production, using the three instruments, is about 100 LC-MS/MS panels per day compared to the 500 IA panels per day for one instrument. Facility space is about 70 square feet and another 500 square feet for extraction and pipetting processes. Facility associated costs are higher than for IA testing. LC-MS/MS requires nitrogen gas, methanol, acetonitrile, and other chemicals, unlike IA testing. The transport of the chemical waste is another cost factor not incurred in IA testing.

It becomes very clear that LC-MS/MS technology to perform drug testing, particularly under Tier 1, requires more cost and resources. LC-MS/MS testing is necessary as many drugs do not have commercial IA reagents available. The non-IA drugs must be analyzed by the LC-MS/MS. Drugs either conjugate or are free in the patient samples and some can be detected intact or have metabolites. Various technical methods are required to analyze, and hence, labor and costs increase. Laboratories try to optimize service quality and as well as technical quality. If specimen volumes are adequate, individual assays are set up for specific drugs. With other drugs, the LC-MS/MS technology can sort out various drugs at the same time. What must be recognized is that one size does not fit all in drug analysis, and testing costs vary across the industry depending on what type of testing is being conducted and its complexity.

Another benefit of LC-MS/MS technology is in the analysis of “designer” street drugs in toxicology samples that turn over rapidly in structure and frequency of use. Laboratories can

spend up to 20% of department costs on research and development to detect newly prescribed drugs or newly transformed street drugs. The drugs present in synthetic cannabinoids ("Spice") change rapidly, and labs struggle to keep up with testing for the variations of these drug structures. There are additional costs assumed by the laboratory in ensuring they can appropriately test to provide the information required by physicians for this purpose.

Proposal

NILA requests that CMS reconsider the payment rates for G0480-G0483 to ensure that the rates more appropriately reflect the number of drugs being tested within a given drug class and cover the complexity, cost, and expertise needed to perform such testing. Our recommendation is as follows:

Code	**Number of Tests Per Tier**	**Crosswalk**
G0480	Up to 7	CPT 82542 * 6
G0481	8-14	CPT 82542 * 8
G0482	15-21	CPT 82542 * 10
G0483	22+	CPT 82542 * 12

CMS should continue to crosswalk the codes to CPT 82542 and implement the suggested modifiers that better recognize the high number of tests performed within a given drug class and the complexity and resulting cost of providing such tests. The industry has worked hard to analyze the costs associated with providing definitive drug testing in reference to the processes described earlier in this letter. Depending on the type, focus and size of the laboratory, those costs can vary. However, the complexity and higher costs associated with necessary LC-MS/MS testing are universal. The industry recommended rates, as requested by NILA, represent a significant discount from 2015 rates following negotiations with Medicare Administrative Contractors and as a result of being required to price testing by drug class. NILA recommends that these rates are needed to cover the costs of complex definitive drug testing.

NILA would also like to address a comment made at the CLFS public meeting by CMS that in 2016 to-date, a large volume of laboratories are billing within tier 4. From NILA's assessment, laboratory members are primarily billing within tiers 1-3, with minimal billings at the tier 4 level. NILA is concerned with the perception that this is otherwise, and recommends that the agency conduct a review to determine why and what type of laboratories are primarily billing in tier 4. We want CMS to understand and recognize that this billing practice does not reflect the broader industry, particularly the small and mid-size independent laboratory market.

Billing Instructions – Definitive Drug Testing

NILA likewise formally requests that CMS revise the billing instructions included with the final rate determinations that effectively force toxicology laboratories to bill under the first tier for

definitive tests by restricting the use of a single "drug class" to once per day. These stipulations combined inhibit laboratories that are genuinely trying to provide prescribing clinicians with meaningful clinical results, and actually reward groups that provide only a minimal scope of testing.

The drug class table in the 2015 AMA CPT manual was designed to facilitate the test-by-individual-code schedule (e.g., one of the "drug classes" is the individual drug Oxycodone, and would therefore, never need to be billed more than once). The table was never designed for, and is not suitable for, the tier-by-drug class schedule currently in place. Several of the drug classes defined in the 2015 AMA CPT manual are too broad for application under the 2016 schema. For example, consider the drug class - Stimulants, synthetic. Over 50 known synthetic designer drugs fall under this single drug class, and the number continues to grow. Under the 2016 tier by-drug-class schedule, the 50-component test panel and the 1-component test will both count as "1" against the tier count, and labs are limited to using each drug class only once per day. In other words, both labs will be reimbursed equally for entirely different levels of service, which CMS should never permit as policy. This failing is not limited to just the Stimulants, synthetic class, or even just the classes of illicit substances. This limitation is common to several of the larger drug classes delineated in the 2015 AMA CPT manual. A lab that performs a single test for one drug, say something as simple as alcohol on a desk top analyzer with no laboratory expenses, is reimbursed the same as a lab that provides a complete panel of testing for opiates, amphetamines, benzodiazepines, cocaine and heroin (13 drug tests in 5 different drug classes).

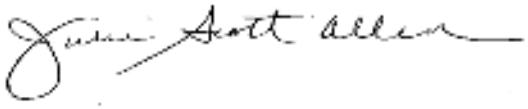
NILA respectfully requests that CMS modify its billing instructions and remove the requirement that each drug class may only be used once per day. NILA recommends that in its place CMS permit certain drug classes, primarily the larger drug classes, to be used more than once per day, based on the number of the drugs tested from within the drug class.

Conclusion

NILA's comments represent industry consensus on pricing reconsideration for definitive drug testing, as presented at the July 2016 public meeting where every speaker that addressed reconsideration of the definitive drug tests proposed the same recommended crosswalk and payment rates. During the PAMA Advisory Panel vote that followed public comments, the panelists overwhelmingly voted in support of NILA's recommended formula and rates for G0480-G0483. We request that CMS adjust the pricing as recommended in these formal comments. We appreciate the opportunity to submit written comments following NILA's

presented remarks at the CLFS meeting, and would be pleased to discuss this issue further as CMS works to finalize a decision on reconsideration.

Sincerely,



Julie Scott Allen
Washington Representative, NILA

Attachments

Cc: Sean Cavanaugh, Deputy Administrator and Director, Center for Medicare
Steve Phurrough, MD, Chief Medical Officer
Valerie Miller, Hospital and Ambulatory Policy Group
Glenn McGuirk, Hospital and Ambulatory Policy Group
Sarah Harding, Hospital and Ambulatory Policy Group