



June 29, 2016

Mr. Marc Hartstein  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

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

**Re: Request for CMS to Allow Reconsideration for Final Payment Determination for HCPCS Code G0480 - Definitive Drug Testing and Notice to Present at July 18, 2016 Public Meeting**

Dear Mr. Hartstein and Ms. Blackford:

In follow up to submission of a formal reconsideration request on January 15, 2016 (attached) and to our conference call on June 20, 2016, the National Independent Laboratory Association (NILA) respectfully requests that the Centers for Medicare and Medicaid Services (CMS) allow for reconsideration of the CMS final payment determination for HCPCS Code G0480 for definitive drug testing (tier 1). NILA's rationale for reconsideration and recommendations for doing so are outlined below for your consideration.

NILA is also writing to provide notice of its intent to present at the July 18, 2016 public meeting, specifically to address reconsideration of the CMS final payment determinations for HCPCS Codes G0481-G0483 (tiers 2-4) for definitive drug testing. If CMS decides to allow for reconsideration of HCPCS Code G0480 (tier 1), NILA will also present its recommendations for how the agency should address this code going forward. The presentation will be delivered by Cheryl Maplesden of Assurance Toxicology Services, a member of NILA and a small community-based toxicology laboratory located in San Antonio, TX.

**Reconsideration Proposal – 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 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) produces results for multiple medications and/or illicit substance with one analyte or aliquot. This is simply an incorrect view of the technology and the testing process. Depending on the referring provider's order, toxicology laboratories will 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 analytic reagents and instrument set up due to variances 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 metabolites are 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 machinery 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 number of analytes/aliquots prepared for the purpose of performing the testing under G0480:

#### **G0480 – Up to 7 drug classes**

<b>Drug Class</b>	<b>Medications and Illicit Drugs</b>	<b>Number of Analytes/Aliquots</b>
Amphetamine	Phentermine	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, Benzoylcegonine	2
Oxycodone	Oxycodone, Noroxycodone	2
Fentanyl	Fentanyl, Norfentanyl	2

*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 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 (\$24.60) * 6
G0481	8-14	CPT 82542 (\$24.60) * 8
G0482	15-21	CPT 82542 (\$24.60) * 10
G0483	22+	CPT 82542 (\$24.60) * 12

CMS should continue to crosswalk the codes to CPT 82542 and implement modifiers that will better recognize the high number of tests performed within a given drug class and the complexity and resulting cost of providing such tests, as recommended. If CMS were to consider creating a modifier, it is reasonable and necessary that G0480 (Tier 1) would be included for reconsideration.

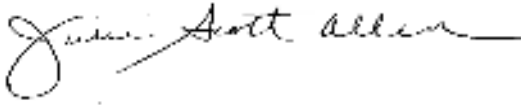
While not subject to pricing reconsideration, because it further affects reimbursement for testing under the tiered structure, NILA formally requests that CMS revise the billing instructions included with the final rate determinations that effectively force toxicology laboratories to bill under the first tier for definitive tests by restricting the use of a single “drug class” to once per day. Under the current instructions, for example, a laboratory that is performing definitive testing on one patient sample for opiates (4 drugs), opioids (3 drugs), and oxycodone (1 drug) plus benzodiazepines (5 drugs) and multiple anti-depressants would only receive the \$80 reimbursement amount. The instructions have the consequence of further undercutting reimbursement to the laboratories for testing performed at the request of physicians.

**Conclusion**

We respectfully request CMS allow for reconsideration of G0480 for tier 1 definitive drug testing. We thank you for giving this additional consideration as an area for reconsideration

discussion at the upcoming public meeting. We look forward to your response in advance of that meeting, and we look forward to addressing all of these issue and our recommendations in a presentation at the meeting.

Sincerely,

A handwritten signature in cursive script, reading "Julie Scott Allen", followed by a horizontal line.

Julie Scott Allen  
Washington Representative, NILA

Attachment

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