July 1, 2015

American
Clinical Laboratory
Association

VIA EMAIL

Marc Hartstein
Director, Hospital and Ambulatory Policy Group
Centers for Medicare and Medicaid Services
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Baltimore, MD 21244

Dear Marc:

On behalf of the American Clinical Laboratory Association ("ACLA"), I am writing to express ACLA's concern about CMS's recent announcement that it will create only two new G-codes to cover all drugs of abuse ("DOA") testing. We recognize that the pricing for these codes is to be discussed at the upcoming Annual Clinical Laboratory Public Meeting, but we wanted to let you know of our more fundamental concerns about the codes themselves as soon as possible. As you know, ACLA represents local, regional and national laboratories that provide a wide range of testing, including drugs of abuse testing. As a result, almost all ACLA members have an interest in these policies and their implementation.

As discussed below, although we support the need to reduce unnecessary and inappropriate utilization of DOA testing, we believe that two codes are not sufficient to adequately reimburse for the legitimate types of testing that are ordered by physicians. As we discuss below, we believe six codes should be created that will adequately cover DOA testing: two codes for presumptive testing and four codes for definitive testing. In addition, we urge CMS to request that participants at the Public Meeting comment on its coding proposal (in addition to making comments on potential pricing levels) so that it will receive a complete understanding of the various approaches that would be useful and how those approaches might be priced. By doing so, we believe that CMS will have this information long before it must make a final announcement in November.[1]

A. Background

As you know, revision of the DOA codes has had a long and complicated history. CMS first instituted new G-codes for some DOA tests in 2010, and then revised the description for those codes again in 2011. Around the same time, the AMA's CPT Code Panel began to look at revising the existing codes, and after extensive discussion and input from numerous stakeholders including CMS, the Panel published new codes in 2014, which were to be effective in 2015. However, CMS declined to implement these new codes and, at the end of 2014, it created new G-codes that corresponded to the then-existing CPT and HCPCS codes and advised all laboratories to continue to bill as they currently were, but using the new G codes. Now, CMS has come forward with a

[1] In fact, in order to ensure that laboratories have time to implement whatever changes CMS ultimately determines in this area, we urge CMS to announce its intentions in September, when it issues preliminary NLAs for all new testing.

new proposal that will replace all of the existing codes with two codes—one for screening and one for definitive testing.

This long history underscores the difficulty of developing coding requirements that discourage unnecessary testing on the one hand, while also fairly reimbursing for the legitimate testing that occurs, on the other. At the outset, ACLA wishes to be clear that it strongly supports the need for clear coding and billing requirements that will help eliminate the unnecessary testing that too often goes on in the area of DOA testing. While outside the scope of the coding and pricing recommendations in this letter, we are aware of CMS's concern about the proliferation of physician office laboratories that have begun to do high complexity testing in their offices using sophisticated instrumentation, such as mass spectrometry. We have specific views regarding this trend and would like to discuss with CMS ways to control potential overutilization of this testing.

At the same time, ACLA also believes it is important to ensure that appropriate testing is fairly reimbursed. ACLA believes that CMS's approach, which lumps all testing into only two codes—and two payment levels—fails to differentiate between different methods of legitimate testing. As a result, Medicare will either overpay for some tests, thereby encouraging additional unnecessary testing, or underpay for other tests, thereby penalizing labs that perform these legitimate testing services. ACLA therefore supports a system that recognizes additional codes that will allow for fair reimbursement of all services, while still offering a more streamlined system of DOA coding and billing. We urge CMS to consider these alternatives before the Public Meeting on July 16.

In the announcement of the new codes to be considered at the Public Meeting, CMS states it is proposing to create two new G-codes, which will be the exclusive method of coding all DOA testing. The two proposed codes are:

GXXX1	Drug Screen, any number of drugs or drug classes, any procedures(s) methodology(ies), any sources(s) per day
GXXX2	Drug test(s)(confirmatory and/or definitive, qualitative and quantitative), any number of drugs or drug classes, any procedure(s)/methodology (ies), any sources(s), includes sample validation, per day.

Thus, CMS would recognize only two codes, one for the "drug screen" and one for the confirmatory or definitive tests. As noted below, ACLA does not believe this approach is sufficient.

B. Presumptive vs. Definitive Testing

Today, when DOA testing is performed, the first step is often a "presumptive" test, which allows for an initial determination of whether a patient may have certain drugs in his or her system. These findings are then subsequently "confirmed" by a more accurate form of testing, when necessary. This presumptive testing can have multiple separate and distinct purposes, as outlined below.

- Drug rehab: The purpose of drug testing in this application is to determine whether or not the patient has taken prohibited drugs. It is important to recognize that patients in rehab programs may also be under medication assisted rehab treatment, as described below.

- Medication-assisted rehab: The purpose of testing these patients is compliance monitoring to determine whether or not the patient is taking prohibited drugs as well as prescribed drugs, because the individual is supposed to be taking only *prescribed* drugs.

- Pain management: There can be multiple testing objectives in monitoring patients being treated for chronic pain. These patients are being prescribed strong painkillers to alleviate their symptoms; therefore the first purpose of the testing is compliance monitoring to detect the presence of the prescribed drugs. Second, the testing is performed to determine whether or not the patient is taking non-prescribed drugs, either in addition to, or as a substitute for, the prescribed drugs. Lastly, this testing is also used to ensure that the patient is not diverting those drugs for improper purposes.

These different purposes require different types of presumptive testing. Depending on the clinical setting and the physician's risk assessment of the patient, multiple drug testing methods and options may be selected by the provider including, but not limited to, the following:

- Waived tests, such as a test cup or dipstick that can make a presumptive determination of whether certain drug classes may be present in the patient's urine.

- Laboratory-based testing with options that include modifications to improve sensitivity for drug detection.

The type of presumptive testing used will depend on the individual patient's situation. For patients in a drug rehab program, a very simple method that indicates the possible presence of a drug may be all that is required. Therefore, for these patients, it may be sufficient to utilize a waived test as a presumptive test, such as a cup or dipstick that can make a gross determination of whether certain drug classes may be present in the patient's urine. For pain management patients, these waived methods are not sensitive enough to distinguish between a patient who has taken the prescribed dose of medication and one who has taken just enough to test positive on the test (often referred to as "pill scraping"). For this latter determination to be made, even on a presumptive basis, requires a more sophisticated immunoassay test, which is usually done in an independent laboratory, rather than the simple waived tests used in the other circumstance.

Additional information about the specific types of drugs or the levels of those drugs is often necessary, in which case definitive confirmatory testing is performed. It is important to recognize that presumptive drug test results consist of either negative (drug-free or drug below cutoff) or results that require additional definitive testing (results equal to or greater than the cutoff). Definitive testing is appropriate to rule out false positive and to identify true positive drug testing results.

The different types of testing, presumptive and definitive, are based on the scientific design of the assay and its ability to distinguish between the chemical structures of the analyte being

tested. Presumptive tests are qualitative analyses that are not able to distinguish between different drugs within a drug category. For example, presumptive assays cannot identify morphine from hydromorphone, two drugs that would typically be grouped together into the opiate category. These presumptive findings are then subsequently "confirmed" by a more sensitive/definitive form of testing, when necessary. Definitive procedures may be qualitative or quantitative and are able to identify individual chemical structures, which enable the assay to distinguish drugs within the same category. To continue the example, a positive opiate presumptive test could then be tested by a definitive assay to determine which specific drug caused it to be positive, such as morphine or hydromophone.

C. A single "drug screen" code is insufficient.

As discussed above, there are different types of presumptive drug tests, which are performed for different purposes and which employ different methodologies. Therefore, to recognize these differences, ACLA believes there should be two separate "presumptive" drug codes. (We believe that the term "presumptive" is more accurate than "screening" because an independent laboratory has no way to determine whether the test is being done for screening purposes, but the underlying technology is, by definition, used to make a presumptive determination.)

GXXX3	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation, including instrumented-assisted when performed (e.g., dipsticks, cups, cards, cartridges), includes sample validation, per date of service.
GXXX4	Drug, test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented test systems (e.g., discrete multichannel chemistry analyzers utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, HPLC, GC, mass spectrometry), includes sample validation, per date of service.[2]

It is appropriate to have two different codes to represent this testing because the two different levels of service or methodologies have vastly different costs. If only one price is established for both types of testing, then CMS will overpay for the less expensive waived test or underpay for the more expensive immunoassay test. Therefore, it seems more advisable to establish separate reimbursement levels for each type of service to ensure accurate reimbursement by Medicare.

The testing methodologies, many of which are waived tests represented by proposed GXXX3, are relatively inexpensive. Therefore, we believe those tests could be cross-walked to the existing code, G0434, which would give them a price of approximately $19.00. However, the immunoassays are more expensive to perform because the inputs used for the tests are more costly

[2] ACLA prefers the term "per date of service" rather than "per day" because "per day" could raise concerns if the testing covered more than one day. "Date of service" is very specific, consistent with billing rules that specify the date of service as the date the specimen was drawn and with current NCCI guidelines.

and they must be performed on sophisticated, and more costly, instruments. Therefore, we suggest cross-walking them to G0431at a price of $98.96.[3]

D. <u>A single definitive code also is inappropriate</u>.

It is also inappropriate to have a single code to define all definitive tests. First, as noted above, we believe CMS should avoid the term "confirmatory" testing, because the laboratory usually has no way to determine whether screening testing was previously performed by another laboratory or physician's office. Again, however, it is not sufficient to have a single code that covers all definitive testing, as explained below.

Definitive testing plays a vital role in the drug testing process. When a patient is tested with a presumptive test, those results must still be confirmed by definitive testing because every point-of-care test has certain limitations, whether it is the test's sensitivity, its cross-reactivity, or its intended use. Immunoassays provide only presumptive results, may have high rates of false positives and negatives, and typically are designed to identify classes of drugs rather than the presence of a specific drug (e.g., morphine vs. heroin.). As a result, it is necessary to run a definitive test to confirm the presumptive results.

With regard to this definitive testing, ACLA believes there is a fundamental misunderstanding about how this testing is performed. There seems to be an incorrect view that when this testing is done using Liquid Chromatography/Mass Spectrometry (LC/MS-MS) instruments,[4] the laboratory introduces a single sample into the instrument, and it simply "spits out" vast numbers of results showing what drugs are present and at what concentrations. Not surprisingly, given that we are talking about very sophisticated and complex testing, the true situation is far more complicated.

When LC/MS-MS is used to test for the definitive presence of numerous drugs, it is generally necessary to do several separate runs on the instrument. This is because different drugs or drug groups require different analytic reagents and instrument setup due to differences in the chemical structure of particular drug classes. Further, different drugs and drug groups may also necessitate different sample preparation. In some instances, the specimen can be tested with minimal preparation. In other instances, the specimen may have to be diluted or concentrated to obtain an accurate result. The extent of sample preparation may vary depending on what drugs and/or metabolites are being tested for. As the specimen is tested for a higher number of drugs, the likelihood that some additional specimen preparation will be necessary increases, and, as a result, so does the likelihood that additional runs on the LC/MS instrument will be required. Obviously, additional runs are more expensive because they require additional resources and staff time to administer and monitor the testing. Therefore, it seems inappropriate to have a single code—and payment level—for all definitive testing.

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[3] We note that all of these tests will likely be re-priced in 2017, when the new price reporting requirements of PAMA have been implemented. Therefore, ACLA believes that the simplest and more direct process should be used to price these new codes now. As a result, we urge CMS simply to cross-walk ACLA's new proposed codes to the corresponding codes that already exist.

[4] Today, most of this testing is done using liquid chromatography tandem mass spectrometry (multiple stage mass spectrometer), and abbreviated as LC/MS-MS.

In light of these circumstances, CMS should utilize tiered coding and pricing, which would reflect the increased costs of doing more testing. ACLA suggests the following codes and tiers for this new type of testing:

G0005	Drug test(s), definitive, qualitative or quantitative, any procedure(s), methodology(ies), (e.g., TOF, MALDI, LDTD, DESI, DART, HPLC, GC, mass spectrometry) any sources, includes sample validation, 1-7 drugs, per date of service.
G0006	Drug test(s), definitive, qualitative or quantitative, any procedure(s), methodology(ies), (e.g., TOF, MALDI, LDTD, DESI, DART, HPLC, GC, mass spectrometry) any sources, includes sample validation, 8-15 drugs, per date of service.
G0007	Drug test(s), definitive, qualitative or quantitative, any procedure(s), methodology(ies), (e.g., TOF, MALDI, LDTD, DESI, DART, HPLC, GC, mass spectrometry) , any sources, includes sample validation, 16-34 drugs, per date of service.
G0008	Drug test(s), definitive, qualitative or quantitative, any procedure(s), methodology(ies), (e.g., TOF, MALDI, LDTD, DESI, DART, HPLC, GC, mass spectrometry) any sources, includes sample validation, 35 or more drugs, per date of service.

As CMS is aware, Palmetto already uses a very similar approach when paying for DOA testing, except it pays individually for each drug when the laboratory tests for fewer than 8 drugs. ACLA believes that it is appropriate to pay for all the testing on tiered level; therefore we propose a new tier that would cover tests 1-7 as well. In pricing these the top three tiers, ACLA believes it is reasonable to use the pricing levels established by Palmetto. This would create a certain amount of predictability in the process. We also propose a new price for the tier with 1-7 drugs, which follows the same basic formula used by Palmetto, as explained below. ACLA proposes the following payment levels:

G0005	$154.00
G0006	$186.00
G0007	$218.00
G0008	$250.00

Each of Palmetto's existing tiers were $32.00 apart; therefore, we have proposed a price for the first tier that is $32.00 lower that the existing tier price of $186.00. That results in a price of $154.00.

We urge CMS to consider requesting additional coding approaches before the meeting, with pricing suggestions for those approaches. We believe this will ensure that CMS has adequate input long before it becomes necessary to announce the preliminary determinations in September and the final pricing decisions in November.

We look forward to discussing these matters with you further. If you have any additional questions or need any further information, do not hesitate to contact me.

Sincerely yours,

JoAnne Glisson
Senior Vice President