DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR

ACTION REFERRAL

TO	DATE
Waldrep	9-20-11

DIRECTOR'S USE ONLY	ACTION REQUESTED
1. LOG NUMBER 10-137	[ ] Prepare reply for the Director's signature DATE DUE _____
2. DATE SIGNED BY DIRECTOR _____ cc: Giese Cleared 10/18/11, letter attached.	[X] Prepare reply for appropriate signature DATE DUE 9-29-11 [ ] FOIA DATE DUE _____ [ ] Necessary Action

APPROVALS (Only when prepared for director's signature)	APPROVE	* DISAPPROVE (Note reason for disapproval and return to preparer.)	COMMENT
1.			
2.			
3.			
4.			

Should we log?
log to Son
cc: BZ
* Maureen can assist

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North Kingstown, RI 02852
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Fax: 401-667-0330
www.dominiondiagnostics.com

DOMINION
DIAGNOSTICS
Unparalleled Laboratory Excellence.

September 8, 2011

Ms. Melanie "BZ" Giese, RN, Deputy Director
Medical and Managed Care Services
State of South Carolina
P. O. Box 8206
1801 Main Street
Columbia, SC 29202

Dear Ms. Giese:

Thank you for the opportunity to meet with yourself, Director Keck, and other representatives of the Department of Health and Human Services. We think that the meeting was productive and were pleased that Dominion Diagnostics could present an overview of its capabilities.

As we discussed, I am enclosing some information that I have collected regarding the applicability of the G codes. The implementation of these codes started at CMS in 2010. In 2011 there were modifications to the codes and the descriptions attached to them as well as the reimbursement.

At the present time, CMS reimburses laboratories such as Dominion under Code GO431. The reimbursement under this code is a bundled price of $102, which is paid no matter how many individual drug tests are performed on a specific specimen. The Code is specific to each patient encounter, and I believe that there is a limit of not more than one patient encounter per day absent exceptional circumstances. The implementation of this Code by CMS has effectively reduced the typical reimbursement for drug testing in half. This has decreased the amount spent by CMS on drug testing.

Since the date of the adoption of the CMS change in coding, we have also seen a number of states move towards the G Code. This may well be required under the recent Patient Protection and Affordable Care Act. This legislation requires the states to adopt the same Correct Coding Initiatives and MUE's that are used by CMS. In our experience, we have seen this occur so far in North Carolina, Maryland, Oklahoma, and Washington. Other states may follow, and in fact I recently saw a notice from the state of South Carolina indicating that you were adopting these coding edits. If this is in fact the case, then you will need to set a bundled

price for Code GO431 which will be approximately equivalent to what you are presently paying for CPT Code 80100 x 5. This is the methodology that has been used by the other payers to set the reimbursement for Code GO431.

It would be Dominion's experience that, by adopting the G Codes (both GO431 and GO434), South Carolina should see a significant reduction in the amount it spends on drug testing. These codes will reduce the reimbursement for laboratories such as Dominion, but more importantly will reduce the amount you are spending for testing that is performed by point-of-care testing devices. As you recall, these are the relatively cheap cups that provide an instant result for a number of drug classes that are presently billed and reimbursed at the same level as full-service laboratory testing.

As we also discussed, I have asked our IT Department to try and pull together some of the same information we provided to other states regarding test frequency and the rate of positives. This information should be forthcoming in the next week. Once it is available, we will send it to you for your review and use. We have also been able to produce a summary of our Comprehensive Analysis of Reported Drugs (CARD) ™ data, which provides an overview as to the number of unexpected drug tests results and the reasons for the unexpected results. I am enclosing this summary data for your review and use.

You also requested that we provide you information regarding what other states have done relative to drug testing. As discussed above, we have seen some states move towards the adoption of the G Code. Other states have used some of the methods listed below to try and reduce utilization:

1. Place a limit on the number of units of CPT Code 80101 that will be paid for per patient specimen.

2. Reduce the reimbursement paid per CPT Code 80101.

3. Place a limit on the number of times that a patient may be drug tested throughout the year. (This was only done in Vermont to our knowledge, and the limit is no more than eight tests per month.)

4. Require preauthorization for the testing of some specific drugs that have low positive rates.

The above are just some of the methods we have seen throughout the country in the last few years. If you need more specifics on any of these, we would be happy to provide it. However, I would suggest that each one of these needs to be thought out so that it does not produce unintended consequences such as ultimately increasing the number of medical office visits that the Department of Health and Human Services will end up paying for or increasing the

cost of care downstream due to the inability of the clinicians to adequately make use of laboratory services.

We would be pleased to discuss these matters further with you if you believe it to be appropriate. Please let us know if you have any questions.

Very truly yours,

Mark A. McSally

MAM:jm
Enclosures

cc: Mr. Robert M. Kerr
Ms. Susan B. Bowling

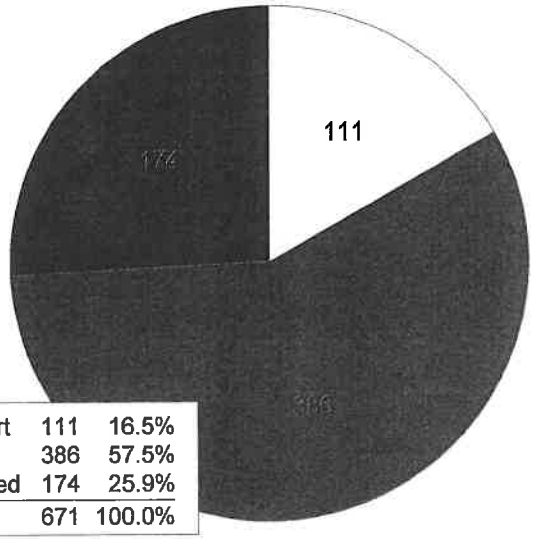
DOMINION DIAGNOSTICS **DRAFT**

Comprehensive Analysis of Reported Drugs (CARD)™ *

SOUTH CAROLINA

Quarter 1, 2011

Overall CARD Summary



Clinical Alert	111	16.5%
Expected	386	57.5%
Not Expected	174	25.9%
Total:	671	100.0%

Overall Total Specimens: 921 **Total Patients: 507**

Overall CARD Summary - Specimens: 671 **Patients: 391**

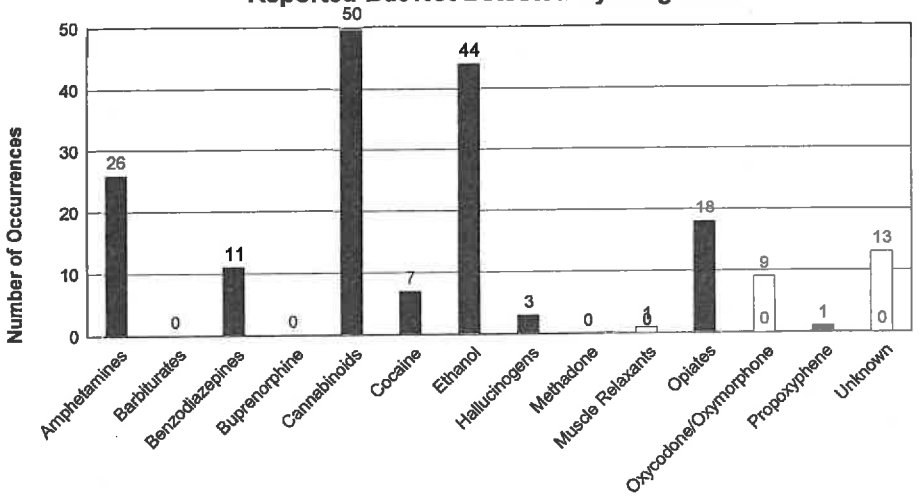
When calculating CARD Summary Pie Chart results as either "Expected", "Not Expected", or "Clinical Alert", the following conditions were applied:

"Expected": The total number of specimens in which ONLY Expected messages were generated

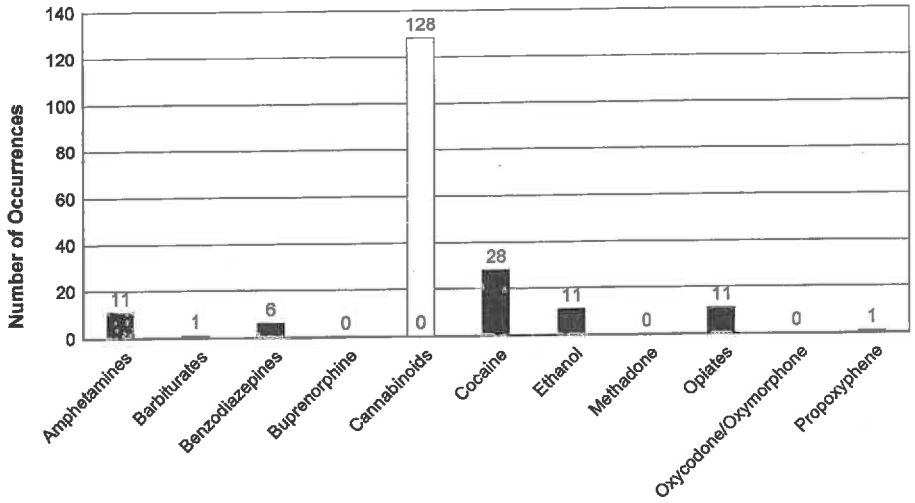
"Not Expected": The total number of specimens in which at least one "Not Expected" message was generated

"Clincal Alert": The total number of specimens in which at least one "Clinical Alert" message but no "Not Expected" messages were generated

Reported But Not Detected By Drug Class



Detected But Not Reported By Drug Class



DOMINION DIAGNOSTICS

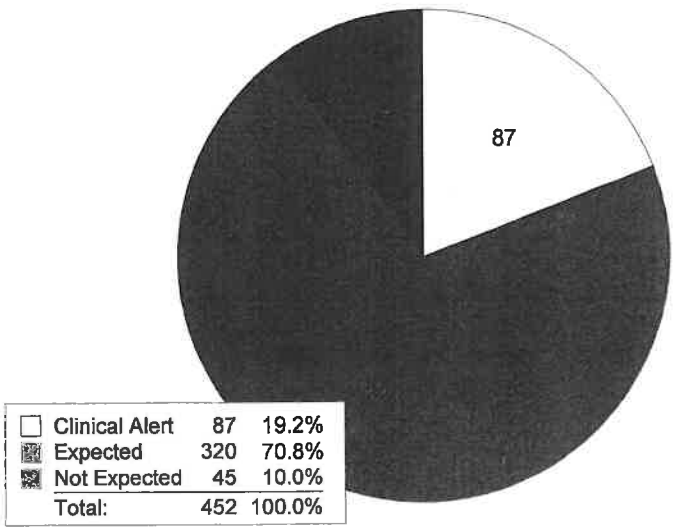
DRAFT

Specimen Analysis: No Treatment-Related Medications or Self-Reported Drug Misuse*

SOUTH CAROLINA

Quarter 1, 2011

Summary Analysis



Clinical Alert	87	19.2%
Expected	320	70.8%
Not Expected	45	10.0%
Total:	452	100.0%

Summary Analysis - Total Specimens: 452 **Total Patients: 273**

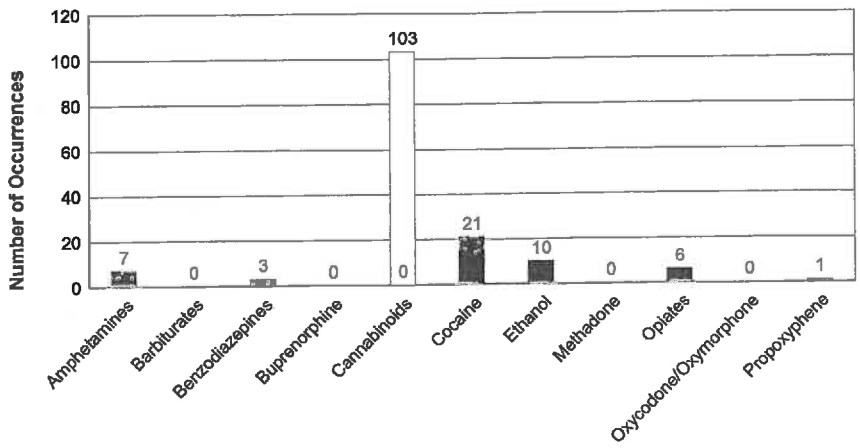
When calculating CARD Summary Pie Chart results as either "Expected", "Not Expected", or "Clinical Alert", the following conditions were applied:

"Expected": The total number of specimens in which ONLY Expected messages were generated

"Not Expected": The total number of specimens in which at least one "Not Expected" message was generated

"Clinical Alert": The total number of specimens in which at least one "Clinical Alert" message but no "Not Expected" messages were generated

Detected But Not Reported By Drug Class



DOMINION DIAGNOSTICS

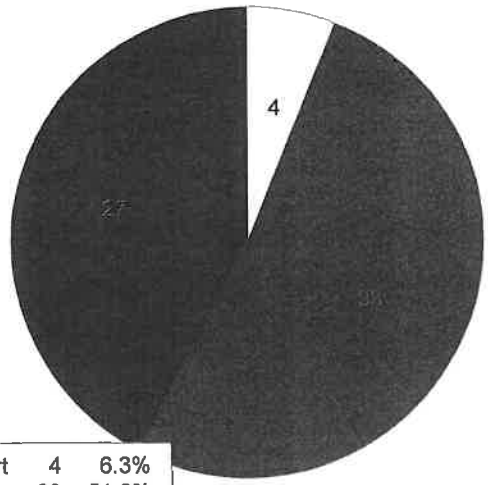
DRAFT

Specimen Analysis: Adherence to Treatment-Related Medications*

SOUTH CAROLINA

Quarter 1, 2011

Summary Analysis



Clinical Alert	4	6.3%
Expected	33	51.6%
Not Expected	27	42.2%
Total:	64	100.0%

Summary Analysis - Total Specimens: 64 **Total Patients: 50**

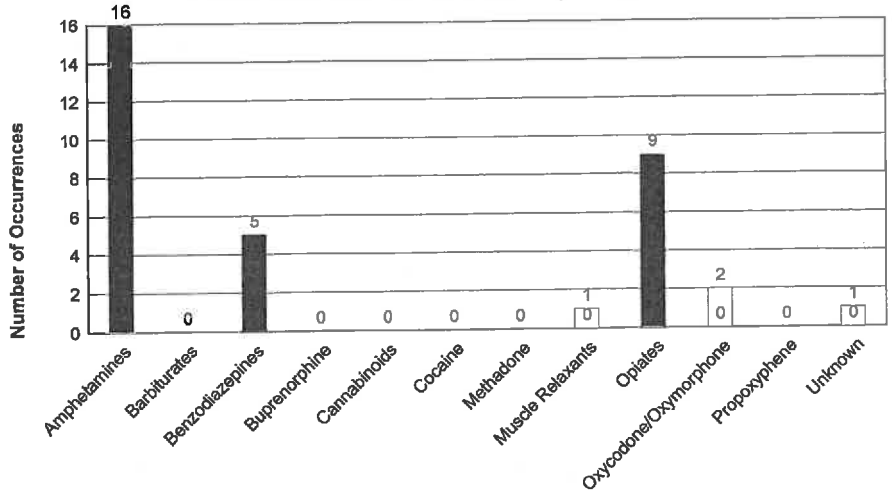
When calculating CARD Summary Pie Chart results as either "Expected", "Not Expected", or "Clinical Alert", the following conditions were applied:

"Expected": The total number of specimens in which ONLY Expected messages were generated

"Not Expected": The total number of specimens in which at least one "Not Expected" message was generated

"Clincal Alert": The total number of specimens in which at least one "Clinical Alert" message but no "Not Expected" messages were generated

Prescribed But Not Detected By Drug Class



DOMINION DIAGNOSTICS

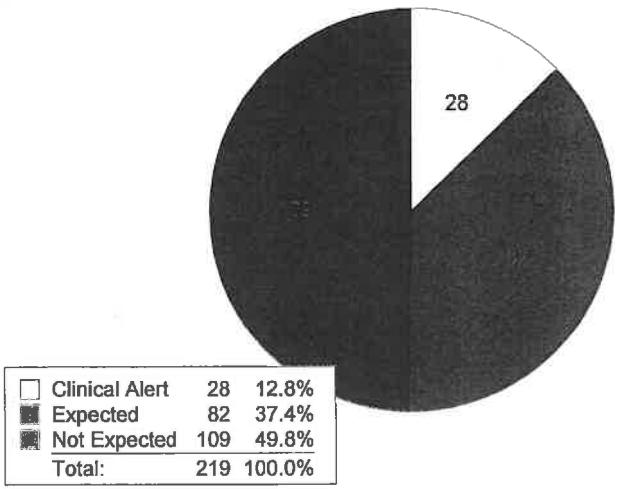
DRAFT

Specimen Analysis: Self-Reported Drug Misuse*

SOUTH CAROLINA

Quarter 1, 2011

Summary Analysis



Clinical Alert	28	12.8%
Expected	82	37.4%
Not Expected	109	49.8%
Total:	219	100.0%

Summary Analysis - Total Specimens: 219 **Total Patients: 156**

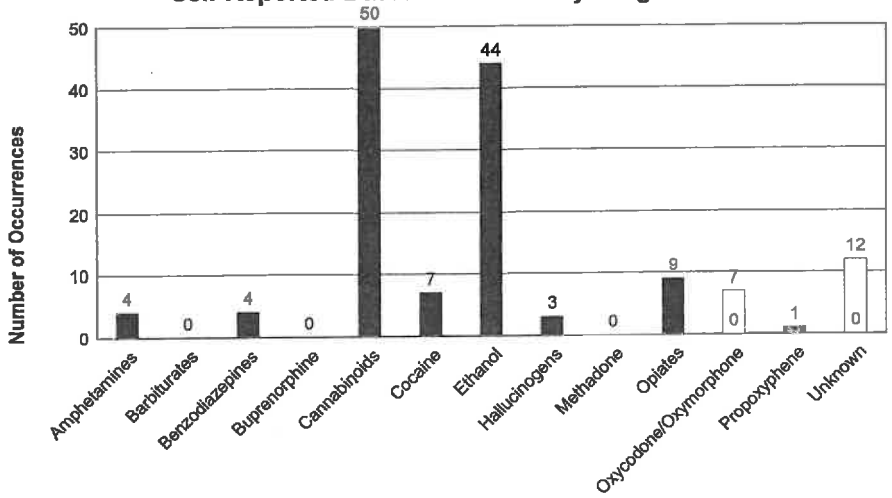
When calculating CARD Summary Pie Chart results as either "Expected", "Not Expected", or "Clinical Alert", the following conditions were applied:

"Expected": The total number of specimens in which ONLY Expected messages were generated

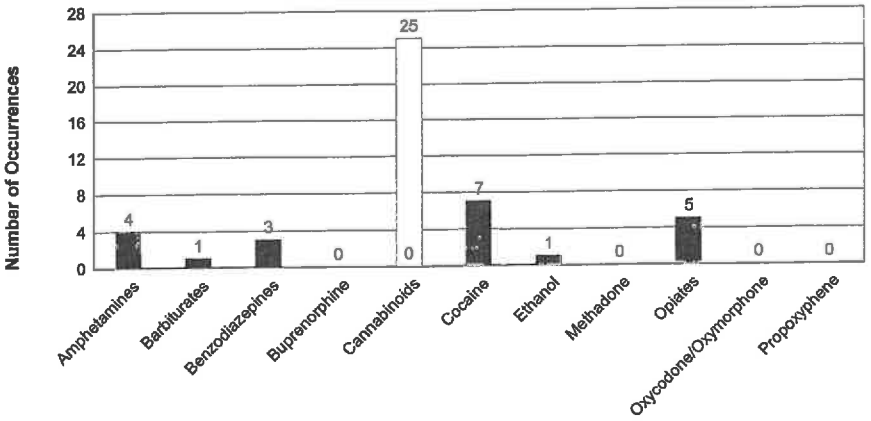
"Not Expected": The total number of specimens in which at least one "Not Expected" message was generated

"Clincal Alert": The total number of specimens in which at least one "Clinical Alert" message but no "Not Expected" messages were generated

Self-Reported But Not Detected By Drug Class



Detected But Not Self-Reported By Drug Class



DOMINION DIAGNOSTICS

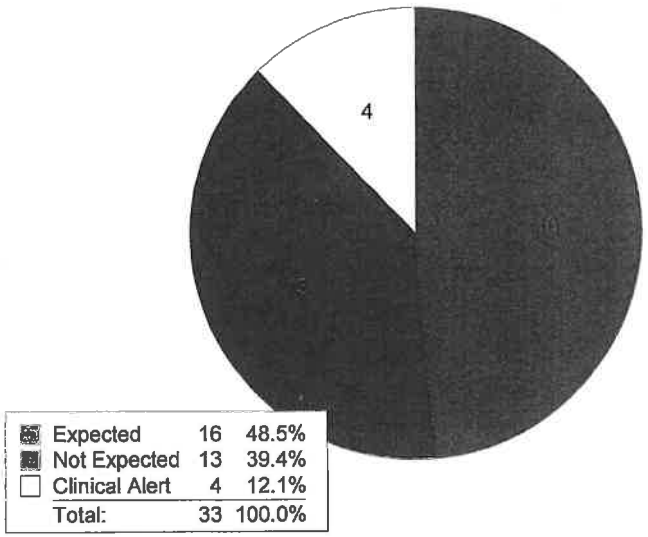
Specimen Analysis: Self-Reported Drug Misuse When Adherent to Treatment-Related Medications*

DRAFT

SOUTH CAROLINA

Quarter 1, 2011

Summary Analysis



Expected	16	48.5%
Not Expected	13	39.4%
Clinical Alert	4	12.1%
Total:	33	100.0%

Summary Analysis - Total Specimens: 33 **Total Patients: 22**

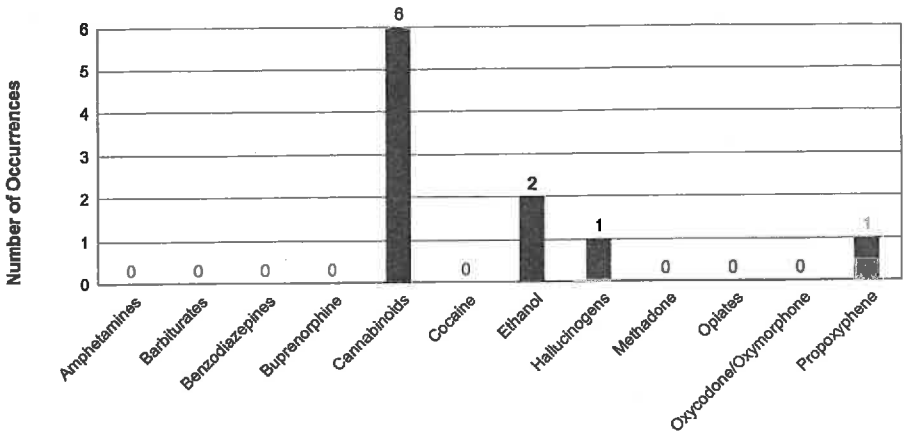
When calculating CARD Summary Pie Chart results as either "Expected", "Not Expected", or "Clinical Alert", the following conditions were applied:

"Expected": The total number of specimens in which ONLY Expected messages were generated

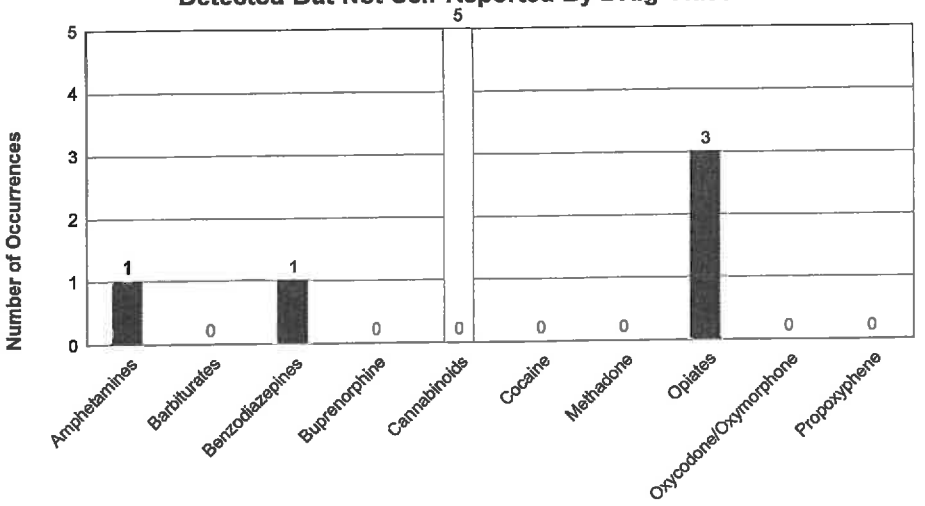
"Not Expected": The total number of specimens in which at least one "Not Expected" message was generated

"Clincal Alert": The total number of specimens in which at least one "Clinical Alert" message but no "Not Expected" messages were generated

Self-Reported But Not Detected By Drug Class



Detected But Not Self-Reported By Drug Class



Calendar Year (CY) 2011
Centers for Medicare & Medicaid Services (CMS)
New Clinical Laboratory Fee Schedule Test Codes
And Final Payment Determinations

Reconsideration Code
84145

Reconsideration Code Description
Procalcitonin (PCT)

Industry Recommended Crosswalk
83880—Natriuretic peptide; **OR** 84146—Prolactin

CMS Final Crosswalk Decision
82308—Calcitonin

Rationale
CMS received comments supporting both crosswalks as outlined above as well as additional suggestions. One of the concerns presented was that the PCT test is a high complexity test, while the Prolactin test is not. In addition, data was presented by some laboratories showing that the current crosswalk (which reflects a payment of $27.76) is not sufficient to cover the cost of the test kit from the manufacturer, much less the staff time and additional costs incurred in performing the test. Commenters generally support the assertion that, most of the time, the Procalcitonin test is performed stat, which means that it cannot be processed in a batched manner. Finally, commenters continue to assert that the Prolactin test is dissimilar to the Procalcitonin test for other reasons, such as the fact that the Procalcitonin test provides results about a possible life-threatening infection, while the Prolactin test provides results about hormone levels.

CMS has thoroughly considered all of these comments. We continue to believe that a crosswalk to Natriuretic peptide would not be appropriate. However, we recognize that there may be an alternative crosswalk that is more appropriate than Prolactin. During the comment period, a crosswalk to Calcitonin was suggested as a viable alternative. Procalcitonin is a prohormone of the calcium modulating hormone Calcitonin. Both Procalcitonin and Calcitonin belong to the class of "sandwich" assays. Both tests are performed on blood involving similar steps, and both Procalcitonin and Calcitonin have identical sequences. In addition, a crosswalk to Calcitonin would yield a payment of $38.36 which would cover the current cost of the test kit.

Commenters were generally supportive of our FINAL recommendation to crosswalk Procalcitonin to Calcitonin.

Reconsideration Code
84431

CMS Final Crosswalk Decision
2 TIMES 86353—Lymphocyte transformation, mitogen (phytomitogen) or antigen induced blastogenesis PLUS 2 TIMES 82397—Chemiluminescent assay

Rationale
Commenters suggested that CMS neglected to include a crosswalk for the "selection" step that is performed as part of this test. However, we continue to believe that the "CD4 T-cell Selection & ATP Release" step is accurately reflected in our methodology. Last year, this test was crosswalked to a combination of CPT code 86353 and CPT code 82397. While CPT code 86353 does reflect cell stimulation, the process utilized for this test code is more complicated than that utilized in the Cylex stimulation step. As a result, if CMS were to include an additional code crosswalk to specifically reflect the "selection" step, the "stimulation" step crosswalk to CPT code 86353 would have to reflect less than 100 percent of the payment for this test code in order to be accurate. By allowing a 100 percent crosswalk to CPT code 86353, we are recognizing the value of the additional "selection" step that involves using an endpoint bead aggregation assay - a much simpler process than the sophisticated and expensive flow cytometry methodology recommended by the commenters as a separate crosswalk to represent this step. There is agreement between the commenters and CMS that the crosswalk to CPT code 82397 accurately reflects the third step in the test process - detection and measurement by chemiluminescent assay.

Additionally, commenters asserted that the payment for the crosswalked test codes should be multiplied by four since the test is performed on a stimulated and unstimulated patient plus a stimulated and unstimulated control subject. CMS disagrees with this approach; however, we do recognize that the test requires separate stimulated and unstimulated preparations. As a result, we believe that a crosswalk of two (2) times CPT code 86353 plus two (2) times CPT code 82397 is appropriate and addresses the concerns of the commenters.

The manufacturer continues to express dissatisfaction with our crosswalk decision. However, cost data from the manufacturer has been inconsistent. Therefore, we continue to believe that our FINAL recommendation is appropriate.

Reconsideration Code
G0430

Reconsideration Code Description
Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

Industry Recommended Crosswalk
G0430—Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure; **OR** 80101—Drug screen, qualitative, single drug class method (e.g., immunoassay, enzyme assay), each drug class

CMS Final Crosswalk Decision
Delete

Rationale
This temporary test code is no longer necessary; therefore, CMS recommends the deletion of it. CMS recognizes that the CPT committee created new CPT code 801XX in order to represent the programmatic need for G0430. However, CMS has discovered that neither of these test codes is properly described in order to control improper billing and utilization of these types of tests.

Reconsideration Code
G0431

Reconsideration Code Description
Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter

Industry Recommended Crosswalk
80101—Drug screen, qualitative, single drug class method (e.g., immunoassay, enzyme assay), each drug class

CMS Final Crosswalk Decision
5 TIMES G0430—Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

Rationale
CMS recommends changing the descriptor for this test code to more accurately reflect the high complexity confirmatory drug screening tests performed in the laboratory setting. By setting the payment at a multiple of five (5) times the price of testing for one drug of abuse, we are recognizing that multiple drugs are often tested through one specimen and that the high complexity tests that are performed in the laboratory setting require more resources than the simple dipstick test kit tests performed outside the laboratory setting.

CMS received comments from the industry suggesting multiples of up to 12 when pricing this code. Commenters confirmed that the tests performed in the laboratory setting require additional resources to perform. CMS believes that a multiplier of five (5) accurately represents the average number of confirmatory tests that might be required from one specimen. This is a FINAL recommendation.

New Code
80104

New Code Description
Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

Industry Recommended Crosswalk
G0430—Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure; **OR** 80101—Drug screen, qualitative, single drug class method (e.g., immunoassay, enzyme assay), each drug class

CMS Final Crosswalk Decision
No recommendation.

Rationale
See the CMS Recommendation Comments under temporary test code G0430 for the discussion. CMS recommends that this test code not be priced under Medicare as the descriptor does not accurately reflect the types of tests that need to be captured for accurate billing and payment here. Instead, the descriptor for G0431 has been edited, and new test code G0434 has been created. See all these discussions for a complete picture of the drugs of abuse testing codes and how CMS proposes to price them under Medicare.

New Code
G0434

New Code Description
Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter

Industry Recommended Crosswalk
Commenters stated that they do not have enough information to provide a recommendation at this time.

CMS Final Crosswalk Decision
G0430—Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

Rationale
CMS created this new test code based on a programmatic need to accurately reflect both CLIA waived and moderate complexity testing for drugs of abuse per patient encounter rather than per dipstick test. As a result, CMS also recommends changing the descriptor to more accurately reflect this goal. This reflects the fact that in any given patient encounter, no matter how many drugs of abuse tests are performed and no matter whether these tests are CLIA waived (simple dipstick test kit) or moderate complexity (reader outside the laboratory setting), proper billing would be one time per patient.

Commenters expressed that further clarification from CMS concerning this test code would be appreciated, especially concerning the moderate complexity level of testing. CMS will be issuing a Medlearn article to provide further guidance concerning the drugs of abuse. Commenters also appreciated the distinction between the simpler quantitative drugs of abuse tests and the more complex qualitative drugs of abuse tests. This is a FINAL recommendation.

New Code
82930

New Code Description
Gastric acid analysis, includes pH if performed, each specimen

Industry Recommended Crosswalk
82928—Gastric acid, free or total, each specimen

CMS Final Crosswalk Decision
82926—Gastric acid, free and total, each specimen

Rationale
CPT code 82928 has a descriptor of "gastric acid, free OR total, each specimen" while CPT code 82926 has a descriptor of "gastric acid, free AND total, each specimen." CMS believes that CPT code 82926 is a more accurate reflection of this test as it applies to both free and total results.

We received no further comments on this recommendation.

New Code
83861

New Code Description
Microfluidic analysis utilizing an integrated collection and analysis device; tear osmolarity

Industry Recommended Crosswalk
83909—Molecular diagnostics; separation and identification by high-resolution technique (e.g., capillary electrophoresis), each nucleic acid preparation PLUS 83935—Osmolality; urine; **OR** Gapfill

CMS Final Crosswalk Decision
83909—Molecular diagnostics; separation and identification by high-resolution technique (e.g., capillary electrophoresis), each nucleic acid preparation

Jurisdiction 11 Part A
Medicare Drug Screen Testing

MLN Matters® Number: SE1105
Related Change Request (CR) #: N/A
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation Date: N/A

Provider Types Affected
This article is for clinical laboratories billing Medicare Carriers, Fiscal Intermediaries (FIs), or Part A/B Medicare Administrative Contractors (A/B MACs).

Provider Action Needed
This article describes how clinical diagnostic laboratories should bill for certain types of tests that are covered under Medicare and paid based on the Clinical Laboratory Fee Schedule (CLFS). Specifically, the article addresses the billing of two CLFS Healthcare Common Procedure Coding System (HCPCS) test codes - G0431 (Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter) and G0434 (Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter) - beginning January 1, 2011. HCPCS code G0434 is new for Calendar Year (CY) 2011. Please be certain that your billing staffs are aware of these changes.

Background
Each year, the Centers for Medicare and Medicaid Services (CMS) hosts an Annual Public Meeting to discuss test codes that have been established by the Common Procedural Terminology (CPT) committee, and may be covered by Medicare, and paid based on the CLFS in the upcoming calendar year.

During the 2009 Annual Public Meeting, CMS introduced two new CY 2010 HCPCS codes for reporting qualitative drug screen testing - G0430 (Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure), which was reported once per procedure and G0431, which is reported once per drug class. (Please note that HCPCS code G0430 was deleted beginning January 1, 2011). After the introduction of these codes, CMS determined that it needed to further refine these drug screen testing codes and revise the descriptors to avoid unnecessary or excessive utilization of HCPCS code G0431 for relatively simple point-of-care tests that screen for multiple substances. During the 2010 Annual Public Meeting, CMS introduced HCPCS code G0434 to report qualitative point-of-care drug screen testing and to limit billing for such testing to one time per patient encounter. CMS also revised the descriptor for HCPCS code G0431 to emphasize that the code describes all screening for multiple drug classes per patient encounter.

CMS recognizes that there could be rare instances where a patient requires multiple, medically necessary screening tests for drugs of abuse to be performed in a single day. For instance, a patient seen in an outpatient pain clinic who requires a drug screening test as a part of his/her care is later admitted to an emergency department after an automobile accident and requires another medically necessary drug screening test. The use of "per patient encounter" will allow payment to be made for this rare circumstance.

Effective January 1, 2011, CMS will utilize two test codes to report drug screen testing:

- HCPCS code G0434 (Drug screen, other than chromatographic; any number of drug classes, by

CLIA waived test or moderate complexity test, per patient encounter) will be used to report very simple testing methods, such as dipsticks, cups, cassettes, and cards, that are interpreted visually, with the assistance of a scanner, or are read utilizing a moderately complex reader device outside the instrumented laboratory setting (i.e., non-instrumented devices). This code is also used to report any other type of drug screen testing using test(s) that are classified as Clinical Laboratory Improvement Amendments (CLIA) moderate complexity test(s), keeping the following points in mind:

- HCPCS code G0434 includes qualitative drug screen tests that are waived under CLIA as well as dipsticks, cups, cards, cassettes, etc, that are not CLIA waived.
- Laboratories with a CLIA certificate of waiver may perform only those tests cleared by the Food and Drug Administration (FDA) as waived tests. Laboratories with a CLIA certificate of waiver shall bill using the QW modifier.
- Laboratories with a CLIA certificate of compliance or accreditation may perform non-waived tests. Laboratories with a CLIA certificate of compliance or accreditation do not append the QW modifier to claim lines.
- Only one unit of service for HCPCS code G0434 can be billed per patient encounter regardless of the number of drug classes tested and irrespective of the use or presence of the QW HCPCS modifier on claim lines.

- HCPCS code G0431 (Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter) will be used to report more complex testing methods, such as multi-channel chemistry analyzers, where a more complex instrumented device is required to perform some or all of the screening tests for the patient. Note that the descriptor has been revised for CY 2011. This code may only be reported if the drug screen test(s) is classified as CLIA high complexity test(s) with the following restrictions:
  - HCPCS code G0431 may only be reported when tests are performed using instrumented systems (i.e., durable systems capable of withstanding repeated use).
  - CLIA waived tests and comparable non-waived tests may not be reported under test HCPCS code G0431; they must be reported under test HCPCS code G0434.
  - CLIA moderate complexity tests should be reported under test HCPCS code G0434 with one (1) Unit of Service (UOS).
  - HCPCS code G0431 may only be reported once per patient encounter.
  - Laboratories billing HCPCS code G0431 must not append the QW HCPCS modifier to claim lines.

CMS has also made changes to the following related tests:

- HCPCS code G0430 was deleted as of January 1, 2011;
- CPT code 80100 has not been priced under Medicare effective January 1, 2011; and
- CPT code 80104 has not been priced under Medicare effective January 1, 2011.

Also, please remember that CPT code 80101 has not been priced under Medicare since July 1, 2010.

Additional Information
CMS publishes a list of test products with CLIA waived status each quarter. Providers may use this list to determine if a particular test product can be appropriately performed by a laboratory with a CLIA waiver and is eligible to be billed using the QW HCPCS modifier. Concerning CLIA moderate or high complexity tests, providers should confirm a test's status with the test manufacturer.

Additional information concerning the CLFS can be found at
http://www.cms.hhs.gov/ClinicalLabFeeSched on the CMS website.

If you have questions, please contact the Palmetto GBA Provider Contact Center at their toll-free number, (866) 830-3455.

Disclaimer

last updated on 02/22/2011
ver 1.0.5.8

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CodeMap® Compliance Briefing: July 15, 2011

Editor's Welcome:

On Monday, July 18, CMS held its annual meeting for public input concerning reimbursement for new codes included in the upcoming 2012 Clinical Laboratory Fee Schedule (CLFS). Also discussed at the meeting were several codes created last year but now being reconsidered by CMS for payment adjustments. Although we have discussed the new and reconsidered codes in previous CodeMap® Compliance Briefings, one surprising development occurred at the CMS meeting. Several presenters offered somewhat unusual proposals concerning drug screening code G0434. In fact, a coalition of laboratory professional organizations and diagnostics manufacturers presented this proposal. This week's briefing will review the recent changes concerning coding and reimbursement for drug screening procedures and the associated proposals for 2012. The presentations at Monday's meeting indicate that the recent controversies and confusion surrounding drug screening coding and reimbursement are far from over. As always, forward any questions, comments, or suggestions via email.

Sincerely,

Gregory Root, Esq.

Drug Screening Coding/Reimbursment 2012

by: Charles Root, Ph.D.

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Introduction: Explosion in Performance of Drug Screening Procedures

Medicare Part B payments for qualitative drug screenings increased from $19.4 million during 2005, to over $166 million in 2009. This dramatic increase amounted to average annual growth of over 150%. Approximately half of these tests were performed using CLIA waived methods,

and by 2009, CMS paid over 40% of the total payments to physician office labs. As screening test volume increased, so did confirmation testing, going from 20,000 tests in 2005, to over 350,000 in 2009. The tremendous growth attracted the attention of CMS since it was unsupported by either demographic changes or increased incidence of drug abuse in the Medicare beneficiary population.

Historically, qualitative drug tests were reported using CPT code 80101 (drug screen, qualitative, single drug class method, each drug class). This code was reported once for each separate drug class determined. As new technology made possible low cost, easy to use CLIA waived cups and cards that delivered results for up to 15 tests at a time, reimbursement became out of line with the cost to perform qualitative drug tests. Test devices costing less then $20 could yield over $200 in Medicare reimbursement.

CMS' Response to Dramatic Increases in Utilization

Starting in 2010, CMS took steps to limit what they percieved as widespread overutilization of qualitative drug tests by issuing a series of new HCPCS codes designed to bring reimbursement in line with actual test costs. At present, the following two codes must be used for all Medicare qualitative drug testing:

1. G0434: Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter

This code is used to report any CLIA waived or moderately complex drug screening test regardless of the number of drugs or drug classes determined. It can only be reported once per patient encounter.

At a maximum, Medicare reimburses $20.47 for G0434.

2. G0431: Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter

This code may only be reported if the drug screen test(s) is classified as a CLIA high complexity test(s). Like G0434, G0431 may only be reported once per patient encounter regardless of the number of drugs or drug classes determined.

At a maximum, Medicare reimburses $102.33 for G0431.

Recent Lab Coalition Proposal

By including both waived and moderate complexity tests under G0434, CMS effectively reduced reinbursement for all qualitative drug screens by 90%, whether performed with simple cups or expensive automated analyzers. As a result, most hospital and reference laboratories are losing money on every qualitative drug screen they perform. In an attempt to resolve this situation, a coalition of test manufacturers and laboratory organizations requested reconsideration of HCPCS

code G0434 and presented the following recommendations at the July 18th Clinical Laboratory Stakeholder's Meeting.

The following two-part recommendation was presented by the coalition and supported by several laboratory associations.

1. Create the following new code to describe moderate complexity, instrumented systems.

G043x: Drug screen, other than chromatographic; any number of drug classes, by instrumented moderate complexity test systems intended for repeated use and not capable of being read by direct optical observation (e.g., spectrophotometers, fluorometers, multichannel chemistry analyers), per patient encounter.

This new code would be crosswalked to 4 X G0434 for a maximum of $81.88.

2. Modify existing HCPCS code G0434 as follows to apply only to simple (waived or non-waived) devices.

G0434: Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or non-instrumented moderate complexity test systems capable of being read by direct optical observation (e.g., dipsticks, cups, cards), per patient encounter

Payment for revised G0434 would remain at $20.47.

At this point, it is anyone's guess as to how CMS will reconsider these codes. Whatever changes CMS implements for 2012, the **2012 CodeMap® Reimbursement Manual** will include detailed explanations, coding guidance, and the latest reimbursement amounts concerning drug screening procedures. Please see below for special, limited time discounts on all **2012 CodeMap® Reimbursement Manuals.**

Log #137

South Carolina Department of Health & Human Services

Anthony E. Keck, Director
Nikki R. Haley, Governor

October 18, 2011

Mark A. McSally
Dominion Diagnostics
211 Circuit Drive
North Kingstown, Rhode Island 02852

Dear Mr. McSally:

We appreciate the opportunity to meet with you, representatives of Dominion Diagnostics and associates of Kerr and Company to discuss your laboratory practices. We subsequently received the information you shared related to your Comprehensive Analysis of Reported Drugs and CMS laboratory coding history. We look forward to receiving the additional information you provided to other states regarding test frequency and the rate of positives.

The South Carolina Department of Health and Human Services is in the process of revising its Alcohol and Drug Testing Policy. We will issue a Medicaid Bulletin with revisions to Medicaid policy and reimbursement for drug screens to be effective December 1, 2012.

Should you have any additional questions or concerns, please contact Ms. Maureen Ryan at 803-898-2660.

Sincerely,

Sam Waldrep
Deputy Director

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Brenda James - Response Log 137

From: Teeshla Curtis
To: Brenda James
Date: 10/18/2011 12:40 PM
Subject: Response Log 137
CC: Gabriele Jefferson; Pheobia Cooper
Attachments: Ref Log 000137 Response.PDF

Brenda,

Attached is the response for Log 137.

Teeshla

Brenda James - Log 137

From: Teeshla Curtis
To: Brenda James
Date: 10/06/2011 5:15 PM
Subject: Log 137

Brenda,

Can you change the due on Log 137 to 10.18?

Thanks,
Teeshla