



Recent Developments in Clinical Laboratory Reimbursement: A System in Transition

Clinical laboratories face significant coding and reimbursement challenges in 2015 and beyond. As testing technologies advance, clinical applications rapidly evolve, and health care cost management pressures inexorably increase, a long static and highly stressed billing and payment landscape is being forced to evolve. The transition, which we believe is likely in time to provide a solid foundation for future growth and development of the laboratory industry, is undeniably messy and painful.

The purpose of this paper is to provide information to clarify the coding and billing issues that toxicology labs are dealing with today, and to put those issues into the context of other changes affecting the broader laboratory industry. We will address, in turn:

- 1. CPT code changes for toxicology implemented January 1, 2015 and how Medicare has – and has not – implemented those changes;**
- 2. How CPT and Medicare have responded to major laboratory technology changes in other areas, as exemplified in coding and reimbursement for Molecular Pathology tests, tests performed with Next Generation Sequencing (NGS) technologies, and Multianalyte Assays with Algorithmic Analyses (MAAAs);**
- 3. Coding compliance and the transition to ICD10;**
- 4. FDA's initiative to actively regulate Laboratory Developed Tests (LDTs); and**
- 5. The coming rebasing of Medicare's Clinical Laboratory Fee Schedule (CLFS) pursuant to Congress' passage of the Protecting Access to Medicare Act (PAMA) of 2014.**

Toxicology coding and Medicare

In 2014, AMA approved a major reorganization of coding for toxicology tests to be implemented January 1, 2015. The reorganization was intended to achieve a number of improvements:

- To eliminate ambiguity and improve specificity; the prior coding regime did not provide clear guidance concerning proper coding for all tests, and codes did not optimally identify the test that was performed;
- To create a framework that is adaptable to new tests and evolving technologies; as the pace of technology development increases, the CPT committee has become increasingly sensitive to the need – in many different areas - for a code structure that is conducive to integration of new tests and technologies;
- To allow identification of clinical settings; this is accomplished not through CPT itself, but by Place of Service codes required in the billing process (e.g. Office – “11”; Inpatient Hospital – “21”; Skilled Nursing Facility – “31”; Independent Laboratory – “81”); and
- To allow identification of specimen sources; a few toxicology codes identify the source of the specimen tested (i.e. blood, urine, etc.) but most do not; when the same test is performed on more than one type of specimen, each is billed separately with modifier “59”.

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Substantively, the new Toxicology coding schema replaces the dominant organizing framework of qualitative vs. quantitative tests that characterized the prior schema. Codes now reflect a framework based upon three major categories:

1. **Presumptive testing**
2. **Definitive testing (qualitative or quantitative)**
3. **Therapeutic drug assays (quantitative).**

The new coding schema includes five (5) new codes for presumptive testing and fifty nine (59) new definitive test codes. The presumptive testing codes specify different analytical techniques;¹ the definitive testing codes. The new coding schema is well explained in the AMA's CPT manual for 2015, and laboratories are advised to rely on that source for specific CPT coding guidance.

The change in the coding schema for toxicology placed a significant burden on payers: How would payment be established for the new codes? This problem was especially difficult for Medicare, which pays for clinical laboratory tests under constraints imposed by law and regulation. Those constraints have been more dramatic for the CLFS than for any other Medicare payment system, and Medicare's options for setting payment rates for new codes are extremely limited. Those options are:

1. **"Cross-walking" is used to set the fee schedule amount for a new code that designates essentially the same tests as an old code; because analytical method and laboratory costs are essentially the same as for the old code, the payment can also be set at the same level; this works under very limited circumstances; and**
2. **When "Cross-walking" cannot be used, Medicare is required to resort to "Gap-filling" - using available data on payment for tests that are technologically cognate to the tests represented by a new code, along with whatever data might be available on the cost of providing tests, to set a payment amount for a new code; "Gap-filling" can be done at the national level, but Medicare more frequently assigns the process to its regional contractors, with the intention of allowing regional variation until a national determination can be made.**

As 2014 came to a close, it became increasingly clear that Medicare could not successfully determine fee schedule amounts, either national or regional, for the new toxicology codes by the beginning of 2015. Medicare's evaluation and decision process on such matters is complicated by its need – or desire - to assure not simply that a payment amount is in place for each code, but that payment is "not excessive."

Medicare released final guidance for toxicology test coding and billing on December 2, 2014. (See <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2015-CLFS-Codes-Final-Determinations.pdf>.) Essentially, Medicare instructs laboratories as follows:

1. **Ignore the new 2015 CPT codes for toxicology;**
2. **Where toxicology test codes used in 2014 remain available, use those codes in 2015; where CPT 2015 retained a 2014 toxicology code but revised instructions or descriptors, ignore the revisions and use the code precisely as it would have been used in 2014; and**
3. **Where a 2014 toxicology code has been deleted from CPT 2015, use a HCPCS "G" code newly created by Medicare to replace it.**

¹ For example: CPT 80300 - Drug screen, any number of drug classes from Drug Class List A; any number of non-TLC devices or procedures, (eg, immunoassay) capable of being read by direct optical observation, including instrumented-assisted when performed (eg, dipsticks, cups, cards, cartridges); CPT 80301 - Drug screen, any number of drug classes from Drug Class List A; single drug class method, by instrumented test systems (eg, discrete multichannel chemistry analyzers utilizing immunoassay or enzyme assay); ... CPT 80304 - Drug screen, any number of drug classes, presumptive, single or multiple drug class method; not otherwise specified presumptive procedure (eg, TOF, MALDI, LDTD, DESI, DART).

The Final Determination document linked above contains a detailed test-specific table describing how CPT 2014 toxicology codes should be billed to Medicare in 2015. If the resolution of similar issues in the recent past serves as a model for CLFS toxicology test rate setting, laboratories should anticipate full implementation of the new CPT code schema effective January 1, 2016, but should not rely on Medicare implementing clear national payment amounts – an instruction to regional contractors to use gap-filling in 2016, in anticipation of national rates in 2017, is highly probable.

Experience with Molecular Pathology, NGS and MAAAs

The treatment of the revised toxicology coding schema is an almost perfect parallel to the way that Medicare adopted and established payment for a new coding schema for molecular pathology tests in recent years. Review of that case is instructive in illuminating Medicare’s concerns and limitations in implementing major coding innovations.

Prior to 2012, coding for molecular pathology testing had been widely acknowledged as “broken” for years. Codes created decades ago, when little such testing was performed and almost none was clinically useful, described analytical steps in the process of arriving at a result.² Billing entailed “stacking” the steps performed by the laboratory (often a dozen or more, with multiple iterations of certain steps), and payment was determined by summing the payment values of the steps coded.

Besides its cumbersome nature, this schema had two fatal flaws:

- 1. Different laboratories might tests for the same genetic trait using different combinations of steps, resulting in completely different code stacks and resulting payment amounts; and**
- 2. Billing codes provided payers with no information of any kind as to what was being tested; even the most common molecular pathology test could not be billed electronically; all tests needed paper processing and review.**

A special AMA committee, with participation from numerous affected constituencies (including both industry and payer representatives) studied this problem in detail and came up with a schema which has since been implemented:

- 1. The most frequently used molecular pathology tests are identified by specific codes; these tests can, if payers desire, be billed and processed electronically; payment is to be based upon the output of the test, not the laboratory’s process decisions;**
- 2. Other tests submitted for review are assigned to one of nine (9) codes on the basis of complexity; all tests in the same complexity “level” are expected to be paid at the same level, but the code does not identify the analyte; tests in this category might later be assigned test-specific codes if utilization warrants; and**
- 3. A single “Molecular pathology test – not otherwise specified” code is available for tests not yet reviewed by CPT for assignment.**

This schema is, on review, extremely responsive to the needs of both payers and laboratories, while it recognizes and provides a channel for adaptation to, the rapid proliferation of molecular pathology tests and their clinical utilization. The new schema was introduced into CPT effective January 1, 2012, but – probably in anticipation of payer implementation difficulties - the old “stacking” codes were not simultaneously deleted.

Medicare, despite being an active participant in the code development process, was unable to establish payment amounts for the new codes. (Establishing payment for molecular pathology tests posed problems substantially greater than that posed by the more recent toxicology case; the translation from diverse packages of analytic steps, with fee schedule pricing that had little discernible relationship to testing costs, to analyte-specific codes was dauntingly

² Examples of molecular pathology codes prior to the 2012 revision, are: CPT 83891 - Molecular diagnostics; isolation or extraction of highly purified nucleic acid, each nucleic acid type (ie, DNA or RNA); CPT 83892 - Molecular diagnostics; enzymatic digestion, each enzyme treatment; CPT 83894 - Molecular diagnostics; separation by gel electrophoresis (eg, agarose, polyacrylamide), each nucleic acid preparation; CPT 83896 - Molecular diagnostics; nucleic acid probe, each; CPT 83898 - Molecular diagnostics; amplification, target, each nucleic acid sequence.

difficult). For 2012, Medicare instructed laboratories to use the old “stacking” codes; for 2013, it instructed laboratories to use the new codes, but mandated regional gap-filling for payment determination. National payment amounts for the new molecular pathology codes were finally implemented effective January 1, 2014.

Medicare is now engaged in the same process with regard to NGS codes and MAAAs. Once again, AMA has created new codes to reflect new testing technology; once again, the codes have been implemented (effective January 1, 2015) but Medicare has not been able to determine appropriate payment; once again, regional contractors have been instructed to set payment using gap-filling techniques. It appears that uptake of new codes and establishment of predictable payment by Medicare will always lag a year or two behind code implementation. Laboratories need to expect these delays, not be surprised by them.

Coding compliance and the transition to ICD-10

Improper coding can have significant negative impacts on a laboratory. Failure to update billing systems to reflect test coding changes can result in rejection of claims, the need to resubmit, and accompanying billing cost increases and delays in payment. Failure to provide valid and appropriate diagnosis codes in billing can have the same impact.

In addition to the ongoing changes in CPT codes for toxicology tests, laboratories also need to adapt their systems to the pending replacement of ICD-9 diagnosis codes by ICD-10, slated to be effective October 1, 2015. On and after that date, the diagnosis code used to document the clinical appropriateness of a laboratory test will need to be taken from among the 69,000 7 digit ICD-10 diagnosis codes. The 14,000 current 5 digit ICD-9 diagnosis codes will cease to be valid for billing purposes on October 1, and use of those codes when coverage requires diagnostic justification will result in claim rejections.

A smooth transition to ICD-10 is also important for billing integrity. Over the years, Medicare has been very attentive to laboratory coding and billing compliance issues. Penalties for improper billing can be very severe; in the most extreme case, where the improper billing is made with knowledge that it is improper, prosecution under the False Claims Act raises the possibility of a monetary penalty up to \$11,000 for each false claim (and a single bill may contain a number of distinct claims) as well as treble damages. Even when past improper billing is voluntarily disclosed, the statute calls for payment of double damages.

Billing compliance is particularly difficult when coding systems are changing. Consistent improper use of a test code that carries a higher payment than the proper code invites close enforcement scrutiny. Similarly, improper diagnosis coding can induce an insurer to payment for a test which would, given an accurate diagnosis, not be covered. Even if a coding error is inadvertent, dealing with an enforcement investigation can be difficult and expensive. It is therefore prudent for every laboratory to be scrupulous in its billing practices. Toxicology laboratories need to be extremely careful in their CPT coding practices, and should by now have taken serious action to be prepared for the introduction of ICD-10 on October 1.

Rebasing the CLFS – the PAMA Reform

PAMA, passed by Congress on April 1, 2014, mandates (among other things) a completely new market-based Medicare payment schedule for clinical laboratory tests. Under the new law, Medicare payment to laboratories effective January 1, 2017 will, for each test, be based upon the weighted median payment rate by private insurers for the test. Laboratories are required to report private insurer payment amounts beginning January 1, 2016. In addition, a newly defined class of Advanced Diagnostic Laboratory Tests (ADLTs), consisting of “sole source multi-analyte tests with a unique algorithm yielding a single result” or “a test that is cleared and approved by the FDA” will, upon introduction after January 1, 2017, be paid at market list price for the first 9 months, at which time market-based pricing will be implemented. PAMA dictates a timetable for critical Medicare steps toward implementation of the new market-based payment system, and restricts certain previously permissible Medicare revisions (e.g. implementation of rate revisions based upon technology change, new national clinical laboratory coverage determinations) in anticipation of the market pricing adjustment.

Like the coding changes discussed above, market-based pricing for clinical laboratory tests responds to a glaring shortcoming of the prevailing system. The Medicare CLFS was implemented in the early 1980s, and relative payment amounts for different tests have been frozen for more than 30 years – years in which extraordinary changes in testing technology and equipment have revolutionized the economics of clinical laboratory testing and massive consolidation has transformed the industry. It has been many years since Medicare payment for a clinical laboratory test could be expected to bear any reasonable relationship to cost.

Industry representatives have protested the initiative, on the grounds that it will markedly reduce laboratory revenues. For some laboratories, depending upon their business mix, this is likely to be true, as many laboratory contracts with private payers establish payment at some specified discount from the Medicare rate. Unfortunately, neither Congress nor Medicare is sympathetic to the industry position. Both of those parties believe that Medicare payment should be near the bottom of the payment range for any service. Their expectation is that Medicare pays close to provider cost, and that profit, if any, comes from private payers.

PAMA provides laboratories with protection from crushing short-term payment reductions by limiting any annual Medicare reduction due to market-based pricing to 10% in 2017, 2018, and 2019, and to 15% in 2020, 2021, and 2022. Given these circumstances, it seems apparent that contracts that set private reimbursement at a discount from Medicare create a Medicare payment death spiral. Positive action to stabilize private insurer payment rates, or to increase them, can limit and/or reverse the impact of PAMA on total laboratory revenues.

FDA regulation of LDTs

The FDA has announced its intention to cease its long-established exercise of regulatory discretion with regard to clinical laboratory tests performed by sole source laboratories under CLIA certification, and to implement a risk-based process for identifying tests that will need to receive FDA review and clearance. FDA has issued draft guidance on the initiative and a proposed risk-based regulatory framework for LDTs and has a fairly robust program for securing public comment and industry input. See the agency's website at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm> to review the copious available documentation.

It is understandable that developers of LDTs should balk at a new layer of regulatory oversight and a potential impediment to market access. They argue that FDA review would impose a regulatory burden that is unnecessary in light of current requirements for laboratory and test certification under CLIA. But they should not be surprised that FDA rejects that argument.

The FDA's standard for marketing clearance is that a device, including an in vitro diagnostic, be "safe and effective for its intended clinical use". CLIA review addresses technical and procedural proficiency in test performance, managerial oversight of the laboratory to assure good laboratory practices, and – for an individual test – the analytical validity and reproducibility of test results (i.e. does the test actually measure what it professes to measure, and does it do so within established standards of reliability?). CLIA does not address the intended use of a test in the clinic. It does not assure that the test is clinically useful, nor does it define the circumstances in which it might be useful. But tests marketed under CLIA are often positioned as providing meaningful input to clinical decision making. FDA believes that such positioning, absent the kind of review that FDA would perform and that CLIA cannot, introduces the possibility of erroneous – hence harmful – guidance to clinicians.

FDA does not propose to eliminate CLIA certification as a commercialization route for LDTs. It proposes to identify tests that introduce significant clinical risk in the absence of the protection afforded by formal market clearance and subject those tests to review. Laboratories might consider the marketing advantages associated with the clinical evidence required to secure FDA clearance and embrace the initiative.

Concluding Thoughts

The U.S. health care system is evolving rapidly. Technology is advancing at an unprecedented pace, most particularly in the field of diagnostics broadly defined. Concern about unsustainable costs and disappointing quality performance, combined with the increased care requirements of an aging population, has prompted the development of new organizational and financial structures to align the incentives of the professionals and institutions delivering health services. The coding and reimbursement changes discussed above are a product of that system evolution.

Of necessity, clinical laboratories must understand the changing environment in which they operate and respond effectively to the threats and the opportunities that system evolution brings. We've addressed reimbursement and coding changes in this White Paper, and will continue to monitor and report on further developments in this area as they occur. We'll also be providing our insight and perspective on other critical clinical laboratory operating issues, such as the implications of widespread adoption of electronic health records (EHRs) and Medicare's implementation of standards for practitioners' and hospitals' "meaningful use" of EHRs.

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