Agenda

- Legislative, Compliance, Regulatory Committee (LCRC)
- 2016 CPT Code Changes
- 2016 CMS HCPCS Changes
- New Molecular Diagnostic codes
- MolDX Z codes
- PAMA Update

LCRC Committee Charge

- To monitor, inform and educate CLMA members regarding federal legislation, regulatory and compliance issues including Medicare and Medicaid and/or other Federal programs and advocate on behalf of CLMA members to national organizations and federal agencies that impact the laboratory profession.

- To provide education and tools for CLMA members to engage in grassroots advocacy.

- To provide ongoing education around federal, regulatory (CMS, FDA, CDC, etc), compliance and reimbursement issues that impact CLMA members through KnowledgeLab, Education on Demand, Webinars, the CLMA website and CLMA member communications.

- Represent CLMA on any industry-wide coalitions as they come up.
Legislative Day – March 14-15, 2016

• CLMA is a cosponsor along with ASCLS, ASCP, AGT and AMT

• LCRC members and other CLMA members travel to Washington DC to meet with their Senators and Representatives on current issues

• 2016 issues include
  • PAMA implementation
  • Thank you for medical device tax delay
  • LDT follow-up, current status
  • HCPCS versus CPT codes

Pathology Coding Caucus (PCC)

• PCC reviews all new CPT code requests, modifications and deletions

• CLMA is a voting member of the PCC

• The PCC advises the AMA CPT Editorial Panel

2016 CPT Codes

- 28 new codes
- 11 deleted codes
- 52 revised codes
New codes

- 80081 Obstetric Panel with HIV
  - Medicare will cover this as well as the old OB panel 80055
  - They also added coverage for 86850, AB screen to CLFS

Deleted Codes

- 82486, 82487, 82488, 82489, 82491, 82492 chromatography codes, analyte not elsewhere specified
- 82541, 82543, 82544 column chromatography, non-drug analysis
- 83788 Mass spectrometry, not elsewhere specified

Revised Codes

82542
- Column chromatography, includes mass spectrometry if performed (e.g., HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, or GC/MS, HPLC/MS), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen, quantitative, single stationary and mobile phase

83789
- Mass spectrometry and tandem mass spectrometry (e.g., MS, MS/MS, MALDI, MS-TOF, QTOF), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen

86709
- Hepatitis A antibody (HAAb), total

86708
- Hepatitis A antibody (HAAb), IgM antibody, IgM antibody
Infectious agent antigen detection by immunoassay technique (e.g., enzyme immunoassay technique (EIA), enzyme linked immunosorbent assay (ELISA), immunochemiluminescent assay (IMCA)) qualitative or semi quantitative, multiple step method; adenovirus enteric types 40/41

The parent code 87301 language carries down to child codes 87305-87451

Microbiology Changes

Codes 87502, 87503

- Revised to clarify that reverse transcription is included, when performed for influenza virus

87502
- Influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types

+87503
- Influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, each additional influenza virus type or sub-type beyond 2 (List separately in addition to code for primary procedure)

G code in Microbiology

G0472
- Hepatitis C antibody screening, for individual at high risk and other covered indication(s)
HPV Screening Coverage

- Human Papillomavirus Medicare Screening Coverage
  - Effective as of July 9, 2015
  - Covered once every 5 years
  - Bill with new HCPCS code G0476
  - Will be MAC priced until inclusion in CLFS 1/1/2017
  - POS must be independent lab or office
  - ICD-9 codes (for dates prior to 10/1/2015) V73.81, special screening exam AND V72.31, routine gynec exam
  - ICD-10 codes Z11.51, encounter for screening for HPV, AND either Z01.411, encounter for gynec exam with abnormal findings OR Z01.419, encounter for gynec exam without abnormal findings

- Reference Change Request 9434 – Screening for Cervical Cancer with HPV Testing – NCD 210.2.1

Pathology Code Changes

- 88346 Immunofluorescent study - Immunofluorescence, each antibody per specimen, direct method - Initial single antibody stain procedure
  - 88347 indirect method
  - 88350 each additional single antibody stain procedure (List separately in addition to code for primary procedure)

Changes from per antibody to per specimen

Molecular Updates (MoPath, MolDx)

- 25 Additional Codes
  - 8 Tier 1 Codes
  - 7 Genomic Sequencing Codes (Next Gen Sequencing)
  - 10 Multianalyte Assays w/ algorithmic analyses (MAAAs)

- Revised Codes
  - 9 Tier 1 Codes
  - 5 Genomic Sequencing Procedures & other Molecular Multianalyte Assays

- New/Revised verbiage determines the code to use.
3/14/2016

**Tier 1 Molecular Pathology Additions**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81170</td>
<td>ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis, variants in the kinase domain</td>
</tr>
<tr>
<td>81162</td>
<td>BCR/ABL (breakpoint cluster region and Abelson murine leukemia viral oncogene homolog 1) (eg, chronic myeloid leukemia, acute lymphoblastic leukemia), gene analysis, full sequence analysis and full duplication/deletion analysis</td>
</tr>
<tr>
<td>81218</td>
<td>CBLB (CBL binding protein 1) (eg, acute myeloid leukemia), gene analysis, full gene sequence</td>
</tr>
<tr>
<td>81219</td>
<td>CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9</td>
</tr>
<tr>
<td>81272</td>
<td>AKT4 (protein kinase C, type A, catalytic subunit 4) (eg, acute myeloid leukemia), gene analysis, targeted sequence analysis (eg, exons 8, 11, 13, 17, 18)</td>
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**Molecular Pathology Notes**

- Codes include all analytical services performed, including cell lysis, extraction, digestion, amplification, detection, etc.
- Procedures required prior to cell lysis, such as microdissection (88380, 88381) are reported separately.
- To report only interpretation and report, modifier 26 may be appended to the specific molecular pathology code.
- Procedures not specified in Tier 1 should be reported using either appropriate Tier 2 code or unlisted code, 81479.
- NCCI edits when billed with molecular codes from microbiology section and/or in situ hybridization codes.

**Genomic Sequencing/Multianalyte Additions**

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<td>81412</td>
<td>Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Carvan disease, cystic fibrosis, Fanconi anemia, group C), gene analysis, genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CTR, HNCC, GA, HECA, HNCA, and TK11</td>
</tr>
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<td>81432</td>
<td>Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel, must include sequencing of at least 14 genes, including ATM, BRC1, BRIP1, CDH1, MSH1, MSH2, NBN, PALB2, PTEN, RAD50, STK11, and TP53</td>
</tr>
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<td>81433</td>
<td>Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), duplication/deletion analysis panel, must include analysis for BRC1, BRIP1, MSH2, and STK11</td>
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<tr>
<td>81434</td>
<td>Hereditary retinoid disorders (eg, retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes, including ARCO, CRX, CNX, CYF, FGR, HNE, KIF1B, KIF1D, NCDN, NRP1, PRPH2, PRPS1, RBP1, and TBP</td>
</tr>
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<td>81435</td>
<td>Hereditary retinoblastoma tumor disorders (eg, retinoblastoma, retinoblastoma, retinoblastoma, retinoblastoma), genomic sequence analysis panel, must include sequencing of at least 8 genes, including MAX, SDH, SDH, SDH, SDH, and SDH</td>
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Genomic Sequencing/Multianalyte Additions

81438  Hereditary neuroendocrine tumor disorders (e.g., medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma, duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL).

81442  Noonan spectrum disorders (e.g., Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndromes). Multianalyte analysis panel, must include sequencing of at least 12 genes, including BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, SF3A1, RET, SMAD2, and SOI.

These codes are panels associated with various disorders where the testing is performed by genomic sequencing analysis. The code descriptors define specifically what genes must be tested as well as the minimum number of genes that must be tested in order to assign that given CPT code.

If all components are NOT tested, assign code(s) from the Tier 1 or Tier 2 or if not listed, use unlisted code 81479.

Multianalyte Assays with Algorithmic Analysis

81490  Autoimmune (hematologic/oncologic) analysis of 12 biomarkers using immunoassays, utilizing serology, prognostic algorithm reported as a disease activity score (Do not report 81490 in conjunction with 81503).

81493  Coronary artery disease, miRNA gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score.

81525  Oncology (solid), miRNA gene expression profiling by real-time RT-PCR of 12 genes (2 content and 1 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score.

81528  Oncology (hematologic) screening, quantitative real-time target and signal amplification of 10 DNA markers (miR-144, 143, 199a, 222, 34a, 378, 497, 513a, 515c, 663) utilizing whole peripheral blood, algorithm reported as a positive or negative result. Do not report 81528 in conjunction with 81517 and 81518.

81535  Oncology (hematologic), live tumor cell culture and chemotherapeutic response by DMP-stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination.

481536  Oncology (hematologic), live tumor cell culture and chemotherapeutic response by DMP-stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination. (Use separately in addition to code for primary procedure). Do not report 81536 in conjunction with 81556.

MAAA’s Continued

81538  Oncology (solid), next-generation sequencing signature, including analysis A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival.

81540  Oncology (solid), tumor of unknown primary, miRNA gene expression profiling by real-time RT-PCR of 92 genes (73 content and 19 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype.

81545  Oncology (solid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (good, intermediate, or poor).

81595  Cardiology (heart transplant), miRNA gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subtraction of peripheral blood, algorithm reported as a rejection risk score.

0009M  Metastatic breast (mammary 21, and 16) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each mutation.

0010A  Oncology (solid), proteome cancer (biological assay for four proteins (total PSA, free PSA, intact PSA, and human kallikrein 2 (hK2)) by patient age, digital rectal examination status, and no history of prior prostate biopsy, utilizing plasma, biopsy, algorithm reported as a probability score.
Molecular Pathology Code Revisions

• Codes that have undergone revision due to addition of gene specific codes:
  • 81210
  • 81275
  • 81355
  • 81401
  • 81402
  • 81403
  • 81404
  • 81405
  • 81406
  • 81435
  • 81450
  • 81455

Molecular Pathology Reimbursement

• Many covered only once per lifetime
• Codes added to Tier 1 81162-81314
  • CLFS reimbursement based on CMS crosswalk
  • Subject to coverage criteria by contractor LCD
  • Medicaid coverage by state fee schedule
  • Commercial coverage as determined by medical policy
• Codes added to Genomic Sequencing & MAA 81412-81442
  • CMS gap filled
  • Subject to coverage criteria by contractor LCD
  • Medicaid limited coverage by state fee schedule/policy
  • Commercial coverage as determined by medical policy

Molecular Pathology Reimbursement

• Codes added to MAAA’s 81490-81595
  • CMS gap-filled
  • Subject to coverage criteria by contractor LCD
  • Medicaid limited coverage by state fee schedule/policy
  • Commercial coverage as determined by medical policy
• Codes added to proprietary MAAA’s 0009M-0010M
  • CMS gap-filled
  • Subject to coverage criteria by contractor LCD
  • Medicaid limited coverage by state fee schedule/policy
  • Commercial coverage as determined by medical policy
Molecular Pathology Reimbursement

- MoIDX Registration
  - Laboratories submitting CMS part B claims for CPT codes:
    - 81161-81393 Tier 1 Molecular Pathology
    - 81400-81408 Tier 2 Molecular Pathology
    - 81410-81471 Genomic Sequencing & MAA
    - 81490-81599 MAA's
    - 88380-88381 Microdissection
    - G0492 HCPCS professional interpretation
    - G001M-0019M Proprietary MAA
    - 81479, 84999, 85099, 86849, 87999, 88199, 88299, 88399, 89398 NOC
  - To CMS jurisdictions:
    - JE (CA, NV, HI)
    - JF (WA, OR, ID, MT, UT, WY, AZ, ND, SD, AK)
    - JM (NC, SC, VA, WV)
    - J15 (TN, OH)

- Z-Code Identifiers
  - McKesson Diagnostics Exchange
    - Unique 5 character alpha-numeric code associated with specific MDx test
    - Specific to CPT codes – provides granularity
    - Billing lab must submit application
      - Whether developed in-house, or
      - Purchased from reference lab
  - Examples
    - 81218 – CEBPA gene analysis
    - 14 entries

- 2016 CMS Drug Screen Codes
  - Three new presumptive G codes
    - G0477 point of care test visual read
    - G0478 point of care test with instrument read
    - G0479 all other presumptive drug screen performed by instrumented chemistry analyzers
  - Four new definitive G codes
    - G0480 definitive method such as GC/MS, LC/MS – NOT EIA or enzymatic methods; 1-7 drugs
    - G0481 8-14 drugs
    - G0482 15-25 drugs
    - G0483 26 or more drugs
### CPT vs HCPCS

#### Presumptive

<table>
<thead>
<tr>
<th>Current CPT</th>
<th>Current HCPCS</th>
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<tbody>
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</table>

#### Definitive

<table>
<thead>
<tr>
<th>Current CPT</th>
<th>Current HCPCS</th>
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</table>

### PAMA Update

- Protecting Access to Medicare Act of 2016, Section 216
- Passed April 1, 2014
- Section 216 reforms how the Medicare Clinical Laboratory Fee Schedule is priced
Brief History of CLFS

• Established in 1984 based on historical charges
• Included increases based on CPI
• Subject to congressional freezes and negative updates
• No changes due to technological advancements e.g. TSH

Current Fee Schedule Update System

• New CPT codes are either crosswalked to existing code payment or
• Gap filled using contractors payment rates – example is the molecular diagnostic codes
• Existing codes are subject to reconsideration of payment rate the first year. After that they are set for life, except for macro fee schedule ups and downs

Why Change?

• System doesn’t provide for macro-rebasing of payment rates based on cost. Still using 1984 data as base
• Prices cannot adjust except for inflation or congressional action (may be up, mostly down)
• OIG issued a report in 2013 comparing lab test payment rates.
• CMS is aware of private payer deals that are below the Medicare rate
• CMS was in process of a unilateral technological review of payments
Preliminary Rule

- Published in the Federal Register on October 1, 2015
- Gave stakeholders until November 24, 2015 to comment on rule
- Was supposed to be effective January 1, 2016
- No final rule has been published as of February 26, 2016
- No word from CMS on its status

Applicable Laboratories – Who Must Report?

- A lab that meets the CLIA definition of a lab and
- A lab that receives over 50% of its Medicare revenue from the CLFS and PFS during the reporting period and
- Has greater than $50k in CLFS revenues ($25k for the first reporting period)

Is either a lab itself or has at least one component that is

Consequences of Criteria

- This will remove hospitals from applicable as they won’t likely meet the 50% threshold
- This will remove most physician offices as they won’t meet the $50k threshold
Reporting at What Level TIN or NPI?

• Proposal is to have companies report at the Tax Identification Number (TIN) level. One report for the entire company.

• NPI or CLIA level reporting would include more labs
  • Example – a core lab that does outreach and is part of a hospital system or POLs under hospital TIN

Who are the Reporting Labs then?

• CMS estimates that no hospitals will report

• 6% of physician labs may report

• 48% of independent labs may report (TIN related)

• Hospital lab outreach having a separate TIN

CMS calculates that with these labs reporting they will capture 96% of physician office lab revenue and 99% of independent lab revenue
Voluntary Reporting?

• If a laboratory doesn’t meet the criteria they can’t be included in the data set

• This creates a “cherry picked” set of laboratories which will be the large commercial laboratories, regional independent labs and only other labs that have their own TIN number.

Applicable Payers

• All private payers including group health plans, Medicare Advantage and Medicaid MCO plans

• Does not include Medicaid fee for service

• Does not include other governmental payors

• Does not include capitated plans

Applicable Data

Data set to include:
1. HCPCS code (CPT)
2. Each private payer rate separately
3. Volumes at each private payer rate – if rate changes during the year both rates with volumes must be reported.
Data Cont.

- The rate is after any discounts or other concessions are applied.
- Does not include deductible or copay amount
  - So a $80 test with $20 copay would be reported as $80, not the $60 insurance pays.
- Do not include the payer name.

Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1, 2014</td>
<td>PAMA passed</td>
</tr>
<tr>
<td>June 30, 2015</td>
<td>Deadline for PAMA proposed rule publication</td>
</tr>
<tr>
<td>October 1, 2015</td>
<td>PAMA proposed rule is published</td>
</tr>
<tr>
<td>November 24, 2015</td>
<td>Deadline for proposed rule comments</td>
</tr>
<tr>
<td>??????</td>
<td>Final rule is published</td>
</tr>
<tr>
<td>??????</td>
<td>Public chance to comment on final rule</td>
</tr>
<tr>
<td>Jul 1 - Dec 31, 2015</td>
<td>Data collection period</td>
</tr>
<tr>
<td>Jan 1 - Mar 31, 2016</td>
<td>Data reporting period</td>
</tr>
<tr>
<td>April 1 - Nov 2016</td>
<td>CMS calculates new rates</td>
</tr>
<tr>
<td>November 1, 2016</td>
<td>CMS published new rates</td>
</tr>
<tr>
<td>Jan 1, 2017</td>
<td>New rates are effective</td>
</tr>
</tbody>
</table>

Rate Setting Process

- CMS will calculate the weighted median price for each code (midpoint of the data set).
- Rate will be national without geographical variation.
- Will be in effect for 3 years with no inflation update or productivity decrease – except ADLTs annually.
- Will still be subject to sequestration.
New Test Process

• New clinical diagnostic lab tests (CDLT) will be priced similar to existing process using cross-walk and gap fill until the next data reporting cycle
• These will be discussed by the PAMA payment advisory panel
• There will still be the public meeting in July with an opportunity for public comment

Advanced Diagnostic Laboratory Tests (ADLT)

Tests offered by a single lab and must meet one of the following criteria:
1. Include DNA or RNA analysis and use an algorithm
2. Provide new clinical diagnostic information that can't be created from existing tests or a combination of existing tests
3. FDA cleared or approved

Problems with the Proposed Rule

• CLMA submitted comments along with every other major laboratory society

• CLMA has these concerns
  • Timeline – The final rule was supposed to be out by June 30, 2015. It is still not published, but the deadline to comply remains March 31, 2016.
  • Applicable Laboratories – The proposed rule eliminates most hospital data and is designed to capture the independent laboratory pricing. CLMA feels like the applicable laboratories should include all providers over a certain payment threshold.
  • Data Collection and Fee Calculation Process – The rule does not give any details on what data or how to submit it.
Congressional Letter

The Protecting Access to Medicare Act of 2014 (PAMA) (P.L. 113-93) includes the most significant reforms to the Clinical Laboratory Fee Schedule (CLFS) since it was established in 1984. PAMA requires the development of a first-of-its-kind, mandatory reporting system in which applicable laboratories must report all of their private payment rates and test volumes to CMS. The goal of this new reporting system is to develop a market-based reimbursement system to replace the current fee schedule. Clinical laboratories ranging from community independent laboratories, physician office laboratories, hospital-based laboratories, national laboratories, and other laboratories would report private market data, and CMS would calculate median rates so that Medicare rates could be based on a true picture of the laboratory market.

However, under CMS’s current proposal, a number of laboratories are prohibited from participating in the reporting process. We are deeply concerned that this prohibition will skew the market data, resulting in Medicare rates that are not reflective of true market prices. We recommend that CMS consider a more inclusive approach to determining which laboratories should report data and to allow any laboratory to voluntarily report data.

In addition to the need to broaden the universe of reporting laboratories, CMS must reconsider the proposed timeline. Laboratories will be establishing new information systems to collect, assess, and validate test sets according to regulations that have yet to be finalized, and then quickly report the data to CMS beginning in January 2016. Failure to meet this deadline or errors in reporting could yield penalties of up to $10,000 per day. The proposed timeline presents a significant challenge to the laboratory community as it provides little time to prepare, certify, and submit upwards of millions of data points based on a yet-to-be-released set of Agency requirements. Accurate reporting is essential to establishing appropriate reimbursement rates. Additionally, we encourage CMS to provide greater time between the publication of revised reimbursement rates and their effective date as well as outline a formal process for laboratories to call attention to potential errors in calculating the rates.

Excerpts

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Additionally, PAMA also creates a new category of tests, Advanced Diagnostic Laboratory Tests (ADLTs). In order to be considered an ADLT, a test must analyze multiple biomarkers of "DNA, RNA, or proteins," among other factors. Despite this clear language, the proposed rule excludes "protein" from the criteria. Protein-based diagnostics are being used to make clinical decisions regarding patient care today, and encouraging further development in this area is crucial. CMS should revise the ADLT definition to reflect the statute's inclusion of proteins.
Senate Letter

- Signed by 19 Senators

Senate Signatures
Senate Finance Steps In

- Senate Finance Committee has the same questions
- Wrote a letter to CMS on January 5, 2016 asking for delay and inclusion of more providers
- Signed by Chairman Orrin Hatch and Ranking Member Ron Wyden

Excerpts

It is critical that the laboratories reporting the private sector data used to determine Medicare payment rates are representative of the marketplace. CMS proposed to use Tax Identification Numbers (TINs) of laboratories to identify providers. It is our understanding that CMS established a list of laboratory TINs based on the number of TINs identified by the American Society for Clinical Pathology (ASCP) and the Clinical Laboratory Services (CLS) division of the American Medical Association (AMA). We urge CMS to consider this approach, which would also ensure a randomized sample of laboratory TINs that would be representative of the national market.

We are also concerned that CMS plans for laboratories to submit data under the proposed methodology would result in duplicate reporting of laboratory services. Laboratories would be required to report information that would be included in the Medicare payment rates. To avoid such duplication, CMS should consider using the existing laboratory TINs to identify laboratories that report data to the Medicare program.

Summary

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- 2016 CPT Code Changes
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- PAMA Update