Molecular Pathology Reimbursement: Current State of Play

Part I of a two-part webinar series on the current crisis in molecular pathology reimbursement

June 10, 2013

ACMG
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About The Speaker

Genevieve Tang
Associate Director, Strategic Product Planning
Quorum Consulting, Inc.
genevieve.tang@quorumconsulting.com

Ms. Tang's expertise is in working with medical technology innovators to develop short- and long-term reimbursement strategies that optimize market access. In addition to her work in reimbursement strategy development, Ms. Tang has successfully advocated for positive payer coverage policies, secured new billing codes, and established favorable payments for a wide range of technologies. Having previously worked in a molecular biology lab at the Lawrence Berkeley National Laboratory, she holds a special interest in molecular diagnostics, and to date has worked with numerous labs and companies to respond to the reimbursement challenges facing the industry today.

Webinar Objectives

- ✓ Review the background on molecular pathology coding changes in 2013
- ✓ Understand how Medicare rates are being established through the gap-filling process
- ✓ Provide an update on the Medicare gap-filling process and key milestones moving forward

Background on Molecular Pathology Coding Changes

Rationale for Development of the MoPath Codes

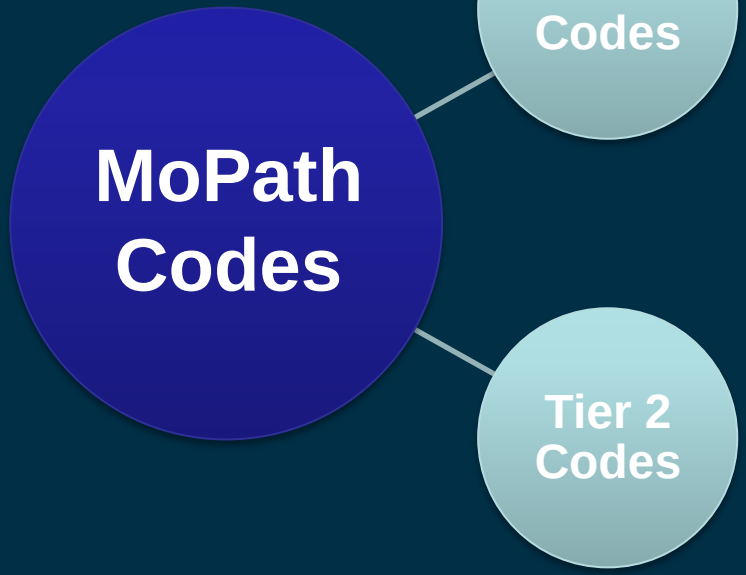
Payer Needs

- Payers were concerned about a lack of transparency under the old “code stacking” system, which did not allow them to identify the tests being billed
- There was an urgent need for a new coding framework to address this problem

Coding Solution

- In 2012, the American Medical Association (AMA) created new **analyte-specific** molecular pathology (MoPath) CPT[1] codes
- These codes replaced the methodology-based “stacking” codes effective January 1, 2013

MoPath Coding Structure



- 105 Codes
- Represent most of the commonly performed single-analyte molecular tests
  - e.g., CFTR, FMR1

- 9 Codes
- Represent lower volume procedures than Tier 1 procedures
- Arranged by 9 levels of technical resources and interpretive work by the physician or other qualified health care professional

- If an analyte-specific coding option is not available, CPT code 81479 (unlisted molecular pathology procedure) should be used

As of January 1, 2013, laboratories must use MoPath codes to bill for molecular diagnostic testing

Tier 1 MoPath Codes for Commonly Performed Tests

Test	CPT	Descriptor
Cystic Fibrosis	81220	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)
Molecular Cytogenomics	81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
	81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
Fragile X	81243	FMR1 (Fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
	81244	characterization of alleles (eg, expanded size and methylation status)
Short Tandem Repeat Analysis	81265	Comparative analysis using Short Tandem Repeat (STR) markers; patient and comparative specimen (eg, pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [eg, buccal swab or other germline tissue sample] and donor testing, twin zygosity testing, or maternal cell contamination of fetal cells)
Hematopoietic Stem Cell	81267	Chimerism (engraftment) analysis, post transplantation specimen (eg, hematopoietic stem cell), includes comparison to previously performed baseline analyses; without cell selection
Long QT Syndrome	81280	Long QT syndrome gene analyses (eg, KCNQ1, KCNH2, SCN5A, KCNE1, KCNE2, KCNJ2, CACNA1C, CAV3, SCN4B, AKAP, SNTA1, and ANK2); full sequence analysis
Prader-Willi; Angelman	81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A) (eg, Prader-Willi syndrome and/or Angelman syndrome), methylation analysis

Coding for Physician Interpretation and Reporting

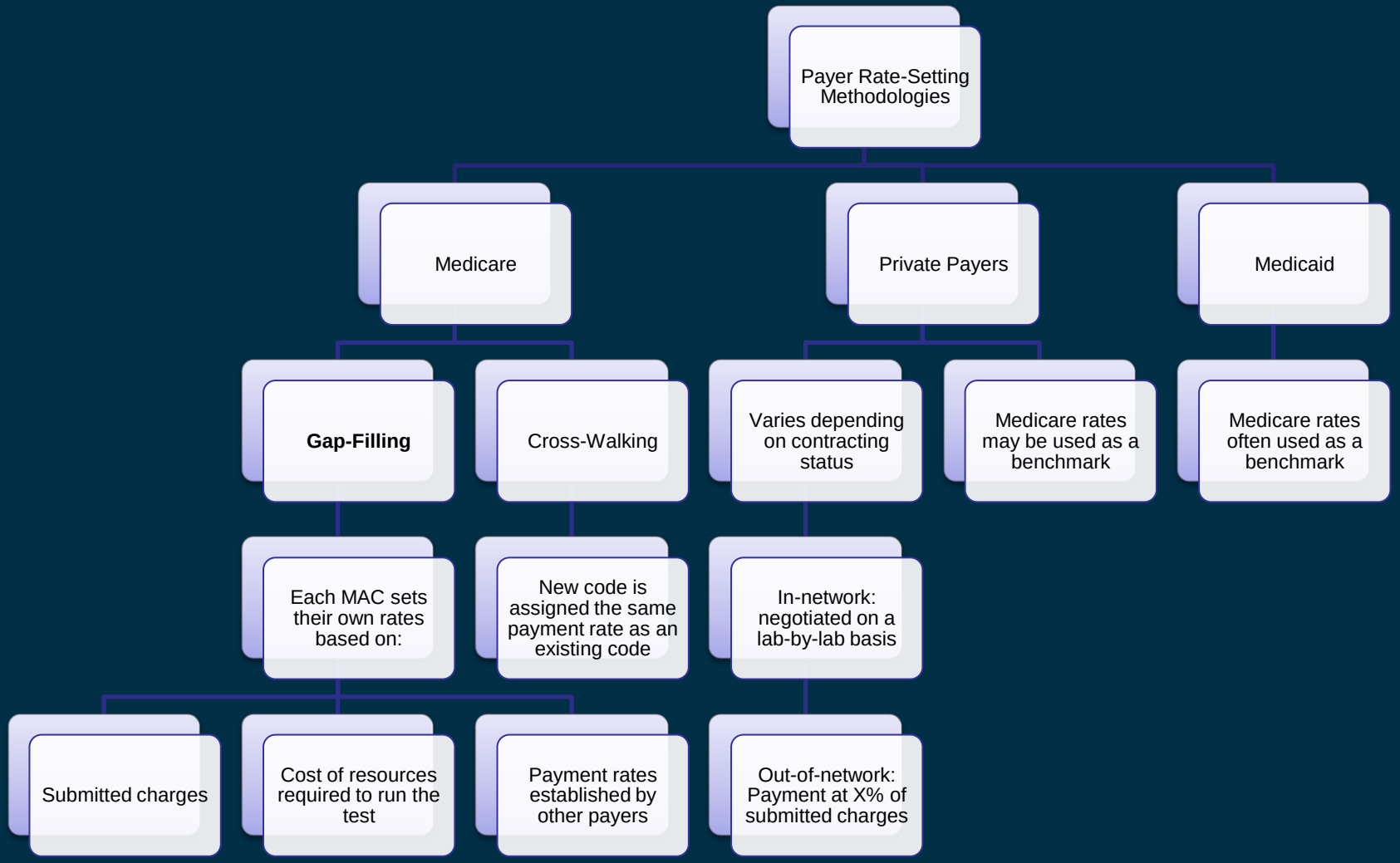
- CMS created Healthcare Common Procedure Coding System (HCPCS) code G0452 *(Molecular pathology procedure; physician interpretation and report)* effective Jan 1, 2013[1]
  - This code allows physicians to bill for interpretation and reporting services that go beyond the technical reporting of test results
  - The code can NOT be billed by non-physician geneticists or other lab personnel
    - The rates established for the Tier 1 and Tier 2 codes are meant to account for work performed by non-physician personnel, including PhD-certified geneticists
  - In 2013, this code is reimbursed at $18.71 under the Medicare Physician Fee Schedule (MPFS)

HCPCS G0452 can be billed for molecular diagnostic interpretation and report only when performed by a physician

[1] **Centers for Medicare and Medicaid Services. Calendar Year 2013 New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes And Final Payment Determinations. Accessed November 6, 2012, at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2013-Final-Payment-Determinations-11052012.pdf**

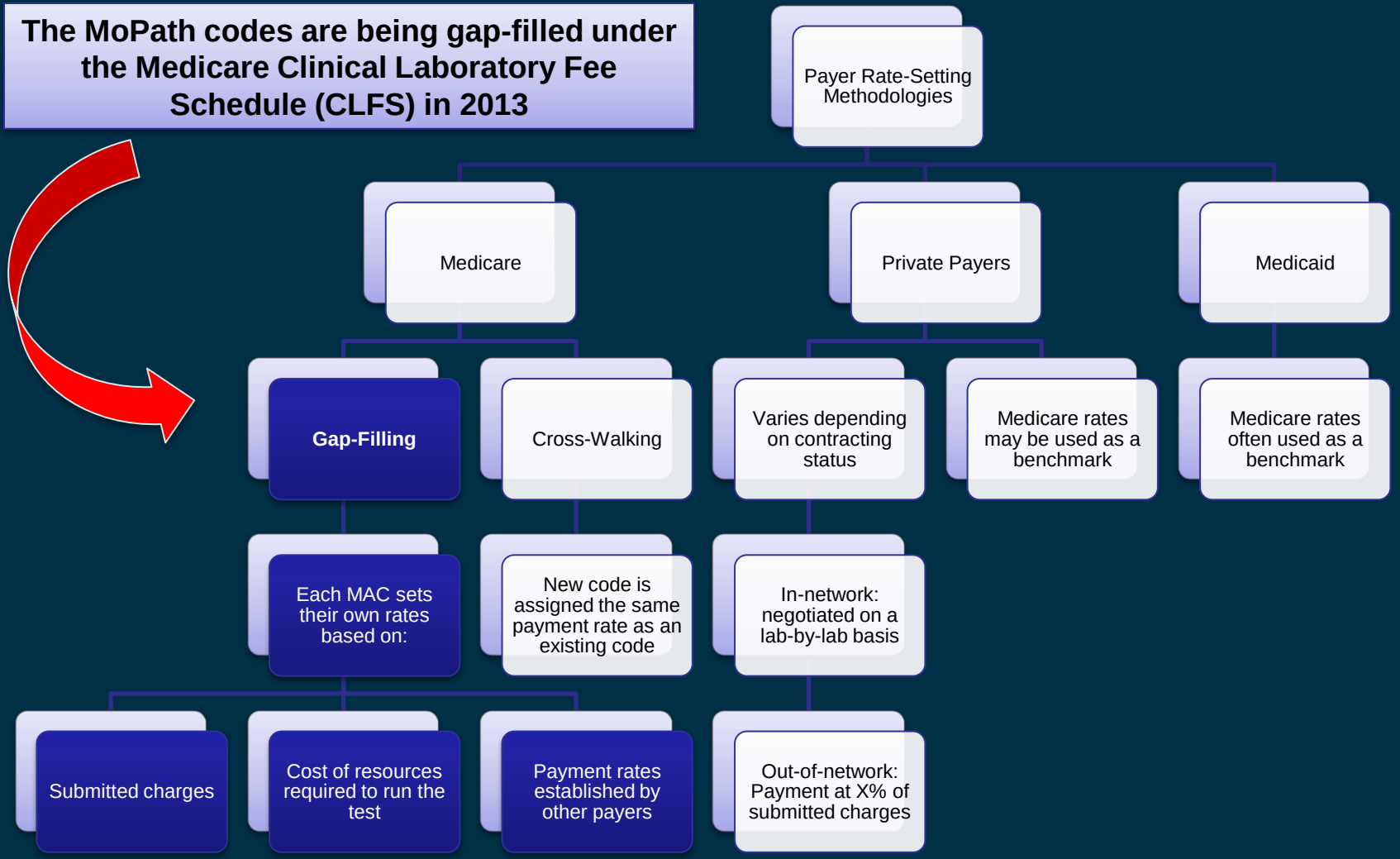
Overview of The Medicare Rate-Setting Process

Overview of Different Rate-Setting Methodologies



Overview of Different Rate-Setting Methodologies

The MoPath codes are being gap-filled under the Medicare Clinical Laboratory Fee Schedule (CLFS) in 2013



What is Gap-Filling?

In 2013

- Medicare Administrative Contractors (MACs) establish regional payment rates for labs in their jurisdictions based on the following inputs[1]:
  - Charges for the test and routine discounts to charges
  - Resources required to perform the test
  - Payment amounts determined by other payers
  - Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant

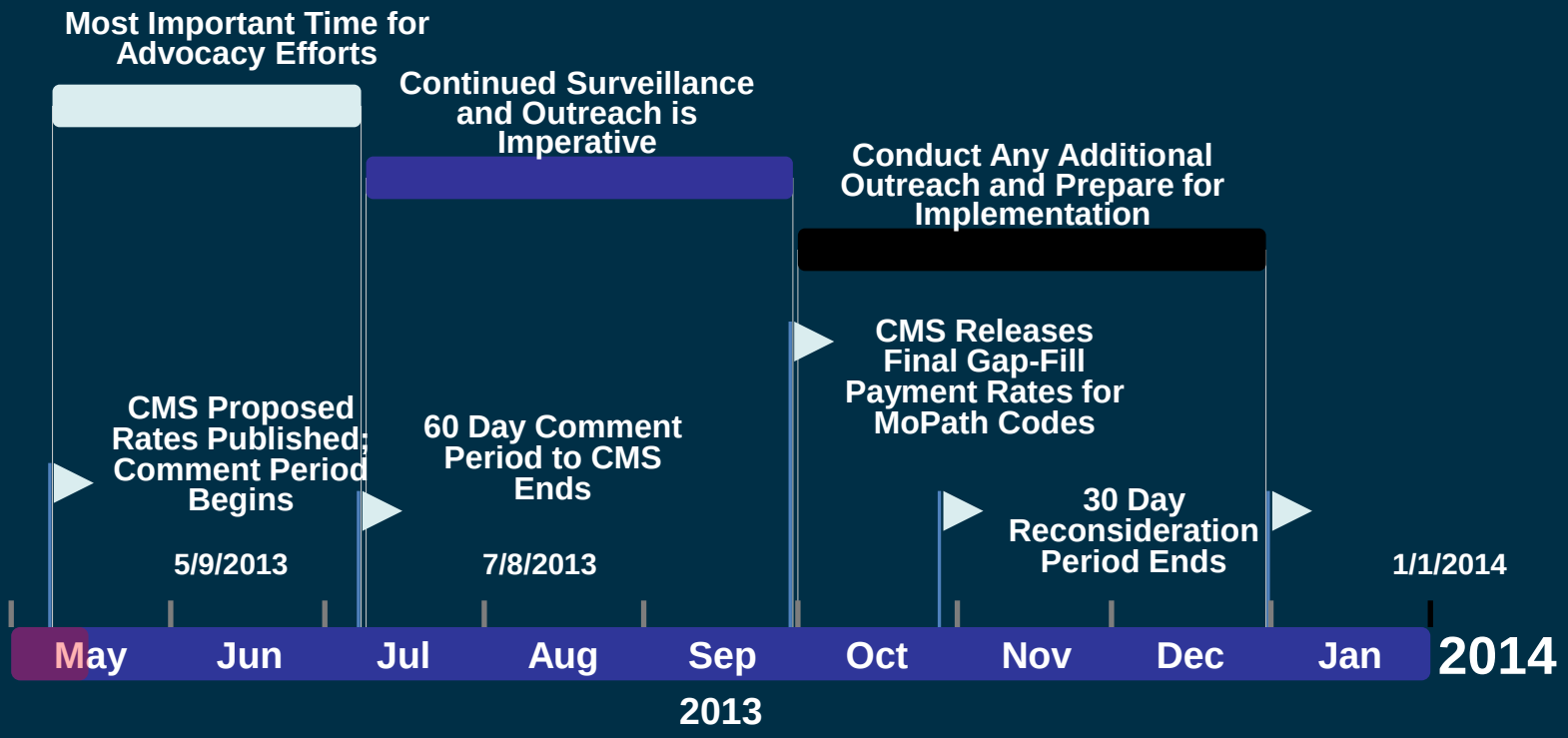
In 2014

- A national payment rate for each code is determined as the median of the MAC gap-fill rates
  - This is referred to as the **National Limitation Amount (NLA)**

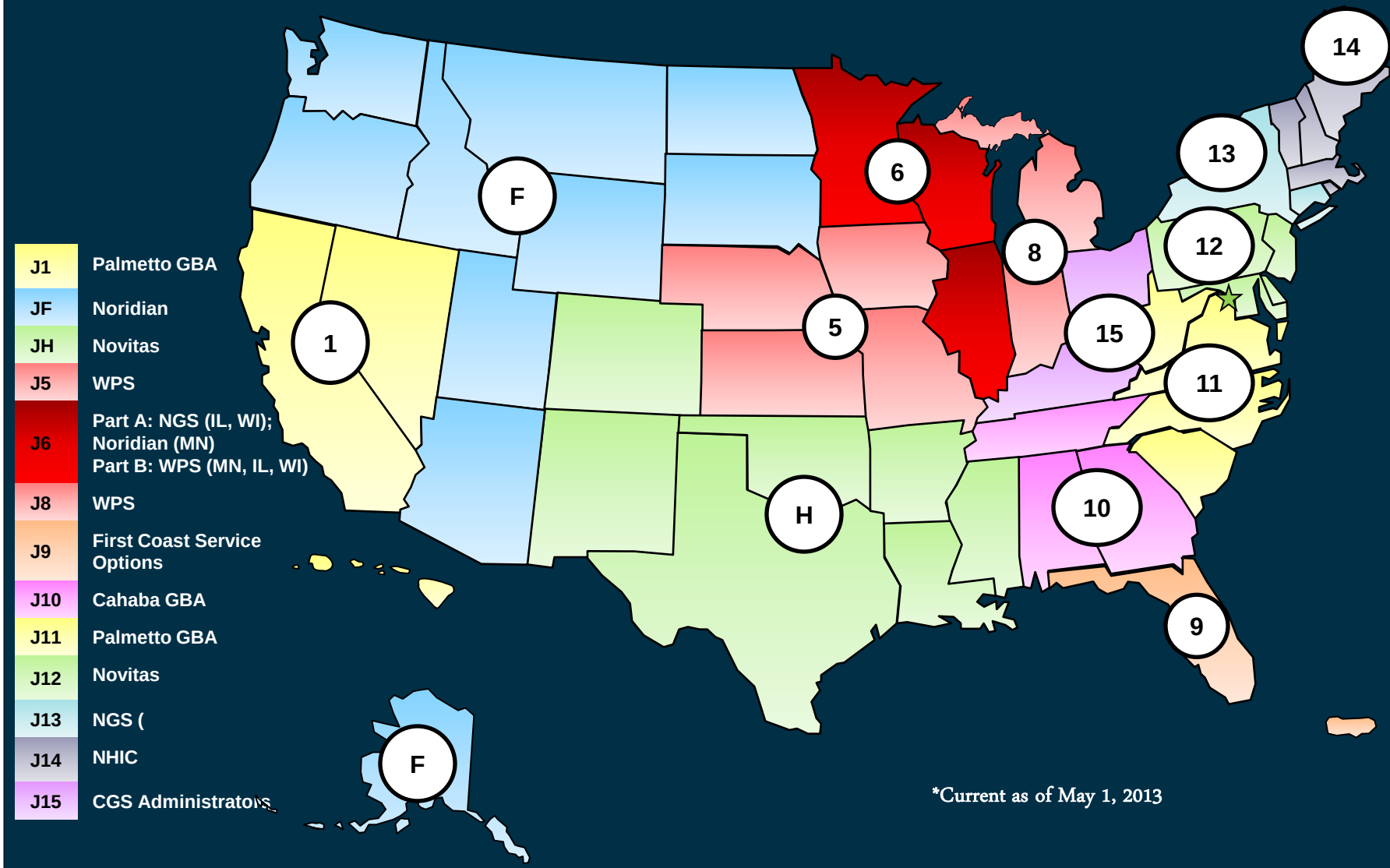
[1]Code of Federal Regulations (CFR) Title 42 - Public Health, Part 414 – Payment for Part B Medical and Other Health Services, Section 414.508 – Payment for a new clinical diagnostic laboratory test.

2013 Medicare Gap-Filling Timelines

Key gap-filling milestones are aligned with critical windows for labs to influence rate-setting outcomes



Medicare Administrative Contractor (MAC) Landscape*



*Current as of May 1, 2013

The Downstream Effect of Medicare Gap-Filling

- As the single largest payer in the country, the rates set by Medicare often heavily influence Medicaid and private payer reimbursements as well
  - These payers often benchmark their own payment rates to Medicare fee schedule amounts (e.g., X% of Medicare rates)
- This means that even if Medicare is not a significant payer for your lab, the outcome of the Medicare gap-filling process is likely to affect you as well
- Medicaid and private payers may also be undertaking activities similar to gap-filling to establish payment rates for the MoPath codes

Medicare gap-filling outcomes are likely to impact other payer reimbursements as well

Updates on Recent Medicare Rate-Setting Developments

CMS Issued Proposed MAC Gap-Fill Rates on May 9, 2013

- A 60-day comment period was initiated on May 9, 2013
  - All comments should be sent to MoPathGapfillInquiries@cms.hhs.gov
  - Labs are encouraged to copy their local MAC on communications to CMS
  - CMS requests that commenters submit cost, test methodology, and any other information to support pricing for specific codes
- CMS will issue final gap-fill payment rates in September 2013, followed by a 30-day reconsideration period
- The National Limitation Amounts (NLAs) for MoPath codes will go into effect on Jan 1, 2014
  - NLAs are calculated as the median of the MAC gap-fill rates for each code

The deadline for submitting comments to CMS on the interim MAC payment rates is July 8, 2013

Proposed MAC Gap-Fill Rates Were Released On May 9, 2013

Test	CPT Code	Palmetto	Novitas	First Coast	Cahaba	NGS/ WPS	Noridian/ CGS/ NHIC
Cystic Fibrosis	81220	$800.46	$1,343.57	$1,004.30	$1,200.00	N/A	N/A
Molecular Cytogenomics	81228	$646.14	$646.14	$646.14	$123.00	N/A	N/A
	81229	$675.56	$675.56	$675.56	$2,900.00	N/A	N/A
Fragile X	81243	$60.51	$60.51	$67.06	$123.00	N/A	N/A
	81244	$100.09	$100.09	$100.09	$123.00	N/A	N/A
Short Tandem Repeat Analysis	81265	$414.94	$414.94	$339.58	$123.00	$470.24	N/A
Hematopoietic Stem Cell	81267	$149.72	$149.72	$335.86	$123.00	$149.72	$149.72
Long QT Syndrome	81280	N/A	N/A	$3,140.90	$123.00	N/A	N/A
Prader-Willi; Angelman	81331	$73.22	$73.22	$58.31	$50.00	N/A	N/A

N/A = No published rate

Please refer to the CMS website to view all proposed rates:
http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html

Understanding the Proposed MAC Gap-Fill Rates

- **Many of the MACs appear to have coordinated on their proposed gap-fill rates**
  - Noridian, CGS, Novitas, and WPS used Palmetto's payment rates for many or nearly all of the MoPath codes
  - With a few exceptions, NGS and NHIC have the same fee schedule
- **Although some MACs (such as Palmetto) established payment rates for individual analytes assigned to each Tier 2 code, CMS did not include them in their release**
- **Some MACs, such as NHIC, have issued revised fee schedules after the publication of CMS' MAC payment file**
  - This reinforces the fact that MACs may still be actively updating their gap-fill fee schedules, thus presenting an opportunity for labs to continue directly engaging the MACs during this 60-day comment period

Frequently Asked Questions (FAQs)

Q: Given the challenges to date with the new MoPath codes, can we still bill with the old "stacking" codes?

Answer: Technically speaking, as of January 1, 2013, the old methodology-based stacking codes (CPT 83890-83914; 88384-88386) have been retired and are no longer available for use.

However, due to ongoing delays in MoPath rate-setting, a handful of private payers still appear to be accepting claims with the old stacking codes for the time being. In contrast, Medicare will not process claims with those codes.

Please contact individual payers as needed to verify their current coding guidelines for molecular diagnostic procedures.

Q: How did CMS determine the payment rate of $18.71 for HCPCS code G0452?

Answer: CMS directly crosswalked the RVUs for CPT 83912-26 *(Molecular diagnostics; interpretation and report)* to HCPCS code G0452 because the latter is essentially a one-for-one replacement for the former. As a result, this translated into a payment rate of $18.71 under the 2013 Medicare Physician Fee Schedule.

Note that G0452 can only be reported for reporting and interpretation services provided by physicians. At the present time, CMS intends payment for the services provided by geneticists and other non-physician personnel to be included in the CLFS payment for the MoPath codes.

Q: Will there be retroactive payment adjustments after the gap-fill rates are finalized in Sep?

Answer: No. CMS intends the gap-fill rates finalized in September to be implemented from that point onwards only.

Before then, labs will be reimbursed according to the current MAC fee schedules.

Coming Up Next

- Part II in this webinar series will focus on:
  - Recommendations for what laboratories can and should be doing *now* to influence the MoPath rate-setting process
  - An overview of the critical time windows for advocacy efforts over the next 6 months

Event	**Molecular Pathology Reimbursement: Taking Action in a Time of Crisis**
Date	Tuesday, June 11, 2013
Time	12:00 – 1:00pm EDT/ 9:00 – 10:00am PDT