Webinar 2: Influencing The Rate Setting Process

A Molecular Pathology Coding and Reimbursement Webinar Series in partnership with Quorum Consulting

February 14, 2013

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Background and Learning Objectives

Molecular Pathology Reimbursement Webinar Series:

- This is the second in a series of four webinars intended to educate laboratory providers on the new molecular pathology (MoPath) codes for 2013, and how you can play a role in ensuring sustainable reimbursement for these services moving forward.

Learning Objectives For Today's Webinar:

- Understand the role that laboratories can play in ensuring accurate and sustainable reimbursement for the MoPath codes in 2013 and beyond
- Understand the timeline of critical communication periods with payers during the rate setting process in 2013
- Be aware of best practices for engaging payers during the rate setting process

Illumina is providing this review of the molecular pathology reimbursement landscape in collaboration with Quorum Consulting for educational purposes only. The content should not be considered legal advice. For official ruling on the MoPath codes readers should consult CMS, the AMA, and other sources as appropriate.

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Review of the MoPath Rate Setting Process

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How are Payers Setting Payment Rates for the MoPath Codes in 2013?

Medicare

- Tier 1 and Tier 2 MoPath codes will be **gapfilled** for Medicare payment in 2013
- Local Medicare Administrative Contractors (MACs) will be responsible for setting regional fee schedule amounts in 2013

Medicaid and Private Payers

- Medicaid and private payers may use a variety of methods to set payment rates, but often use Medicare as a benchmark
- Some payers may also undertake activities similar to gapfilling to develop their MoPath fee schedules

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What Does the Medicare Gapfilling Process Entail?

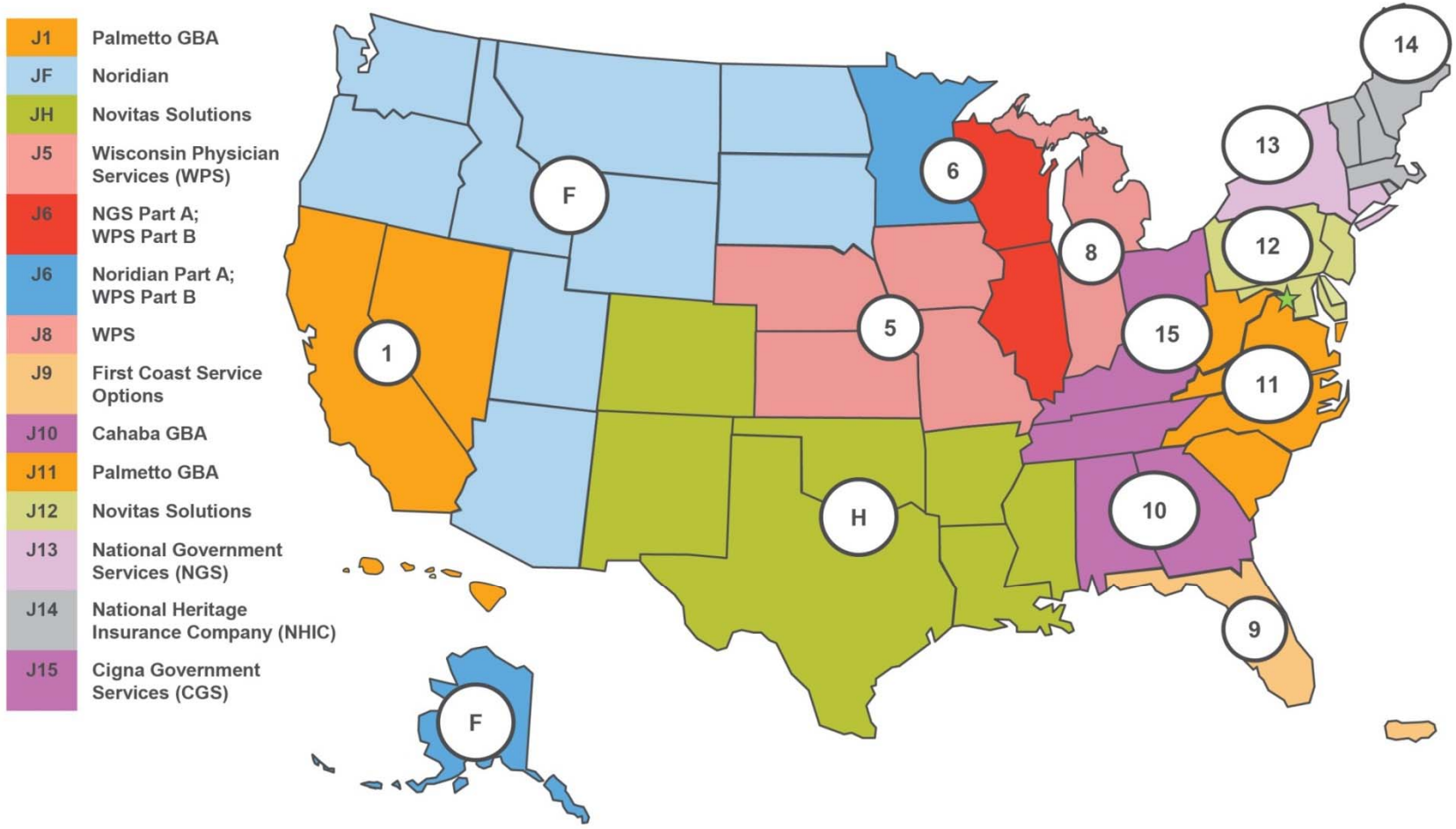
- In 2013, local MACs will set regional fee schedule amounts for each Tier 1 and Tier 2 code based on any combination of the following information:

  - 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.[1]

- In 2014, the national payment rate for each code will be calculated as the median of the local fee schedule amounts set by the MACs in 2013
  - This median payment rate 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.

Medicare Administrative Contractor (MAC) Jurisdiction Map



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Medicare Gap-Filling Timeline for Tier 1 and Tier 2 Codes

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The Role of Laboratories in MoPath Rate Setting

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What Role Can Laboratories Play in the Rate Setting Process?

Laboratories can play a key role in rate setting by providing the proper inputs to drive the proper outputs

It is imperative that payers have the right information to make the right decisions on payment rates for the MoPath codes

While some payers may reach out directly to your laboratory to request the information, others may not

Laboratories should be proactive in reaching out to payers to clarify their rate setting processes and timelines, if unknown

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Key Messages to Payers Will Vary by Payer Type

Medicare

- While some MoPath procedures may not be ordered for Medicare beneficiaries in high volumes, Medicare payment determinations can influence other payers' decisions.
- Therefore, it is critical that MACs accurately gapfill **all** MoPath codes.

Medicaid and Private Payers

- What methodologies will be used to determine payment rates for the MoPath codes, and what are the timelines?
- What information can my lab provide to facilitate accurate rate setting for the relevant codes?

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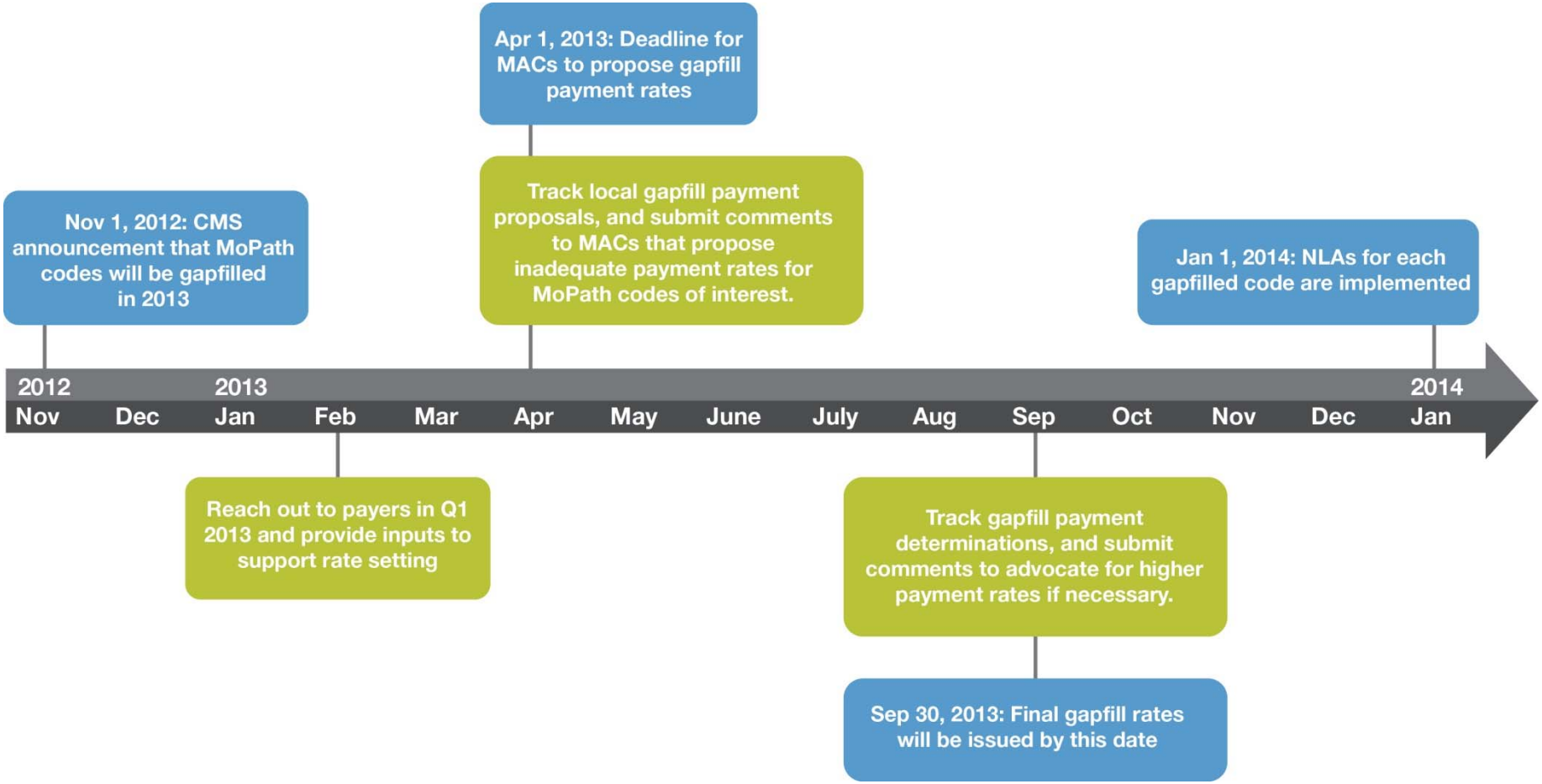
Suggested Timeline for Payer Engagement and Advocacy



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Best Practices for Engaging Payers

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Four Steps to Effective Payer Engagement and Advocacy

Step 1	Identify Top Payer Targets for Advocacy Efforts
Step 2	Prepare a Rate Setting Dossier for Each Test/Code
Step 3	Customize Talking Points for Each Payer on Payer Type
Step 4	Monitor Rate Setting Outcomes and Take Action as Needed

Step 1: Identify Top Payer Targets for Advocacy Efforts

- Identify the top 5-10 payers that your laboratory most frequently bills, making sure to include the MAC in your jurisdiction

- Reach out to the target payers on your list to clarify their rate setting processes and timelines

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Step 2: Prepare a Rate Setting Dossier for Each Test/Code

- Develop a “rate setting dossier” that includes the following materials for each relevant test/code, as well as any other type of data that a payer may request

Rate Setting Input
Submitted charges for the test and routine discounts to charges
Cost analysis of resources required to perform the test
Payment amounts determined by other payers
Previously billed code stack(s) and payment amounts
Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant
Clinical background information (e.g., clinical vignettes, published studies)
Projected future testing volume

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Step 3: Customize Talking Points for Each Payer/ Payer Type

Medicare

- Accurate rate setting is necessary to ensure sustainable reimbursement and continued patient access to medically necessary tests
- Accurate gapfilling for ALL Tier 1 and Tier 2 codes is necessary because Medicare payment rates can influence other payers' payment policies

Medicaid and Private Payers

- Accurate rate setting is necessary to ensure sustainable reimbursement and continued patient access to medically necessary tests
- Laboratories should have the opportunity to provide input during the rate setting process so that the proper inputs are used to derive appropriate payment rates

Step 4: Monitor Rate Setting Outcomes and Take Action as Needed

- Laboratories should monitor rate setting outcomes throughout 2013 by tracking payments for claims submitted with MoPath codes
- Identify payers with inadequate payment rates, and re-engage them to advocate for higher payments
- For Medicare, make note of the deadlines for proposed and final MAC gapfill determinations, and submit comments if needed during the subsequent comment periods

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Suggested Timeline for Payer Advocacy Activities

Jan – Mar 2013	• Identify target payers • Reach out to target payers to clarify rate setting processes & timelines • Prepare rate setting dossiers for all tests/codes of interest • Engage payers to field follow-up questions as needed
Apr – Jun 2013	• Monitor payment amounts for claims submitted with MoPath codes • Follow up with any payers providing inadequate payments to request a correction to the fee schedule amount • Track the proposed Medicare gapfill payment amount in your jurisdiction, and submit a comment letter to the MAC if needed
Jul – Dec 2013	• Continue monitoring payment amounts for MoPath codes, and follow up with payers to advocate for higher payments as needed • Track the final Medicare gapfill payment amount in your jurisdiction, and submit a comment letter to the MAC if needed

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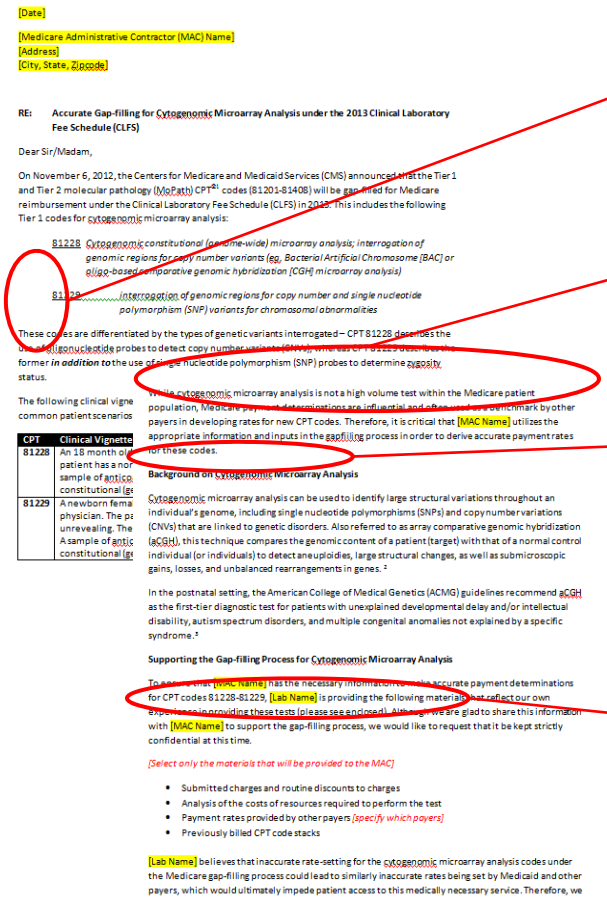
Sample Payer Advocacy Letters can be Downloaded at www.illumina.com/reimbursement



[Date]

[Medicare Administrative Contractor (MAC) Name]
[Address]
[City, State, Zipcode]

RE: Accurate Gap-filling for Cytogenomic Microarray Analysis under the 2013 Clinical Laboratory Fee Schedule (CLFS)

Dear Sir/Madam,

On November 6, 2012, the Centers for Medicare and Medicaid Services (CMS) announced that the Tier 1 and Tier 2 molecular pathology (MoPath) CPT® codes (81201-81408) will be gap-filled for Medicare reimbursement under the Clinical Laboratory Fee Schedule (CLFS) in 2013. This includes the following Tier 1 codes for cytogenomic microarray analysis:

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 *interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities*

These codes are differentiated by the types of genetic variants interrogated – CPT 81228 describes the use of oligonucleotide probes to detect copy number variants (CNVs), whereas CPT 81229 describes the former ***in addition to*** the use of single nucleotide polymorphism (SNP) probes to determine zygosity status.

The following clinical vigne
common patient scenarios

CPT	Clinical Vignette
81228	An 18 month ol patient has a nor sample of antico constitutional (ge
81229	A newborn fema physician. The pa unrevealing. The A sample of antic constitutional (ge

While cytogenomic microarray analysis is not a high volume test within the Medicare patient population, Medicare payment determinations are influential and often used as a benchmark by other payers in developing rates for new CPT codes. Therefore, it is critical that [MAC Name] utilizes the appropriate information and inputs in the gapfilling process in order to derive accurate payment rates for these codes.

Background on Cytogenomic Microarray Analysis

Cytogenomic microarray analysis can be used to identify large structural variations throughout an individual's genome, including single nucleotide polymorphisms (SNPs) and copy number variations (CNVs) that are linked to genetic disorders. Also referred to as array comparative genomic hybridization (aCGH), this technique compares the genomic content of a patient (target) with that of a normal control individual (or individuals) to detect aneuploidies, large structural changes, as well as submicroscopic gains, losses, and unbalanced rearrangements in genes. [2]

In the postnatal setting, the American College of Medical Genetics (ACMG) guidelines recommend aCGH as the first-tier diagnostic test for patients with unexplained developmental delay and/or intellectual disability, autism spectrum disorders, and multiple congenital anomalies not explained by a specific syndrome.[3]

Supporting the Gap-filling Process for Cytogenomic Microarray Analysis

To ensure that [MAC Name] has the necessary information to make accurate payment determinations for CPT codes 81228-81229, [Lab Name] is providing the following materials that reflect our own experience in providing these tests (please see enclosed). Although we are glad to share this information with [MAC Name] to support the gap-filling process, we would like to request that it be kept strictly confidential at this time.

[Select only the materials that will be provided to the MAC]

- Submitted charges and routine discounts to charges
- Analysis of the costs of resources required to perform the test
- Payment rates provided by other payers *[specify which payers]*
- Previously billed CPT code stacks

[Lab Name] believes that inaccurate rate-setting for the cytogenomic microarray analysis codes under the Medicare gap-filling process could lead to similarly inaccurate rates being set by Medicaid and other payers, which would ultimately impede patient access to this medically necessary service. Therefore, we

Identify the specific MoPath CPT code(s) of interest

Summarize the key takeaway(s) for the payer (e.g., proper rate setting is crucial for sustainable lab reimbursement)

Provide a clinical and procedural overview of the test(s) of interest, including the indication(s) for medical necessity

Identify the relevant information being provided to support accurate rate setting for the test/code(s) of interest, and reinforce the importance of setting appropriate rates to ensure continued patient access

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Frequently Asked Questions (FAQs)

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Q: If a payer does not reach out to my laboratory to request information for MoPath rate setting, how can we get involved in the process?

- Although some payers may not proactively request information from laboratories for rate setting purposes, it does not mean that they would not be interested in receiving such information. **Laboratories are strongly encouraged to be proactive in reaching out to payers to identify and/or create opportunities for providing input**, to ensure that payers derive accurate payment rates for MoPath codes of interest.

Q: Since Medicare is not a significant payer for the tests performed by my laboratory, is the Medicare gapfilling process relevant to us?

- **Laboratories are strongly encouraged to participate in the Medicare gapfilling process even if they do not submit claims to Medicare on a large scale.** The Medicare Administrative Contractors (MACs) are required to determine gapfill payment rates for all Tier 1 and Tier 2 codes in 2013, regardless of whether or not they are typically billed for a Medicare patient population. Since other payers frequently use Medicare payment rates as a benchmark for their own payment policies, this means that the outcome of the Medicare gapfilling process could very well impact reimbursement from other payers (e.g., Medicaid, private).

Q: What is the deadline for providing payers with information to support MoPath rate setting?

- Each payer may adhere to different timelines in their rate setting process for the MoPath codes. Therefore, laboratories should make sure to provide each payer with the appropriate rate setting inputs according to their indicated timelines. In general, however, be aware that most payers will likely seek to establish or finalize their MoPath fee schedules as soon as possible. Therefore, **payer advocacy activities should be conducted with urgency, ideally in January – March 2013.**

Q: My laboratory has pre-existing contracts with some private payers that establish reimbursement at a percentage of submitted charges. Does MoPath rate setting apply to us in these cases?

- If your laboratory is contracted with a private payer such that reimbursement is not based on a defined fee-for-service schedule, you should **contact the payer to confirm whether the same payment methodology will apply to the MoPath codes in 2013**. Depending on when your current contract is set to expire, also consider initiating a conversation with the payer to discuss potential reimbursement methodologies that may be employed in the future. **If fee schedule-based payment is a possibility at a later time, it may be in your laboratory's best interest to participate in the rate setting process now.**

A Golden Opportunity for Laboratories

- Laboratories can play a crucial role in the MoPath rate setting process by providing payers with the inputs needed to determine accurate payment rates

- Laboratories should take advantage of this golden opportunity to ensure sustainable reimbursement for their services in 2013 and beyond

Proper rate setting is crucial to sustainable reimbursement, and laboratories are strongly encouraged to engage payers on this critical issue with urgency

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Coming Up Next: Coverage, Coding, and Payment for Cystic Fibrosis Genetic Testing

- You are invited to attend the next webinar on **Tuesday, February 19 at 9:00 a.m. PT** to learn about:
  - The coverage landscape for CF genetic testing
  - The coding options for CF genetic testing in 2013 and beyond
  - The inputs that payers may use for rate setting in 2013, and how to develop a detailed costing analysis for your test that will support accurate rate setting

Please visit our website at
https://www.illumina.com/reimbursement
for additional resources
and background information on
molecular diagnostic coding and reimbursement in 2013

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Questions?

- Please type your questions into the Webex Q&A box