THE IMPACT OF PAMA REGULATIONS

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BACKGROUND

- Current Medicare Clinical Lab Fee Schedule (CLFS) payments based on 1984 cost data which has been adjusted over years
- Late 2013 and early 2014, Centers for Medicare and Medicaid Services (CMS) announced it was going to unilaterally change the fee schedule based on technology
- Concern expressed over government reimbursing for laboratory testing at rate greater than private payers estimated to be between 18 and 30%
- In response April, 2014, Congress included in PAMA how CLFS would be updated
- CMS published proposed PAMA lab rules September, 2015
- Final rules published June 17, 2016
- Rules takes effect in 60 days

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PROVISIONS OF PAMA REGULATIONS

- Requires reporting to CMS of private payer test volumes and reimbursement rates ("applicable information") by "applicable labs"
- Weighted medians of private payer rates for each analyte will be used to set Clinical Diagnostic Laboratory Test (CDLT) payment rates
- PAMA rules establish data collection and data reporting periods
- Creates a new category of test Advanced Diagnostic Laboratory Test (ADLT) with its own data reporting and payment rules

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WHAT IS AN "APPLICABLE LAB"?

- Laboratory bills Medicare under its own National Provider Identifier (NPI)
- During data collection period, lab receives majority of Medicare revenue under Medicare Physician Fee Schedule and/or CLFS
- Receives more than $12,500 in CLFS revenue during the six month data collection period

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WHAT IS "APPLICABLE INFORMATION"?

- Listing of each individual analyte, and the volume and reimbursement received from each private payer during the collection period for each of the individual analytes
- Reported by HCPCS code – if a code is not listed, it is not reportable
- Does not include capitated reimbursements, nor multiple tests paid with single dollar amount

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WHO IS A PRIVATE PAYER?

- Health insurer or group health plan including any co-pays received
- Medicare advantage plan
- Medicaid managed care organization
- Self-pay patients

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EXAMPLE OF REPORTING RAPID STREP TEST

LAB ABC

Payer 1 UHC

Payer	Payer rate	Payer volume
UHC Product 1	$5	1,000
UHC Product 2	$9	1,100
UHC Product 3	$6	900
UHC Product 4	$2.50	5,000
UHC Product 5	$4	3,000
TOTAL	Range $2.50 – $9	11,000

Out of 11,000 tests, the average price of test 5,500 and 5,501 is the weighted median **$4.00**

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WHAT ARE THE TIMELINES?

STEP	TIMING
Data Collection Period	January 1– June 30, 2016 and every 3 years thereafter
"Six month window" – opportunity for lab to compile data	July 1– December 31, 2016
"Data reporting period" – during which labs will report info to CMS	January 1– March 31, 2017
CMS will develop new rates	April –August 2017
CMS will publish preliminary rates	September, 2017
CMS will publish final rates	November, 2017
New rates go into effect	January 1, 2018

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RATE REDUCTION IMPLEMENTATION

- For each individual HCPCS code, Medicare will determine the median dollar amount of data submitted and this will be rate used to calculate CLDT fee schedule for each analyte and implement it January 2018
- Rate reduction for 2018, cannot exceed 10% of current CLFS
- Rates reduction for 2019 and 2020, cannot exceed 10% of prior year fee schedule
- Data collection be done for January–June 2019, and reported January–March 2020, for use in next 3 year cycle
- For each of those three years (2021–2023) rates can be reduced by a maximum of 15% of prior year fee schedule

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EXAMPLE OF RATE REDUCTION

YEAR	CLFS PAYMENT	
2017	$10.00	
2018	$ 9.00	(-10%)
2019	$ 8.10	(-10%)
2020	$ 7.29	(-10%)
2021	$ 6.20	(-15%)
2022	$ 5.27	(-15%)
2023	$ 4.48	(-15%)

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AH! BUT THE EXAMPLE IS EXTREME

- The sky is not falling as was discussed when regs were first issued for comment in September 2015
- CMS estimates 5.6% reduction from CLFS spending in year one (2018)
- However, estimate based on very limited information
- Also note that reduction estimates do not represent across-the-board cuts as each lab test can move down or up by different amounts
- CMS estimates there will be a savings of $520 million in 2018, and a total savings of $2.3 billion over 5 years

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STILL MANY UNKNOWNS

- Estimated 5% of POL will report but estimated to be 95% of volume
- Many sub-rules yet to be released by CMS
- Exact reporting format unknown
- BUT a robust revenue cycle management system that can capture the information for submission is essential

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SUMMARY
WHAT DO WE NEED TO DO?

- Work with your financial management team and determine if you're an applicable laboratory. If so, determine with them how to extract data

- Remember, an applicable laboratory:
  - Bills under NPI
  - >50% of Medicare revenue received from PFS and/or CLFS
  - Revenue from CLFS in excess of $12,500 during the data collection period of January 1, 2016 – June 30 2016

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THANK YOU

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