



Labs Take Lead in Transforming Healthcare
**Using Quality Management and Lean
to Add Value, Improve Patient Outcomes,
and Lower Cost of Care**

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My Premise: Lean Labs Have Opportunity

- Healthcare is transforming at a swift pace.
- Value-based payment will reward physicians for achieving improved patient outcomes.
- Thus: clinical labs are perfectly positioned to help physicians use tests:
 - To diagnose disease earlier and more accurately;
 - To guide selection of appropriate therapies; and,
 - To monitor patient's progress.

Why These Changes?

Healthcare's New Clinical Care Paradigms

- Keep patients out of hospitals!
- Detect disease early, when easier to treat.
- Actively help patients manage their chronic diseases.
- Use incentives to encourage positive lifestyle choices and activities.
- Support these goals with molecular and genetic knowledge as it is developed.

Powerful Healthcare Trends

Attributes of 'New' Healthcare

- Integrated healthcare networks that deliver seamless, integrated clinical care.
- Payment based on value, not fee-for-service.
- Personalized or precision medicine, (requiring more diagnostic testing).
- Proactive care, not reactive care.
- Healthcare big data, informed by clinical lab test results.

Understanding Volume to Value

- **Old:** hospitals, physicians, labs paid by fee-for-service.
- *More tests = more revenue.*
- **New:** payment for value
- *Now, more tests = higher costs, less profit.*
- Labs must demonstrate that their lab test services contribute to improved patient outcomes and decrease the cost of care.

A Word on MACRA...

Understanding MIPS & APMs

- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).
- Replaces SGR formula.
- New payment model for physician professional fees; data baseline is 2017.
- Merit-Based Incentive Program (MIPS).
- Advanced Alternative Payment Models (APMs).
- Speeds transition away from Fee-for-Service.

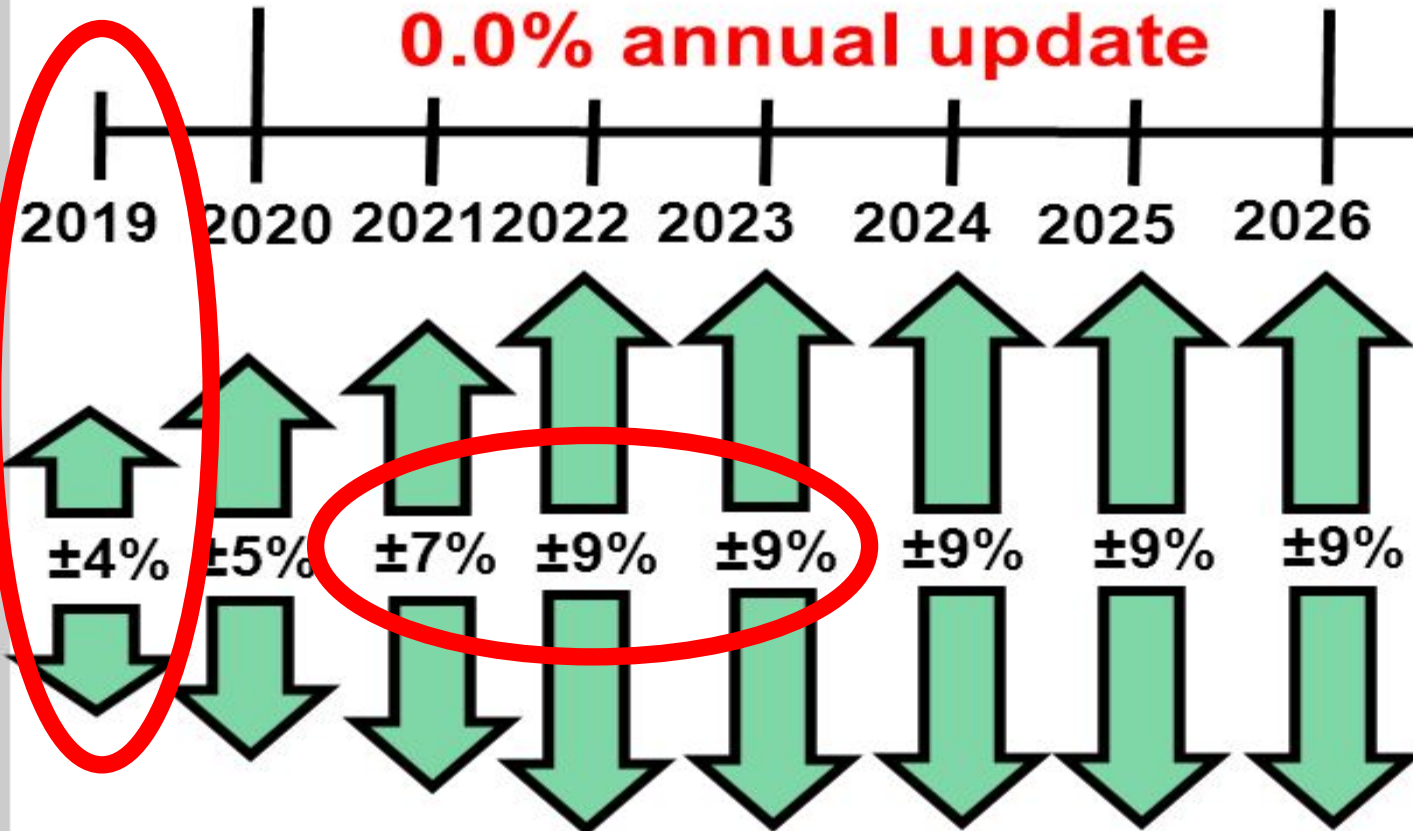
Payment Under MACRA

MIPS OR APM

APM: Bonus of 5% of PFS payments annually

APM
0.75% annually;
no bonus payments

0.0% annual update



MIPS
0.25% annually, PLUS
penalties/bonus up to
± 9%



American Hospital
Association

A Word on PAMA

Lab Market Price Reporting

- Protecting Access to Medicare Act of 2014 (PAMA).
- Medicare Part B lab spend: \$7 billion in 2015.
- On January 1, 2018, lower Medicare Part B Clinical Laboratory Test Fees took effect.
- **CMS now says fee cuts will total \$680 million** just in 2018! *(That's up from the \$400 million estimate.)*
- Less revenue from lab services that have CPT code reimbursement from 2018 forward.

Impact of Fee Cuts on Labs Is Huge

- Lab economics recognizes value of economies of scale when payment is fee-for-service.
- As fee-for-service disappears, clinical labs will be paid according to how they add value to physicians and help improve patient outcomes.
- Big change for clinical labs and physician labs, since higher volume no longer guarantees success.

Big Trend in Medicine

Personalized, Precision Medicine

- During your career: reactive medicine and acute care.
- Shift is away from “practicing to the average” based on clinical trials.
- Coming soon to a provider near you:
 - Proactive Medicine.
 - Personalized Medicine (Precision Medicine).
 - Genetic and molecular analysis; whole human genome sequencing.

Big Trend in Medicine

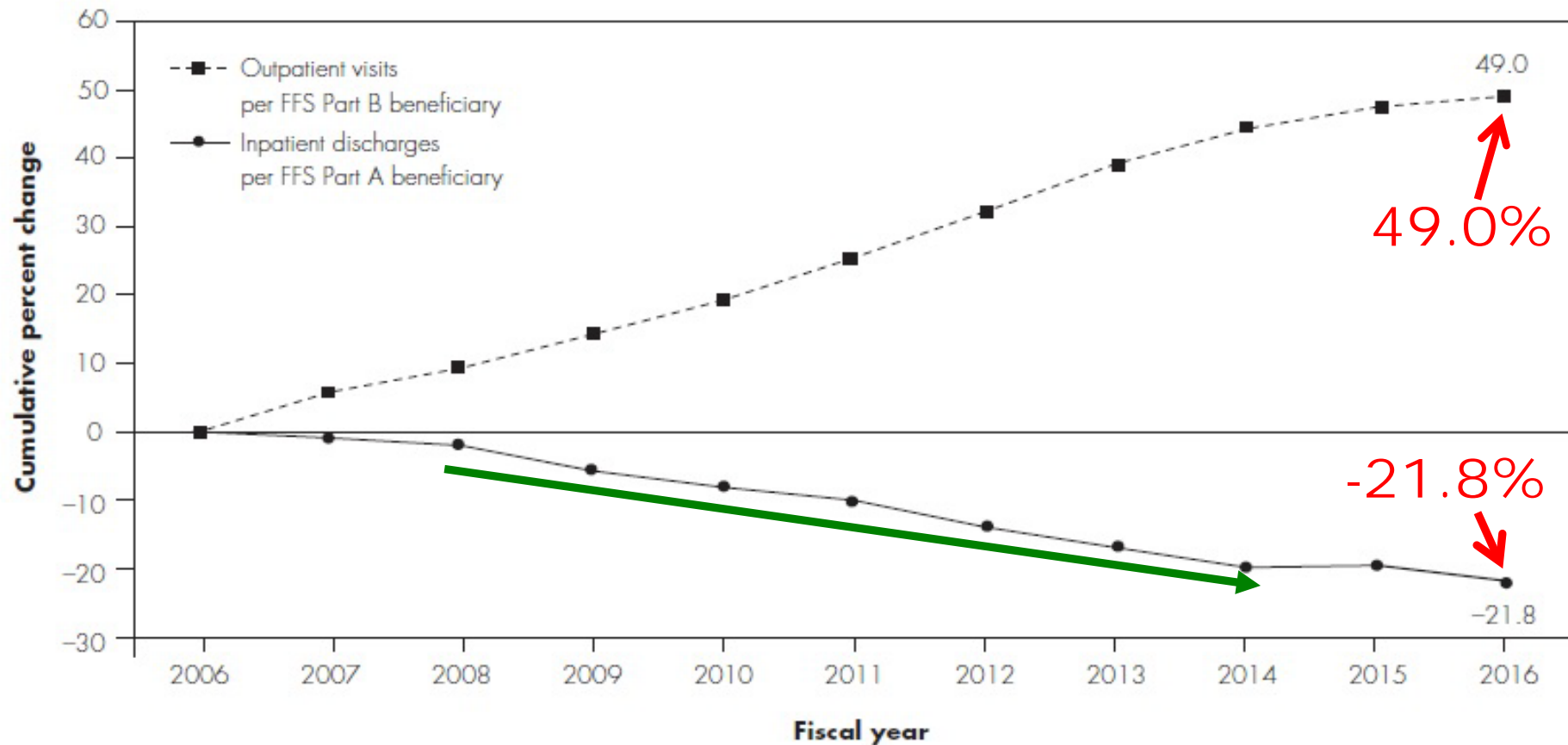
Keep People Out of Hospitals

- Hospitals are the most expensive places to provide healthcare.
- Hospital inpatients are at risk for hospital-acquired infections, medical errors, falls, and similar events.
- Easier to get better outcomes at a lower cost per episode of care by treating patients in outpatient settings.

**FIGURE
3-1**

2006-2016

Medicare inpatient discharges per beneficiary declined as
outpatient visits per beneficiary continued to increase



U.S. is shifting care away from hospitals.

Inpatient procedures shrinking by single digits each year.

Outpatient procedures growing at double-digit rates annually.

Source:
MedPac Report to Congress:
Medicare Payment Policy, March 2018

Big Trend in Medicine

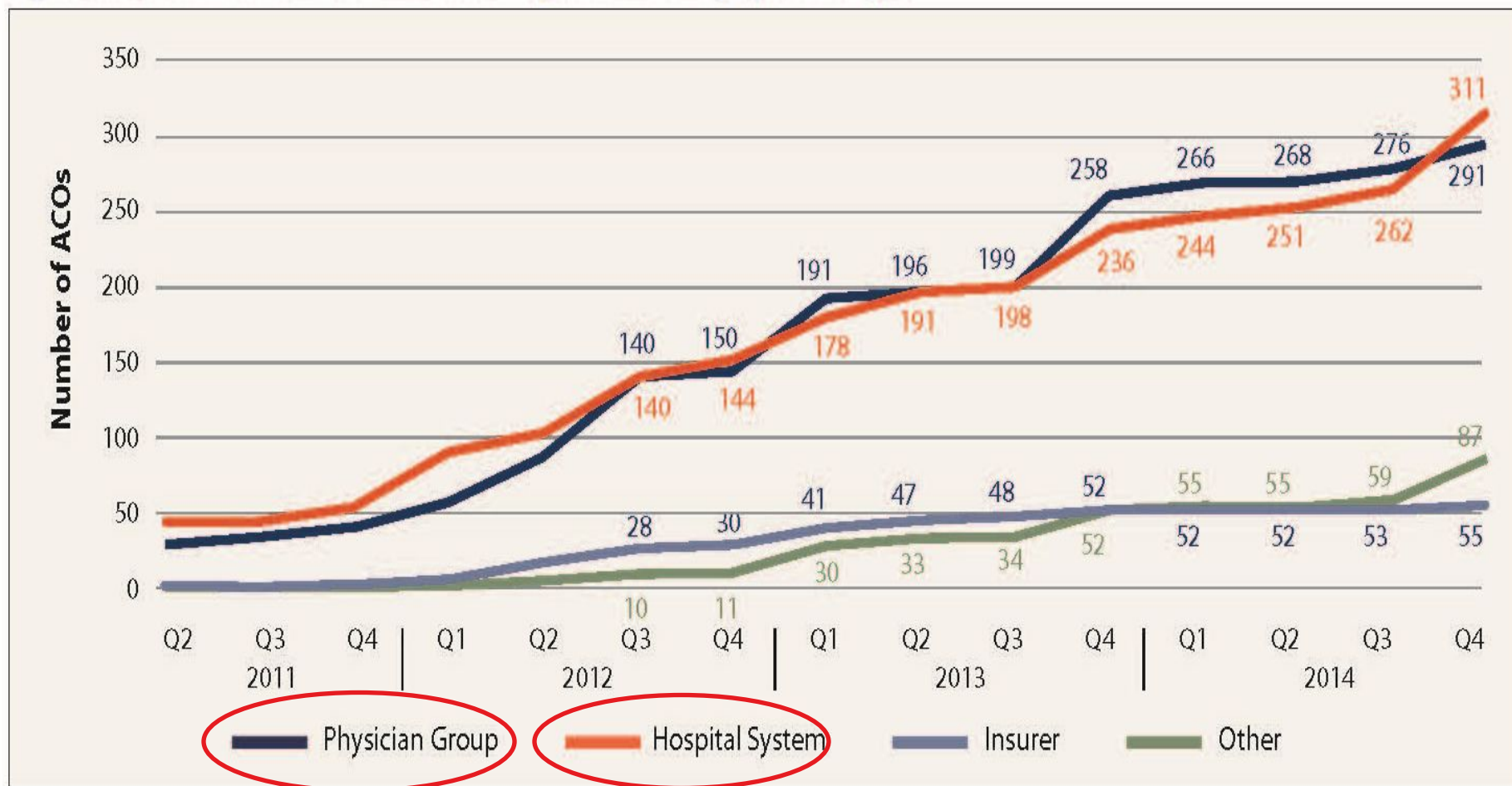
Integration of Care Delivery and Clinical Care

- New **paradigm of proactive care** requires integration of physicians, hospitals, nursing homes, pathology labs, ancillary service providers.
- Examples of fully-integrated delivery organizations emerging, particularly in United States and Canada.
- Accountable care organizations (ACOs).
- Patient-centered medical homes (PCMHs).

ACO Growth in U.S.

Hospital Systems and Physicians jockeying to control care via their own ACO.

Figure 1. Growth in Accountable Care Organizations by Sponsor Type*

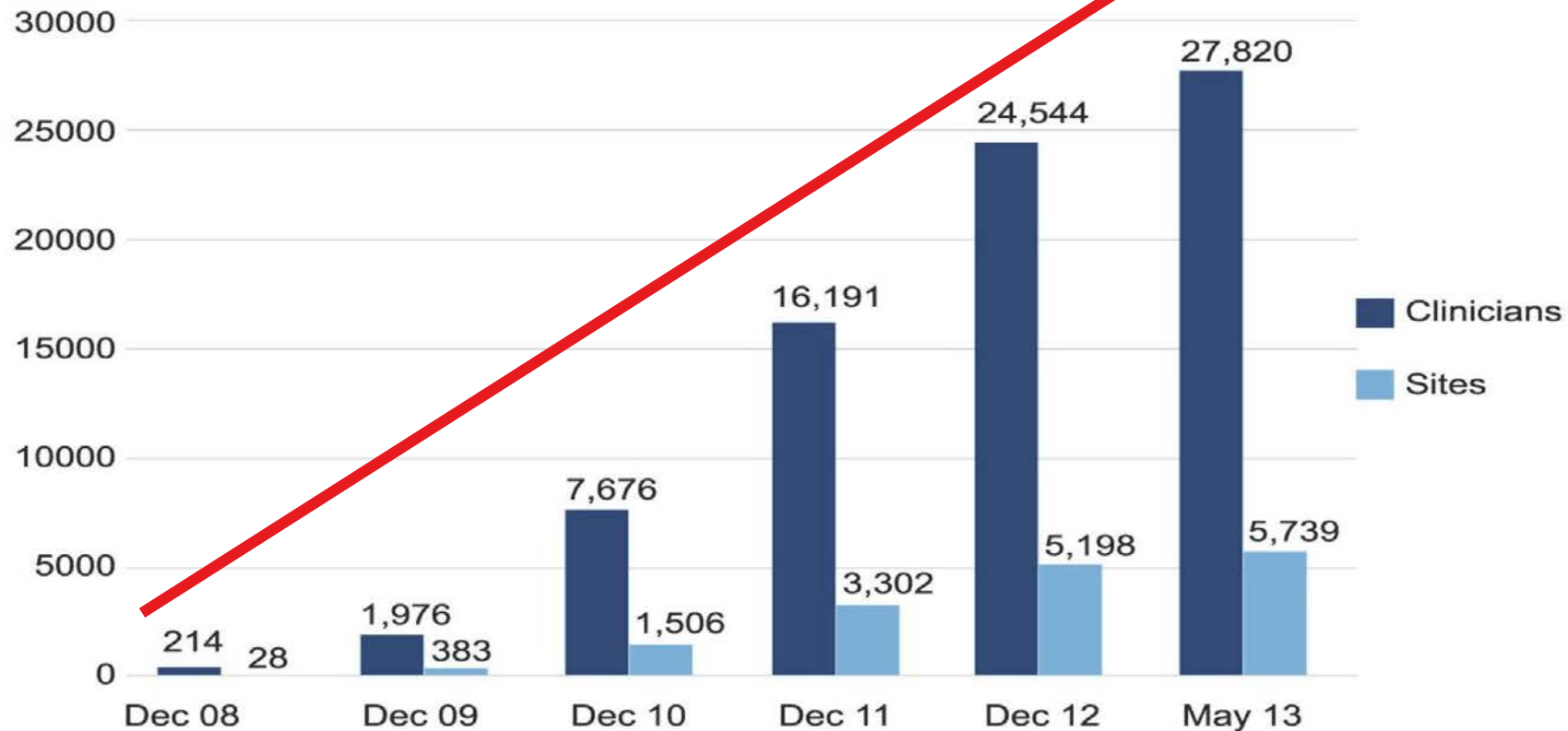


* Includes ACOs with both government and commercial contracts. Source: Leavitt Partners, 2015.

Patient-Centered Medical Homes Also Growing in U.S.

Figure #1

NCQA PCMH Growth 2008-2013



Source: National Committee for Quality Assurance, 2013

Patients Expect Better Quality

- Patients have higher expectations.
- Expect fewer errors.
- Expect better quality.
- Expect services that are personal and top-flight.
(Think Amazon.com.)
- Lab's experts in Lean, Six Sigma, process improvement know how to teach it; can thus help their lab teammates and referring physicians.



CompuNet JV Breaks Up after 30 Years

- Lab joint venture founded in 1986 in Dayton, Ohio.
- Premier Health bought out Quest Diagnostics in 2017.
(Valley Pathologists Inc. still has equity.)
- Premier Health said:
 - Gain “local oversight of lab testing services... to meet patient’s needs.”
 - Ensure more rapid turn-around times for patient lab results
 - Use 100% local control to enhance testing capabilities “which impact the local community.”

What's Changing for Labs?

- Pressure to cut costs, boost productivity.
- New standards of quality. *(Think Six Sigma quality.)*
- Adoption of 'System of Prevention.'
- Payment based on value.
- More intense use of information technology and data analytics.

Coming to a lab near you...

Cultural transformation in the operation
of Medical Laboratories

Attributes of 'New' Lab

- Speedier work flow, shorter cycle times.
- Attacks non-value added processes.
- Continuously improves.
- Sophisticated use of informatics.
- Collaborates with providers to deliver more value from lab test data.
- Contributes to measurable improvement in patient outcomes, lower cost of care.

Key Attributes for Labs

- **ONE:**
Achieve operational excellence via adoption of quality management systems.
- **TWO:**
Develop mastery of information technology to sustain lab's operational performance and contribute to improving patient outcomes.
- **THREE:**
Engage in effective collaborations with physicians in care settings outside the lab.

But Changes Needed for Labs to Deliver Value

- Future success for labs requires changes in lab operations; plus...
- ...a working culture where lab staff and pathologists can recognize value.
- Shift from “system of inspection” to “system of prevention” teaches lab team to recognize value-added vs non-value added.
- Use of modern quality tools and practices.

Attributes of Lab 1.0 vs. Lab 2.0

Clinical Lab 1.0: *Transactional*

Clinical Lab 2.0: *Integrative*

SICK CARE

- Receive Test Sample
- Result Test Sample

HEALTH CARE

- Population Health using Lab data
- Total Cost-of-Care leveraging Lab data
- Time-to-Diagnosis
- Optimization of: diagnosis, therapy, monitoring
- Care Optimization
- Screening Optimization

DISEASE SCREENING

- Protocol-driven
- Scheduled by Treating Physician
- Lab is derivative

RISK MANAGEMENT

- Identification of Risk
- Real-time tracking of Risk
- Escalation/De-escalation of Acuity

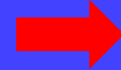
Attributes of Lab 1.0 vs. Lab 2.0

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WELLNESS PROGRAMMING

- Managed by Treating Physician
- Lab is Derivative



WELLNESS PROGRAMMING

- Gaps-in-Care closed using Lab data
- Outcomes of program using Lab data

Predictive Analytics

- What will happen? When? Why?

PAYMENT MODELS

- Lab is a Commodity
- Value is Cost-per-Test



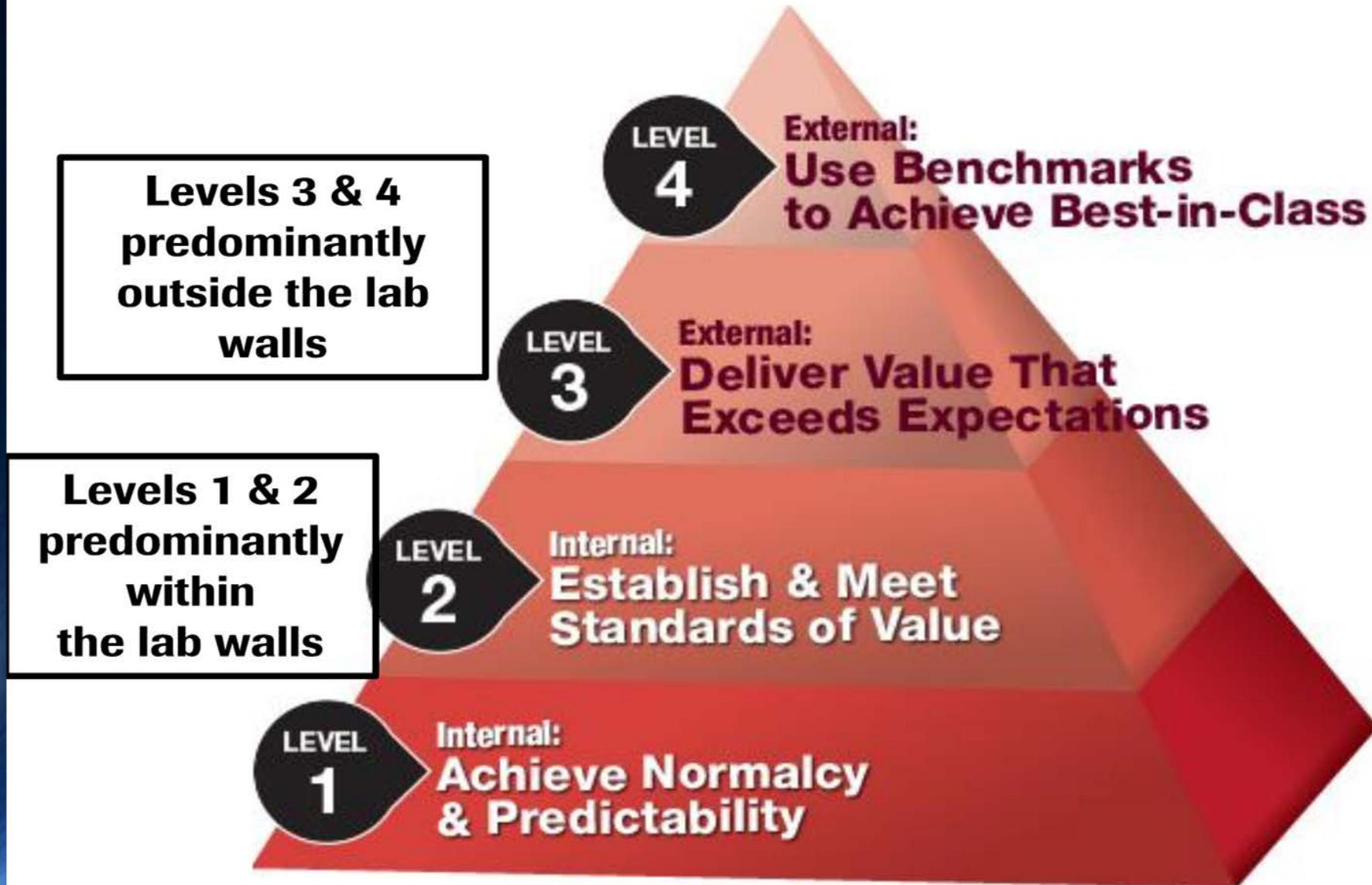
PAYMENT MODELS

- Value of Lab for Total Cost-of-Care

Opportunity to Use... Laboratory Value Pyramid

**Four-step path for labs to move
from current state to best-in-class.**

The Four Levels of the Lab Value Pyramid



*Timely, accurate information needed
in real time for Operational and Clinical Success*

Healthcare Big Data, Lab Informatics

- Labs must regain control of information technology.
- Real-time analytics for managing work processes.
- Database capabilities to assemble lab test data with other relevant clinical data.
- Ability to analyze large amounts of data to identify opportunities to improve value of lab test results by helping physicians improve patient outcomes.

Informatics, Big Data, & Labs

- Healthcare big data will address two ends of the care spectrum:
 - Analysis in support of population health management.
 - Analysis in support of personalized medicine; diagnosis and treatment of individuals.
- Lab test data is essential in support of both activities.
- Lab test data comprises 70% or more of the average patient's health record.

Delivering More Value with Lab Testing

- Accurate lab results reported on time won't be good enough!
- Labs must help hospitals, physicians use lab tests more efficiently...
- ...to produce better patient outcomes while lowering overall cost of care

Added Value Case Study

How innovative labs and clinicians are leveraging lab tests to improve patient outcomes!

Foundation for this success is robust lab informatics and data analysis capabilities that convert lab data into intelligence that physicians can use.

Big Data Led by the Lab

- Example of TriCore Reference Laboratory in Albuquerque, New Mexico.
- Formed in 1998 by University of New Mexico Health Sciences Center and Presbyterian Healthcare Services .
- Produces 60% of patient lab results in New Mexico.
- Has access to patient clinical data electronic health record (EHR) systems.

TRICORE REFERENCE LABORATORIES

Services

12 clinical specialties

2900 highly specialized tests

11,200,00+ diagnostic tests per year

Generate ~60% of New Mexico's clinical laboratory data

98.6% of all tests are performed in TriCore facilities

Footprint

1300+ employees

30 courier routes across New Mexico

60+ draw sites throughout New Mexico

50+ pathologists and scientists

99% patient satisfaction

Laboratory

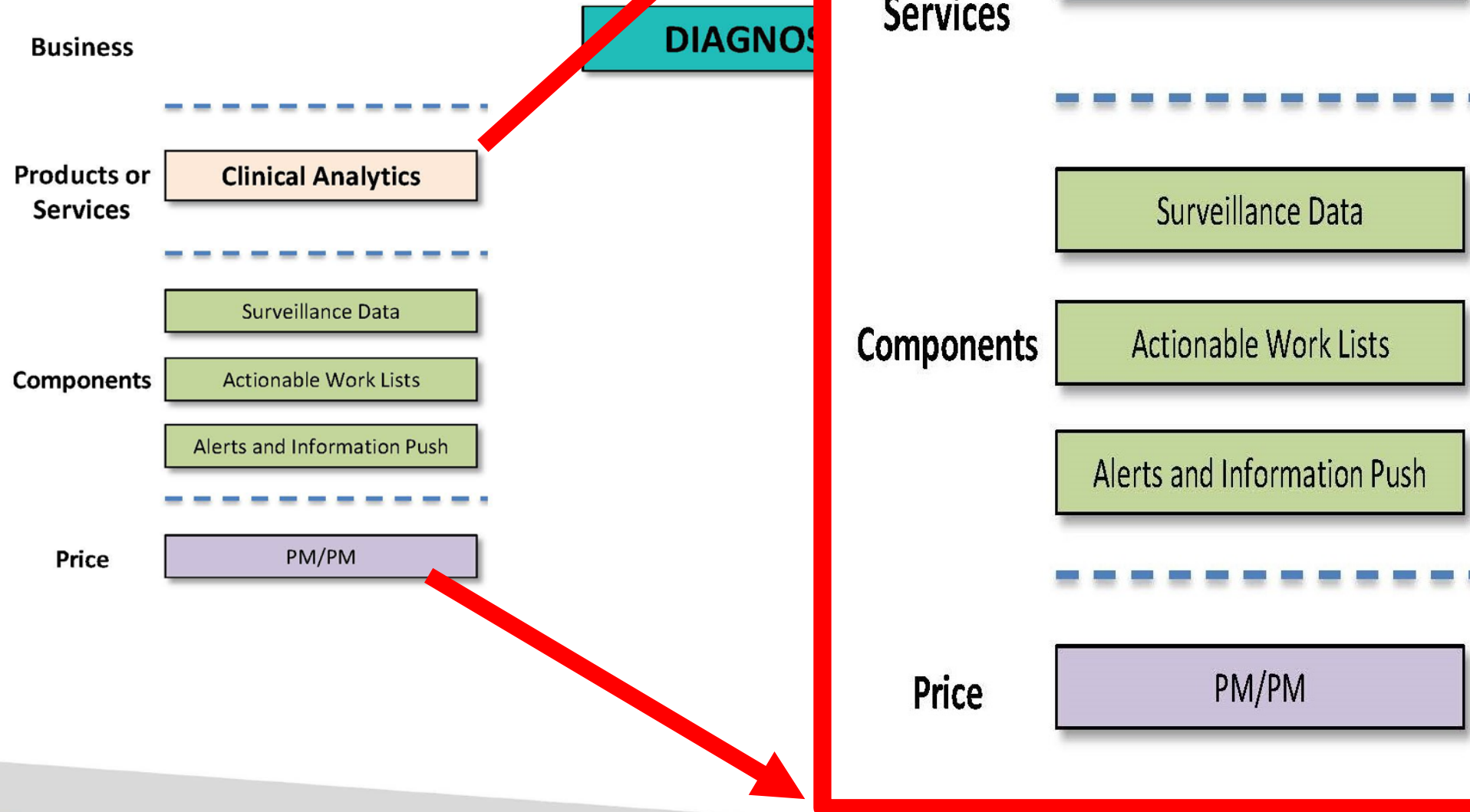
Nationally recognized Hematopathology consult service

The first multi-site **CAP 15189** accreditation

14 hospital laboratories



TRICORE'S LAB 2.0 STRATEGY



METHOD: NEW MEXICO POPULATION AND PREGNANT WITH MEDICAID

Diabetes

10



Prenatal

582



Hepatitis C

13



582

Corporation



ONE MCO PILOT AND PROJECTION

Health Condition	Measure/Outcome	2016 MCO Performance ¹	TRL Clinical Analytics Result ²	ROI
Prenatal	Timeliness of Prenatal Care NMHSD PM #5	75%	77%	\$766,766 ^{3,4}
	Post-Partum Care NMHSD PM #5	58%	60%	\$766,766 ^{3,4}
	Frequency of Prenatal Care NMHSD PM #6	56%	72%	\$766,766 ^{3,4}
	Total ROI from Prenatal = \$4,898,408!			\$1,184,851 ³
	Preterm Delivery Outcome	20%	11%	\$1,367,009 ^{2,5}
	ER Utilization (Prenatal Members Only)	33 visits per month	30 visits per month	\$46,250 ^{2,6}
Diabetes	Hemoglobin A1c Testing PM #4	82%	92%	\$766,766 ^{3,4}
	Nephropathy Screening PM #4	87%	91%	\$766,766 ^{3,4}
	ER Utilization (Diabetic Members Only)	54 visits per month	38 visits per month	\$240,000 ^{2,6}
Hepatitis C	NMHSD Hepatitis C DSIM	350 members	1,577 members	\$1,610,208 ⁴
TOTAL				\$8,282,148

1. BCBSNM Audit Review Table. http://www.hsd.state.nm.us/uploads/FileLinks/485263ae1ad040ea9d52673aef6109b4/2016_HEDIS_BCBS.pdf (Accessed: March 21, 2018)

2. Results projected from pilot performed with BCBSNM Special Beginnings September 2017 through April 2018

3. Assumes BCBSNM's revenue for Centennial Care is approx. \$536,736,096. Health Notes. Program Evaluation Unite. Legislative Finance Committee. January 13, 2017 https://www.nmlegis.gov/Entity/LFC/Documents/Health_Notes/Health%20Notes%20-%20Medicaid%20managed%20care%20rates.pdf

4. New Mexico Human Services Department. Request for Proposals. RFP#13-630-8000-0001 Centennial Care http://www.hsd.state.nm.us/uploads/FileLinks/c06b4701fbc84ea3938e646301d8c950/Centennial_Care_RFP_and_Contract__8_28_12_FINAL_.pdf (Accessed: August 11, 2017)

5. Thanh NX et al. Health Service Use and Costs Associated with Low Birth Weight-A Population Level Analysis. (2015) *J Pediatr*. 167(3): 551-556

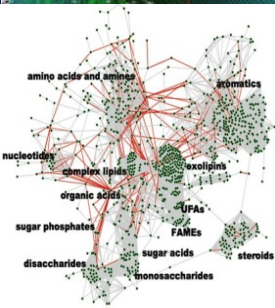
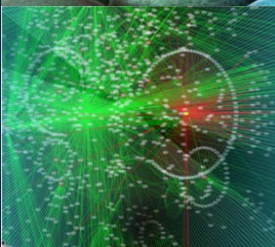
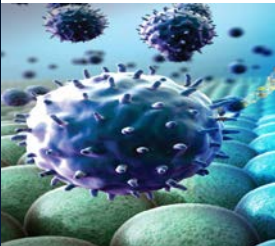
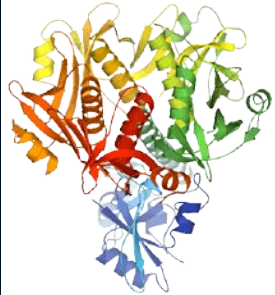
6. Center for Disease Control and Prevention. Health, United States, 2016. <https://www.cdc.gov/nchs/data/abus/abus16.pdf#093> (Accessed: August 29, 2017)

More Multi-Analyte Testing

- Time to recognize a fact little-noted in scientific literature or news media.
- Medicine and healthcare are about to be overwhelmed by tsunami of useful biomarkers.
- Such biomarkers, when incorporated into multiplex laboratory tests, will give pathology lab amazing tools to diagnose disease earlier and with more precision.
- Clinical labs and anatomic pathology groups will have “monopoly” on such testing.

Genomics

- Genomics: **20,000-25,000** human protein-coding genes.
- Proteomics: **250,000** to **one million** estimated in human cells.
- Microbiomics: **10,000** species in humans so far have more than **8 million** genes.
- Transcriptome: **tens of millions?** (est.).
- Metabolome: **40,000** annotated metabolite entries.



But Don't Forget!

- There are 320 million Americans who continue to need clinical lab tests.
- Someone will do this work.
- Message is for your laboratory to get out ahead of these trends.
- Be one of the providers that do this work... by delivering clinical value.

Final Thoughts on Change...

“In a chronically leaking boat,
energy devoted to changing
vessels is more productive than
energy devoted to patching leaks.”
—**Warren Buffett**



“You miss 100% of the shots you never take!”
—**Wayne Gretzky**