

Healthcare's transformation and labs' response...

Understanding the Changes in Healthcare and Clinical Lab Marketplace

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My one
BIG
Theme
today!



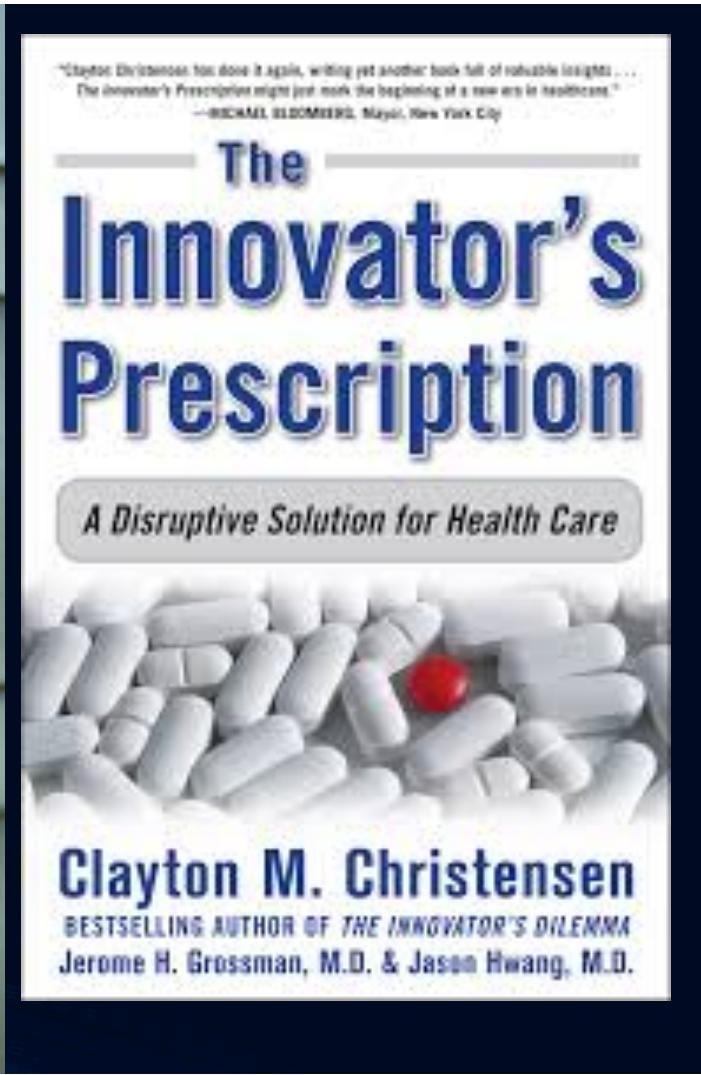
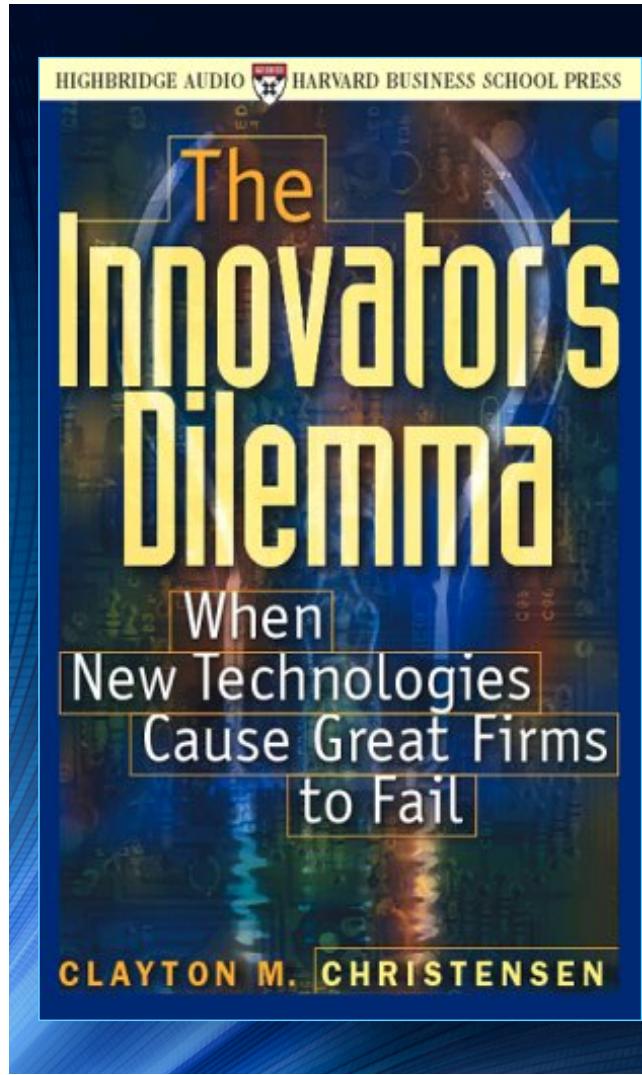
Disruption
Ahead

Clayton Christensen

Harvard Business School

“The reason why it is so difficult for existing firms to capitalize on disruptive innovations is that their processes and their business model that make them good at the existing business actually make them bad at competing for the disruption.”





Why PAMA May Be Poised to Disrupt Lab Industry

➤ Federal law is about to have pernicious effects, including eroding the financial stability of many labs

»»CEO SUMMARY: *This will be one of the most challenging years facing the clinical lab industry since the early 1990s, when closed panel HMOs were the disruptive force that generated deep cuts in lab test prices. However, unlike HMOs of that era, the CMS scheme to collect private payer lab test prices and use that data to set Medicare clinical laboratory test prices is proving to be an indiscriminate tool that is beginning to undermine the financial integrity of many labs.*

IT IS NOW THE FIFTH YEAR since passage of the Protecting Access to Medicare Act of 2014 (PAMA) to limit changes

to the Medicare Part B Clinical Laboratory Fee Schedule (CLFS) change the financial

Three Sectors with Disruptors

- Healthcare disruptors
- Clinical laboratory, pathology disruptors
- Opportunities for clinical labs, pathology groups

First, Disruptors in Healthcare

- Proactive care
- Transition from fee-for-service to value-based methods
- Ongoing consolidation among all categories of providers

Healthcare's Disruptors

- Proactive care and what it means
- Transition from fee-for-service to value-based methods
- Ongoing consolidation among all categories of providers

Why These Changes?

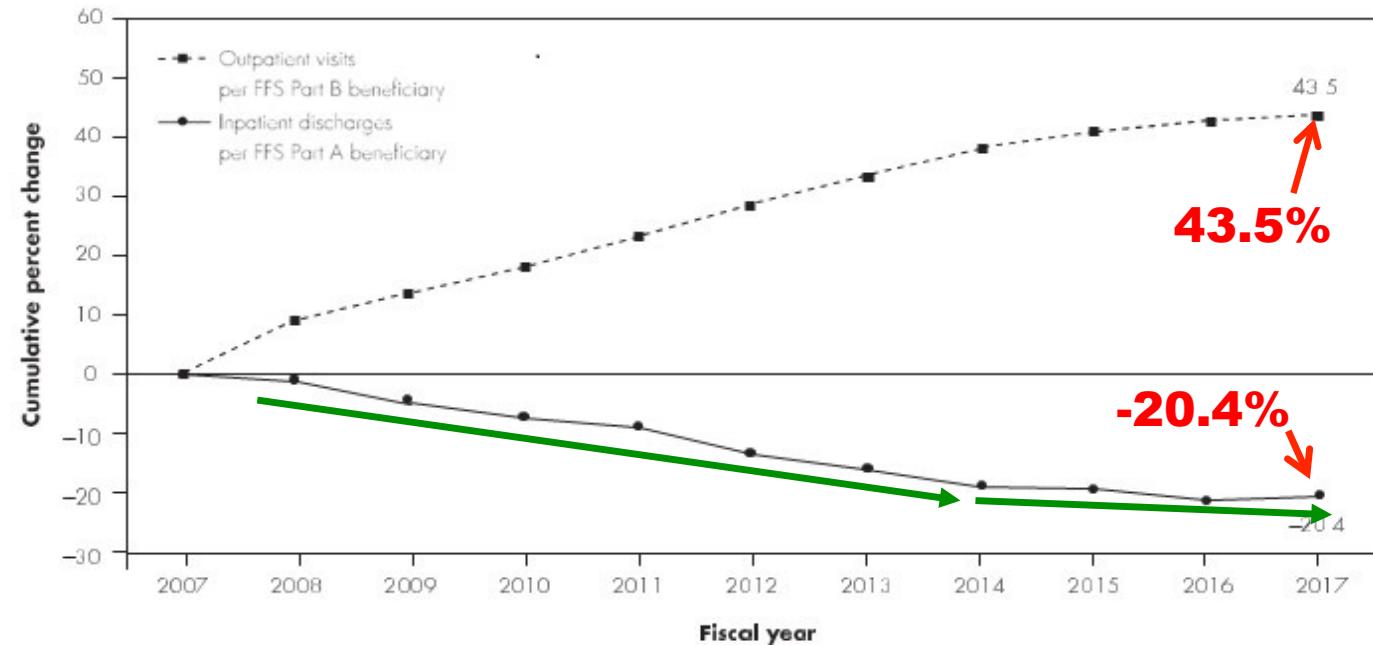
Proactive Care... not Reactive Care

- 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.
- Step-by-step adoption of precision medicine to improve patient outcomes.

**FIGURE
3-2**

2007-2017

Medicare inpatient discharges per beneficiary and outpatient visits per beneficiary increased from 2016 to 2017



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 2019

Healthcare's Disruptors

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We All Know the Negative Factors Associated with Fee-For-Service

- FFS provides little or no reward for delivering holistic and value-based care.
- FFS incentivizes doctors to order unnecessary tests and procedures to generate more income, encourages them to practice “defensive medicine.”
- FFS leads to an increase in overall healthcare costs over time since patients and providers are not fiscally accountable.

Decline of Fee-for-Service Accelerates

Proportion of Business Aligned with Fee-for-Service



CHANGE
HEALTHCARE

Four Value-based Payment Models

- **Pay-for-Coordination:** a primary care physician leads and coordinates care between multiple providers and specialists. (PCMH model)
- **Pay-for-Performance (P4P):** healthcare providers incentivized to meet certain quality and efficiency benchmark measures. Physician reimbursements directly related to achieving these performance measures; e.g., the Hospital Readmission Reduction (HRR) program and the Skilled Nursing Facility Value-based Program (SNFVBP)

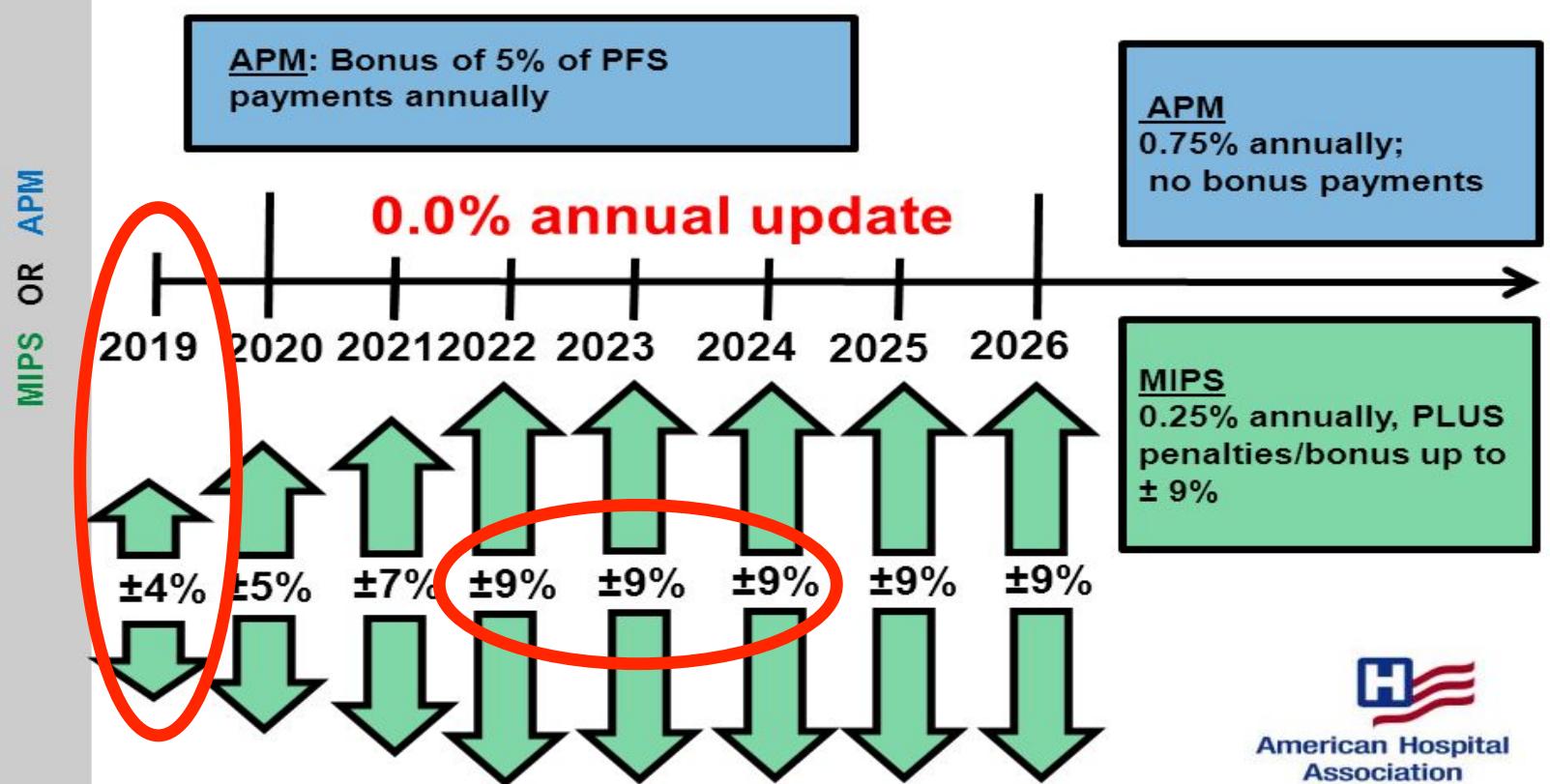
Four Value-based Payment Models

- **Bundled Payment or Episode-of-Care Payment:** healthcare providers are reimbursed with a set amount of money to pay for a specific episode of care, such as a hip replacement, and any complications. Providers keep any realized net savings.
- **Shared Savings Programs (Upside and Downside):** physicians form entity groups and provide population health management. Quality and efficiency achieved through coordinated, team care; realized net savings given back to the provider: e.g., ACOs.

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



Healthcare's Disruptors

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Consolidation of Care Delivery Is Disruptive Trend

- Integrated healthcare networks that deliver seamless, integrated clinical care.
- Accountable Care Organizations (ACOs)
- Patient-Centered Medical Homes (PCHMs)
- Independent Physician Organizations (IPAs)
- Health insurers acquiring physician practices.

Look at Consolidations!

2017

- Aetna and Humana failed
- Anthem and Cigna failed
- **Ascension** (the largest Catholic health system in the U.S.) announced plans to purchase Illinois' largest Catholic system, **Presence Health**.

2018

- Advocate-Aurora Merger Complete (\$11 billion)
- CVS-Aetna (\$70 billion)
- Cigna-Express Scripts (\$71 billion)
- Beth Israel Deaconess Medical Center-Lahey Health merger
- Dignity Health and Catholic Health Initiatives still merging

Clinical Laboratory, Anatomic Pathology Disruptors

- Government and private payers**
- Regulatory Changes**
- Eroding laboratory finances**

Second, Lab Disruptors

- **Government and private payers**
 - **Regulatory Changes**
 - **Eroding laboratory finances**

What's Disruptive Today With Payers, Reimbursement

- PAMA price cuts to Medicare Part B lab tests.
- Medicaid, private payers enacting similar lab test price cuts.
- Payers narrowing networks.
- Payers' denying coverage for tests; prior-authorization requirements.
- Tougher government and private payer audits of labs; big recoupment demands.

What's Disruptive Today With Payers, Reimbursement (cont.)

- Growth of Medicare Advantage enrollment, shifts patients away from Part B.
- Payers want more complete data sets from labs.
- Payers want providers that help their HEDIS scores and STAR scores for Medicare Advantage.

UHC Sets July 1 Launch for New Preferred Network

United Healthcare's New “Preferred Laboratory Network”

- Seven labs companies are “PLN” labs
- 300 in-network labs remain
- PLN labs have: access, quality, lower prices,

costs. Another goal is to have clinical laboratories and anatomic pathology groups support the triple aim of improving patients' experience and population health, while reducing cost of care.

SEEKING LOWER COSTS, SHORTER WAIT TIMES, AND IMPROVED PATIENT OUTCOMES from clinical laboratories and anatomic pathology groups

selected lab partners to deliver on UnitedHealthcare's triple aim in the lab space,” said Linda Simmons, UHC's Vice-President National Lab Program

Lab Disruptors

- Government and private payers
- Regulatory Changes
- Eroding laboratory finances

Increased Compliance Cost, More Risk

Regulations as Disruptors

- Support Act and EKRA: conflicts with Anti-Kickback Law
- New regulations for National Correct Coding Initiative (NCCI) as of Jan. 1. Many labs not getting paid.
- FDA's oversight of LDTs, genetic tests.
- CMS continues to struggle with coverage guidelines and reimbursement for new assays.
- Medicaid in many states cutting lab test reimbursement.

Lab Disruptors

- **Government and private payers**
- **Regulatory Changes**
- **Eroding laboratory finances**

Ongoing Financial Pressures

Lab Revenue, Budget Issues

- PAMA Medicare Lab Test Price Cuts.
- Medicaid, insurers following Medicare with fee cuts.
- Confusion with new NCCI guidelines on coding.
- Hospitals and health systems trimming lab budgets.
- Restrictive coverage guidelines for lab tests.
- Narrowing networks.

Opportunities for Clinical Labs, Anatomic Pathology Groups

- Operational
- Clinical Lab 2.0 to Add Value
- Precision Medicine, Population Health

Third, Lab Opportunities

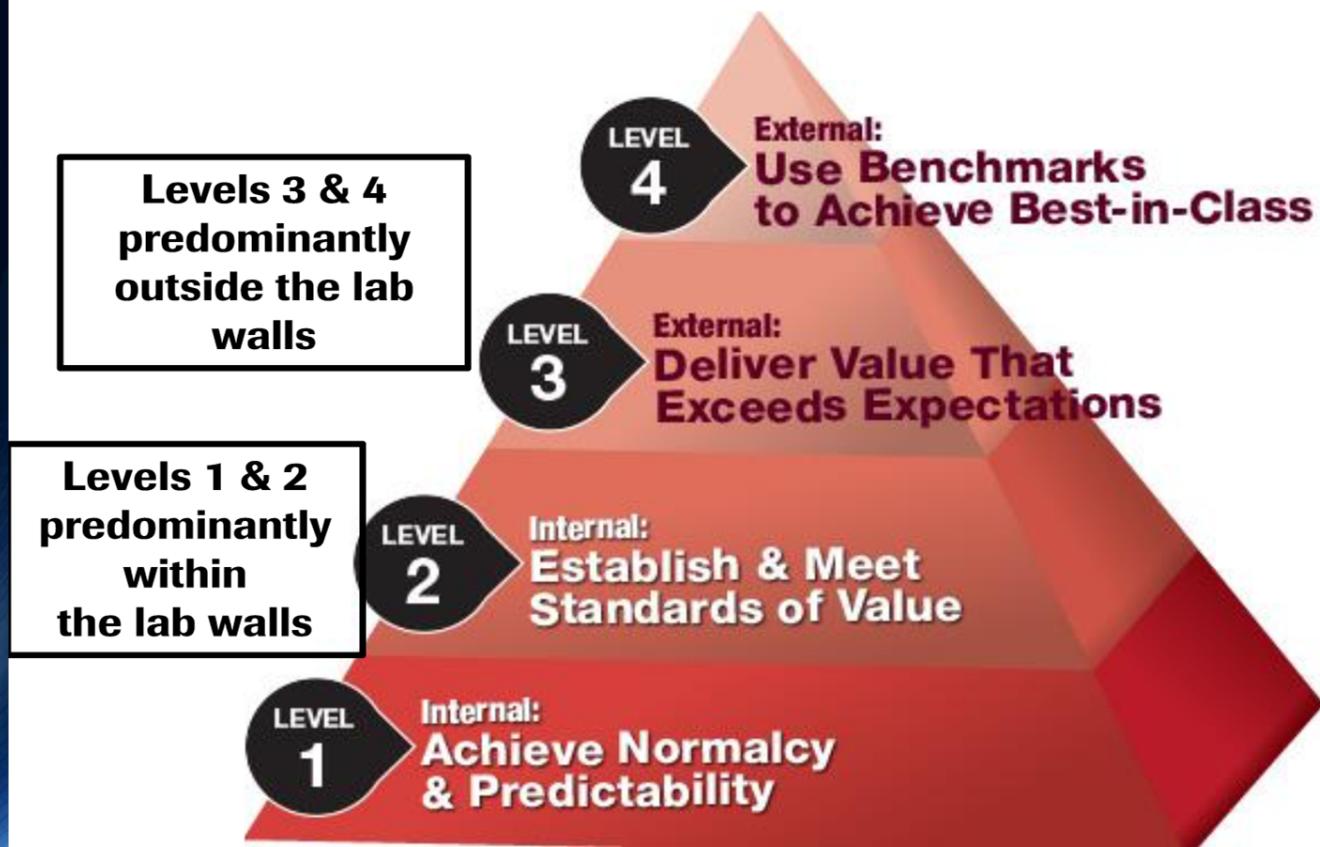
- Operational
- Clinical Lab 2.0 to Add Value
- Precision Medicine, Population Health

Aligning Labs with Healthcare's Needs

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.

The Four Levels of the Lab Value Pyramid



Lab Opportunities

- Operational
- Clinical Lab 2.0 to Add Value
- Precision Medicine, Population Health

Attributes of Lab 1.0 vs. Lab 2.0

Clinical Lab 1.0: *Transactional*

SICK CARE

- Receive Test Sample
- Result Test Sample

Clinical Lab 2.0: *Integrative*

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

Source: *Improving American Healthcare Through “Clinical Lab 2.0”: A Project Santa Fe Report, Academic Pathology Volume 4: 1–8*

Attributes of Lab 1.0 vs. Lab 2.0

Clinical Lab 1.0: *Transactional*

WELLNESS PROGRAMMING → WELLNESS PROGRAMMING

- Managed by Treating Physician
- Lab is Derivative

Clinical Lab 2.0: *Integrative*

WELLNESS PROGRAMMING → WELLNESS PROGRAMMING

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

Predictive Analytics

- What will happen? When? Why?

PAYMENT MODELS → PAYMENT MODELS

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

PAYMENT MODELS → PAYMENT MODELS

- Value of Lab for Total Cost-of-Care

Source: *Improving American Healthcare Through “Clinical Lab 2.0”: A Project Santa Fe Report, Academic Pathology Volume 4: 1–8*

TRICORE'S LAB 2.0 STRATEGY

Business

DIAGNOSIS

Products or Services

Clinical Analytics

Components

Surveillance Data

Actionable Work Lists

Alerts and Information Push

Price

PM/PM

Products or Services

Clinical Analytics

Components

Surveillance Data

Actionable Work Lists

Alerts and Information Push

Price

PM/PM

Lab Opportunities

- Operational
- Clinical Lab 2.0 to Add Value
- Precision Medicine, Population Health

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.

More Primary Care Docs Will Offer Genetic Tests

➤ Prominent health networks see benefits in offering precision medicine, genetic testing

»» **CEO SUMMARY:** *This summer, both Geisinger Health and Sanford Health will introduce genetic tests designed specifically for use by primary care physicians in their daily practice. This is a significant milestone on the road to wider deployment of precision medicine services. In the case of Sanford Health, it plans to offer patients a \$49 genetic test that looks at susceptibility for 60 diseases and 30 drug-gene interactions. The test won't be billed to insurers, but will be paid for by the patient.*

In RECENT MONTHS, several innovative health networks announced plans to provide genetic tests to patients being seen in primary care clinics. This is a development that has important implications

These are all factors in the decision of Geisinger Health, of Danville, Penna., to begin offering DNA sequencing to patients as part of routine preventive care. In May, Geisinger officials announced

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.

Healthcare's transformation and labs' response...

***Change Always Creates
New Winners and New
Losers...***

Healthcare's transformation and labs' response...

***Change Creates
Opportunity!***

Final Thoughts on Change...

We always overestimate
the change that will occur
in the next two years
and underestimate
the change that will occur
in the next ten. Don't
let yourself be lulled
into inaction.

-Bill Gates





A green road sign with a white border and four mounting holes, mounted on a wooden post. The sign displays the text "Opportunity Just Ahead" in large, bold, white, sans-serif letters. The background consists of a bright blue sky filled with scattered, fluffy white clouds.

Opportunity
Just Ahead