

*Era of Shrinking Lab Budgets, PAMA Price Cuts...*

# **Why Quality Management Is Your Lab's Best Strategy to Survive and Thrive**

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**QUALITY**  
Management

# *Let's Talk QMS for a Moment...*

- **Quality Management System (QMS)**
- A QMS is a set of policies, processes and procedures required...
- ...for planning and execution (production/development/service)...
- ...in the core business area of an organization (i.e., areas that can impact the organization's ability to meet customer requirements).
- **ISO 9001 is an example of a QMS.**



## *Primary Elements of a QMS*

- Recognize interested party requirements including Licenses to Trade, guidelines, customer requirements, and the chosen management system standard(s).
- Ensure that all requirements have been met.
- Confirm that employees receive applicable training in the quality system requirements.
- Determine processes, their interaction, inputs and outputs.



## **More QMS Attributes**

- Produce records or evidence that system requirements have been met.
- Measure, monitor and report the performance of the QMS.
- Plan changes to the QMS and take actions to address risks and opportunities as a result of changes.
- Perform internal audit to analyze the QMS and correct nonconformities.
- Continually improve the QMS.

# *Disruptors in Healthcare*

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

## *Why These Changes?*

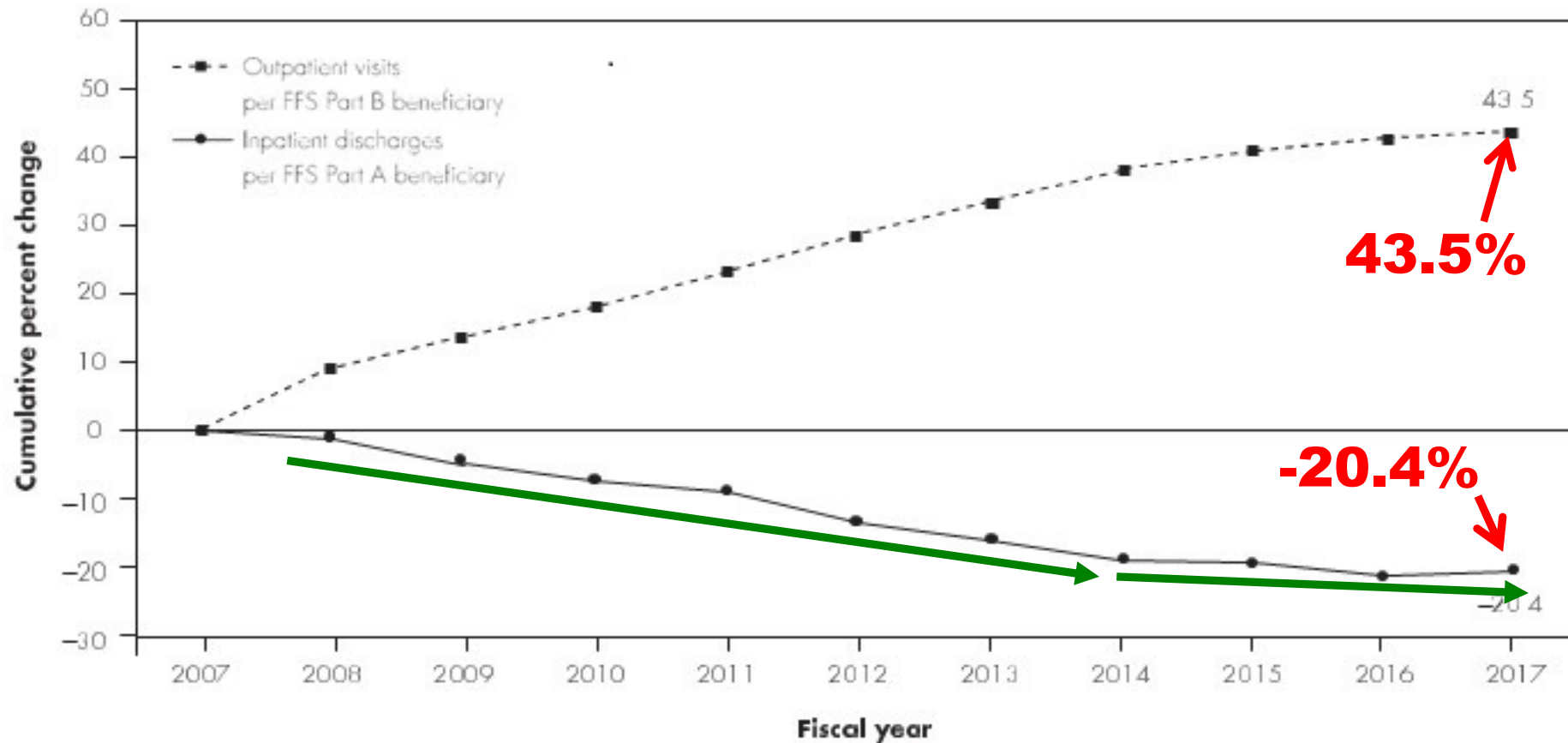
# *Proactive Care... not Reactive Care*

- 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*

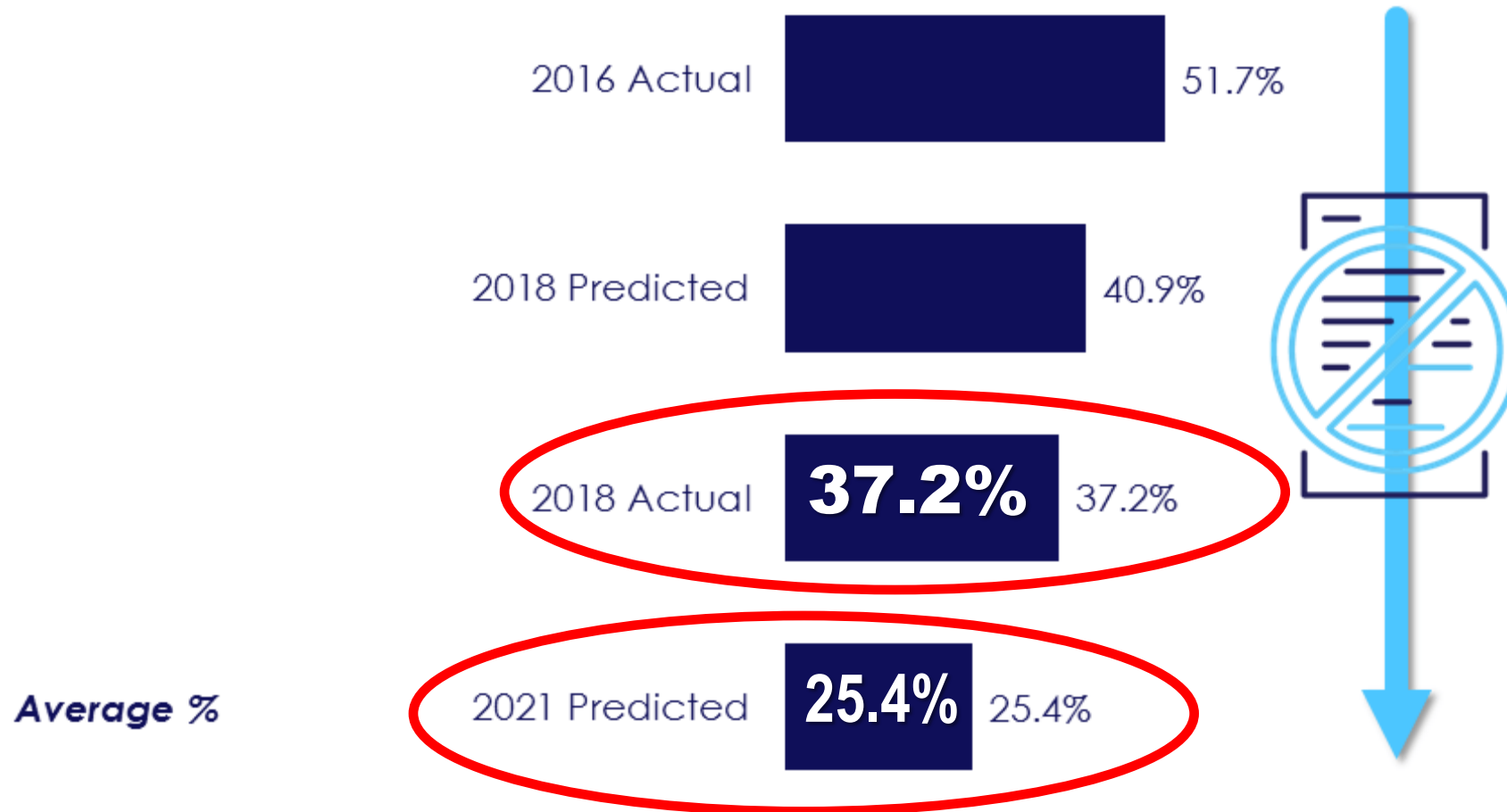
- Proactive care and what it means
- **Transition from fee-for-service to value-based methods**
- Ongoing consolidation among all categories of providers

# ***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



# ***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; first data baseline was 2017.
- Merit-Based Incentive Program (MIPS).
- Advanced Alternative Payment Models (APMs).
- Speeds transition away from Fee-for-Service.

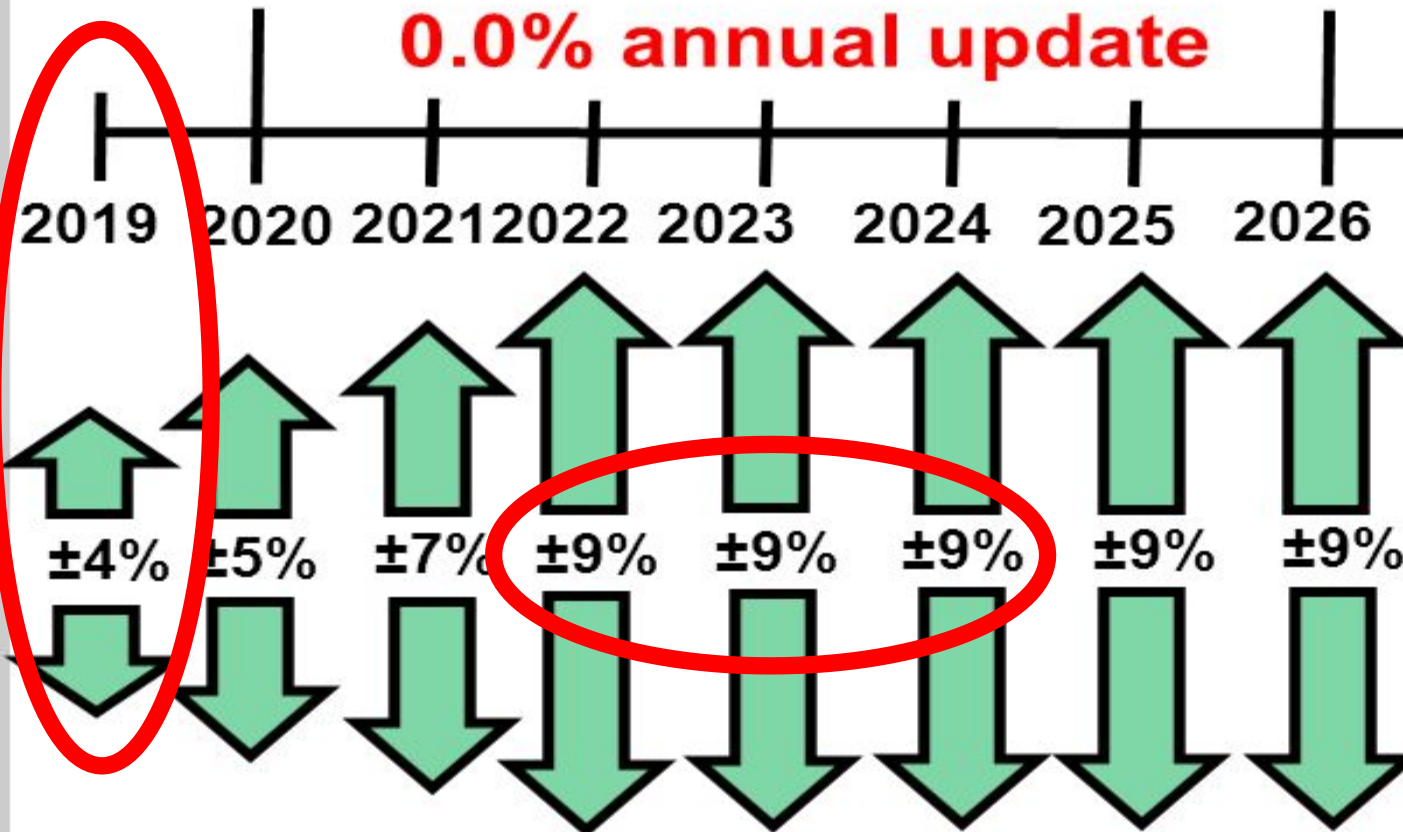
# Payment Under MACRA

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

# ***Hospital/Health Networks: Fewer “Haves,” More “Have Nots”***

- Navigant study of 2,000 rural hospitals: “21% are at high risk of closing based on their total operating margin, days cash-on-hand, and debt-to-capitalization ratio. This equates to 430 hospitals across 43 states that employ 150,000 people!”
- Modern Healthcare Metrics: 53% of all stand-alone hospitals in the US suffered operating losses during each of the last five years (2012 to 2017). Conversely, about half (26%) of health system-affiliated providers have lost money.

# *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**

# ***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 Deaconness Medical Center-Lahey Health merger
- Dignity Health and Catholic Health Initiatives merging.

# ***Clinical Laboratory, Anatomic Pathology Disruptors***

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

# *Lab, Pathology 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.)***

- Payers want more complete data sets from labs.
- Payers want providers that help their HEDIS scores and STAR scores for Medicare Advantage.
- Risk adjustment at health plan level and at provider level is opportunity for labs/diagnostic providers to add value.
- These are opportunities for your labs to help health insurers with enriched data—and be paid for that data!

# *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
- 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.
- Hospitals and health systems trimming lab budgets.
- Restrictive coverage guidelines for lab tests.

# ***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**

## ***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.

PERFORMANCE

COMPANY

EFFICIENCY

SIGMA SIX

KAIZEN

CONTINUOUS  
IMPROVEMENT

**LEAN**

MANUFACTURING

DMAIC

QUALITY

PRODUCTIVITY

SYSTEM

MANAGEMENT

# *Here Come the Millennials!*

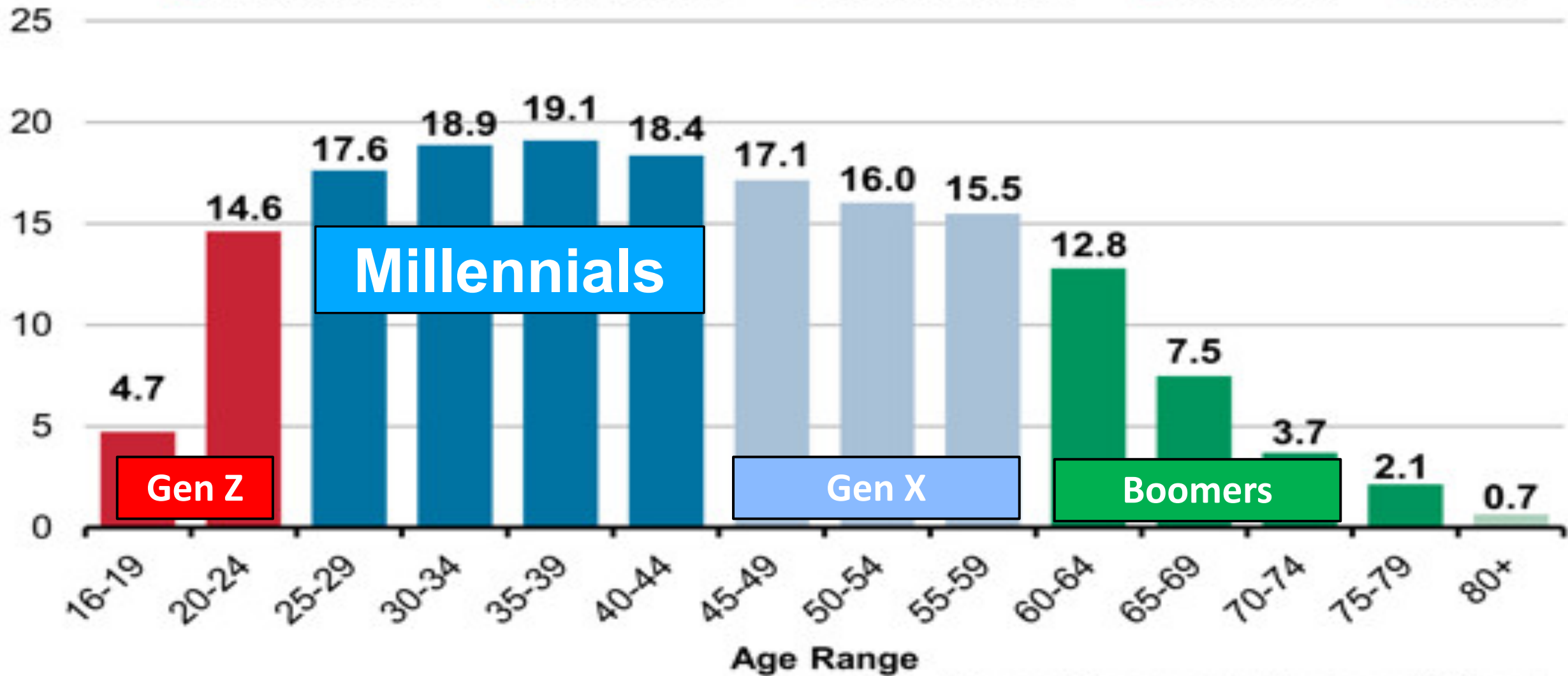


**By 2025, Millennials will make up 75% of the workforce!**

# The Workforce in 2025

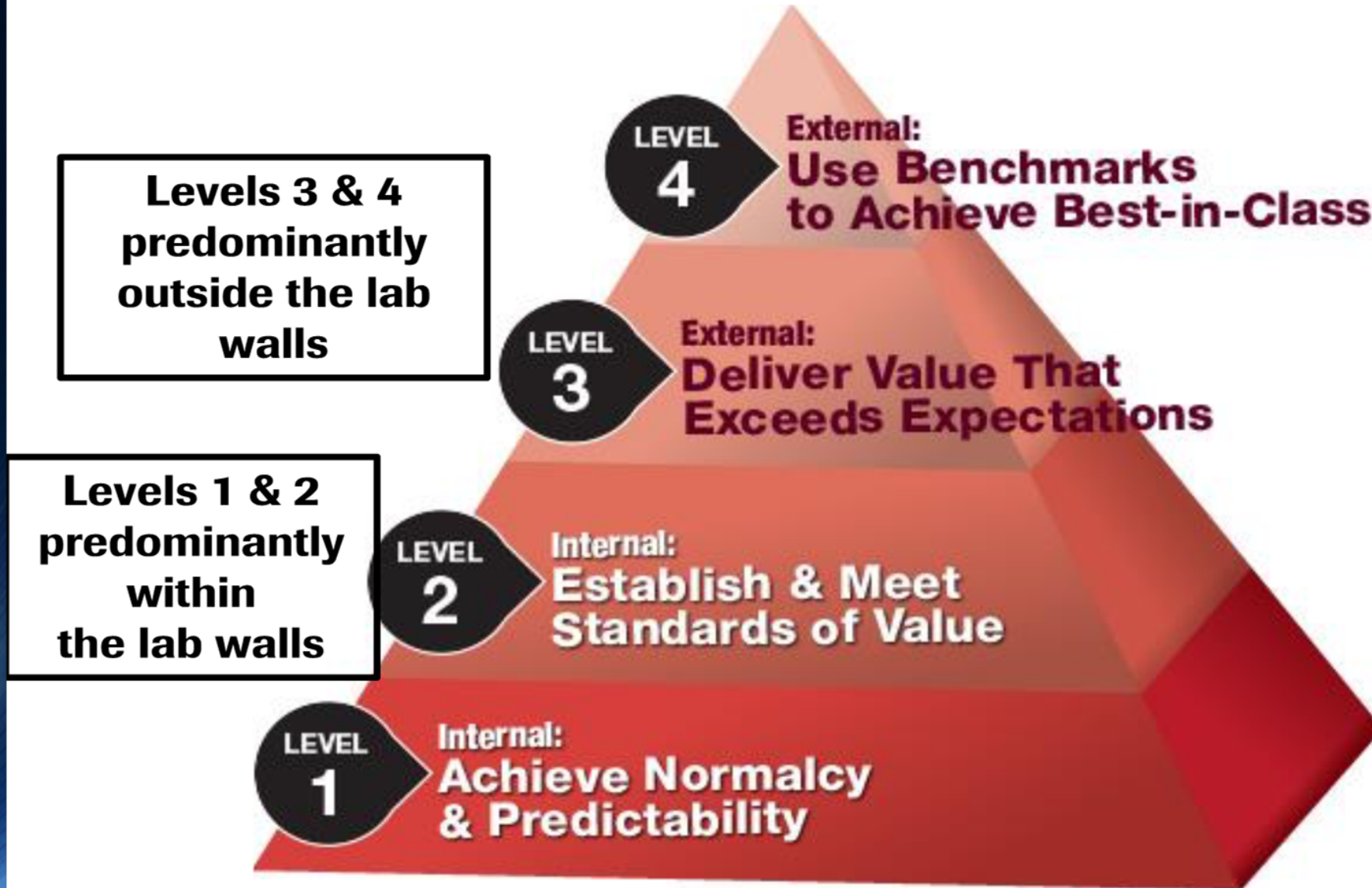
Projected size of U.S. labor force (in millions) by age, for the year 2025

■ Generation Z ■ Millennials ■ Generation X ■ Boomers ■ Silent



Source: Department of Labor | WSJ.com

# 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*

## 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

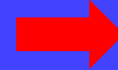
# Attributes of Lab 1.0 vs. Lab 2.0

## Clinical Lab 1.0: *Transactional*

## Clinical Lab 2.0: *Integrative*

### 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

# *Lab Opportunities*

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

# *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.

# METHOD: NEW MEXICO POPULATION AND PREGNANT WITH MEDICAID

Diabetes

10



Prenatal

582



Hepatitis C

13



582

# ONE MCO PILOT AND PROJECTION

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

1. BCBSNM Audit Review Table. [http://www.hsd.state.nm.us/uploads/FileLinks/485263ae1ad040ea9d52673aef6109b4/2016\\_HEDIS\\_BCBS.pdf](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](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](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/hus/hus16.pdf#093> (Accessed: August 29, 2017)

*Healthcare's transformation and labs' response...*

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



# *Now You Know Why QMS Is Useful Lab Strategy*

- Clinical labs, pathology groups must operate at lower cost, but equal or better quality.
- Labs must become better at using data to support improved patient outcomes.
  - Lean/Six Sigma labs already use real-time data to manage workflow, protect internal quality.
  - Strategy is to shift internal skillsets to helping external providers.
- Quality Management System is framework to deliver value to all stakeholders served by the lab.

# *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**

