DELIVERING ON THE VALUE OF LABORATORY MEDICINE
HEALTHCARE IS CHANGING

CMS Payment Changes 2015-2018

Medicare’s commitment towards quality-based payments grows.

Quality based payment programs
- Hospital Value-Based Purchasing
- Hospital Readmissions Reduction
- Hospital-Acquired Condition Reduction
- End-Stage Renal Disease (ESRD)
- Quality Incentive
- Value-Based Modifier

Alternative payment programs
- Pioneer Accountable Care Organization
- Medicare Shared Savings Program
- Bundled Payments for Care Improvement
- Comprehensive Primary Care Initiative
- Patient Centered Medical Homes

- All Medicare payments
- Percentage of payments linked to quality programs
- Percentage of payments linked to alternative programs

Current | By 2016 | By 2018
80% | 85% | 90%
20% | 30% | 50%
### CLINICAL LABORATORIES ARE CHANGING

How much do you agree or disagree with each of the following statements?

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>Rating Average</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>The shift, FROM fee for service, e.g. “clinical laboratory fee schedule” reimbursed TO bundled, capitated or value-based reimbursement, is commanding significant attention from our parent organization.</td>
<td>18</td>
<td>27</td>
<td>131</td>
<td>142</td>
<td>84</td>
<td>3.61</td>
<td>402</td>
</tr>
<tr>
<td>Significant change in our laboratory will occur as a direct result of this</td>
<td>18</td>
<td>29</td>
<td>135</td>
<td>146</td>
<td>74</td>
<td>3.57</td>
<td>402</td>
</tr>
<tr>
<td>Our lab feels significant pressure to demonstrate our value to our institution’s senior leadership.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Our lab feels significant pressure to cut costs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

answered question 402
skipped question 67
Figure 1. Rates of Use of Imaging Services, as Compared with Rates of Other Physician-Ordered Services, per Medicare Beneficiary (2000–2007).

Data are from the Medicare Payment Advisory Commission’s analysis of physician claims for Medicare beneficiaries. Included are services paid under the physician fee schedule.

THE PUBLIC IS TOLD ABOUT OVER-TESTING

AARP Bulletin
Real Possibilities

- Goodbye Nursing Home?
  New Technology Lets You Stay Put
  PAGE 20

- Dave Barry
  You’ll Laugh Out Loud
  PAGE 40

- Mustang!
  50 Years of Fun
  PAGE 6

- Murder Twist
  New Truths About A Tragic Crime
  PAGE 24

- Boomer TV
  The Shows We Loved in 1964
  PAGE 46

- AARP News
  Washington Watch
  PAGE 30

Doctors Say:
Skip These Tests!

Doctors warn that some of the common medical tests routinely taken by Americans do more harm than good, waste billions of dollars and could endanger your health or even your life...

PAGE 12
And the payers promote a narrow look at the problem.

WHICH LEADS TO A NARROW FOCUS

To provide accurate, timely test results at the lowest possible cost

Our measures evolve from that focus

- Analytical process control
- Error logs such as missing ID, hemolysis, short fills, interface error logs, incomplete requisitions, uncollected samples, order entry errors, lost specimens, contaminated specimens
- Prolonged turn-around time (narrowly defined)
- Incident reports and corrected result reports (reactive and poor proxies for patient outcomes)
WE'VE TRIED REVERSING THE PRESSURE
BY SELLING OUR VALUE

Results for Life
LAB TESTING: BETTER HEALTH, IMPROVED OUTCOMES

- Detecting & Treating Disease
- Preventing Disease
- Changing the Course of Disease
- Managing Chronic Disease
- Saving Money, Saving Lives
- Tailoring Care for the Individual

STORIES from PATIENTS

Patients speak-out on the value of lab testing
...Watch Video

Hemoglobin A1C Test and Pre-Diabetes
57 million Americans suffer from pre-diabetes, but this convenient, consumer-friendly test can help pull them back from the brink.

Read press release
Read more...
70% of medical decisions are driven by the laboratory
“70%” of the medical record contains laboratory data
Lichtenberg-2005
“Day without a lab”
Lewin-ACLA 2009

All approaches fail to articulate what’s broken; what consequences exist with the current approach; and what opportunities are being missed.
EXAGGERATED FOCUS ON COST IS INAPPROPRIATE

National Health Expenditure (2014)
$3,000 billion

Medical Laboratory Expenditure (2014)
$73.4 billion

MLE/NHE=2.4%

THE 3%
Overutilization is common (mean=20.6%) but varies systematically (n=38)

- by clinical setting – initial (43.9%) vs. repeat (7.4%)
- By test volume – low volume tests (32.2%) vs. high (10.2%)
- measurement – restrictive (44.2%) vs. permissive (12.0%)

Underutilization is also widespread, but understudied (mean=44.8%), (n=8)

Of 307 closed cases (ambulatory) studied because they alleged missed or delayed diagnosis, 181 involved diagnostic errors that harmed patients.

<table>
<thead>
<tr>
<th>Process Breakdown</th>
<th>All Missed Diagnoses (n = 181), n (%)</th>
<th>Missed Cancer Diagnoses (n = 106), n (%)</th>
<th>Missed Noncancer Diagnoses (n = 75), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to order appropriate diagnostic or laboratory tests</td>
<td>100 (55)</td>
<td>12 (16)</td>
<td>52 (69)</td>
</tr>
<tr>
<td>Adequate diagnostic or laboratory tests ordered but not performed</td>
<td>17 (9)</td>
<td></td>
<td>37 (49)</td>
</tr>
<tr>
<td>Diagnostic or laboratory tests performed incorrectly</td>
<td>15 (8)</td>
<td></td>
<td>7 (9)</td>
</tr>
<tr>
<td>Incorrect interpretation of diagnostic or laboratory tests</td>
<td>67 (37)</td>
<td>1 (1)</td>
<td>18 (24)</td>
</tr>
<tr>
<td>Responsible provider did not receive diagnostic or laboratory test results</td>
<td>23 (13)</td>
<td>6 (8)</td>
<td></td>
</tr>
<tr>
<td>Diagnostic or laboratory test results were not transmitted to patient</td>
<td>22 (12)</td>
<td>7 (9)</td>
<td></td>
</tr>
<tr>
<td>Failure to refer</td>
<td>47 (26)</td>
<td>19 (18)</td>
<td>28 (37)</td>
</tr>
<tr>
<td>Failure of a requested referral to occur</td>
<td>9 (5)</td>
<td>8 (8)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Failure of the referred-to clinician to convey relevant results to the referring clinician</td>
<td>3 (2)</td>
<td>2 (2)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Patient nonadherence to the follow-up plan</td>
<td>31 (17)</td>
<td>21 (20)</td>
<td>10 (13)</td>
</tr>
</tbody>
</table>

Clinicians are not always sure of what to order (14.7%)*
Clinicians are not always sure of what to do with results (8.3%)*
Clinicians don’t always retrieve results
Clinician’s training curriculum indicates the problems will persist (8 hours)**

**Smith, B. et al (submitted) Medical Student Education in Laboratory Medicine in United States Medical Schools: A 2014 Status Report
What medical students are taught about the diagnostic tests they will use in practice?

What diagnostic tests do doctors order in practice and are required to interpret the test results by themselves?

AN EDUCATIONAL MISMATCH WITH MEDICAL PRACTICE COMPETENCY

- Anatomic pathology tests
- Radiology tests
- Clinical laboratory tests

Provided courtesy of Dr. Michael Laposata, Vanderbilt University Medical Center
SO WHAT DOES THIS TELL US ABOUT DRIVING LAB VALUE?
Value = f(net outcomes)

= (delivered benefit - delivered harm)

Delivered benefit = clinical + financial

Delivered harm = clinical + financial

Value has both a technical and a personnel component

OR

Value = health outcomes achieved that matter to patients relative to the cost of achieving those outcomes (Porter)
TESTING-RELATED BENEFITS

- More accurate, timely and lower cost diagnosis
- More effective treatments with less wasted expense
- More engaged and healthier populations
- More efficient and effective health systems
**MAXIMIZE VALUE BY REDUCING HARMS FROM FIVE PRIMARY FAILURE MODES**

<table>
<thead>
<tr>
<th>Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>An inappropriate test is ordered</td>
</tr>
<tr>
<td>An appropriate test is not ordered</td>
</tr>
<tr>
<td>An appropriate test result is misapplied</td>
</tr>
<tr>
<td>An appropriate test is ordered, but a delay occurs somewhere in the total testing process</td>
</tr>
<tr>
<td>The result of an appropriately ordered test is inaccurate</td>
</tr>
</tbody>
</table>

*Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Quality & Safety. 2013 August 16*
A FOCUS ON VALUE WOULD REQUIRE A CHANGE IN PRIORITIES

- Operational efficiency is focused on reducing cost and systematic errors
- Clinical effectiveness is focused on improving patient outcomes
INTERVENTIONS EXIST THAT IMPROVE TESTING-RELATED VALUE

- **Utilization Appropriateness**
  - CPOE design and monitoring
  - Algorithms, clinical pathways, guidelines
  - Reflex testing
  - Data mining
  - Inter-physician variance analysis

- **Process Robustness**
  - Process monitor
  - Discharge monitor

- **Interpretation and Action Appropriateness**
  - Interpretive comments
  - Data mining
  - EMR interface
  - Trigger tools
WE MUST MAKE IT EASIER TO ORDER THE RIGHT TEST

<table>
<thead>
<tr>
<th><strong>Key Name</strong></th>
<th><strong>Synonyms/Confounders</strong></th>
<th><strong>Abbreviation(s)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkaline Phosphatase</td>
<td>Alkaline Phos blood</td>
<td>ALP, Alk Phos, AP, AKP</td>
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<tr>
<td></td>
<td>Alkaline phosphomonoesterase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alkaline phosphohydrolase</td>
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<tr>
<td></td>
<td>Alkaline phenyl phosphatase</td>
<td></td>
</tr>
<tr>
<td>Beta HCG</td>
<td>BHCG (serum qualitative)</td>
<td>BHCG, HCGB, Beta-HCG</td>
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<tr>
<td></td>
<td>Beta-Chorionic Gonadotropin</td>
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<tr>
<td></td>
<td>Blood vs urine Beta HCG</td>
<td></td>
</tr>
<tr>
<td>Complete blood count with</td>
<td>Hematology profile; blood count; hemogram</td>
<td>CBC</td>
</tr>
<tr>
<td>differential</td>
<td>CBC with diff</td>
<td>CBC d/p</td>
</tr>
<tr>
<td></td>
<td>CBC with differential</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CBC with differential and platelets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CBC w/diff &amp; PLT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CBC diff plts</td>
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</tbody>
</table>

Study of 2644 patients at 2 tertiary care hospitals of which 1095 had 2033 test results (lab, radiology) returned after discharge.

191 of results were potentially actionable (9%).

61% of respondents with potentially actionable results were unaware of results.

A systematic review found failure to follow-up was a significant problem for in-patients, for in-patients being discharged and for ED patients.

WE MUST ELIMINATE “ORPHAN” TEST RESULTS


“It’s a simple stress test—I do your bloodwork, send it to the lab, and never get back to you with the results.”
For patients being treated with Plavix, there is an opportunity to reduce the risk for thrombosis by performing pharmacogenomics testing to determine if Plavix is likely to be effective based on the patient’s genetic profile.

At Vanderbilt alone, 6400 patients on medication x 60 adverse events avoided per year x $25,000 per adverse event = an estimated savings of $1.5 million.
Diagnosis Detection: Repeat Serum Creatinine Results (2009-2011)

- 5,324 lab orders placed for patients with an abnormal creatinine not repeated within 90 days
- 2,565 total labs repeated within 90 days (48%)
- 1,311 abnormal results (51%)
- 1,078 New CKDs identified

Kanter – 2012 – “Reducing Diagnostic Errors By Closing The Loop On Outpatient Care”
Medication Monitoring: Annual Medication Monitoring Results (2011)

Digoxin, ACE/ARB, Diuretics, Anti-convulsants combined

117,776 lab orders placed for patients missing appropriate annual medication monitoring labs

94,831 letters mailed (81%)

61,587 labs completed (65%)

10,022 abnormal results (16%)

Michael Kanter, MD “Reducing Diagnostic Errors By Closing The Loop On Outpatient Care.” Presented at the 5th International Diagnostic Error in Medicine conference, Baltimore, 2012.
Diagnosis errors are defined as misdiagnosis, missed diagnosis, or delayed diagnosis\(^1\)

Diagnostic errors occur in 10-15% of cases,\(^2\) with more than 50,000 DxE in primary care and 40-80,000 annual deaths in hospitals\(^3\)

One in twenty adults in outpatient settings experience a diagnostic error annually\(^4\)

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\(^3\) Newman-Toker DE. Measuring Diagnostic Errors in Primary Care - Invited Commentary. *JAMA Internal Medicine* 2013 February 25

HOW MANY OF YOU HAVE ENCOUNTERED DIAGNOSTIC ERRORS?
Improving Diagnosis in Health Care
Getting the right diagnosis is a key aspect of health care: it provides an explanation of a patient’s health problem and informs health care decisions.

Yet...

- Diagnostic errors persist through all settings of care and harm an unacceptable number of patients.

- In every research area, diagnostic errors were a consistent quality and safety challenge.
Definition of Diagnostic Error

The failure to:

(a) establish an **accurate** and **timely** explanation of the patient’s health problem(s)

or

(b) **communicate** that explanation to the patient
RECOMMENDATION 1

1A: Health care organizations should ensure that health care professionals have the appropriate knowledge, skills, resources, and support to engage in teamwork in the diagnostic process.

This includes:

- **Interprofessional** and intraprofessional teamwork.

- **Collaboration among pathologists, radiologists, and treating health care professionals** to improve diagnostic testing.
RECOMMENDATION 1

1B: Health care professionals & organizations should partner with patients and their families as diagnostic team members.

They should:

- Create environments where patients and their families can learn and engage in the diagnostic process and share feedback and concerns.

- Ensure patient access to EHRs, including clinical notes and diagnostic testing results.

- Include patients and their families in efforts to improve the diagnostic process.
RECOMMENDATION 3

3A: Health IT vendors and ONC should work together with users to ensure that health IT used in the diagnostic process:

– Demonstrates usability
– Incorporates human factors knowledge
– Integrates measurement capability
– Fits well within clinical workflow
– Provides clinical decision support
– Facilitates the timely flow of information among patients and clinicians
RECOMMENDATION 5

5: Health care organizations should:

- Promote a non-punitive culture that values open discussion and feedback on diagnostic performance.

- Design the work system to support patients, their families, and health care professionals in the diagnostic process.

- Ensure effective and timely communication between diagnostic testing health care professionals and treating health care professionals across all health care settings.

INSTITUTE OF MEDICINE
RECOMMENDATION 7

7A & 7B: CMS and other payers should:

- Provide coverage for evaluation and management (E&M) activities, including time spent by pathologists, radiologists, and others in advising clinicians on diagnostic testing.

- Reorient relative value fees to more appropriately value the time spent with patients in E&M activities.

- Modify documentation guidelines to improve the accuracy of information in the EHR and to support decision making in diagnosis.

- Assess the impact of payment and care delivery models on the diagnostic process & diagnostic error.
IN SUMMARY, WE CAN PROVIDE TESTING-RELATED VALUE IN MANY WAYS

- Test order management
- Result utilization management
- End-to-end process management
- Patient engagement
- System surveillance
- Population management
- Advancing science
- Leveraging information
CALL TO ACTION

- The first step is the decision to change
- Maintain focus on operational efficiency, but make clinical effectiveness a comparable focus
- Ensure cost analysis is based on systems cost not laboratory cost
- Learn how to tell the story
- Grow the evidence-base – participate in ICE
ICE is a platform for soliciting and promoting case studies of clinical laboratories positively impacting patient outcomes.
The ICE initiative demonstrates the value of clinical laboratory physicians and scientists in improving patient outcomes. It accomplishes this by providing training, guidance and incentives for the collection of evidence that will in turn link testing-related interventions, regardless of where they occur, to patient benefits. ICE then acts as a platform for the sharing of the best practices that result.
### INCREASING CLINICAL EFFECTIVENESS - 2015

<table>
<thead>
<tr>
<th>Title</th>
<th>Speaker</th>
<th>Institution/Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>From Order to Result: Helping the Patient Get the Right Test</td>
<td>Jessie Conta</td>
<td>Seattle Children's Hospital</td>
</tr>
<tr>
<td>The Future of Transfusion Medicine at UnityPoint Health</td>
<td>Carol Collingsworth</td>
<td>Unity Point Health</td>
</tr>
<tr>
<td>How Technology Contributed Dramatically to Decreasing HAI's and Delivering High Value Outcomes</td>
<td>Denise Geiger</td>
<td>Mather Hospital</td>
</tr>
<tr>
<td>Central Ohio Primary Care and Local Specialty Group Working Hand in Glove for Better Patient Outcomes</td>
<td>Rebecca Burk</td>
<td>Central Ohio Urology Group</td>
</tr>
</tbody>
</table>
2016 Submissions Came from Eight Countries

- Canada (1)
- Ethiopia (2)
- India (1)
- Italy (2)
- Turkey (2)
- Uganda (1)
- United Kingdom (5)
- United States (9)
<table>
<thead>
<tr>
<th>Title</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>High sensitivity cardiac troponin I at presentation enables early</td>
<td>Clare Ford, <em>Royal Wolverhampton NHS Trust</em></td>
</tr>
<tr>
<td>safe discharge of patients</td>
<td></td>
</tr>
<tr>
<td>Improving Stat Protime Turn Around to Improve Emergency Department</td>
<td>Susan Traub, <em>Kaiser Permanente South Sacramento Medical Center</em></td>
</tr>
<tr>
<td>Patient Throughput</td>
<td></td>
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<tr>
<td>GeneXpert MTB/RIF® assay for the diagnosis of smear-negative</td>
<td>Mulualem Tadesse, <em>Jimma University</em></td>
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<tr>
<td>pulmonary tuberculosis</td>
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</table>
2016-17 ICE Details

• Submission period: June – October 2016
• Web-based resources from CLMA and CDC

- Webinars
- Reading list
- Published scoring criteria
- Library of accepted submissions

• International panel of reviewers
• Opportunities to promote the best work
The CLMA-led Innovative Program has Attracted Important Partners
KnowledgeLab – Executive War College
EuroMedLab
ICE 2015-16 Reviewers

- Julian H Barth, MD
- Consultant in Chemical Pathology & Metabolic Medicine, Leeds General Infirmary

- Julie A. Gayken
- Senior Director of Laboratory Services (Retired), HealthPartners/Regions Hospital

- Michael J Hallworth FRCPath
- Consultant Biochemist (retired), Royal Shrewsbury Hospital

- Brian R. Jackson, MD, MS
- Vice President, Chief Medical Informatics Officer, ARUP Laboratories
ICE 2015-16 Reviewers

- Michael Kanter, M.D.
  Regional Medical Director of Quality & Clinical Analysis, Southern California Permanente Medical Group

- Mary Nix, MS, PMP
  Health Scientist Administrator, Agency for Healthcare Research and Quality (AHRQ)

- Rick Panning, MBA, MLS(ASCP)CM
  Senior Administrative Director, HealthPartners and Park Nicollet Care Group Laboratories

- Tim Skelton, MD, PhD
  Medical Director Core Laboratory & Laboratory Informatics, Lahey Hospital & Medical Center
CDC Seeks & Offers Help

- Reduction in blood culture contamination
- Reduction in blood sample hemolysis in ED’s.
- Pre-analytical practices that improve urine culture results
- Timely and accurate reporting of critical values
- Improved laboratory test selection using clinical decision support (especially due to confusing lab test names)
- Laboratory triggers that improve patient safety
Drive improved outcomes

Measure your impact

Submit your ICE abstract
The clinical lab’s mission **should not just be:**

To provide accurate, timely, low cost test results

Although necessary, it is not sufficient

The clinical lab’s mission **should be:**

To rapidly and efficiently enable the accurate **diagnosis** of conditions, the selection of appropriate **treatments** and the effective **monitoring** of health status*

*Epner, Paul, “Impact of Laboratory Services on Diagnostic Errors,” ThinkLab ‘11*
QUESTIONS?