2018 Outlook for the Clinical Laboratory Industry

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Learning objectives

Understand the latest policy initiatives affecting the Affordable Care Act for the short and long term.

Discuss the outlook for federal budget cuts to Medicare and Medicaid and the impact they would have on both beneficiaries and providers, including labs.

Review the status of a new Medicare market-based payment system for lab testing and how payment rates will change starting in 2018.

Identify top federal policy challenges for labs over the next year.

Today's agenda

- Health Reform and the Affordable Care Act
- What's ahead for Medicare & Medicaid
- Laboratory-Developed Test update
- Implementation of Medicare's new Market-Based payment system for Labs

Tax Cuts and Jobs Act

- Repeals individual mandate under the Affordable Care Act (ACA) effective Jan 1, 2019.
- Individual mandate is designed to control adverse selection and expand the risk pool on the individual health insurance market by penalizing those who don't obtain coverage.
- Leaves other key ACA provisions in place including the employer mandate, market reforms, patient protections.

Individual Mandate Repeal: Expected Impact

- CBO estimates that without individual mandate up to 13 million people could lose coverage by 2027.
- Average premiums on the individual and small group markets could go up about 10% more than they would otherwise rise predicts the CBO.
- Cause younger and healthier people to forgo coverage.
- This would drive up costs for insurers and potentially cause some carriers to exit individual market in 2019 and beyond.

Administrative Actions Weaken the ACA

- End $9 billion of subsidies in 2018 to insurance companies that help low-income customers pay out-of-pocket costs.
- Loosen restrictions on short-term health insurance and promote association health plans.
- Cut funding by 40% for navigators that help people enroll.
- Reduce spending on advertising and promoting ACA enrollment from $100 million to $10 million.
- Shut down ACA website for 12 hours most Sundays during open enrollment.

ACA Update for 2018

- ACA remains alive but impaired - Congress not expected to repeal in 2018 due to political dynamics.
- Despite an enrollment period cut in half and far less outreach, nearly 8.8 million enrolled for 2018.
- There are an estimated 700 health plans in the individual and small group markets, down sharply from an earlier estimate of 2,400.
- Plan deflections resulted from insurers not earning enough profit when competing with plans narrowing networks and lower costs.

Status of ACA Stabilization

- Bipartisan legislative fixes to help stabilize ACA individual market where 22M people get coverage debated as part of end-of-year 2017 spending bill.

- Alexander-Murray bill would restore funding for the cost-sharing reduction subsidies (CSR) for 2 years.

- Cohen-Nelson measure would provide $10.5 billion in reinsurance funding for high-cost patients.

- Many experts say CSR bill won't do much to stabilize markets but reinsurance funding could lower premiums and keep insurers selling plan on the exchanges.

- 2018 outlook uncertain with White House & GOP House opposed or dubious so far — best bet is to attach to "must pass" legislation.

How Labs Are Impacted by Health Reform

- New payment and services delivery models – ex. bundled payments, ACOs - demonstrate lab value proposition and casual connection between testing and clinical utility.
- Sustained Medicare payment reductions
- Increased patient financial responsibility due to higher deductibles & co-payments — collections & bad debt.
- Continuing industry consolidation
- Need for new revenue sources: ex. clinical trials, DAT

What to Watch for in Medicare

- Congress waived budget rules that would require an automatic 4% Medicare cut as part of a short-term funding bill passed in December.

- As required by the 2010 PAYGO Act, automatic cuts were triggered by passage of tax legislation which added $1.5 trillion to the federal deficit over 10 years.

- Fastest growth in Medicare is Medicare Advantage (MA) plans which have grown by 71% since 2010 with 19 million enrollees in 2017, one-third of all Medicare beneficiaries.

Medicaid in Spotlight

- White House and GOP Congress were unsuccessful in 2017 in switching Medicaid to a system of per capita financing (i.e., block grants) as part of efforts to repeal and replace the Affordable Care Act.

- Trump Administration is moving ahead to allow states to use Section 1115 waiver authority to reshape Medicaid.

- Expect some states to seek waiver provisions relating to work requirements (KY approved), drug screening & testing, eligibility time limits, and premiums with disenrollment for non-payment by traditional Medicaid populations.

- More than 74 million people were enrolled in Medicaid and CHIP in 2017 as opposed to 58M+ Medicare beneficiaries.

What's Ahead for Medicare & Medicaid

- Pressure remains on GOP side, particularly in the House; for implementing additional Medicare & Medicaid savings in 2018 due to growing U.S. budget deficit but minimal appetite on Senate side with razor thin GOP majority (51-49).

- Latest intelligence is that Congress will not even attempt to pass a 2018 budget given dynamics surrounding mid-term elections so congressional cuts in Medicare or Medicaid highly unlikely.

- Expect additional executive actions by White House this year to make further administrative changes in both programs.

CMS Open to Changing CLIA Regulations

- CMS seeks public comments on revisions to the following areas of CLIA regulation:
  - Personnel and histocompatibility requirements
  - Flexibility to impose alternative sanctions for labs issued Certificate of Waiver (CoW) determined to have participated in a PT referral
  - Appropriate sanctions in situations where a lab referred its PT samples to another lab & reported those results
  - Updating fees for CLIA compliance and other fees
- Comments due to CMS by March 5
- Send via e-mail to http://www.regulations.gov

Regulation of Laboratory-Developed Tests (LDTs)

- FDA posted “discussion paper” early last year outlining its substantially revised “possible approach” in the oversight of LDTs.

- Paper reflects a risk-based, phased-in approach but backs away from many of most onerous provisions of draft guidance.

- Current marketed LDTs would be “grandfathered” — not expected to comply with most or all of FDA’s regulatory requirements including premarket review, QSR, registration and listing — only exception would be when its necessary to protect the public health.

FDA Revises Its LDT Approach

- Phase-in review of new and significantly modified LDTs could be accomplished over shorter period of time (4 vs 9 years) because high number of grandfathered products and would begin with tests posing the greatest risk to patients in event of false result.

- Discussion draft circulated by Reps. Bucshon (R-IN) and DeGette (D-CO) for “The Diagnostic Accuracy and Innovation Act” which creates new category and regulatory structure for in vitro clinical tests (IVCTs) which includes both test kits and LDTs under FDA and mandates lab operations to be regulated by CMS/CLIA.

LDT Oversight: Live or Dead?

- Trump Administration keeping its pledge to slash federal regulations with both HHS and FDA leadership seen as pro-industry and resistant to additional regulation.

- Possible further hearings dealing with LDT oversight during current Congress but zero likelihood for enactment of legislation given its low priority plus general malaise gripping Capitol Hill.

- Given regulatory and political climate, don't expect to see any substantive action on LDT oversight through 2018.

Protecting Access to Medicare Act (PAMA)

- Represents seismic shift in the way Medicare prices clinical laboratory tests — moves from charges to market-based rates.
- Final figures for 2018 show that Medicare reimbursement for about 75% of all lab tests on the CLFS drop in 2018 with cumulative reductions averaging roughly -35% for many high volume procedures.
- For about 10% of tests codes on the CLFS there would be an increase in 2018 over the NLAs on the CLFS in 2017.
- Medicare due to save $670M in 2018, nearly 20% of $7B spent last year (CMS had estimated $390M in savings).

PAMA Timeline

- Apr 1, 2014 - Congress passes PAMA
- Sep 25, 2015 - CMS releases proposed PAMA rules
- Jan 1 - Jun 30 - applicable labs collect private payor data
- Jun 17, 2016 - CMS publishes final PAMA rules
- Jan 1 - May 30, 2017 - applicable labs report pricing and volume data to CMS (data reporting extended 2 months)
- Sep 22, 2017 - CMS publishes preliminary PAMA prices with comments due to agency by Oct. 23
- Nov 17, 2017 - CMS publishes final PAMA prices
- Jan 1, 2018 - lab market-based rates become effective

PAMA Refresher

- For lab tests furnished on or after Jan. 1, 2018, payment is equal to weighted average of median private payor rates determined for each test.
- Private payor rates are based on data collected and submitted to CMS by applicable labs.
- Payment rates updated every 3 years using current data with collection period constituting first 6 months of year prior to reporting (next period: Jan 1 - Jun 30, 2019).
- Creates single national fee schedule with no geographic adjustment, annual update, budget neutrality adjustment.
- Forms new category of lab tests — advanced diagnostic laboratory tests (ADLTs) — differentiates between new and existing ADLTs.

Advanced Clinical Diagnostic Test Criteria

- PAMA defines an advanced diagnostic laboratory test (ADLT) that is covered by Medicare Part B as follows:
  - Covered under Medicare Part B
  - Offered and furnished only by a single laboratory
  - Not sold for use by a lab other than the lab that designed the test (or a successor lab)

ADLT Criteria

- Meets one of the following three criteria:

1. The test is an analysis of multiple biomarkers of DNA, RNA or proteins combined with a unique algorithm to yield a single patient-specific result.
2. The test is cleared by the Food and Drug Administration (FDA).
3. The test meets other similar criteria established by the Secretary.

ADLT Reporting and Payment

- PAMA makes a distinction between new and existing ADLTs and imposes differing reporting requirements and payment calculations.

- Existing ADLT: Paid under the CLFS prior to January 1, 2018 - payment and reporting same as all CDLTs except must report every year rather than once every 3 years.

- New ADLT: Payment not made under the CLFS prior to January 1, 2018 — Payment rate for a new ADLT during the initial three calendar quarters is equal to the actual list charges of the applicable laboratory. After initial three quarters: new ADLT payment rate is based upon the volume weighted median private payor average.

PAMA Phase-in of Cuts

- Starting in 2018, there is a six-year phase-in of any payment cut.
- From 2018-2020, no more than 10% reduction per year.
- For each year from 2021-2023, no more than a 15% reduction.

Definition of Applicable Laboratory

- Defined as having majority of Medicare revenues paid under the CLFS or Physician Fee Schedule (PFS).

- Final rule changed definition so that a lab using its National Provider Identifier (NPI) is considered an applicable lab if more than 50% of its total Medicare revenues received under both CLFS and PFS.

- This was a change from proposed rule where CMS used the Taxpayer Identification Number (TIN) which excluded virtually every hospital lab from reporting.

Minimal Reporting of Hospital Labs

- Hospital outreach lab that are independently enrolled in Medicare with its own NPI meets the definition of applicable laboratory.

- So long as outreach lab have 50% of its revenues are from CLFS and PFS services and revenues from the CLFS are at least $12,500 during data collection period.

- Of the thousands of hospital outreach programs in US, only 21 ended up collecting & reporting data which was included in the first round of PAMA rate calculations.

Why Hospital Reporting Matters

- Only those hospital outreach programs are required to report data if they had their own NPI during the initial data collection period Jan. 1 to June 30, 2016.

- Since this NPI requirement excluded the vast majority of outreach programs from reporting, this means the generally higher rates for hospital testing compared to independent labs were not reflected in the 2018 median private payor prices.

- This is resulting in lower prices for lab tests under new CLFS.

Key PAMA Issues

- PAMA data reporting did not constitute a true market- based analysis since so many labs were excluded.
- Definition of “applicable lab” led to exclusion of most hospital labs which perform about half of all US testing.
- Data show prices of high volume tests is driven largely by Quest and LabCorp which represented 70- 80% of test volume submitted.
- Weighted median calculation instead of a weighted average further distorts market value. Pricing is being skewed with a weighted median calculation based solely on the mix of submitting providers — requires statutory fix.

2018 PAMA Payment Summary

- Top 20 high volume tests paid by Medicare are cut an average of about 28% over 2018-2020.

- Top 6 high volume test by Medicare spending are reduced by an average of just under 36% (TSH, comp. metabolic panel, CBC w/auto diff, lipid panel vitamin D hydroxy & glycosylated hemoglobin.

- Genetic & molecular tests (many ADLTs) receive more favorable pricing with sole source proprietary tests showing biggest gains.

Cautious Good News

- For 2018, CMS decided to pay for 23 individual chemistry tests previously bundled into automated test panels (ATPs).
- Medicare paid $700+ million for ATPs in 2016 but labs will receive more in 2018 when billing out for individual panel tests (estimated $50 million plus in additional payments).
- CMS says going forward it will continue to consider the efficiencies of APTs and their appropriate payment methods (one option is to switch to G codes).
- Compliance red flags for any lab developing customize panels where medical necessity cannot be demonstrated.

PAMA Legal & Legislative Strategies

- ACLA files federal lawsuit against HHS challenging process used by CMS in calculating market-based rates - does not stop new rates from taking effect January 1.

- Asks court to require HHS to publish new rule with pricing data for all segments of industry but no government response expected until February or later.

- Regardless of outcome, legislative solution is required to mandate that HHS modify its approach during the next data collection and reporting period starting in 2019.

Industry Impact

- Expect virtually all labs except few which have sole source proprietary tests to suffer financially with margins taking a significant hit.
- Most at risk are community and rural labs (serving vulnerable Medicare groups such as nursing home and home bound patients).
- Watch for lower Medicare rates to also impact Medicaid (no higher than Medicare) and commercial rates that are often set at percentage of Medicare.
- Look for more alliances and consolidations among lab companies and organizations.

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