

A question of capital: Will lab purchasing take a U-turn?

Anne Paxton

June 2014—If they made disaster movies about the laboratory industry, you could cue the voice talent right now, because all the plot elements seem ready at hand. *In a world where an economy haltingly recovers from the blows of recession, a series of double-digit reimbursement cuts for laboratory services looms. New financial accounting standards lurk in the background, threatening to roil traditional equipment rental arrangements. A mammoth national health insurance program rolls out, generating fears of one set of dictates to rule them all. Meanwhile, hospitals bent on mergers and acquisitions relentlessly starve their own departments—especially laboratories—of capital budgets, making the No. 1 priority simple survival.*

But the plotline for laboratory executives trying to steer through these hazards isn't at all predictable. There are alarming signs, certainly, but also reasons for optimism, and a host of unknowns. Will all of these factors lead to rumblings, tremors, or seismic shifts for the laboratory industry? And what are the implications for laboratory purchasing of instruments and other equipment in 2014 and beyond?

When CAP TODAY talked with directors of several of the largest laboratory operations in the country about their own purchasing plans, their forecasts were decidedly mixed. Opinions differ as to whether circumstances call for a buying binge, just procurement as usual, or a batten-down-the-hatches response.

From Stan Schofield's perspective, for example, the Medicare/Medicaid reimbursement cuts in store for laboratories due to the Protecting Access to Medicare Act of 2014, signed April 1, are casting a big shadow over the industry. "It will be challenging. We're moving from difficult to dire," says Schofield, president of NorDx and senior vice president of MaineHealth in Scarborough, Me.

As co-founder and managing principal of the Compass Group, a trade association representing 23 laboratory corporations associated with large integrated health care delivery networks, Schofield conducts product evaluations and negotiates purchases on behalf of hundreds of hospital laboratories. Based on reimbursement cuts, unwelcome new accounting standards, and other pressures on hospitals, what he sees shaping up is an unprecedented financial crisis for the laboratory industry that is sure to shrink purchasing.



Dr. Brown

Some other Compass members echo that outlook—but not necessarily with the same perspective. Dan R. Brown, PhD, is system director of laboratories for the newly merged \$8 billion Baylor Scott & White Health, formed in late 2013 and now the largest not-for-profit health care system in Texas. He agrees the nation's health care system is experiencing the biggest and fastest changes in decades, but he doesn't see a financial crisis if systems are prepared appropriately. For his own network, new cost controls are in place, but so are integration and harmonization of labs that are leading to the purchase of many new platforms. "We're not downsizing," Dr. Brown says, "but more in a rightsizing mode to adequately serve our patient needs. We're in a period of transformational change."

Similarly, at the large academic medical center of New York University, where there has been an aggressive building and expansion campaign in recent years, the laboratory also is rebuilding and enlarging and will need new instruments, says Mark S. Lifshitz, MD, director of clinical laboratories for the NYU Langone Medical Center. Hurricane Sandy is no small factor in the laboratory's rebuilding plans, since the flooding from that catastrophic 2012 weather event took out the medical center's ground-level blood bank. That loss accelerated the renovation and rebuilding project that was already underway for the entire clinical laboratory. "We have plans to buy a lot of new equipment," Dr. Lifshitz says. And, he notes, NYU, like several other New York City major medical centers, is expanding its network and laboratory capabilities.



Ward

In North Carolina, on the other hand, Ritu W. Ward, MS, MT(ASCP), assistant vice president for the laboratory network at Carolinas Healthcare System, which includes 41 hospitals, sees laboratories retrenching. "Our vendors have traditionally provided us breakpoints in materials and costs according to utilization, based on our ability in the lab to drive more testing. But for growth, we are in the opposite paradigm now. Labs are not betting on the fact of large volume; we are controlling our cost per unit for producing that test. So when vendors come to the table and say, we have a price break if your volume increases, because that will take you to tier two, I have to tell them that's no longer on the table." Previous volumes can no longer drive the vendors' price structure, she says. That's a bygone era.

One area where her laboratory network is pushing back is on charges for preventive maintenance, which have verged on the exorbitant, she says. "We're trying to negotiate on that and say we do require 24/7 availability but not an average of \$17,000 per year for maintenance on one piece of equipment." To help keep costs down, her integrated delivery network is also driving hard to have preventive maintenance done on a regular basis, just like a car.

Giving physicians more guidelines about test ordering is another piece of the puzzle. "In our world we are looking at care plans that allow a standard approach for a predictive diagnosis. In the past, it was just a gunshot approach of ordering a panel. Now we're educating our physicians to be very specific and order just what tests they need. So our physicians are not involved in what kinds of equipment we use or reagents we purchase to provide them what they need, but they are partnering with us to do the right test at the right time."

Maintaining outreach volumes within a competitive market is a challenge but essential for her network because outreach is the revenue producer. "But we're also looking at lower volume there, because physicians may choose not to use as many tests or may not order them as frequently."

Reimbursement is also unpredictable at best, Ward says. "We have certain estimates of how much total revenue is going to be lost for us, but every day in the literature there are some new changes coming into place." It's not only the Medicare cuts, which will be deep, but the fact that non-Medicare private payers will follow the same logic, she says.

As to the Affordable Care Act, she believes its impact is difficult to predict but that it may be more about insurance reform rather than laboratory or payment reform. "Obamacare will provide care for individuals who weren't able to get it before, but when they get to the EDs they may be pretty sick, not just the average patient coming in for a workup. So that drives up acuity and utilization, and at the end of the day, the payment for all of that is going to be the same."

But there are many unknowns, she agrees. “We’ve all heard in previous years that we need to do more with less, but that used to be something between the administrators and the analysts. Now we have more physician involvement, we have more educated consumers asking questions about charges, and there is just more awareness and much more need for transparency.”

Amid the uncertainty, she confirms that instrument acquisitions are still part of the game plan at her network. “We’re looking for more automated technology in areas where there are lots of manual processes, such as automation in microbiology.” For other instruments, however, “we’re looking at an extended lifespan. The purchasing environment is very competitive. More mergers are taking place among vendors, and we as consumers can take advantage of that by asking for multifaceted contracts, versus one expert area at a time.”

“For instance, if we are looking for instruments in cytogenetics and a vendor there has been purchased by a larger vendor, it’s in our best interests to talk about the entire line of their products we are utilizing, versus negotiating one separate contract at a time. As large a footprint as we have, if we’re in silos the vendors are in silos too. And we can have better price points if we deal on the basis of a package contract.”

At least in health care, the application of Lean principles to hospital and laboratory processes brings improvement, but it also tends to highlight the waste that’s already in the system, Ward points out. “So it can be used as a lever to drive costs down.” That’s one reason why she takes the newest round of cuts and restructuring differently from cyclical ebbs and flows of the past: “Whatever changes we make now, no matter where our journey in the laboratory takes us, will be permanent. They won’t just be containments for a year or two.”

Making instruments last longer is part of the laboratory order set at Alegen Creighton Health, says Sheryl Wilson, MHA, MT, DLM (ASCP), senior director in charge of laboratory services for the Alegen Creighton system, which has six acute-care hospitals, four critical-access hospitals, and an on-site reference lab in the southwest Iowa and Omaha, Neb., areas. About a year and a half ago, Alegen was acquired by the national 78-hospital chain Catholic Health Initiatives, one of the largest chains in the country. “We are now part of a much bigger network and have the opportunity for growth,” Wilson says.

“Alegen Creighton system used to operate pretty independently of CHI, but Nebraska and southwest Iowa are under a single board of directors. The laboratory will likely become a service line across the state, and laboratory services will come under a uniform system approach.” More crucially, capital for acquiring equipment is in short supply. “Just recently, our depreciation schedules were revised. So if we thought we were going to replace something in five or seven years, the message is you might want to rethink that.”

In the past, expectations for depreciation might have been five to seven years for most instruments, maybe 10 or 15 years for refrigerators. “Now, even if the expectation is five years, seven may be used.”

For areas where innovation is less frequent, even a longer time frame is probably in store. “We happen to have Siemens Vista analyzers for chemistry, which is a very robust new platform, and some of our sites have already been on that platform for more than five years. Normally we upgrade or replace in a seven-year time frame, but now it will probably be more like 10. I don’t see anything right now in that arena that is new emerging technology, so those instruments will probably be extended as long as they can be.”

Molecular testing is much more active with a number of different approaches, new tests, and new menus being offered. But for technologies like MALDI-TOF that haven’t been widely adopted yet and are not quite 100 percent proven, Wilson says, new equipment requests won’t necessarily see smooth sailing.

In the past, proposals for new instruments had to go to the hospital president, then the system president, and their fate varied depending on how many hundreds of thousands of dollars were involved. Now the levels of review for different purchase levels have multiplied. “If we were just proposing insourcing and the return-on-investment analysis showed it would be much more efficient and economical to bring it in-house, those were pretty easy. But even those are less frequent these days,” she adds. “You’re competing against other technologies or programs, so

even if it's a positive for the system overall, there's no capital."

The immediate result for her laboratory has been a surge in reagent rentals, says Wilson, noting that that has been the approach for the latest PCR technology and possible new microbiology automation. "In the last six months, we've done more reagent rentals than in the last six years. It's not that management is encouraging it; it's just that if you don't have capital, it's the only thing that makes sense."



Dr. Lifshitz

Other strategies the laboratory is adopting: spending \$25,000 to get an upgrade on an instrument to extend its life, rather than buying the latest model, and buying previously owned equipment. "Going to a used equipment vendor is new to us, but in the last year or two we have purchased two chemistry analyzers and an immunology analyzer, which are both very sophisticated and high-volume instruments, from previous owners."

The projections Wilson is working with show inpatient testing volumes continuing to decline while outreach testing will climb. "That's what we're seeing and what others are seeing across the country. It's been pretty consistent for the last several years."

Dr. Lifshitz, too, says inpatient test volume will continue to decline. But he cautions against jumping to conclusions based on this trend. "The landscape can't be completely defined by the total volume. The volume of billable tests will drop, but there will be pockets of certain tests and panels that will increase, if they lead to quicker diagnoses and better outcomes, and are valuable in lowering overall patient costs." He says some of the new molecular microbiology testing falls into this category, for example, as do certain point-of-care tests.

It's important to remember that the laboratory is a mandatory component of the hospital, which can't function without it, he points out. "What does come into play sometimes are issues of choice. Are you getting the super-duper five-star model or the two-star model? Are you acquiring equipment for a short period while you evaluate further upgrades or options, or are you leasing on a five-year deal?"

Longer depreciation periods would make sense for some instruments, Dr. Lifshitz adds. "We've had equipment in the past that lasted eight or nine years, depending on the maintenance and service schedule. But that works for mature and relatively stable technologies like a cell counter or general chemistry analyzer where there's nothing revolutionary coming around. That's fundamentally a different business than where you have new technologies with higher impact. Those may cost more, but on the flip side, they may change the entire equation in the laboratory."

The nature of utilization is changing, Dr. Lifshitz believes. "Everyone is concerned about the cost of delivery, and here at NYU, we are cutting length of stay and cutting utilization. What I find is that for the first time, everyone in the medical center is aligned with a similar goal, how to 'rightsize' utilization, maybe increasing it for a few new high-value tests but usually decreasing it as part of an overall change in clinical ordering strategies."

But NYU has been successful in its financial management for the past several years, and as the laboratory moves into its new, larger quarters, he doesn't foresee difficulty in acquiring new technology. "It will fit hand in hand with the testing model we want to create—that is, a highly efficient approach."



Dr. Plapp

Farther west, however, projected declines in inpatient testing and some effects of the Affordable Care Act have put Saint Luke's Regional Laboratories, part of Saint Luke's Health System in Kansas City, in a cost-cutting frame of mind, says laboratory medical director Frederick V. Plapp, MD. Another board member of the Compass Group, Dr. Plapp agrees with Stanley Schofield that times are tight. "In our health care system, there was a sudden slump in the first quarter. We had started preparing for it last year and thought we would be ahead of the game. But it's happening faster than we expected." For his nine-hospital system, it means multimillion-dollar cuts.

One source of the problem is lower inpatient volume in general, with more patients being self-pay. "We think this is happening because in response to health care reform, employers are shifting employees into high-deductible insurance plans with higher out-of-pocket expenses." Under health care reform, the hospitals thought there would be more insured patients, but in Kansas and Missouri the state governments have opted not to accept the Medicaid part of health care reform, so the Medicaid-covered population has not expanded as predicted.

That gap has left in limbo some of his laboratory's plans to purchase analyzers in chemistry, hematology, and microbiology. "That money was approved and became available in January, but the hospital administration has not yet released the funds." Dr. Plapp wouldn't call it an emergency. "But we have to find more ways to stretch our budgets further," he says.

Although outreach testing has been a tried-and-true solution for many hospital laboratories hoping to increase testing volumes—and was one of the central reasons the Compass Group was formed—not every laboratory can take advantage of it. At Baylor's North Texas division, Dr. Brown says, "Our hospitals do very little outreach business due to bond restrictions, and thus we cannot pull outreach to fill capacity. This pushes us toward maximizing our productivity and efficiency within our hospitals." Overall hospital test volumes in that division have not changed dramatically over the past several years.

But Dr. Brown believes continuing hospital consolidation and the need for harmonization that it drives will be a major influence on laboratory purchasing. In 2010, Baylor partnered with Texas Oncology, U.S. Oncology (now McKesson), and one of Baylor's pathology groups to form a core laboratory operation in Dallas/Fort Worth called Medfusion. Much of the molecular, flow cytometry, and microbiology testing moved from the hospitals to Medfusion as a result. "Consolidation of that work gives us the ability to invest in newer technologies such as mass spectrometry and next-generation sequencing, and also enhances testing efficiencies and lowers overall episode-of-care cost for us," Dr. Brown says.

Combined with Baylor's recent merger with Scott & White Health, which expanded the health care system to Central Texas, this unification will help push large instrument decisions in future years to include harmonization of testing platforms in coagulation, blood banking, chemistry, and hematology, to allow for a single standard of care, Dr. Brown says. Laboratory information systems are the same in both regions. "So in the near future both divisions will have completely deployed our enterprise Soft Computer LIS. This move will add great efficiencies for the labs," he notes.

While his system does not believe everything must be standardized, "Harmonization of test platforms has many advantages. It produces standard reference ranges, standard reporting, LIS and EHR benefits. And other tangible benefits include standard quality and performance metrics, policies and procedures, system competencies, and training benefits."

Harmonization also, of course, brings tremendous leverage and negotiating power for purchasing. "Within the lab we basically have a combined, 'two-armed' evaluation and negotiating process with all our vendors. We'll have our pathologists involved with the scientific technical assessment to compare the accuracy and precision of each different vendor's instrument. Then, in addition, our lab administrative directors will do usability evaluations, where they take front-line personnel and have them work on a particular platform." Negotiations with instrument manufacturers are collaborative between the laboratory and supply chain, which adds further synergies to the leveraging process, he says.

Dr. Brown believes the industry will continue to consolidate through mergers and acquisitions of hospital and physician groups. He agrees with Baylor Scott & White CEO Joel Allison, who projected in a recent interview that in 10 years there may be only 150 large, integrated health care delivery systems in the nation.

But over the near term, Dr. Brown expects reimbursement changes, some of them draconian, to be one of the most significant factors affecting laboratory purchasing plans. "The recent changes in CMS reimbursement for the 88300-309 series, with a 50 percent cut in one of the highest-volume pathology procedures, and more recently, the IHC G-code changes in anatomic pathology, have had an impact on everyone."

Significant pressures have already been in play through Affordable Care Act cuts, sequestration cuts, bad debt payment cuts, and coding adjustment cuts. "Additional Medicare payment cuts under consideration would affect outpatient hospital, indirect medical education, bad debt payment, and critical-access hospital payment. We are also well aware of proposed CMS changes for 2016, which would limit reimbursement based on amounts being paid to third-party payers. This is going to dramatically reduce the payments for lab services."



Schofield

Stan Schofield believes the promise of reimbursement cuts is the leading factor affecting laboratory purchasing decisions today, but that a larger set of pressures on hospitals must also be taken into account.

Chief among these is declining patient volumes. "2009 was the peak year for all volumes, and nobody has hit those volumes since then," Schofield says. "Across the board, physician office visits are down six percent. Hospital stays are down four to six to eight percent, depending on your locale. And a lot of elective subspecialty areas like gynecology are off 10 percent. More health care systems are moving to tightly controlled and managed operational structures, so all of this is adding up to fewer visits and fewer tests being ordered."

"All hospitals are at a crossroads financially, and that has to translate into capital and capital acquisition," when they need to decide whether to purchase a second robot surgical unit or a second MRI scanner, he points out. In addition, hospitals have been mandated under the federal government's meaningful-use program to upgrade their informatics, so for the past three or four years, everyone has been moving to massive integrated information systems.

"If you're running a lab in a 600-bed hospital, the operating expenses of the laboratory are around \$25 to \$30 million a year. But an information system is around \$150 million. It's probably the largest capital item in any hospital or health care system in this country today, outside of building new hospital structures. So that's where a lot of the demand is and a lot of the money is going." There are federal subsidies for meaningful use, he adds, and labs benefit from those indirectly, but not in a way that helps the lab cover expenses because it's money that goes to the hospital.

Another factor has been new standards for accounting for leased equipment. Under FASB 2013, proposed accounting standards issued by the Financial Accounting Standards Board, leases are now being included as a capital expense, Schofield explains. "Labs have always competed for capital dollars within the hospital, and they probably did OK but not great compared to imaging, oncology, radiation therapy, and IT. Labs were never on top of that competitive capital food chain, so reagent rental deals were created and labs could get new equipment."

"In the past, an asset like an instrument being leased was always listed as an operating expense, and it really didn't go into bond covenants and commitments because it went year to year. But FASB 2013 changed that," Schofield says. Organizations that are in financial difficulty may still use reagent rentals as a means to get equipment, but many labs, hospitals, and health systems adopted the proposed guidelines when they were proposed; most organizations are capitalizing the assets and adding them to the balance sheet. "So now those leases go on the books for five years, they're listed on asset sheets, and they have to be depreciated." The accounting change really shook up laboratories initially, Schofield says. "Suddenly labs have to compete again for those capital dollars to get their chemistry and hematology analyzers."

Purchasing is also shifting away from the old model based on test volume, he points out. "Historically the diagnostic companies counted the number of clicks on an instrument and spread it over a period of time. That's how they determined the value of the deal. But two years ago, large organizations with new computer systems coming online started adopting tighter utilization management, and suddenly the traditional measures of the value of the deal were out of date."

Utilization started dropping for two reasons, he thinks. "One, the health care system is moving to population-based medicine, where the less you do the better off you're going to be financially on a pool of capitated money. And second, computer systems now allow people to define better order sets and set controls that limit doctors from ordering whatever they want. A doctor ordering a \$2,000 assay is probably going to be flagged and questioned." Along with these changes, he adds, the insurance industry has started setting new and higher copays and deductibles for subscribers to their insurance plans.

But more momentous has been Medicare's plans to dramatically cut reimbursement for laboratory tests. A January 2013 report from the HHS Office of the Inspector General concluded that the Centers for Medicare and Medicaid Services could save about 30 percent on laboratory tests by paying rates like those paid by insurance companies—an estimated savings of \$980 million out of the \$8.2 billion Medicare paid for lab tests in 2010.

In response, "the government said over five years we'll take the top 20 tests by volume, 54 percent of Medicare expenditures, and re-price them due to automation and advances in technology," Schofield explains. "That was in part because Quest and LabCorp have been selling tests to commercial insurance companies at Medicare rates minus 25 to 30 percent for years, and the government said 'we want the same deal.'"

After passage of the Protecting Access to Medicare Act in April, the CMS announced it would start paying a blended rate that would reduce payments through a series of 10 percent cuts in the clinical lab fee schedule, with 250 to 300 tests per year being re-priced until over five years there would be 1,250 tests re-priced and re-positioned, Schofield says. "Under the new formula, the government will take all lab work in 2015 and 2016 and take what labs like mine get paid from commercial insurance and blend it into a sustainable growth rate formula. That's what we'll get paid in 2017." But as he sees it, the cuts will compound over the next seven years to shrink laboratory reimbursement even more.

His own laboratories' reimbursement is down about 13 percent in the past 24 months.

"Everybody is watching what's going to be happening with these formulas, and we're expecting a minimum 20 percent reduction in reimbursement. So with reimbursement reduced and utilization being brought under control, people are not going to be running out and trying to do new deals on equipment unless they have more information."

As a result, he predicts that redundancy of equipment will be a luxury. "People who have equipment that is broken

and tired will be replacing it, but in a selective, judicious process, and they aren't going to be committing to any big deals until they know financially what's before us. If your outreach program revenue is going to get cut by 20 to 30 percent, then it may not make sense to run that program, and then you don't need as big a piece of equipment or as many of them. There are a lot of dynamics in play here."

Schofield does not think the diagnostic companies are exactly in sync with these dynamics. "They have commanded a high-cost infrastructure, and we in the labs have been slashing and burning and becoming very efficient. At the meetings, you see an army of salespeople there, but there are very few people with checkbooks trying to do deals. So I think their management costs are way over-inflated given the economics of their customers, the laboratories. And the diagnostic companies need to take a hard look at their offerings and re-size and re-position themselves for the new economics."

In his laboratory purchasing negotiations on behalf of hundreds of hospitals, Schofield has been proceeding with caution. "This past year, we've done some very interesting arrangements around mass spectrometry for microbiology, and we've discussed some small pieces of equipment like centrifuges and blood gas instruments, but we have no massive contracts with firm, hard commitments. All the deals I have set up were pricing proposals without commitments—and certainly no penalties for not hitting certain test volumes."

In short, while purchasing at some labs continues as before, others have been ordered to contract, and at many labs, something more like a holding pattern is evident pending clearer directions on the payment picture. The undiminished hospital consolidation, the momentum generated by the Affordable Care Act, and the continuation of health care as one of the driving forces in the economy are real trends. But the laboratory reimbursement forecast, plus laboratories' position in the competition for funds within the hospital and other constraints on capital, are ensuring that for the time being, uncertainty remains the order of the day.

[hr]

Anne Paxton is a writer in Seattle.