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Vision quest—fresh look at AP automation

Karen Titus

What do pathologists see when they sign out their cases? Peter P. Patterson, MD, MBA, saw the four or five mouse clicks and cursor movements he tapped out for each of the 40 cases that fill a typical day. "My wrist used to get sore after the 10th case," says Dr. Patterson, a senior pathologist at Yuma (Ariz.) Regional Medical Center.

What does 35 years of histotechnology experience look like? Often it comes wrapped in wisdom and know-how. But Jesus Ellin, PA(ASCP), HT(ASCP), has seen a flip side among histotech veterans—reliance on hidebound practices. "I'm guilty of it myself," says Ellin, also of Yuma. Even a mere 10 years in the lab have fossilized his habits. "I do things the same way, keep things in the same place—'My way's the best way.'"

What does a new rapid tissue processor convey? At Holland (Mich.) Hospital, many in the lab saw the instrument as backup to the existing processor. "They said, 'Now we won't have any capacity issues when we run this overnight,'" recalls Edward P. Fody, MD, director of pathology for the hospital. He pictured something else: dispensing with the old MO of overnight processing and early morning embedding/cutting and moving toward continuous flow processing. "We run that thing 24 hours a day."

Longstanding practices are born and die hard for the same good reason: They're usually created by smart people tackling tough problems with what they have on hand. In that sense, nothing has changed in anatomic pathology laboratories, which remain

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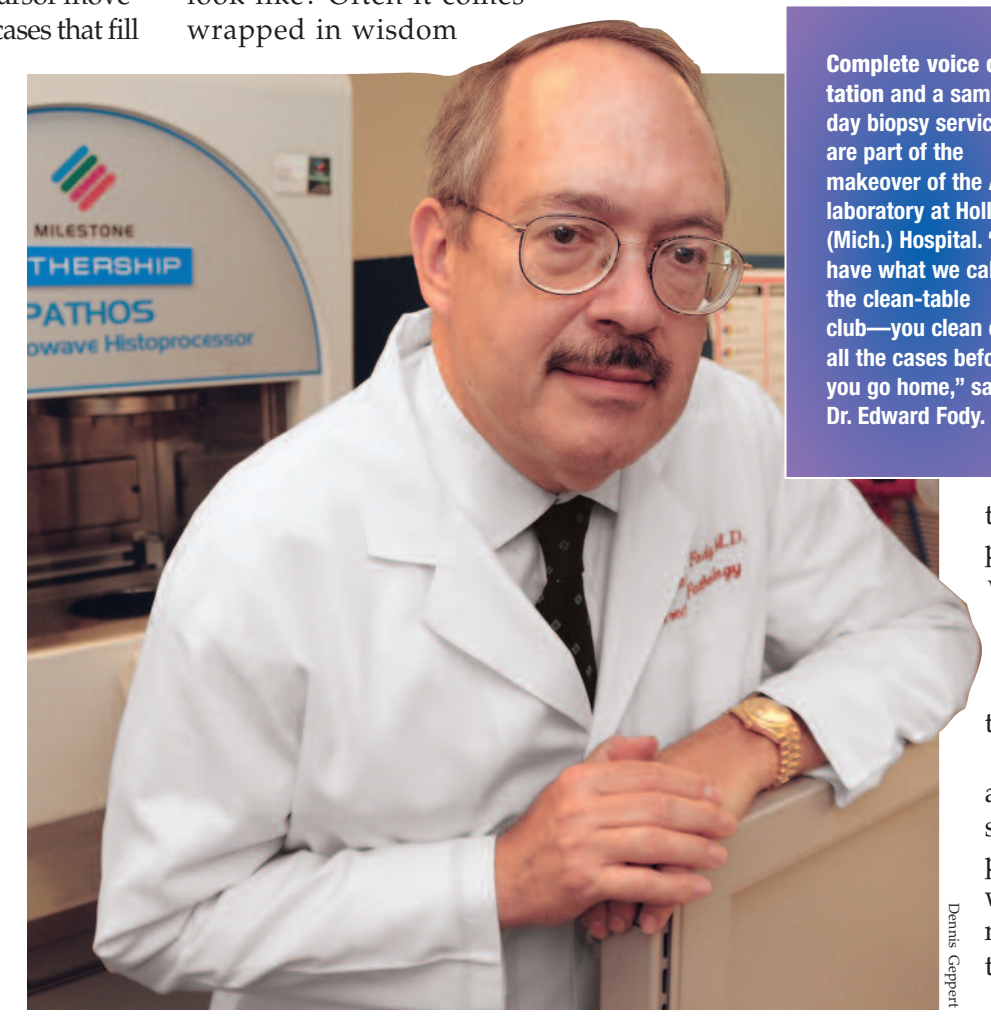

Dennis Geppert

Complete voice dictation and a same-day biopsy service are part of the makeover of the AP laboratory at Holland (Mich.) Hospital. "We have what we call the clean-table club—you clean out all the cases before you go home," says Dr. Edward Fody.

Things heat up for personalized testing

Anne Paxton

There's no question that targeting therapies based on biomarker tests is becoming common practice. Mara G. Aspinall, past president of Genzyme Genetics, Westborough, Mass., calls this new practice of personalized medicine a tremendous opportunity for pathologists. Speaking at the CAP Futurescape conference in Chicago in June, Aspinall said she prefers the term "specific medicine" because it underscores the critical role of precise diagnosis in treating patients effectively.

In hematologic malignancies, for example, "five-year survival has gone from zero to 70 percent, because we have the ability to do not just morphology but fundamental molecular work to get an expanded characteri-

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Wins, worries on reimbursement battlefields

Karen Lusky

All may be fair in love and war, but health care providers do seem to end up with the short end of the payment stick often enough in the tug-of-war with Medicare and other payers over reimbursement. Lately, however, labs and pathologists have scored some victories in the payment arena. But major challenges remain, including ones that create an uneven playing field and threaten patients' access to innovations in testing. The good news is that there's no shortage of ideas and efforts in the lab community to address them.

The latest fight over a tight budget involved the Medicare Improvements for Patients and Providers Act of 2008 (HR 6331), which Congress passed in mid-July by overriding a presidential veto. President Bush reportedly objected to the measure because it tapped Medicare Advantage funding to subsidize physician payment. The legislation reversed a 10.6 percent physician fee cut set to go into effect on July 1, and repealed Part B competitive bidding for labs.

Importantly, the Medicare package repeals not only CMS' legislative directive to do a lab competitive bidding demonstration but also the agency's authority to use the bids

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CMS received in the San Diego demonstration to change the lab fee schedule, says Alan Mertz, president of the American Clinical Laboratory Association. A federal judge in April had granted the laboratory plaintiffs' motion for a preliminary injunction to halt the demo and prevent CMS from releasing the names of the bid winners.


Mertz

Repeal of competitive bidding represented a major, collaborative advocacy effort by the industry, Mertz says. And the "silver lining to the effort," he adds, is that Congress now has a much better understanding of the complexity of lab services. "It's not just a widget that everyone can bid on—it's a service."

Repeal of competitive bidding came at a price, however. It was important for labs to provide some savings for the competitive bidding demonstration repeal, estimated to cost labs $10 million to $20 million over five years, says David Mongillo, ACLA's vice president for policy and medical affairs. Thus, under HR 6331, he says, labs will give up 0.5 percent of the scheduled update over the next five years—$600 million less overall.

Mertz says the lab community reached a "unanimous consensus" that the $600 million was worth it because labs hadn't had an update except for one year out of the last 10. "So the fact we are getting a 1.5 percent update or more if inflation is higher is quite a win. . . ." For 2009, in fact, the inflation adjustment will result in labs getting about a 4.5 percent update, Mertz noted in a July 23 ACLA-sponsored LabLine audioconference on the Medicare legislation.

Moreover, allowing competitive bidding to move ahead would have ultimately cost the lab industry a lot more than the $10 to $20 million cited by the bill, Mertz adds. For example, the estimated cost to repeal competitive bidding for durable medical equipment for one year is $1 billion, and to delay it for five years, $6 billion. "The cost of repealing it entirely is far more than that."


Mongillo

"So yes," for labs, "$600 million is well worth it."

Reimbursement specialist Charles Root, PhD, president of CodeMap Inc., Barrington, Ill., thinks labs would have accepted a two to three percent cut two years ago to get rid of competitive bidding. He observes that it sometimes seems "CMS proposes something that's so cumbersome and costly to an industry that the industry will say, 'Yes, instead, I will just take a cut.'"

While the sentiment in the lab industry is "Ding! Dong! Competitive bidding is dead," not everyone sees the issue as that black and white—or finished.

Known to stir the pot on the issue, consultant Joe Plandowski favored Medicare competitive bidding for labs as a potential corrective measure, albeit a rough one, for an industry in which "you have United Healthcare buying clinical pathology tests for less than half of what Medicare is paying to buy the same test," which isn't fair, in his view.

"If I were running Medicare, there's no way I'd put up with that," says Plandowski, president, Lakewood Consulting Group, Lake Forest, Ill. "I'd simply require a most-favored-nation clause installed which says I get the lowest price you give everyone else. The problem with that is the paperwork nightmare." But if Medicare competitive bidding occurred, Medicare fees would go down, "and for labs to survive, all of the non-Medicare fees will have to go up. It'd be turmoil for two to three years until labs readjusted the market to what's proper payment for all parties."

Some think Medicare competitive bidding could creep back if the lab community isn't vigilant. In investigating the origins and history of lab competitive bidding at CMS, *Dark Report* executive editor Robert Michel found that its roots in the agency extend back almost 25 years. Thus, it seems reasonable to assume, Michel says, that one or more individuals in the CMS, Congress, or both have a personal agenda to make competitive bidding a reality and could resurrect it in the future.

Technically, CMS has broad demonstration authority under the Medicare law to do demonstrations, according to attorney Peter Kazon, who spoke at the ACLA audioconference on the Medicare legislation. And in the past when CMS was talking about doing a demonstration before the Medicare Modernization Act in 2003 authorized it, the agency was doing so under its broad demonstration authority, he says. "But we all think that would be a fairly foolish thing" for CMS to do a competitive bidding demo on its own now that Congress has repealed competitive bidding. Both Congress and the laboratory industry would likely raise "some fairly strong objections," says Kazon, of Alston & Bird LLP, Washington, DC.

With Medicare competitive bidding crossed off the list of most pressing payment concerns for now, many in the lab industry are turning to another competitive threat: the anti-markup rules for anatomic pathology services.

CMS' anti-markup rules, which went into effect this year, stripped the profit incentive from operating so-called pod or condo labs. But the rules still allow non-pathology specialties to put labs in their own offices and mark up AP services, says attorney Jane Pine Wood, who presented on the anti-markup rules and other reimbursement and regulatory issues at the 2008 Executive War College sponsored by *The Dark Report*.


Wood

The way the anti-markup rules work now, if a pathologist interprets an 88305 on site for a urology group, for example, the group could pay the pathologist less than the full Medicare allowable and then bill Medicare for the full amount, says Wood, of McDonald Hopkins LLC, Dennis, Mass. So "obviously there's an incentive for the specialist to pay the pathologist less in order for the specialist to make more."

And the question, says attorney Kazon, is whether CMS will continue to allow that sort of practice. "Many people today would point out that allowing specialists to obtain pathology services at a reduced price and then bill to Medicare at full price was never the intention of the ancillary service exception under the Stark law, on which many of

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December

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Volunteer pathologists needed in Ghana

Pathologists Overseas, a nonprofit organization dedicated to introducing or improving pathology and lab services in developing countries, is initiating a project at the Komfo Anokye Teaching Hospital in Kumasi, Ghana. Volunteer pathologists are needed to staff the histopathology laboratory and to train two local physicians as surgical pathologists. Assignments are for one-month periods throughout the year. Local housing is provided; volunteers are responsible for air travel and local living expenses. Contact Thomas Coppin, MD, for more information: coppin_thomas@hotmail.com.

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these arrangements rely," he says.

CMS' proposed physician fee schedule update for calendar year 2009 published in June includes proposed modifications to the anti-markup rules that would make it harder for non-pathology specialists to profit from AP services provided in their own offices.

Wood notes that CMS is asking for comments on one proposal that would prohibit a markup on any Medicare service provided or supervised by a physician who works for more than one practice. The proposed change would mean that physician groups that hired a part-time pathologist to do the AP work who also worked for a pathology group couldn't mark up AP services.

CMS is only fielding that proposal for feedback at this point. "Presumably," Wood says, "the agency would publish the proposed regulatory text and then have a comment period on the proposed text," which means "we are some time from this being implemented, if it is."

One proposed provision that could end up in this year's final physician fee rule, however, would require pathologists to provide on-site supervision of technologists performing the technical component of AP services in physicians' offices, Wood says. "The provision is a little confusing in terms of how it would apply to AP because some of the AP technical component services don't require CLIA certification," she notes. But "CLIA does not permit a urologist or GI specialist to supervise technologists for CLIA-covered services, so a pathologist would be required to supervise such services on site."

If CMS' proposals were implemented, only the large specialist groups with the volume to hire a full-time pathologist would be able to mark up AP services, Wood predicts. "A GI group, for example, would have to really pay the pathologist a decent salary with benefits and maybe put the person on a partnership track." And Wood finds that approach sits well with some of her multispecialty physician group clients. It "fits their philosophy because they are offering lab and imaging and want the pathologist to be an equally valued member of their practice group."

Private payer contracts have generally been silent on the markup issue, Wood says, but that appears to be changing. "The new United Healthcare standard contract says that a group cannot bill for lab services for which it does not have a CLIA certification," though the contract language arguably applies only to clinical laboratory testing, Wood notes. "The payers are starting to take notice, but they will probably wait for Medicare's lead on the issue. If CMS adopts the proposals, I'd expect that within a year or two, we'd see a lot of private payers jumping onboard."

In her War College presentation, Wood also noted that about 20 to 25 states have laws prohibiting or restricting account billing, which is defined as selling the technical or professional component of an AP service to the referring physician at a discount so the physician can bill it at a markup. Each law "is a little different as some apply only to the professional component, whereas others apply to the technical component. Still others require some disclosure of the markup to the payer and patient," she explains. Wood predicts states will clamp down more on this issue but will wait to see what the federal government is going to do.

> For HER2 testing, $98 is considered to be a 'nice price, but when you look at the bigger picture in terms of its impact, it's kind of ridiculous.'
>
> **Charles Root, PhD**

The "big elephant" in the lab industry, in the view of Plandowski, is the issue of what's going to happen with the Medicare physician fee schedule. Even with Congress stepping in and reversing the damage with the proposed but averted 10.6 percent cut, the trend is a steady downturn, he says. And "the problem is that all other payers follow Medicare, which makes it even uglier."

The Medicare legislation passed in July provides an 18-month fix for physician payment, halting what was going to be a 10.6 percent cut for 2008 and providing a 1.1 percent increase for 2009, said Denise Bell, CAP director of federal legislative affairs, in the ACLA's July 23 audioconference on the bill. "And that 1.1 percent increase does replace what was predicted to be a 5.4 percent cut for 2009," Bell said.

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> "CMS and HHS are agencies full of bright people who will continue to be challenged to find ways to reduce health care costs."
>
> **Louis Wright Jr., MD**

Padget

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Dennis Padget, MBA, CPA, FHFMA, president and founder of DLPadget Enterprises Inc., Simpsonville, Ky., says the legislation provides "yet another override of the impact of the 1997 sustainable growth rate [SGR] law," with Congress failing to correct the deficiencies in the SGR formula.

At some point, Congress will have to think about a permanent fix, Bell said, which is quite costly. And it's "anyone's guess what's going to be on the table to pay for a permanent solution," she said. "We may even see physician specialties competing with other physician specialties for dollars as [Congress] looks toward a more permanent remedy."

The issue, Bell said, "is going to continue to be a big-ticket item for the physician community," including the CAP.

As for payment of clinical laboratory services under Medicare Part B, ACLA's Mertz sees a "large issue brewing about whether the entire clinical lab fee schedule is due for reform." He notes that the fee schedule, which was essentially established in 1984, has been changed only a little since then—"mostly cut." And there is pressure and interest within the lab community and on Capitol Hill to revisit it, he says.

The U.S. Department of Health and Human Services' Office of Inspector General 2008 work plan, in fact, calls for a study looking at the pricing of clinical laboratory tests paid by Medicare. According to the work plan, the OIG will review Medicare payment rates for certain laboratory tests, comparing them with other federal, state, and private plan payment rates. OIG will also "determine the extent of variation in payment rates among contractors." The OIG notes that its previous work showed that Medicare paid "significantly higher prices than other payers for certain laboratory tests." The report is scheduled to come out in fiscal 2009, says OIG spokesman Donald White.

Vince Stine, director of government affairs at the American Association for Clinical Chemistry, says the OIG, in doing the study, has "pretty much made the rounds in talking to the lab groups." And during AACC's conference call with the OIG, Stine didn't get the impression that the OIG is being told to target a particular issue. He says, "They did ask about variation in payments among different Medicare contractors and whether that was hurting patient access. It was more of an open-ended discussion to identify areas that they should be looking at. It wasn't clear where it will ultimately go."

CodeMap's Dr. Root, who was on the conference call with the OIG and AACC, agrees there's a consensus building on the need to do something to straighten out the lab fee schedule. He thinks it would be "an easy fix to bring up the lab pricing to the national limitation amount," which is the maximum amount Medicare will pay for a test, "and probably fairly noncontroversial. Doing so would help certain tests in certain states," where reimbursement is very low, he says.

The fee schedule is not favorable to new technology, he adds. "We are working with antiquated codes," which reflects the fee schedule's inability to recognize the value of an in vitro diagnostic test in terms of pricing and payment, he says. "The rule of thumb is that for most new codes granted, Medicare prices them within $16 to $25. We have worked it up where we can get $48 for things like BNP." Thus, $98 for HER2 testing is considered to be a "nice price," he says. "But when you look at the bigger picture in terms of its impact, it's kind of ridiculous," given the expense of the Herceptin treatment.

Companies with laboratory-developed, unique tests can negotiate for higher payment with Medicare and key private payers in their locality. But Dr. Root is hearing from Medicare medical directors that resistance to the approach is beginning to appear, mainly owing to the amount of money being spent. "Thus, this may not be a viable—or at least not as easy—

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strategy for new companies entering the marketplace. Dramatic downstream savings may be required to make it work."

Meanwhile, laboratory companies with proprietary molecular technology are taking a hit from Medicare date-of-service and bundling rules that are affecting their ability to get paid in some cases for followup testing on hospital-obtained specimens.

As attorney Kazon explains, CMS' bundling rules require the hospital to bill Medicare for testing done for a hospital patient. Under Medicare rules, the date of service for a lab test is the date the specimen was collected. Therefore, if testing is done on a specimen taken when a patient was a hospital inpatient or outpatient, the date of service for any testing done on that sample will be the date the patient was in the hospital. Therefore, CMS considers that testing done on a hospital patient, even if the patient has long since left the hospital when the service is actually ordered or provided.

"Thus, when the physician orders additional testing on a biopsy or blood specimen taken when the person was in the hospital, the date of service is the date it was collected, which, according to CMS, makes the hospital responsible for billing for the testing, even if the patient is not in the hospital at the time the service is ordered. The one exception is where the service is ordered 14 or more days after the patient has left the hospital."

CMS established this "14-day rule" in its 2007 physician fee schedule rule. At that time, CMS clarified that the date of service for testing on these specimens must be the date the test/service is performed (and hence billed directly by an independent lab to Medicare rather than the hospital) if:

- The patient's physician ordered the test/service at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure (inpatient or outpatient);
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test/service do not guide treatment provided during the hospital stay.

In the case of a chemotherapy sensitivity test/service performed on live tissue, the date of service of the test/service must be the date the test/service was performed only if the decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge (and all of the aforementioned criteria are met), according to CMS.

CMS' clarifications heightened awareness among independent labs and hospitals about who needed to be paying for what and when. When the rule came out, Genomic Health, which developed and sells Oncotype Dx, a prognostic test for hormone-responsive breast cancer, immediately asked CMS if the bundling rules applied to its test for outpatient- and inpatient hospital-obtained breast biopsies when the date of service determined under the rule related back to outpatient and inpatient breast biopsies.

Popovits

"The informal answer we received from CMS is that, yes, the rules do apply to our test in both settings," reports Kimberly Popovits, president and COO of Genomic Health.

Genomic Health bills Oncotype Dx using an unlisted procedure code under the clinical lab fee schedule. "What makes it complicated is that the local Medicare contractor in California, to whom we submit claims when our laboratory bills Medicare for the test, developed a payment rate for the test using the unlisted code," Popovits says.

And "if hospitals have to pay for our services, then the hospital has to bill its own FI for the test," which puts Genomic Health in the situation of going to some 30 FIs to explain that Medicare agreed on a certain payment rate when it covered the test, she adds.

Oncotype Dx lists for $3,820. "Our list price when Medicare assigned a payment rate for the test was $3,460, so it is lower than today's list price," Popovits says.

RedPath Integrated Pathology has also found that its PathFinderTG cancer test, approved for reimbursement by Medicare in 2007, is being seriously affected by the date-of-service and bundling rules. The test's leading ap-

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plication is to diagnose indeterminate cases of pancreatic cancer accurately, though it can also be used to provide diagnostic and prognostic information for other cancers. In one small study at the University of Michigan, the test was able to reduce the number of pancreatectomies and Whipple procedures on benign pancreatic conditions by 66 percent, says Mary Del Brady, president and CEO of the company.


Brady

But in one month, January of this year, hospitals across the country canceled 66 percent of the Medicare cases that either were sent or intended to be sent to RedPath when they found out that they would be responsible for the cost of the test, Brady says.

Like Oncotype Dx, PathFinderTG is a high-dollar test. "PathFinderTG is $4,000 to $4,500, with Medicare Part B [paying] at a lower but favorable rate when we can bill it," she says. "Private payers don't have the 14-day rule. But Medicare currently comprises about 45 percent of our payer mix."

And RedPath finds that hospitals are denying or delaying access to the testing for all their patients in an effort to comply with the need to provide the same level of service "or not" to all patients, Brady says.

XDx has had a similar experience with its AlloMap molecular expression testing to identify acute cellular rejection in heart transplantation. There have been instances, says Pierre Cassigneul, president and CEO of the company, of transplant centers no longer being able to offer the noninvasive method to identify patients who have a low probability of moderate/severe rejection.

Thus, concludes RedPath's Brady, the rule's impact could "very well put small, highly specialized laboratories, with the latest technology and the highest promise, either out of business or years away from productivity."

ACLA's Mongillo reports that ACLA is trying to get the date-of-service payment issue remedied administratively through CMS, "and barring that, looking to Congress to fix it."

There may be light at the end of the payment tunnel for expensive new molecular technology. And that will be when payers see the light about how powerful it is and how it can ultimately save health care dollars, in the view of Louis D. Wright Jr., MD, a member of the CAP Board of Governors and chair of the CAP Personalized Healthcare Committee. Until then, however, he predicts an "enormous amount of pushback from payers" about the testing.

"One thing that exemplifies the whole genomic effort is warfarin," he says, noting that some people are "so sensitive to the drug that you can wave warfarin in front of their face and they start to bleed." And the inability to identify those overreactors costs society more than a billion dollars annually in mortality and morbidity, Dr. Wright says. "Now we know having at least two bad-boy genes causes people to overreact to warfarin. Fortunately, work is underway to identify how to turn off those rogue genes, and we have testing to predict more effectively how to treat someone so they don't bleed excessively."

As for payment for pathologists' growing role in molecular-testing–driven health care, Dr. Wright notes that the CAP's Council on Government and Professional Affairs is constantly evaluating the reimbursement climate for pathologists. And "we have been pushing them to think outside the traditional CPT box because there are other ways to get reimbursed." For example, the evaluation and management codes that clinicians use provide opportunities for pathologists to bill for assessing and monitoring patients for personalized medicine based on molecular and genetic testing outcomes, he points out.


Dr. Wright

"Competitive bidding got slapped down," he says, which "I think is just another one of the government's initiatives to try to figure out how to control costs—and it won't be the last. CMS and HHS are agencies full of bright people who will continue to be challenged to find ways to reduce health care costs. In fact, HHS' initiative on personalized health care, which is what the new sciences of genetics and molecular medicine really deal with, is a long-term initiative that the agency believes will truly reduce health care costs while substantially improving care."

CAP governor and pathologist James Robb, MD, a consultant to the National Cancer Institute, notes that the HHS secretary has initiated the Critical Path Initiative at the Food and Drug Administration, a fast-track initiative for new drugs and the tests that will identify the patients who will benefit from those drugs.


Dr. Robb

The NCI's Office of Biorepositories and Biospecimen Research where Dr. Robb consults is leading the effort to develop evidence-based biospecimen best-practice protocols for quality biospecimen annotation, collection, processing, and storage. "We are cooperating with CAP's Council on Scientific Affairs to develop these protocols," which are for cancer but will apply to all human disease, he says. (See story in CAP TODAY next month for more detail.)

"NCI's intramural and extramural researchers are developing new test systems that are just mind-boggling" but depend on high-quality biospecimens. He predicts, in fact, that "the spigot will open for new clinically validated molecular array tests in about two to five years if high-quality biospecimen collection protocols are rapidly adopted."

"Money," says Dr. Wright, "is a very, very important issue in this new science. People don't want to do things they aren't going to be paid for—that's human nature, and it doesn't mean they are bad people. So it's a challenge, and financial reward is always at the front of the line, but it's important to focus on the very real theme of hope and opportunity posed" by what's coming with the evolution of genetics and molecular science.

Industry veteran Dennis Padget puts the ongoing reimbursement struggles facing the lab industry in perspective when he points out that over the years, there always seems to be a reimbursement crisis, "and we always find a way to survive.

"Life goes on," he says. □

Karen Lusky is a writer in Brentwood, Tenn.