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Rx Drug Safety

FDA BEEFS UP NSAID WARNINGS, PULLS BEXTRA

The Food and Drug Administration said April 7 it had requested that Pfizer Inc. voluntarily withdraw its painkiller Bextra from the market, and that the drugmaker had agreed to suspend sales and marketing of the so-called Cox-2 inhibitor in the United States "pending further discussions with FDA officials."

The agency also called on the manufacturers of 19 other prescription "non-steroidal anti-inflammatory drugs" to include the strongest possible "boxed" safety warnings, stating that use of the drugs could increase the risk of heart attack, stroke, and gastrointestinal bleeding. The warning will be carried — both on packaging inserts and medication guides that each patient will receive — by Pfizer's Celebrex, which will be the only Cox-2 specific NSAID remaining on the market, as well as older "non-selective" NSAIDs such as naproxen.

The FDA singled out Bextra for removal from the market because it offers only the same risks and benefits as other prescription NSAIDs, except that it carries a uniquely high risk of rare but potentially lethal skin conditions, said Steven Galson, acting director of the FDA's Office of New Drugs, in a media briefing. In February, an FDA advisory committee recommended allowing Bextra to remain on the market, but by a narrow 17-13 vote.

Galson said over-the-counter NSAIDs will also carry increased information about potential risks, but in general these drugs

continued, page 2

Inside this week ...

Does This Class Have Class Rankings?.....2

Medicare Advantage Plans To Get 4.8-Percent 2006 Pay Hike.....2

CMS Seasoned Staff Going, Going, Gone?.....3

And What About Those Fraud Fighters?.....3

Zerhouni: NIH Stockholding Rule Will Get A Second Look.....4

Murray, Clinton Will Put Hold On Crawford.....5

AMA: Seniors Will Lose Access To Physicians.....5

Specialists Nix Imaging Standards...6

In Medicine & Health Perspectives this week ...

THE BAD NEWS: UNLESS MEDICAL PRACTICE IS REENGINEERED, I.T. WON'T HELP

Hoping that clinical information technology will help solve a host of health care's quality and safety problems? Not so fast, said many experts at an April 5 Washington forum convened by the National Institute for Health Care Management.

Not only is U.S. medicine dominated by small physician practices that face severe challenges to adopting clinical IT, but the whole process of switching to computerized health care runs the risk of merely "digitizing dysfunctional systems," said one physician attendee at the forum to discuss the relationship between workflow in physician offices and IT implementation.

• **Small doc practices' road to IT is "fraught with peril," says federal computer czar.** One key fact is already clear: It's been hard for even large institutions like hospitals and large physician groups to incorporate electronic health records, computerized prescribing, and other IT applications into their practice. And it is harder still for small clinics and physician practices. The rate at which medical organizations try and ultimately fail to implement clinical IT systems is currently cited at around 40 percent, a particularly striking proportion, given that the lion's share of health-care organizations have not yet even attempted implementation.

What's also clear, however, is the health system can ill afford to have small-group practices fall far behind in IT, said forum participants.

For one thing, "a huge proportion of care provided to Medicare beneficiaries is provided in very small units," said Agency for Healthcare Research and Quality chief Carolyn Clancy, MD.

Perspectives continued, page 7

continued from page 1

“are not a problem” as long as consumers take them at the recommended dose and for the recommended, generally short duration

The FDA’s announcements marked a continuation in its review of NSAIDs that began last year when Merck and Co. was forced to withdraw its Cox-2 inhibitor Vioxx from the market. Galson told reporters that the latest NSAID announcements “are unlikely to be the last.” He said, “Clinical investigations continue, and in our new spirit of keeping the public informed earlier on drug safety issues, ... we may be providing further modifications as new information comes to light.”

The FDA’s “new spirit” and aggressive action won some qualified praise on Capitol Hill, but calls for a more independent office of drug safety and more transparency regarding clinical trials will surely continue. For instance, Senate Finance Committee Chair Chuck Grassley (R-IA) said, “It will be good news if today’s action, which goes further than the recommendations of the FDA’s advisory panel, is a turning point ... Otherwise today’s action may raise more questions than it answers for patients and their doctors.”

Grassley, who championed an FDA whistleblower on the dangers of Vioxx, lamented that “FDA officials repeatedly say that Vioxx was handled properly, and they would act no differently today. It’s hard to see how this squares with suspending the sale of Bextra and increasing the warning level for Celebrex.”

DOES THIS CLASS HAVE CLASS RANKINGS?

Some of the outside experts on the FDA’s NSAID advisory panel suggested that different NSAIDs pose different cardiovascular risks, with the Cox-2’s perhaps on the more dangerous end and naproxen (which is sold under the brand name Aleve) perhaps even giving some protection against cardiovascular ills. On this issue, Galson acknowledged, “There is a lot of data, and a lot of the data conflicts.”

In the end, though, “the conclusion that we’ve come up with is that the cardiovascular risks of these drugs are what we consider a class effect. There may be slight differences between the drugs, or even larger differences,” said Galson, “but we don’t have enough data to really rank-order these drugs by risk.”

However, Alistair Wood, MD, who chaired the advisory panel, offered a different bottom line. Wood told the *New York Times* that Celebrex posed particularly clear cardiovascular risks and that physicians and patients should turn to it only as a last resort. “By labeling everything, you might be trivializing the label

on Celebrex,” said Wood, a professor of medicine and pharmacology and associate dean at Vanderbilt.

Medicare Private Plans

MEDICARE ADVANTAGE PLANS TO GET 4.8-PERCENT 2006 PAY HIKE

Medicare Advantage private health plans will get a 4.8-percent per capita payment increase for 2006, the Centers for Medicare and Medicaid Services announced April 4. That’s down from the 6.6-percent boost plans got for 2005 and the 10.6-percent update they received in 2004.

Next year, a new crop of MA plans — preferred provider organizations serving much larger regions, including multi-state areas — will enter Medicare in numbers that are as yet unknown. But 2005 has seen a hefty boost in applications to serve Medicare as “local” plans, which operate on a county-by-county basis. The relatively generous recent annual pay boosts and increased responsiveness by federal regulators to health plans’ concerns are credited with the sector’s growth.

In 2005, more than 130 new MA plans have begun serving beneficiaries, “including 50 organizations completely new to the Medicare program,” according to CMS. Another 96 current participants plan to enlarge their service areas this year.

MA plans are “not just in the big cities any more,” said Administrator Mark McClellan at an April 5 hearing before a Senate Homeland Security and Government Reform subcommittee. “Three-fourths of rural beneficiaries will have access to a Medicare Advantage plan” — including so-called private fee-for-service plans — and “one-third of rural beneficiaries will have access to a coordinated care plan,” an “unprecedented” proportion, according to CMS.

Some plans will get more than a 4.8 percent pay hike next year. Seventy-five percent of plans’ MA payments will be adjusted for patient risk in 2006, up from 50 percent in 2005. This means that plans enrolling sicker beneficiaries should have an easier time remaining as financially strong as plans with healthier populations.

“We are concentrating Medicare’s payments to reward plans that help beneficiaries with complex medical problems prevent complications, through greater access to prescription drugs and care-coordination services,” said Administrator Mark McClellan in a statement. Plan payments will be 100-percent risk-adjusted in 2007.

In a December analysis, Mathematica Policy Research scholars Lori Achman and Marsha Gold examined the use MA plans made of the enhanced payments Congress has granted them over the past two years as lawmakers attempt to stabilize and expand the program.

Among their findings: Average monthly premiums dropped from \$34 to \$25, and plans slowed what had been a large-scale shift to generic-only drug coverage.

In addition, average out-of-pocket costs declined. For example, the percentage of enrollees who paid more than \$15 for a primary-care physician visit was cut in half — from 22 percent to 11 percent — between January and March 2004. Overall, healthy beneficiaries got more OOP-cost relief than sicker enrollees, Achman and Gold say.

Medicare Administration

CMS SEASONED STAFF GOING, GOING, GONE?

In a year of budget stringency like this one, it may not mean much in the end. But some Capitol Hill lawmakers have begun sounding alarms about the potential pitfalls of trying to administer the new, more complicated Medicare program that launches in 2006 with Medicare's traditionally low administrative funding and an aging workforce that could bolt for the doors at any time.

"Having the right people at [the Centers for Medicare and Medicaid Services] is key to the successful implementation of the program," said Sen. George Voinovich (R-OH) at an April 5 hearing of the Homeland Security and Governmental Affairs management-oversight subcommittee he chairs. "Even before passage of the Medicare Modernization Act, CMS was coping with administrative challenges."

Voinovich cited a National Academy of Social Insurance report that pointed out the administrative-funding gap at CMS. Between 1992 and 2002, Medicare benefit outlays grew by 97 percent and claims by 50 percent, according to NASI. At the same time, program-management funds increased by only 26 percent while the number of "authorized full-time equivalent" staff positions grew by 12 percent.

"Currently, 18 percent of CMS' workforce is eligible to retire," Voinovich noted in his opening hearing statement. And "the number is significantly higher, 30 percent, in its career Senior Executive Service." SES was established by Congress in 1978 as an elite executive corps to serve in key federal positions just below top presidential appointees.

Over the past three years, "CMS has lost a quarter of its career executives to retirement," Voinovich went on. "If that does not seem like a daunting challenge, 46 percent of the existing CMS workforce will be eligible for regular retirement by 2009."

CMS is keenly aware of its staffing challenges, and has committed itself to hiring 400 new employees who will primarily focus on the

multiple facets of MMA implementation, Administrator Mark McClellan told the Senate subpanel.

So far, 345 of those workers have been brought on board, including 20 people at top executive levels. Expertise of the new staff includes health-information infrastructure and drug-information services. Fifteen of the 345 new hires have backgrounds in pharmacy or pharmacy benefit management, according to McClellan's testimony. Other new staff include a former state pharmacy board president and the senior medical director from a Blue Cross Blue Shield health plan that has implemented a quality-based payment system for providers.

CMS is one of several federal agencies working with the non-profit Partnership for Public Service to retool its hiring and worker-management processes for tough challenges ahead, said Partnership Vice President Marcia Marsh. Not only are many current CMS staff on the verge of retirement, but "there is a very thin pipeline of talent waiting in the wings to replace the skilled and experienced workers who will walk out the door," she testified.

The approximately 500 total new hires CMS has contemplated acquiring for the MMA-implementation push would constitute about 10 percent of the agency's total workforce and would "double their normal annual hiring," Marsh said.

AND WHAT ABOUT THOSE FRAUD FIGHTERS?

To help out with MMA implementation, CMS also is moving some existing staff into different agency roles. Recently, some of those redeployments raised eyebrows among attorneys and advocacy groups concerned with Medicare fraud.

Kimberly Brant, who directs the program-integrity group in CMS' office of financial management, said in a speech to a pharmaceutical compliance conference in Philadelphia April 1 that **95 CMS regional staffers are being redeployed to act as "relationship managers" for MMA implementation, Los Angeles attorney Mark Kleiman tells M&H. Questioned by audience members, including Kleiman, after the speech, Brant indicated that "almost all" the redeployed workers will come from CMS' "benefit integrity" — read, anti-fraud — staff, Kleiman says.**

Benefit-integrity staff's primary responsibility is to reduce Medicare fraud and abuse by providers and suppliers, by identifying and pursuing cases of suspected fraud, according to documents from CMS and its contractors.

With the amount of new money and new, untried business arrangements that will pour into and out of Medicare when the MMA launches next year, the shift of benefit-integrity staff to other duties is "pretty bleeping amaz-

ing,” says Kleiman. **“The smart money is that there will be new opportunities for fraud” — many of them likely as yet unforeseen — under the new MMA programs. So “people who are watching the money are heartbroken about this,” he says.**

“Relationship manager” is a term of art in contract management denoting a worker who facilitates and maintains smooth communications and manages dispute resolution processes between a contracting entity and its vendors. MMA will not only add new organizations to those that CMS ordinarily works with but will add new dimensions to reimbursement and other regulations involving traditional Medicare participants such as skilled nursing facilities. Brant explained that among CMS’ regional staff, benefit-integrity officers have the most sophisticated knowledge of Medicare’s multi-faceted reimbursement and contracting arrangements and thus are best suited to the touchy diplomatic tasks of relationship management, Kleiman says.

CMS confirms that regional staff are being deployed into new, relationship-management spots but not that the lion’s share of the redeployments involve benefit-integrity units. “The staff doing outreach is coming from all program areas in the regions, not just the benefit-integrity area,” says an e-mail from agency spokesperson Peter Ashkenaz.

NIH Conflicts of Interest

ZERHOUNI: STOCKHOLDING RULE WILL GET A SECOND LOOK

After demanding last year that the National Institutes of Health crack down on potential conflicts of interest involving its scientists’ finances and outside consulting work, lawmakers are having second thoughts about the very tough rules that emerged from the Department of Health and Human Services’ Office of Ethics earlier this year.

Under the new provisions, many NIH scientists would not be permitted to hold stock in biotechnology, drug, chemical, or medical-device companies and also would be banned from much consulting work, not only with private companies but with universities and professional groups. The rules, scheduled to become final this month, also “limit the families of all other NIH employees, including secretaries, food handlers, elevator operators, lab technicians, electricians and others — employees who clearly cannot have relevant conflicts of interest — from holding more than \$15,000 in equity in these companies,” restrictions that seem “unlinked to preventing conflicts of interest,” writes the Assembly of Scientists, a group representing senior NIH researchers.

Under questioning from lawmakers at a Senate Appropriations subpanel hearing April 6, NIH Director Elias Zerhouni, MD, said that HHS will rethink the stock-divestiture portion.

This provision is “one that we have to re-evaluate very quickly,” said Zerhouni, who’s already heard from some top researchers that they may leave the agency or not join its staff because of the stock-holding ban.

Potential defectors include James Battey, MD, director of the National Institute on Deafness, an NIH scientist for more than two decades who is a former chair of NIH’s human stem-cell task force. Battey has said he’s more than likely to retire later this year because stock holdings in a family trust he manages put him in conflict with the rule; he’s applied for a top position with California’s new stem-cell research organization, the Institute of Regenerative Medicine. However, Battey has also indicated that revisions to the conflict-of-interest regulation could change his mind about leaving his federal post.

Chair Arlen Specter (R-PA) and top-ranking Democrat Tom Harkin (D-IA) told Zerhouni that they’re concerned about a potential scientific brain drain because of the rule. It “must be revised ... before you lose too many people,” said Harkin.

Zerhouni defended the tough provisions against most external consulting work by NIH scientists, saying that he thinks those provisions should stand until NIH has systems in place to do much more detailed monitoring of its scientists’ outside activities.

But he said that HHS has always intended that the rule be tested on the ground before becoming final and that he’s confident that some changes will be made, especially in the stock-divestiture portions. The regulation’s “philosophy ... is in my view, one that would be more appropriate for a regulatory agency rather than a scientific agency,” he said.

Specter also had asked NIH institute directors to write to the subcommittee about whether the Bush administration’s strict limitations on funding embryonic stem-cell research are slowing medical progress and risking NIH’s previously unquestioned position as biomedical science’s premier research institution. Several scientists wrote that they share Specter’s concerns.

Progress by NIH-funded scientists “has been delayed” because of the limited number of stem-cell lines they are permitted to use for research, wrote Elizabeth Nabel, MD, director of the National Heart, Lung, and Blood Institute. “The NIH has ceded leadership in this field to the new California agency.”

Zerhouni declined to criticize President Bush’s policy of funding research using only 22 stem-cell sources, but he clearly implied that his private view differs from Bush’s. Asked by Specter what ethical purpose is served by disallowing research on excess embryos in fertility clinics that ultimately will be thrown away, Zerhouni answered, “I think you have to ask that of those who hold that view.”

Congress plans to take up the issue of expanding funding for embryonic stem-cell research sometime this summer.

Emergency Contraception

MURRAY, CLINTON WILL PUT HOLD ON CRAWFORD

Democratic senators Patty Murray (WA) and Hillary Clinton (NY) intend to place a “hold” on President Bush’s nomination of Lester Crawford to head the Food and Drug Administration until the agency decides whether to approve the over-the-counter sale of “Plan B” emergency contraceptives.

“The FDA advisory committee has recommended approval of Plan B based on safety and effectiveness, but the agency continues to drag its feet,” Murray said in an April 7 statement. “This is too important a decision to be endlessly delayed for ideological reasons.”

Murray and Clinton plan to put their hold in place after Crawford’s scheduled April 13 confirmation hearing. This would prevent the full Senate from voting on Crawford, a veterinarian who already serves as acting FDA commissioner.

Also known as the “morning-after” pill, Plan B consists of two high-dose contraceptive pills, taken 12 hours apart within 72 hours after intercourse, that work by preventing ovulation, fertilization, or implantation of a fertilized egg. **Plan B is already available by prescription, but the sooner the pills are taken the better they work, and OTC advocates say time spent obtaining a prescription will result in more unwanted pregnancies and abortions.**

There have also been increasing reports of pharmacists refusing to fill prescriptions for birth control and other medications on the grounds that dispensing these drugs would violate their consciences. The *Washington Post* reported March 28 that at least 11 states are considering laws that would explicitly give pharmacists this right, in addition to the four states that already have such laws.

The maker of Plan B, Barr Laboratories, originally submitted an OTC application in April of 2003, and that December an agency advisory panel voted 23-4 to recommend approval. But in May 2004, Steven Galson, acting director of the FDA’s Center for Drug Evaluation and Research, overruled the panel and his own staff by turning Barr down, citing concerns about whether girls under 16 could use Plan B safely without a doctor’s supervision.

In July 2004, in an effort to address Galson’s concerns, Barr submitted a modified OTC application for Plan B that would continue to require prescriptions for girls under 16. This is the application currently in front of the FDA.

Medicare Physician Payment

AMA SAYS SENIORS’ ACCESS TO DOCS IN JEOPARDY

Seniors will lose access to their physicians if Congress does not reverse looming cuts in Medicare physician compensation.

That’s the case American Medical Association president Edward Hill, MD, made in an April 5 briefing. Based on an AMA survey of its member physicians, Hill said 38 percent of physicians will decrease the number of new Medicare patients they accept, and 18 percent will decrease the number of established Medicare patients they treat, if the 5 percent cut called for under current law goes into effect as scheduled on Jan. 1, 2006.

As Hill acknowledged, the access argument is one that his organization has made frequently in pushing causes from increases in Medicare physician payments to caps on non-economic damages in medical malpractice cases. And it hasn’t always been borne out: **“If you look at history, it will tell you that doctors will complain, but then take what they get and keep seeing Medicare patients,”** said Hill.

“But we’re concerned that we’re reaching the point now where you can’t operate a business with that philosophy any longer,” continued the family physician from Tupelo, MS. Hill readily admitted that physicians are among the most highly paid members of society, saying that he would “never try to defend the personal income of physicians.” But he noted that the costs of running a medical practice, which went up by 41 percent from 1991-2005, are expected to increase another 15 percent in the six years beginning in 2006. In contrast, Medicare physician payments went up only 18 percent from 1991-2005, and would decrease by 26 percent under current law from 2006 through 2011.

The AMA wants Congress to scrap the “sustainable growth rate” formula — which links physician pay to the gross domestic product — and replace it with a system akin to those Medicare uses to compensate other types of providers. The Medicare Payment Advisory Committee has recommended replacing the SGR with “the same approach that is used for hospitals and nursing homes under Medicare — a system where payment updates would reflect practice cost inflation. We could not agree more,” Hill said.

According to the Congressional Budget Office, though, that switch would cost the federal government upwards of \$45 billion over 5 years, and such a large price tag probably makes this option a nonstarter in today’s extremely tight budget climate. Most observers expect Congress to enact a temporary fix instead, giving physicians a one or two year bump, perhaps condi-

tioned on the reporting of quality information to pave the way for pay-for-performance system in the coming years.

One caveat: The cost of a permanent physician payment fix could come down some if the AMA succeeds in convincing the Centers for Medicare and Medicaid Services to make certain administrative changes — notably removing the cost of physician-administered drugs from the SGR calculations — that would raise spending under current law, thus increasing the baseline against which the cost of any legislative changes would be measured.

Medical Imaging

SPECIALISTS RALLY AGAINST PROPOSED IMAGING STANDARDS

Medicare should not impose new accreditation standards on physicians who bill the program for interpreting diagnostic imaging scans, the Coalition for Patient-Centered Imaging said at an April 5 Capitol Hill briefing.

The Medicare Payment Advisory Commission proposed such standards in its March report to Congress. Alarmed by the rapid growth in imaging services, the commission also proposed other steps, such as strengthening the restrictions against physicians having financial interests in the imaging centers to which they refer patients.

The CPCI is a coalition of 18 medical and physician groups formed to promote the use of in-office imaging by physicians other than radiologists. The coalition says that in-office imaging provides patients with quick, first-rate treatment, avoiding separate trips to a hospital outpatient department or radiology center and substituting for more invasive procedures such as catheterization or exploratory surgery.

The CPCI argues that, at best, MedPAC's proposed standards would be yet another layer of expensive and unnecessary bureaucracy, duplicating the stringent training and standards already required by the various medical specialties. At worst, CPCI fears that new Medicare standards would mean that only radiologists would be allowed to interpret imaging tests.

MedPAC has not proposed this — in fact, MedPAC executive director Mark Miller said exactly the opposite in March 17 testimony to the House Ways and Means Health Subcommittee — but the CPCI cites what it says are danger signs from the commercial insurance market. Private-sector plans have been “hammered on” by the American College of Radiology, said William Gee, MD, a practicing urologist who also teaches at the University of Kentucky School of Medicine. As a result, “plans have come up with some methodologies to restrict imaging,” he said. “The implication has been that, if a radiologist does it,

then it must be appropriate.”

MedPAC said the per-beneficiary volume of physician-based imaging grew at an annual average of 10.1 percent from 1999-2002 and 8.6 percent from 2002-03, as opposed to annual growth rates for all physician services of 5.2 percent from 1999-2002 and 4.9 from 2002-03. But the April 5 CPCI briefing featured a Lewin Group study that compared the growth in imaging services not just to other physician services, but to all services included in Medicare Part B.

Over the 1999-2003 period, the volume of all imaging services — including those performed at hospital outpatient departments as well as physicians' offices — grew at an average annual rate of 8.7 percent, modestly faster than the 7.9 percent growth rate for all Part B services, said Lane Koenig, a coauthor of the Lewin report. Over this period, the growth rate in physician-based imaging was 10.8 percent, according to Koenig. That was double the 5.4 percent growth rates in hospital-based imaging, reflecting a shift in imaging services from the latter locale to the former, he said.

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Christopher Fleming, JD, Senior Washington Editor, (202) 233-0014; chrisf@eliresearch.com
Marcia Clemmitt, MA, Editor in Chief; (202) 233-0013; marciac@eliresearch.com
Tom Mullen, Executive Editor, (800) 798-1856

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Medicine & Health Perspectives

continued from page 1

In addition, **because the nation depends so heavily on small-group physician practice, “successful implementation in physician’s practice ... is the basis” for development of a robust market that can actually produce appropriate, effective clinical IT technologies, said National Health Information Technology Coordinator David Brailer, MD**

It’s largely the job of Clancy’s small agency, along with the Centers for Medicare and Medicaid Services, to find ways to assist providers to adopt IT and use it to improve the quality and safety of care. Brailer’s key charge: Ensure that a market develops to supply the nation with affordable, interoperable clinical IT.

Brailer and the administration remain “agnostic” on what kind of market is appropriate to clinical IT — “aggregated” or “disaggregated,” in which separate products are provided to each customer according to individual needs — said Brailer. “We just need a market,” and to get a market, physicians must be adopting the technology.

That being the case, “I take it upon myself to help physicians in small offices stay in the game of health-care IT,” Brailer vowed.

While Brailer deliberately remains on the sidelines, some forum participants argued against too much market disaggregation, in which products are tailored to the specifics of different practices.

If that’s the road the U.S. market takes, “we will have the same conversation 10 years from now as today,” said Simon Samaha, MD, senior vice president of New Jersey’s Cooper Health System. Other countries are taking a patient-centered approach to IT-infrastructure development, looking to a future in which health information follows the patient, he noted. “I’d be very very cautious and concerned about taking a vision into the future” that is physician-practice centered rather than patient-centered, he said.

• ***Can medical care and practice management accommodate computers’ step-by-step algorithms?*** A salient fact about computerization of any activity is that e-processes proceed step-by-step in same-way-every-time sequences — often designed by engineers who may have somewhat sketchy knowledge of the real-world environments in which programs will operate — while most activities that haven’t gone electronic ... well ... don’t.

That may be particularly true in the complex, very human worlds of medical care and practice management, especially in small practices, virtually all forum participants said.

Physicians and their staffs adopting computerization find themselves “going from implicit to explicit” in the myriad activities of

daily work, said Brailer. That means “engineering processes that were never thought through” in the first place. In addition, because e-medicine creates an explicit audit trail of who did precisely what when, computerizing may pose the added human challenges of creating “a culture of accountability that is very hard to adjust to.”

Physicians, rather than other medical staff such as nurses, may have the most trouble with this, said Brailer. Reminded by another panelist that he should include nurses in his remarks about the difficulties of adjusting to clinical IT, he said that “I chose the word ‘physician’ deliberately. ... I’ve seen nurses be much much much more willing” to adapt to the demands of the e-world. “I hope the nurses will help physicians along.”

Clinical IT today is mostly the “land of the giants” — large organizations that have the wherewithal to undertake capital improvements and management overhauls — said Robert Wah, MD, information management director for the Defense Department’s TRICARE health program. The danger is that “small physician practices will be squeezed out of the market” and may not even “be able to practice medicine in the future” unless more efforts are made to help them keep up.

• ***No stripping, please.*** One big problem that small offices face: Since health-care IT began in the large-provider sector, much of the product that’s available isn’t suitable for small practices, some forum participants said.

Hospital-oriented information systems are very structured and bureaucratic, which “doesn’t fit at all” in a small office setting where the staff’s workflows are often disrupted as they see patients, said David Kates, vice president for clinical product management with WebMD Practice Services.

But today’s big vendors serve big customers, like hospital systems. The result, according to Brailer: Big vendors reach into the physician sector “and impose a workflow model” that isn’t appropriate. E-products sent to doctors’ offices tend to be large-hospital products “stripped down” of some components but still far too complicated, he said.

Instead, vendors must begin asking, “What is the context of the workflow?” and learn to understand the nature and scope of a small-physician practice.

And no matter how small the practice, clinical IT implementation will almost certainly mean dealing with multiple vendors, said Vanderbilt University School of Medicine Professor Nancy Lorenzi. “There is not one vendor out there who said, ‘We have it all,’” said Lorenzi, who spent the past five years computerizing nearly 100 very small practices in several clinical networks.

Furthermore, expertise on organization management that's suitable for small practices also is a rare commodity, said Bob Williams, MD, director of health-care consulting for Deloitte. "Most people involved in health-care organizational issues come from inpatient" work, said Williams.

Although efforts are beginning, so far, physician practices and medical societies haven't perfected a system and an ethic of sharing doctor-specific IT experience to stand in place of what the more experienced hospital sector can't provide, several participants said.

"When I tried to get the practice down the street from us that bought from the same vendor to come talk to us" about their IT-adoption process, "they weren't interested," said Richard Baron, MD, founding physician of Philadelphia's Greenhouse Internists.

• **Tailor products for small physician groups, but don't tailor too much.** Some panelists cautioned that there's a downside to tailoring products to match the way physicians practice today. Practice patterns aren't necessarily very good.

It's important to remember that the goal of adopting e-systems is not just to use e for e's sake but to improve the quality and safety of medicine, said several speakers.

That being the case, **"automation of dysfunctional processes" doesn't get you anywhere, said Peter Basch, MD, medical director for e-health of the Washington, DC-based non-profit provider group MedStar Health. "When I hear the word 'automation,' I cringe. I would rather hear 'transformation.'"**

Several other forum members who have also accomplished e-transformation of multiple small facilities agreed with Basch's thought. The implication is daunting, however: Before adopting computerization, physician practices must have clear objectives and goals for how e-transformation should change their practices for the better, both for themselves and their patients, said Basch and others.

Don't put in a clinical computer system until you've clearly articulated "your vision" of how your practice will be different, and better, afterwards, said Lorenzi. Otherwise, you can't make smart choices among products or get the wholehearted staff buy-in that's necessary for success, she said. As the Cheshire Cat told Alice in Wonderland, "if you don't know where you want to go, it doesn't matter which path you take."

• **As usual, it's a people problem.** Staff buy-in is the most crucial feature in implementing IT, and getting it depends on making explicit and solving any personal and political problems brewing in an organization before IT is introduced, said Lorenzi. When a new computer system is brought in, all buried organizational and personal problems rise to the surface and can destroy the IT effort quickly if not addressed.

There is a 35-percent sabotage rate in health-care IT implementation, Lorenzi said. "You can have the best hardware and software" but if the entire staff doesn't take "ownership" of the new system and commit to it, "it will be destroyed."

"Getting everyone engaged will take some time." That's especially true because doctors' offices, unlike some other organizations, have a tough time putting any other work on hold to allow time — and provide a calm, undistracted atmosphere — to help workers adapt to new computers. There "are so many things happening in doctors' offices that the stress level gets extremely high," Lorenzi said.

Her listeners often shrug off her cautions on the personal and political office issues that she says can doom IT implementation, said Lorenzi. "This is all common sense," is the usual criticism, she said. "But I say, 'If so, why do we have a 40 percent failure rate?'"

• **It always comes back to the payment system.** Establishing and implementing an IT system that fulfills the goal of improving care quality and safety faces another familiar obstacle, said Basch. "The issue is our toxic payment system."

EHRs, for example, are looked on as a godsend by those who advocate building a strong preventive care and chronic-care management focus into the health-care system. The catch: Such activities generally are not reimbursed, by either public or private payers, said Basch.

Implementing IT — which is expensive — can greatly facilitate many provider actions that will improve health-care quality and safety. But without major payment-system revisions, doctors who take the big step to clinical IT can be caught in a cash-crunch catch-22, said Basch. When IT is implemented, "doctors immediately notice a tradeoff between using the technology optimally and having a reasonable bottom line."

PEOPLE

Jennifer Young steps into a new position at the Department of Health and Human Services. She'll be the first to occupy a new job at the department, Acting Senior Counselor for Health Policy. Young, who has held health staff positions for the House Ways and Means Committee, the Senate Finance Committee, and the National Governors Association, has been serving as HHS Assistant Secretary for Legislation.

New at the Centers for Medicare and Medicaid Services, in another newly created post, is **Dan Schreiner**. He'll be Medicare's first ombudsman, a role that Congress created as part of 2003's Medicare Modernization Act. Most recently, Schreiner's been an independent health-policy consultant. Earlier, he served in the HIV/AIDS bureau of the Health Resources Administration.