

## POLICY &amp; PRACTICE

**Waxman: FDA Plan Is Flawed**

The Food and Drug Administration is considering new guidance that would allow drug companies to use journal articles to promote “potentially dangerous uses” of drugs and medical devices without prior FDA review and approval, according to a top lawmaker. Rep. Henry Waxman (D-Calif.), who chairs the House Committee on Oversight and Government Reform, urged the FDA in a Nov. 30 letter to reconsider its draft guidance, which the congressman said was close to being finalized. “The draft guidance that I have obtained would, in effect, allow drug and device companies to short-circuit FDA review and approval by sponsoring drug trials that are carefully constructed to deliver positive results and then using the results to influence prescribing patterns,” Rep. Waxman said. “This undercuts the prohibition on marketing of unapproved uses of drugs and devices.” He asked the FDA to provide detailed information on the development of the new policy and how it would address his concerns.

**N.J. Blocks Stem Cell Measure**

New Jersey Gov. Jon Corzine (D) will press ahead with efforts to promote stem cell research in the state, even after voters rejected his proposal to borrow \$450 million to fund research grants. Although the measure’s defeat means there will be less state funding available for research, “the governor does expect they will be able to find additional dollars in the private sector,” said spokesman Jim Gardner in an interview. State lawmakers already have authorized about \$20 million in funding for a new Stem Cell Institute of New Jersey and for research grants, and that money is not affected by the bond initiative’s failure, Gardner said. The \$450 million bond referendum would have provided financing for stem cell research grants to eligible institutions over a 10-year period. The grants would have been awarded after review by an independent research panel and after consideration of the commercial viability of the projects. Mr. Gardner said it’s too early to tell if Gov. Corzine will attempt to bring a new bond initiative before the voters this year.

**Woman-Specific Drugs in Pipeline**

More than 700 medicines for diseases that disproportionately or solely affect women are currently in development, according to a report from the Pharmaceutical Research and Manufacturers of America. According to the PhRMA report, drugmakers are developing new products to treat arthritis, women-specific cancers, diabetes, obstetric-gynecologic conditions, and mental illnesses, among other things. The drugs in development include 135 medicines for cancers affecting women, including 95 for breast cancer, 47 for ovarian cancer, and 17 for cervical cancer. In addition, drug manufacturers have 125 medicines in the pipeline for arthritis and muscu-

loskeletal disorders, which disproportionately affect women, and 106 drugs in the pipeline for autoimmune disorders, which collectively afflict 23.5 million Americans, the majority of them women. Other medicines in development include treatments for diabetes, glaucoma, irritable bowel syndrome, urinary tract infections, asthma, Alzheimer’s disease, migraine, depression, anxiety and sepsis, all of which PhRMA said affect women more than men.

**Report: Counseling Violates Ethics**

Information that doctors in 23 states are required to provide to women either verbally or in writing before an abortion falls short of fundamental ethical principles because it is inaccurate or irrelevant, a nationwide analysis of state counseling requirements from the Guttmacher Institute found. The counseling required by these 23 states “in many cases appears to be designed more to influence rather than inform a woman’s decision whether to have an abortion, for instance by exaggerating the physical or mental health risks of abortion, or by including information on certain abortion procedures that is irrelevant to most women,” according to the report in the Guttmacher Policy Review. Report coauthor Rachel Benson Gold said in a statement that the widespread misinformation is “particularly troubling” in light of a recent Supreme Court decision, *Gonzalez v. Carhart*, that defers to legislatures, rather than the weight of the evidence, in cases where there is medical disagreement on the potential consequences of abortion. “There is ample reason to worry that some state legislatures will view the Supreme Court’s ruling as a green light to set up a new array of misleading counseling requirements that in reality are attempts by politicians to muscle their way into private medical decisions that should be between a woman, her family, and her doctor,” Gold said.

**Maternal ‘Toolkit’ Developed**

The National Business Group on Health, which represents large employers, in November released a new guide designed to help employers improve the health of pregnant women, children, and adolescents, as well as potentially reduce their health care costs. “Investing in Maternal and Child Health: An Employer’s Toolkit” provides a model of a medical benefits package aimed at providing guidance on benefit design, employee cost-sharing recommendations, and actuarial cost-impact data employers can use to estimate the cost of adopting the recommended benefits. The toolkit also includes data on the cost of maternal and child health care services, and the business case for investing in healthy pregnancies and primary care services, along with educational materials for employees about maternal and child health topics.

—Jane Anderson

# Cleveland Clinic Unveils State-of-Art EMR System

BY JANE ANDERSON  
Contributing Writer

The Cleveland Clinic has established a state-of-the-art electronic medical records system to provide the best information not only to clinicians, but also to patients, according to one of the system’s architects.

The goal is to make sure that patients—who now have access to literally billions of pages of medical information online—can get the most relevant and accurate information as part of their electronic health record, said Dr. C. Martin Harris, chief information officer of the Cleveland Clinic Foundation.

“We need to get prepared for the coming consumerism in health care, because patients will have access to medical advice that no longer comes from the physician or nurse,” said Dr. Harris. He cited research that shows about one-third of medical information available online is of high quality, one-third could be useful but would require some interpretation, and the last third is “completely off the mark.”

“One of the things we clearly have to understand is what information patients and consumers have access to and what tools they have to gain access, so that we can tailor our services,” Dr. Harris said during a virtual conference sponsored the Healthcare Information and Management Systems Society (HIMSS).

Over the past 5 years, the Cleveland Clinic has built a foundation-wide e-health program that’s completely integrated with its clinical programs, Dr. Harris said.

The e-health initiative features electronic medical records, test ordering and results, pharmacy records, and care reminders for physicians. But it also includes access to medical records and certain test results for patients, along with medical information that’s been vetted for accuracy and appropriateness.

“It allows us to establish an ongoing relationship with patients after they leave the physician’s office and after they leave the hospital bed,” Dr. Harris said, adding that the Cleveland Clinic set out to develop tools for both doctors and patients when it created the system. “It is a single tool that goes from the initial ambulatory visit to the hospital and back again,” he said.

A total of 5,662 physicians use the electronic medical record module, including about 1,500 employed by the Cleveland Clinic and approximately 4,100 who practice in hospitals in the Cleveland Clinic system. Once other clinicians and support personnel are added, there will be about 33,000 users for the system, Dr. Harris said.

On the outpatient side, the system integrates schedules, laboratory results, other medical documentation, a computerized physician order entry system, and

best practice alerts, Dr. Harris said. In one mode, physicians can communicate either informally or formally; in formal mode, comments are added to the medical record, he said.

On the inpatient side, it’s exactly the same tool, although it incorporates some different elements, including a medication administration record, vital signs, and clerk order entry, Dr. Harris said, adding that “almost all of our nursing documentation is online at this point.”

The system keeps track of recommended screenings and medical procedures for all patients, and provides that list to the physician electronically at the time of an office visit, allowing the physician to focus on what hasn’t been done and might be needed. “That’s a very powerful technique,” Dr. Harris said.

The system also provides safety tools and will alert physicians to potential drug-drug interactions and other possible problems, Dr. Harris said. “It’s virtually impossible for

a physician to remember every drug-drug interaction they might see in a particular patient,” he said, noting that the average Cleveland Clinic patient is 65 years old and is taking at least six prescription medications.

Patient services include the ability to view medical records, health reminders, and health care schedules, as well as features that allow them to request appointments and renew prescriptions, Dr. Harris said. “Our goal is to get as much information in front of the patient as possible.”

In fact, the Cleveland Clinic actually is releasing certain routine test results via this online system directly to patients, Dr. Harris said. “We’re moving from having the physician screen it [and approve the information’s release] to having it automatically released after about 24 hours,” he said.

In addition, patients are being sent a list of health maintenance activities, such as routine screenings, they should be arranging for over the course of a calendar year, Dr. Harris said. And, the system produces a “health issues” list for patients to have and share with their physicians, he said.

The Cleveland Clinic’s system also provides a streamlined process for getting a second opinion for a serious diagnosis. This process, Dr. Harris said, is available to any patient, not just those in the organization’s service area, and is offered directly to patients with payment expected up front; patients are provided with instructions on how to seek reimbursement from their insurers.

The goal of all this is to provide the best, most comprehensive information to patients in a format that’s easy to use and understand, Dr. Harris said. “What we know is, we’re going to have to make these tools available to patients and add value.” ■

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