Personal Data Records Raise Legal, Security Issues

BY JOEL B. FINKELSTEIN
Contributing Writer

BALTIMORE — Personal health records may be the next step in the evolution of health information technology, but these electronic documents raise several legal and security issues for long-term care facilities.

"PHRs might in fact have the opportunity to leapfrog over things that are happening in electronic health records," Dr. Steven Labkoff, director of business technology for Pfizer Inc., said at a meeting on long-term care health information technology.

The main difference between personal health records (PHRs) and electronic health records is who owns them. Ideally, patients should own their PHRs. But it is still unclear who should control what information is entered in the document and, perhaps more important, who should be able to delete information from the record, experts said at the meeting, sponsored by the American Health Information Management Association (AHIMA).

An online public survey conducted in 2003 found that 71% of respondents believed that personal health records would improve the quality of health care, said Jill Burrington-Brown, the practice manager for health information management products and services at AHIMA.

"The time is now to accelerate the development of personal health records," she said, citing a report from Connecting for Health, a project of the Markle Foundation to promote the adoption and use of personal health records.

Administrators have had to struggle with how much access the public should have; for example, should adult children be allowed to look at parents' records?

"A second finding was that PHRs are a means to necessary ends, such as increased consumer health awareness, activation, safety, and self-efficacy," she said.

During roundtable discussions, meeting attendees said that they thought personal health records are a potentially important component of health information technology efforts, but many also had misgivings about the security risk represented by giving seniors, some with cognitive deficits, electronic access to their health records.

"Every day is a day that we work on security to make sure it is tight and concise," said Daniel Wilt, director of information technology for Erickson Retirement Communities.

Erickson has launched a pilot program that allows residents to remotely access laboratory results, physician notes, and medical histories. The system also allows them to set appointments and keep health journals.

"They want their labs. That's the one thing they really want. They go to the medical center, they run back upstairs, they go to their computers, and they ask 'It's been 20 minutes; where are my labs?' We have to explain it takes 24 hours," he said.

While most users really like the system, administrators have had to struggle with how much access the public should have. For example, Mr. Wilt said, should administrators allow adult children to look at records or let residents change information that they deem incorrect?

By definition, personal health records need to be individually owned, said Ms. Burrington-Brown.

"The individuals own the PHR in a similar way as we own money in the bank. There is some conversation in the industry about who really owns that, because of who produces it. That is a conversation that is going to be going on" for quite some time, she said.

Industry groups are working on a standard format for personal health records, while groups such as the American Health Information Community and the National Committee on Vital and Health Statistics are developing standards to ensure interoperability and security of those documents.

"We have a lot of PHR activities occurring at many levels," she said. ■

FDA Is Cracking Down on Unapproved Rx Drugs

BY ALICIA AULT
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The Food and Drug Administration announced that it is renewing efforts to ensure that all drugs currently sold by prescription either go through its formal approval process or be taken off the market.

The agency has periodically targeted some of these products using its existing authority. Now, the FDA has issued more formal guidance that spells out for manufacturers how it will prioritize enforcement, and what route they can take to prove safety and efficacy of their products.

There are many reasons why unapproved products are on the market, said Dr. Steven Galson, director of the FDA's Center for Drug Evaluation and Research, at a press briefing sponsored by the agency.

Most were marketed before passage of the 1962 Food, Drug, and Cosmetic Act, which required formal proof of safety and efficacy. Or their makers may simply have begun selling the products without seeking the agency's approval, he said, noting that the FDA will issue a new drug code number for a product even if it was never approved.

Many of the unapproved drugs are listed in the Physicians' Desk Reference. Some are advertised in medical journals. Those initially flagged for attention include products that are potentially hazardous, lack evidence of effectiveness, or appear fraudulent. If the manufacturers don't seek approval, they will be subject to enforcement action, Dr. Galson said. But in most cases, the FDA will not remove a drug from the market if it has been shown to have some medical utility. Examples include some manufacturers' levothyroxine and phenobarbital products.

The agency estimates that less than 2% of prescription drugs have not received its imprimatur. That still means potentially thousands of products that aren't approved.

Many of the drugs are cough and cold preparations that include pheniramine maleate and dexbrompheniramine maleate, or single-ingredient narcotics such as codeine phosphate and oxycodone HCl. Sedatives like chloral hydrate are also unapproved.

The agency recently announced that it is requiring makers of carbinoxamine-containing products to seek approval by late September. Any unapproved products still on the shelves at that date will be ordered off the market, said Deborah M. Autor, FDA associate director for compliance policy.

The FDA said it was targeting carbinoxamine because of safety concerns, including 21 deaths since 1983 in children under age 2 that may be related to the ingredient. Carbinoxamine is used in cough and cold treatments, mostly for children.

Physicians, pharmacists, and patients can go to the FDA's Web site (www.accessdata.fda.gov/scripts/cder/drugsatfda) to determine if a drug is approved. The database includes only approved drugs; unapproved products will not be listed. ■

WHO Launches Effort to Standardize Access to Clinical Trial Registry Data

BY KERRI WACHTER
Senior Writer

The World Health Organization has launched a major initiative to standardize the way that information on clinical trials is made available to the public.

In an attempt to address growing public concerns about the transparency of medical research involving human participants, WHO is recommending 20 key details that all clinical trial registries should include.

"Registration of all clinical trials and full disclosure of key information at the time of registration are fundamental to ensuring transparency in medical research and fulfilling ethical responsibilities to patients and study participants," Dr. Timothy Evans, assistant director-general of the WHO, said in a written statement.

WHO's International Clinical Trials Registry Platform is not itself a registry but provides standards for all clinical trial registries. These standards require information about: sources of monetary or material support, primary and secondary sponsors, contacts for public and scientific queries, countries of recruitment, health conditions or problems studied, interventions, key inclusion and exclusion criteria, study design, date of first enrollment, target sample size, recruitment status, and primary and secondary outcomes.

The voluntary initiative is part of a growing movement toward greater accessibility to clinical trial information, prompted in part by high-profile cases involving the suppression of data by pharmaceutical companies.

In the European Union, all clinical trials conducted in member states are required to be registered in the EudraCT database, supervised by the European Medicines Agency. In the United States, www.ClinicalTrials.gov (developed and run by the National Institutes of Health) enrolls publicly and privately funded clinical trials worldwide.

However, there are several hundred other national and private clinical trial registries around the world. The Registry Platform seeks to bring participating registries together in a global network to provide a single point of access to the information stored in them, according to a WHO statement.

The WHO Registry Platform is expected to launch a Web-based search portal later this year that would allow interested individuals to search among participating registries for clinical trials taking place or completed throughout the world.

For more information on the registry platform, visit www.who.int/ictrp/en. ■

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