

E-Health Information Campaign Shapes Pharmaceutical Regulation



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FDA is proposing electronic systems and procedures for filing drug labeling information and facility and product data.

One aspect of healthcare that Republicans and Democrats seem to agree on is the need to develop a national electronic health information system. The Medicare Modernization Act (MMA) requires that government establish technical standards that will permit providers to share electronic medical records (EMRs) and to electronically prescribe medications. In response, FDA (among many agencies working to comply) is stepping up efforts to set standards and policies for a broad range of electronic filing and reporting activities.

In April, President Bush set a 10-year goal for developing an EMR system and promised \$100 million in grants to hospitals and healthcare providers to establish electronic health (e-health) information initiatives. A few weeks later, Health and Human Services (HHS) Secretary Tommy Thompson appointed the first national health information technology coordinator, David Brailer, former CEO of California-based CareScience. Thompson also announced additional technical developments toward a broad e-health network. HHS is supporting the work of Health Level 7 (HL7), a voluntary accredited standards development organization for healthcare, to establish e-health standards for collecting information about demographics, units of measure, immunization, and clinical encounters.

The National Committee on Vital and Health Statistics also is developing standards for e-health billing and electronic prescribing. In May, the panel proposed draft recommendations for electronic billing standards and efforts to reach consensus on standards for electronic prescribing. The panel is soliciting opinions from pharmacists, pharmacy benefit managers, and payers as it works to reach agreement on numerous policies. One expected action will be the recommendation for

adopting the SCRIPT standard that is already in use by leading electronic-prescribing networks (e.g., SureScript, RxHub, and ProxyMed).

HHS is charged with finalizing electronic prescribing standards for the Medicare pharmacy program in 2008, but Secretary Thompson hopes to move faster. The MMA calls for HHS to establish initial standards by 1 September 2005 and for a pilot project to be conducted during 2006.

FDA at the table

A main component of an electronic prescribing system is access to accurate, up-to-date information about prescription drugs based on FDA-approved labeling. The agency is building a system that will provide this information in a format accessible and readable by all computer systems. The work builds on FDA's efforts during the past decade to develop policies and systems for the electronic submission of data and documents. FDA officials have led efforts with the International Conference on Harmonization (ICH) to establish common standards and formats for the electronic filing of market applications for new drugs and biologics and for collecting data about adverse events. In July 2003, FDA issued a draft guidance about electronic submissions of periodic post-marketing adverse drug reports (ADRs). This involves an ICH initiative to establish common ADR procedures for all regulatory authorities.

The broader federal e-health campaign is accelerating several FDA initiatives and giving IT activities a higher profile in the agency. In April, FDA Acting Commissioner Lester Crawford named Randy Levin director for health and regulatory data standards in the Office of the Commissioner. Levin represents FDA in developing federal e-health policies and now oversees FDA's electronic prescribing and e-health record initiatives as chairperson of the FDA Data Council. He also works closely with the FDA Management Council to advance the development, adoption, and implementation of data standards across the agency.

Levin comes to the commissioner's office from the Center for Drug Evaluation and Research

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(CDER) where he headed the Office of Information Management (OIM). He will continue to serve as CDER's associate director for medical informatics and will function as a scientific advisor and consultant to CDER management on policies related to medical informatics and strategic direction for information management.

CDER established OIM in August 2003

to coordinate a range of IT-related activities, including training reviewers in the use of electronic submissions, overseeing CDER's document rooms, and entering data into CDER databases. This organizational change reflected the growing importance and growing volume of electronic submissions to the agency. About 75% of drug filings are now electronic, primarily investigational new drug appli-

Common language

The latest wrinkle in the health information standards area is the choice of medical terminology to be used for electronic prescribing and electronic medical records. FDA has spent almost a decade working with ICH to gain international acceptance of the Medical Dictionary for Regulatory Activities (MedDRA) system for submitting data to regulatory authorities. Since 1997, FDA has encouraged manufacturers to use MedDRA to describe medical conditions, symptoms, laboratory tests, and other items when filing adverse event reports, market applications, and other documents.

In April, however, HHS Secretary Thompson announced that federal e-health communications should be based on Systemized Nomenclature of Medical Clinical Terms (SNOMED CT). HHS is working with other federal agencies to make the SNOMED CT medical vocabulary developed by the American College of Pathologists available for free to all users.

FDA officials say that they are sticking to MedDRA for now because they have invested so much time and resources in the terminology. The agency is examining opportunities for "mapping efforts" that will link MedDRA to SNOMED.

cations (INDs) and adverse drug event reports, totalling nearly 300,000 per year. Unfortunately, only about 10–20% of drug amendments and supplements are electronic submissions, a volume that FDA would like to expand.

With Levin assuming new agencywide responsibilities, direct management of OIM now falls to Linda Burek, who previously headed CDER's Office of Information Technology. Margo Burnette takes over Burek's previous position, which puts her in charge of CDER's IT staff.

Change for electronic labeling

A current priority for FDA is the establishment of an electronic labeling system for drugs. The aim is to speed up FDA review of initial labeling and postapproval changes and to be able to communicate such changes quickly to pharmacists, physicians, and patients. Adopting a more efficient and accessible system for providing up-to-date drug-labeling information also fits regulatory efforts to make drug-product labels more useful and more comprehensible.

To this end, FDA recently issued a new rule requiring manufacturers to submit



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product labeling data electronically when filing a new drug application, a supplement, or an annual report (see “Washington Report” in *Pharmaceutical Technology’s* February 2004 issue). The new policy was scheduled to go into effect in six months on the basis of a standard electronic format that would be described in a companion FDA guidance on electronic submissions.

The task of spelling out a standard format for submitting electronic labeling information initially appeared fairly straightforward because FDA and manufacturers have been sending and receiving labeling content electronically in portable document format (PDF) since 1999. However, in February 2004, FDA published a draft guidance calling for a switch from PDF to a new structured product labeling (SPL) system. The change reflects a desire to adopt an electronic labeling system that will permit the exchange of FDA labeling information with other public and private computer systems as part of the electronic prescribing and e-health initiative. In the

February guidance, FDA said that it planned to switch to SPL by the end of this year to process and manage labeling and labeling changes (see “Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Content of Labeling” on www.fda.gov/cder/guidance/index.htm).

Manufacturers generally supported the new system but requested more time to carry out such a major change. In particular, small biotechnology companies anticipate difficulty in adopting SPL quickly, said the Biotechnology Industry Organization (BIO) in comments on the proposed guidance in April. Astra Zeneca estimated that in a best-case scenario, it would take a manufacturer six to nine months to set up, configure, validate, and test an extensible markup language (XML)-based SPL system once it became available. The company also noted a current lack of vendor support for this initiative.

During a June meeting with manufacturers, Levin addressed these concerns and

offered a more flexible implementation timetable. In addition, seven software vendors attended the meeting to demonstrate their interest and capability for providing SPL software to pharmaceutical companies. Even though the December electronic labeling rule became effective officially in June, Levin emphasized that until FDA establishes a system for receiving and storing manufacturer data in SPL, the agency will accept electronic labeling data in either PDF or SPL formats. FDA hopes that the first phase of this project, which involves completing regulations, standards, and systems needed to switch labeling content from PDF to SPL, will be completed for prescription drugs by July 2005. The plan is to extend the program to all drugs by 2006.

Landmark event

FDA and industry experts point out that although the switch to SPL may be complex, it can be a beneficial move. The system not only will distribute labeling information quickly and more broadly, but

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the restructuring of the labeling information involved will yield better organization and more-consistent information in a set format. Labeling information will be accessible by various computer systems while remaining in a human-readable format. SPL also will facilitate labeling review, editing, storage, dissemination, analysis, and other uses. FDA will be able to evaluate labeling changes by section,

making it unnecessary for a manufacturer to submit the entire labeling document if altering only one piece of information. Access to data supporting labeling information also will permit additional analysis of subpopulations. Such analyses are useful in assessing safety signals and evaluating adverse events.

At the Drug Information Association annual meeting held in June, CDER Med-

Seeking secure signatures

The prospect of transmitting more information and regulatory documents electronically has focused the attention of industry IT experts on the need for a more secure and efficient electronic signature system. To accomplish this task, a group of 12 manufacturers are working on a Secure Access for Everyone initiative, which aims to establish a global digital-identity standard for electronic signatures.

The program combines hardware, software and communication protocols to affix verifiable and secure electronic signatures to legal documents, explains Alan Goldhammer of PhRMA. The group recently completed Phase I of the project, which involves publishing a baseline standard providing the legal infrastructure, policies, guidelines and technical specifications for the project. FDA, the European Medicines Agency, and US and European industry organizations are establishing a global standard that will facilitate electronic submissions of data to regulators around the world. One aim is to have this system linked to the electronic CTD for documents that require electronic signatures.

ical Officer Steve Gitterman described the development of the SPL system as "truly a landmark event in patient healthcare" because it provides a mechanism to make labeling changes immediately available to the medical community. The new system will allow for faster FDA turnaround on labeling review and public access to more-accurate information about prescription drugs.

The SPL system uses HL7's clinical document architecture. This architecture enables information to be exchanged in XML, which is the standard that is likely to provide the basis of a national e-health information system. The plan calls for manufacturers to submit labeling information to FDA, which will then transmit it to the National Library of Medicine (NLM). NLM in turn will make the information available electronically to all users through its DailyMed system.

The SPL standard was developed by a small group within the HL7 Technical Committee on Regulated Clinical Research Information Management (RCRIM-TC). Now a special SPL working group, which was formed in January, includes most pharmaceutical companies, FDA representatives, and software vendors. The group is developing a common style sheet for presenting labeling content and an im-



Pushing doctors and hospitals into electronic communications

For any electronic prescribing or e-health system to work, healthcare providers have to join the program, which they have been slow to do. To improve quality of care and rein in healthcare costs, an employer group is offering bonuses to physicians who implement EMR systems. Under the "Bridges to Excellence" program administered by the National Committee of Quality Assurance, industry leaders are paying providers in five cities as much as \$50/patient for implementing EMR systems. The sponsors estimate that broader use of information systems can cut the cost of healthcare by about 4–5%, and that these savings cover more than the cost of the bonuses.

Although private incentives seem to be making an impact, some legislators believe that mandates are needed to speed e-health initiatives along. Senator Edward Kennedy (D-MA) introduced legislation in May that would require most healthcare providers to implement EMRs and electronic claims processing by 2011 or face reduced reimbursement from federal health programs.

Financial incentives also seem to be encouraging hospitals to report quality of care data to Medicare, as seen in the huge jump in the number of hospitals participating in the National Voluntary Hospital Reporting Initiative. Last October, only about 400 hospitals were submitting quality information to this voluntary program, which was established in December 2002 to collect data on 10 quality measures.

In May, CMS announced that almost 3500 hospitals had signed up. The surge comes from a provision in the Medicare law that requires hospitals to begin quality reporting by 1 July 2004 or face a 0.4% reduction in their Medicare payment update for 2005. Federal officials are encouraged that valid standards, technical assistance, and financial incentives will lead to broad voluntary adoption of e-health systems.

plementation guide and aims to pilot-test the SPL exchange with FDA this year.

RCRIM-TC also is establishing standards for other aspects of clinical product development. The committee recently issued standards for transmitting clinical laboratory data from laboratories to sponsors, and it produced standards for submitting electrocardiogram data to FDA. Also in the works is a standard for manufacturers to file drug stability data with FDA. This effort aims to standardize the structure and content of stability test data to facilitate electronic transfer of this information to regulatory authorities and also enhance the use of the data by manufacturers themselves.

Despite general support for the SPL electronic labeling system, the implementation process will have to address a number of issues. One concern is how FDA will deal with labeling that is already under review as well as amendments to labeling that was previously filed in PDF. Another issue is whether the SPL standard fits electronic filing requirements adopted by ICH for the common technical document (CTD). Levin says that there is no problem; the CTD provides primarily an organizational structure for submitting information for drug registration but that the data can be in SPL or PDF or another format. What may be more difficult, however, is submitting adverse drug event reports in SPL with various regulatory authorities around the world.

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Link to facility lists

Once FDA establishes the SPL electronic labeling system, that data will provide FDA with the information it requires to track each drug registered with the agency and where it is manufactured. These data are part of the FDA Unified Registration and Listing System, which covers multiple product areas. FDA now has established modules for registering food facilities as required

by recent antiterrorism legislation. Another module lists drug manufacturing facilities, together with key information about every drug made at each plant. The listings identify products by national drug codes and provide information about ingredients, strengths, shape, and color.

Once manufacturers are able to file labeling information electronically, FDA will be able to use that information for its fa-

cility and product listing databases, which the FDA guidance notes will eliminate "redundant data collection" and improve efficiency. Also, the system will provide more-accurate listing information, Levin explains, which FDA uses to schedule and track plant inspections, user-fee billing, and other agency purposes. The current paper-based system often carries incorrect NDC numbers and out-of-date information, particularly from drug repackages and relabelers.

Going paperless

Another activity that will support and be supported by FDA's electronic labeling initiative is a long-time manufacturer effort to establish a paperless label system. Pharmaceutical companies have been working for years to develop a system for transmitting labeling information electronically to pharmacies and thus eliminate the need to distribute millions of pieces of paper to drug stores. A coalition that includes pharmacists, IT firms, and manufacturers conducted a pilot test of a limited electronic information distribution system with 10 pharmacies last year. Now the group is launching a larger test at 260 pharmacies in 10 cities that covers prescribing information for all approved drugs. Sponsors of the program hope for full-scale implementation by 2005.

In what some observers describe as a "perfect storm" in drug information communication, the FDA electronic labeling initiative will allow manufacturers to update product labels daily, and the industry initiative will distribute that information to prescribers, pharmacists, and patients. In the end, these users will be able to use the information to reduce prescribing errors and adverse drug events and improve patient care. **PT**

FYI

Pharmaceutical water systems

The University of Wisconsin—Madison, department of engineering professional development will offer a course entitled, "Pharmaceutical Water Systems," on 20–22 October 2004, in Las Vegas, Nevada. This course is designed for plant engineers, quality control chemists and microbiologists, and quality assurance personnel. For further information, contact Michael F. Waxman at 608.262.2101 or waxman@epd.engr.wisc.edu, or visit <http://epdweb.engr.wisc.edu/WEBG208>.

