

Drug Pedigree Mandate Could Be Expensive

According to a new study, complying with legislation proposed by two U.S. Congressmen could cost as much as \$110,000 per pharmacy—and more than a billion dollars for a large chain.

By Beth Bacheldor

July 7, 2008—A coalition of retail pharmacies has released a study that estimates the cost of implementing RFID and 2-D serialized bar-coding as part of a federally mandated track-and-trace system could be as high as \$110,000 per store. Conducted and prepared by [Accenture](#) for the [Coalition for Community Pharmacy Action \(CCPA\)](#)—which is comprised of the [National Community Pharmacists Association \(NCPA\)](#) and the [National Association of Chain Drug Stores \(NACDS\)](#)—the study was carried out during the past month and a half in response to the proposed [Safeguarding Pharmaceuticals Act of 2008 \(HR 5839\)](#), introduced in April of this year.

Introduced in the U.S. House of Representatives by Steve Buyer (R-Ind.) and Jim Matheson (D-Utah), HR 5839 would require the [U.S. Food and Drug Administration \(FDA\)](#) to generate a unified pedigree standard that companies would then need to use to track and trace pharmaceuticals as they traverse the supply chain (see [U.S. Congressmen Seek to Specify a Track-and-Trace Technology for Drugs](#)). This would amend the [Federal Food, Drug, and Cosmetic Act](#), and has been referred to the [House Energy and Commerce Subcommittee](#) on Health for review. The prospects for passage are uncertain at this early stage.

The Accenture study based its findings on research of media and literature regarding counterfeit drugs, as well as surveys of NACDS and NCPA members selected at random. The company also conducted verbal interviews with a subset of NACDS and NCPA members, and developed a cost model to estimate the cost implications of such an implementation.

Retail pharmacies are not opposed to track-and-trace technologies that would bolster the safety and security of the pharmaceutical supply chain, says Charlie Sewell, senior VP of government affairs for the NCPA, and co-president and founder of the CCPA. But the concern, he says, is that federal and/or state mandates calling for track-and-trace systems would currently be too costly for many retail pharmacies. In particular, he notes, the coalition is "adamantly opposed to HR 5839 in its present form."

NACDS, in a press release issued after HR 5839 was introduced, claimed the adoption and implementation of track-and-trace systems "would be extremely complex and costly for retail pharmacies and others in the supply chain, and without the desired benefit. These systems are many years away from full development, have not been fully tested and lack uniform standards and patient privacy safeguards."

The study determined that costs would range between about \$84,000 and \$110,000 per pharmacy for the hardware, software, infrastructure, and labor and resources necessary to implement a track-and-trace system. In addition, it also determined cumulative costs covering a seven-year timeframe. The authors assumed the track-and-trace system would be fully implemented within the first year, but that there would be other costs associated with the system in subsequent years, including maintenance, hardware and software upgrades, compliance and so forth.

According to the study, a "large" chain, consisting of 14 distribution facilities and 4,000 pharmacies, would incur a total cumulative cost of \$1.3 billion, while a "medium" chain would face a \$46.6 million total cumulative cost for one distribution facility and 100 pharmacies. The typical "small" chain would experience a total cumulative cost of \$3.9 million with no distribution facilities and 15 pharmacies, whereas an "independent" pharmacy with no distribution facilities and two pharmacies would incur a total cumulative cost of \$472,275.

Sewell says community pharmacies, which are already struggling, may be put out of business altogether if a mandate requiring them to support track-and-trace technologies were passed at the present time. "This could be the straw that breaks the camel's back," he states. "It would really make the economic viability of community pharmacies come into serious question, and it would definitely have an impact on chain pharmacies."

The study based its analysis on the following assumptions: that the system would be fully implemented within the first year of a seven-year timeframe, that it would incorporate both RFID technology and 2-D bar codes, and that the RFID technology would include both ultrahigh-frequency (UHF) and high-frequency (HF) systems. The study breaks down timeframes and percentages regarding when, and to what extent, each technology would be implemented.

The assumptions were necessary, Sewell says, simply because there are so many questions as to what a federal mandate would require, or how any such system would be implemented. "Like so much legislation, the parameters aren't necessarily all spelled out," he says. "The problem is, it is all up in the air—nobody has a definite handle as to how this is all going to work."

The FDA's Prescription Drug Marketing Act (PDMA) of 1987 requires drug distributors to document (via a pedigree, though not necessarily in electronic form) the chain of custody as drug products move through their distribution system. The agency has considered track-and-trace technologies for some time, and does advocate the use of RFID to create pedigrees for prescription drugs in an effort to combat drug counterfeiting and improve drug safety.

Several states have either enacted or are currently considering enacting legislation calling for pedigrees. Florida has a pedigree law, for instance, requiring pharmaceutical distributors to document the chain of custody of prescription drugs in that state. And California's proposed legislation calling for an electronic pedigree (e-pedigree) system in its state has been pushed out from an effective date of 2009 to 2011, because the pharmaceutical industry indicated it would be unable to meet the earlier deadline (see All Eyes on FDA for Drug Pedigree).

Unlike the PDMA, which requires only drug distributors to create and maintain pedigrees, HR 5839 also calls for manufacturers and retail pharmacies to employ a drug identification and tracking system to create and maintain pedigrees. Florida's law requires only wholesale distributors to create pedigrees, while California's proposal includes manufacturers, distributors and retailers.

What many, including the coalition of pharmacies, would prefer—if, indeed, there are to be any government mandates—is a federal mandate that would supersede state laws. "We'd like to see a federal system, as opposed to 50 systems," Sewell says. However, he notes, the government must be more specific in its requirements. "There needs to be a single technology identified that multiple vendors could provide," he explains, rather than allowing for multiple technologies, such as both RFID and 2-D bar codes. "If we have to support more than one technology, that adds to the costs."

While HR 5839 does include a clause calling for the Secretary of Health and Human Services to award grants

to "eligible entities to facilitate the purchase and enhance the utilization of a drug identification and tracking system," it also requires those entities to generate matching funds. According to Sewell, grants should cover all of the hard costs associated with a track-and-trace system, in terms of hardware and software, because retail pharmacies will still need to fund the time and resources for the administration and compliance of such a system.

RELATED_ARTICLES "We want to work with the government to come up with a cost-effective track-and-trace solution," Sewell states. "But if you just pass legislation that sort of says, 'go do it,' it leaves everything to the regulatory agency to determine how it will be done. We have no confidence that it will get done in a fashion that will be beneficial to either our pharmacies or the consumers."

Rather than enacting a federal mandate such as HR 5839, NACDS suggests Congress institute federal requirements for uniform state wholesale drug distributor licensure standards; implement an FDA-administered certification program for manufacturers, distributors and pharmacies assuring adherence to secure supply chain practices; require chain-of-custody pedigrees only for distributions by uncertified supply chain entities; and ensure a uniform and strong national safety regimen through federal preemption of state laws.

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