nothing has united the sometimes fractious players in the pharmaceutical industry like California's e-Pedigree requirement for prescription drugs. The e-Pedigree law states that all drug packages must contain a serialized number for tracking the movement of pharmaceuticals through the supply chain to combat counterfeit or adulterated products. California was the first state to set a deadline for e-Pedigree compliance—for January 1, 2009. However, generic and brand-name manufacturers; wholesalers; purchasing cooperatives; and community, chain and hospital pharmacies pressed the California Board of Pharmacy to delay the deadline. On March 25, 2008, the Board moved the date back by two years to January 1, 2011.

The prospect of the looming 2009 deadline had conjured up nightmare scenarios in the pharmacy sector. It is the pharmacies, more than the manufacturers or the wholesalers, that have the more complex technical task and that face the higher cost hit, based on percentage of revenues. The big revenue hit would come from the need to purchase various types of bar code readers, radiofrequency identification (RFID) chip readers, and software and database upgrades so that pharmacies will be able to authenticate each individual package from the bar code or the RFID chip (or both) attached to each package label. Underlying that pyramid of costs is the unpalatable fact that no single, intraoperative e–Pedigree technology exists, nor is one likely to appear—even by the beginning of 2011.

The two-year delay might seem as if it is giving the participants a lot of time, but it is not. Some pharmacies anticipate that they will be able to conquer the technical conundrums and costs related to e-Pedigree, but Walgreens' boast in September 2007 that it was preparing a “very big catcher’s mitt” to catch the variety of serialization technologies likely to cross its plate sparked a perturbed retort from PharmKee, Inc., a group of 10 pharmacies serving rural areas in California. David Wilcox, president of PharmKee, replied that he could afford only a very small mitt and that he was likely to get hit, figuratively and financially, in some delicate places come January 1, 2011.

The e-Pedigree requirement is likely to knock the wind out of many pharmacies. In response to the Board’s March 25 decision to reset the deadline to 2011, Bruce Roberts, RPh, Executive Vice President and Chief Executive Officer of the National Community Pharmacists Association (NCFA), said this:

While we certainly support the concept of using Track-and-Trace technology to limit the fraud and abuse of prescription drugs, the 2009 deadline was a logistical impossibility that lacked specificity for the affected parties. We hope the delay will allow those lingering issues to be addressed, including providing financial relief for community pharmacies that would be required to buy the expensive equipment for this unfunded mandate.

Those “lingering issues” are momentous; they resonate not only for pharmacies, manufacturers, and wholesalers doing business in California but also for industry participants nationally. Other state legislatures, most notably New York, are in the process of following in California’s footsteps. Maybe, more importantly, there is a chance that the Food and Drug Administration (FDA) will adopt its own, national e-Pedigree requirement, one that might parallel California’s—or it might not.

In the FDA Amendments Act (FDAAA) that was passed last September, Congress included a section that requires the FDA to develop a standardized numerical identifier … no later than 30 months after the date of the enactment of FDAAA. This … identifier is to be applied to a prescription drug at the point of manufacturing and repackaging at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.

The FDAAA doesn’t appear to have set a deadline for the FDA to actually require application of that “identifier” to the drug package; however, the FDA has been concerned for the past decade about counterfeit drugs. In February 2004, the FDA’s Counterfeit Drug Task Force issued a report mentioning that the agency expected widespread adoption of RFID tagging of drugs in 2007, based on what technology suppliers and drug companies were saying at that time.

That advance never happened. In fact, even now, in mid-2008, few companies are placing RFID tags on product containers beyond very limited pilot projects. Everyone talks about Pfizer’s tagging of sildenafil (Viagra) coming from France; this has been going on for about a year. But even in this most celebrated case of RFID tagging, some matters have not been resolved.

Tom McPhillips, Vice President of the U.S. trade group at Pfizer, says that in December 2007, the company began to exchange pedigree information with only one trading partner...
(probably a wholesaler, although he doesn’t identify the partner).

“This was the result of six-plus months of effort between solution providers, trading partners, and Pfizer,” Mr. McPhillips told the California Pharmacy Board in January 2008. He added that it was his “best estimate” that electronic serialization at the item level for the company’s entire product line would take his company five to seven years.

The expense of the RFID tags—7 cents to 25 cents per tag, depending on the type (high frequency or ultra-high frequency) and the volume, in addition to some of the technological issues (such as the lack of interoperable standards)—has forced many companies to use only two-dimensional (2D) bar codes on their packages. Biogen Idec is probably the first company that will be able to serialize all of its packages for its products (which number only two), by January 1, 2009, far ahead of any other firm. Biogen Idec is putting 2D DataMatrix bar codes on each package of vials and syringes of its two multiple sclerosis products—interferon beta-1a (Avonex) and Natalizumab (Tysabri)—in part because the FDA has not approved RFID for use on packages of biologic agents.

Bob Hamm, Executive Vice President of Pharmaceutical Operations and Technology at Biogen Idec, states:

“RFID is the ultimate solution. However, it is still unproven where biologics are concerned. Biogen Idec opted for 2D bar codes based on the information available when we were designing our solution.”

“Biogen Idec is the first company to publicly announce item-level serialization for its entire product line,” says Kamal Mustafa, President of Secure Symbology (SSI, Inc.).

SSI, a company in Wayne, New Jersey, is providing the bar code printing, product aggregation, and database operations that were installed at Catalent’s commercial packaging facility in Philadelphia, where both Avonex and Tysabri are packaged. Catalent is based in Somerset, New Jersey.

It is the serialization of each item-level package that is the expensive part of the California e-Pedigree requirement, making previous packaging operations look like horse-and-buggy days. In the past, only the lot number and expiration date were printed in a large linear bar code.

After the serialization is completed, creating and integrating the e-Pedigree down the distribution line, and authenticating it, are technically the more difficult parts of the process. SSI’s Mustafa claims that the cost of installing his “modules”—three on the Biogen Idec lines—can range anywhere from $100,000 to $400,000. In Biogen Idec’s case, the company is paying an incremental additional cost for every carton of product printed with a 2D bar code on the Catalent line, an incremental cost that basically reflects SSI’s capital costs.

Costs are also a huge issue for wholesalers and pharmacies. Whereas RFID is the high-cost option for manufacturers, it is the low-cost option for wholesalers. When a Biogen Idec truck pulls up to an AmerisourceBergen warehouse in California, the guys working there must open each carton of Avonex and Tysabri and pull out each carton to read the 2D DataMatrix bar code with the serial number. This task is incredibly labor-intensive.

Barbara Brungess, spokeswoman for AmerisourceBergen, says:

While we strongly prefer that manufacturers embrace RFID because it offers the most efficient solution, we are willing to work with those who roll out 2D bar code serialization as an interim step. This is especially true for biotech manufacturers, as the industry still awaits the results of studies conducted by the FDA to determine what effect, if any, the scanning and reading of RFID tags has on biological products.

Given their economies of scale and their small number of distribution centers, wholesalers will probably be much better able to handle the different serialization technologies that arrive on their doorsteps. Pharmacies face the same challenge, except that the costs will be a much larger percentage of revenues than for the wholesalers, and other workforce concerns will crop up in relation to e-Pedigree authentication.

Typically, wholesaler “A” sends to each pharmacy a “tote”—a large sack of sorts—containing cartons of products from all the manufacturers with whom that wholesaler works. After the California requirement kicks in, each manufacturer may use one of a number of different serialization technologies, thereby creating an authentication nightmare for pharmacies. One retail pharmacy chain told the California Board of Pharmacy that it would take $54 million for one distribution center covering 591 pharmacies to achieve end-to-end serialization.

David Wilcox of PharmKee thinks that independent pharmacists should be compensated for the costs associated with buying multiple scanning technologies. The estimated costs for a retail pharmacy to comply with e-Pedigree requirements are anywhere between $10,000 and $40,000. These expenses include obtaining the hardware and software as well as the staff training necessary to administer, monitor, and maintain the system, as required by law. Chain pharmacies estimate their initial per-store implementation costs at $25,000 to $35,000 and an additional $5,000 to $6,000 per year.

The California Pharmacy Board is unlikely to balk again on the e-Pedigree requirement in January 2011. So the pitch is coming. Walgreens may have a big catcher’s mitt by then, but other pharmacies may have to settle for a long chest protector.