

## **Are you trying to make sense out of the California 2009 Mandate?**

### **Briefly describe Northern Apex and some of the projects you have been involved with.**

Northern Apex is a leading, long time and well respected RFID integrator that is proudly celebrating a decade in the world of RFID. Our experience is broad and deep as we work across all frequencies including active, passive, LF, HF and UHF. Northern Apex focuses on vertical markets, including one of our main vertical markets, pharmaceutical. We also are involved with custom, hard to find solutions. Over the past decade, Northern Apex has played a key role in numerous RFID projects including the first ever RFID tagging of item level pharmaceuticals – Oxycontin with Purdue Pharma. We have integrated RFID into scores of manufacturing lines for tagging or tracking products through the production cycle, introduced unique RFID products to the market and teamed with other service providers to deliver partial or complete RFID-based solutions. Additionally, we have testified before congress as an industry witness regarding Pharmaceutical Supply Chain Security.

### **Give us an overview of the California e-pedigree legislation and describe its impact on the pharmaceutical industry.**

There is current legislation scheduled to take effect in California on January 1, 2009 that requires an electronic pedigree as well as serialization for all drugs sold in the state. The purpose is to secure the drug supply chain from counterfeiting, diversion and other schemes that threaten patient/public safety. E-pedigree is a system that electronically and securely records the ownership of a drug throughout the supply chain. With previous pedigree requirements, the distributor was the source for initiating the pedigree. California has chosen to begin with the manufacturer so that the chain of ownership begins with the manufacturer and continues through the distribution and retail process to the end customer. Serialization, by California's definition, is a way of assigning a unique identification number, established by the manufacturer, to a saleable unit. While pedigree laws and serialization are in place in multiple states today, this legislation takes e-pedigree to new levels by requiring:

- 1) The pedigree must be electronic, not paper.
- 2) Manufacturers will initiate the e-pedigree. In the past, distributors initiated the e-pedigree.
- 3) The pedigree applies at the sales unit level rather than lot level or some other higher level.
- 4) Serialization is also required at the sales unit rather than a higher level.

The California legislation is having a significant impact on the entire pharmaceutical industry from manufacturers, including generics and brand names, to distributors and retailers, contract packagers and re-packagers. Also affected are industry organizations, standards organizations and enforcement groups. Everyone is following the developments, paying particular attention to the Board of Pharmacy meetings, the development of standards and keeping an eye on the FDA. Some are taking action, many are not. A handful of pilot programs, some high profile and costly, have been initiated to evaluate and investigate the various technologies for serialization and e-pedigree. Many are waiting to see if the Board of Pharmacy delays the legislation until 2011.

### **What role does the California Board of Pharmacy play?**

The California legislature empowered the state Board of Pharmacy with the authority to delay the implementation date from January 2009 to January 2011 if the Board "determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state." The Board of Pharmacy has been holding public meetings on the subject to assess the state of readiness of the industry. At the January 23rd meeting, several Board members expressed frustration with the current state of the industry and seemed to dig in their heels regarding a delay in implementation. They felt the information that was presented to the Board regarding the implementation date wasn't sufficient in terms of the number of submissions or the

evidence presented. In fact, their website states that “the Board has repeatedly made clear in prior meetings that it believes the industry ought to be able to comply with the requirements of the pedigree statutes by January 1, 2009. This is particularly the case since the electronic pedigree requirements were first legislated into California law in substantially similar form in 2004, giving a total lead time for the industry of four or more years.” The Board has already delayed implementation once and is legitimately concerned that another delay will simply take the pressure off the industry and everyone will be back in two years debating the same issues. The Board has called an additional meeting for March 25<sup>th</sup> to hear further arguments regarding the implementation dates and industry readiness for compliance.

### **How is the industry in general responding or reacting?**

Industry reaction is all over the map. Utilizing pilots, a handful of players are seriously working towards compliance. Some of these pilots are being conducted in conjunction with supply chain partners while others in the industry are behind the curve in the planning stages. Most however, have done little or nothing, choosing to wait and see what happens as standards emerge, technology improves and prices come down. In some respects, the industry as a whole is overwhelmed by the issues that are involved and largely believes that a delay in implementation is inevitable.

### **What are some of the key issues that have emerged?**

Cost is always a significant issue, but there are other important issues as well. Because no single technology standard has been specified, interoperability among supply chain partners is a major issue particularly down the supply chain. While the FDA recommends RFID, the FDA and the state of California will accept serialization utilizing 2D data matrix technology or HF RFID or UHF RFID. For some downstream organizations this will require three different kinds of readers and other related equipment, software, training and processes depending on the technology that the manufacturer uses. Other issues include the disruption to production lines to integrate the solution into the manufacturing environment, updating and coordinating with the IT systems and the production down time that would be required to accomplish these changes. FDA re-validation after a change to a production line is an enormous concern; that an investment will be made in a technology that will be deemed or doomed as the “wrong” technology because industry goes in a different direction.

### **Are there other issues?**

The Board is wrestling with at least two other key issues – inference and grandfathering. Both were discussed at the January Board meeting but no decisions have been made. An example of inference is when a case of items is received and the tag on the case is scanned, the database is queried and the items that the database says are in the case are allowed to be accepted into inventory without scanning each individual item. The presence of each item is inferred based on the parent-child relationship established by the organization selling the case. Grandfathering means allowing existing inventory that is not serialized to be exempt from the January 2009 mandate. Testimony was given that there is already product on some distributor and retail shelves that will still be there a year from now.

### **What are some of the challenges the supply chain is facing?**

The challenges are the same for everyone but the priority may change based on where an organization fits in the supply chain. For example, manufacturers will be required to select a technology and method for serializing their product. A manufacturer has the option of 2D bar code, HF RFID or UHF RFID. The selection process may require a significant testing cycle and cost analysis. Downstream partners, however, will only have to read and verify the serial numbers and if inference is allowed at some level such as a case level, then downstream partners will not have to read every label in a case, simply the one case label from which they can infer the other units are present. Another example is the multiple

technology issue. While a manufacturer has the freedom to select one compliant technology, the retail outlets and distributors must be prepared to handle any and all compliant technologies.

### **What are some of the lessons learned from your years of integration experience?**

Follow a phased approach. Time and again this lesson has proven to be critical. Train wrecks and runaway projects are avoided by following project phases that build on previous successes and lead to the eventual goal.

Expect the unexpected. This is not a fatalist view that becomes a self-fulfilling prophecy. This is a realistic approach that tries to anticipate what could potentially go wrong and prepare for it. Organizations that approach projects in this fashion tend to be equipped to deal with real life situations that threaten success.

Be flexible. We have learned over the years to be flexible rather than rigid when solving a problem or executing a project phase. This approach tends to allow creativity and facilitate discovery of multiple potential solutions.

### **What advice do you have for the organization that is just getting started?**

Take the legislation seriously! Even if there is a delay, the requirement is inevitable.

Get started now! The task is daunting and will likely take longer than expected.

Deploy components that go to the long term solution. You only want to do this once.

Follow standards. Enough said.

Follow the lead of the Big Three distributors. Their RFID with 2D backup requirement could become the standard.

Go beyond meeting the mandate, find an ROI. Perhaps by extending the solution to other areas of the enterprise an improvement in efficiencies will outweigh the cost of the system. It doesn't hurt to look.

Partner with an experienced integrator. The technology is not off the shelf plug and play, especially RFID. Plus, an experienced integrator will be able to guide you through all of the issues discussed in this paper. In the long run, this will save you time and money.