An Rx Prescription and Bulk Drug Tracking and Authentication Architecture

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Executive Summary

Accessing information, from anywhere, at anytime, securely, is commonplace today. The time has come to use technology and communications to reduce fraud and errors in prescription drugs and eliminate counterfeit drugs. The practice of medicine will improve, and the solution can pay for itself.

Key West Technologies proposes a solution for tracking and authenticating Rx Prescriptions and their associated physical drugs. Applied in a “region”, the solution will significantly curtail both fraudulent Rx Prescriptions and counterfeit drug traffic. The region is somewhat arbitrary as well as scalable, defined by a regional regulatory structure. It mandates that all Rx Prescriptions written within the region, and bulk drugs imported into the region, be tracked in a "Regional Pharma Database". All participants must conform to a defined tracking and authentication standard.

The standard for Rx Prescription tracking will involve an encrypted "authentication code" printed on the prescription in electronically readable form. The Regional Pharma Database will generate the “authentication code”. This authentication code, similar to a barcode number, will be combined with other randomized information from the prescription itself for authentication by the fulfillment pharmacy. The standard for bulk drug tracking will involve the "electronic tagging" of, and tracking of all drugs imported into the region by means of the same Regional Pharma Database.

Here is how it works. First, an Rx Prescription will be generated by a healthcare provider utilizing the authentication and tracking framework. Then the pharmacy will validate the prescription using the same authentication and tracking framework, and link it to the actual authenticated drugs used in its fulfillment. This will curtail fraudulent Rx Prescriptions and counterfeit drug traffic in a region. The same framework inherently provides an opportunity to bring a plethora of other benefits to the various stakeholders in the healthcare industry.

The Regional Pharma Database, while remaining fully HIPAA compliant, could provide the healthcare industry and the government with early warning trend data for bio-terrorism or other epidemic outbreaks. It could also provide trend data with regard to prescription medication.

This Regional Pharma Database can provide healthcare providers a valuable resource for drug information including on-demand as well as real-time drug interaction analysis. The Regional Pharma Database could provide healthcare providers Emergency Medical Records for patients being treated in an emergency situation, by permission or mandate.

This envisioned framework will benefit each of the industries stakeholders with virtually no negative consequences. This is a "framework" built around an "open standard" that allows each of its users great flexibility. The database can be accessed and used by any IP / Internet browser capable device including specialized low cost Rx Prescription terminals, traditional computers, Personal Digital Assistants (PDAs), and even mobile phones. Virtually any printer can print the prescription.

The framework and its associated process will provide society the obvious benefits associated with curtailing fraudulent Rx Prescriptions and counterfeit drugs. The healthcare provider will benefit from improved accuracy and security of prescription medication. In addition, they can practice better medicine through real-time access to drug information, real-time / transparent drug interaction evaluation and warning, and less time spent writing prescriptions and dealing with associated pharmacy calls and errors. Drug manufacturers will benefit by better public image as well as recovered revenues from the significant decline in counterfeit drugs in the region. In addition, they also benefit from the inherent logistic benefits they and their network of distributors realize. The Pharmaceutical industry benefits from better public image by participating in the fight against fraudulent Rx prescriptions, as well as more efficient and accurate fulfillment. The patient benefits from all of these. Everyone wins and the cost is completely offset by the benefits.

The Solution

Rx Prescription Authentication and Tracking

The solution has a primary objective of tracking and authenticating Rx Prescription and their associated bulk drugs within a defined controlled region for the purpose of curtailing fraudulent prescriptions and counterfeit drug traffic within that region. The notion of region is somewhat arbitrary and can be easily applied to a city, a county, a state, a nation, any other geographical region that can be regulated in its totality to conform to "standard practice".

The framework is based on a multidimensional regional database, securely accessible via the Internet by regional healthcare providers, regional pharmacies and drug manufacturers, illustrated in Figure 1.0. Multidimensional means that the "Regional Pharma Database" is actually comprised of several discrete databases and that it is completely scalable in terms of database sizes and the number of databases within. Each of these databases supports a specific feature of framework

and interoperates on a relational basis. Each of these databases reflects and maintains the "open standard" for its specific use. It should be noted that the actual database could physically reside anywhere in the world and for practical matters of "disaster recovery" will most likely have a primary physical location, and a second co-location outside of the region. The database by design can be accessed by any device that has an Internet browser and can connect to the Internet using Internet Protocol (IP). This includes traditional office desktop computers, mobile computers

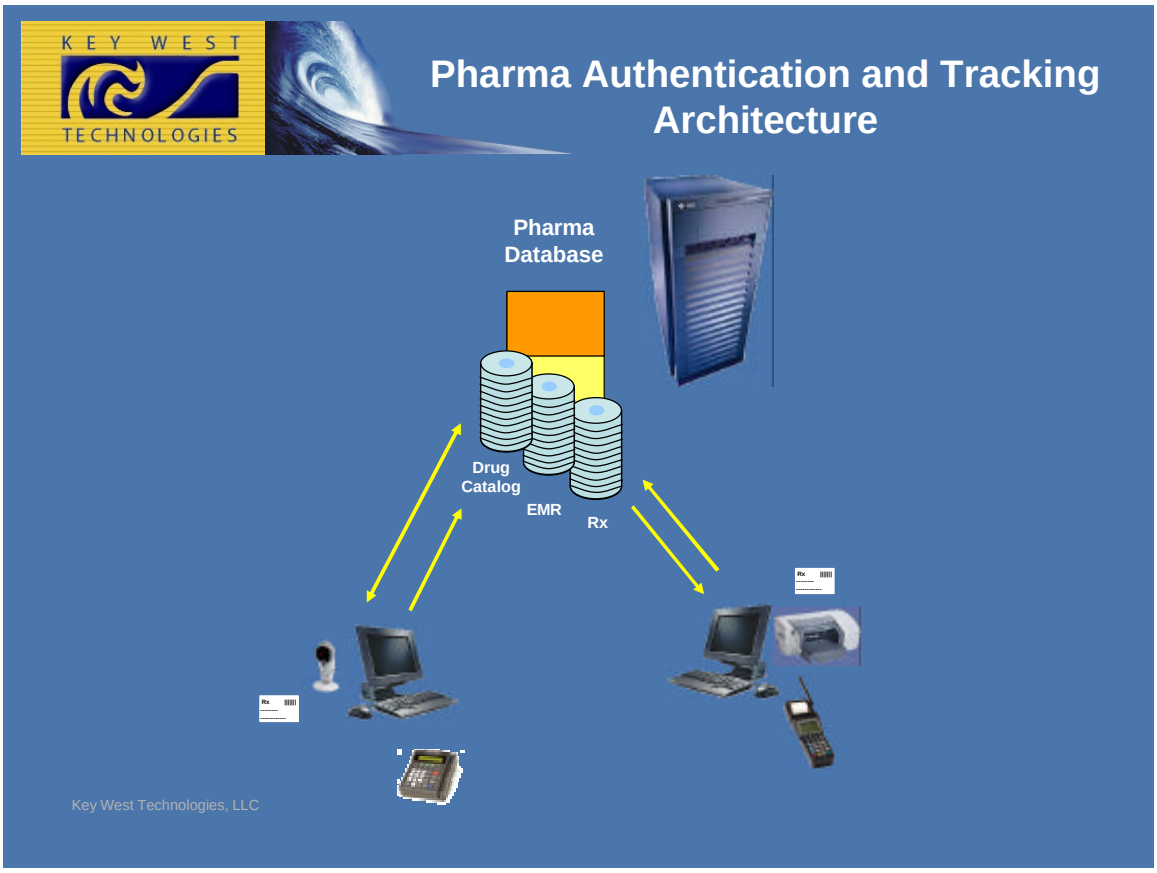

Figure 1.0 The fundamental framework for tracking and authenticating Rx Prescriptions and bulk drugs.

like laptop computers and Personal Digital Assistants (PDA), web-enable mobile telephones and a range of new low cost specialized terminals. The detailed architecture for authenticating and tracking Rx Prescriptions is illustrated in Figure 2.0.

This element of the Regional Pharma Database stores and manages the "authentication codes" that are associated with Rx Prescription written within the region. This authentication code is envisioned to be similar to a UPC barcode in that it is essentially a unique number assigned to each Rx Prescription. In practice an alphanumeric combination is preferable in order to get the maximum number of authentication codes from the fewest bytes in the database [(1)]. The actual authentication is based on a combination of the authentication code and other randomized information from the prescription itself. This database is initialized with a

large set of authentication codes in the "available" status. That is they exist as valid authentication codes ready for use.

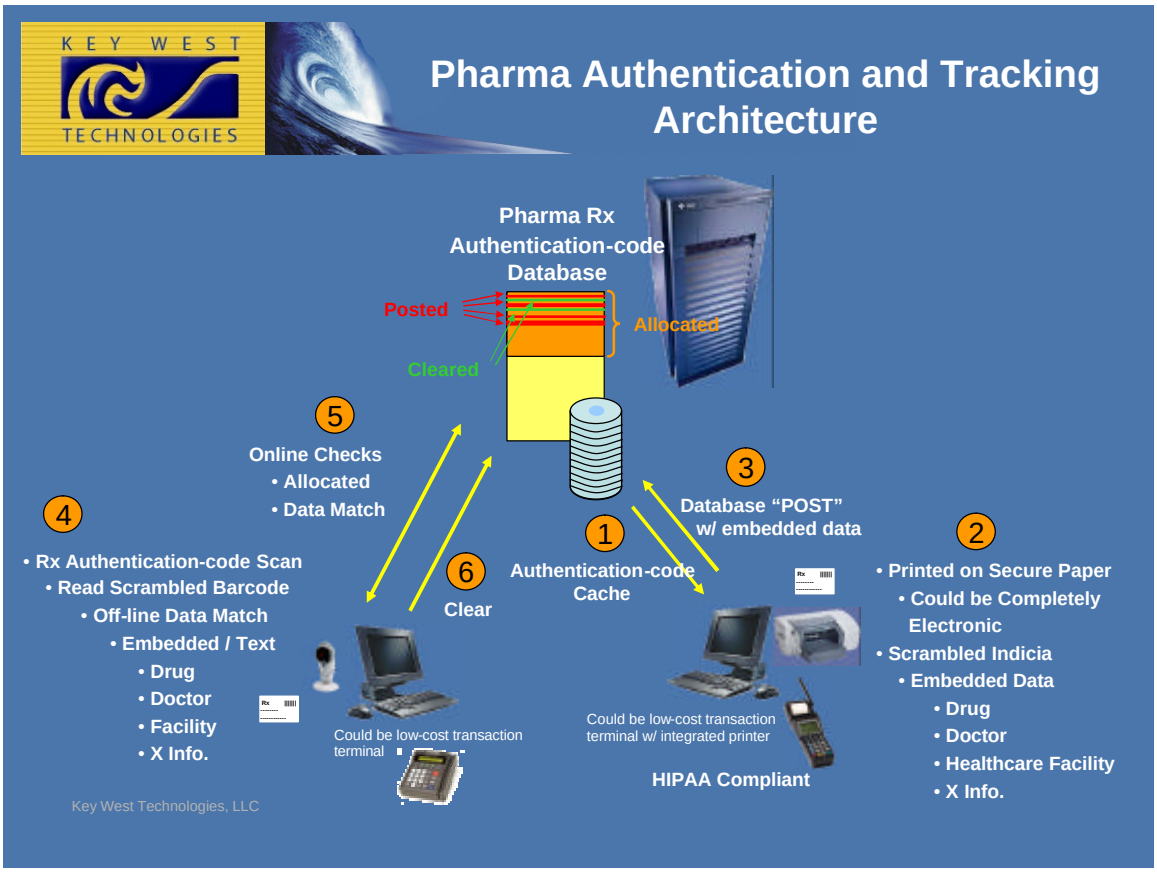

Figure 2.0 The Pharma Tracking and Authentication architecture for Rx Prescriptions.

The first step in this schema is for a healthcare provider to write an Rx Prescription, and retrieve an "allocated" authentication code from the database. This could easily involve validating that the healthcare provider is authorized to write prescriptions within the region, and to use the Regional Pharma Database to do so. This retrieval again can be accomplished by using any of the devices we have already mentioned. The provider can use a new low cost specialized terminal (Rx-Terminal). These authentication codes can be downloaded from the database on-demand, one-at-a-time, or in blocks to use over time. In any case, retrieving an authentication code will change its status in the database from "available" to "allocated". This means it has been assigned to a specific healthcare organization or individual healthcare provider. The authentication code can only be used by the "downloader", and can only be used once. This provides the first barrier to fraud. The healthcare provider proceeds with the Rx Prescription writing procedure by inputting the normal prescription information via the Rx-Terminal. This process might also involve the healthcare provider using the Rx-Terminal to enter a "pin" code.

The low cost specialized Rx-Terminals will provide the healthcare provider a combination of iconic and typed information entry. Each prescription will have the healthcare providers name and contact information as well as the name of the patient, the prescription itself and instructions for the patient. Figure 3.0 shows a

sample Rx Prescription. When the healthcare provider completes the prescription input, the software in the Rx-Terminal combines the authentication code with the entered information (random content) and the "electronic-signature" of the healthcare provider, and encrypts it into a secure graphical format known as "Scrambled Indicia".

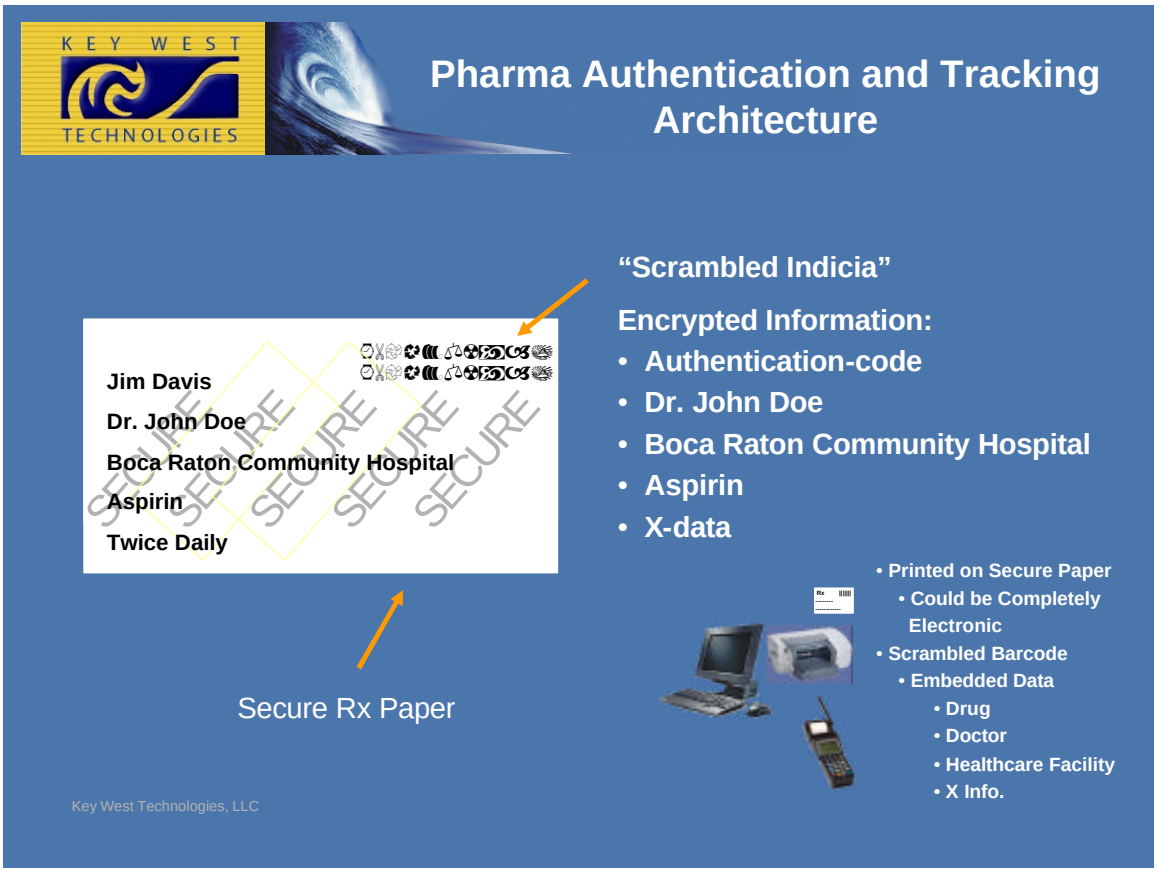

Figure 3.0 An example Rx Prescription illustrating the information entered by the healthcare provider and the "Scrambled Indicia" authentication image.

Scrambled indicia is much like it sounds, scrambled markings. The information is scrambled together and translated into an image of lines and wiggles that are visually meaningless. The Rx Prescription is printed, optionally on secure Rx paper, and the authentication image is simultaneously uploaded to the Regional Pharma Database.

Upon receiving this upload the Regional Pharma Database server (RDS) temporarily decrypts the authentication image and extracts the name of the patient, the drug that is being prescribed, and whether or not the patient has given permission to participate in the regions Emergency Medical Record (EMR) program[(2)]. If the patient is participating in the regions EMR program the RDS retrieves the appropriate EMR from that segment of the database and in real-time evaluates the implications to the patient in taking the prescribed drug. This would include adverse interaction between the prescribed drug and drugs that were prescribed to the same patient in the recent past as well as other pertinent pre-existing medical factors. Drug interactions would be evaluated by determining the names of the drugs recently prescribed from the EMR database, and extracting their specific drug-interaction parameters from the

Drug Catalog database - another discrete database within the Regional Pharma Database. This database provides on-demand information on virtually every drug that might be prescribed within the region. These parameters and other information from the EMR are used to quickly build an evaluation matrix. If any issues are uncovered, the RDS immediately sends a "warning message" to the uploading Rx-Terminal and awaits acknowledgement. The Rx-Terminal suspends printing the prescription and displays the warning message on its display. The healthcare provider can acknowledge the warning message or change the prescribed drug. Upon acknowledgement or a successful evaluation of the changed prescription the RDS appends the encrypted authentication image to the authentication code in the database and changes its status to "posted". The Rx-Terminal completes printing the prescription including the healthcare provider's written signature. The prescription is handed to the patient for fulfillment at a pharmacy of choice and potentially sent directly to a particular pharmacy electronically, at the patient's request.

The patient presents the prescription at the chosen pharmacy for fulfillment, whether electronically sent or not. Again, refer to Figure 2.0. The pharmacy scans the prescription "in" using any of a number of different "connected" devices with associated scanner capabilities, from low cost to sophisticated multifunction. Pharmacies can continue to use their legacy equipment or opt for new low cost equipment that integrates with their current equipment and management system. The initial scan reveals the random content embedded within the encoded scrambled image for visual inspection, clearly and legibly. This clear and legible display of the prescription improves dispensing accuracy and saves the pharmacist time over the historical struggle to read handwriting. The embedded information should obviously match what is written on the prescription. Passing this initial offline check the pharmacy can begin to fill the prescription while the terminal transmits the complete scrambled image to the online Regional Pharma Database for final validation. The RDS decodes the image and verifies that the encoded "authentication code" is valid; that it is "posted" and that the random information stored in the database by the healthcare provider at the time the prescription was "posted" matches the random information encoded in the image transmitted by the pharmacy. If this validation fails for any reason a warning is sent to Pharmacy as well as others that have an interest in this authentication. Such warnings could easily be integrated into the Pharmacies "payment system" in such a way as to prevent the transaction from being completed. Upon successful completion of his validation the RDS transparently and relationally associates the drugs called for by the prescription with the tracked and authenticated bulk drug shipments known to be in the pharmacy's inventory. This check utilizes another one of he discrete databases that make up the overall Regional Pharma Database. If the associated drug cannot be found in database a warning is issued to the Pharmacy as well as others that have an interest in this authentication. Again this warning could easily be integrated into the Pharmacies "payment system" in such a way as to prevent the transaction from being completed. If the association is successful the RDS makes preparations to adjust the tracked inventory quantity of the specific drug for the pharmacy in the database upon the transactions completion.

The Pharmacy completes the filling of the prescription and proceeds to complete the transaction with the customer by delivering the prescribed drugs and collecting payment. Upon return to the payment terminal the Pharmacist either observes a

warning message and aborts the transaction, or does not and completes the transaction in the normal manner. Completion of the transaction simultaneously transmits its "cleared" status to the Regional Pharma Database. This "cleared" status takes the prescription's "authentication code" out of circulation for an arbitrary period of time, 30 days for instance, as an additional mechanism to increase the barrier to the success of a fraudulent prescription. The "cleared" status also completes the depletion of the fulfilling Pharmacy's inventory in the Regional Pharma Database for the prescribed drug. Note that no one anywhere in this process has actually seen an authentication code; it has been managed exclusively by the RDS of Regional Pharma Database.

Bulk Drug Authentication and Tracking

The bulk drug authentication and tracking system is an element of the multidimensional Regional Pharma Database. It is intended to track bulk drug shipments from manufacturers around the world into the hands of patients. The architecture and schema provide for tracking these bulk drug shipments from their origins, manufacturers, through their channel of distributors to individual pharmacies and ultimately to patients. The fundamental architecture and schema of this system is illustrated in Figure 4.0.

The design calls for a "certified" drug manufacturer desiring to import drugs into the controlled region "registers" and "tags" each drug shipment, using an "authentication code", in the Regional Pharma Database. The bulk drug authentication and tracking schema is very similar to that of the Rx Prescription schema. Drug manufacturers retrieve "valid" authentication codes from the Regional Pharma Database, and use them to uniquely identify specific physical shipments of drugs. Only certified manufacturers will be authorized to distribute drugs within the region and to retrieve "authentication codes from the Regional Pharma Database. Each "allocated" authentication code is associated with the specific "certified drug manufacturer code" upon its retrieval. This retrieval can be accomplished by using any device that can connect to the Regional Pharma Database over the Internet and run Internet browser software. These authentication codes can be downloaded from the database on-demand, one-at-a-time, or in blocks so as to build an offline cache for incremental usage over time. In either case, retrieving an authentication code will change its status of the "valid" authentication code in the database from "available" to "allocated". This means it has been assigned to a specific drug manufacturer. The authentication code can only be used by the "downloader" and can only be used once, providing the first barrier to successful counterfeiting.

The drug manufacturer packages the drugs being shipped in the controlled region, in what might be called a "ship group". The manufacturer might package and ship drugs for the distribution channel in higher quantity containers than what ultimately reach a specific pharmacy. In this distribution system, individual distributors, would break down large quantity shipments into smaller quantify shipments as necessary. This is done to minimize various operating cost associated with distribution, including inventory management and shipping cost. It is the containers in this "ship group" that

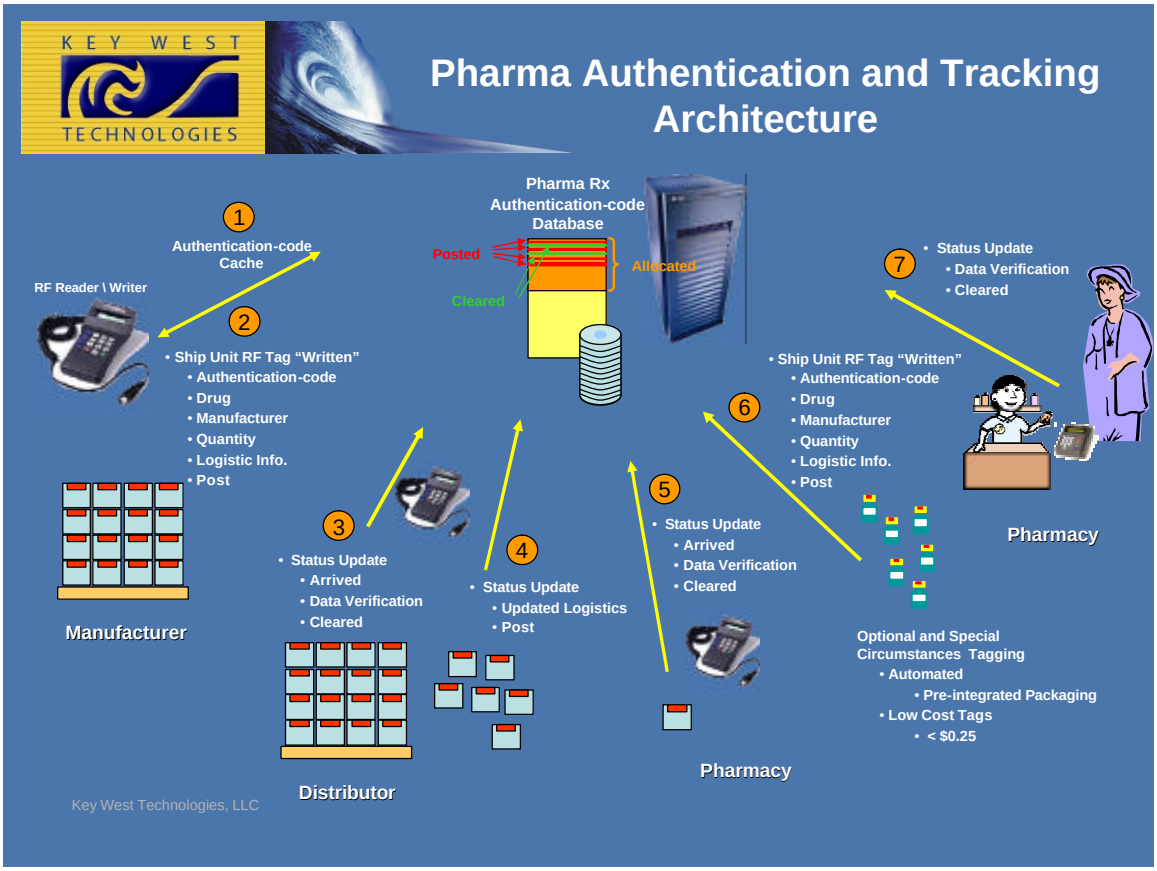

Figure 4.0 An example Bulk Drug Authentication and Tracking architecture and schema illustrating the information entered by the drug manufacturer and its progression through the supply chain.

are initially registered and tagged. For purposes of this narrative we will use a shipment of drug Alpha from a manufacturer located in Europe shipping into the United States.

Consider a hypothetical case in which the manufacturer has packaged drug Alpha in individual containers of 10,000 units each; refer to Figure 4.0. Each of these containers has an electronically readable tag that combines the authentication code with specific information about the shipment (random content) in a standardized encrypted format, the authentication content. This tag could take many forms, depending on the requirements. It could be as simple as a printed label that must be physically viewed and scanned one-at-a-time as it moves through the supply chain. In some cases, it could be new RF-Tags that can be read many-at-a-time without physically viewing them. This RF-Tag technology, when combined with Global Positioning System (GPS) fleet management, can even be used to track bulk drug shipments while they are in transit. Figure 4.0 illustrates a pallet of these RF-Tagged containers. Each tag contains a unique authentication code, the manufacturers name and contact information, the packer's I.D., drug name and quantity, date of shipment and next destination. As the pallet leaves the manufacturer's factory the authentication content in each tag is uploaded to the Regional Pharma Database, validated and saved.

The authentication content is temporarily decoded by the Regional Pharma Database server (RDS) into its constituent elements. The authentication code is validated by determining that the "allocated" authentication code and associated manufacturer stored in the Regional Pharma Database match the same information in the authentication content being uploaded. Upon validation the "allocated" status is changed to "posted" and is saved in the database with complete, encrypted authentication content. This process initially repeats itself when a distributor receives the shipment.

The distributor receives the shipment and scans the pallet upon its arrival. With RF-Tag technology the scan provides the distributor with an immediate and complete inventory check and accounting of everything tagged on the pallet. The scanned authentication contents of each tag is uploaded to the Regional Pharma Database and validated. Validation, in this instance, means that the uploaded authentication content matches the authentication content stored in the Regional Pharma Database. Further it validates that the receiving entity is consistent with destination information stored with the authentication code, in this case, by the manufacturer. Given no warnings from the validation procedure the distributor breaks down the pallet into the smaller individual packages intended for shipment to various pharmacies.

At this point, the distributor might combine containers from multiple manufacturers into a new ship group packages to be sent to a particular pharmacies. The process for each of these containers would have been the same up to this point. The authentication content stored in each container's RF-Tag in the various ship group packages are augmented to include the Distributor's Information, packer's I.D., date of shipment and its next destination. This updated authentication content is uploaded to the Regional Pharma Database and stored with the associated authentication codes. The authentication code statuses remain "posted". The packages are shipped to various pharmacies in the controlled region.

The pharmacy receives the ship group package and scans the package upon its arrival. The scan provides the pharmacy with an immediate and complete inventory check and accounting of everything in the tagged package. Note again that a single package received might contain a number of different drugs from a number of manufacturers. The scanned authentication content of each tag is uploaded to the Regional Pharma Database and validated. Here, validation means that the uploaded authentication content matches the authentication content stored with the hidden authentication code in the Regional Pharma Database. Further it validates that the receiving entity is consistent with the destination information stored with the authentication code, in this case stored by the distributor. Given no warnings from the validation procedure the pharmacy adds the various drugs to its in-store inventory. For example, the container of Alpha drug having 10,000 units is added to an existing authenticated inventory of 1200 units. This brings the pharmacies total inventory of authenticated Alpha drug to 11,200 units.

The patient presents a prescription at the pharmacy for fulfillment. Again, refer to Figure 2.0. The pharmacy scans the prescription "in". The initial scan reveals the random content embedded within the encoded scrambled image for visual inspection. The embedded information should obviously match what is written on the prescription. Passing this initial offline check the pharmacy can begin to fill the prescription with authenticated drugs from their inventory. The pharmacy's terminal transmits the complete scrambled image to the online Regional Pharma Database for final validation. The RDS decodes the image and verifies that the encoded "authentication code" is valid; that it is "posted" and that the random information stored in the database by the healthcare provider at the time the prescription was "posted" matches the random information encoded in the image transmitted by the pharmacy. If this validation fails for any reason a warning is sent to Pharmacy as well as others that have an interest in this authentication. Such warnings could easily be integrated into the Pharmacies "payment system" in such a way as to prevent the transaction from being completed. Upon successful completion of his validation the RDS transparently and relationally associates the drugs called for by the prescription with tracked and authenticated bulk drug shipments known to be in the pharmacy's inventory. On the basis that only authenticated and tracked bulk drugs can be imported into the controlled region, the complete inventory of the pharmacy is accurately reflected in the bulk drug segment of the Regional Pharma Database. If the associated drug cannot be found in database a warning is issued to the Pharmacy as well as others that have an interest in this authentication. Again this warning could easily be integrated into the Pharmacies "payment system" in such a way as to prevent the transaction from being completed. If the association is successful the RDS makes preparations to adjust the tracked inventory quantity of the specific drug for the pharmacy in the database upon the transactions completion.

The Pharmacy fills the prescription and completes the transaction with the customer by delivering the drugs and collecting payment. If the Pharmacist observes a warning message on the payment terminal, he or she aborts the transaction. Completion of the transaction simultaneously transmits its "cleared" status to the Regional Pharma Database. The "cleared" status completes the depletion of the pharmacy's inventory of Alpha Drug in the Regional Pharma Database by the prescribed amount. In our example, the 11,200 units of Alpha Drug are reduced by the prescription quantity of let say 100 units, leaving 11,100 in the authenticated inventory. Note that throughout this process, no one has actually seen an authentication-code. It has been managed exclusively by the RDS of Regional Pharma Database.

The proposed architecture and schema will significantly reduce fraudulent prescriptions and counterfeit drugs within the region. Relatively unsophisticated individuals carry out a significant percentage of these abuses. This solution will virtually eliminate those intrusions. Remaining abuses, carried out by more sophisticated individuals and groups, can be eliminated on the basis of cost, risk and reward. Although the reward remains unchanged, both the cost of defeating the system and the risk of being detected are increased significantly.

Notes:

(1) A byte of information, 8 bits, can reflect any digit from 0 to 9 or any character of the alphabet from "a" to "z". That is 36 different symbols. In notation limited to numeric symbols, 0 to 9, two bytes could reflect a maximum of count of 100 (10 x 10). Using an alphanumeric notation, 0 to 9 and "a" to "z", two bytes could reflect a maximum count of 1296 (36 x 36).

(2) Related / potential features / functions of the Pharma Authentication and Tracking Architecture.

Pharma Authentication and Tracking Architecture

Related Features:

- **Emergency Care**
  - Emergency Personnel Access to “Critical” Patient Data
    - General Medical Data (Blood Type, etc.)
    - Recent Pharma History
      - Drug Interaction Query
  - Permission Based
  - Authenticated Access
  - Multiple Delivery Models
    - Data Over IP (Text / Voice)
    - Computer, Pager, PDA, Cell Telephone, Wired Telephone

Key West Technologies, LLC