Elimination of medication errors through "Positive Patient Medication Matching"

With additional benefits of compliance with the "Healthcare Insurance Portability and Compatibility" requirements and improved patient cares and services

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INTRODUCTION:

The following news and data have surfaced over the last two years concerning patient care quality and safety. They have been the inspiration and driving force for the solution being outlined below.

- There were 3.0 billion prescriptions per year being made in year 2000 with an average cost of approximately \$40 each. (Reported in "Pharmaceutical Industry Year in Review-2000" by NDCHealth)
- There were 770,000 injuries caused by medication errors. (Study by Agency for Healthcare Research and Quality, cited by "Time", April 23, 2001)
- There were an estimated 44,000 to 98,000 fatal incidences arising from these 770,000 injuries with the total cost of \$177.4 billion for hospital admissions and long-term care admission. The cost of death and other compensations have not been estimated. (*Study by Institute of Medicine, cited on "Federal Register"/Volume 66, No.232, December 3, 2001*)
- Healthcare represents approximately 14% of the US economy at \$1.2 trillion. Among the cost, it was estimated that \$590 billion is spent on appropriate treatment, \$400 billion is spent on inappropriate treatment, and \$210 billion spent on administrative tasks. (Cited by NDCHealth on Reported in "Pharmaceutical Industry Year in Review-2000")
- Assistant U.S. Heath Secretary Bobby Jindal announced a proposal to requiring the use of barcode on both medication and on the patient's ID tag. (Dow Jones News, 12-0301)

One must conclude that there is substantial room for improvement in this critical industry of patient and medical care. Any solution that cost less than \$177 billion will be a cost saving at least to the society as a whole.

The technological and logistic solution outlined here represents a cost of less than \$2.0 billion per year to implement. It has the potential to eliminate all of the preventable medication errors. The resulting benefits not only save lives but also reduce the cost of the healthcare expenses by at least \$175 billion and may be over \$200 billion when the reduction in administrative tasks are included. The same solution may have substantial impact to the \$400 billion of inappropriate treatment by preventing them either through better diagnostic management or accountability logistics. It will certainly reduce the cost of compliance to the new federal healthcare requirements.

The "Healthcare Insurance Portability and Accountability Act" (HIPAA) passed in 1996 and the compliance is due in the coming years. The industry has estimated that, the responsibility may add another \$3 billion or more per year to the current \$210 billion cost of administrative tasks. The following are some of the requirements of HIPAA that may be solved with the solution being discussed in this proposal:

- Provide controlled access of medical charts to the patient and to keep track of record of who has seen them.
- Provide faster health claims and processing.
- Provide streamlined enrollment processing in health plans.
- Provide and facilitate the first reporting of injuries.
- Provide improved referral certification and authorization.

In this proposed solution, there are may "side" benefits that come with the use of the automatic radio frequency identification (RFID) technology of HIPA-TAG[™], that has been specially engineered to fit the form-factor for medication applications. One of the many "side" benefits is the facilitation of compliance to all of those aspects listed above with minimal additional cost. When automatic identification technology (AIT) is properly managed and interfaced with the medical information systems, the administrative tasks will be dramatically more efficient. It may even help to deflate important part of the \$210 billion that the healthcare industry expensed in administrative tasks.

The controlling of counterfeit drugs are another potential benefits to using the method discussed in this proposal. According to the World Health Organization, more than 7% of the world's pharmaceuticals are bogus. Among these counterfeit drugs, 60% have no active ingredients, 16% have the wrong ingredients, and 17% have incorrect among of ingredients (U.S. News & World Report", July 11, 2001).

The cost to the pharmaceutical industry is estimated to be \$2 billion. This cost estimation does not include the costs to the patients and society in terms of counterfeit drug related medication errors. One can only assume that it is much higher than \$2 billion when many injuries due to counterfeit drugs are included.

The solution discussed here made use of the current available RF identification technology and web-base information system to automatically provide the positive patient medication matching to totally eliminate avoidable medication errors. The side benefit of this automatic identification of patient and medications are efficiency in administrative tasks through the automatic interfacing with the medical information systems in existence. This low cost RFID solution has been developed over the last few years and is now matured with appropriate infrastructure for use in the healthcare industry.

REDUCTION OF MEDICATION ERRORS USING HIPA-TAG™:

While detailed accounts of medication errors need to be studied, the medication errors that occur in inpatient and outpatient healthcare dispensing of the healthcare system at least include the following:

- Medications dispensed by the pharmacist are different from the prescription by the physician
- Wrong instructions or dosages
- In confusion, medications are given to the wrong patients
- Medications that cause allergic reaction of the patient
- Medications that interact with each other
- Medications that are given because of errors in diagnostics

The first five of the six error types can be readily solved with a better logistics and information system and thus totally avoidable. The RFID HIPA-TAG[™] solution discussed in this paper helps to implement such logistic solution easily than the barcode system being proposed. Figure 1 is a representation of barcode and RFID tag that can be attached onto the medications. The basic differences are discussed.



Barcodes can be read by a reader and translate into alphanumeric data when related to a database can provide detailed information on both medications and patient. Scanning or reading requires human intervention to assure line-of-sight and is relatively easy for larger and flat label. The proposed RSS (reduced Space Symbology) is smaller than the standard Universal Product Code (UPC) of 1.5 by 1 inch. With 14 digit "Global Trade Item Number". The printed label 2-D composite label may also include lot number, etc. One problem is that it is hard to read in the real world environment and particularly difficult for unit dosage that may be small and round in shape.



RFID HIPA-TAG[™] shown here consists of an IC-chip that is connected to an antenna coil built on a flexible plastic substrate. When interrogated by a reader at 13.56 MHz, it automatically relates the information that has been encoded in the chip to the reader. HIPA-TAG[™] complies with ISO 15963 and is usable anywhere in the world. The plastic tag is paper thin and lined behind the printed label. The data storage capability varies from 52 characters to more than 1000 characters. Thus these RFID tags can provide detailed information of the medications when used along side the ID wristband of the patient. The reading of these tag is by proximity within 12 inch and does not requires line-of-sight and is automated in HIPA-TRAKKER[™] using patentpending antenna arrays.

Figure 1: Printed labels can incorporate the RSS barcode or RFID. HIPA-TAG[™] has been designed to fit even smallest syringes or vials and contains. The cost of HIPA-TAG[™] is \$0.50 each that may be 10 times higher than RSS barcode. However, the ability to automatically identify and facilitate data collection with or without linking to the central computer and ease of usage in the healthcare environment can actually mean lower cost when time and labor is considered.

With an improved medical information system and logistics in data collection, documentation, and correlation, even the diagnostic errors may be avoided in most of the cases. RFID HIPA-TAG[™] can dramatically reduce the time and effort to identify, collect, and correlate these medical data. The difference between barcode and RFID in terms of capability and usage are listed in Table 1 below.

Table 1: Comparison between barcode and RFID HIPA-TAG™ in terms of properties, canability and the usage conditions						
	Barcode (Linear and 2-D)	RFID HIPA-TAG™				
DATA CAPACITY	 Code 39, Code 128 2-D has improved data capability with increase effort in reading. 	 0.05-2.0 KB Abundant of memory for individualized data. 				
WORLDWIDE USE & ACCEPTIBILITY	Universally used. Established standard.	ISO-15963 is an established standard. 13.56MHz RFID is accepted worldwide.				
EASE of DECODING	 Easy for labels on larger size tags on flat or large radius surfaces. Difficult to very difficult when labels are applied onto smaller vials and syringes commonly used in medical industry. Must be read line-of-sight and requires substantial human intervention. 	 Can be read automatically without regard to orientations and position. Can be read automatically without line- of-sight for handheld reader. MEDI-TAG on label can be on smallest vials and syringes and maintain a readable distance of over 8-inch. 				
ABILITY to UPDATE or to INCLUDE INDIVIDUALIZED PERSONAL DATA	 Data are normally static. Possible for "individualized" data but must be programmed to print right before application onto object. Impossible to update after it is placed onto subject. Must use a new label. 	 Data are normally dynamic. Can include individualized data before or after the tag-label application. Updating information can be performed anytime before or after the tag-label is applied. 				
DATA INTEGRITY and AUTHENTICITY	 Data is printed and changes or tampering will be noticed unless a "new" identical looking label is used. Subject to mechanical damages. 	 Data is encoded electronically and last 10 years with >100,000 read-write. Patent-pending "relational-check-code" guarantees data integrity. 				
COST of TAG	Very low at pennies.	Higher cost at quarters.				
COST of USAGE	 Higher labor content for reading vials and syringes that are smaller in sizes. Requires lots of human intervention to ensure data correctness. Must be linked to central database. 	 Same ease in reading and cost effectiveness for large and small sizes. Can operate and function with equal effectiveness with or without central database. 				
ERRORS and COST-OF-ERROR	 Improvement over printed label. Cannot match patient with medication- operations without linking to database. 	 Positive Patient Medication-Matching eliminates all errors in medications that causes loss of \$177 Billion +. 				

While barcode is established and much lower cost per application, in unit-dose or unit-of-use packaging could be difficult. Thus the cost of implementation on the healthcare providers sides could be substantial. It is possible that the difficulty in reading make them more susceptible to be ignored or by-passed and cause errors. This inability to read readily and subsequently can induce errors and is well known in the airline industry. The sophisticated barcode readers today can only read 50-80% of the baggage and require substantial human intervention. The results are the mishandled baggage we encounter when we travel.

Using barcode like RSS and supplementing them with lot/date will certainly help in reducing the medical errors. Its successful operation depends on the diligence of the

users and the functioning of the central computer and the online information system. There is not adequate data on the barcode to allow off-line operation. In the case of RFID HIPA-TAGTM, the data are included in the individual tag. They can be read and provide the data required to perform the patient-medications matching even if the central computer or information system is not available for a period of time.

The cost of each RFID HIPA-TAG[™] application is currently \$0.50 in comparison to the \$\$0.05 for the barcode. It adds less than 1.5% to the \$40 cost of each prescription. The ability of the HIPA-TAG[™] technology in automatically identifying the patient with minimal human intervention and to include all relevant information without requirement of direct linkage to the central database can be very useful in emergency situations. The lesser demand on human intervention lower the cost in adoption with lesser time and effort. The capability to automatically read up to 50 medications labeled with HIPA-TAG[™] at a time not only reduce the labor cost, but also the human error.

The process to reduce medication errors using RFID HIPA-TAG[™] starts at the incorporation of all relevant data of a prescription drug in the label as summarized in Figure 2. Similarly, RFID HIPA-TAG[™] is placed on the patient ID wristband. Before the medications are administered, they are read and compared against the ID of the patient for positive matching of patient and medications. The medications are automatically identified and checked against any possible interaction and potential allergic reaction.

Using this patent-pending "positive patient medication matching" approach, all of the common errors such as wrong drugs for the patient, potential allergic interactions, potential drug interactions, dosage and special instructions can all be cross checked against the patient automatically.

The advantage of RFID based HIPA-TAG[™] is the ability to achieve such matching automatically within seconds without undue attention and effort from the medical professionals that are pressed for time. In contrast, if barcode labels are used, each medication must be manually scanned and could take minutes. If the medical information is not online, the medication process must wait for it to come back on before any matching process can be achieved.

The treatment time and information are automatically recorded and sent to the medical information system for updating of all of the medication treatments that the patient received. All of the avoidable medication errors can be prevented at the critical time and point-of-care.

The cost of implementing such process for all 3.0 billion prescriptions made each year can achieved with less than \$2 billion. Thus, it represents at least \$175 billion saving to the healthcare industry.

In fact, the cost of \$2 billion in using such solution is more than paid for with the time and labor eliminated in manually updating the medication records for the patients.

Figure 2A:		AIT Medication Tag Writer		X
All prescribed mediations are	A	Static		
tagged with HIPA-TAG™		Serial No.	6B76550200000001	
identifying the NDC number,				
lot/date, dosage, special			Last Name (10chars)	First Name Middle Initial
instructions, the intended		Patient Name	Washinton	John K
nationt's name the physician		Physician Code	32 (0 - 65535)	6chars
and the phermanist ate		Sickness/Treatment Code	16 (0 - 65535)	
and the pharmacist, etc.		Pharmacist Code	56 (0 - 65535)	
		NDC Number	13241 - 2342 -	- 24 (99999 - 999 - 99)
		Dosage	12 (0 - 255)	
		Time Between Dosage	6 (0 - 255)	
		Lot Number	4567245634 (0 - 9999999999)
		Expiration Date	March 💌 🚺	2003
		Instruction/Comments	After meal	Data Encryption 🔽
	And I	(12chars)		
	939		Write Reset	Exit



Figure 2B: During the admission process, a patient HIPA-TAG[™] is placed inside the ID wristband identifying the patient name, gender, SSN, birth date, blood type, allergies, admission date, contact name and phone, attending physician, the diagnosed ailments, and other relevant information.



Figure 2C:

Before any medications are administered to the patient, the patient HIPA-TAG[™] is read and the medications with HIPA-TAG[™] are also automatically identified and used to positively match with the patient for correct treatment, potential allergic reactions, drug interactions with current and other drugs in the body system, correct dosage, etc. Any mismatch will be manifested for correction.

COUNTERFEIT DRUG PREVENTION AS SIDE BENEFIT OF USING HIPA-TAG™:

The potential of controlling the counterfeit drugs is another side benefit to using RFID HIPA-TAG[™] on prescription medications.

According to the World Health Organization, more than 7% of the world's pharmaceuticals are bogus. With more than 93% of these counterfeit drugs being totally bogus without proper active ingredients, the potential damage to the society and patients can be substantial. Even though there is a lack of documentation in these damages, the cost to the pharmaceutical industry is well documented and estimated to be more than \$2 billion.





DATA ON THE RFID HAVE BEEN CHANGED

Printed labels and barcodes can be easily replicated and lend themselves for counterfeiting.

Expensive and specialized drugs are counterfeited more often than others and can cause irreparable harm to the patient.

Figure 3: RFID chip has a unique serial number that cannot be duplicated. In addition, HIPA-TAG[™] uses a patent-pending "relational-check-code" method to encode on the "read-write" memory segment and to read and authenticate the data encoded on the tag as demonstrated on the far right of the in form of warning manifest.

The cost of tagging all of the annual 3 billion prescribed medications at \$0.50 each is \$1.5 billion. There may be additional cost of infrastructure in terms of equipment and readers. In general, RFID readers cost less than the barcode readers. The total system cost to the industry when amortized over five year is estimated to be less than \$0.5 billion per year.

The ability to automate the retail process with the automatic identification capability of RFID is another side benefit that cannot be overestimated. This automated process should help to pay for some if not all of the \$2.0 billion cost of implementation. In fact, it may even help to substantially reduce the overall \$210 billion in administrative tasks in the healthcare industry every year,

Thus, if the healthcare industry adopts the HIPA-TAG[™] for all medications, the benefit of eliminating the possibility of counterfeiting alone will pay for the total implementation cost of \$2.0 billion per year. The cost saving to the healthcare system is well over \$177.4 billion for eliminating the medication errors, the immeasurable cost of lives and compensation, some saving among the \$3 billion cost of HIPAA compliance, and substantial reduction in the cost of \$210 billion of administrative tasks.

HEALTHCARE INSURANCE PORTABILITY AND ACCOUNTABILITY COMPLIANCE AND BETTER PATIENT SERVICES AS SIDE BENEFIT FOR USING HIPA-TAG™:

The "Healthcare Insurance Portability and Accountability Act" (HIPAA) passed in 1996 and the compliance to the requirements are due in the coming years. It is estimated that it may add at least another \$2-3 billion in infrastructure cost to the \$210 billion of administrative tasks cost.

The federal guidelines are forcing the healthcare industry to catch up in the use of information systems like those used in manufacturing sectors. There have been substantial new solutions in electronic prescription that will help in minimizing errors in dispensing the correct medications called for by the physician. There are also some communication and information solutions to facilitate the real-time accessibility of the patient data and charts using browser-based Internet/Intranet system.

The RFID HIPA-TAG[™] technological solution was primarily designed to solve the supply chain problems. The ability to easily achieve the "positive patient medication matching" automatically without undue human intervention is only one of benefits that can be reaped with this automatic identification technology. When coupled with other available technologies and interfaced with medical information systems, HIPA-TAG[™] can dramatically improve the healthcare delivery, security, and privacy with less labor and cost to the industry.

HIPA-TRAKKER[™] is an Internet/Intranet real-time browser-based information solution developed by Avante International Technology, Inc. It couples RFID HIPA-TAG[™] and HIPA-TRAKKER[™] antenna array reader technologies to achieve automatic identification and traceability of patient, medications, medical records, medical infrastructure and healthcare staff to improve the healthcare portability and accountability. The following are some of the requirements of HIPAA that may be solved with the HIPA-TRAKKER[™] solution discussed in this proposal:

- Provide access of medical charts to the patient and the record and traceability of "who" has seen them in protecting the privacy of the patients.
- Provide faster health claims and processing.
- Provide streamlined enrollment processing in health plans.
- Provide and facilitate the first reporting of injuries.
- Improved referral certification and authorization.

One of the technology pieces that will help to facilitate the security and privacy of the healthcare system is to provide acceptable human interface to the medical information system. In particular, means to identify the physician during the course of administering the medical process. Most of the current information systems require frequent change of "code" or "password" in accessing patient records. Some adopt the public key and private key method and infrastructure used in Internet/Intranet. This particular method while common is quite cumbersome and non-intuitive in the real world applications in the healthcare system.

HIPA-TRAKKER[™] uses a newly developed technology of capturing the user signature online via Internet and Intranet at real-time. The signature is captured in such way that it can be coupled with a signature-recognition solution to verify the user if necessary. The use of this real-time signature capturing capability was developed to help the voter registration process (<u>www.registration-trakker.com</u>).

The digitized electronic signature uses a special algorithm that affords subsequent signature recognition. The memory file from this digital images uses less than 300 bytes. It is less than 10-100 times those using traditional graphic means. Figure 4 is an illustration of this real-time signature enabling solution.



Figure 4: HIPA-TRAKKER[™] is a real-time digitized signature enabled healthcare information system that provides immediate solutions the following requirements:

- Physician can sign their electronic prescriptions before transmitting to the pharmacist.
- Physician can sign their electronic orders for any treatments.
- Physician and staff can sign any treatments they have finished providing to specific patients.
- Physician can access a specific patient records with their signature as biometrics authentication.
- Electronic medical referral/authorization can be provided and signed by physician online.
- Patients can access their records with their signature.
- Health claims can be filed and signed online.
- Healthcare enrollment can be applied for and signed online.
- First injury can be reported and signed online.
- HIPA-TRAKKER[™] provides the first voiceassisted interfaces to help the visually impaired patients in filing claims, enrollments, etc.

In addition to the real-time signature capturing capability, any processing and data collected and performed will be configured with the signature and "wrapped" as a single tamper-obvious electronic file that is transmitted in the standard secured 128-bit encryption protocol. This "double" encryption process provides additional security and privacy to the healthcare system.

The transition from paper based systems to electronic prescription, electronic medical records and data access and updating, and providing healthcare services using this signature-based biometrics affords both real and perceived security and privacy.

This browser-based Internet/Intranet data capturing system can be easily linked and interfaced with existing medical database systems as illustrated in Figure 5 below. HIPA-TRAKKER[™] is a three-tier system that can handle forms, pictures, video, graphics and other forms of electronic data.

Figure 5: HIPA-TRAKKER[™] System Overview and Workflow. The system facilitates healthcare processing automation, automatic identification of patients, medications, treatments, and staff, etc.



HIPA-TRAKKER[™] when coupled with HIPA-TAG[™] and HIPA-TRAKKER[™] for automatic identifications can be utilized to replace and facilitate many of the current administrative tasks. All of the data entry is performed either by the patients or by the physician and staff at the point-of-care and at real-time.

It eliminates the need for any transcribing of data afterward and thus potential human errors. This aspect of the service capability afforded by HIPA-TRAKKERTM actually helps to reduce some of the cost in the \$210 billion of administrative tasks.

CONCLUSIONS AND PERSPECTIVES:

Medication error reduction can be readily achieved with the use of "positive patient medication matching" protocol. This "positive patient medication matching" can be achieved with any automatic identification technology including barcode and RFID smart tags. The RFID HIPA-TAG[™] automatic identification technology not only fit the form factor of smallest syringes and vials much better than barcode, it also minimizes human intervention and thus potential errors.

While per tag or label cost of HIPA-TAGTM is higher than barcode label, the corresponding labor cost saving and error reduction advantages far outweigh the cost by several orders of magnitude. With the proper usage of such AIT and interfacing with the medical information system has the potential of total eliminating the current medication errors.

The system cost saving can be as high as \$177 billion plus the immeasurable saving of human lives and injury compensations.

The "side" benefits with the use of HIPA-TAGTM are also substantial. They include the controlling of counterfeit drugs that cost the industry more than \$2.0 billion each year, the compliance of HIPAA that is going to cost the industry \$3.0 billion each year, and reduction in time and effort in the \$210 billion administrative tasks.

December 26, 2001