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(54) **CONTROLLED SUBSTANCE TRACKING SYSTEM AND METHOD**

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(57) **ABSTRACT**

A method for tracking prescriptive medications is provided whereby a complete prescriptive medication history including active and inactive prescriptive medications is stored for a plurality of patients utilizing a plurality of pharmacies wherein the pharmacies may be affiliated or unaffiliated. The information may be selectively retrieved through a secure computer connection by entities such as hospitals, doctors, pharmacies, insurance companies, government agencies and the like. The information may be utilized to benefit the patient whereby a doctor is able to obtain an accurate view of the complete prescriptive medication history of the patient including prescriptive medications by other doctors. Hospitals will be able to obtain, in accord with the invention, a prescriptive medication history prior to treatment such as emergency treatment where such information is not normally available. The stored data for each prescriptive medication transaction includes searchable data such as the patient's name, address, doctor, pharmacy, aberrant use flag, and the like.

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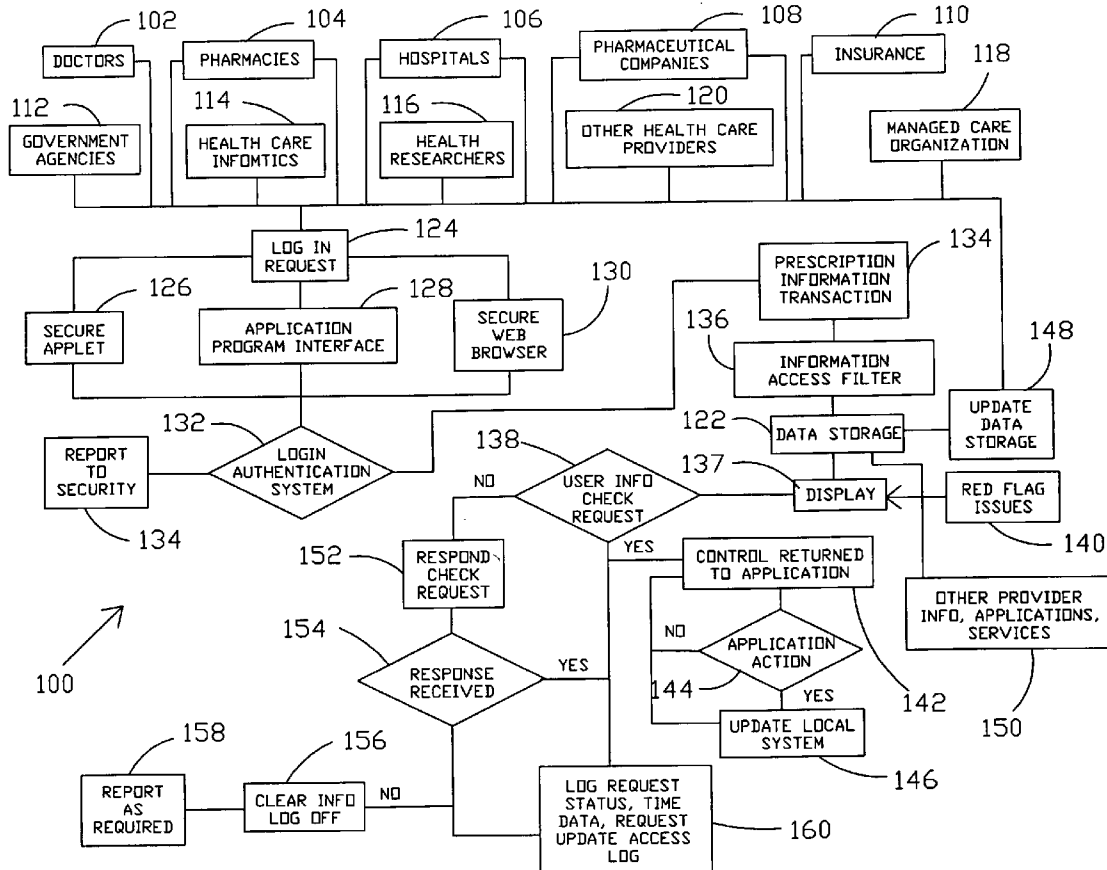
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Related U.S. Application Data

(63) Continuation of application No. 10/062,251, filed on Jan. 31, 2002, now abandoned.

(60) Provisional application No. 60/332,807, filed on Nov. 14, 2001.



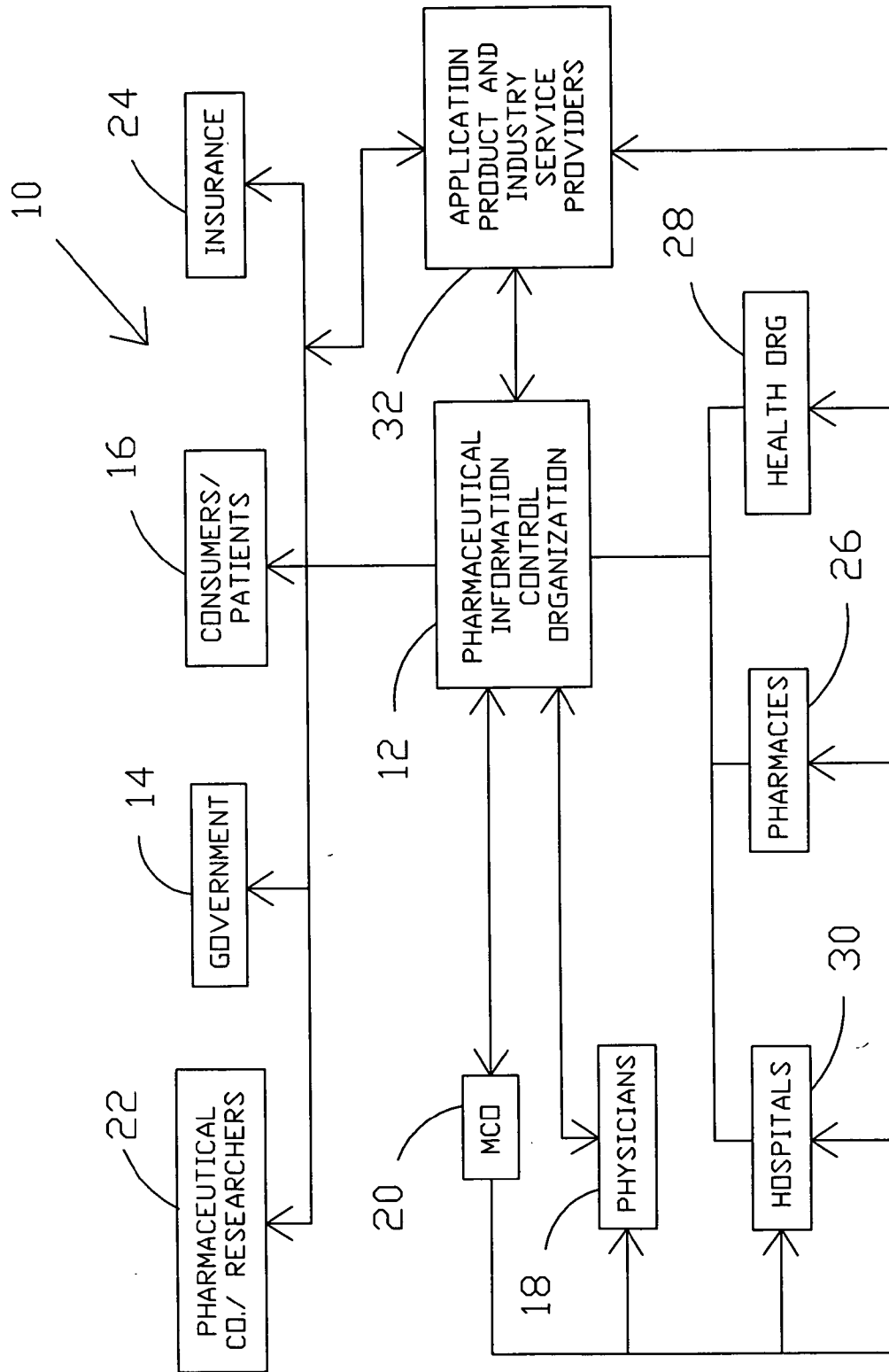


FIG. 1

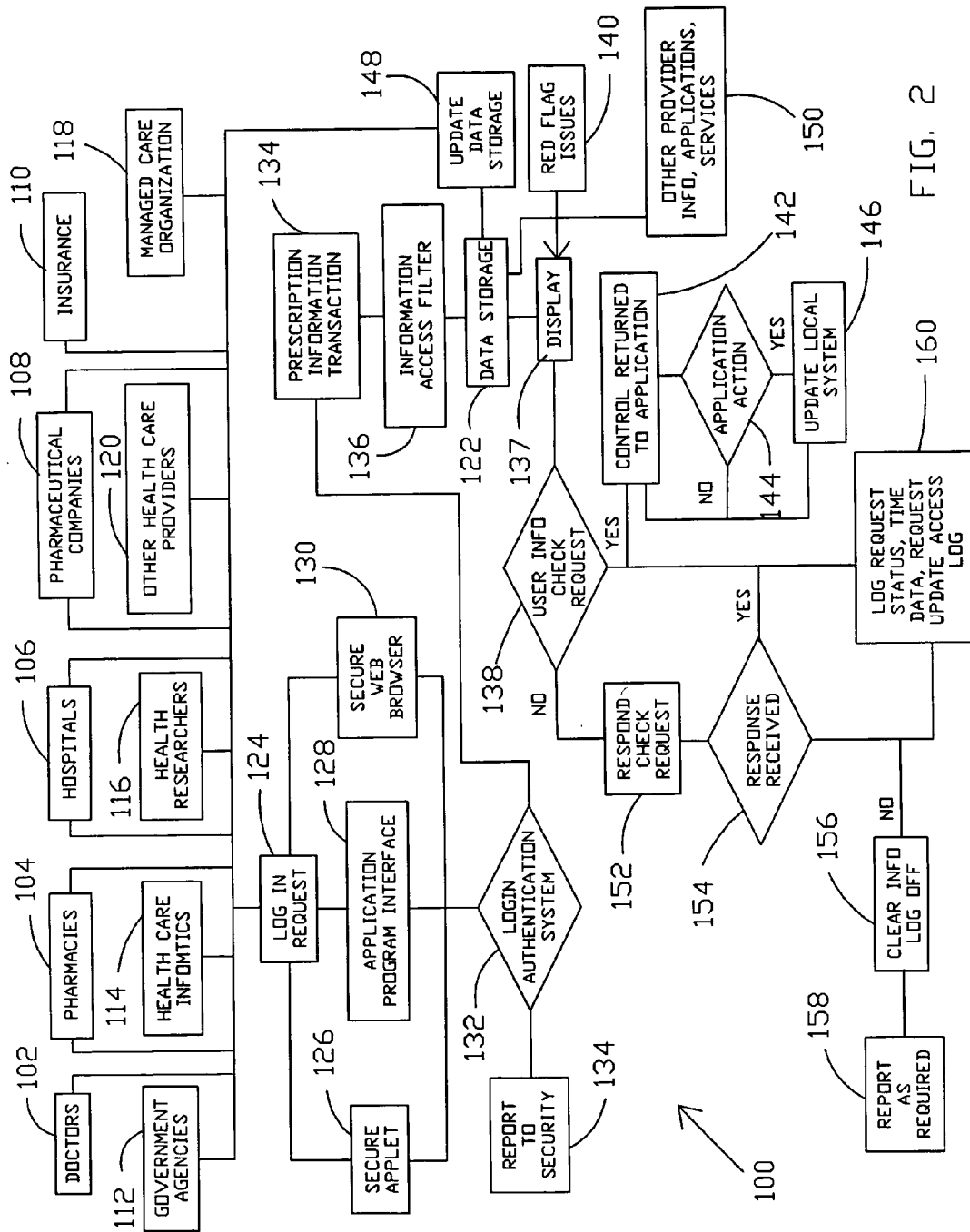


FIG. 2

CONTROLLED SUBSTANCE TRACKING SYSTEM AND METHOD

[0001] This application claims the benefit of U.S. Provisional Application No. 60/332,807, filed on Nov. 14, 2001, and is a continuation of U.S. application Ser. No. 10/062,251, filed Jan. 31, 2002.

TECHNICAL FIELD

[0002] The present invention relates generally to methods for tracking controlled substances and, more specifically, to methods especially suitable for tracking and managing prescription information in aggregate.

BACKGROUND ART

[0003] Although the exact frequency of prescription drug abuse is unknown in the United States, it has been reported that more than fifty percent of all emergency room visits for drug-related problems are connected to prescription drug misuse or accidental overdose. It has also been estimated that in some communities, more than sixty percent of medical examiner cases are related to prescription drugs.

[0004] It is estimated that more than four million people a year in the U.S. misuse or abuse prescription drugs. For instance, according to an August 1999 article in the Journal of the American Geriatrics Society, older Americans (age 65 and older) currently account for 12.5% of the total US population, but consume 25% of all prescription medications. It is documented that 17% of the senior population misuses medications, accounting for approximately \$2 billion loss annually.

[0005] The AMA estimates that 5% of physicians are grossly negligent and 1-1.5% are dishonest in their prescribing of pharmaceuticals. This would amount to a cost of \$2.5 billion annually.

[0006] Three hundred fifty thousand adverse medication errors (probably far greater not reported) occur each year among one-half million nursing home residents in the United States. One employee in ten has a problem with alcohol/drugs. Absenteeism is 66% higher among drug users.

[0007] Among drug users, health benefit utilization is 300% higher, disciplinary actions are 90% higher, and employee turnover is significantly higher. Forty-seven percent of workplace accidents are drug related.

[0008] In fact, it is clear that the Healthcare industry is facing a number of challenges today unlike ever faced before. An educated, consuming public has ever increasing expectations for exponential improvement in healthcare delivery, while at the same time, economic pressures are forcing tighter controls over cost, efficiency and quality.

[0009] The industry has widely recognized a need for better efficiencies, but without notable success in many areas, including prescription abuse. For instance, the Healthcare Information Portability and Accountability Act (HIPAA) mandates making the exchange of information more ubiquitous, secure, and efficient but does not provide a solution with respect to prescription tracking and abuse. While it is well known that it would be desirable to reduce

dancy, and improve informational flow, the solutions to such overwhelming problems are generally unavailable.

[0010] In 1993, prescription drug sales were \$25 billion. Since that time prescriptions have risen more than 50%, totaling close to three billion prescriptions annually. With soaring costs, the sum of prescription drugs is currently greater than \$50 billion annually, with limited ability to control or manage those costs.

[0011] These estimates are only for the cost of drugs themselves, and don't include many of the highly significant tangential costs associated with abuse, additional healthcare requirements and costs associated with drug interactions, insurance fraud resulting from purchase of class drugs for resale on the street, dispensing of wrong prescriptions due to misread prescriptions, and the like, which are proportionally of greater cost.

[0012] It would be desirable to provide a healthcare utility that can assist substantially in reducing these misused and abused prescriptions. It would be desirable to provide major changes in the delivery of prescription drugs that produce measurable social and economic impacts on spending within the healthcare value chain including less abuse-related healthcare costs, fewer erroneous prescriptions, more accountability, and better tracking and management of prescriptions.

[0013] Patents that involve attempts to solve the above or related problems include the following:

[0014] U.S. Pat. No. 6,067,524, issued May 23, 2000, to Byerly et al., discloses a method and system for generating advisory messages to pharmacy patients that includes appending patient-specific information to a data record containing normally transmitted information. The data record is transmitted between a third party computer and a pharmacy computer during a pharmacy transaction. The data record transmitted to the pharmacy computer is captured by an advisory computer as the data record is received by the pharmacy computer or after the data record is transmitted to the pharmacy computer, and the patient-specific information is extracted from the captured data record. The advisory computer generates an advisory message based on the extracted patient-specific information, and it transmits the generated advisory message to a pharmacy printer. The advisory computer includes a memory containing a data structure for storing the patient-specific information, the normally transmitted information, and the generated advisory message. A computer program product includes a computer storage medium and a computer program code mechanism embedded in the computer storage medium for causing a computer to generate an advisory message. The computer program code mechanism includes a first computer code device configured to append the patient-specific information, a second computer code device configured to capture the data record transmitted to the pharmacy computer, a third computer code device configured to extract the patient-specific information from the captured data record, a fourth computer code device configured to generate the advisory message based on the extracted patient specific information, and a fifth computer code device configured to transmit the generated advisory message to the pharmacy printer.

dispensing, tracking and managing pharmaceutical product samples by communicatively linking prescribers and pharmacies to a central computing station. The method entails utilizing product trial media that is exchanged for actual pharmaceutical product. The media is encoded with information that identifies a particular pharmaceutical trial product, such as by magnetic encoding similar to that used with credit cards. The media is distributed to participating medical doctors or prescribers who then activate the media via the central computing station. The prescriber then transfers the activated media to patients who then present the media to participating pharmacies. Before filling the pharmaceutical trial product identified by the media, the pharmacy validates the media via a link with the central computing station. Then, the pharmacy dispenses the prescribed pharmaceutical trial product. The central computing station also includes a database that records data related to the use of the media so that all pharmaceutical trial products can be accounted for.

[0016] U.S. Pat. No. 5,542,420, issued Aug. 6, 1996, to Goldman et al., discloses a health care system for specifying edibles to individual subjects. The personalized method and system for storage, communication, analysis and processing of health-related data comprises a storage containing data relating to health and edibles and is adapted to receive data on the conditions and characteristics of the individual subjects. The health care system further comprises input terminals adapted to be coupled to the storage means for providing data on the conditions and characteristics of the individual subjects, and a health computer for correlating the data relating to health and edibles with the data on the condition and characteristics of an individual subject to provide a personalized prescription of edibles.

[0017] U.S. Pat. No. 5,628,530, issued May 13, 1997, to G. B. Thornton, discloses a method and system for collectively tracking demographics of physician prescribed starter drug samples dispensed to a plurality of patients from a plurality of different dispensing locations employs a multi-part product specific sample drug voucher, such as a smart card or a preprinted two part voucher, which has a marketing information portion and a separable prescription portion to be completed by the prescribing physician with starter drug sample quantity and dosage information along with patient demographic information. The prescription portion is segregated from the marketing information portion at the pharmacy either electronically by a card reader, if it had been encoded on a smart card by the physician, or physically by separation along a perforation, if recorded on a two part voucher, and is electronically retrievably stored in the pharmacy computer from where this tracking information is electronically transmitted to a central remote computer, such as at the drug manufacturer, for subsequent rapid market analysis.

[0018] U.S. Pat. No. 5,737,539, issued Apr. 7, 1998, to Edelson et al., discloses an electronic prescription creation system for use by professional prescribers at the point of care which has a prescription division subsystem permitting creation of a single prescription to be automatically divided into two components for fulfillment of one portion quickly and locally at higher cost and of another portion by remote mail order taking more time but providing a cost saving for a major part of the prescription. The prescription creation

and current drug, drug formulary and patient history information, with dynamic creation of a transient virtual patient record, the information being presented to the prescriber before completion of the prescription, permitting enhancement of the quality of prescribing decisions.

[0019] U.S. Pat. No. 5,758,095, issued May 26, 1998, to Albaum et al., discloses a system and method for ordering and prescribing drugs for a patient. This system includes an improved process for facilitating and automating the process of drug order entry. The user may interact with the system in a variety of ways such as keyboard, mouse, pen-base entry or voice entry. The system includes a database containing medical prescribing and drug information which is both general and patient-specific. The system also permits the user to view current and previously prescribed medications for any patient. The system can alert the user to potentially adverse situations as a result of the prescribed medication based on information in the database. The system also can automatically determine product selection based on descriptions and can automatically communicate the order to a pharmacy. Further, the system includes a means for automatically displaying messages to the user relating to predetermined situations. For example, such situations may include a medication which is not available in the formulary or the prescription of a non-recommended medication. The system streamlines the order entry process and makes information important to the drug ordering process easily available.

[0020] U.S. Pat. No. 5,845,255, issued Dec. 1, 1998, to C. Mayaud, discloses a wirelessly deployable, electronic prescription creation system for physician use that captures into a prescription a patient condition-objective of the prescribed treatment and provides for patient record assembly from source elements, with privacy controls for patient and doctor, adverse indication review and online access to comprehensive drug information including scientific literature. Extensions to novel multi-drug packages and dispensing devices, and an "intelligent network" remote data retrieval architecture as well as onscreen physician-to-pharmacy and physician-to-physician e-mail are also provided.

[0021] U.S. Pat. No. 5,991,731, issued Nov. 23, 1999, to Colon et al., discloses a computer system and method for managing data used in conducting clinical studies concerning subjects at a plurality of participating, geographically distributed clinical sites, wherein each participating clinical site having a computer or inputting, transmitting and receiving data over the Internet. An Internet network server computer is interfaced to a database host computer through a private network. The system communicates data over the Internet to determine patient eligibility, randomization and initial prescriptions, which can then be adjusted by the physician online. The final prescription is printed out for signature and sent electronically to a distribution center. Study data is maintained in a database in the host computer behind a firewall provided in the Internet server computer.

[0022] U.S. Pat. No. 5,832,449, issued Nov. 3, 1998, to D. W. Cunningham, discloses a new and improved method of dispensing, tracking and managing pharmaceutical product samples by communicatively linking prescribers and pharmacies to a central computing station. The method entails

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