

EXHIBIT

1048

1/21/16

Sensitive Drug Distribution System and Method

Field of the Invention

5 The present invention relates to distribution of drugs, and in particular to the distribution of sensitive drugs.

Background of the Invention

10 Sensitive drugs are controlled to minimize risk and ensure that they are not abused, or cause adverse reactions. Such sensitive drugs are approved for specific uses by the Food and Drug Administration, and must be prescribed by a licensed physician in order to be purchased by consumers. Some drugs, such as cocaine and other common street drugs are the object of abuse and illegal schemes to distribute for profit. Some schemes include Dr. shopping, diversion, and pharmacy thefts. A locked cabinet or safe
15 is a requirement for distribution of some drugs.

 Certain agents, such as gamma hydroxy buterate (GHB) are also abused, yet also are effective for therapeutic purposes such as treatment of daytime cataplexy in patients with narcolepsy. Some patients however, will obtain prescriptions from multiple doctors, and have them filled at different pharmacies. Still further, an unscrupulous physician
20 may actually write multiple prescriptions for a patient, or multiple patients, who use cash to pay for the drugs. These patients will then sell the drug to dealers or others for profit.

 There is a need for a distribution system and method that directly addresses these abuses. There is a further need for such a system and method that provides education and limits the potential for such abuse.

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Summary of the Invention

 A drug distribution system and method utilizes a central pharmacy and database to track all prescriptions for a sensitive drug. Information is kept in a central database regarding all physicians allowed to prescribe the sensitive drug, and all patients receiving
30 the drug. Abuses are identified by monitoring data in the database for prescription patterns by physicians and prescriptions obtained by patients. Further verification is

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made that the physician is eligible to prescribe the drug by consulting a separate database for a valid DEA license, and optionally state medical boards to determine whether any corrective or approved disciplinary actions relating to controlled substances have been brought against the physician. Multiple controls beyond those for traditional drugs are imposed on the distribution depending on the sensitivity of the drug.

Education is provided to both physician and patient. Prior to shipping the drug for the first time, the patient is contacted to ensure that product and abuse related educational materials have been received and/or read. The patient may provide the name of a designee to the central pharmacy who is authorized to accept shipment of the drug. Receipt of the initial drug shipment is confirmed by contacting the patient. Either a phone call or other communication to the patient within a set time after delivery may be made to ensure receipt. Further, a courier service's tracking system is used to confirm delivery in further embodiments. If a shipment is lost, an investigation is launched to find it.

In one embodiment, the drug may be shipped by the central pharmacy to another pharmacy for patient pick-up. The second pharmacy's ability to protect against diversion before shipping the drug must be confirmed. This ability may be checked through NTIS and State Boards of Pharmacy.

Prescription refills are permitted in the number specified in the original prescription. In addition, if a prescription refill is requested by the patient prior to the anticipated due date, such refills will be questioned. A lost, stolen, destroyed or spilled prescription/supply is documented and replaced to the extent necessary to honor the prescription, and will also cause a review or full investigation.

The exclusive central database contains all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information. Several queries and reports are run against the database to provide information which might reveal potential abuse of the sensitive drug, such as early refills.

Brief Description of the Drawings

FIG. 1 is a block diagram of a computer system for use in implementing the system and method of the present invention.

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- FIG.s 2A, 2B and 2C are a flowchart describing a method for sensitive drug distribution at least partially utilizing a computer system such as that shown in FIG. 1.
- FIG. 3 is a flowchart of a physician success program at least partially implemented on a computer system such as that shown in FIG. 1.
- 5 FIG.s 4A and 4B are a flowchart describing a method for handling refill requests at least partially utilizing a computer system such as that shown in FIG. 1.
- FIG. 5 is a flowchart of a process for requesting special reimbursement when a patient is uninsured or underinsured at least partially utilizing a computer system as that shown in FIG. 1.
- 10 FIG. 6 is a flowchart of a process for inventory control at least partially utilizing a computer system such as that shown in FIG. 1.
- FIG. 7 is a block diagram of database fields.
- FIG. 8 is a block diagram showing a list of queries against the database fields.
- FIG. 9 is a copy of one example prescription and enrollment form.
- 15 FIG. 10 is a copy of one example of a NORD application request form for patient financial assistance.
- FIG. 11 is a copy of one example voucher request for medication for use with the NORD application request form of FIG. 10.
- FIG. 12 is a copy of certificate of medical need.
- 20 FIG.s 13A, 13B and 13C are descriptions of sample reports obtained by querying a central database having fields represented in FIG. 7.

Detailed Description of the Invention

In the following description, reference is made to the accompanying drawings that form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the scope of the present invention. The following description is, therefore, not to be taken in a limited sense, and the scope of the present invention is defined by the appended claims.

pharmacy outlets. It is distributed by overnight carriers, or by US mail in one embodiment to potentially invoke mail fraud laws if attempts of abuse occur.

FIG. 1 is a simplified block diagram of a computer system 100, such as a personal computer for implementing at least a portion of the methods described herein. A central processing unit (CPU) 110 executes computer programs stored on a memory 120. Memory 120 in one embodiment comprises one or more levels of cache as desired to speed execution of the program and access to data on which the programs operate. The CPU is directly coupled to memory 120 in one embodiment. Both CPU 110 and memory 120 are coupled to a bus 130. A storage 140, I/O 150 and communications 160 are also coupled to the bus 130. Storage 140 is usually a long term storage device, such as a disk drive, tape drive, DVD, CD or other type of storage device. In one embodiment, storage 140 is used to house a database for use with the present invention. I/O 150 comprises keyboards, sound devices, displays and other mechanisms by which a user interacts with the computer system 100. Communications 160 comprises a network, phone connection, local area network, wide area network or other mechanism for communicating with external devices. Such external devices comprise servers, other peer computers and other devices. In one embodiment, such external device comprises a database server that is used in place of the database on storage 140. Other computer system architectures capable of executing software and interacting with a database and users may also be used. Appropriate security measures such as encryption are used to ensure confidentiality. Further, data integrity and backup measures are also used to prevent data loss.

FIG.s 2A, 2B and 2C represent an initial prescription order entry process for a sensitive drug, such as Xyrem. At 202, a medical doctor (MD) sends a Rx/enrollment form via mail, fax, email or other means to an intake/reimbursement specialist at 204, who makes a copy of the RX/enrollment form that is stamped "copy". The original fax is forwarded to a pharmacy team. The enrollment form contains prescriber information, prescription information, checkboxes for the prescriber indicating they have read materials, educated the patient, understand the use in treatment, and understand certain safety information, and also contains patient information.

The prescriber information contains standard contact information as well as license number, DEA number and physician specialty. Patient and prescription



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