(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION

(19) World Intellectual Property Organization International Burcau

# 

#### (43) International Publication Date 20 March 2003 (20.03.2003)

# PCT

## (10) International Publication Number WO 03/023681 A1

(51) International Patent Classification7:

G06F 17/60

(21) International Application Number: PCT/US02/29106

(22) International Filing Date:

13 September 2002 (13.09.2002)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 60/318,973

13 September 2001 (13.09.2001)

(71) Applicant (for all designated States except US): RTIN HOLDINGS, INC. [US/US]; 3218 Page Road, Longview, TX 75605 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SOLOW, Laurence, I. [US/US]; MedEx Systems, Inc., 540 Elmwood Park Blvd., Jefferson, LA 70123 (US). RAU, Ann, E. [US/US]; MedEx Systems, Inc., 540 Elmwood Park Blvd., Jefferson, LA 70123 (US).

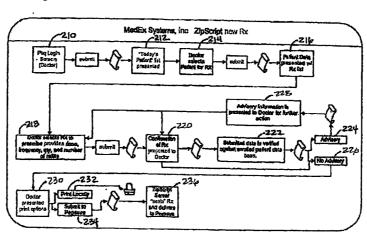
- (74) Agent: ETHERTON, Sandra, L.; Etherton Law Group, LLC, P.O. Box 27843, Tempe, AZ 85285-7843 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU. CZ, DB, DK, DM, DZ, BC, EB, BS, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KB, KG, KP, KR, KZ, LC. LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

#### Declarations under Rule 4.17:

as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA,

[Continued on next page]

(54) Title: METHOD AND SYSTEM OF PROVIDING MEDICAL PRODUCTS



(57) Abstract: The invention provides for a consolidated provider system that bypasses the typical prescription ordering process and enables a physician to enter a medical product order, such as prescriptions (218), directly to a product provider, such as a pharmacy, to correlate an initial prescription order against a database of recommended products for a given medical condition, to make choices on medical products, to receive feedback on the choices (228), cross check a patient's medical history for potential adverse effects from the product recommendations, and fulfill reorder requests requiring a physician's approval. In at least one embodiment, the invention utilizes secure, broadband, wireless technology and a portable handheld computing device. The invention can include a centralized call center that offers reauthorization and new prescription requests for management services.

# WO 03/023681 A1 MARKATAN MARKA

CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PI, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, MI, MR, NE, SN, TD, TG)

• . . .

(

(

ί

as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN,

IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

#### Published:

- with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ĺ

#### APPLICATION FOR PATENT

INVENTORS:

LAURENCE L SOLOW

5

TITLE:

METHOD AND SYSTEM OF PROVIDING MEDICAL

**PRODUCTS** 

ANN E. RAU

10

# SPECIFICATION

# FIELD OF THE INVENTION

The present invention relates to providing products. More particularly, the present invention relates to providing medical products, such as prescriptions.

15

# BACKGROUND OF THE INVENTION

Many medical products, and particularly prescription drugs, are ordered after a visit to a physician's office. A physician usually examines a patient and recommends a regimen of health care, often including prescription drugs. The physician will write out on a piece of paper in a scrawl that only a physician can imitate the prescription drug, dosage, frequency, quantity, and number of refills available, if any. The physician generally relies on his experience and/or memory regarding the particular drug, dosage, and any conflicts with other drugs that may be prescribed or that the patient may already be taking.

25

30

20

The patient then typically takes the handwritten prescription to a pharmacy of their choice, where a pharmacist must correctly interpret the physician's handwriting and correctly dispense the prescription drug with appropriate notation. For physiciancontrolled refills, the patient contacts the physician's office. The physician's office employs staff to take the requested information and seek the approval of the physician for the refill. Often, the physician must review the patient's file history to determine

10

15

20

whether a refill is appropriate. Sometimes, the staff interrupts the physician between patients to obtain his or her authorization on the refill. In some cases, the physician will order the patient to return to the physician's office for a follow-up visit to determine the need for the refill.

With cultural changes in our society, such typical health care is becoming antiquated. As an example of the cultural change, the amount of patient prescriptions of approximately 3 billion outpatient prescriptions from 1992 to 1999 has increased between about 45% to about 50% or more. The increase is expected to continue to rise to about 4 billion prescriptions by 2005 and continue inclining thereafter. However, the number of retail pharmacists available to dispense those prescriptions is expected to rise only about 6%, evidencing an emerging nation-wide shorage of licensed pharmacists in the United States. Thus, shortages of filling the prescriptions dictate needs for more efficiency.

Further, it has been estimated that about 15% of handwritten prescriptions contain errors. The Institute of Safe Medication Practices (ISMP) estimates that illegible handwriting generates about 150 million calls each year from pharmacies to physicians to clarify prescriptions. Errors in prescription drugs include prescribing the wrong drug, prescribing an inappropriate dosage of the correct drug, prescribing a drug to which the patient is allergic, prescribing a drug which adversely reacts with another drug the patient is taking, or dispensing the wrong medication as a result of the physician's illegible handwriting.

Also, pharmaceutical companies have generated new and better drugs that are more specialized to certain symptoms as opposed to other generalized drugs. The physician may be unfamiliar or unsure of the appropriateness of prescribing the drugs and, therefore, may rely upon past prescriptions of older drugs. If the physician

5.

10

20

25

wishes to prescribe a newer drug, the physician may consult a physician's reference manual to determine appropriate uses, conflicts with other drugs known as "drug allergy" conflicts. With today's time limits, physicians are reticent to perform such additional analyses.

Further cultural changes include an aging population, transportation problems, working parents, and busy schedules that have increased the need for finding a more efficient method of obtaining prescription drugs other than taking the prescription to a pharmacy, standing in line, and purchasing the prescription drug-

Therefore, there remains a need for providing medical products, such as prescriptions, more efficiently and with less error than conventional methodologies.

# SUMMARY OF THE INVENTION

The invention provides for a consolidated provider system that bypasses the typical prescription ordering process and enables a physician to enter a medical product order, such as prescriptions, directly to a product provider, such as a pharmacy, to correlate an initial prescription order against a database of recommended products for a given medical condition, to make choices on medical products, to receive feedback on the choices, cross check a patient's medical history for potential adverse effects from the product recommendations, and fulfill reorder requests requiring a physician's approval. In at least one embodiment, the invention utilizes secure, broadband, wireless technology and a portable handheld computing device.

In one embodiment with a few simple keystrokes, the system permits a physician to securely access a list of scheduled patients, select the appropriate medication and dosage from a customized list of most prescribed medications (or add a new medication to this list), confirm the order, and electronically transmit the

(

{

15

20

prescription to a product provider, such as a pharmacy. The product provider can begin processing the order for dispensing and rapid delivery to the patient's home, office or other location. The process of providing the medical product can occur without the typically intervention of a hand-written order by the physician, a staff person interpreting the order, telephoning the order to a product provider, a staff person at the product provider taking the order, and then filling the order.

The invention can include a centralized call center that offers reauthorization and new prescription requests for management services. The present invention can also provide a method for the physician to acreen refill new authorization requests, approve requests, and forward the approval to a centralized location.

#### BRIEF DESCRIPTION OF THE DRAWINGS

A more particular description of the invention, briefly summarized above, may be had by reference to the embodiments thereof that are illustrated in the appended drawings and described herein. However, it is to be noted that the appended drawings illustrate only some embodiments of the invention. Therefore, the drawings are therefore not to be considered limiting of its scope, for the invention may admit to other equally effective embodiments.

Figure 1 is a schematic view of one embodiment of the provider system.

Figure 2 is a schematic view of another embodiment of the provider system.

Figure 3 is a schematic view of another embediment of a provider system.

Figure 4 is an exemplary flowchart schematic of a portion of one embodiment of the provider system.

Figure 5 is an exemplary flowchart schematic of another portion of one 25 embodiment of the provider system.

Figure 6 is an exemplary flowchart schematic of another portion of the provider system for refilling orders for the medical products.

Figure 7 is an exemplary flowchart schematic of another portion of the provider system for refilling orders for the medical products.

# DETAILED DESCRIPTION OF THE INVENTION

### I. Overview

5

10

15

20

25

The description herein is provided in the context of a method and system for providing prescription products, which can include providing a prescription order for a patient at a physician's office through delivering the product to the patient through the use of a pharmacy. It is to be understood that the invention is limited only by the claims, as various medical products besides prescriptions and pharmacies can be used and are meant to be included within the scope of the present invention. Thus, the terms "prescriptions", "pharmacles", and the like, while offering a context to one embodiment of the system, are to be used broadly and to include medical products and associated provider services therefor, as would be apparent to one with ordinary skill in the art given the understanding of the disclosure contained herein. Further, the term "physician" is used broadly and includes any health care provider authorized to perform the applicable health related duties, such as nurses, associated staff, clinicians, pharmacists and their associated staff, and others so situated.

In one embodiment, the present invention provides a prescription provider system that allows a physician to select a prescription, confirm the appropriateness of the prescription, and order the prescription in some examples, "on the fly" without having to write the prescription by hand on paper, deliver to the paper to the patient or a staff member to place the order, and then those persons communicate the order to

yet another person at a pharmacy with the associated risk of a miscommunication or other error from the handwriting along the process. Further, the system can be linked to computing device having a database and associated software containing a patient's medical history, including currently prescribed drugs, medical condition, known allergies, and other information. The system can be used to reliably enter a prescription directly to product provider, to correlate an initial prescription order against a database of recommended products for a given condition or medical history of a patient, fulfill authorizations request remotely, or a combination thereof. In at least one embodiment, the invention utilizes secure, broadband, wireless technology.

The provider system can also perform automated screening of newly prescribed medications against the patient's medical history to.

- Identify various medications that are appropriate for the entered diagnosis;
- Alert physicians to potential dosage errors;
- Cross-reference the prescribed medication against the entered diagnosis to ensure that look-zlike or sound-alike medications are not confused;
- Flag pre-existing medical or concurrent medical conditions that would preclude the use of certain medications; and
- Warn physicians to potential adverse drug events resulting from negative interaction of the prescribed medication with known allergies or other known prescribed medications taken by patient.

The provider system, through its centralized call center, can also offer reauthorization and new prescription requests management services to physicians, enabling physicians to relieve key personnel from these time-consuming, non-revenue

(

15

10

20

25

25

(

producing tasks. Thereafter, the provider system can also provide physicians and patients at the point of care with other healthcare-related services, such as electronic medical records management, supply management, third-party billing services and more.

The provider system can further operate a full-service pharmacy that has been located and designed in one embodiment to facilitate a rapid, such as a same-day; delivery service at a nominal-cost. This business model, which creates centralized operations using automated prescription dispensing technology instead of the placing the traditional pharmacy-in-every-neighborhood, enables the provider system to absorb the costs associated with offering same-day, nominal-cost home delivery by eliminating the need for maintaining multiple physical locations, along with duplicate inventory, personnel and the like.

Its centralized operations were also designed to facilitate its role in coordinating the orders of products. The provider system is responsible for receiving, dispensing, promptly delivering to patients, collecting applicable co-payments and billing third-party payors for all prescriptions that patients of member physicians elect to have filled electronically. In other words, the provider system can serve as the exclusive provider of substantially all prescriptions that patients choose to have electronically filled at the point of care and delivered, usually within hours, to the location of the patient's choosing,

Using the ordering database, the provider system can also determine when the patient may need a refill. The provider system contacts each customer prior to their current prescription running out to inquire as to whether they would like the prescription refilled and delivered. This role may assist in increasing patient compliance with the prescribed course of treatment.

10

20

(

In addition, the provider system can associate with employers to enrich their employer benefits package at little or no cost to the employer or employee. For example, employers who offer a prescription drug benefit in designated areas are eligible. Employees who enroll, at no cost, in the provider system can receive delivery of a prescription or other product. The prescriptions may be called in, faxed, entered through a data communication medium to the provider system, or other communication methods. In one embodiment, employees who avail themselves of this benefit can pay only their co-payment upon delivery. The provider system can take care of any third-party billing.

As demonstrated above, the comprehensive, bundled prescription services package offered by the provider system follows the prescription process from start to finish, giving the opportunity to offer physicians, patients, managed care plans and employers unparalleled benefits, as summarized below:

#### 15 II. Benefits in at least some embodiments

#### A. Benefits to the Physician

Through the provider system, physicians can have the ability to:

- · Drastically reduce their exposure to liability by
  - Bliminating all errors resulting from illegible
    handwritten prescriptions;
  - Electronically screening new prescriptions against the patient's medical history to prevent adverse drug events related to dosage errors, known allergies and negative drug-to-drug interactions; and

- Electronically screening new prescriptions against the patient's diagnosis to minimize errors resulting from look-alike and sound-alike drugs;
- Reduce the burden on themselves and their staff by:
- Relieving key personnel from the non-revenue producing tasks associated with phoned-in reauthorization and new prescription requests; and
  - Reducing the amount of calls received from pharmacies seeking clarification of illegible handwritten prescriptions;

Increase their cost savings by:

- Eliminating the need for dedicated personnel to handle phone-in reauthorization and new prescription requests;
   and
- Minimizing their exposure to malpractice claims resulting from prescription-related errors, which should ultimately be reflected in reduced medical malpractice insurance premiums;
- Increase patient safety and satisfaction by:
  - Streamlining the finistrating process for phoned-in reauthorization and new prescription requests;
  - Minimizing—or, if home delivery is chosen,
     substantially eliminating—needless delays at the
     pharmacy, resulting from illegible handwritten

5

10

15

20

(

(

(

prescriptions or undetected allergic or negative drug-todrug reactions; and

 Freeing up key personnel to devote more time to direct patient care instead of administrative tasks.

### B. Benefits to the Patient

Through the provider system, patients can enjoy:

- \* Increased safety by
  - Eliminating substantially all errors resulting from illegible handwritten prescriptions;
  - Electronically screening new prescriptions against the patient's medical history to prevent adverse drug events related to dosage errors, known allergies and negative drug-to-drug interactions;
  - Electronically screening new prescriptions against the patient's diagnosis to minimize errors resulting from look-alike and sound-alike drugs; and
  - Providing all of the patient's member physicians with access to the patient's comprehensive medical history, by combining diagnoses and prescribed medications from all of the patient's member physicians in a single readily accessible and secure electronic database;
- Increased convenience by:
  - Providing same-day, nominal-cost delivery of prescriptions to patient's home, office or other location;

10

5

15

20

ĺ

- Arranging for the preparation and submission of insurance claims on the patient's behalf;
- Streamlining the frustrating process of phoned-in reauthorization and new prescription requests; and
- Providing refill management services;
  - Increased cost savings by:
    - Minimizing the unnecessary purchase of additional prescriptions by getting the prescription right the first time; and
  - Eliminating the need to take time away from work to travel to (and wait endlessly at) the pharmacy for prescriptions to be filled.
  - C. Benefits to the Workplace

Through the provider system, corporate employers can enjoy:

15

20

١.

5

10

- Increased productivity and cost savings by
  - Substantially reducing the need for employees to leave work to deliver, wait for and pick up prescriptions at the pharmacy; and
  - Reducing sick leave taken by employees to treat problems related to preventable adverse drug events;
- · Increased employee satisfaction by
  - Enriching the healthcare benefit package for the employees and their family members at little or no cost to the employee or the employer;

10

15

20

(

- 1

- Eliminating the need and the inconvenience to take time away from work or leisure to travel to and wait at the pharmacy for prescriptions to be filled; and
- Making available nominal costs or free delivery to the employee's office of prescription drugs for the employees and their family members and eliminating the headaches associated with the time-consuming preparation and submission of insurance claims.

#### D. Benefits to Managed Care Plans

Through the provider system, managed care plans can enjoy:

- · Increased cost savings through the
  - Reduction of costs associated with the treatment of serious medical problems associated with preventable adverse drug events, such as allergic reactions, negative drug-to-drug interactions, dosage errors and administering the wrong drug due to illegible handwriting or confusion with look-alike or sound-alike medications; and
  - Reduction of prescription costs associated with replacing inappropriate prescriptions by getting it right the first time.

#### III. Hardware and software

The provider system provides the solution through software and associated hardware that eliminates prescription errors resulting from illegible

20

25

(

handwriting; and can screen prescribed medications against the patient's own medical history to minimize gross related to dosage, sound-alike or look-alike drugs, patient allergies and negative interactions with other medications taken by the patient.

In at least one embodiment, the provider system provides the solution through software and associated hardware that utilizes automated prescription dispensing technology to increase the volume of prescriptions that each pharmacist can accurately fill per shift by six fold or more; and centralizes its pharmacetuical operations and using same-day, nominal-cost home or office delivery of prescriptions and mail-order delivery of refills as the primary methods of delivering prescriptions to patients, thereby eliminating the need to have a pharmacist sited in every neighborhood, as all traditional walk-in pharmacies must do.

# 15 1. Electronic Prescribing Technology

The provider system advantageously includes an electronic prescribing unit. The electronic prescribing unit in at least one embodiment includes a computer device, such as a lightweight, hand-held personal computer, for example, the iPaq by Compaq Computer, loaded with software to accomplish to the various aspects and options discussed herein, such as selecting, ordering, checking, confirming, and authorizing additional orders, such as refills.

Each electronic prescribing unit can be customized to meet the unique needs of its physician-user. This customization includes the incorporation of the physician's patient list and most prescribed medications to allow real-time access of this information right from the unit. The electronic prescribing unit is generally designed to be fast and user friendly, allowing physicians to order and confirm prescriptions in

15

seconds with just a few keystrokes. The interaction of the electronic prescribing unit in the system is further described in reference to Figures 1-7.

# Electronic Screening of New Prescription Orders.

The associated software can include automated prescription screening, such that each time a physician uses the electronic prescribing unit to order a new prescription, the software can automatically screen the new order against the patient's medical history to:

- Identify various medications that are appropriate for the entered
   diagnosis;
  - Alert physicians to potential dosage errors and negative interactions
     with known allergies and/or existing prescribed medications;
  - Cross-reference the prescribed medication against the patient's recorded diagnosis to ensure that look-alike or sound-alike medications are not confused;
    - Flag pre-existing medical conditions or concurrent medical conditions that would preclude the use of certain medications in individual patients.

### 20 3. Management of Reauthorization and New Prescription Requests.

The provider system can offer physicians the option of having their patients' phoned-in reauthorization and new prescription requests managed by the provider system. Patients who phone their physician's office can be greated by a voice menu, directing the patients to press a certain number on their touchtone keypads or choose an option through voice-activation for calls relating to prescriptions. At that point, the calls will be automatically forwarded to a provider system call center technician, who

15

20

25

U

will access the patient's medical history and record the patient's request for a reauthonization of an existing prescription or a new prescription.

For new prescription requests, the provider system call center technician can record the patient's reported symptoms and specific prescription requests, if any. At their convenience, perhaps at scheduled intervals throughout the day, the physician and his staff can review the pending phoned-in reauthorization and new prescription requests through a secure provider system webpage or other mode and efficiently respond to each request. The provider system can then, at the patient's option, either channel the prescription to a default product provided for prompt delivery of the prescribed medication directly to the patient's home or office or forward the prescription to another product provider, such as a local pharmacy, of the patient's choice. If the prescription request is denied by the physician, the provider system can promptly notify the patient and advise the patient to schedule an appointment with the appropriate physician. The provider system can relatively seamlessly transfer the patient between its own system and the physician's office during telephonic or other interactive communications.

# 4. Comprehensive Medical Record.

As an added benefit for patients who see more than one physician, the provider system database can compile medical information received from multiple physicians that are members of the provider system into a single, comprehensive medical history for each patient. Thus, even if an elderly patient forgets to notify his or her member cardiologist of a medication prescribed by a member general practitioner, the provider system's automatic screening process against the patient's updated medical history would alert the cardiologist to any potential negative

10

15

20

25

(

interaction of any newly prescribed medications with the medications prescribed by the general practitioner.

# 5. Automated Speech-to-Text Conversion.

For those physicians with limited computer experience, the provider system, can also include voice-recognition technology that enables physicians to simply dictate their orders into their electronic prescribing unit, which automatically convert, in real time, the physicians' speech to text displayed on the computing screen to facilitate the prescription confirmation process.

The provider system can also offer other healthcare-related services such as electronic medical records management, supply management, third-party billing services, and other associated services with modifications to the software, as would be known to those with ordinary skill in the art given the understanding provided by the description herein. The provider system can be used with individual patients or groups of patients, for example, at hotels, nursing homes, correctional facilities, and other multiple needs entities.

#### 6. Security.

The provider system has addressed wireless security by using 128-bit encryption for communications between the electronic prescribing unit and a wireless bridge. In one embodiment, the provider system employs virtual private network (VPN) tunneling to securely transmit data from the provider system site to a computer terminal in the physician-user's office. Within the office, the provider system can use wireless encryption protocol (WEP) to securely transmit data from the computer terminal in the physician-user's office to the electronic prescribing unit.

Asternatively, the provider system can provide VPN tunneling from a server at the physician's office or other site to each associated electronic prescribing unit.

In addition, security in the electronic mansmission of data is also assured by the following:

Providing physician-users with a confidential login and password in order to access the software on the electronic prescribing unit;

- Automatically disconnecting access to the software after 30 minutes of nonuse;
- Immediately disconnecting access to the software upon receiving a
   report of a lost or stolen electronic prescribing unit;
  - Limiting the ability of the physician-user to prescribe only for those patients listed under "Today's Appointments" or another selected time period or criteria (the addition of "walk-in" patients is permitted only if the physician-user enters an additional password);
- Providing physician-users with a print-out of all prescriptions generated from the electronic prescribing unit;
  - Utilizing firewalls and secured site layers (SSL) that meet industry
     standards of the medical and pharmaceutical communities; and
  - Offering bio-security measures, such as thumb print verification,
     for maximum security.

#### Redundancy.

20

25

(,

ij

The provider system can also provide backups and redundancy, such as using an additional server in a remote location. In addition, the provider system can utilize related software from third parties, such as Oracle's Parallel Server System, to help ensure uninterrupted service, even during times of natural disaster.

10

15

25

1

(

(

# 8. Automated Prescription Dispensing Technology.

The provider system can advantageously incorporate automated prescription filling equipment and software to maximize efficiency and accuracy in dispensing medications. As a non-limiting example, the provider system can use a Baker-APS Productivity Station<sup>TM</sup>. The Productivity Station<sup>TM</sup> is designed to quickly and efficiently process over 90 to about 120 prescriptions per hour. Over an eight-hour shift, this amounts to about six times the industry average of 150 to 180 prescriptions per day filled by a pharmacist with the aid of a technician.

Turning specifically to the Figures, the present invention can be further described as follows:

Figure 1 is a schematic view of one embodiment of the provider system. In one embodiment, the provider system 2 can include a centralized system 4, a remote system 6, and a product provider system 8, although more or less modules may be used.

In general, the central system 4 contains patient membership information, relevant patient medical histories, and other patient-specific information. Further, the central system 4 can include physician membership, database information on drug-to-drug negative interactions, drug-to-allergy interactions, data on new drugs, and a multitude of other information relating to medical needs. The central system 4 can communicate requested information to the remote system 6 upon demand or in downloads for remote use by the system.

The remote system 6 can be located, for example, at a physician's office. The remote system 6 can interact with the central system 4 to receive data, such as medical history, data on drugs, patient lists and other related information. The remote system

20

( (

11

6 can transmit to the central system prescription orders, updated medical history and patient lists, and other information as might be useful in maintaining the database, filling orders, and management of the services provided herein.

The product provider system 8 can be located at a product provider, such as a pharmacy. The central system 4 and/or the remote system 6 can communicate to the product provider system 8 orders for products transmitted from the remote system 6 or the central system 4 to tangibly provide the prescription product that is ordered to the patient or other recipient. The product provider system can provide for delivery of the prescription to a home or office of the recipient.

More specifically, the central system 4 can communicate with a router 28 in at least one embodiment. The router 28 can be provided by the communications company, such as the telephone company, or with the provider system. The router 28 accesses a network 26, such as a local area network (LAN), a wide area network (WAN), a global communications network such as the Internet, or other types of networks. Advantageously, the communication uses broadband technology, such as DSL. T1 lines and associated equipment, and other types. The internet 26 can provide a medium of communication information between the central system 4, remote system 6, and product provider system 8.

In at least one embodiment, the central system can include a hub 32 that can direct incoming data transmissions to various portions of the central system and outgoing data transmissions to the remote system 6 and/or product provider system 8. The hub 32 can be coupled to a server 34. The term "coupled" is broadly used herein, and includes any type of connection, whether the connection be physical, mechanical, as well as electrical, wireless, sonic, or other forms of electromagnetic connections.

25 The server 34 can be a Hewlett Packard Netserver, in at least one embodiment.

(

(

ĺ

10

15

20

25

The server 34 can be coupled to a database element 44 for storing the relatively large amounts of patient, physician, product information used in the present invention. In at least one embodiment, a Sun Enterprise 450 can be used as the database element. Further, the central system 4 can include an additional server 36. The server 36 can be a Sun Enterprise 250 in at least one embodiment. The servers 34, 36 can also store queued information that may be selected from the remote system 6, described herein. Terminals 38, 40, and 42 can be coupled to the server 36 (or the server 34) for directing, reviewing and otherwise using information stored on the servers 34, 36, and database element 44, as a call center or other interaction.

In at least one embodiment, remote system 6 can be located in a physician's office or other remote place from the central system 4. Generally, information communicated to and from the central system 4 can enter an exit the remote system 6 through a modem or other communication device 24. In at least one embodiment, a firewall may be created by providing a computing device 12 that is coupled to the communication device 24 and a hub 20. The hub 20 can link the computing device 12 with another computing device 10, where temporary and/or permanent information from the central system 4 can be stored and used at the remote site.

The computing device 10 can be an onsite computer containing a display, a memory storage device, input devices such as keyboards, voice activated systems and other known input devices, and other elements common to a computer. The computing device 10 can include minimal to large data memory elements, depending on the requirements and desires of the user and the setup personnel. For example, the database element 44 and servers 34, 36 can communicate minimal amounts of information to the computing device 10 to minimize access time and download time for each communication period. However, such minimal communication may require

15

2.0

11

11

more communication periods to communicate the information from the central system to the remote system and back. Alternatively, the central system can send large amounts of data as downloads that can be stored on the remote system's computing device 10 or other stored medium. Thus, a larger amount of time may be required initially, but can minimize the amount of communication periods.

In at least one embodiment, one or more electronic medical product devices 16, 18 are provided. It is to be understood that the medical product devices can be used to order and/or manage related information for any medical product, and especially prescriptions. Advantageously, the medical product devices include wireless handheld portable computers, such as an iPaq, presently available from Compaq Computer Corp., Houston, Texas, USA. Other appropriate portable units can include units manufactured by Casio, Pahn Pilot, and others. In such an embodiment, the devices 16, 18 can communicate to the other components in the remote system through a transceiver 14. The devices 16, 18 can be carried with a position from patient to patient if the devices are portable or can be more stationary mounted in various offices where the patients are examined.

Depending on the selections made by the physician on the medical product devices 16, 18, the medical product devices can communicate an order through the transceiver 14, through the hub 20, and either to the computing device 12 or the computing device 10. In some cases, the patient and/or physician may elect to print out the medical product, such as a prescription, on a piece of paper, or other medium for the patient to take to a pharmacy. In such cases, a printer 11 may be used. In other cases, the physician may send the order directly from the physician's office to the central system 4, so that the order is processed without the need for intermittent

(

(

10

15

20

23

printing. In either case, the use of handwritten prescription notes, which have historically caused difficulty, is substantially eliminated.

To obtain the product ordered, the central system 4 can direct an order from the remote system 6 to the product provider system 8. In at least one embodiment, the product provider system 8 can include a printer 46. Printer 46 can print the prescription or other product ordered, where personnel or programmed devices can fill the order. In other cases, a printout may be unnecessary and the central system can communicate the order directly to an electronic medium, such as an electronic ordering system, for automatically processing of the order. Alternatively, the remote system 6 can communicate directly to the product provider system 8 to fulfill an order, as is appropriate.

Figure 2 is a schematic view of another embodiment of the provider system 2. The provider system is similar to Figure 1 and includes a central system 4, remote system 6, and an optional product provider system 8. In at least one embodiment, the communications between the central system 4 and the remote system 6 and/or product provider system can be accomplished by communicating with wireless system 49. The wireless system 49 can include any form of wireless communication, known to those with ordinary skill in the art. The schematic is merely illustrative.

In at least one embodiment, a transceiver 50 may be located at or near the remote system 6. Another transceiver 54 may be used to forward messages between the remote system 6 and the central system 4. A transceiver 54 can be located at or near the central system 4. The transceiver 50 can be coupled to a modern or other device of the remote system 6. Similarly, the transceiver 54 can be coupled to the router 28 of the central system 4. Thus, communication between the central system 4 and remote system 6 can perhaps be more direct than through the use of the Internet

15

20

11

or other networks, as is explained in Figure 1 and assist in maintaining confidentiality.

However, each embodiment may also use encryption to further maintain security of the data transmitted back and forth.

In some embodiments, the transceiver 50 and transceiver 54 may be sufficiently close that transceiver 52 is unnecessary. Thus, it should be understood that the number of transceivers shown is merely illustrative and can vary. Further, it is to be understood that the transceivers can also be coupled to the product provider system 8 for remote communication as well.

Figure 3 is a schematic view of another embodiment of a provider system. The embodiment of Figure 3 is similar to the embodiments shown in Figures 1 and 2 and comprises a central system 4, a remote system 6, and a product provider system 8. The central system 4 can communicate to the remote system 6 and the product provider system 8. In some embodiments, a product provider may not be located in sufficient proximity to the central system 4 to efficiently order products. In such cases, it may be advantageous to use a network 60 to link to one or more other product providers in system 8 that are at remote locations. This link may be in addition to or in lieu of the previously described link to the product provider more proximate to the central system 4. The remote product provider may also use a printer 46 or may use a direct link to computing devices (not shown) for receiving, filling, storing, and processing information. Although not shown, it is to be understood that the remote system 6 may be directly linked to the product provider system 8.

Figure 4 is an exemplary flowchart schematic of a portion of one embodiment of the provider system. The schematic diagrams of Figures 4-7 help show the various interactions of the software created to carry out the teaching of the present invention.

(

10

15

20

25

Further, reference may be made to elements shown in Figures 1-3 in describing the schematic flowcharts of Figures 1-4.

The software in at least one embodiment can be written using a programming language known as PHP programming language with a Linux operating system. Other programming languages such as PERL can be effectively used as well. PHP is a server-side, cross platform, HTML-embedded scripting language. Like PERL, the PHP program processing is done generally by the server. PHP can be used to perform all applications traditionally handled by CGI programs, such as collecting and processing data from Web pages, dealing with cookies, logging user actions, and so forth. Its strength lies in the simplicity with which Web pages can be made to interact with many known databases programs such as dBase, Oracle, Informix, and Sybase. Other programming languages/operating systems, such as Microsoft ASP along with Microsoft SQL can be used, as would be known to those with ordinary skill in the art and the above non-limiting list is merely exemplary.

A remote site, such as a physician's office, can download periodically patient data contained on a database, such as on database element 44, in Figures 1-3 The patient data can include, for example, a list of anticipated patients' scheduled during a time period. The patient data can also include known allergies, current prescriptions, and other present and past medical history of those patients. In other embodiments, the information may not be provided to the physician in a downloaded fashion, but may be provided real-time through broadband access, hardwire installations, or other data communication techniques. Thus, the exemplary embodiment shown in Figure 4 is but one example of providing a physician patient information.

In step 110, a physician can direct that patient data be provided manually or automatically from a centralized database located at the central system 4 to the remote

( -

( (

(1

10

15

20

system 6. The term "physician" is used broadly herein and includes the physician's staff, aids, associated physicians, and other health care personnel. The database can have patients associated by clinic and/or a specific physician operating through the clinic. Further, the database can have the patients' medical history and other patient information. Upon login, a clinic and/or physician list is presented in step 112. The login can be performed at the central system 4 with operating personnel entering and processing the data. Alternatively, remote personnel, including the physicians and their staff, can access and process patient and appointment information.

Generally, the physicians' list will include registered members of the provider system 2. In step 114, a physician and/or clinic is selected that is appropriate to the entry of data or inquiries of the system. The selection helps the appropriate physician and/or clinic to isolate relevant patient data. In step 116, the patient data entry screen is presented. The patient data entry screen can be used to enter patient information and/or obtain information on selected patients, and other entry or retrieval of appropriate patient information. In step 118, a list of patients scheduled for a particular time period, such as the day's appointments, is entered into the system or modified if information already in the system has changed. Such selection can be based on information provided by the physician communicating with the call center through voice, facsimile, digital, use of a network, or other forms of communications. In some embodiments, a confirmation in step 120 may be requested.

The entered and/or selected patient information can be placed in a clinic and/or physician queue in step 122. The queued information can reside in one or more of the servers 34, 36 at the central system 4. Advantageously, the queue can be accessed periodically by the medical product device 16, 18. Alternatively, the information can be downloaded to a remote computer, for example, computing

10

20

25

(

devices 10, 12 in the remote system 6. In one embodiment, the information can be downloaded into a portable handheld device that accompanies the physician as the physician examines patients. In step 124, the process is complete and the system is logged out in step 126.

Figure 5 is an exemplary flowchart schematic of another portion of one embodiment of the provider system. Figure 5 is complementary figure to Figure 4 after the patient information is loaded into a queue in step 122 and the process completed.

In step 210, one or more medical product devices 16, 18, shown in Figures 1-3 can be used to login to obtain pertinent information on selected patients and other relevant information on the patients, drug information, advisory data, and so forth. The medical product devices can be portable handheld devices such as the iPaq by Compaq, described above. Alternatively, the medical product devices can be other portable computers or fixed terminals and/or computers hardwired in each physician's office where the patient is examined. The medical product devices can obtain information from the central system 4, from one or more of the computing devices 10, 12 or even from its own memory, depending on where the information is queued.

After login, the physician can be presented a patient list for the time period earlier selected in step 212. Advantageously, the communication can occur in a wireless environment, so that as the physician moves from office to office, the physician can continue to carry the medical product device.

The patient list and other information can be retrieved during examination of a patient. After the physician has examined the patient, determine a possible cause of the patient's visit to the physician, and determined an initial recommendation for a prescription or other medical panduct, the physician can select a particular patient for

15

20

(1

a prescription in step 214. The physician can also receive and review relevant patient data, such as the patient's medical history in step 216, in selecting appropriate prescriptions. The patient data can be presented in such a manner that the physician can select specific prescription drugs for the particular patient, or can enter symptoms and diagnosis into the medical product device and receive possible options that may be correlated to the symptoms or diagnosis in selecting a prescription.

In step 218, the physician can select an appropriate prescription, prescribe a dose, frequency, quantity, and number of refills. Upon entry of the various selections, a physician can submit the information to the provider system 2, such as through the remote system 6 to the central system 4. In step 222, the submitted data may be correlated against patient data existing in the database element 44. The database may contain information that would suggest an alternative to the physician's recommendation. Such alternatives could include new datas of which the physician may presently be unaware, drugs that might adversely interact with the particular patient, the patient's allergies, or other drugs that the patient may be currently taking.

Even if no alternatives are recommended, the database information may alert the physician of advisory information of potential hazards or other issues of which the physician may wish to know. Thus, an advisory in step 224 may be issued. In other cases, no advisory may exist or be issued in step 226. In step 228, the advisory information is presented to the physician for further action and can appear on the medical product device 16, 18. The advisory information can be linked back to requesting confirmation by the physician of the proposed prescription in step 220. Alternatively, the physician can revise his or her selection and select a different prescription, dose, frequency, and so forth, as in step 218.

15

ĺ

If the physician is satisfied with the selection, or if no advisory exists, the physician can be presented with print options in step 230. Generally, the patient can decide where to obtain a prescription. It is generally to the patient's advantage to minimize time and complexity. Thus, the patient will often elect to have a prescription submitted directly to a pharmacist in the product provider system 8 in step 234. Alternatively, in step 232, the patient can elect not to have the prescription submitted directly and can request the prescription be printed locally, such as in the physician's office.

If the patient elects to submit directly to a pharmacy, the prescription can be encrypted or otherwise "sealed" to maintain patient confidentiality and the prescription electronically delivered to the pharmacy. Advantageously, the information can be transmitted directly from the medical product device by the physician without handwritten prescriptions that are subject to misinterpretation or without the typical handling of a written prescription by the patient and ultimately to a pharmacist.

The prescription transmission generally can occur through any form of reliable communications, such as a global communication network, a wide area network, microwave, satellite, and other data transfer methods known to those with ordinary skill in the art. Advantageously, communications inside and outside the remote system 6, such as the physician's office, and to and from the central system 4 and/or product provider system 8 can occur using wireless communication methods.

To maintain confidentiality, a virtual private network (VPN) can be used, known to those with ordinary skill in the art, given the understanding provided by the present disclosure. A VPN connection "tunnels" directly between sites over a publicly accessed communication system. The tunneling restricts other from viewing

15

20

25

(1

; (

data or otherwise accessing transmitted data and is considered a substantially secure transmission method. Further, one or more of the wireless transmissions in the remote system 6 can be sent using encryption protocol, such as 128-bit encryption methods, to add to the security of the information transmitted therein. In other embodiments, a VPN may be used to link the central system 4 to each medical product device 16, 18. Other security measures can be taken, including confidential logins and passwords, automatically disconnecting after periods of nonuse, limiting the physicians' abilities to prescribe for patients that are not in the physicians' queues without further authorization, firewalls, secured site layers (SSL), and other security measures.

Figure 6 is an exemplary flowchart schematic of another portion of the provider system for refilling orders for the medical products. The present invention can also provide for a refill request option. In step 310, a person entering patient refill information or a person seeking useful information may login to enter the central system 4. The person handling the information can be a staff person at a call center who handles call requests from patients or physicians, a patient seeking a refill, a physician (or staff member), or some other authorized person.

The entry can be manual, as can be done by a person audibly, through a dialor voice-activated system, or through a data transmission, such as a local keyboard or some other input device. The entry can be local with personnel at for example the central system 6 or remote by personnel accessing the information over a network system.

Alternatively, the entry can occur automatically, such as may be programmed into a person's computing device. In step 312, a clinic and/or physician list is presented from the various members of a database. In step 314, the appropriate clinic

10

15

20

1

(

and/or physician is selected that correlates to the particular patient requesting refilit information. If the patient is a member of the provider system, the data can also be accessed based on the patient, where the data can have, for example, the last attending physician and other physicians, past prescriptions, doses, number of allowed refills and other related information.

In step 316, the refill information is captured. In one embodiment, call center personnel or devices can capture prescription information from a patient via telephone communication. Such information can be communicated audibly, or through dial or voice activated recognition systems. In other embodiments, the information can be captured electronically, where a person or a computer device may electronically enter the requested information through data transmission methods.

In step 318, the call center can enter a prescription request into a clinic and/or physician queue. Again, such enuy can be manual through interaction or electronic methods or automatically, for example, through programming.

It is to be noted that the description has used the call center and a central system 6 as an example in which to login to obtain various information. The information could be obtained from other portions of the provider system 2, such as the product provider system 8 or the remote system 4, as would be apparent to those with ordinary skill in the art, given the understanding provided by the description of the invention contained herein.

In step 320, a confirmation of the requested refill can be presented and if confirmed, the refill request can be placed in the physician's queue in step 322. In step 324, the entry of the information into the physician's queue can complete this portion of the process and a logout screen can be presented in step 326.

10

20

25

į į

Figure 7 is an exemplary flowchart schematic of another portion of the provider system for refilling orders for the medical products. Figure 7 represents a flowchart that complements the flowchart shown in Figure 6. In Figure 7, the physician decides whether to grant the refill request entered in Figure 6.

In step 410, a computing device, such as the medical product device 16, 18 can be used to login to the provider system 2, such as in the remote system 6. In step 412, a prescription refill request or other medical product request, can be presented through a screen on the medical product device.

In step 414, the physician can review the prescription request by patient. Advantageously, a physician can review the request at the physician's convenience between patients, on break, at lunch, at a remote location, or other appropriate times. If appropriate, the physician can submit an approval in step 416. In some embodiments, the physician can be presented with relevant patient data before authorizing the refill in step 418, such as medical history, previous numbers of refills, other prescriptions being taken and so forth.

In step 420, the physician can approve the prescription base, frequency, quantity, and the number of refills at his or her discretion. In step 422, a confirmation of the prescription can be presented to the physician.

In step 424, the submitted data from the prescription can be compared with available patient information in the provider system's database, if the patient is a member of the provider system and has a medical history in the database.

The database can also check for advisories in step 426. If an advisory exists, the physician may wish to learn additional information. If no advisories exist in step 428, the process can continue based on the prescription already entered. If the advisory exists, it can be presented to the physician for further consideration in step

(

(

ţ

10

15

20

25

430. The physician can review the advisory and confirm the prescription in step 422, if the physician still wishes to prescribe the prescription as presented. However, if the physician wishes to alter the prescription, the physician can change the prescription in step 420. Once the physician has confirmed the prescription, reconfirmed the prescription after an advisory (or if no advisory exists as in step 428) the physician can be presented with print options in step 432. The patient can elect to have the refull submitted directly to the product provider system 8 in step 436. If the patient so selects, the database and subsequent program can provide the information to the pharmacy in a secure environment to help preserve patient confidentiality in step 438. Alternatively, if the patient does not wish to have the prescription submitted directly to a pharmacy, the patient can request a print of the refull in step 434. The printout can be at a variety of sites, including the remote system 6, the central system 4, o the product provider system 8, the patient's home or office, or other appropriate locations.

Returning to the step 414 in which the physician reviews the prescription, the physician can decline the refill in step 440. The physician may decline the refill based upon his own knowledge, or after review of the patient data in step 418. The physician can enter the declination, which can be transmitted to the remote system 6 and/or the central system 4 to process the declination in step 442. In some embodiments, the physician may be presented with options to decline in step 444. For example, the physician can issue instructions that the patient must return for an office visit, or other instructions.

In step 446, the reason for the declination can be placed in a call center queue, for example, associated with a central system 4. In some embodiments, personnel at a call center may confact the requesting person to explain the reason for the declination and offer the options that the physician presented, such as a follow up visit. The

15

20

( (

. (

personnel at the call-center can link the patient directly to the physician's office, such as transferring a telephone call so that the patient can make the requested follow up visit. Alternatively, the personnel can make an appointment, generally using the physician's calendar loaded into a database, or can instruct the patient to contact the physician, or other appropriate options. The communication can be telephonic, through recorded messages, in person, over data transmissions such as email and with networks such as the Internet.

In at least one embodiment, a patient can contact the physician's office, enter a selection menu from a list of options for refill requests and be transferred to a call center as part of the central system 4 of the provider system 2. The call center can explain that the call center handles the particular physician's refill requests. Refill information can be taken either manually or automatically as explained in the process steps of Figure 6. The call center can then allow the physician to access the information, make decisions, and receive a physician's instructions as explained in Figure 7. The call center then can recontact the patient, and explain the declination so that the center can contact the physician and reconnect the patient with the physician's office in a seamless manner.

Further, the patient can contact the physician's office, a call center, a product provider, or some other portion of the provider system 2 to request a refill, for example, over a network, such as the Internet. The refill information can be requested either through menus or emails. The physician can be informed of the request and answer at some appropriate time and manner through the provider system as described above. The refill approval or decline can be communicated to the patient. If granted, the physician and/or patient can direct the refill request to a product provider where

(

(

20

the product can be refilled and perhaps delivered with little further effort by the physician or patient.

While the foregoing is directed to various embodiments of the present invention, other and further embodiments may be devised without departing from the basic scope thereof. For example, the various mothods and embodiments of the invention can be included in combination with each other to produce variations of the disclosed methods and embodiments. Also, the directions such as "top," "bottom," "left," "right," "upper," "lower," and other directions and orientations are described herein for clarity in reference to the figures and are not to be limiting of the actual device or system or use of the device or system. The device or system may be used in a number of directions and orientations. Further, the order of steps can occur in a variety of sequences unless otherwise specifically limited. The various steps described herein can be combined with other steps, interlineated with the stated steps, and/or split into multiple steps. Additionally, the headings herein are for the convenience of the reader and are not intended to limit the scope of the invention.

Further, any references mentioned in the application for this patent as well as all references listed in the information disclosure originally filed with the application are hereby incorporated by reference in their entirety to the extent such may be deemed essential to support the enabling of the invention(s). However, to the extent statements might be considered inconsistent with the patenting of the invention(s), such statements are expressly not meant to be considered as made by the Applicant.

### **CLAIMS**

#### What is claimed is:

5

( !

- 1. A system and method for providing a medical product as described herein.
  - 2. A system for providing a medical product, comprising:
- a) a central system having a server coupled to a communications device and a database;
- b) a remote system having at least one electronic medical product device, the device adapted to communicate a medical product order to the central system.
- 10 3. The system of claim 2, further comprising a product provider system coupled to the central system.
  - 4. The system of claim 2, where the electronic ordering device comprises an wireless, handheld computing device.
    - 5. A method of providing medical products, comprising:
- a) providing at least one computing device having a database and a communications device;
  - b) providing a remote electronic medical product device;
  - c) reviewing patient information contained on the medical product device;

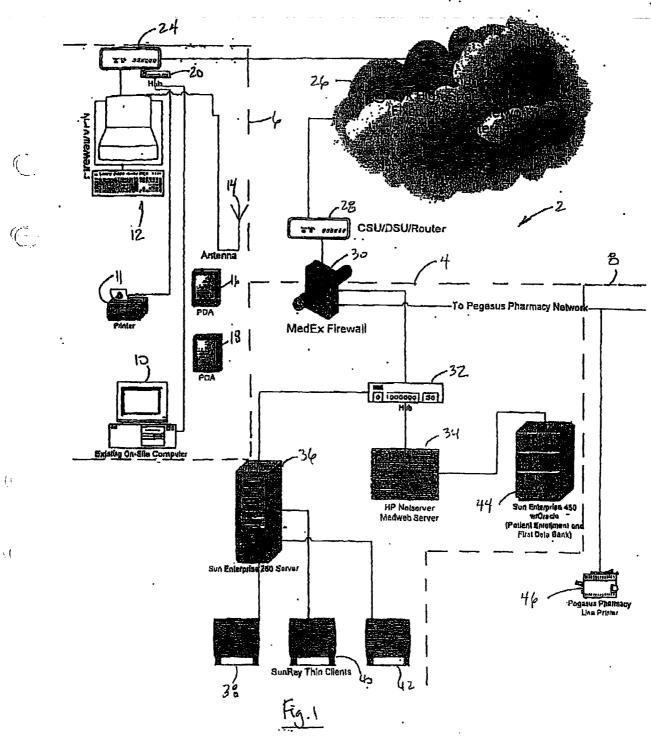
- d) directly ordering a medical product from the medical product device.
- 6. The method of claim 5, wherein the ordering is based on the patient information.
- 5 7. The method of claim 5, wherein the medical product comprises a prescription.
  - 8. The method of claim 5, wherein directly ordering comprises bypassing handwriting a prescription for the medical product.

Q.J

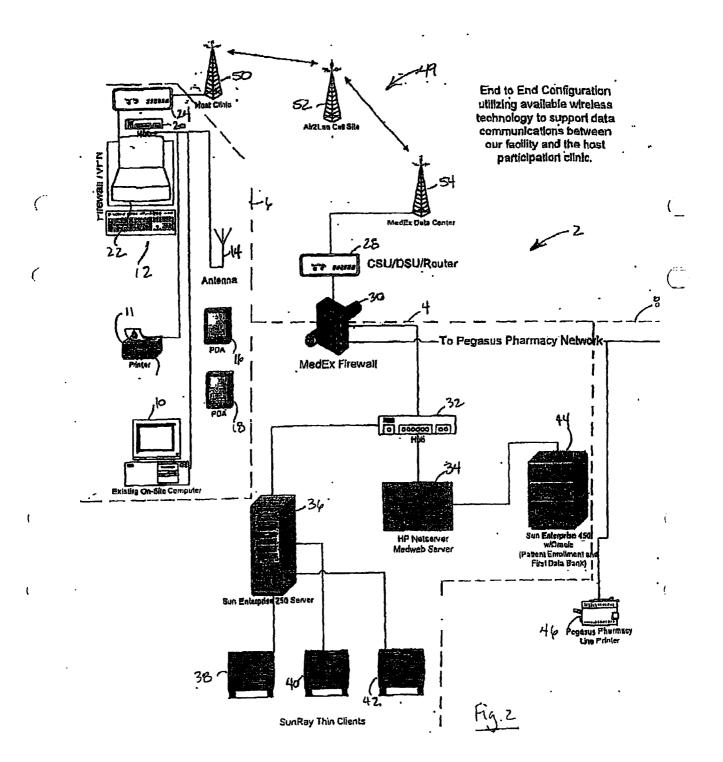
(

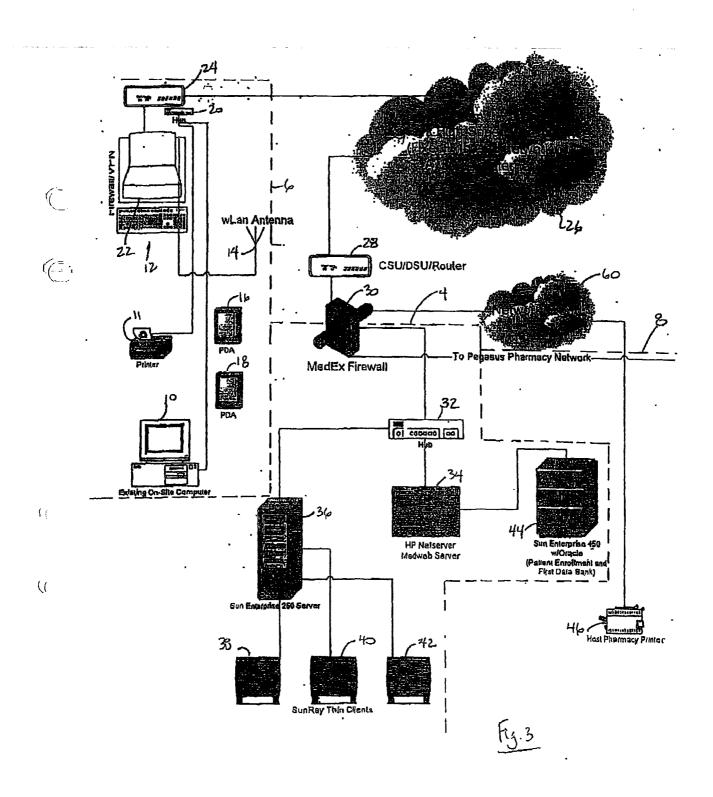
(

(



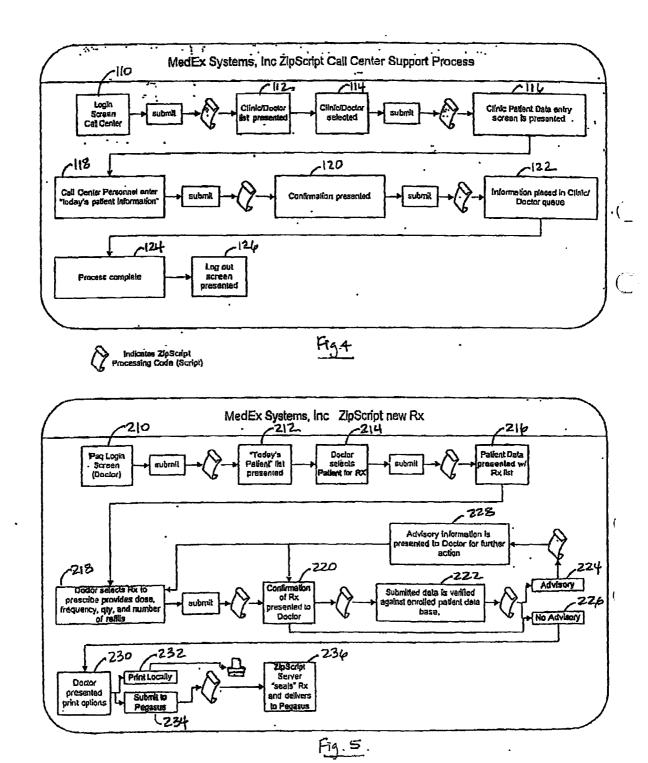
()





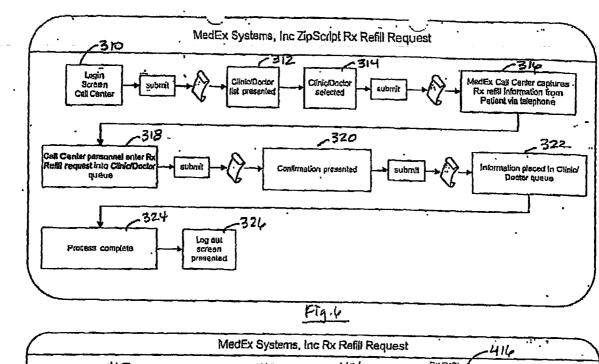
(

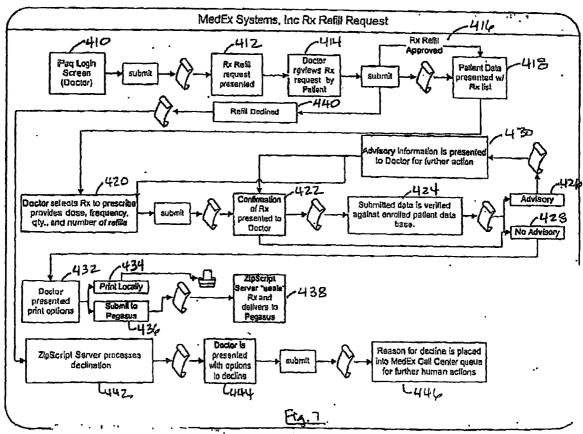
(



((\_\_

(1





• ĺ .