State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: September 6, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Citation and Fine Program**

At the June Enforcement Committee meeting, the California Retailers Association (CRA) requested that the review of the board's Citation and Fine Program be placed on the agenda for discussion the next Enforcement Committee meeting.

As requested, the matter was placed on this agenda. Subsequently, CRA requested that the agenda item be deferred until the December 7th meeting. Committee Chair Bill Powers agreed to place the Citation and Fine Program on the December agenda for discussion. However, since the topic was already noticed for this meeting, opportunity to discuss the program will also be provided at this meeting.

Background Material

Attachment 1
Overview of the investigation process that includes recommended actions that the board may take including the issuance of a citation and fine

Attachment 2
Citation and fine data since the program's inception

ATTACHMENT 1

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

INVESTIGATION PROCESS

Complaint Investigation

When the Board of Pharmacy ("Board") receives a complaint or uncovers potential violations of the law through its own efforts, the matter may be assigned for investigation to either an enforcement analyst or to an inspector.

During the course of the investigation, evidence is obtained in order to determine if the alleged violation of the law occurred. As part of the investigation, the licensee may be asked for documents (e.g., business records, patient records, and/or policies and procedures) and/or for statements regarding the events that transpired. Licensees are encouraged to respond in a timely and accurate manner, as the information is used as part of the investigative record. A licensee's responsiveness or non-responsiveness may be considered as a factor in mitigation or aggravation.

If it is believed that a violation of pharmacy law took place, the licensee may be advised of the alleged violation on the inspection report. This notification will simply notify the licensee the violations of pharmacy law that the inspector or enforcement analyst believes occurred. This notification is not the Board's final or formal determination regarding the matter. It is also neither a citation nor is it a disciplinary action.

At this time, the licensee will be provided with another opportunity to respond in writing to the alleged violation. In the written response, the licensee may address the specifics of the violation, as well provide any mitigatory information that the licensee wishes to have included in the investigation report.

After the investigation is completed and there is a determination by the inspector or enforcement analyst that the law was violated, the case is referred to a supervising inspector for review. If the supervising inspector determines that there was no violation or that the violation was so minor as to not merit any action, then the case may be closed and the matter goes no further.

Recommended Actions

If after review by a supervising inspector, it is determined that action may be warranted, the case is then referred to the executive officer. The executive officer, with the assistance of the supervising inspectors, reviews the matter and determines what is the appropriate course of action to pursue. The types of action that may be undertaken include:

- **Case Closure – No Further Action**
  The executive officer may decide that no action is now warranted. That may occur when the executive officer determines that there was no violation, that the violation

was so minor as to not merit an action, or that the mitigating circumstances were such that it would be best not to pursue an action. The matter then ends.

- **Order of Correction**

If an Order of Correction has been issued, the licensee can contest the order by requesting an office conference with the executive officer. However, if no office conference is requested, compliance with the order is not an admission of the noted violation. The order of correction is not considered a public record for purposes of disclosure.

- **Further Investigation**

The executive officer may decide that there is insufficient evidence to determine if a violation occurred or if any action is warranted. The executive officer may then send the matter back for further investigation.

- **Letter of Admonishment**

After review, the executive officer may issue a Letter of Admonishment to the licensee for failure to comply with Pharmacy Law. The letter will include a reference to the statute or regulation violated, a description of the nature and facts of the violation, and a notice to the licensee of available appeal rights.

- **Citation and Fine**

After review, the executive officer may issue a citation, with or without a fine. The citation will be issued to the licensee and will include a reference to the statute or regulation violated. It will also include a description of the nature and facts of the violation, as well as a notice to the licensee of the appeal rights.

The following factors are considered when issuing a citation with or without a fine:

- Gravity of the violation.
- Good or bad faith of the cited person or entity.
- History of previous violations.
- Evidence that the violations were or were not willful.
- Recognition by the licensee of his/her wrongdoing and demonstration of corrective action to prevent recurrence, e.g., new policies and procedures, protocol, hiring of additional staff, etc.
- Extent to which the cited person or entity has cooperated with the Board's investigation and other law enforcement or regulatory agencies.
- Extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violation.
- If the violation involved multiple licensees, the relative degree of culpability of each licensee should be considered. In the case where the staff pharmacist failed to consult, the pharmacist-in-charge and the pharmacy may also be issued a citation and fine, if warranted by the circumstances.
- Any other relevant matters that may be appropriate to consider.

Fine Amount

The Board's regulation provides that a fine can be up to a maximum of $5,000 per licensee for each investigation

If an investigation involves multiple licensees (e.g., a staff pharmacist, the pharmacist-in-charge, a pharmacy technician, and the pharmacy), then each licensee may be cited and fined. The amount of each fine will depend on which of the above factors are present and applicable to each licensee. The Citation and Fine Committee will consider the amount of the fine on a case-by-case basis.

Request for an Office Conference

A licensee has 14 calendar days after service of the citation and fine to request an office conference with a board member and supervising inspector, pursuant to the California Code of Regulations, title16, section 1775.4, subdivision (b).

Appeal Process for Citation and Fines

Payment of a fine does not constitute an admission of the violation charged. A licensee has 30 days after service of the citation and fine to file a written appeal (request for a hearing). Appeals are referred to the Attorney General's Office for a hearing in accordance with the Administrative Procedure Act. For more complete description on the entire the appeal process please see California Code of Regulations, title 16, sections 1775, subdivision (c), and 1775.4.

Disciplinary Action

The executive officer may determine that the violation is substantial and warrants discipline of the license. The matter is then referred to the Attorney General's Office, where, if appropriate to do so, an accusation is prepared, which identifies the alleged violations of pharmacy law.

ATTACHMENT 2

Fines Assessed
Statistic Comparison

Statistic Category	02/03	03/04	04/05
Total number of citations issued	908	1410	689
Average days from case open to citation	228	142	177
Total amount of fines assessed	$407,775.00	$939,259.00	$365,525.00
Total amount of fines collected to date	$361,975.00	$852,707.00	$405,579.00
Number of office conferences requested	124	399	409
Total number of conferences held	20	21	20
Total number of appearances	97	197	350
Number of citations dismissed	20	82	100
Number of citations modified	17	72	68
Number of citations affirmed	60	43	173

A Comparison of the Top Ten Violations by License type by fiscal year

Pharmacists	%	Pharmacists	%	Pharmacists	%	Pharmacists	%
2002 – 2003		**2003 – 2004**		**2004 – 2005**		**2005 - 2006**	
1716 - Variation from prescription	27	1716 - Variation from prescription	42	1716 - Variation from prescription	48	1716 - Variation from prescription	52
1707.2 – Duty to consult	8	4051(a) - Conduct limited to a pharmacist; conduct authorized by pharmacist (unlicensed activity by a revoked pharmacist)	8	1716/1761 - Variation from Rx / Erroneous Rx	16	1716/1761 - Variation from Rx / Erroneous Rx	18
1714(d) – Operational standards and security	7	1716/1761 - Variation from Rx / Erroneous Rx	7	1714(d) - Operational standards and security; pharmacist responsible for pharmacy security	6	1764/56.10 et seq. - Unauthorized disclosure of prescription and medical information	5
1761- Erroneous or uncertain prescriptions	5	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	5	1717(b)(4)/4076(a)(4) Preprinted multiple check off Rx blanks/ container requirements for labeling - Name of the prescriber	4	4081(a)- Records of dangerous drugs kept open for inspection	5
4076/4077- Rx container labeling requirements	5	4125/1711 - Quality assurance program	4	4059 – Furnishing dangerous drugs or devices prohibited without prescription	3	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	3
4081/4332/4333 – Records of dangerous drugs.	2	4301(q) - Engaging in any conduct that subverts or attempts to subvert an investigation of the board.	3	4125/1711 - Quality assurance program	2	4051(a)- Conduct limited to a pharmacist; conduct authorized by pharmacist	3
4115/1793.7 – Pharmacy technician/ Requirements for Pharmacies Employing Pharmacy Technicians	2	4063 – Refill of prescription for dangerous drug or device; Prescriber authorization.	3	1715 - Self-assessment of a pharmacy by the pharmacist in charge	2	4063- Refill of prescription for dangerous drug or device; prescriber authorization	3
1764/56.10– Unauthorized disclosure of Rx	2	4231/1732.5 - Requirements for renewal of pharmacist license/ Accreditation agencies	2	1716/4076(a)(4) - Variation from prescription/ container requirements for labeling - Name of the prescriber	2	1707.2(b)- In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously be dispensed	3
4059.5 - Who may order dangerous drugs	1	1707.2 – Duty to consult	2	1707.2 – Duty to consult	2	1761(a) - Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	3
1716.2 - Records requirements-compounding for future furnishing	1	1715 - Self-assessment of a pharmacy by the pharmacist in charge	2	4116/1714(d) - Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist responsibility for individuals on premises; Regulations/Operational standards and security	2	4052(a)(5)- Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider	3

A Comparison of the Top Ten Violations by License type by fiscal year

Pharmacies	%	Pharmacies	%	Pharmacies	%	Pharmacies	%
2002 – 2003		**2003 – 2004**		**2004 – 2005**		**2005 - 2006**	
1716 - Variation from prescription	21	1716 - Variation from prescription	21	1716 - Variation from prescription	35	1716 - Variation from prescription	34
1714 (b) – Operational standards & security	9	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	9	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	26	1716/1761 - Variation from Rx / Erroneous Rx	15
1761- Erroneous or uncertain prescriptions	6	4125/1711 - Quality assurance program	7	1715.6 – Reporting drug loss	12	4125/1711 - Quality assurance program	6
4115/1793.7 – Tech activities permitted; Req. supervision/Req. for PHY with techs	5	1716/1761 - Variation from Rx / Erroneous Rx	4	1716/1761 - Variation from Rx / Erroneous Rx	12	1717(e) No licensee shall participate in any arrangement.., whereby medications may be left at, picked up from…, any place not licensed as a retail pharmacy.	6
1707.2 – Duty to consult	4	1715 - Self-assessment of a pharmacy by PIC	3	4125/1711 - Quality assurance program	6	4059.5(a)– Dangerous drugs and devices may only be ordered by an entity licensed by the board	4
4081/4332/4333 – Records of dangerous drugs	3	4076 - Prescription container requirements for labeling	3	4115(e)-Pharmacy Technician license required	4	1715.6- Reporting drug loss	4
1764/56.10 – Unauthorized disclosure of Rx	2	4328 -Misdemeanor permitting compounding, dispensing, or furnishing by non-pharmacist	2	4127.1(a) - License to compound injectable sterile drug products required	2	4063- Refill of prescription for dangerous drug or device; prescriber authorization	4
4076/4077 - Rx container labeling requirements	2	4116/1716(b) -Security of dangerous drugs & devices/Operational standards and security; pharmacy responsible for pharmacy security	2	4116/1714(d) - Security of Dangerous Drugs and Devices in Pharmacy: Pharmacy responsibility for individuals on premises;	2	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	4
4067 - Internet: Dispensing Dangerous drugs or Devices without prescription	2	1716.2 - Record requirements - compounding for future furnishing	2	1708.2 – Discontinuance of business	2	4081(a)- Records of dangerous drugs kept open for inspection	4
4125/1711 – Quality Assurance	2	4113(a)(c)/1709.1 - Pharmacist in charge notification to board and responsibilities /Designation of a pharmacist in charge	2	1714(c) - Operational standards and security; the pharmacy must be maintained in a sanitary condition	1	1708.2- Discontinuance of business	2

A Comparison of the Top Ten Violations by License type by fiscal year

Pharmacists in charge	%	Pharmacists in charge	%	Pharmacists in charge	%	Pharmacists in charge	%
2002 – 2003		2003 – 2004		2004 – 2005		2005 - 2006	
4115/1793.7 – Pharmacy technician license req. /Requirements for PHY with techs	13	1716 - Variation from prescription	11	1714(d) - Operational standards and security; pharmacist responsible for pharmacy security	28	1716 - Variation from prescription	1
1714(d) – Operational standards and security	12	4125/1711 - Quality assurance program	11	4125/1711 - Quality assurance program	12	4081/1718- Records of dangerous drugs kept open for inspection/Current inventory defined	1
1707.2 – Duty to consult	6	1714(b) - Operational standards and security; pharmacist responsible for pharmacy security	9	1716/1761 - Variation from prescription/Erroneous or uncertain prescriptions	7	1716/1761 - Variation from Rx / Erroneous Rx	1
1715 - Self-Assessment of a pharmacy by the Pharmacist-in-Charge	5	1715 - Self-assessment of a pharmacy by PIC	5	4127.1 – License to compound injectable sterile drug products required	6	4125/1711 - Quality assurance program	1
4081/4332/4333 – Records of dangerous drugs.	5	1716.2 - Record requirements - compounding for future furnishing	4	4051/11207/4036 - Conduct limited to a pharmacist; conduct authorized by pharmacist/Only pharmacist or Intern authorized to fill prescription/Pharmacist	6	1714(c)/4005- Operational Standards and security; Pharmacy shall be clean and orderly/ Board may Adopt Rules and Regulations	1
4125/1711 Quality Assurance	5	4342/USP 25th edition page 10 - Actions by board to prevent sales of preparations or drugs lacking quality or strength	3	4115(e) -4115(e)-Pharmacy Technician license required	6	4125/1711- Pharmacy quality assurance program required/Quality assurance program	1
1716 - Variation from prescription	5	4115(e) - Pharmacy technician license required	3	4059 – Furnishing dangerous drugs or devices prohibited without prescription	4	1717(f)- A pharmacist may transfer a prescription for Schedule III, IV, or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations § 1306.25...	1
1761- Erroneous or uncertain prescriptions disclosure of Rx	3	1793.7(e) - Requirements for pharmacies employing pharmacy technician - Job description and written policies and procedures required	3	1715 - Self-assessment of a pharmacy by the pharmacist in charge	4	4059.5(a)- Dangerous drugs and devices may only be ordered by an entity licensed by the board	5
4076/4077 - Rx container labeling requirements	3	1716/1761 - Variation from Rx / Erroneous Rx	3	4114 – Intern pharmacist: activities permitted	2	1710(a)- A hospital pharmacy which predominantly furnishes drugs to inpatients of that hospital my furnish drugs to walk-in customers, provided that sales do not exceed 1% of all pharmacy's prescriptions.	5
1716.2 - Records requirements-compounding for future furnishing	3	4116/1716(d) -Security of dangerous drugs & devices/Operational standards and security; pharmacist responsible for pharmacy security	2	1305.11(a) - Unaccepted & defective order forms; No order form shall be filled if not complete, legible, or properly prepared, executed, or endorsed; or shows any alteration, erasure, or change of any description	2	4063- Refill of prescription for dangerous drug or device; prescriber authorization	5

Citation Appeals to Attorney General's Office

	FY 02/03	FY 03/04	FY 04/05
Citation Appeals	84	23	24
Citations Settled	75	12	10
Citations to Hearing	1	1	0

citation and fine upheld at hearing - 1
citation and fine upheld and reduced at hearing - 3

AGENDA ITEM E

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: September 6, 2005

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Legibility of Prescriptions

At the last board meeting pharmacist Jim Colucci requested that the board consider a future agenda item to require all prescriptions be printed, typed, or computer generated to improve legibility and prevent prescription errors. During the course of the ensuing discussion two bills were mentioned, SCR 49 (Speier 2005) relating to medication errors, and AB 1589 (Chapter 464, Statutes of 2001) relating to e-prescribing.

Senate Concurrent Resolution 49 (Speier 2005) relating to medication errors, would create a panel to study the causes of medication errors and recommend changes in the health care system that reduces errors associated with the delivery of prescription and over the counter medication to consumers. The resolution would require the panel to convene by October 1, 2005, and to submit to the Assembly Committee on Health and the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006. It is anticipated that SCR 49 will be passed by the Legislature this session. A copy of the resolution is attached.

Assembly Bill 1589 (Chapter 464, Statutes of 2001), Business and Professions Code section 2028, required the Medical Board to consult with the Board of Pharmacy and commission a study to evaluate the electronic transmission of prescriptions by physicians and surgeons and report its results to the Legislature on or before January 1, 2003. The bill specified that the Medical Board's report include recommendations on whether the electronic transmission of prescriptions should be encouraged, methods to encourage physicians and surgeons and other specified persons to use this method to transmit prescriptions, and to identify systems to protect the privacy of patients, including the issuance of a digital certification. AB 1589 did not appropriate funds for the Medical Board to conduct the study.

In 2001, Medical Board staff consulted with Paul Riches, Legislation Coordinator for the Board of Pharmacy, who suggested that the Medical Board review a November 2001, California Health Care Foundation Report titled, E-Prescribing. The Medical Board reviewed the report, adopted it as meeting the requirements of AB 1589, and submitted the report to the Legislature. A copy of the report is attached.

AMENDED IN ASSEMBLY AUGUST 30, 2005

AMENDED IN SENATE JUNE 30, 2005

AMENDED IN SENATE JUNE 15, 2005

Senate Concurrent Resolution No. 49

Introduced by Senator Speier

May 17, 2005

Senate Concurrent Resolution No. 49—Relative to medication errors.

LEGISLATIVE COUNSEL'S DIGEST

SCR 49, as amended, Speier. Medication errors panel.

This measure would create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The measure would require the panel to convene by October 1, 2005, and to submit to the *Assembly Committee on Health and the* Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

Fiscal committee: no.

1 WHEREAS, Numerous studies establish that medication errors
2 cause injury and death to patients and consumers; and
3 WHEREAS, The Institute of Medicine estimates the cost for
4 treatment of drug-related morbidity and mortality may run nearly
5 $77 billion a year nationally; and
6 WHEREAS, Research demonstrates that most injuries
7 resulting from medication errors are not the fault of any

individual health care professional, but rather represent the failure of a complex health care system; and

WHEREAS, The Federal Food and Drug Administration has approved 122 chemical compounds since 2002, and over 17,000 existing trade and generic names of products exist, many of which sound alike or are spelled alike; and

WHEREAS, These products are also packaged and distributed in similar shapes and forms; and

WHEREAS, The demand for prescription drugs is expected to substantially increase; and

WHEREAS, Medication errors occur in all settings in which prescription drug products are prescribed, dispensed, furnished, ordered, or otherwise provided; and

WHEREAS, Many factors contribute to a poor understanding by many consumers and patients about their prescriptions, including frequent switching of generic brands that are each different colors and shapes so that the same drug looks different and confuses the patient making it hard to easily spot mistakes; overworked pharmacists; reduced time with physicians for patients to be given important drug information; patients seeing multiple physicians that may be unaware of each other's care plans; patients often using vitamins, herbs, and over-the-counter drugs that can react with the medications they take and that both the physician and pharmacist do not know about; and

WHEREAS, Research has demonstrated that improved communication between patients and their health professionals is the most effective means of reducing errors and drug misadventures and improving health care outcomes; now, therefore, be it

Resolved by the Senate of the State of California, the Assembly thereof concurring, That a special panel be formed to study causes of medication errors; and be it further

Resolved, That the Legislature shall convene the panel no later than October 1, 2005; and be it further

Resolved, That the panel shall recommend improvements, additions, or changes to be constructed and implemented for the significant improvement of the health care system by reducing errors associated with the delivery of prescription and over-the-counter medications to consumers; and be it further

~~*Resolved,* That the panel membership shall consist of appointees of the Senate Committee on Health and the Assembly Committee on Health; and be it further~~

Resolved, That the Speaker of the Assembly shall appoint to the panel a member of the faculty of a school of pharmacy, a representative of the California Pharmacists Association, a representative of the California Association of Health Plans, a representative of the Pharmaceutical Research and Manufacturers of America, a member of the California Medical Association, a *member or representative of the Assembly Democratic Caucus, a* member or representative of the Assembly Republican Caucus, and a consumer representative; and be it further

Resolved, That the Senate Committee on Rules shall designate the chair and appoint to the panel a representative of the California Retailers Association Chain Drug Committee, a member of the California Society of Hospital Pharmacists, a representative of the Generic Pharmaceutical Association, a representative of a public health organization, a member of the California Nurses Association, a representative of ~~the American Association of Retired People~~ *AARP*, a representative of the Consumer Health Care Products Association, *a member or representative of the Senate Democratic Caucus,* and a member or representative of the Senate Republican Caucus; and be it further

Resolved, That the members of the panel shall not receive compensation, but shall be reimbursed from private sources for necessary travel expenses for the purpose of attending meetings of the panel, including any public meetings that the panel schedules*, and the panel shall be funded by private sources*; and be it further

Resolved, That the panel shall submit to the Senate Committee on Health *and the Assembly Committee on Health* a preliminary report of its conclusions and recommendations by March 1, 2006, and a final report of its conclusions and recommendations no later than June 1, 2006; and be it further

Resolved, That the Secretary of the Senate transmit copies of this resolution to the author for appropriate distribution.

O

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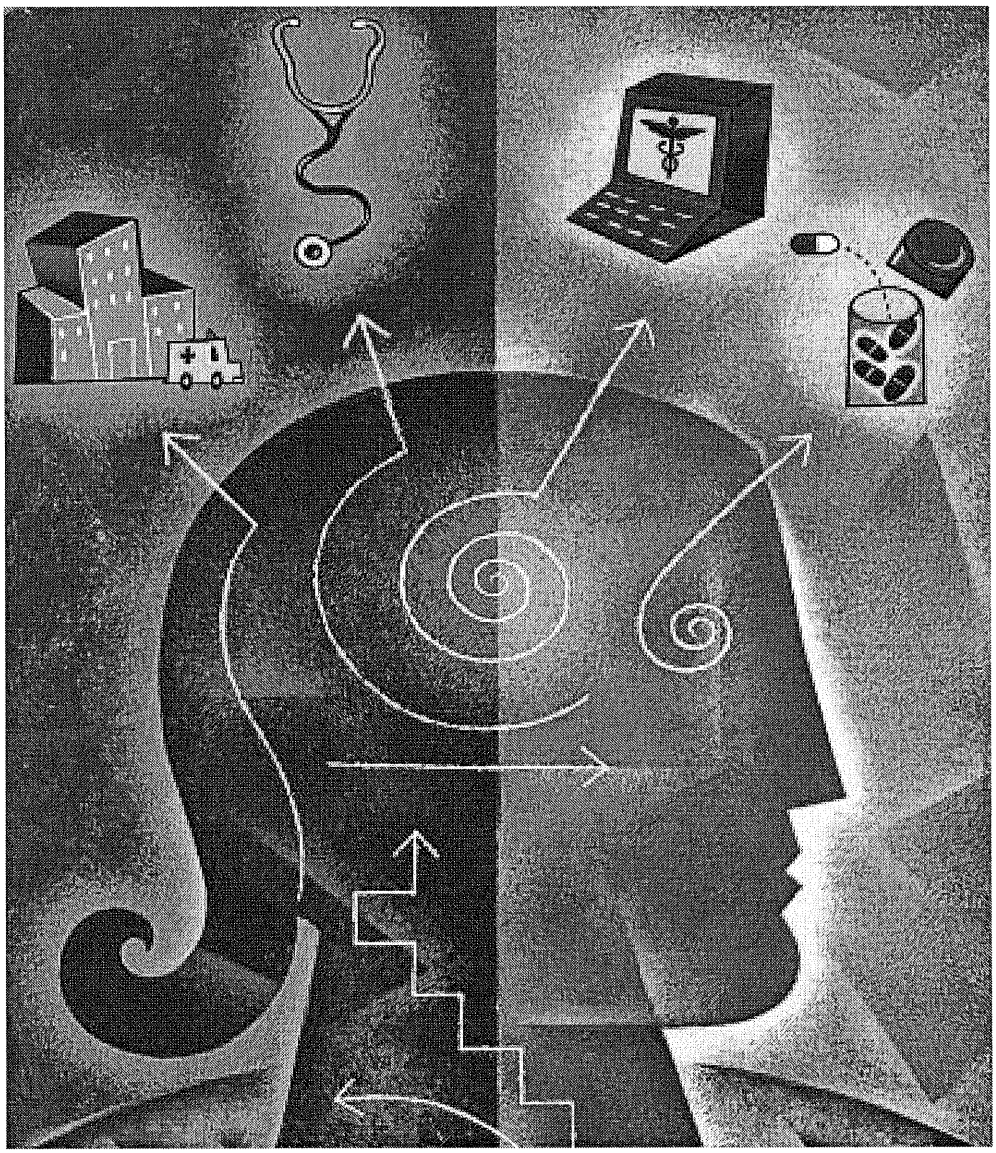
FOUNDATION



E-Prescribing

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E-Prescribing

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Acknowledgments

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The authors would like to acknowledge the assistance of the following individuals who agreed to be interviewed for the report: Rita Amalfitano of The Medical Group, Beverly, Massachusetts; Dr. Andrew Barbash of Mid-Atlantic Permanente Medical Group; Dr. Shahe Komshian of San Jose Medical Group, San Jose, California; and Cheryl Norris of Kokomo Family Care Clinic, Kokomo, Indiana. They would also like to thank the Institute for Safe Medication Practices for information on state regulations on e-prescribing and Erica Drazen and Jane Metzger of Emerging Practices for their review and suggestions.

The **California HealthCare Foundation**, a private philanthropy based in Oakland, California, focuses on critical issues confronting a changing health care marketplace by supporting innovative research, developing model programs, and initiating meaningful policy recommendations.

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Overview

ELECTRONIC PRESCRIBING (E-PRESCRIBING) IS the use of an automated data entry system to generate a prescription, rather than writing it on paper. Automation of the outpatient prescribing process has many potential benefits to different health care stakeholders. Patients and physicians benefit from:

- Improved patient safety, through generation of legible prescriptions that have been checked by the computer for possible harmful interactions;
- Better formulary adherence, through checking against health plan formularies at the point of prescribing;
- Streamlined communication of prescriptions to pharmacies, resulting in receipt of clean, legible, formulary-adherent prescriptions, thus reducing calls back to physician offices to clarify inconsistencies; and
- Improved patient satisfaction, through rapid prescription fulfillment and fewer errors.

Pharmaceutical companies, health plans, pharmacy benefit managers (PBMs), and employers can benefit as well. Pharmaceutical companies seek data on physician prescribing habits, as well as opportunities to market directly to physicians using new technologies. Health plans and PBMs are looking for new ways to control drug expenditures through improved adherence to formularies; they want to use physician prescribing data to improve their products and services. Pharmacies and PBMs benefit from process efficiencies associated with clean, accurate prescriptions.

Technologic advances, particularly new handheld devices with user-friendly interfaces, and wireless network technologies offer new approaches to encouraging physician adoption of computers. A number of vendors have developed e-prescribing software applications for these devices, which they are marketing to physician practices. Most such vendors base their revenues on sale of information to third parties, or on transaction-based charges to pharmacies, PBMs, and physicians. To date, physicians have been asked to pay modest fees for the use of these systems. Applications typically perform formulary and drug-drug interaction checking. Increasingly, applications are being bundled with other clinical applications such as charge capture, laboratory ordering and results viewing, and dictation.

Although experience to date is limited, many physicians who have tried e-prescribing are satisfied with the benefits they have enjoyed. Most commonly cited are improved efficiencies associated with decreased call-backs from pharmacies. The advantage of safer prescribing and patient satisfaction associated with increased convenience are also mentioned. Experienced users list the following as important success factors for implementation of e-prescribing: Cultivate and use an enthusiastic physician champion to promote adoption; implement functions incrementally and sequentially, rather than all at once; consider reducing physician workload during the initial implementation phase; and keep the system simple to use.

E-prescribing can also be performed using ambulatory electronic medical record systems (AMRs), which offer several advantages, including a more robust database of patient information available at the point of prescribing. The disadvantages are system cost, complexity, and far greater difficulty of implementation, compared with mobile prescribing systems.

In spite of the apparent benefits of e-prescribing, these systems have been slow to gain popularity with physicians. Possible reasons for this include the difficulty of marketing to the large percentage of practitioners in small and medium-size practices; physician skepticism about the actual value delivered by e-prescribing; technology market instability; and physicians' desire for a broader range of functions before changing their workflow to accommodate mobile computing.

Early experience indicates that the benefits of e-prescribing are real, and outweigh the costs of implementation. It seems likely that e-prescribing is here to stay; the rate of adoption is less certain and will depend upon a multitude of factors.

Purpose

PRESCRIBING MEDICATION IS THE PHYSICIAN'S most frequently used, efficacious, and potentially dangerous therapeutic tool, outside of surgical intervention. The proper or improper use of prescription drugs has a profound effect on patient outcomes, and, because prescription drugs are expensive, the physician's selection of drugs has a major impact on the cost for hospitals and health plans. These same costs generate the vast revenue streams that support pharmaceutical companies—the world's most profitable industry. Thus, management of prescription medications directly or indirectly affects every stakeholder in health care.

The prescribing process is an important component of workflow in every physician practice and hospital unit. But the traditional approach to medication management is inefficient and error-prone, entailing six basic processes: selecting a drug; checking for allergy, drug-drug, and other interactions; checking formulary; handwriting prescription; and mailing or giving the paper prescription to the patient for hand-carrying to the pharmacy.

Several industry trends are converging to create interest in utilizing new technologies to improve the prescribing process. The technologic advances include Web technologies and business models, handheld devices with user-friendly interfaces, and wireless network technologies, all of which offer new approaches to encouraging physician adoption of computers. At the same time, industry-wide concern about patient safety—in the wake of the 1999 Institute of Medicine report "To Err Is Human"—has spurred interest in employing technologies to simplify and enhance the safety of the prescribing process. Rapidly increasing costs of prescription drugs are prompting health plans to seek new approaches to improving formulary adherence among physicians. Pharmaceutical companies are seeking new avenues to reach physicians for advertising purposes, and drug companies and others seek access to data on physician prescribing patterns.

As a result of these trends, there is a high level of industry interest in the topic of electronic prescribing. Yet what exactly "electronic prescribing" (e-prescribing) means depends on whom you ask. In addition, different parties perceive different benefits from e-prescribing, making the construction of a coherent business model around the process challenging.

The purpose of this report is to clarify the concept of e-prescribing and examine its status in practice today—how it is used; business considerations of different parties; obstacles to adoption; and prospects for the future.

I. What Is E-Prescribing?

FOR THE PURPOSES OF THIS REPORT, E-PRESCRIBING is defined as "Entering a prescription for a medication into an automated data entry system (handheld, PC, or other), and thereby generating a prescription electronically, instead of handwriting the prescription on paper." A typical scenario for e-prescribing is shown in Figure 1 on the following page.

This definition does not specify the nature of the data entry device or software or the extent to which the prescription is communicated electronically beyond the walls of the physician's office.

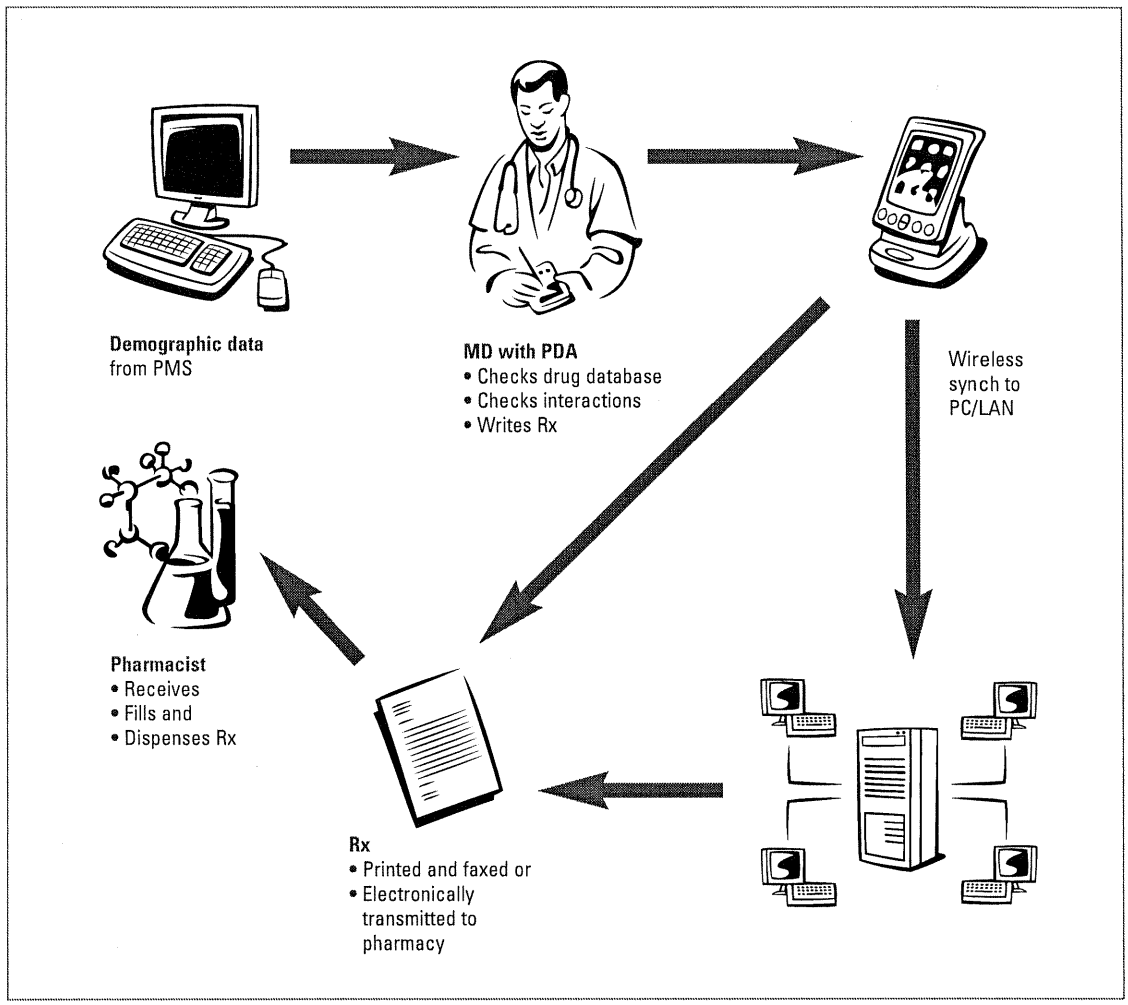
While the definition does not specifically exclude inpatient electronic prescribing (intentionally, as ideally the processes for prescribing in inpatient vs. outpatient settings would be identical), this report concentrates on electronic prescribing in the outpatient setting for three reasons. First, at present the two prescribing processes are entirely different in terms of physical setting, workflow, organizational entities (hospitals vs. retail pharmacies), and information requirements. Second, the important topic of electronic prescribing in the inpatient setting has been discussed at length in a previously published *Primer on Physician Order Entry*.[1] Finally, the ambulatory environment is the focus of industry interest in e-prescribing today.

At present, e-prescribing in the ambulatory setting occurs in two principle forms: using handheld devices loaded with e-prescribing software, or using ambulatory electronic medical record (AMR) systems, which can be done on a PC or, in some cases, on a handheld device. Both technologies are discussed, although the mobile prescribing model is emphasized, as this is where there is the greatest amount of activity at present.

The Potential Benefits

Given the complexities and inefficiencies inherent in the traditional approach to prescription management, it is not hard to imagine potential benefits from automation. In the best conceivable scenario, improvements in efficiency, accuracy, and appropriateness of medication prescribing would yield a variety of benefits to patients, physicians, and payers. In addition to potentially improving current processes, electronic prescribing introduces new potential sources of value to some parties, such as "e-detailing" to physicians by pharmaceutical companies.

Figure 1. Typical E-Prescribing Scenario



Benefits to Patients

First and foremost, patients stand to benefit from the enhanced safety of the medication management process afforded by e-prescribing (see Figure 2, page 14). In the inpatient setting, automated prescribing has been shown, when properly implemented, to reduce medical errors and adverse drug events.[2a, 2b] In the outpatient setting adverse drug events are a frequent cause of hospital admission and morbidity.[3] A movement championed by the Institute for Safe Medication Practices, calls for the universal adoption of e-prescribing and the abandonment of handwritten prescriptions by the year 2004,[4] for the improvement of prescribing safety.

In the ideal scenario, prescriptions would be checked against a patient's current medications, allergies, diagnoses, body weight, and age for possible interactions, appropriateness, and dosage. Prescriptions would be legible, and patient information about their medications, including indications, properties, side effects, and instructions for administration, would be dispensed with the medication. The e-prescribing system would build and maintain a permanent record of the patient's medication history over time. Patient adherence to medication regimens could potentially be improved through closed-loop communication of refill data to payers and physicians.

Patients would benefit from improved efficiencies as well. Prescriptions would be sent electronically to the patient's pharmacy of choice by secure electronic connection and would be available for pickup upon the patient's arrival. Alternatively, prescriptions for chronic care drugs would be communicated automatically to the mail order pharmacy. Automated formulary checking would ensure that patients received drugs on their health plan or PBM formulary whenever possible, reducing costs to patients.

Benefits to Physicians

Physicians would benefit from an effective e-prescribing system in several ways. The increased safety and accuracy of the prescribing process created by improved access to data and clinical decision support would serve to enhance physician satisfaction and peace of mind. Financial benefits could accrue as well, as malpractice insurers offered discounted premiums for use of such systems. Perhaps the greatest benefit to physicians would come in the form of enhanced efficiencies gained by reducing the number of call-backs from pharmacies—regarding illegible prescriptions, non-formulary medications, potential drug interactions, incorrect dosages, renewal requests, and the like. One industry estimate holds that pharmacists make 150 million calls a year to physicians to clarify prescriptions.[5] Greater patient satisfaction would also enhance physician satisfaction and improve patient retention.

Benefits to Health Plans and Pharmacy Benefit Managers (PBMs)

Health insurers and PBMs would benefit through financial savings associated with better formulary adherence, less therapeutic duplication, and reduction in incurred costs associated with adverse drug events. In addition, they could benefit through improved access to data on physician prescribing patterns and patient medication profiles, which would support better medical and formulary management programs. They would also benefit from higher patient satisfaction and retention and improved patient adherence to therapeutic regimens.

What's Good for GM Really Is Good for America!

Like health plans and pharmaceutical companies, large employers have begun taking an active interest in e-prescribing. Since the release of the 1999 IOM Report "To Err is Human," which set out the costs of medical errors in human and financial terms, these influential stakeholders have been championing patient safety.

The Leapfrog Group, a coalition of large employers, is establishing incentives for hospitals to implement computerized physician order entry as a means of reducing medication errors. General Motors, a prominent Leapfrog purchaser—and the largest private health insurance purchaser in the country—is going farther. GM will work with an Internet medical records company, Medscape, to share the costs of providing mobile e-prescribing systems to 5,000 Medscape physician users who care for GM employees, in the interests of improving safety and curbing prescription drug costs. The company, with 1.2 million workers and retirees, spends $1 billion annually on prescription medications.

The system, Medscape Mobile, will permit access to patients' electronic medical records at the point-of-care, as well as performing e-prescribing. The initial pilot project will provide data for Medscape and GM to analyze prescribing patterns and medication safety. GM and Medscape will share the cost savings accruing from the use of the system.[6]

Benefits to Pharmaceutical Companies

The chief opportunities for pharmaceutical companies to realize value from e-prescribing include an alternative route for access to physicians for detailing and access to physician prescribing data for use in marketing and sales planning. In addition, improved patient adherence to medication prescriptions would directly increase revenues from drug sales.

Other parties stand to gain as well: Employers could benefit from reduced health care costs and healthier, more satisfied workers; medical risk (malpractice) insurers could benefit from reduced claim losses; and Internet pharmacies could continue to thrive on e-prescriptions. Some of these benefits are summarized in Table 1.

Table 1. Potential Benefits of E-Prescribing

BENEFIT	Description	Mechanisms	Benefactors
Improved Safety of Prescribing Process	Reduced adverse drug events due to safer prescriptions; results in less harm to patients and lower costs of care	• Complete, legible prescriptions, properly formatted • Prescriptions checked for drug-drug, drug-allergy, drug-disease interactions • Prescriptions checked for proper dose for age, weight	• Patient • Physician • Health plan • Employer • Malpractice insurer
Reduced Costs Through Improved Efficiencies	Automated prescribing process results in greater accuracy, fewer inconsistencies, better adherence to intended course of therapy and formulary restrictions	• Fewer pharmacy call-backs to physicians to clarify prescriptions, formulary issues • Savings to plans, PBMs, and patients through better formulary adherence • Greater convenience to patients: prescriptions ready for pickup upon arrival at pharmacy	• Physician • Pharmacy • Health plan • PBM • Patient
Improved Sales, Marketing	E-detailing; access to prescribing data	• E-detailing enhances access to physicians for pharmaceutical companies; • Prescribing data facilitates better marketing planning	• Pharmaceutical company • Health plan • PBM
Improved Product Design	Access to physician prescribing data, patient medication data	• Data permit better medical management, formulary management	• Health plan • PBM

Requirements for Physician Adoption of E-Prescribing

For e-prescribing to provide value to anyone, physicians must use the systems, and the systems must, in turn, deliver the functions that enable realization of the benefits above.

Physician adoption of e-prescribing systems depends, in turn, on three principal requirements: fit with practice workflow, provision of perceived value to the physician, and affordability. In other words, the system must be useable without incurring significant inconvenience; it must be perceived by practitioners as better in some way than what they have now; and it must be inexpensive.

Workflow Considerations

The system's fit with physician workflow has implications for hardware and system software functionality. E-prescribing applications should have user-friendly interfaces (easily navigated screens, menus, etc.), and should offer as much patient-specific data as is practical to the prescribing physician. At a minimum this includes basic patient demographic data (name, date of birth, address, medical record number, insurance information). Such data should be automatically imported into the e-prescribing application from the office practice management system (PMS). This can be done on a daily batch basis, based on the physician's office schedule for the day.

The choice of device has implications for workflow as well. Small handheld devices are more convenient to carry and handle than the larger, tablet-type devices or PCs. The method for communication between mobile devices and other systems is also an important consideration. For example, devices that require synchronization by docking with networked cradles are less convenient than ones that synchronize continuously via wireless local area network (LAN) technology. These considerations are further discussed in the section on technology, page 28.

Perceived Value of the System

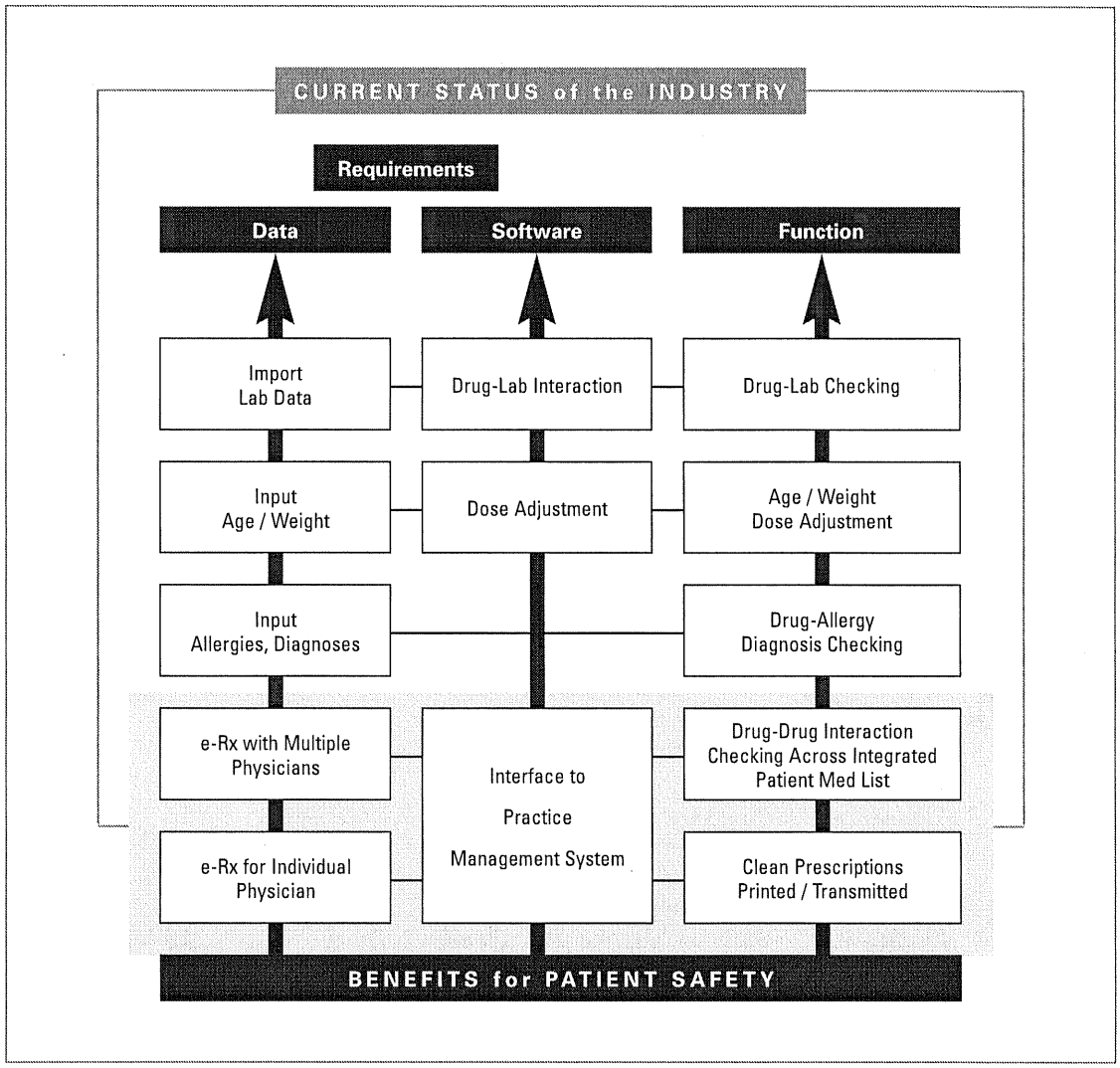
Better data availability and clinical decision support for prescribing depend on the functionality of the particular e-prescribing application in use. Databases accounting for the majority of managed care formularies in the United States are available and widely used by mobile prescribing vendors, making formulary checking generally straightforward.

Virtually all of today's e-prescribing applications offer extensive menu-driven drug databases and perform, at a minimum, drug-drug interaction checking. The ability to detect drug-drug interactions presupposes that a patient's previous and still-current medications were prescribed through the same application and are, therefore, recorded in the system database. Often this is not the case, as patients frequently receive prescriptions from different physicians, who may work in different practices and, therefore, do not use the e-prescribing system. In addition, different vendor systems vary in the length of time they retain prescribing data before purging them.

The ability to perform drug-allergy and drug-diagnosis checking is dependent on the ability to enter these data types into the system. Some vendors require entry of diagnosis or allergy information prior to prescribing; others do not have such functionality. Dose adjustments based on age and weight are not commonly possible with today's applications; such functions are particularly important in working with pediatric and elderly populations, and could contribute further to prescribing safety.

Most mobile e-prescribing systems in use today are implemented so as to print prescriptions locally at the physician office, to be handed to the patient, or to fax prescriptions to the patient's pharmacy. Few prescriptions are sent electronically, for a variety of reasons. First, some states prohibit transmitting prescriptions electronically, although it is generally believed that these barriers will be eliminated in the near future.

Figure 2. Improved Patient Safety with E-Prescribing



(see box on state regulations, on the following page). Second, many physician offices are not yet prepared to send electronic prescriptions to pharmacies, nor are some pharmacies able to receive them. Finally, concerns about security and confidentiality remain unresolved. Recent efforts to develop an electronic prescribing exchange may remove some of these barriers.[11] In the meantime, cleanly printed or faxed prescriptions should remove much of the inefficiency of the current manual prescribing process and, thus, yield many of the benefits of convenience to physicians.

Other kinds of functions may appeal to physicians as well. Applications increasingly being bundled with e-prescribing include charge capture (which enhances revenue capture), laboratory and diagnostic test ordering, and results lookup online. Preliminary evidence suggests that most mobile prescribing vendors are moving in the direction of offering multiple applications as a package; this could serve to accelerate physician adoption of e-prescribing systems.

State Regulations on Electronic Prescriptions

Currently, 11 states have laws prohibiting electronic transmission of prescriptions; two states plus the District of Columbia don't even allow electronic faxing of prescriptions. But that's just the tip of the complexity iceberg of state-by-state regulation of electronic prescribing.

Below is a snapshot of the current state of regulations, as of March 2001, and it's certain to change quickly. For example, New Jersey is currently working to change its laws to legalize e-prescriptions.

- Eleven states prohibit e-prescription transmission from both in-state and out-of-state prescribers: the District of Columbia, Georgia, Idaho, Maine, Maryland, Nebraska, New Jersey, New Mexico, South Carolina, South Dakota, and Vermont.
- Four states allow electronic transmission of prescriptions with the exception of certain drug types:
  - Kentucky, Texas, and Wisconsin: No Schedule II substances
  - New York: No controlled substances
- Three states allow electronic transmission from in-state prescribers only: Hawaii, Wisconsin, and Arizona (for AZ, electronic transmission of information is permitted, but a hard copy must be received by the pharmacy).
- Electronic transmission of prescriptions from both in-state and out-of-state prescribers is not addressed by state legislation in Alabama, Alaska, Guam, Montana, Oregon, Pennsylvania, Puerto Rico, Rhode Island, and Wyoming.
- Electronic transmission of prescriptions from out-of-state prescribers only is not addressed in state legislation in Arizona and Utah (in-state transmission is specifically permitted).
- Three states limit faxing of prescriptions. In Vermont and the District of Columbia, neither phone nor electronic faxing of prescriptions is allowed; Alabama permits only phone faxing of handwritten prescriptions.

Source: [8, 9, 10, 11]

Affordability

Physicians whose practices do not generate significant profits have been loath to invest substantial capital in new information systems that are not absolutely essential to their operations. While e-prescribing vendors differ in their approach to licensing fees for physicians, no mobile prescribing vendors in the market at the time of this writing (as distinct from ambulatory medical record products that include e-prescribing) charge in excess of $250 per month per physician, and some products are offered free of charge.

II. Business Models for E-Prescribing

THE PHYSICIAN USER BASE IN THE PRACTICE OF electronic prescribing is still small.[12] According to a recent study, four to seven percent of physicians are currently generating prescriptions electronically, with 25 percent interested in doing so in the future. Allscripts, an e-prescribing vendor with one of the largest user bases, reports having 15,000 physician users as of February, 2001.[13]

The current user market is divided across the products of a handful of e-prescribing vendors. Appendix A lists some of the more prominent companies at the time of this writing. New vendors continue to appear. The low level of market penetration implies significant opportunity for vendors—both established and emerging—to gain large numbers of new users. While the availability of venture financing has declined significantly in the past year, and while it is likely that a market shakeout will eventually result in the dominance of a small number of companies, at the time of this writing, the dominant feature of the market is that of opportunity.

Vendors of e-prescribing applications are attempting to leverage combinations of benefits to different parties in such a way as to provide value to all and generate revenues for themselves. To be successful, they must cobble together coalitions to provide the up-front capital infusion required to establish a user base, and providing the necessary functionality to those users to ensure payback to investors and revenues for the vendor. This is proving to be a tricky task.

Eight Principles of Business Models

Following are some of the principles, or assumptions, that underlie today's e-prescribing business models:

1. ***While the physician is the target user of e-prescribing systems, he or she is not the paying client.*** Most vendors believe that physicians will not pay the full cost of e-prescribing systems, and therefore cannot be counted on as a significant revenue source. Some vendors believe that physicians must make a token investment in the system—in the range of $50 to $200 per-month, per-physician—in order to increase their commitment to making the system work.

2. ***Ability to improve formulary adherence is valuable to health plans and PBMs.*** Managed care organizations that bear the risk for medication costs can realize substantial savings by improving physician use of preferred medications. In addition, many health systems and IPAs with at-risk medication contracts also benefit from better formulary adherence.
3. ***Access to physicians (face time or screen time) is valuable to pharmaceutical marketers.*** Pharmaceutical companies spent $4.3 billion on physician detailing in 1999.[7] Recent studies indicate that electronic detailing (e-detailing) over the Internet is far more cost effective than print advertising.
4. ***Aggregate data on prescribing patterns are valuable to multiple parties.*** Pharmaceutical companies pay large amounts of money for industry prescribing data for use in marketing and sales development efforts. In addition, health plans and PBMs could benefit from having such data on their members, as it would assist in product design, medical/disease management, and other business and care improvement activities.
5. ***E-prescribing can improve patient adherence to medication regimens, which translates to increased sales for pharmaceutical companies, healthier patients, and lower costs to insurers.*** This assumption is the least well verified. It is not clear that current implementation models for e-prescribing will yield the kind of closed-loop feedback on medication adherence (i.e., physicians being informed of patient adherence to a refill schedule for chronic medications; patients being reminded that they should be needing a refill) required to improve compliance.
6. ***E-prescribing yields improved patient satisfaction, which will translate to greater patient loyalty to physicians and health plans.*** While this assumption seems logical, experience is currently too limited to support it with data. Anecdotally, patients do appreciate immediate transmission of their prescription to the pharmacy.
7. ***Electronic transactions save receiving parties money compared with paper-based transactions.*** This argument has been the primary fuel behind the business models of many Internet health care connectivity models. It has been estimated that health plans and PBMs would pay $0.65 to $1.50 for each electronic, formulary-verified prescription and that pharmacies would pay $0.25 each to receive clean electronic prescriptions.[14]
8. ***Enhanced patient safety reduces costs for several parties.*** Malpractice insurers are willing to discount premiums for physicians who use e-prescribing systems. At least one national carrier offers discounts to physicians using a particular vendor's e-prescribing product. The Leapfrog Group, a coalition of large employers committed to obtaining "giant leaps forward" in the quality of patient care, has targeted automated prescribing in the inpatient setting as one of their three initial initiatives. Leapfrog member General Motors has committed to funding the provision of e-prescribing systems to physician practices, in the interest of reducing adverse drug events.[6]

Sponsorship-based and Transaction Fee-based Models

Several parties—pharmaceutical companies, health plans, and PBMs in particular—stand to realize substantial financial benefits from the adoption of e-prescribing by physicians. Most vendor business models are, therefore, structured around some version of sponsorship or subsidization of e-prescribing systems by one or more of these players. For example, a pharmaceutical company might pay the majority of the costs for system purchase and implementation for some number of user licenses, with users paying a nominal fee.

In return, physicians might be asked to view several "e-detail" productions per month, and the e-prescribing vendor would agree to make available aggregate prescribing data to the pharmaceutical company for a fee, when such data had been accumulated in the system. In the case of health plans and PBMs, the *quid pro quo* is the use of appropriate formulary checking software by the plan's physicians.

Increasingly, there is discussion in the industry of transitioning from sponsorship models to transaction fee-based models in which revenues are generated by per-transaction fees based on the estimated value to the receiving parties. Such a structure generates revenues in direct proportion to transaction volume, and therefore will likely be more widely used once larger numbers of physicians have implemented e-prescribing systems, and as other transactional applications (e.g., laboratory test ordering) are bundled with e-prescribing on the same devices.

III. Operational Considerations of E-Prescribing

E-Prescribing and the Prescription Management Process

In order to describe the specific processes involved in e-prescribing, it is useful to examine the six-stage prescription management process in the outpatient setting and see how e-prescribing alters the process. (See Figure 3 on the next page.)

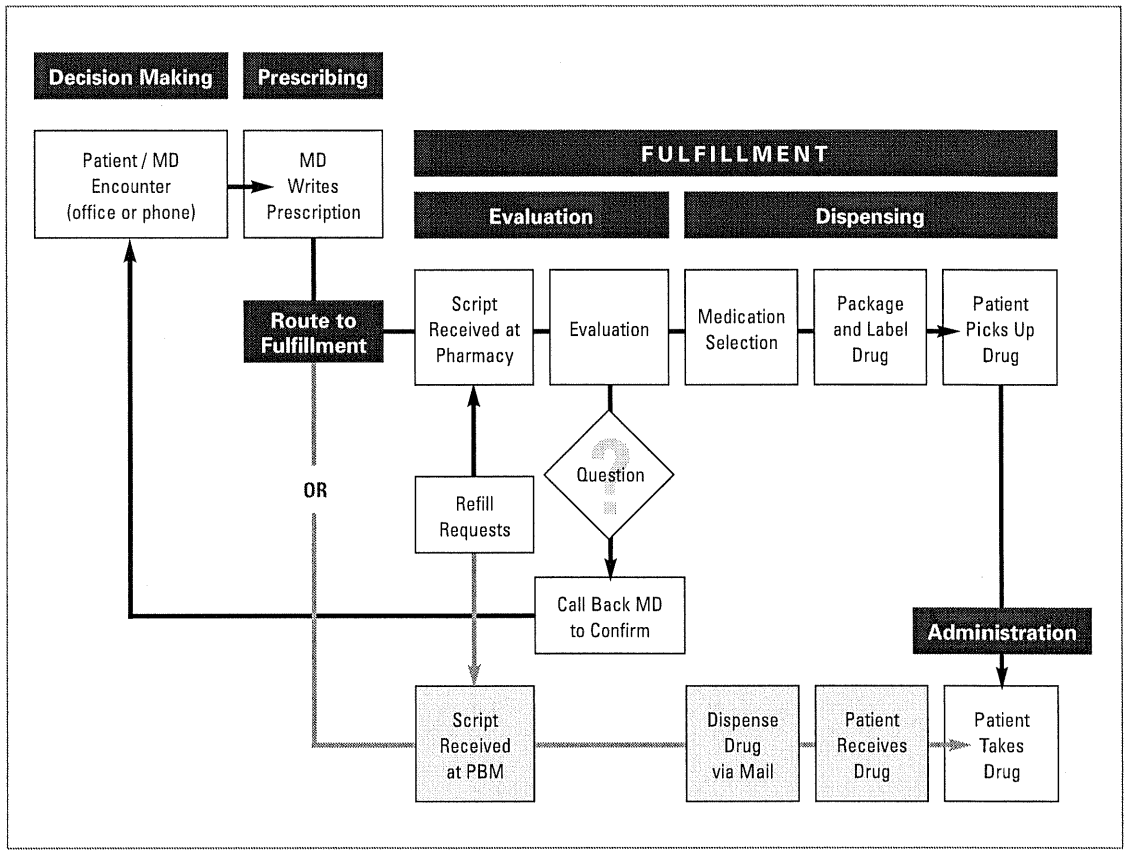
1. ***Decision making.*** The prescribing process begins with the clinician's assessment of a patient's condition and needs. The assessment is traditionally based on history taking (interviewing the patient; reviewing past records), physical examination, and review of any laboratory or other diagnostic studies. The clinician may at this point decide to order additional studies. He or she then arrives at a presumptive clinical diagnosis and selects a course of treatment that may include medications.

   The decision making stage is critical to understanding prescribing because information that should be gathered at that stage is essential to safe and effective prescribing. For example, failure to gather information about history of allergies, other diseases, and medications the patient is already taking may result in the prescribing of a medication to which the patient is allergic or to a dangerous drug-disease or drug-drug interaction.

   What are the implications for e-prescribing? In order to reduce adverse drug events through screening for drug-drug, drug-allergy, and drug-diagnosis interactions, data must somehow be entered into the system. Such data are not generally imported from practice management systems. Some systems allow the physician to manually enter diagnostic and allergy data at the time of history taking; others do not. Entering concurrent medications that have not been ordered through the system presents greater difficulties. With most of the mobile e-prescribing vendors there is no good way to enter this information. Ambulatory medical record vendors more commonly capture these data.

   Other applications that are increasingly being bundled with e-prescribing systems may improve the efficiency of the decision making process. The ability to view recent laboratory results is one example. Another is the ability to view previous diagnoses from charge capture data.

Figure 3. Outpatient Medication Management



2. ***Prescription writing.*** Having made a therapeutic decision and selected a class of drug, taking into consideration possible allergy, drug, and disease interactions, the physician writes the prescription. In the case of paper prescribing, this may involve selecting a medication, dose, duration, etc., from memory, or it may involve looking up information in a drug reference source.

   With e-prescribing, the clinician is generally able to access the patient's demographic data (which have been imported from the practice management system); the clinician selects the patient's record and, using the prescribing application, selects a specific medication preparation, dose, route, and duration. This is generally done using pick lists on a handheld device; one manufacturer, however, offers voice-activated prescribing on a mobile computer. The application checks for adherence to any applicable formulary and alerts the clinician to any potential allergic or other drug interactions. In most mobile e-prescribing applications, the logic to perform these functions is located in the handheld device; but in some cases synchronization of the device with a local or even remote server is required to complete the checking process. Separate drug reference applications may be packaged with the e-prescribing software, facilitating lookup of additional information.

3. ***Communication to pharmacy.*** If a prescription is handwritten, the clinician hands it to the patient who takes it to the pharmacy; or in some cases, a first-time prescription may be telephoned to the pharmacy. (With certain exceptions, renewals are commonly handled by telephone.) In the case of e-prescribing, when all requisite checks have been completed, the clinician submits the prescription for dispensing. This may involve synchronizing a mobile device using a docking cradle, beaming the prescription information to a printer or network infrared port, or synchronizing automatically over a wireless local area network. Depending on the vendor system, the prescription may then be printed in the physician's office and given to the patient to fill, faxed to the patient's pharmacy, or sent electronically to the patient's pharmacy. At the time of this writing, most system implementations use the print or fax option; electronic transmission of prescriptions is possible, but currently less common. Prescriptions may also be sent electronically to PBMs' online pharmacies or Internet pharmacies (see box to the right).

Case in Point: The Medical Group, Beverly, MA

Vendor	PenChart
Product	PenChart medical record
In use since	1998
Number of physicians using the product	22

The experience of this Massachusetts practice sheds some light on the advantages of prescribing from an integrated AMR system. The PenChart ambulatory medical record system provides mobile prescribing functionality in the context of an integrated medical record. A mobile touch pad device is used for most data entry and lookup functions.

As implemented at The Medical Group, the system performs drug-drug, drug-allergy, drug-diagnosis, and formulary checking; other rules can be written into the system as well. Prescriptions are faxed to pharmacies electronically, and are ready for patients as soon as they arrive to pick them up. The practice uses the system for prescription renewal as well as first-time prescriptions.

Rita Amalfitano, the group's executive director, sees the electronic processing of refills as one of the system's greatest benefits. Using the AMR's workflow functionality, requests can be routed electronically within the practice to a single designated nurse; the system has eliminated a multiple-day backlog they experienced with their previous manual process. The principle disadvantage of the system is the need to hand-input formulary exceptions; staff have not been able as of this writing to download current formularies for the product. Amalfitano would also like to see a notification protocol implemented with the electronic faxing function, to alert them to server problems before prescriptions are sent.

Where Do the Online Pharmacies Fit In?

Internet pharmacies were riding high on the dot-com boom of 1999. PlanetRx once boasted a share price of $150; Drugstore.com and others attracted top industry talent and vast quantities of venture capital. Forrester Research predicted that online prescribing would reach $15 billion a year by 2004. Two years later, PlanetRx has been delisted from the NASDAQ and the Internet pharmacies are falling as fast as they rose. What happened? Will Web pharmacies survive in any form?

The entire ehealth sector suffered badly following the NASDAQ crash of spring, 2000. But other fundamental problems with the Internet pharmacy business concept plagued these companies from the outset. Revenues depended on low margin, over-the-counter, and non-medication items plus prescription drugs; in the long run, companies hoped that prescription sales would increase and carry a larger portion of the revenue growth. Unfortunately, they failed to make adequate allowance for several realities of the retail prescription drug market.

First, most consumers have prescription drug plans that are operated by PBMs. Consumers purchasing prescriptions at retail pharmacies exercise this benefit by paying a modest co-pay; the pharmacy manages the PBM relationship. Consumers who don't buy through their PBM pay full price. It took the e-pharmacies a while to build the needed PBM partnerships; and during this time, many PBMs built their own Web pharmacies, some of which are now generating significant revenues: Merck-Medco processed 4.2 million prescriptions in 2000, generating $460 million in revenues—more than all of their online competitors combined.[15]

Second, e-pharmacies are excluded automatically from half of the prescription market, since about half of all prescriptions are written for same-day pickup. Patients needing antibiotics for an acute infection will not wait a week for their drugs to come in the mail.

Finally, e-pharmacies have fared badly in the brand recognition game. With PBMs and retail chains with established brands opening their own online sites, and online-only stores unable to fill a substantial subset of consumers' needs (for same-day prescriptions), e-pharmacies have spent large amounts of cash in unsuccessful bids to establish themselves with consumers. With venture capital shunning the sector, e-pharmacies must find new ways to build brand awareness.

Recently, online pharmacies have been redirecting their efforts toward new partnerships and marketing models.[16] Some are launching co-branding campaigns and discount plans with local health plans and providers or contracting to provide chronic medications to populations. In any case, the e-pharmacy of the future appears better adapted to addressing niche applications than to transforming the industry.

4. ***Fulfillment.*** Having received the prescription by paper, fax, or electronic submission, the pharmacist enters the order into the pharmacy's information system, checks for any known contraindications, and then dispenses the medication to the patient. A similar process occurs with mail-order prescriptions. If a prescription is faxed or electronically communicated, the prescription may be ready when the patient arrives at the pharmacy. In any case, a prescription written from an e-prescribing system will be machine printed, easily legible, and likely conform to an available dosage and preparation of the medication. Also, there is none of the uncertainty or opportunity for misinterpretation afforded by a telephoned prescription. This saves all parties considerable inconvenience associated with call-backs to the physician's office and reduces the likelihood of transcription errors.
5. ***Administration.*** In the outpatient setting patients (or whoever is caring for them at home) are responsible for self-administering their medications. While e-prescribing processes do not play a direct role here, byproducts of their use—such as patient medication information that can be generated by some systems—could assist patients in the proper use of their medications and alert them to potential side effects or food or drug interactions.
6. ***Prescription renewals.*** The volume of work generated by renewal requests in the average physician office practice can be nearly overwhelming. Office practice nurses have told us they spend up to 50 percent of their time answering telephone renewal requests. Many offices set up separate renewal lines, sometimes with automated systems to record the requests. Frequently, renewals are checked for appropriateness by nursing staff and filled without consulting the physician, according to practice-specific guidelines.

The impact of e-prescribing systems on the renewal process is not entirely clear. In principle, the technology could facilitate the renewal process from the physician's point of view; it is easier to see the prior prescription online and point-and-click to perform the renewal. Often renewals are not handled directly by the physicians but by other office staff. If non-prescribing clinicians in the office have access to the system, it speeds the renewal process by allowing rapid access to the patient's medication record; the process would be further accelerated if these non-prescribing personnel were permitted to use the system to dispense the renewal prescription.

However, because workflow surrounding renewals differs significantly from that for first-time prescriptions, mobile prescribing applications may not be as easily implemented for this process. A number of organizations that are adopting e-prescribing have specifically excluded the renewal process from their initial implementation for this reason. E-prescribing for renewals works better in the context of an AMR, where a physician or other clinician can easily view the patient's problem list and other relevant information, in addition to the medication list.

Operational Issues for the Large Practice

One of the great advantages of mobile e-prescribing systems is their relative ease of implementation, in comparison with the effort required to implement an AMR. But some of the potential benefits of e-prescribing are directly proportional to the number of physicians in a practice who use the system. Uniform usage promotes the building of a more complete patient medication record on the system, which in turn facilitates better interaction checking, easier cross-coverage of patients by others in the practice, and more uniform workflow around prescription management throughout the office. It appears that implementing e-prescribing systems at large practices, while easier than putting in place a full-blown AMR, holds a number of challenges.

Several important implementation factors change when an e-prescribing system is made operational across a large practice, compared with a single practitioner or small number of physicians. First, workflow changes affect a larger number of non-prescribing staff, who must be trained to use the system or follow new procedures for certain aspects of care provision. Second, there is likely to be a greater variance in the level of enthusiasm for the system among the larger number of physicians. This holds important implications for successful implementation because, if only a portion of the physicians in the practice use a new e-prescribing system, dual and potentially conflicting workflows are created, which creates havoc in practice administration.

Users at large practices that have implemented e-prescribing systems point to success factors much like those for successful AMR implementation:

- Have several physician champions who tirelessly promote the adoption of the system and work to resolve problems as they appear.
- Implement new functionalities incrementally. For example, start with e-prescribing, then add results lookup or charge capture (when practical). This allows physicians and staff time to get used to the technology and to changes in workflow.
- Consider reducing physician workload slightly at the beginning of implementation to allow time to work out problems.
- If doing a phased implementation involving a subset of practitioners at the outset, recruit the most enthusiastic users for the pilot and celebrate their successes publicly.
- Recognize the trade-off between level of functionality and simplicity of implementation. Some organizations establish basic functionality of e-prescribing as quickly and as broadly as possible and elect to delay addition of valuable functions—such as doing renewals electronically or adding results lookup—in order to address other priorities first.

Security, Confidentiality, and HIPAA Rules

Any technology that generates physician- and patient-specific data also generates concerns about the use and security of the data. These concerns are heightened in the case of e-prescribing technologies because a stated intention of some vendors is the sharing of these data with third parties for commercial purposes. Thus, the use of e-prescribing technology raises a series of questions that must be addressed.

Most patient data available to physician practices is considered confidential as a matter of course. The advent of the pending HIPAA (Health Insurance Portability and Accountability Act) regulations on security and privacy carries important and specific implications for the use of e-prescribing technology.

Case in Point: San Jose Medical Group, San Jose, CA

Vendor	Allscripts
Product	TouchScript Personal Prescriber
In use since	November 1999
Number of physicians using the product	134

Dr. Shahe Komshian, CEO of the San Jose Medical Group, is enthusiastic about his organization's experience with electronic prescribing, calling it "the most intelligent decision we have made for our practice." The group implemented the Allscripts Personal Prescriber in late 1999 and has succeeded in bringing on board all but two of its physicians as users.

At the time of this writing the group uses the system exclusively for first-time prescriptions; further functionality will be implemented soon, including charge capture, laboratory test ordering and results lookup, and e-dictation. As implemented at their site, the system performs formulary checking plus drug-drug, drug-allergy, and drug-diagnosis interaction checking to promote safe prescribing. The drug-diagnosis feature is possible because the system requires inputting the patient's diagnosis before writing prescriptions.

As to the benefits of the system, Dr. Komshian points to time-savings, both for physicians and patients. Immediate savings are realized due to reduced call-backs from pharmacists and patients. After physicians became facile in the system's use—about two months—they perceived up-front time-savings as well. Komshian's top two recommendations for a successful e-prescribing implementation:

- Do not start without some solid internal champions.
- Implement new functions incrementally.

There are two ways in which HIPAA regulations could potentially apply to e-prescribing technology and practices. First, the HIPAA standards for electronic data interchange (EDI) dictate the content and format for certain categories of electronically transmitted patient data. At present, e-prescribing is excluded from these regulations, which apply only to payer-related transactions, though this could change in the future. However, security/privacy regulations will apply to all organizations that are electronically transmitting any of the covered payer-related transactions. As most practices perform such transactions, these regulations will affect most practices that would use e-prescribing systems.

Security Regulations

The pending security regulations will require that affected organizations have in place certain measures for securing the electronic transmissions of patient data. These are principally vendor requirements. While the rules may be modified, at the time of this writing they include the following elements:

- ***Secure point-to-point electronic transmission of the prescription.*** If transmission occurs over a public network, as is likely, then encryption is the required industry standard.
- ***User access controls:*** an approach for determining who should have access to which pieces of prescribing and related viewing functionality and the technical capabilities to execute those access classifications.
- ***Entity (user) authentication:*** the technical methods for verifying authorized users (generally username/password, biometrics, or some combination).
- ***Audit trails:*** the ability to track who enters data and perhaps (yet to be clarified) who accesses data.
- ***Data authentication and integrity controls:*** technical measures to ensure data have not been changed or altered within the system or during transmission.

Privacy Regulations

The privacy component of the regulations will require that affected organizations adhere to certain standard practices surrounding confidentiality. While they are subject to modification, as of this writing they include:

- Providers must hold "business associates"—partners such as pharmacies, health plans, PBMs, e-prescribing vendors, and pharmaceutical companies—accountable for the use of patient-identifiable information they receive. In addition, patient data must be scrubbed of identifying information before they can be used for other than operational, treatment, and billing purposes. This clearly includes use for marketing and sales.
- Policies and procedures must be established that outline the organization's standards for using and disclosing patient-identifiable information, including employee discipline, and termination procedures.
- Staff must be trained in the organization's policies and procedures governing use and disclosure of patient-identifiable information.
- Patient consent must be obtained upfront at the time of registration, granting the organization permission to use or disclose the patient's health information for payment, treatment, or other health care operations.
- A patient privacy notice must be posted and available to patients, explaining all of the organization's routine uses and disclosures of protected health information, as well as the methods the organization uses to protect that information and the patients' rights with regard to that information.
- Use of patient-identifiable protected health information for marketing purposes is restricted to uses by and for the provider itself; this implies that patient authorization is required if the organization seeks to sell or share prescription information with another entity for marketing purposes.

Selling Clinical Data: The Privacy Problem

Recent business deals have pushed to the forefront of public debate questions of appropriateness and legality of sharing or selling clinical data. The AMA, concerned with the apparent ease of access that pharmaceutical marketers have to physician-specific prescribing data, is looking for ways to prevent DEA numbers from being used for purposes other than verification; and patients are concerned about receiving marketing materials for classes of drugs they are taking.[17] A deal between the American Medical Group Association and Aventis Pharmaceuticals to create a national database of claims, laboratory, and prescribing information from AMGA's members (representing 67,000 physicians) is raising eyebrows among privacy advocates and legislators. AMGA states they will not provide patient- or physician-identifiable information to Aventis, but observers are skeptical.[18] WebMD and Quintiles recently settled a feud over provision of claims data to Quintiles, which sells such data to pharmaceutical companies. WebMD expressed concerns about whether the data-sharing violated state privacy laws; under the resolution reached, WebMD will remove data that could be used to identify patients, such as zip codes and exact dates of birth.[19] Even the RxHub announcement by PBMs to promote electronic prescribing is being viewed warily by some who fear that patient-identifiable data will make its way upstream from the PBMs to their pharmaceutical parents and partners.[5]

The debate will likely continue for some time. While all of the parties under siege hasten to assure us that these concerns are unfounded, one thing seems clear: If patient-identifiable data—released without the patient's specific authorization for such use—reach pharmaceutical companies and other parties as a byproduct of the e-prescribing process, it will constitute a violation of the HIPAA privacy rules. While the care provider will likely be held primarily responsible, e-prescribing vendors may be culpable as "business associates." Such concerns cannot be taken lightly in an industry where some players' business plans depend upon such data sharing arrangements.

Some of the technical security requirements are being addressed today by most e-prescribing vendors (such as encrypted transmissions and user authentication controls). More problematic will be construction of user access controls and audit trail functions. These requirements will pose major challenges for all vendors of clinical information systems.

The privacy rules will likewise challenge provider organizations wishing to use e-prescribing. They must establish and adhere to contracts that describe accountability of vendor organizations, health plans, pharmacies, and others for their use of patient-identifiable data; they must obtain consent from patients for the use of such data and establish appropriate policies, procedures, and the like. While there are not at present specific rules about how some of these requirements must be met, most physician practices do not adhere to these standards today, but must do so if they are affected by the HIPAA rules.

Sharing Data with Third Parties

Privacy concerns surrounding the sale and use of customer data have brought a number of Internet companies into the crosshairs of public debate. In health care the debate is no less rancorous, as patient privacy advocates and physician professional organizations lobby for protection of patient- and physician-identifiable data, and companies scramble to understand the implications of being "business associates" of providers. At present, there is little oversight of the use of these data, aside from the implications of HIPAA legislation. Individual vendors must decide for themselves how to handle data sharing with third parties, recognizing that they will likely be subject to both the scrutiny of consumer advocates and HIPAA regulations.

IV. Technology: Applications

SEVERAL TYPES OF CLINICAL SOFTWARE applications contain e-prescribing functionality for the outpatient environment. These include ambulatory medical record systems and mobile e-prescribing systems.

Ambulatory Medical Record Systems

AMRs are complex, multifunctional software packages that support administrative and clinical operations of physician practices. Packages typically include scheduling, registration, billing, managed care, and patient care modules. Patient care functionality usually includes clinical documentation, clinical results lookup, workflow functions such as in-office messaging and ordering of tests and prescriptions. More complex systems offer decision support functions such as alerts and reminders. Increasingly, AMR development is moving toward greater use of Web technology, in terms of both user interface and for connectivity with outside parties (insurers, patients, etc.). Client-server architectures dominate, but there is increasing movement toward application service provider (ASP) models. Applications are accessed by PC, although at least one AMR vendor is currently launching a mobile prescribing module. Other vendors allow use of mobile devices for all functions as an adjunct to PCs or even as the primary user interface.

E-prescribing from an AMR platform offers the advantages of working in an integrated system and having access to far more sophisticated clinical decision support. As an integrated system the AMR offers simpler workflow around the prescribing function. Basic patient demographic data are already in the system for existing patients and do not need to be imported in daily batches from a separate system. Information from the prescribing application feeds into the patient's electronic medical record and can be sent to billing or other systems as needed. In particular, the prescribing application serves to build the patient's longitudinal medication record—a critical part of the patient's history.

AMR prescribing functions include, at a minimum, a drug database for medication ordering, using pick lists and drop-down menus; a formulary module to check for adherence to the patient's health plan formulary; and in-office printing of prescriptions. Many AMRs offer additional clinical decision support functionality, starting with drug-drug, drug-allergy,

Case in Point: Kokomo Family Care Clinic, Kokomo, IN

Vendor	McKesson
Product	PracticePoint Rx
In use since	September 1999
Number of physicians using the product	14

The Kokomo Family Clinic wanted to implement an AMR, but to do it incrementally. They chose McKesson's ASP PracticePoint product, and decided to start with e-prescribing. The product is currently used for new and renewal prescriptions; a separate module for laboratory management is being implemented. The practice sends prescriptions by fax server to pharmacies, or electronically to one mail-order pharmacy.

Cheryl Norris, system administrator, views the incremental implementation approach as key to Kokomo's success in building physician commitment. They reduced each physician's patient load by 10 percent for the first two weeks following implementation, to allow time to get used to the system. Norris also believes the ASP model saves time, and Kokomo physicians believe they are providing better quality patient care.

and drug-disease interaction checking. AMRs with rules engines can be programmed to offer condition-specific prescribing advice, recommend checking drug levels, and other alerts and reminders.

There are several disadvantages of AMRs in comparison with mobile e-prescribing systems. First, traditional client-server AMRs are very expensive. License and implementation costs range in the tens of thousands of dollars per physician, and ongoing support costs are also great. Web-based ASP model products are often less expensive and spread out the costs of implementation; some offer less depth of functionality, which facilitates implementation. Second, AMR systems must be used in environments where all practitioners and office staff at the practice are using the same system; and these systems drastically alter the way physicians and staff do their daily work. As a result, implementing an AMR system requires enormous time and expense in redesign of physician and office workflow to accommodate the new system. These factors of cost and extraordinary effort of implementation are important reasons why AMR systems have failed to achieve greater market penetration.

Table 2. Advantages of AMR vs. Mobile Systems for E-Prescribing

AMR E-Prescribing	Mobile E-Prescribing
Decision support based on access to more complete patient record at point of prescribing • Allergies • Diagnoses • Laboratories • Clinical documentation	Inexpensive to purchase and support
E-prescribing contributes to integrated AMR	Ease of implementation (depending on interface requirements)
Multiple users' data integrated in one patient record (possible with mobile e-prescribing, but less common)	Convenience of mobile platform
More sophisticated decision support can be programmed into prescribing module: appropriateness rules, adherence to care guidelines; etc.	Easy to update formulary, drug databases by download from Internet
Data more easily suited to aggregate, practice-level analysis (physician prescribing profiles, etc.)	Simplicity of use

Mobile E-Prescribing

Over the past several years a host of vendors have developed e-prescribing software for use on handheld mobile computers. This sector of the industry attracted large amounts of venture financing in the late 1990s as industry observers predicted that the convenience, user-friendliness, and ease of implementation of focused applications on personal digital assistant (PDA) platforms would lead to rapid adoption of e-prescribing, charge capture, and other applications by physicians. At the time of this writing, there are a handful of vendors established, to some degree, in this space and many more entrants.

While most vendors debuted with single-application systems, there is a trend toward bundling of applications, with vendors developing a suite of functions including prescribing, charge capture, e-dictation, and results lookup, plus access to assorted reference volumes.

E-Prescribing Applications

While there are variations in style of presentation and sequence of ordering, all e-prescribing applications have certain basic functions in common. First, all use a drug database for ordering, which contains a very extensive, though not exhaustive, list of prescription compounds, including generic and brand name preparations, and available forms (table, capsule, liquid, etc.) and doses. There are variations on the schema for looking up medications (by brand name vs. by generic, for example). Drug databases must be updated regularly by downloading a current version over the Internet.

To support formulary checking, e-prescribing applications must also include a health plan/PBM formulary database, against which to check prescriptions for formulary compliance. Databases are available that contain formularies from thousands of plans across the country; these are updated frequently, and revisions must be downloaded online on a regular basis.

A "favorites" list of medications most frequently ordered by each device's physician user is also fairly standard. The list speeds the selection of common medications. These vendors have the ability to perform, at a minimum, drug-drug interaction checking between medications currently or previously ordered through the system. Most mobile e-prescribing systems do not offer an easy method to populate the patient's medication record with medications prescribed off of the system; this makes drug-drug interaction checking incomplete in those instances (more common than not) where patients take medications prescribed by different physicians, not all of whom use an e-prescribing system.

The ability to input additional patient information, such as allergies and diagnoses, is more variable among vendors, although charge capture applications can address the latter.

Table 3. E-Prescribing Applications: Basic and Additional Functions

Basic	Additional
Drug database for prescribing	Associate diagnosis with prescription
Formulary checking	Drug-allergy interaction checking
Drug-drug interaction checking (for medications ordered on same system)	Drug-disease interaction checking
Favorites list of frequently-ordered drugs	Drug reference database

Interfaces

E-prescribing applications must have a mechanism for inputting or importing basic patient demographic data, by manual entry, and also, preferably, from a practice management system. The critical variations here surround the ease of implementing or, in some cases, developing these interfaces. Some vendors have ready-made interfaces constructed for one or more practice management systems; others will construct the interface for a charge, which can be substantial.

Availability or ease of development of interfaces to practice management systems depends in part on the e-prescribing vendor's relationship with different practice management system vendors. Some mobile prescribing vendors have ownership or tight business relationships with practice management system vendors, and may demonstrate a clear preference in interface development as a result. On the flip side, practice management vendors can make interface construction very difficult if they choose not to cooperate with an e-prescribing vendor whom they consider a competitor of theirs, or of a business partner. In selecting a vendor, ease of interfacing should be a prime consideration.

Case in Point: Mid-Atlantic Permanente Medical Group, Bethesda, MD

Vendor	EPhysician
Product	EPad
In use since	February 2001
Number of physicians using the product	12

Dr. Andrew Barbash and his colleagues at the Mid-Atlantic Permanente Medical Group implemented the ePad system in February 2001, and are already enjoying the benefits. The system as implemented currently employs formulary checking and drug-drug interaction checking, and the Facts and Comparisons drug reference. Prescriptions are faxed to pharmacies.

In addition to the satisfaction of providing better patient care, the practice's major benefit is in time savings from reduced pharmacy callbacks. The online medication reference tool has also proven quite useful. The one potential drawback they see to the system is the current requirement to synchronize the mobile device in a sync cradle with every prescription written, which is problematic for some physicians.

Dr. Barbash is particularly happy with the relationship Mid-Atlantic Permanente has been able to build with ePhysician. He praises their commitment to perfecting the product in use, before adding additional functionality, as well as their customer responsiveness in this, their largest facility implementation to date.

Charge Capture

Charge capture has become a popular application in its own right as it can assist practices in maximizing their revenue capture by greatly increasing the accuracy and efficiency of coding, the first step in the billing process. The application contains a database of ICD-9 and CPT codes that the provider uses to code each patient encounter or procedure. While several companies make stand-alone charge capture applications, some combine e-prescribing and charge capture. There are several benefits to this combination, beyond the convenience of housing two useful applications on one mobile device.

- First, assigning a diagnostic code to each patient allows the diagnosis to be included on the prescription, which serves to improve patient safety by providing the pharmacist with indication information.
- Second, capturing a diagnostic code permits at least partial construction of a patient problem list, which theoretically enables some level of checking for drug-disease interactions.

It should be noted that ICD-9 data, when coupled with prescriptions, are coveted highly by pharmaceutical companies as the combined data permit them to track off-label prescribing and other use patterns.

Results Lookup and Test Ordering

Several mobile computing vendors offer, or are close to rolling out, laboratory test ordering and results viewing, usually via interfaces with practice management systems or AMRs, or via connectivity arrangements with reference laboratories. It is not clear how extensive a longitudinal record of laboratory results will be maintained on these systems. The ability to view recent laboratory results while considering medications for a patient can be very valuable, for example, with medications that require titration to appropriate serum concentrations or with drugs that should not be given in the presence of certain laboratory anomalies (e.g., digoxin and low potassium). While not available from mobile prescribing vendors today, automated drug-laboratory interaction checking is an important component of clinical decision support for inpatient physician order entry. Such functionality could be developed for mobile e-prescribing applications in the future.

E-Dictation

Vendors are taking advantage of the digital dictation capabilities of mobile devices to offer online dictation and transcription services. Transcribed reports are generally accessed by PC and can be printed or otherwise included in the patient's medical record.

Drug References and Other Reference Sources

In addition to access to the prescribing database, it can be very useful to have easy access to prescribing information at the point of care; and accessing data quickly through a mobile application may be more convenient than looking through reference books. A recent study showed that 22 percent of the questions physicians have as they are seeing patients relate to medications.[20] Another study examining the utility of a drug reference database on a mobile platform showed that physicians and medical students saved time, gained prescribing knowledge, and felt that they provided better care using the system.[21] Several e-prescribing vendors bundle a drug reference application with their prescribing software.

V. Technology: Hardware, Software, and Operating Systems

THE PAST SEVERAL YEARS HAVE WITNESSED THE explosion in popular use of the mobile computing platform generally called the personal digital assistant (PDA). Devices such as the Palm Pilot offer the convenience of a pocket-size device on which to store and record contacts lists, addresses, and schedules; by connection with a PC or wireless network, devices can send and receive email and users can surf the Web.

This level of convenience, and the track record of broad user acceptance, underlie much of the current industry optimism surrounding the future of e-prescribing using these devices. If physicians are using PDAs to keep addresses and receive stock quotes, surely widespread adoption of electronic prescription writing should be right around the corner.

The specific characteristics of mobile computing devices should hold important implications for adoption of e-prescribing. This section discusses the common hardware, operating systems, and network connectivity technologies used by electronic prescribing systems. A more detailed description of the technology of wireless computing, including the standards utilized and specific hardware requirement for wireless communication, is contained in the CHCF publication, *Wireless and Mobile Computing.*[22] This report does not discuss the technology platform of the AMR, as it typically uses standard client-server architecture and platforms and is, therefore, generally well understood.

Devices and Operating Systems

PDAs can be categorized as either palm-size or handheld. Most of the smaller palm-size devices, manufactured by Palm or others, utilize some version of the Palm operating system. Handheld computers primarily use Microsoft's Windows CE operating system. The relative benefits of the two operating systems are outlined in Table 4. Briefly, the Palm system operates a small touch screen that is manipulated with a stylus; data can be entered using menus or a simple character recognition language. The Windows CE system presents an interface that more closely resembles the standard PC desktop and is manipulated by a small keyboard and/or touch screen. The Palm system drives smaller devices and is somewhat simpler to use; the Windows system offers greater functionality.

Table 4. Comparison: Palm vs. Windows CE[14, 23]

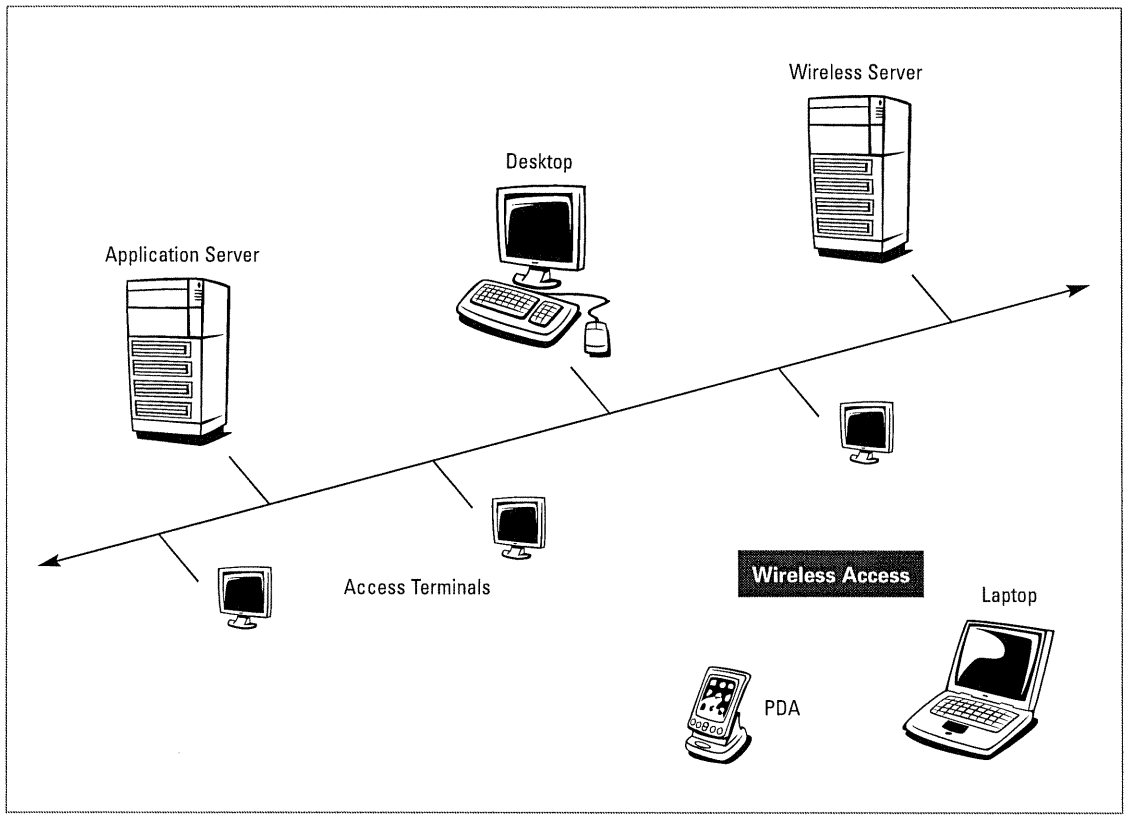
Palm OS Advantages	Windows CE Advantages
• Simple interface	• More versatile than Palm OS
• Low memory requirement	• More advanced graphics
• Long battery life	• More features available, including multimedia applications
• High system stability/reliability compared with Windows devices	• Broader audio and video support
• Wireless Web access available for select models	• Ability to read documents created in compatible software, such as MS Word and Excel
• PDAs with Palm OS tend to be smaller in size and weight (most fit into a lab coat pocket)	• Color display

Connectivity: PC and Network Connections for the PDA

PDAs can connect with desktop PCs via a synchronization cable and cradle or using radio frequency technology. They can also connect and exchange data over a physician practice's local area network (LAN). Entire LANs can also be constructed to be wireless, with transmitter/receiver devices—called access points—serving as the link to a traditional LAN (see Figure 4). While different hardware vendors have used a variety of communication protocols, a single standard appears to be emerging (IEEE 802.[22] The various models of PDA are capable of different kinds of connectivity; some have wireless LAN adapters integrated into the device while others can use PC cards to provide this connectivity.

Approaches to connectivity hold important implications for workflow around e-prescribing. For example, a requirement to physically synchronize the PDA following the input of each patient's prescriptions, in order to send the prescriptions to the printer, fax server, or electronically to the pharmacy, causes some degree of inconvenience in the course of practice. If a wireless LAN is to be used, positioning of the access points must be carefully planned to ensure coverage of all practice areas where physicians may wish to access the network.

Figure 4: Wireless LAN



Wireless LAN technology has other limitations that may affect the convenience of e-prescribing. These include:

- Slow data transfer speed compared with wired LAN (7 Mbps vs. 10-100 Mbps).
- Potential for frequency interference with biomedical equipment (more of an issue in a hospital setting).
- Lack of data interface standards with legacy information systems (requires that the mobile computing vendor construct point-to-point interfaces).

In the typical physician practice setting, only the last of these represents a major inconvenience for e-prescribing. Interface issues are discussed on page 31.

PDAs can also communicate with some devices, such as printers and other PDAs, using infrared technology. Some mobile e-prescribing systems require the physician to "beam" new prescriptions to the infrared port of a local printer after seeing each patient.

Other Connectivity Modes

Wireless WAN (wide area network) represents another connectivity technology, in which satellite networks provide radio frequency coverage of large geographic areas. There is limited experience in the use of WAN technology for e-prescribing. Wireless Internet, a technology based on mobile phone communications standards, may find favor for e-prescribing systems in the future.

Connectivity from the Practice to the PBM or Pharmacy

Most e-prescribing systems currently implemented do not send prescriptions electronically but rather transmit them via electronic fax or simply print the prescription in the physician's office and hand it to the patient. When prescriptions are sent electronically, an industry EDI (electronic data interchange) standard is typically used. This format provides a degree of security beyond that of standard email.

The development of better standards for transmission of e-prescriptions may be accelerated by the PBM industry's RxHub initiative. This effort, sponsored by PBMs, could facilitate the establishment of connectivity from physician offices to PBMs and pharmacies. The RxHub founders state that the new standards will meet all HIPAA security requirements.

PBMs Create a New E-prescribing Exchange: RxHub

Three pharmaceutical benefits management companies are striving to create an electronic exchange system that will facilitate the sending of prescriptions electronically. Advance PCS, Express Scripts, and Merck-Medco will collaborate—and invest $20 million a piece—to create RxHub, a system that will establish electronic communications standards for e-prescriptions and adhere to HIPAA and other privacy standards. The standards will also incorporate encryption technology to ensure security of transmissions.

The new system will facilitate connectivity between physicians and PBMs. The goal is to route prescriptions directly to the PBMs for formulary checking before being sent to pharmacies. An added benefit: Development of the system should increase incentives for all pharmacies to wire themselves to receive e-prescriptions.[11]

VI. Future Challenges and Emerging Patterns

DESPITE COMPELLING POTENTIAL BENEFITS, AND even a gathering literature of success stories, adoption of e-prescribing by physicians has been slow as of this writing. Mobile prescribing vendors have revised downward their projections of users for the coming year as implementations have fallen behind earlier predictions.

There are a number of possible reasons for the sluggish progress of use of e-prescribing. Several aspects of the structure of the health care industry are likely contributing.

1. ***The difficulty of marketing new technologies to physicians in small and medium-size practices.*** These doctors constitute the majority of practicing physicians, and their geographic dispersal and independence make them difficult to approach in an organized way. Such practices often use only basic practice management systems; even the adoption of this technology occurred only after the complexity of practice administration reached a point where their value was unquestionable. While prescription management may reach a similar level of complexity in the future, it is doubtful that most practitioners experience a clearly felt need for such systems today. Thus adoption will continue to be driven by marketing—by vendors, other physicians, patients, or the media; e-prescribing technology will not sell itself.
2. ***Marketplace instability.*** Physicians may hesitate to invest the time and effort in adopting e-prescribing technologies in an uncertain marketplace. More companies are destined to fail than to succeed in this niche. With investor dollars becoming scarcer and companies failing to demonstrate positive cash flow, physicians may be waiting for the smoke to clear before selecting a system.
3. ***Skepticism about value.*** Physicians may also be skeptical about the value delivered by e-prescribing systems. Indeed, a realistic appraisal of the average system's functionality for reducing medication errors supports some skepticism. In terms of preventing drug interactions, many systems are currently checking for possible interactions with other medications, and perhaps, allergies; medication checking is limited to the drugs prescribed using the same office system. Given that many patients take medications from multiple prescribers, the list is likely to be incomplete.

Thus, in most cases, safety benefits are limited to production of legible prescriptions, checked against a partial list of current medications and, perhaps, allergies. These contributions are significant, but may not live up to the hopes or expectations of physicians considering the switch to e-prescribing.

4. ***Evolution of multifunction systems.*** While implementation lessons suggest practices are better off implementing only one or a few functions at a time, physicians considering e-prescribing or the adoption of mobile computing may be waiting for more multifunction systems to mature before selecting a product. The current movement in the field toward multifunction systems suggests that the vendors feel this is the direction of the market. However, as additional functional demands are put upon these systems, their current advantages relative to AMRs—simplicity, speed of implementation, cost—will likely be diminished. It could be argued that if simple, single-function e-prescribing applications were going to sweep the market, they would have done so by now.

It seems unlikely that concerns about privacy and security are inhibiting physicians from adopting e-prescribing. First, most offices are not transmitting prescriptions electronically—they are printing them locally or faxing them to pharmacies or PBMs. Second, many practices are already performing some electronic claims submissions, which raise many of the same concerns about security as e-prescribing. HIPAA privacy issues could pose challenges for some vendor business models, and require physician practices to examine carefully their contracts with vendors in the future; but these factors probably have not played a significant role in most physicians' consideration of e-prescribing up to the present time.

Several issues currently in play are likely to have profound influence on the future of e-prescribing. First among these are the HIPAA privacy rules, which if implemented in anything close to current form will significantly alter the nature of contracts between providers and their business partners. The rules will hold implications for vendor business models that depend on sharing patient data with third parties. All parties will have to guarantee and verify that patient information is adequately de-identified before it leaves the confines of operations/treatment/payment transactions.

Another evolving dynamic is the relationship between e-prescribing vendors and vendors of other health care IT systems. A great deal will be determined by the degree to which mobile computing vendors are able to integrate their platforms and applications to interact with health care legacy systems, including practice management systems. If past experience were the guide, there would be ample reason for pessimism, as lack of interoperability is the norm rather than the exception in health care.

Several patterns could emerge. One scenario—extrapolated from past experience and recent behavior of some mobile prescribing vendors—has mobile and enterprise vendors pairing up and offering well-integrated systems within the confines of their relationship. This typically restricts the ease of integration of a given mobile platform with those of other vendors. Another scenario involves increasing use of open standards for application building and communications; this could ameliorate the interface challenges and offer practices more vendor options to choose among.

In any case, it seems likely that outpatient e-prescribing, with its clear benefits and relatively few drawbacks, will eventually find its way into broader use in the physician community. The question is how quickly, and how widely will this occur? While enthusiastic analyst reports of two years ago were clearly too optimistic, there remains reason to expect that e-prescribing will play an increasing role in patient care in the future.

Appendices

Appendix A: Representative Vendors Offering Mobile Electronic Prescribing

Appendix B: Glossary

Appendix A: Representative Vendors Offering Mobile Electronic Prescribing

Vendor	url
Allscripts	www.allscripts.com
ePhysician	www.ephysician.com
iScribe	www.iscribe.com
PenChart	www.penchart.com

Appendix B: Glossary

Access Point—Radio based two-port network bridge that interconnects a typical wired Ethernet network to a wireless LAN segment.

Adverse Drug Event—An injury resulting from medical intervention related to a drug.[24]

Adverse Event—An injury caused by medical management rather than the underlying condition of the patient.

AMR (Ambulatory Medical Record)—Multifunctional software packages that support administrative and clinical operations of physician practices and typically include scheduling, registration, billing , managed care, and patient care modules. Sometimes referred to, especially in the inpatient setting, as EMR (electronic medical record).

Application Service Provider (ASP)—A vendor that deploys, hosts, and manages access to a packaged application for multiple parties from a central facility, charging a subscription use fee.

Beaming—Transfer of data or software programs from one PDA to another, or from a PDA to a desktop computer or a printer, using either infrared or radio-wave transmission.

EDI (Electronic Data Interchange)—A direct exchange of data files between two computers. Generally, EDI transmission is faster than electronic faxing and offers more security than email transmission of prescriptions.

Electronic Prescribing (E-Prescribing)—Entering a prescription for a medication into an automated data entry system (handheld, PC, or other), and thereby generating a prescription electronically, instead of handwriting the prescription on paper.

Ethernet—The IEEE standard 802.3. It is a network standard of communication using either coaxial or twisted pair cable. The most widely used for LAN communication, Ethernet typically runs at 10 megabytes per second, though newer systems use 100 Mbps or even a gigabit of transfer.

Formulary—A list of medications (both generic and brand names) that are covered by a specific health insurance plan or PBM.

Hand-held PC or Pocket PC—A more powerful handheld than a PDA, the pocket PC has many of the functions and capabilities of desktop and laptop computers.

IEEE 802.11b—Standard ratified by IEEE in late 1999 and supported by the largest WLAN vendors including Proxim, Lucent, Nortel, and Cisco.

LAN (Local Area Network)—A network that consists of computers that are located in physical proximity of one another and are all connected by wire cables.

Medical Error—The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim in the health care delivery process.

Medication Error—A mistake made at any stage in the provision of a pharmaceutical product to a patient.

Network—A set of computers interconnected with cables (LAN) or wireless (WLAN).

Palm Operating System (Palm OS)—Hand-held computer operating system developed by 3Com and characterized by operating simplicity and extensive information storage capacity.

PBM (Pharmacy Benefit Manager)—An organization contracted by health insurance plans to manage prescription medication benefits.

PDA (Personal Digital Assistant)—A handheld portable organizer; some with Internet access and email functions.

Subscription-based Model—One of two types of business models presently observed with the electronic prescribing vendors. The subscription-based model is based on a monthly fee charged for the use of the hardware and the electronic prescribing software; the fee may be charged directly to physicians or subsidized by a third-party payer. See also transaction-based model.

Sync Cradle—A device that holds the PDA and is connected (via a cable) to a desktop computer, allowing for transfer (syncing) of data in both directions between a PDA and a desktop PC or a network.

Transaction-based Model—The second of two types of business models behind electronic prescribing vendors currently on the market. Under this model, service fees are charged on a per-transaction basis, rather than on a flat monthly charge. Presently, the model works with subsidization by a third-party payer. See also subscription-based model.

Windows CE—Handheld computer operating system developed by Microsoft that includes scaled down version of Word, Excel, Access, and Internet Explorer.

WLAN (Wireless Local Area Network)—A system of three primary types, including two that are based on radio frequency (RF) with spread spectrum modulation schemes: direct sequence spread spectrum (DSSS) and frequency hopped spread spectrum (FHSS). The third type, infrared (IR), is based on light waves and, due to line-of-sight limitations, does not provide the mobility of the RF options.

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AGENDA ITEM F

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: September 6, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Clarification of DEA Requirements**

On January 18, 2005, the Drug Enforcement Administration (DEA) published in the Federal Register a Solicitation of Comments on the subject of dispensing controlled substances for the treatment of pain. Most of the comments that the agency received sought clarification on the legal requirements governing the prescribing of schedule II controlled substances by physicians. Given the comments on August 26, 2005, the DEA reiterated its principles under the Controlled Substances Act and DEA regulations. A summary of the notice is as follows:

- DEA stands firm that the act of a physician writing multiple prescriptions for a schedule II drug on the same day with instructions to fill on a future date is the same thing as writing a refill which conflicts with the provision of CSA that provides "No prescription for a controlled substance in schedule II may be refilled."

- DEA clarified that the Interim Policy did not mean that patients who have been receiving prescriptions for schedule II medications for several years for the treatment of severe pain or attention deficit hyperactivity disorder were required to see the physician each month in order to get another prescription. Physicians that properly determine there is a legitimate medical purpose and acting in their usual course of professional practice can determine whether a patient for whom they are prescribing a schedule II must be seen in person each time a prescription is issued or whether seeing the patient less frequently is consistent with sound medical practice and appropriately safeguards against diversion and misuse.

- If a physician decides to issue the schedule II prescription without seeing the patient, the physician can mail the prescription to the patient or to the pharmacy to be filled. Alternatively, the physician can fax a schedule II prescription to the pharmacy but the pharmacy must have the original signed prescription prior to dispensing the drug to the patient.

- The DEA and CSA regulations contain no specific limit on the number of days worth of schedule II controlled substance that a physician may authorize per prescription. However, any state limitations in place would apply.

DEA plans to complete its review of comments submitted last January and plans to issue a new Federal Register document.

Consortium, Inc. intends to file additional written notification disclosing all changes in membership.

On November 19, 2004, Network Centric Operations Industry Consortium, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on February 2, 2005 (70 FR 5486).

The last notification was filed with the Department on May 11, 2005. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on June 13, 2005 (70 FR 34150).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 05–16961 Filed 8–25–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Storage Bridge Bay Working Group, Inc.

Notice is hereby given that, on August 9, 2005, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et. seq.* ("the Act"), Storage Bridge Bay Working Group, Inc. ("SBB") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the name and principal place of business of the standards development organization and (2) the nature and scope of its standards development activities. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the name and principal place of business of the Standards development organization is: Storage Bridge Bay Working Group, Inc., Redwood City, CA. The nature and scope of SBB's standards development activities are: Promoting the computer industry by supporting and facilitating the development of interoperable and compatible storage components with reference to controller slot compatibility between and among storage solutions. These purposes include the objective of developing and publishing a "storage bridge bay" specification that will serve as a reference and guideline for defining physical, mechanical, electrical and low-level enclosure management requirements for an enclosure controller slot that will support a variety of storage controllers from a variety of independent hardware vendors and independent software vendors. Any storage controller design based on this specification shall be able to fit, connect, and operate within any storage enclosure controller slot design based on the same specification.

Dorothy B. Fountain,

Deputy Director of Operations Antitrust Division.

[FR Doc. 05–16959 Filed 8–25–05; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–271N]

Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Clarification.

SUMMARY: On January 18, 2005, DEA published in the **Federal Register** a solicitation of comments on the subject of dispensing controlled substances for the treatment of pain. Many of the comments that the agency received indicate that there is a need to issue a clarification regarding certain aspects of the prescription requirements for schedule II controlled substances. This document provides such clarification.

DATES: August 26, 2005.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307–7297.

SUPPLEMENTARY INFORMATION: On January 18, 2005, the Drug Enforcement Administration (DEA) published in the **Federal Register** a Solicitation of Comments on the subject of dispensing controlled substances for the treatment of pain. 70 FR 2883. Most of the comments that the agency received sought clarification on the legal requirements governing the prescribing of schedule II controlled substances by physicians in view of DEA's November 16, 2004, Interim Policy Statement. 69 FR 67170. Given these comments, DEA wishes to reiterate the following principles under the Controlled Substances Act (CSA) and DEA regulations.

1. As the Interim Policy Statement states, "For a physician to prepare multiple prescriptions [for a schedule II controlled substance] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance." To do so conflicts with the provision of the CSA which provides: "No prescription for a controlled substance in schedule II may be refilled."

2. Many of the comments that DEA received were from patients who said they have been receiving prescriptions for schedule II controlled substances for several years (for example, for the treatment of severe pain or attention deficit hyperactivity disorder) and have gotten into a routine of seeing their physician once every three months. Many such commenters were under the mistaken impression that, because of the Interim Policy Statement, they now must begin seeing their physician every month. DEA wishes to make clear that the Interim Policy did *not* state that such patients must visit their physician's office every month to pick up a new prescription. There is no such requirement in the CSA or DEA regulations. What is required, in each instance where a physician issues a prescription for any controlled substance, is that the physician properly determine there is a legitimate medical purpose for the patient to be prescribed that controlled substance and that the physician be acting in the usual course of professional practice. 21 CFR 1306.04(a); *United States* v. *Moore,* 423 U.S. 122 (1975).

At the same time, schedule II controlled substances, by definition, have the highest potential for abuse, and are the most likely to cause dependence, of all the controlled substances that have an approved medical use. 21 U.S.C. 812(b). Physicians must, therefore, use the utmost care in determining whether their patients for whom they are prescribing schedule II controlled substances should be seen in person each time a prescription is issued or whether seeing the patient in person at somewhat less frequent intervals is consistent with sound medical practice and appropriate safeguards against diversion and misuse. Physicians must also abide by any requirements imposed by their state medical boards with respect to proper prescribing practices and what constitutes a bona fide physician-patient relationship. 21 U.S.C. 823(f)(1), (4).

3. Under the circumstances described in paragraph 2, in those instances where the physician (who regularly sees a patient) issues a prescription for a

schedule II controlled substance for a legitimate medical purpose without seeing the patient in person, the physician may mail the prescription to the patient or pharmacy. In addition, as the DEA regulations state: "A prescription for a schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted [elsewhere in this section of the regulations]." 21 CFR 1306.11(a). Thus, as this provision of the regulations provides, faxing may be used to facilitate the filling of a schedule II prescription, but only if the pharmacy receives the original written, signed prescription prior to dispensing the drug to the patient.

4. The CSA and DEA regulations contain no specific limit on the number of days worth of a schedule II controlled substance that a physician may authorize per prescription. Some states, however, do impose specific limits on the amount of a schedule II controlled substance that may be prescribed. Any limitations imposed by state law apply in addition to the corresponding requirements under Federal law, so long as the state requirements do not conflict with or contravene the Federal requirements. 21 U.S.C. 903. Again, the essential requirement under Federal law is that the prescription for a controlled substance be issued for a legitimate medical purpose in the usual course of professional practice. In addition, physicians and pharmacies have a duty as DEA registrants to ensure that their prescribing and dispensing of controlled substances occur in a manner consistent with effective controls against diversion and misuse, taking into account the nature of the drug being prescribed. 21 U.S.C. 823(f).

Finally, as stated in the Solicitation of Comments, once DEA has completed its review of the comments, the agency plans to issue a new **Federal Register** document, which will provide a recitation of the pertinent legal principles relating to the dispensing of controlled substances for the treatment of pain.

Dated: August 19, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–16954 Filed 8–25–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–57,428]

Americal Corporation, Henderson, NC; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on June 22, 2005 in response to a petition filed by a company official on behalf of workers at Americal Corporation, Henderson, North Carolina.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 29th day of July, 2005.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E5–4678 Filed 8–25–05; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–57,639 and TA-W–57,639A]

Bernhardt Furniture Company, Plant # 9, Shelby, NC, and Bernhardt Furniture Company, Plant # 14, Cherryville, NC; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on July 28, 2005 in response to a petition filed by a company official on behalf of workers at Bernhardt Furniture Company, Plant #9, Shelby, North Carolina (TA–W–57,639) and Bernhardt Furniture Company, Plant #14, Cherryville, North Carolina (TA–W–57,639A).

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed in Washington, DC, this 10th day of August, 2005.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E5–4683 Filed 8–25–05; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–56,114]

Bourns Microelectronics Modules, Inc., a Subsidiary of Bourns Inc., New Berlin, WI; Notice of Revised Determination on Remand

On June 29, 2005, the United States Court of International Trade (USCIT) granted the Department of Labor's motion for voluntary remand in *Former Employees of Bourns Microelectronics Modules, Inc.* v. *U.S. Secretary of Labor* (Court No. 045–00350).

A petition, dated November 30, 2004, for Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA) was filed on behalf of workers and former workers of MMC Bidding, Inc., Division of Bourns, New Berlin, Wisconsin. The investigation revealed that the workers previously worked for Microelectronics Modules Corporation (MMC), New Berlin, Wisconsin and that the workers' employment with MMC was terminated when Bourns acquired the assets of MMC on October 30, 2003. The investigation also revealed that the Department granted a certification for the former workers of MMC (TA–W–42,217; expired December 6, 2004).

On December 27, 2004, the investigation for the case at hand was terminated because it was believed that the workers were covered by the previous certification for MMC (TA–W–42,217). (The Department had also terminated another investigation for a previous petition for the same location (TA–W–54,790) on June 4, 2004 because the Department found that the workers were covered by the certification for MMC (TA–W–42,217)). The Department's Notice of Termination of Investigation for this case was published in the **Federal Register** (70 FR 3732).

By letter dated January 14, 2005, the petitioner requested administrative reconsideration, stating that the workers were hired by and then separated from Bourns, that the petitioner helped ship machines and documentation to, and provided training to persons in Costa Rica, China and Taiwan, and that parts were being imported to satisfy customers' demands.

By letter dated March 10, 2005, the petitioner's request for reconsideration was dismissed based on the finding that no new facts of a substantive nature which would bear importantly on the Department's determination was provided by the petitioner. On March 11, 2005, the Dismissal of Application

AGENDA ITEM G

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: September 6, 2005

From: Patricia F. Harris
Executive Officer

Subject: **New Labeling Requirements – Physical Description of the Dispensed Medications**

Attached is an article that will appear in the next board newsletter regarding the new requirement that will take effect January 1, 2006. The physical description of the dispensed medication must be included on the prescription, including its color, shape and any identification code that appears on the tablet or capsule. There are also exemptions to this requirement.

Changes to Prescription Medication Container Labels

On January 1, 2006, a new element must be added to labels on prescription containers dispensed from outpatient pharmacies. This requirement is the physical description of the dispensed medication, including its color, shape and any identification code that appears on the tablets or capsules. For example, a prescription label for Ibuprofen Tab 400mg might include the notation, "*This medicine is a white, oval-shaped, film-coated tablet imprinted with IBU 400.*" A label for Pravachol might include, "*Square yellow tablet, Side 1: P, Side 2: PRAVACHOL #20.*"

The following are exceptions to this labeling requirement:

- Prescriptions dispensed by a veterinarian;
- Dispensed medications for which no physical description exists in any commercially available database;
- New drugs for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file; and
- When a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to section 1250 of the Health and Safety Code (e.g., acute care hospital, skilled nursing facility, and correctional treatment center) and the prescription drug is administered to a patient by a licensed certified nurse-midwife, nurse practitioner, physician assistant or pharmacist who is acting within his or her scope of practice.

This requirement appears in the Business and Professions Code section 4076(a)(11)(A).

4074. (a) A pharmacist shall inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription if the drug poses substantial risk to the person consuming the drug when taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and provided the drug is determined by the board pursuant to subdivision (b) to be a drug or drug type for which this warning shall be given.
(b) The board may by regulation require additional information or labeling.
(c) This section shall not apply to drugs furnished to patients in conjunction with treatment or emergency services provided in health facilities or, except as provided in subdivision (d), to drugs furnished to patients pursuant to subdivision (a) of Section 4056.
(d) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each medication given at the time of discharge and each medication given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each medication, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other provision of law shall be construed to require that only a pharmacist provide this consultation.

4075. No prescription for a controlled substance transmitted by means of an oral or electronically transmitted order shall be furnished to any person unknown and unable to properly establish his or her identity. The board may by regulation establish procedures to prevent unauthorized persons from receiving prescription drugs furnished to a patient or a representative of the patient.

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:
(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.
(2) The directions for the use of the drug.
(3) The name of the patient or patients.
(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.
(5) The date of issue.
(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.
(7) The strength of the drug or drugs dispensed.
(8) The quantity of the drug or drugs dispensed.
(9) The expiration date of the effectiveness of the drug dispensed.
(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.
(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:
(i) Prescriptions dispensed by a veterinarian.
(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.
(iii) Dispensed medications for which no physical description exists in any commercially available database.
(B) This paragraph applies to outpatient pharmacies only.
(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.
(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.
(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose
containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.
(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

4077. (a) Except as provided in subdivisions (b) and (c), no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.
(b) Physicians, dentists, podiatrists, and veterinarians may personally furnish any dangerous drug prescribed by them to the patient for whom prescribed, provided that the drug is properly labeled to show all information required in Section 4076 except the prescription number.
(c) Devices that bear the legend "Caution: federal law restricts this device to sale by or on the order of a _____," or words of similar meaning, are exempt from the requirements of Section 4076, and Section 111480 of the Health and Safety Code, when provided to patients in skilled nursing facilities or intermediate care facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.
(d) The following notification shall be affixed to all quantities of dimethyl sulfoxide (DMSO) prescribed by a physician, or dispensed by a pharmacy pursuant to the order of a physician in California: "Warning: DMSO may be hazardous to your health. Follow the directions of the physician who prescribed the DMSO for you."
(e) The label of any retail package of DMSO shall include appropriate precautionary measures for proper handling and first aid treatment and a warning statement to keep the product out of reach of children.

4078. (a) (1) No person shall place a false or misleading label on a prescription.
(2) No prescriber shall direct that a prescription be labeled with any information that is false or misleading.
(b) Notwithstanding subdivision (a), a person may label a prescription, or a prescriber may direct that a prescription be labeled, with information about the drug that is false under either of the following circumstances:
(1) If the labeling is a necessary part of a clinical or investigational drug program approved by the federal Food and Drug Administration or a legitimate investigational drug project involving a drug previously approved by the federal Food and Drug Administration.
(2) If, in the medical judgment of the prescriber, the labeling is appropriate for the proper treatment of the patient.
(c) The furnisher of a prescription labeled pursuant to subdivision (b) shall make, and retain for three years from the date of making, a record stating the manner in which the information on the prescription label varies from the actual drug in the container and documenting the order of the prescriber to so label the container. The prescriber shall make, and retain for at least three years, a record of his or her order to so label the container.

Article 5 – Authority of Inspectors

4080. All stock of any dangerous drug or dangerous device or of shipments through a customs broker or carrier shall be, at all times during business hours, open to inspection by authorized officers of the law.

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption

AGENDA ITEM H

State of California | Department of Consumer Affairs

Memorandum

To: Enforcement Committee | Date: September 7, 2005

From: Patricia F. Harris
Executive Officer

Subject: SB 1307 (Figueroa)
Chapter 857, Statutes of 2004

Last year, the Board of Pharmacy sponsored SB 1307 (Figueroa). Governor Schwarzenegger signed the bill, which became effective January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

The Enforcement Committee is monitoring the implementation of this legislation. One area of close oversight will be pedigree requirement. The bill requires an electronic pedigree by January 1, 2006 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States. The new requirements are as follows:

Electronic Pedigree for Dangerous Drugs (New)
B&PC 4034—requires an electronic "pedigree" by January 1, 2007. Said pedigree will contain information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the drug.
The pedigree must contain all of the following information: (1) the source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source (2) the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers (3) the business name, address, and if appropriate, the state license number, including a California license number if available, each owner of the dangerous drug and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug (4) a certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.
The application of the pedigree requirement in pharmacies will be subject to review during the Board's sunset review in 2008.

Pedigree Required (New)

B&PC 4163— presently allow manufacturers and wholesalers to acquire or furnish dangerous drugs or devices only from or to those authorized by law to possess or furnish those dangerous drugs or devices. This section is in effect until January 1, 2007, when it will be repealed unless a later enacted statute is enacted before that date. If this section is repealed, the new section will prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug at wholesale without a pedigree. Additionally, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree. This section becomes operative on January 1, 2007.

Extension May be Allowed for Implementing Pedigree Requirement for Wholesalers (New)
B&PC 4163.5—authorizes the Board to extend the time allowed for implementing electronic technologies to track the distribution of dangerous drugs within the state if the Board determines that manufacturers or wholesalers cannot meet the requirement by January 1, 2007. The pedigree requirement compliance date may then be extended until January 1, 2008.

Extension May be Allowed for Implementing Pedigree Requirement for Pharmacies (New)
B&PC 4163.6—authorizes the Legislature to extend the time allowed for pharmacies to implement electronic tracking the distribution of dangerous drugs within the state if the Legislature determines that it is not economically and technically feasible for pharmacies to comply with the requirement by January 1, 2007. The date for compliance with the requirement may be extended to January 1, 2009.

It is anticipated that Radio Frequency Identification technology (RFID) will the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

At the April board meeting, Acerity Corporation presented its security software program, which is an electronic authentication process. The system employs a cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications. At the December enforcement committee meeting, there was a presentation by T3Ci. As stated with that presentation, it is not the intent of the Board of Pharmacy to support or endorse any specific technological solution for the electronic pedigree requirement. Acerity Corporation also presented to the Enforcement Committee in June.

Also SupplyScape presented to the Enforcement Committee in June. SupplyScape has developed electronic pedigree software that enables a safe and secure pharmaceutical supply chain that complies with federal and state regulations to prevent counterfeit drugs.

The board continues to participate in the Unified Drug Pedigree meetings. Supervising Inspectors Robert Ratcliff and Judi Nurse participated in their meeting of August 9, 2005.

At the December Enforcement Committee, for this agenda topic, I plan to prepare a list of questions and answers that the board has received regarding the implementation of SB 1307. Also, the committee may want to consider having an open forum for discussion and questions on the law and to send out invitations to the industry to participate.