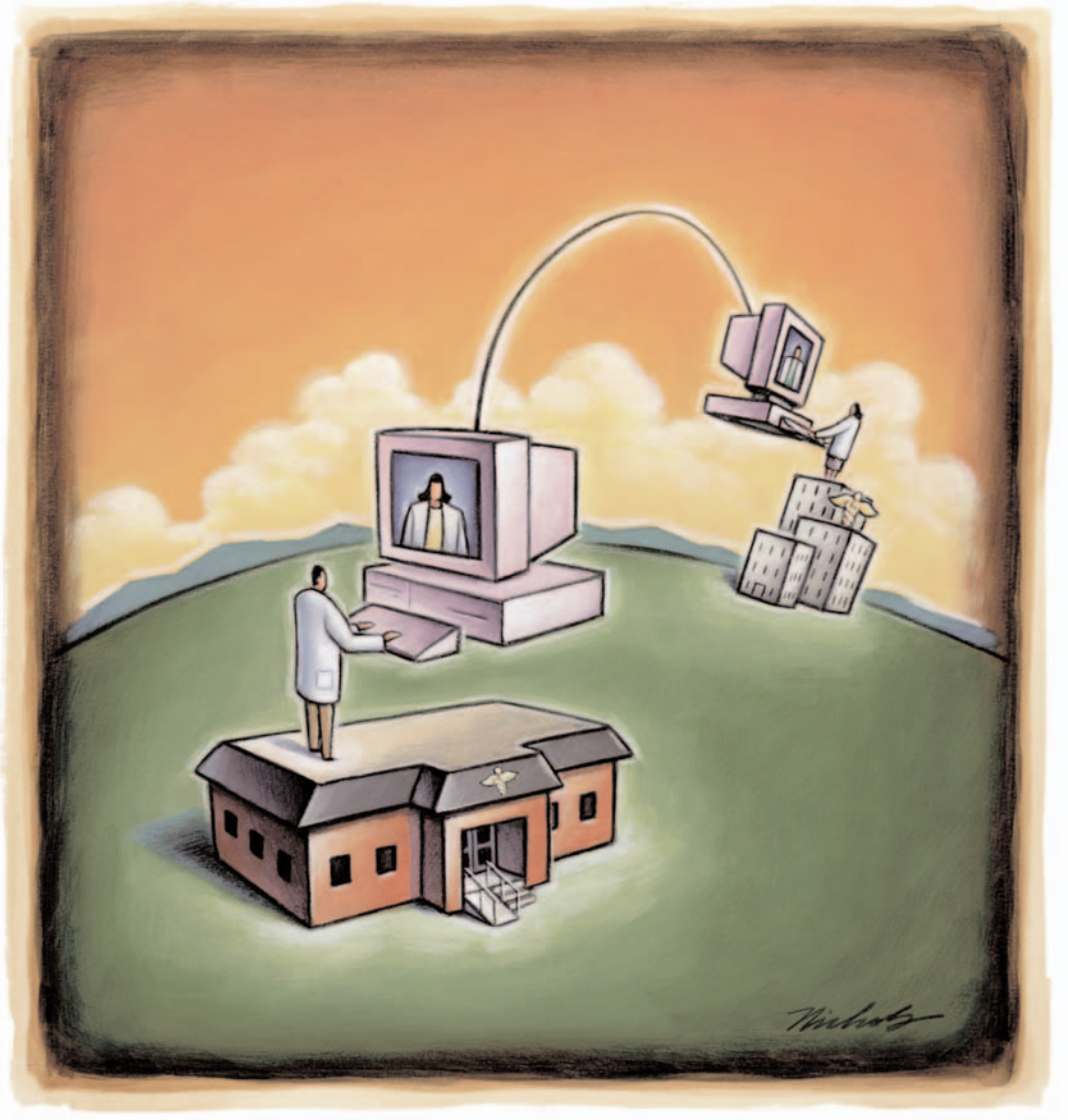
California HealthCare Foundation



The Prescription Infrastructure: Are We Ready for ePrescribing?

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About the Foundation

The **California HealthCare Foundation**, based in Oakland, is an independent philanthropy committed to improving California's health care delivery and financing systems. Formed in 1996, our goal is to ensure that all Californians have access to affordable, quality health care. For more information about CHCF, visit us online at **www.chcf.org**.

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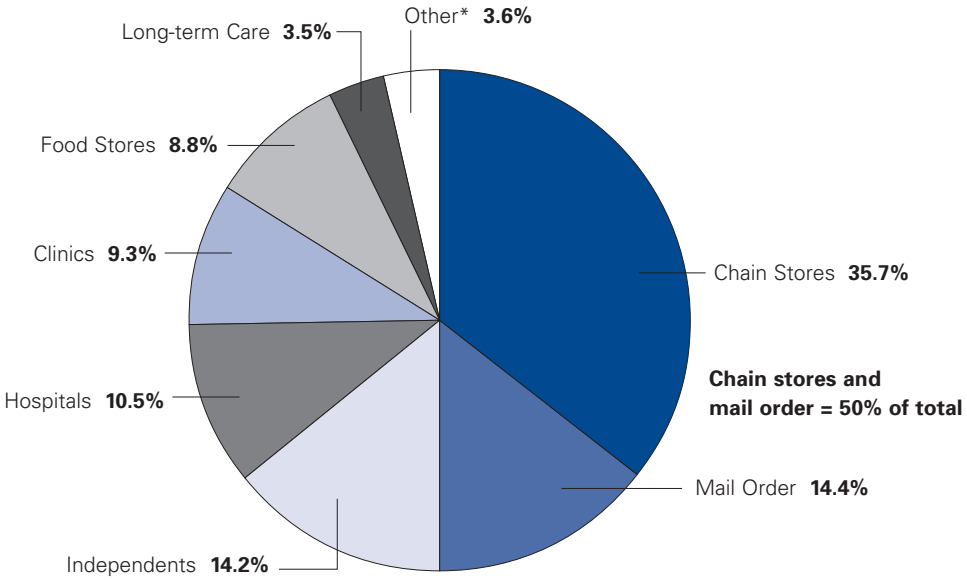
I. Background

Prescription drugs are an integral part of Americans' personal health. At least half of all Americans take one prescription drug regularly, with one in six taking three or more medications.[1] As the U.S. population ages, use of prescription drugs and the number of prescription transactions will increase. Some 3.27 billion prescriptions were written between March 2004 and February 2005. These prescriptions, including those for mail-order drugs, accounted for $221 billion in retail pharmacy and more than 10 percent of national health spending.[2]

The largest retail channels for consumers are chain drug stores and mail order, which together account for more than half of all prescriptions (Figure 1). Mail orders are the fastest growing channel and will continue to expand rapidly as Medicare extends prescription drug coverage to enrollees in 2006. In contrast, the number of independent drug stores—the "mom and pop," privately owned outlets—declined by more than 20 percent between 1991 and 2005.[3] The independents face potential extinction in the wake of expanding chains and discount stores that have found attractive margins in the pharmacy business.

Figure 1. Pharmacy Purchases by Channel



*Includes federal facilities, home health, HMOs, and miscellaneous sources

Source: IMS Health, IMS National Sales Perspectives, August 2004 and February 2005

Although writing a prescription is a relatively simple matter, processing prescriptions can be quite complicated, as it involves a variety of individuals, data transactions, and complex financial agreements and incentives. Potential medication errors due to the complexity of processing are only compounded by paper-based transactions and communications. eRx and electronic health records (EHRs) are expected to improve the process, but use of these tools still is limited.

The Players

Those involved in prescription processing include:

- The patient, who often asks for a drug and gets a prescription, fills the prescription, pays for part or all of it, and consumes the medication.
- The clinician, who prescribes the drug, often using a paper pad.
- The retail pharmacy, which communicates with the payer, patient, and physician's office, and then fills the prescription.
- The pharmacy benefit manager (PBM), which sets the formulary (a list of drugs that can be dispensed), verifies the patient's insurance eligibility, pays for the drug, and, in many cases, dispenses it by mail order. The PBM uses financial incentives to encourage patients to adhere to its formulary and also employs techniques, such as prior authorization and generic substitution, to try to reduce pharmaceutical costs.

Prescriptions in Other Settings

The vast majority of prescribing and dispensing takes place in outpatient or ambulatory care settings. However, three other large venues for Rx delivery are physician offices, hospitals, and long-term care facilities.

Medicare Part B, which covers outpatient physician services, pays for $10.5 billion worth of drugs delivered annually by infusion in physician offices or associated outpatient clinics.[4] (Private health plans also usually cover medications that are dispensed in physician offices.) Most such drugs are various types of chemotherapy. Wholesaling and delivery of drugs generally are controlled by specialty distributors, who use a separate infrastructure to connect with their customers, typically physicians. Beginning in 2005, Medicare reimbursements for these drugs were substantially reduced,[5] with the likely result that some patients will be steered toward more oral therapies and slowly start to receive their medications at pharmacies.

Hospitals and long-term care facilities dispense drugs directly to patients using a combination of written orders and automated systems. At long-term care facilities, a contractor such as Omnicare often manages the in-house pharmacy. In general, a wholesaler controls the supply of drugs to a hospital, where information technology for pharmacy is centered on the correct ordering, dispensing, and administration of prescriptions. The automation of this process—known as electronic medication administration record, or eMAR—is considered to be a solution to the inpatient medical errors that have become a focus of patient safety. But eMAR has little connection to the outpatient prescribing infrastructure; such transactions are billed under Medicare Part A (inpatient services). The Centers for Medicare and Medicaid Services accounts for these drug costs as part of hospital spending, not pharmaceutical spending.

Over time, drugs prescribed and administered in physician offices, infusion centers, hospitals, and long-term care facilities will begin to be included in patients' EHRs. There is plenty of room to improve health care processes by combining that information with the outpatient medication history. But such integration will depend on the longer-term interoperability of health information systems. In the short run, the different types of pharmacy systems will remain independent of each other.

- The pharmaceutical manufacturer, which develops and then markets drugs to patients, doctors, and those who influence the design of formularies.
- The pharmaceutical wholesaler, which is an intermediary between manufacturers and retail pharmacies for the distribution of medications.
- The plan sponsor (health insurer, employer, or government payer), which pays most of the retail cost of prescription drugs and works closely with a PBM to develop the benefits plan. Plan sponsors are increasingly involved in promoting eRx.
- The information technology vendor, which supplies electronic networks for claims or benefit transactions, pharmacy management systems for workflow in the pharmacy, and databases that contain clinical information about medications.

When a patient comes to the clinician with a constellation of symptoms, two out of three visits result in a prescription being written.[6] The prescription can be handwritten on the traditional pad and carried by the patient to a pharmacy to be filled, the clinician's office can send the script directly to a pharmacy by phone or fax, or the office can send it electronically. In some cases, the dispensing pharmacy may be a mail-order facility.

The retail pharmacy plays multiple roles. It:

- Provides quality assurance. A pharmacist reviews the prescription for accuracy and completeness.
- Checks the patient's insurance. The pharmacy electronically routes the prescription through a computer that "cleans" the document by checking codes against parameters such as the pharmacy's identity and location. Once it is clean, the script is sent electronically to the PBM or managed care organization via a network that also conveys patient eligibility, formulary, and payment information.
- Serves as the patient's or PBM's proxy. The pharmacist communicates with the physician's office to arrange a change in the prescription so it matches a formulary better, and, if possible, to get the patient a lower co-payment.
- Collects payment from the patient, be it a co-pay, co-insurance, full cash, or credit-card or debit charge.
- Fills the prescription.
- Educates the patient about how to take the medication.

Patients, prescribers, and pharmacies are obvious players in the way a prescription is handled. But others also influence the processing and financing of prescription drugs. These include PBMs, manufacturers, wholesalers, drug-plan sponsors, and information technology vendors.

Pharmacy Benefit Managers

PBMs are specialized insurers and administrators responsible for funding and administering the pharmaceutical portion of patient care on behalf of health insurers and employers. They have played a growing role in the prescribing process in the last 15 years. The three largest PBMs—Medco Health, Caremark, and Express Scripts—manage prescription drug benefits for more than 150 million patients.[7] At one time, PBMs simply administered insurance claims; today, they play an active role in overall prescription-drug management. Payers, such as employers and health plans, enlist PBMs to tighten cost controls and manage drug utilization. PBMs' many roles include:

- Contracting with pharmacies to create a broad network of pharmacies that patients and enrollees can access;

- Communicating policies among health care providers, employers, and patients;
- Verifying patient-enrollee eligibility;
- Maintaining formularies and preferred drug lists;
- Drug utilization review;
- Claims processing;
- Reimbursing providers and patients;
- Creating strategies for cost and utilization controls; and
- Directly dispensing drugs via their mail-order pharmacy operations.

Pharmaceutical Manufacturers

These companies distribute the brand-name and generic drugs they make primarily through drug wholesalers, but they also sell directly to large retail pharmacies, hospitals, and other bulk purchasers. Among the biggest drugmakers are Pfizer, Merck, and GlaxoSmithKline. The nature of the health care market requires that manufacturers aggressively compete and negotiate favorable positions for their brand-name drugs on PBMs' formularies to ensure that patients have access to the manufacturers' products at the most favorable co-payment tier. Drug companies market their products to physicians and other prescribers using direct-sales forces known as detailers.

Wholesalers

In the distribution system, wholesalers are middlemen between manufacturers and retail pharmacies; they manage inventory and supplies. Wholesalers operate on slim profit margins. Three big wholesalers—McKesson, Cardinal, and AmerisourceBergen—dominate the market. Several of the larger retail pharmacy chains operate their own distribution systems.

Plan Sponsors

Plan sponsors, also known as payers, include employers and other patient aggregators, such as private and commercial health insurers; the federal government (Medicare, the Department of Veterans Affairs, and TRICARE); and state governments (Medicaid). These payers are involved in prescribing because they often cover at least some of the cost of prescription drugs. Their influence on the prescribing process is growing in several ways.

First, plan sponsors are working more closely with PBMs on two fronts: to modify prescribing—that is, alter physicians' prescribing behavior and consumers' fill and refill behavior through formularies and benefit-plan design so they will use or not use certain drugs—and to integrate beneficiaries' use of medications with disease management programs. Second, plan sponsors increasingly are helping physicians with the cost of purchasing, learning how to use, and operating eRx technology.[8] And third, the introduction in 2006 of a Medicare-funded prescription drug benefit, aside from moving significant numbers of seniors (and their prescriptions) into formulary programs that are at least somewhat similar to current PBM programs, will involve federal standards that ePrescribers must comply with. These standards probably will be extremely influential.

Information Technology Vendors

There are three types of information technology vendors that play a major role in the way prescribing currently takes place. One is those that offer private, information-transaction networks that connect nearly all pharmacies so the pharmacies can exchange information. These companies also serve as information clearinghouses. They are the "switch" in prescription processing. As a result of mergers in the late 1990s, NDCHealth (purchased by Per-Sé Technologies in 2005) and Emdeon/Envoy are the two largest vendors.

The second type of information technology vendor are those companies that provide pharmacy management systems, both hardware and software, to retail pharmacists for managing workflow. Pharmacists type most of the information on paper prescriptions into these systems, although most systems can also accept electronic scripts. The systems are integrated with the "switch." Two major vendors are QS/1 and McKesson Pharmacy Systems.

The third type are companies that supply databases containing clinical information about pharmaceuticals. The databases are reference tools used during utilization review, particularly to check for drug interactions. They also contain information about each drug's average wholesale price, which the industry uses as a reference for pricing. The dominant players in this market are First DataBank, Medi-Span, and Multum. Most vendors of pharmacy software, eRx, and EHRs include such databases in their applications.

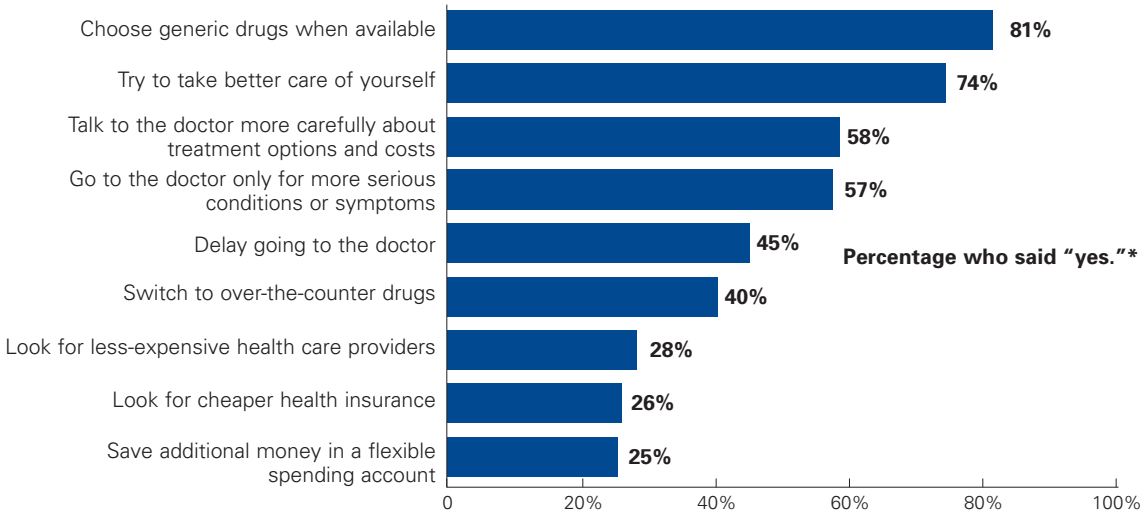
What is a Refill? What is a Renewal?

A refill is the continuation of an existing prescription; the physician might add two automatic refills to a typical 30-day prescription. In such cases, there is no need to contact the physician for a refill.[9] When a prescription does not have any remaining refills or has expired, a renewal prescription is necessary. In these instances, the pharmacy or patient must contact the physician.

Prescription renewal often is a taxing process that involves considerable communication among the pharmacy, the physician's office staff, and the physician. Most communications take place by phone or fax.

Figure 2. Higher Costs Prompt Patients to Change Behavior

"Has increased spending on health care expenses in the past year caused you to…?"



* Number of respondents = 594.

Source: 2004 Employee Benefits Research Institute Health Confidence Survey

Controlling Prescription Drug Costs

Pharmacy benefit managers (PBMs) and health plans use a number of strategies to control prescription drug costs. One is the drug formulary—essentially, a list of preferred medications. Physicians working in hospitals, health plans, and physician groups who are under contract with health plans, PBMs, government agencies, and self-insured employers recommend drugs that, in their clinical judgment, should be on the formulary.

Hospitals, health plans, and other providers establish formularies based on recommendations from pharmacy and therapeutics committees, which comprise practicing physicians and sometimes pharmacists. These committees meet regularly to develop and update the formulary after reviewing the clinical literature to determine which drugs are likely to produce optimal results for patients. If two or more drugs are therapeutically equivalent, then cost-effectiveness also is a consideration.

Formularies are "closed" or "open." A closed formulary means enrollees have access only to a limited number of drugs: the payer generally reimburses only for medications on the formulary, but it will pay for others under certain circumstances. An open formulary typically contains many more drugs that can be prescribed without any financial penalty to the consumer.

Benefit plans incorporate "tiered formularies," in which different tiers of drugs require different co-pays. Many plans use four tiers. The first tier comprises generic drugs with the lowest co-pay, the second comprises "preferred brand" drugs with a higher co-pay, the third includes brand-name drugs that are not preferred and that require a still-higher co-pay, and the fourth comprises "lifestyle-enhancing" drugs. Such a drug might require a 50 percent co-insurance payment from the enrollee.

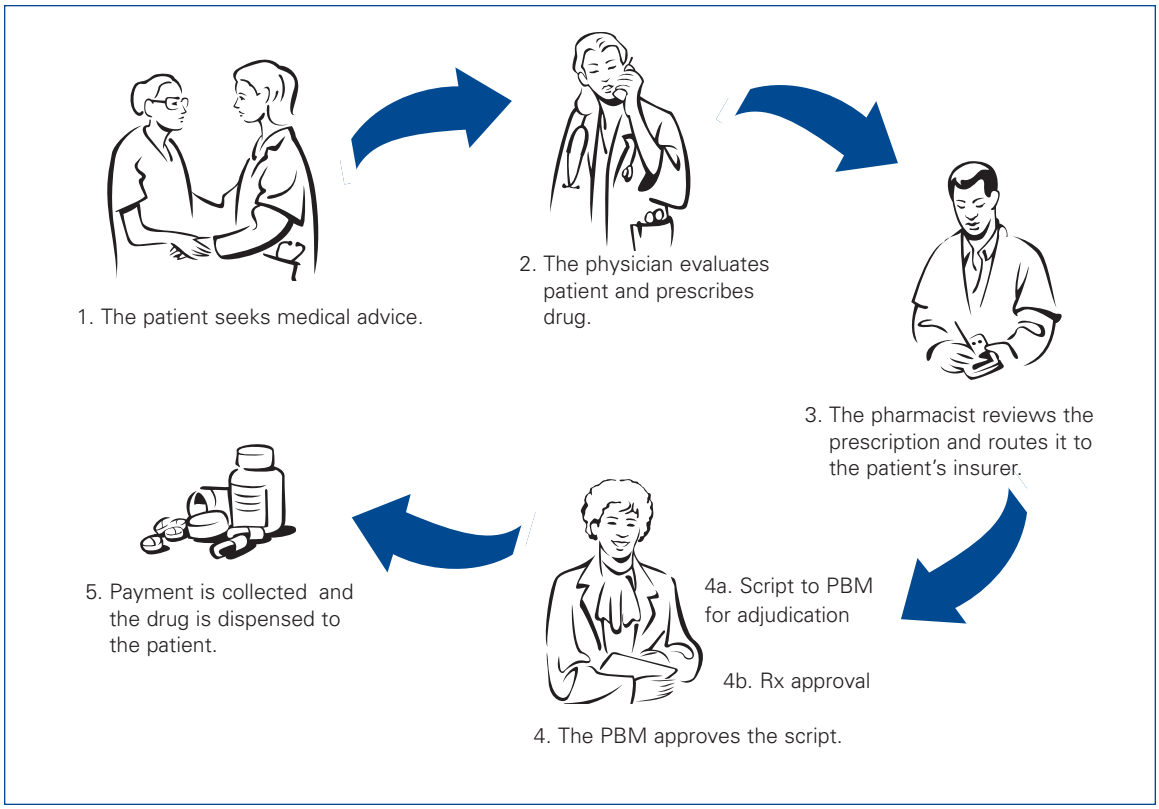
PBMs and health plans use tiered formularies to control drug utilization. The patient has an economic incentive to choose a generic substitute rather than a brand-name drug because the co-pay for a generic is less (see Figure 2 on page 8). However, higher co-pays also can discourage patients from filling a prescription, re-filling an existing prescription, or taking a drug as frequently as prescribed. For example, patients may split pills or skip a dose.[10]

Prior authorization is another cost-containment tool. It limits enrollees' access to prescription drugs by requiring that the prescribing physician get the approval of the health plan or PBM for a medication that is not on the formulary. An increasingly common approach in prior authorization is step therapy: the physician must first prescribe an older, lower-priced drug before getting permission to prescribe a newer, generally higher-priced treatment.

A third, very widespread strategy is substituting generic drugs for chemically identical but more expensive brand-name medications. Both the generic and brand-name products have been approved by the Food and Drug Administration, which has deemed them interchangeable. Once the patents on brand-name products expire, they can be manufactured as generics and are usually sold at substantially lower prices. In many states, pharmacists are allowed to substitute a generic without notifying the physician; Medicaid and other payers often require such substitutions. Therapeutic substitution, wherein the pharmacist replaces a brand-name drug with an alternative brand that is in the same therapeutic category but not exactly equivalent, is not permitted unless a physician requests it.

A fourth strategy—the preferred drug list (PDL)—is one that states use in their role as Medicaid payers. Most states are aggressively developing a PDL because Medicaid programs, which face severe budget deficits, view prescription drugs as a prime target for cost containment. Even though all medications on a state's PDL are available to Medicaid beneficiaries, the program may require prior authorization. Utilization data and the availability of regular and supplemental rebates from manufacturers are considerations when a state decides which drugs to put on its preferred list.

Figure 3. Prescribing 101



The Prescribing Process

Prescribing starts and ends with the patient. Figure 3 shows how a new prescription is processed.

Before patients visit a physician or other prescriber for medical advice, they often see or hear direct-to-consumer advertisements on television or the radio, in newspapers, or on the Internet. These ads promote brand-name prescription drugs and raise awareness of diseases.

During an office visit, the physician-prescriber evaluates the patient and prescribes a drug appropriate for his or her symptoms and other pre-existing conditions. The patient can take the prescription to a retail pharmacy, the physician-prescriber's office can call or send it in by phone or fax, or the patient can send it to a mail-order fulfillment house.

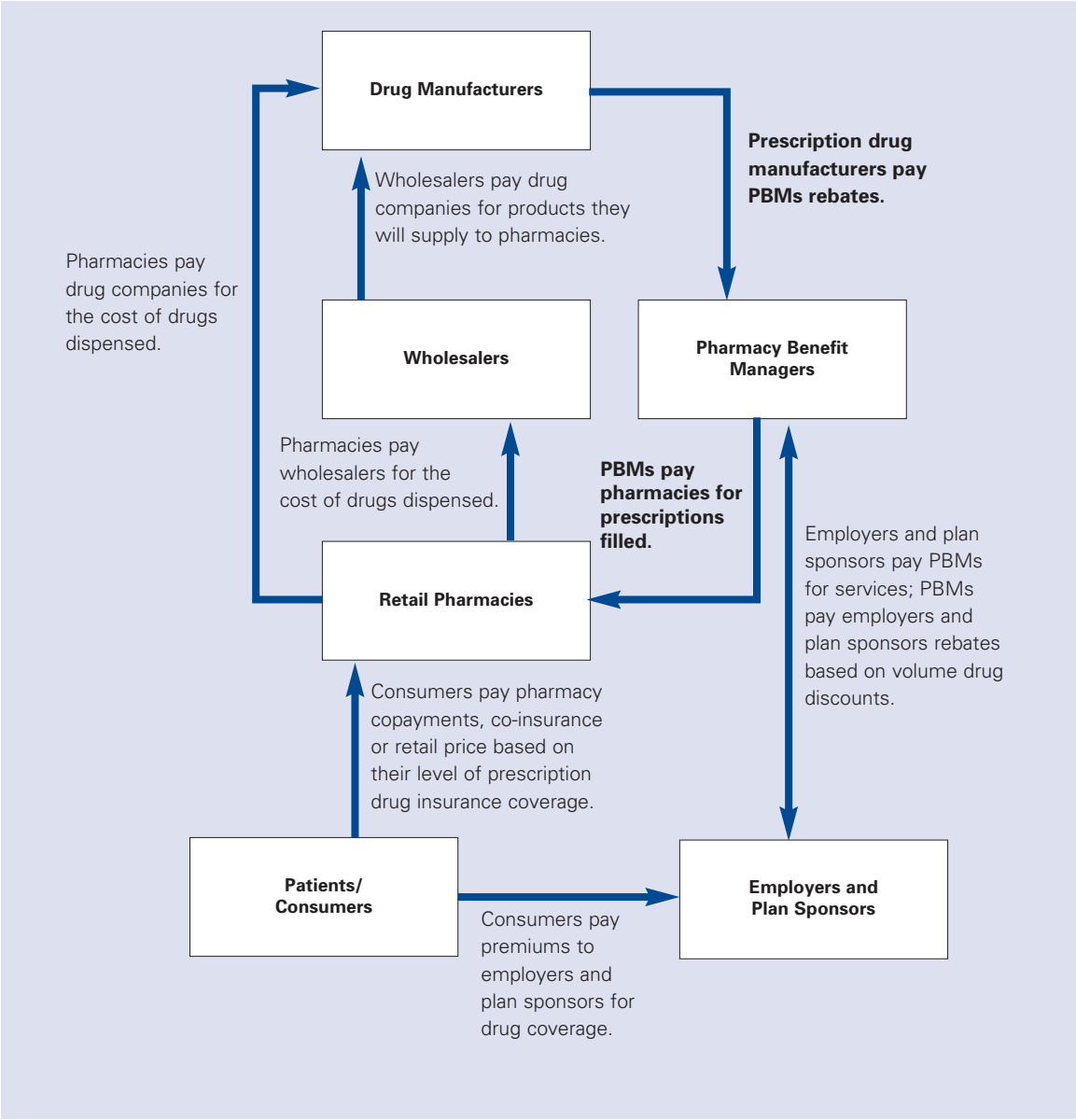
A pharmacist reviews the prescription for completeness and accuracy. Then the script is entered into a pharmacy management system, which electronically routes a claim to the patient's third-party insurer (usually a PBM) for adjudication, typically using the "switch." The PBM approves the prescription and communicates information, including the patient's co-pay and how much the pharmacy will be reimbursed, back to the pharmacy.

Once the PBM approves a drug, the pharmacist fills and dispenses the prescription, and collects payment from the patient. The pharmacist also gives the patient information on how to take the drug. At this point, the pharmacist can provide additional counseling to bolster the patient's compliance with the prescribed therapy and address any other questions he or she may have.

II. Prescription Economics

THE PRICING OF PRESCRIPTION DRUGS IS complicated. Figure 4 illustrates the complex distribution chain through which a drug passes from its original manufacture to the pharmacy for dispensing.[11] Along the way, a drug is repriced before it finally reaches the patient. Different terms describe the cost of a drug at each point in the chain.

Figure 4. The Economics of Prescribing



Pharmaceutical manufacturers distribute their products primarily through drug wholesalers, but they also sell to individual pharmacies, pharmacy chains, hospitals, and others. Wholesalers purchase drugs from manufacturers based on the average wholesale price (AWP), which is published by commercial sources such as First DataBank, Medi-Span, or the Red Book. AWP is based on wholesale pricing information that drug manufacturers provide to the publishers. It is akin to a suggested retail or "sticker" price, but is not generally paid, as purchasers try to negotiate lower prices through discounts, rebates, and free products. The cost that wholesalers pay for drugs from manufacturers is the wholesale acquisition cost (WAC). However, the price they ultimately pay may be the WAC or a lower, negotiated price.

As intermediaries between manufacturers and pharmacies, wholesalers set their selling price using a "cost plus" or a "list price less" formula:

Cost plus = WAC + a percentage mark-up
or
List price less = AWP – a percentage discount

Well before a patient presents a prescription to the pharmacy, the PBM has negotiated with the pharmaceutical manufacturer about the drug's price and position on the PBM's formulary. In these negotiations, the objective of a manufacturer is to achieve the most favorable status on the PBM's formulary for that drug. The PBM, on the other hand, seeks a favorable—that is, discounted—price for the drug. The result is a rebate formula to which both parties agree—in effect, a volume discount. The rebate is then calculated and the manufacturer pays that amount to the PBM, which in turn distributes rebates to its health-plan and employer clients.

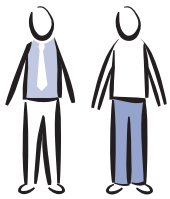
PBMs have become the hidden giants in the current prescribing infrastructure (see page 14). They sell their services based on their ability to reduce drug costs for clients. Typically, PBMs do not bear risk; rather, they provide three services to health plans and employers:

- Transaction processing, including managing the eligibility files, benefits information, and payments related to prescriptions.
- Network and formulary management, such as negotiating drug prices with both manufacturers and pharmacies, and ensuring that the most cost-effective and most appropriate therapies are available to beneficiaries. The PBM controls costs by means of generic substitution, prior authorization, step therapy, compliance programs, and other techniques, all of which tend to add administrative complexity to the prescribing infrastructure.
- Mail-order pharmacies, which usually supply less-expensive, 90-day supplies of medications to beneficiaries who have chronic medical conditions.

The amount of the co-pay or co-insurance payment after a prescription has been filled is predetermined by the patient's prescription benefit plan. The full cash amount paid by an uninsured consumer (including the Medicare-eligible patient who does not have prescription drug coverage) is referred to as the "usual and customary price."

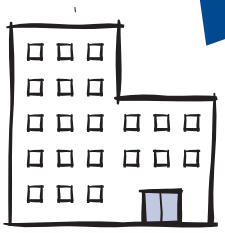
The pharmacy receives payment from the PBM and from payers that have covered the patient's prescriptions filled by that pharmacy. In a computer run at the end of each payment cycle, the PBM generates an analysis of all reimbursements it owes to the pharmacy. It typically pays the pharmacy via wire transfer.

Figure 5. How Money Flows Through the Prescribing Process

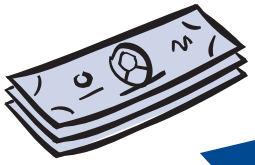


1. The PBM/managed care organization (MCO) negotiates with the pharmaceutical manufacturer regarding drug pricing and formulary position. As part of the formulary-positioning negotiation, the two parties agree on a rebate formula.

2. The physician writes a prescription for the patient. The pharmacy receives the Rx and electronically routes it to the PBM for adjudication. Once the Rx is cleaned and approved, the pharmacy receives the first of two payments: the patient's copayment/co-insurance, to be followed later by payment from the PBM.



3. Every pharmacy in the U.S. is associated with a unique identifier in the National Council for Prescription Drug Programs transaction set, assigned by the National Association of Boards of Pharmacy (NABP). The PBM tracks prescription drug sales through the NABP number and aggregates total drug reimbursements by pharmacy.



4. The pharmacy receives payment from the PBM/MCO based on the previously contracted prices for drugs dispensed.

PBM Controversies: Channel-Switching, the Spread, and Rebates

After several mergers, three PBMs now dominate the pharmacy benefits-management market: Medco Health Solutions, Caremark, and Express Scripts. There has been considerable controversy about whether PBMs actually reduce drug costs and how they make money.

One frequent complaint is that PBMs restrict consumer choice by forcing beneficiaries to get their drugs only from the PBMs' mail-order pharmacies.[12] However, the benefit plan sponsor—usually the employer—endorses this restriction, because it is a rational way to control costs and increase efficiency. The major controversies concern PBMs withholding information from their clients about "the spread" and rebates.

The spread is the difference between the price a PBM tells a client it pays for a drug—in effect, the price the client is charged—and what the PBM actually pays the pharmacy. Critics accuse PBMs of paying much lower prices to pharmacies than they reveal to clients, and of giving clients only a small fraction of the extra profit PBMs earn when they dispense a drug via mail order.[13] (Mail-order pharmacies are more profitable than their retail competitors because they buy in bulk and fill many more prescriptions per pharmacist than retail outlets do.)

A rebate is what a pharmaceutical manufacturer pays to a PBM for driving more volume to the company's brand-name product by putting the drug higher on the PBM's formulary. There are two controversies about rebates. First, while PBMs do pass rebate revenues back to their clients, such as employers, the accounting behind this process is extremely opaque and thus very difficult for clients to audit. PBMs commonly have been accused of either shortchanging their clients (health plans and employers) or colluding with health plans[14] to withhold rebates from employers—in effect, keeping drug prices higher than they need to be.[15]

The second controversy concerns rebate agreements between PBMs and drug manufacturers. According to some critics, such agreements are essentially bribes for PBMs to create formulary incentives or campaigns that favor brand-name products over cheaper generic equivalents.[16]

In 2003, when Senator Maria Cantwell (D-Washington) suggested that PBMs should be forced to reveal information about these contracting arrangements if they wanted to participate in Medicare Part D, PBMs strongly objected.[17] They said that releasing such information would prevent them from contracting on behalf of clients, but cynics drew a different conclusion.

Partly encouraged by a lawsuit in Illinois,[18] the "transparent PBM movement"—a slowly emerging coalition that includes a breakaway group of employers led by Hewitt Associates[19]—will push PBMs to do three things: rely less on the spread and rebates, boost revenue instead by switching fulfillment to the PBMs' mail-order pharmacies, and promote generic substitution more aggressively.

III. The Prescribing IT Infrastructure

ALTHOUGH THE PRESCRIBING PROCESS IS serpentine and depends on many variable communications, some elements have been standardized and automated. These include computer systems that support the internal workflow at pharmacies, and electronic transaction processing between pharmacies and payers. As it stands now, most automated tasks occur after pharmacies receive prescriptions from physicians.

After a prescription reaches the pharmacy, a pharmacist or pharmacy technician manually checks it for completeness and accuracy. The pharmacist then manually enters or scans the script into the pharmacy management system. The computer routes it to the payer, typically via the "switch," for adjudication by the patient's prescription benefit plan.[20]

The pharmacy management system is the central software that virtually all retail pharmacies use. It is a workflow system that provides a to-do list for pharmacists and for the clerks and technicians who work with them. It also contains various databases necessary for managing and operating a pharmacy, including data about drugs and drug interactions, physicians, patients, and insurance. In addition, modern pharmacy management systems are integrated with a barcode checking system that ensures the right drug is dispensed to the right patient. A typical management system can scan a new prescription, assign it a barcode, and require that the pharmacist check the prescription against the barcodes on the big pill bottle from which he or she fills the order, and on the small pill bottle and paper bag the patient takes home.

Pharmacy systems connect or integrate with other systems, such as the interactive voice response system most pharmacies use to accept refill requests; with Web-based refill ordering; and, increasingly, with orders from eRx applications in physician offices. Pharmacy systems also trigger automated filling and "unit of use" dispensing (i.e., dispensing of prepackaged drugs, such as birth-control pills), and typically interact with the point-of-sale system that does the accounting at the cash register. Finally, these systems interact with the "switch."

In general, most pharmacies purchase such systems as a standard software package, although a vendor may host the application as an application service provider. Some wholesalers, such as McKesson, own pharmacy system vendors, and may subsidize the cost of these systems as part of a wider distribution agreement with pharmacies.

Using a combination of dedicated data lines, virtual private networks connected to the Internet, and traditional electronic data exchange, claims information is sent directly to payers. The cost of doing this, usually borne by the pharmacy, is 6 to 10 cents per claim.[21] The two largest networks, owned by Per-Sé Technologies (formerly NDCHealth) and Emdeon, handle the bulk of these transactions, but the networks also offer other services, such as pre- and post-transmission claims checking and editing. Sometimes the pharmacy handles these functions, in which case the pharmacy-system vendor often bills for them.

The adjudication process determines the formulary status of a prescribed drug, the patient's co-pay, and whether the PBM or health plan requires prior authorization for that medication. The pharmacist contacts the physician-prescriber's office by phone or fax if there are any problems with the script. Frequently, the physician's office must issue a new prescription, which is sent by phone or fax to the pharmacy for adjudication and, ultimately, filling and dispensing.

Communications between pharmacies and physician offices account for an estimated 25 percent of pharmacists' time[22] and for up to 20 percent of the workload of physician-office staff.[23] Although faxes and interactive voice response have helped somewhat, phone calls and phone tag to clarify information are generally the rule. Moreover, communication between the prescriber and his or her office staff often is poor, may rely on Post-it Notes, and requires that charts be pulled. ePrescribing has the potential to significantly reduce inefficiencies between the pharmacy and physician's back office as well as within the physician's practice.

IV. Forces Driving the Automation of Prescribing

SEVERAL MARKET AND TECHNOLOGY FORCES in the last decade have been propelling a trend toward greater automation of the prescribing process. These include:

- The growing domination of retail pharmacy by increasingly automated chain stores—including nonpharmacy giants such as Wal-Mart and Safeway—that are fast replacing mom-and-pop independents.
- Automation of central distribution by wholesalers and large retail chains, similar to inventory management in the broader retail sector.
- The increasing number of Americans who have third-party drug benefits, mostly under PBM contracts.
- Fewer large PBMs serving as consolidated purchasers. To control prescribing choices, these PBMs are instead making greater use of formularies. They also are directing more prescriptions to their own, highly automated mail-order pharmacies, a practice known as "channel switching."
- Automation of adjudications between pharmacies and payers using the "switch."

Recently, there has been greater focus on "the final mile" of the prescription process—namely, the transactions between physician and pharmacy that have yet to be widely automated. In this part of the ePrescribing process, caregivers use point-of-care software to write and transmit prescriptions via a proprietary network. The software may be installed on a handheld device or computer, and may be a stand-alone application or a module in an EHR. Some legacy systems just print out a paper prescription or fax it to a pharmacy. eRx systems, in contrast, transmit the information electronically to a pharmacy management system.

Adoption of handheld eRx tools and EHRs by physicians has had several false starts in the last decade. But numerous factors are now reshaping the drug prescribing process and the technology that makes eRx possible:

- The prevalence of medication errors, cited in the 1999 Institute of Medicine report titled "To Err is Human," has greatly raised public and policymaker awareness of patient safety. Using computerized order entry for inpatients and eRx for outpatients to eliminate the fallibilities of handwritten prescriptions is a big part of the solution to this problem, according to eRx proponents.
- The Medicare Modernization Act of 2003 will encourage eRx. It mandates that standards for eRx transactions between Medicare plan sponsors and physicians be in place by 2008 for Medicare-funded prescriptions.
- The growing pay-for-performance movement gives clinicians greater incentive to use eRx and EHRs (the latter typically incorporate eRx).
- Large pharmacy chains and PBMs have made significant efforts to provide a network infrastructure for eRx. This will enable them to take advantage of potential efficiencies when eRx becomes more widespread.
- Technology innovations, cost cutting, pressure from payers, and a new generation of physicians are driving the adoption of EHRs, especially by doctors in large medical groups. The consolidation of EHR vendors has given buyers greater confidence in the companies that have survived.
- Several insurers and technology vendors have teamed up to provide low- or no-cost eRx applications to physicians.
- More vendors of health care information technology are embracing open-systems standards, which boost interoperability among different products.

For these reasons, there has been a dizzying array of product and service announcements regarding eRx. However, gaps remain between the current and the ideal eRx infrastructure.

V. Opportunities and Obstacles

WHY MOVE TO ELECTRONIC PRESCRIBING? FOR more than a decade, using eRx in that "final mile" between the physician's office and the pharmacy has been touted as a way to streamline workflow. In addition to greater efficiency, proponents argue, eRx improves formulary compliance and generic substitution (gains that are reaped mostly by PBMs and payers), patient safety (thanks to more-accurate drug fills), and compliance with chronic-care treatment regimens that enhance health outcomes.

Still, adoption remains low. According to a 2005 study, only 14 percent of physicians use any kind of eRx, and 62 percent of those are in group practices.[24] Doctors are notoriously slow to adopt technologies that do not immediately generate revenue or save time. They have not been receptive to the promise that eRx will generate efficiency-related savings.

But there are several reasons eRx is becoming increasingly attractive. First, potential cost savings at the pharmacy and an opportunity to generate savings through better enforcement of formulary compliance have spurred the formation of two large networks: RxHub and SureScripts. The three biggest PBMs own RxHub, which transmits eligibility, formulary, and benefit information from those PBMs to point-of-care applications in doctor offices, and transmits electronic prescriptions to the PBMs' mail-order pharmacies. Major pharmacy organizations own SureScripts, which enables electronic scripts to be sent from point-of-care applications directly to pharmacies. While not every vendor, pharmacy, and payer is connected to these networks yet, and while not every transaction is ready for prime time, progress in the last two years suggests that RxHub's and SureScripts' *de facto* network standards will dominate when most of the players in the prescription arena eventually join the fold.

Second, adoption of EHRs is gaining traction; after decades of promise, adoption has become a matter of "when," not "if"—at least in large medical groups. Pay-for-performance incentives from health plans, employers, and now Medicare reward physicians for investing in information technology. Meanwhile, particular vendors have become market leaders among the companies that sell mostly to large physician groups. While not

all vendors have fully integrated their eRx modules with the emerging ePrescribing infrastructure, product development is converging, partly because buyers are demanding it.

Third, technology continues to get better and cheaper. Five years ago, handheld devices had to be put in a cradle and synchronized with a server, data storage was expensive, and wireless networks were yet to come. All that has since changed. The development of smart phones, the relatively cheap cost of wireless broadband, and better interfaces for both EHR and eRx applications make it easier and less expensive for physicians to accept technology that is becoming more familiar to them.

Fourth, payers are helping out with the cost of eRx. Several health plans and PBMs are subsidizing the deployment of eRx applications in physician offices. Federal law was explicitly changed to exempt this activity from restrictions that do not allow health care organizations to give physicians goods or services that might be construed as kickbacks. In addition, hospitals are beginning to offer clinical information technology—typically EHR systems—to community-based doctors.

Fifth, success stories create positive buzz. Although still relatively few, physician practices that have adopted EHRs and eRx are starting to see some savings—if not in reduced staff, then at least in reduced overtime and telephone callback hassles. eRx evangelism is beginning to spread among physicians.

Finally, patient safety and compliance are becoming more important to providers and payers. While this is not a decisive issue, doctors are feeling pressure from payers, malpractice insurers, the government, and the public to improve their overall use of information technology, especially as it applies to patient safety.

Nevertheless, obstacles remain. Not the least among these is the general perception among physicians that few benefits will accrue to them if they adopt eRx. Also, cost is problematic for small physician groups. And many physicians still are hesitant to trust hospitals and payers that offer technology support, given the oftentimes rocky business relationship between doctors and hospitals/payers in the 1990s.

Another obstacle—especially for small group practices—is the lack of a clear roadmap for integrating the stand-alone, relatively cheaper eRx applications, which may soon become obsolete, into more-expensive EHR applications. Data standards, legacy systems, and vendor turf battles still are problematic.

A handful of large vendors are marketing EHR applications to large group practices, but most companies that offer eRx are small and have little market penetration. For physicians, this raises a question: why buy products from these small companies if, like their dot-com predecessors, they may vanish tomorrow? Consolidation in this industry fuels physicians' uncertainty, such that potential buyers may decide to wait until clear winners emerge.

Yet another hurdle is getting physicians to understand the long-term business implications of adopting eRx. While studies may show that doctors and their staff can save time on calls to the pharmacy, taking a few such calls over the course of a day might not seem terribly onerous. There is also the dislocation that adopting a new technology could cause. The learning curve, disruption of staff routines, and cutting into precious time for patient care are frightening propositions for a physician who runs a small business.

VI. The Ideal eRx World

ASSUMING THAT A SIGNIFICANT NUMBER OF physicians begin to use eRx, what would the ideal ePrescribing world look like?

In one scenario, a physician might prescribe a drug for a patient using a handheld device running an eRx point-of-care application. The application already would have checked with the patient's insurer to see if he or she is eligible for the drug, provided the correct formulary information, performed safety checks against the patient's current medication history, and provided information about the likely co-pay. The patient could choose the pharmacy, and the physician would then route the script to that pharmacy's management system.

Alternatively, if a patient needed to renew a prescription, the pharmacy management system would alert the physician's point-of-care application and the script would be issued after the physician reviewed it for any necessary changes and confirmed the order.

In both cases, the patient should be able to pick up the drug without any further communication between the pharmacy or other third parties, except for automatic adjudication with the payer.

Both the physician and his or her office staff could monitor workflow—new prescriptions as well as renewals—through their eRx application. They would decide "who does what" in terms of creating prescriptions, getting renewal authorization, ordering changes, and submitting scripts to the appropriate pharmacy. These tasks would likely be integrated with the physician's practice management system, which would deliver a patient's schedule and allow the physician to review that patient's information before a visit. Loaded into the eRx application, this information might include the selected medication; drug utilization review; drug interactions (and any drug-related allergies the patient may have); eligibility; information about the formulary, benefit, and co-pay; and the location of the preferred pharmacy.

The objective is to preclude the need for multiple conversations among the physician, pharmacist, physician-office staff, and patient if a prescription-related problem arises. If, for

example, a particular drug were not on the formulary, the system would alert the doctor during a patient visit, enabling them to discuss other appropriate choices based on the most accurate information available.

The management system at a pharmacy would receive clean scripts directly, saving the time and labor associated with orders taken manually. When the pharmacy communicates with the PBM to adjudicate a claim, the likelihood of a claim being approved the first time would be substantially greater because most preapproval issues would already have been resolved, before the physician's office sends the electronic script. Consequently, dramatically fewer call-backs to the physician would be necessary.

VII. The Future

When the eRx infrastructure has fully evolved, prescriptions will be transmitted from the point of care to the pharmacy on networks owned by companies such as SureScripts, NDC, ProxyMed, and Emdeon. Up to 85 percent of pharmacies are linked to SureScripts and about 45 percent of those accept eRx.[25] RxHub already connects to PBMs' mail-order houses.

Using RxHub, which its owners are marketing in hopes of recruiting more payers to the network, the three largest PBMs can get information about eligibility, formularies, and benefits for 70 percent of the U.S. commercial population.[26] According to the Centers for Medicare and Medicaid Services, by using current pharmacy "switches" Medicare Part D will also be able to deliver such information, at least some of which will make its way into the eRx world.

RxHub gives physicians current and past medication history and information about drug interactions, so they need not rely on patients' memory or possibly incomplete paper records to know which medications patients are taking. This has obvious benefits for patient safety.

Combining information about eRx ordering with information about current and past drug dispensing will enable eRx vendors that work with pharmacies and PBMs (via RxHub) to determine if patients are actually taking their medications as prescribed. Vendors could relay that data to physicians to help doctors improve their patients' compliance.

All of the above-mentioned information sources and capabilities are being integrated into point-of-care technologies. These technologies include stand-alone eRx applications, such as DrFirst Rcopia, Zixcorp's PocketScript, and iScribe, and EHR applications that contain an eRx module, such as Allscripts, NextGen, and eClinicalWorks.

Will Medicare Part D Enhance or Hinder ePrescribing?

Medicare prescription drug coverage, the core part of the Medicare Modernization Act, began in January 2006. This complex program offers a raft of competing incentives to seniors and their current plan sponsors (especially corporations that provide drug coverage to retirees) to move into the new Part D coverage, stay with their existing coverage, or enroll in a private, Medicare-sponsored managed care plan. Seniors still are confused[27] about the options and which plan and benefit choices they should make or will have made for them.[28]

The organizations that will run the new program and that will have signed up to offer a prescription drug plan (PDP) are likely to include all of the major PBMs, as well as many national and regional managed-care companies and several insurers that provide supplemental Medigap coverage. These plans will use existing pharmacy transaction networks for benefits processing. The law also gives PDPs a big role in administering—but not necessarily creating—formularies and benefits.

However, many benefit plans, including most of those in the private sector that provide supplemental drug coverage under Medicare, do not use eRx. Moreover, a proposal in the House version of the bill that would have forced physicians to use eRx for Medicare Part D was amended in the final version, such that PDPs need only be capable of accepting typical eRx transactions in accordance with new standards the Centers for Medicare and Medicaid Services released earlier this year. A pilot program will test the standards, which will be issued in April 2008 and become mandatory in April 2009. But given the turmoil that the Health Insurance Portability and Accountability Act of 1996 created with its timelines, those target dates may well be pushed back.

Much to the dismay of major eRx players, these new federal, mandatory transaction standards will not pre-empt state regulations and will only apply to drugs and patients covered under Part D of Medicare. There are few signs that the standards will extend to, or integrate directly with, Medicare Part B, Medicaid, or mainstream health plans in the private sector.

Important questions regarding Medicare Part D and its impact on eRx include these:

- How big will the program be and what portion of seniors will join PDPs?
- Will the current PBMs be the dominant PDPs?
- Will Medigap plans and managed care companies participate in eRx networks such as RxHub?
- How will PDPs, pharmacies, and eRx vendors convey information to each other about benefit use, such as true out-of-pocket cost and the Medicare coverage gap?

At this early stage, the authors predict that because of Medicare Part D's benefits and incentives, a moderate portion of Medicare recipients will join the program, and that the PDPs and the remaining non-PDP Medigap plans will eventually join the large electronic networks that support eRx. Given seniors' heavy use of pharmaceuticals, this will boost the pressure from pharmacies and payers for eRx. Finally, safe-harbor regulations in the Medicare Modernization Act will allow physicians to accept eRx technology from health plans and other third parties.

Because of uncertainty about the extent of participation in the new program and about the prevailing standards for eRx (not to mention the fact that ePrescribing remains voluntary), the eRx market will not feel the true impact of Medicare Part D for two to four years.

Improving Compliance and Chronic-Care Management

If eRx becomes widespread among physicians, it will offer many opportunities to improve American health care, even in the absence of other data about patients. Patients who have chronic diseases commonly take several prescription drugs, oftentimes inappropriately. eRx can tell physicians if patients are taking their medications.

Many point-of-care eRx applications can combine information from the pharmacy and PBM about medication history and fill rates with their own information about what the physician prescribed. This provides a gauge for compliance with a drug regimen, and gives physicians and their office staff an opportunity to intervene proactively in patient care rather than just respond to patients' requests.

A Role for Incentives

Physicians will migrate to ePrescribing when they perceive that the benefits to their practice and patients outweigh the costs—not just the financial investment, but also the time and hassles associated with start-up. Persuading doctors to abandon the prescription pad and embrace electronic prescribing requires several things:

- The benefits must be apparent.
- Some of the return on investment should be redirected to physicians from PBMs, health plans, and pharmacies, for whom the dividends are clear and quantifiable. This would nudge some physicians to take their first eRx steps. Health plans should develop business models that, beyond giving "free" hardware to doctors, address this early phase. One possibility is for point-of-care eRx vendors to share transaction

Can eRx Work Without EHR?

There is wide disagreement about whether eRx can—or even should—succeed in the absence of a complete electronic health record. A stand-alone eRx application such as DrFirst or iScribe costs considerably less than most EHRs and, when introduced, requires fewer changes in a physician practice. eRx proponents claim that stand-alone eRx applications are an intermediate step to EHRs, which, they believe, are still a decade away from full adoption. However, stand-alone eRx does not offer most EHR features nor most of the patient information that EHRs contain. Some EHR proponents suggest that if stand-alone eRx succeeds, it will ultimately slow the widespread adoption of EHRs.

The truth probably lies somewhere in the middle. Adoption depends to an extent on the relative costs of eRx and EHR applications. Currently, the start-up cost of a stand-alone eRx application ranges from $1,500 to $3,000, excluding a monthly service fee of about $50. Health plans often cover these expenses. In contrast, EHR software alone can cost more than $10,000, and hardware and implementation are much more expensive. By some estimates, up to 40 percent of large group practices have adopted EHRs. The adoption rate is much lower among small practices and not likely to increase much in the foreseeable future.[29]

While physicians generally do not have a good understanding of the road map to eRx or EHR adoption, or of the related technology, workflow, and business models, eRx clearly is an important tool for physicians in small practices who are adopting EHRs. It probably is even more important for them than for physicians in large practices, whose greater concern is reducing the cost of chart pulls and transcriptions rather than fixing prescription workflow problems. Consequently, for the vast majority of doctors in small practices, adoption of these technologies will likely be a collage of stand-alone eRx and EHR. But most physicians, regardless of whether they practice in a large or small group, will continue to postpone the decision and still use paper scripts for at least the next few years.

fees with physicians—that is, to pay them for the electronic scripts they write, based on a carefully constructed reward system.[30] This continuous revenue stream could pay for technology after initial giveaway programs expire.

- Stand-alone eRx applications should provide a clear, practical pathway to an EHR because they are a transitional technology. "Talking about physicians' electronic prescribing independent of the overall EHR is a waste of time," a medical-informatics leader and physician emphasized.[31] "It will not lead to full value from clinical decision support and interoperability." An ultimate objective of eRx is to improve patient safety and care; eRx is much more robust and has greater impact on quality of care when it is part of a larger EHR system.
- Developing a business model to attract physician groups—especially small groups—to eRx would help. Emerging regional health information organizations (RHIOs) might serve as a model for physicians to opt into eRx efficiently. An RHIO could provide information-technology and service-bureau functions to physicians in small practices; those who sign up would receive EHR, service-bureau billing, and support from an application service provider for a modest fee.

Pay-for-performance and pay-for-quality programs are proliferating in both the public and private sectors. Many pay-for-performance programs use rewards for adopting eRx and EHR as key incentives. Furthermore, Medicare Part D will encourage prescription drug plans to offer incentives for reducing medical errors, improving formulary compliance and reducing adverse drug events.

The current state of the ePrescribing infrastructure has been shaped not only by financial incentives, but also by the evolution of clinical practice and information technology, the organization of medical practice, and regulatory and legal constraints. Generally speaking, the pharmacy and payer parts in the prescribing system are among the most automated in health care. There are signs that by mid-2005 many of the above forces will converge and spur greater automation of other aspects of prescribing, as well.

SureScripts has signed agreements with most U.S. pharmacies and pharmacy software companies, enabling them to connect to its transaction network, the largest for eRx. The company expects that more than 50 percent of pharmacies will be on the network by the end of 2005.[32] Among the participating pharmacy chains are CVS, Walgreens, and Wal-Mart, all of them major players.

The Need for Unified Standards

While "interoperability" is a health care mantra at the federal level, there still is much confusion regarding information technology standards. This certainly applies to electronic prescribing. A proliferation of ePrescribing standards across the 50 states, along with vague federal standards for eRx, troubles physicians, pharmacies, and health plans that want to prescribe electronically.

Title I, Section 101 of the Medicare Modernization Act sets "foundational standards" for eRx. Meanwhile, however, state boards of pharmacy promulgate their own eRx rules, which vary among states. For eRx to thrive nationally and for it to achieve interoperability and efficiency, there must ultimately be one unified set of standards. Moreover, these standards must apply to all prescriptions, not just to scripts written for Medicare enrollees. The Centers for Medicare and Medicaid Services has been careful not to overrule state regulations. But variations in state laws and standards have slowed the expansion of eRx, undermined quality, and increased administrative costs. This is one instance in which federal law should pre-empt state law.

VIII. Conclusion

EPRESCRIBING TECHNOLOGIES ARE EVOLVING and penetrating American health care. When effectively implemented, eRx can make physician offices and pharmacies more efficient. However, in debating the future of ePrescribing and hopefully reaching consensus, the primary focus should be on patients—specifically, their health outcomes, their safety, and the quality of care they receive.

The United States has entered an era of convenience pharmacy, shaped in part by consumer demand. This has translated into growth for mail-order and drive-thru pharmacy. It is not likely that patients receive physician or pharmacist counsel in these venues. In the world of increasingly automated prescribing, society must ensure that the education of patients and the support they need to comply with drug regimens and to adopt healthy behaviors do not get lost.

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