

E-Prescribing And The Medicare Modernization Act Of 2003

Paving the on-ramp to fully integrated health information technology?

by Douglas S. Bell and Maria A. Friedman

ABSTRACT: Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 are intended to foster electronic prescribing by requiring standards for interoperability and by permitting third parties to offset implementation costs. Although physicians have been slow to embrace e-prescribing, adoption may increase in 2006, when a new tide of pharmacy messages will arrive from patients entering multi-tier drug coverage under Medicare. However, the e-prescribing systems selected may lack the advanced features needed to improve patient safety and chronic disease control. To optimize the return on Medicare drug spending, the government should consider additional incentives to spur the uptake of more advanced systems.

THE MEDICARE PRESCRIPTION DRUG, Improvement, and Modernization Act (MMA) of 2003 provides prescription drug coverage starting in January 2006. By improving access to medications, the program should improve health outcomes and possibly reduce costs for some health services, such as preventable hospitalizations.¹ Nonetheless, the program's net costs are a major source of concern.

Electronic prescribing systems have the potential to greatly improve the accuracy and efficiency of pharmaceutical use in Medicare. In addition to transmitting orders accurately among prescribers, pharmacies, and health plans, more advanced e-prescribing systems could help physicians avoid prescribing errors, adhere to treatment guidelines, and monitor patients' responses to treatment.² Evidence to support these hoped-for effects remains limited primarily to studies of inpatient order entry at a few academic hospitals.³ However, large effects have been observed with e-prescribing implementation, including an 86 percent decrease in serious medication errors and an increase in formulary adherence from 14 percent to 88 percent.⁴ If commercial e-prescribing systems can reproduce

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Douglas Bell (dbell@mednet.ucla.edu) is a senior natural scientist at RAND in Santa Monica, California, and an assistant professor in the Department of Medicine, David Geffen School of Medicine, at the University of California, Los Angeles. Maria Friedman is a senior adviser at the Centers for Medicare and Medicaid Services in Baltimore, Maryland.

these effects in ambulatory settings, they could greatly improve the quality of outpatient prescribing. On the other hand, one study of an inpatient e-prescribing system identified several ways in which it could increase medication errors, largely because of human-machine interface flaws and poor systems integration.⁵

According to the eHealth Initiative, 5–18 percent of providers use e-prescribing.⁶ Thus, for e-prescribing to benefit Medicare patients, its rate of adoption will need to accelerate. MMA includes provisions to foster e-prescribing through the creation of standards that would increase systems' interoperability and through the removal of rules that could block third-party support of e-prescribing. However, for e-prescribing to influence patients' health outcomes and the overall costs of care, adoption should include more advanced features that would specifically contribute to these effects.⁷ In this paper we review the e-prescribing rules that are now proposed for implementation under Medicare by the Department of Health and Human Services (HHS).⁸ We then review the ways in which these policies might influence the goals of improving patients' health outcomes and controlling health care costs. If e-prescribing policy succeeds in promoting the adoption of systems that are truly interoperable, these systems could serve as a gateway to further system redesign and improvement through the adoption of more advanced electronic health record (EHR) systems.

MMA Provisions

MMA requires that Part D plans support an "electronic prescription program," should any of their providers and pharmacies voluntarily choose to do e-prescribing. This program is required to provide for the electronic transmittal of the following specific types of information among prescribers, dispensing pharmacies, and Part D plans: (1) prescription orders themselves; (2) plan eligibility queries and responses; (3) plan benefit information, including the formulary tier and any prior authorization requirement for a given drug; (4) information on drug interactions, other warnings or cautions, and any dosage adjustments related to the drug being prescribed or dispensed; (5) appropriate lower-cost alternatives, if any, for a drug being prescribed; and (6) the patient's medical history related to a covered Part D drug being prescribed or dispensed.

For each requirement, HHS must promulgate uniform standards that are compatible with existing standards, especially the transactions specified in the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The law requires the issuance of an initial set of standards by 1 September 2005 and the involvement of the National Committee on Vital and Health Statistics (NCVHS) in developing recommendations for them. MMA also requires a pilot project during 2006 to test any standards for which there is not adequate industry experience. Final e-prescribing standards are due by April 2008, with implementation up to a year later.

MMA also protects certain arrangements under which physicians receive sup-

port for implementing e-prescribing technology. Under the Stark physician self-referral statute, certain entities that provide physicians with hardware, software, or training for e-prescribing could be viewed as having a financial arrangement that would bar them from accepting the physician's referrals for a variety of services. MMA authorizes an exception to the Stark rules, enabling health plans, hospitals, and medical groups to provide in-kind support for e-prescribing. MMA also authorizes creation of a "safe harbor" from prosecution under the antikick-back statute, which prohibits any form of payment made for the purpose of rewarding or inducing the generation of federal health care program business. HHS is expected to propose rules that implement these MMA provisions this year.

Standards For E-Prescribing

Following its mandate in MMA, the NCVHS is examining standards for each of the required types of information exchange, as well a number of others (Exhibit 1). MMA called for initial standards to be tested in a pilot project, but it exempted

EXHIBIT 1 E-Prescribing Standards Related To The Medicare Part D Drug Benefit

Function	Standard	Status ^a	Expected effects
Patient selection and data review			
Eligibility inquiry from prescribers and response from plan sponsors ^b	ANSI ASC X12N 270 (inquiry) and 271 (response) v4010, and Addenda ^c	Foundation	Standardization enables any vendor system to work with any plan sponsor
Exchange medication history information ^b	New NCPDP (based on RxHub format) ^d	Potential foundation ^e	Enables decision support to prevent drug-drug interactions, omissions
Exchange medical history information ^b	None proposed	None	Enables decision support to prevent drug-disease interactions, omissions
Prescription generation and safety checking			
Exchange formulary and benefit information ^b	New NCPDP (based on RxHub format) ^d	Potential foundation ^e	Enables formulary adherence, prevents calls from dispenser
Exchange clinical drug information, including drug-drug interactions, warnings or cautions, and dosage adjustments ^b	None proposed; structured product label under development by the FDA	None	Enables decision support
Exchange prior authorization requirements ^b	ANSI ASC X12N 278 ^c	None ^f	Enables more rapid coverage decisions, prevents calls from dispenser
Exchange standardized codes for clinical drugs, dosage forms, and patient instructions	None proposed; RxNorm under development by NLM; "Codified Sig." under development by NCPDP	None	Enables standardized safety checking among different vendor systems

EXHIBIT 1
E-Prescribing Standards Related To The Medicare Part D Drug Benefit (cont.)

Function	Standard	Status ^a	Expected effects
Prescription transmission and fulfillment			
Order transmission between organizations ^b	NCPDP SCRIPT Standard v5.0 ^c	Foundation	Enable interoperability among disparate systems in ambulatory environment ^h
Eligibility inquiry from dispensers and response from plan sponsors ^b	NCPDP telecommunication standard v5.1 and equivalent batch standard v1.1 ^c	Foundation	Eligibility inquiry and response between dispensers and plan sponsors
Security and authentication, e.g., digital signature, PKI	None proposed ^d	None	Enhance public confidence in e-prescribing
Prescriber and pharmacy identifiers	National Provider Identifier (NPI)	None ⁱ	Unique identifier to be assigned by CMS for all prescribers and pharmacies; used to check authentication and for claims
Monitoring and renewal			
Fill status notification	NCPDP SCRIPT	None ^f	Enables nonadherence alerts
Notification of prescription cancellation and changes	NCPDP SCRIPT	None ^f	Enables accurate current medication list

SOURCE: Authors' analysis.

NOTES: E-prescribing functions are organized following a typical sequence of events for new prescriptions, assuming full functionality in the physician's office. In many cases, the functions shown under "prescription generation" can also take place at the pharmacy. ANSI is American National Standards Institute. ASC is Accredited Standards Committee. NCPDP is National Council on Prescription Drug Programs. FDA is Food and Drug Administration. NLM is National Library of Medicine. CMS is Centers for Medicare and Medicaid Services. PKI is public key infrastructure.

^a Foundation standards are those for which "adequate industry experience" makes pilot testing unnecessary. Compliance with these standards will be mandatory from the inception of Part D coverage.

^b Medicare Modernization Act (MMA) requirement for electronic prescribing programs [section 1860D-4(e)(2)].

^c Previously in use as a Health Insurance Portability and Accountability Act (HIPAA) standard transaction.

^d RxHub's proprietary standards for transmitting medication history and for transmitting formulary and benefit information have been submitted to the NCPDP for review and possible accreditation.

^e These standards may be designated as foundation standards if accreditation by a standard-setting body is complete and if there is adequate industry experience with them.

^f While these functions are part of current standards, they are rarely used and thus do not meet the test of having adequate industry experience.

^g Many organizations, especially hospitals, use Health Level Seven (HL7) messaging to transmit prescription orders internally. To improve coordination of care between inpatient and outpatient environments, a harmonization effort is under way to permit bidirectional translation between the HL7 and the NCPDP SCRIPT standards for medication orders.

^h No standards were proposed because the NCVHS determined that the HIPAA standards for security and privacy are an adequate basis for securing electronic prescriptions at this time. S.P. Cohn, letter to Sec. Michael O. Leavitt regarding second set of recommendations on e-prescribing standards, 3 March 2005, www.ncvhs.hhs.gov/050304lt.pdf (23 May 2005).

ⁱ HIPAA rules require the NPI to be in use by 2007. HHS has requested comment on what could be used in 2006 if the NPI is not ready.

from testing any standards for which there is "adequate industry experience."

■ **Foundation standards.** Based on NCVHS recommendations, HHS proposed three "foundation standards" for which industry experience is adequate for adop-

tion without pilot testing. These standards form the basis for HHS's incremental policy to quickly create basic requirements for e-prescribing, to be followed by standards for more advanced functionality as industry experience and technology progress. By creating these foundation standards, HHS is enabling standardized e-prescribing from the outset of the drug benefit. The three proposed foundation standards are (1) ANSI ASC X12N 270/271, for eligibility and benefits inquiries and responses between prescribers and Part D sponsors; (2) National Council for Prescription Drug Programs (NCPDP) SCRIPT standard 5.0, including transactions between prescribers and dispensers for new prescriptions, refills, changes, and ancillary messaging, but excluding the transaction for prescription fill status notification; and (3) NCPDP Telecommunication standard 5.1 for eligibility and benefits inquiries and responses between dispensers and Part D sponsors. In addition, RxHub, a national formulary and benefits exchange, has contributed two proprietary message formats to the NCPDP for possible accreditation as open standards for transmitting formulary information and medication history. HHS has proposed adopting these as foundation standards if they can be accredited in time and if adequate industry experience with exchanging the required information can be demonstrated.

■ **Pilot-testing.** The NCVHS identified a number of additional standards that need pilot-testing (Exhibit 1). Some of these are subparts of existing, widely used standards, but their specific functions are rarely used. As a result, they do not meet the criterion of having adequate industry experience. Examples are the fill status notification feature of the NCPDP SCRIPT standard and the prior authorization feature of the ASC X12N 278. Other standards recommended for pilot-testing are new. For example, the industry has banded together to develop a standard for a structured and codified Sig. (from the Latin *signatura*), which is the part of a prescription containing instructions for the patient, such as "Take one tablet daily."

Another new potential standard is RxNorm, developed by the National Library of Medicine, which provides links from similar generic and brand-name drugs to their active ingredients, components, and dose forms. RxNorm codes could be used as the primary identifiers of orderable drugs in prescription messages, but pilot-testing is needed to see if RxNorm suffices for formulary representation and is interoperable with proprietary coding systems from drug knowledge bases.

Potential Benefits From Advanced E-Prescribing Features

Most of the benefits of e-prescribing for health outcomes and health care costs will depend on advanced features, such as alerts for potentially hazardous prescriptions and reminders for important omitted medications.⁹ However, a field study conducted by RAND has shown that commercially available e-prescribing systems vary greatly in their implementation of these more advanced features.¹⁰

E-prescribing can prevent adverse drug events through patient-specific alerts that warn of potential allergies, drug interactions, and needs for dosage adjustments. However, the value of these safety alerts is undermined if they are fre-

quently triggered for unimportant or erroneous indications. In one widely publicized case, such false-positive alerts were a major factor in the suspension of computerized provider order entry (CPOE) at a major teaching hospital.¹¹ To enable accurate alerts, systems need advanced integration features capable of constructing a complete current medication list and accessing other history information, such as allergies and lab results. RAND's field study found that some form of safety alerting was common among commercial e-prescribing systems, but systems rarely integrated data from external sources to support this alerting. If a new NCPDP standard for exchanging medication history (based on RxHub's proprietary format) can be accredited and vetted for industry experience in time to become a foundation standard, it could increase the value of safety alerting.

Advanced e-prescribing features would also include reminders for prescribers to consider indicated medications that might have been omitted. Serious omissions are frequent for older patients, and computer-based reminders delivered at the point of care have generally been effective for correcting them.¹² However, the RAND field study found that only one of ten systems had implemented any reminders for omitted medications. The development of a standard for exchanging medical history information should eventually help systems identify patients' important prescribing indications, such as diabetes and heart disease.

Patient nonadherence is another problem that causes preventable illness and hospitalizations and that could be addressed by e-prescribing.¹³ The Medicare drug benefit itself should help to alleviate nonadherence resulting from patients' out-of-pocket costs, but nonadherence rates could remain high even for patients with negligible out-of-pocket costs.¹⁴ E-prescribing systems could improve patient adherence by delivering information that helps or convinces patients to take their medications as directed. About half of e-prescribing systems in the RAND study had such features. Claims-based medication history data could also be used to help prescribers identify and negotiate with nonadherent patients, but none of the systems in the RAND study could use claims data in this way. Finally, e-prescribing could address the additional challenge to adherence that will arise from the "doughnut hole," in which patients pay 100 percent of their medication costs. Patients who have an annual drug benefit cap are known to sometimes stop taking medications or stretch doses when they reach their spending limit.¹⁵ E-prescribing systems could display patients' current progress toward the doughnut hole, enabling prescribers to keep some patients out of this zone and to negotiate adherence more carefully for those who enter it. However, none of the systems in the RAND field study had features for dealing with annual spending caps.

Influences On E-Prescribing Adoption

The overall effects of e-prescribing will depend on physicians' and health plans' decisions about whether to invest in it and, if they do invest, on the features of the systems they select. Patients might influence these decisions indirectly if they be-

gin to choose physicians or health plans based on the type of e-prescribing available. Pharmacies—the other actors in pharmaceutical use—may have the least influence on e-prescribing adoption. They are highly motivated because of potential savings in labor, and most have already adopted the systems needed to accept SCRIPT-based prescriptions electronically.¹⁶

Physicians typically expect one of the first benefits of e-prescribing to be a reduction in telephone calls from pharmacies. Industry experts estimate that almost 30 percent of prescriptions require a telephone call from the dispenser.¹⁷ These calls include renewal requests, clarifications, discussions of potential contraindications resulting from the pharmacist's drug utilization review (DUR) process, and notifications regarding coverage problems (such as formulary status). Anecdotal evidence indicates that e-prescribing can save labor in physicians' offices by reducing these calls.¹⁸ One practice reported that reduced pharmacy calls after the implementation of an e-prescribing system saved staff time that amounted to almost one full-time equivalent (FTE) per ten prescribers.¹⁹

Although these efficiencies have not yet compelled physicians to adopt e-prescribing, the volume of pharmacy calls will likely increase in 2006, when millions of new patients will enter Part D plans having multi-tier formularies that could change frequently. To handle this expected increase, physicians would likely need e-prescribing systems that include up-to-date formulary information or, alternatively, some method for dealing with change requests efficiently. Six of ten systems in RAND's field study made some information about formulary status available, but only one system also gave information about the prices of nonformulary options, a feature that would help physicians to negotiate medication adherence with patients who have hit the doughnut hole.²⁰

The expansion of complex drug benefit plans will thrust physicians increasingly into the role of helping patients manage their costs. However, many physicians do not want this potentially time-consuming responsibility.²¹ SureScripts and RxHub, two intermediary networks for e-prescribing, are taking different approaches to this problem.²² RxHub links e-prescribing systems with health plans to make each patient's specific benefit information available at the time prescriptions are created. SureScripts simply transmits prescriptions to the selected pharmacy, leaving the responsibility for checking coverage where it typically takes place today. Although the SureScripts model may entail more follow-up requests from pharmacies, and potentially more delays for patients, systems might mitigate these delays by streamlining change request messaging through the SureScripts network. Some e-prescribing vendors are joining both networks to make the advantages of each available.

Physicians are also interested in e-prescribing as a means of avoiding errors and improving the quality of their work. Even the most basic e-prescribing systems could reduce miscommunication errors such as illegible handwriting. Evidence of error reduction from commercial e-prescribing has yet to emerge, but some mal-

practice insurance carriers are starting to offer discounts for e-prescribing users nonetheless.²³ Furthermore, rapid changes in treatment protocols and the continuous emergence of new medications make it difficult for providers to stay current. Advanced e-prescribing promises to help providers fill their information gaps at the point of care. Finally, systems that can display integrated medication history information may help alert prescribers to potential abuses in which the same prescriptions are obtained through multiple providers and pharmacies.

The costs of implementing e-prescribing are a major barrier for physicians. Industry estimates for the hardware and software costs of a basic e-prescribing system range from \$1,500 to \$4,500 per physician.²⁴ Estimated costs for advanced systems, having complex alerts and reminders, are higher—\$29,000 per physician in the first year and \$4,000 annually thereafter.²⁵ MMA authorizes grants for e-prescribing in 2007, which may help defray some of these costs.

Another barrier to physicians' adoption is confusion about the functionality and comparability of various vendor systems. Most physicians have little means of evaluating the array of features offered by an increasing number of vendors. This barrier could be addressed through the creation of a certification organization that evaluates existing systems in comparison with standards for functionality and interoperability. The Certification Commission on Health Information Technology—a private-sector initiative to compare functionality and develop minimum features for EHRs—may provide a template for this activity.²⁶

Health plans and payers are expected to derive most of the financial benefits that may result from e-prescribing and other forms of advanced health information technology (HIT).²⁷ Anticipating that plans will be interested in funding e-prescribing implementation, MMA addresses potential legal barriers to these arrangements. However, at least two factors might mitigate health plans' interest in funding e-prescribing. First, plans may not benefit much from increasing formulary adherence at the point of prescribing, since they can already enforce formulary adherence at the point of sale. Second, some of the plans operating under Part D will be at risk primarily for pharmaceutical costs, and these plans might not receive the savings in decreased hospitalizations and other services that might be possible with more advanced e-prescribing.

Patients could indirectly influence decisions about e-prescribing adoption if they begin to select providers based on e-prescribing availability and features. Electronic transmission of prescriptions could save patients time at the pharmacy, and systems that provide benefits information during the patient encounter or that automate renewals could reduce the delays that patients encounter when prescriptions are not on formulary or when the pharmacy has a question that needs the physician's attention. Further, e-prescribing could help reassure patients that they are getting the correct medications. However, patients may not view e-prescribing as entirely positive. NCVHS testimony indicated that many patients are concerned about who has access to their medication histories. Mak-

ing a complete medication history available to all involved in the patient's care could improve safety and quality of care, but for some patients these potential benefits could be outweighed by concerns about privacy or about discrimination stemming from knowledge of sensitive conditions, such as HIV/AIDS or mental health diagnoses. Balancing consumers' privacy interests and control of their health information with the interests of patient safety, quality of care, and health care efficiency are important policy considerations.²⁸

E-Prescribing As The Entry Level For EHRs

Many policymakers view e-prescribing as an entrée to more comprehensive information technologies, especially EHRs, that could transform health care into an efficient, information-based enterprise.²⁹ E-prescribing transactions, such as eligibility checks, formulary checks, and medication history, are among the core transactions for EHRs. Since basic e-prescribing transactions are also focused on the limited universe of medications that have been approved by the U.S. Food and Drug Administration (FDA), e-prescribing might present a more feasible entry-level system compared with implementing a full EHR.

The standards-development process initiated by MMA has begun to pave the way toward solving the technical, financial, and political issues that inhibit HIT adoption and diffusion. Perhaps as a result, multiple e-prescribing pilot projects are now emerging across the country, supported by both public- and private-sector payers and with collaboration among broad groups of vendors.³⁰ If these pilot projects succeed, they may demonstrate how to bridge the technical and inter-organizational barriers that have limited the value of EHRs so far, thus paving the way for their growth and adoption. The process that has been followed for establishing e-prescribing standards may also serve as a template for future public-private partnerships to foster interoperability for other health care information technologies.

Given the steep marginal costs for more advanced systems and providers' likely initial motivation to decrease phone calls, the average provider might tend toward implementing simpler e-prescribing systems that focus more narrowly on office efficiency and that implement only the minimum foundation standards, without including more advanced decision support. If even simpler systems turn out to be difficult to implement, there is a risk that providers would enter a period of resistance to further changes, making the more basic e-prescribing systems an absorbing state that would inhibit further progress.³¹ On the other hand, if implementation goes smoothly and standards result in systems that are modular and interoperable across vendors, then the initial adoption of more limited e-prescribing systems could serve as a platform for adding more advanced features.

WITH A ROBUST SET OF INITIAL STANDARDS now available, growing interest from payers, and the impending launch of a managed drug benefit in Medicare, the stage is set for e-prescribing adoption to accelerate rapidly. Given the current incentives for providers, the first wave of adoption is likely to be greatest for systems that are more narrowly focused on improving office efficiency. Thus, the first e-prescribing systems to achieve widespread adoption may lack many of the features with the greatest potential to prevent medication errors and chronic disease complications. However, the existence of foundation standards and the well-defined plans for adding to these standards should encourage vendors and providers to add these important advanced features over time. The strong impetus for interoperability should also facilitate the addition of other EHR functionality. However, progress toward these goals should be monitored carefully, and other incentives, such as “pay-for-performance,” should be targeted strategically to maximize this progress. In addition, much more needs to be learned about the design factors that would enable e-prescribing systems to actually improve patient safety and health outcomes without introducing new risks. Studies should be designed and supported—during the 2006 pilot and beyond—to create rigorous evidence that could guide the development of standards for advanced e-prescribing functionality. With careful attention to expanding the knowledge base and to fostering incremental adoption, e-prescribing could turn out to be a seed for the fundamental transformation of health care.

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