

REVIEW ON PROGRESS OF E-PRESCRIBING

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INTRODUCTION

Healthcare providers are now using a relatively new method called e-prescribing (electronic prescribing) which uses a computerized system to reduce medication prescribing errors and to improve communication between physicians, pharmacists and patients.^[1] The relationship between these stakeholders play in Fig-1: Effectiveness and efficiency, may be increased by sharing medical records, drug lists, patient profiles, and health plans between physicians and pharmacists via e-prescribing.^[2] These are still in the early days of e-prescribing, so potential problems like consistency of software programs and vulnerabilities to fraud are not yet fully studied.

In recent years healthcare professionals have been expected to assume more responsibilities and accomplish more complex tasks. E-prescribing has become popular with them because it helps physicians and pharmacists meet these challenges.^[3] Exponential increases in the volume of prescriptions transmitted electronically have been shown by recent research.^[4] In a recent month e-prescribing was almost nine times higher than the average for the last two years and the number of electronic prescriptions nearly tripled compared to the previous month.^[5]

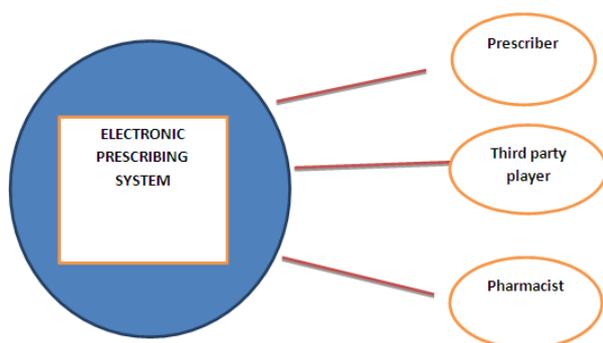


Figure 1: Illustration of the blueprint of e-prescribing.

Electronic prescribing can assist physicians and pharmacist in medical decision making⁶. The amount of time spent in the prescribing process increases with checking with patient's formularies (List of cost effective drugs) which reduces the time spend focusing on the

patient and their care. E-prescribing empowers healthcare providers with patient specific information in a convenience format; otherwise it would take a lot of time to seek out.^[7] Physicians are expected to prescribe drugs that are included in patient's formularies and e-prescribing provides faster access to this information which frees up more time to focus on patient care.

In addition to offering the benefits of providing patient information, electronic prescribing may help professionals to recognize the need to improve patient safety. A drawback to the traditional handwritten prescription process is that significant gaps may happen and jeopardize patient safety. A gap in communication between pharmacist and physician can occur with the traditional method of handwritten prescriptions taken to pharmacy by the patient. This traditional process of prescribing is illustrated in Fig-2:

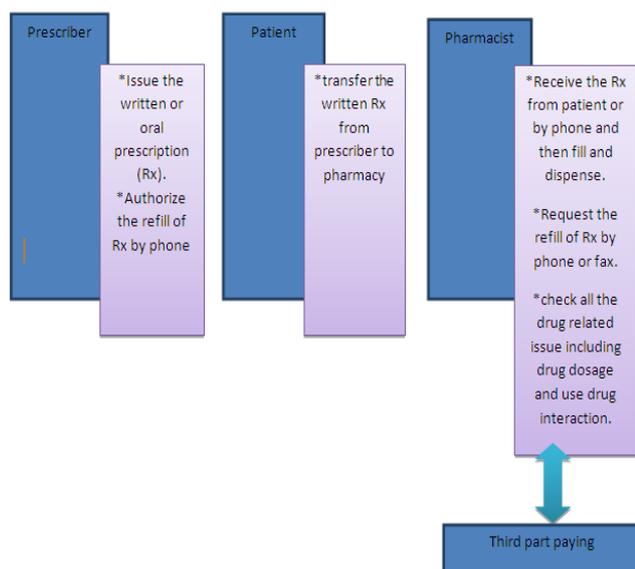


Figure 2: The Traditional Process the Prescribing.

E-prescribing can help improve patient safety by bridging potential communication gaps like this.^[6] Healthcare providers are more pressured to more quickly provide safe and effective medications due to the increasing volume of prescriptions. The e-demand for prescription has been increasing but traditional method of prescribing has changed very little to meet this demand. Trying to keep up with demand with traditional methods can lead to more prescribing and dispensing errors. Electronic prescribing can be seen as an evolution of traditional methods to respond to the increased demand for prescriptions.^[8] It's a technological advancement that helps healthcare professionals to keep up with increased demand while improving patient safety. Our health care system's increasing demands can be met by the potential of electronic prescribing, while at the same time improving patient safety. It's a technological advancement that can benefit both patients and healthcare providers.^[9]

In this review, we will first assess the pros and cons of electronic prescribing system. Next, we will explore the impact of electronic prescribing on the different stakeholders in the process; prescribers, pharmacists, and patients. Finally, we will examine and discuss whether electronic prescribing has a potential to be implemented intensively and analyze the suggestion for solving these problems and to optimize the electronic prescribing system.

Considerations with Eletronic Prescribing

The benefits and issues surrounding electronic prescribing are related to market, regulation and patient's safety. Exploiting the benefits and resolving the issues can be beneficial both the caregivers and the recipients of care.^[10]

Marketrelated Issues

With e-prescribing, most market related issues center around cost. The cost of medications to the patient can be provided by the prescribing system to the physician a better idea of the cost effectiveness of medications. Cost savings opportunities can be discovered for brand name and generic medications.^[11]

The pharmaceutical market is noticeably affected by stakeholders using more cost effective drug information from pharmaceutical companies, pharmacies and third party payers are combined in this system which can impact the frequency that brand name medications are requested.^[11] Use of these systems has also shown that innovative drug products may be prescribed less often, decreasing revenue to drug products may be prescribing beneficial because of the cost savings to them resulting from its use. Patient also benefit from e-prescribing cost saving effects by receiving medications that have lower co-pays.

Issues

The major market related issue that could arise with electronic prescribing is the availability of prescription medication drug pricing along with other information about the same.^[11] Ideally, drug pricing of branded or generic drug should be provided in the electronic prescribing system which can help physicians make a better decision with regards to medication prescription. Physicians can become aware about the cost effectiveness of the medications upon referring the medication's cost related information and other related information reported by the pharmaceutical companies, third party payers and pharmacies.

However, the presence of drug pricing might not be favored by pharmaceutical companies producing branded drugs since generic drugs are preferred and prescribed more in most of the cases. Pharmaceutical companies producing branded drugs may be at a loss drugs as opposed to the expensive branded drugs. On the other hand, third party payers and patients might show a higher inclination towards payment and usage of cost effective medications. Enhanced usage of cost effective drugs fostered by interaction among different stakeholders can be made visible to the pharmaceutical industry through electronic prescribing.^[12]

Regulatory Factors

The e-prescribing issue can be impacted in a couple of different ways by regulatory factors. Legislation and executed in order to implement e-prescribing successfully. For example, e-prescribed prescription contains private health information that has to follow the Health Insurance Portability and Accountability Act (HIPAA) regulations. Hence, it's necessary to establish a separate section regarding e-prescribing's HIPAA regulations. The HIPAA stipulations for e-prescriptions will need to address in future legislation. These will be necessary to ensure that confidentiality and privacy are

maintained between records are supposed to be private between health providers and patients.^[6]

Physicians, who submit prescription to pharmacies electronically, are required to comply with guidelines outlined by the Medicare modernization Act. The standard Medicare is required to follow will be decided by the Department of Health and Human Services e-prescribing pilot programs across the United States. These trails imply there's a potential of mandatory implementation of an e-prescribing process for Medicare patients which promises to cut costs and improve prescription safety. The costs and benefits of e-prescribing will be assessed by a systematic method of pilot studies of e-prescribing. Regulations defining the capacities of the software and system should also be considered. To minimize fraudulent electronic prescriptions and protect patients' privacy and confidentiality measure can be taken in and be required of e- systems. For example, a physician can be required to sign in the e-prescribing program each time with a valid login. Also, a time limit in which to complete a prescription can be set by the physician via the time out function. If the limit passes, the prescriber must re-enter his or her password. E-prescribing regulatory factors will help maximize the benefits of patients and ensure that they can receive the high quality of health care.^[1]

Safety Related Factors

There is a strong correlation between safety related factory and the quality of health care. Introduction e-prescribing can dramatically improve drug safety.^[3] E-prescribing can do much more than just allow physicians to send prescribing to pharmacies electronically.^[6] It can help prescribe drug recommended by insurance health plans and facilitates prescribers to check patient' medical history, allergies, and current drug list and verify drug information such as drug-drug interaction, contraindication, dosages, and indications.

Some field is electronic prescription that prescribers are required to fill out. Therefore, e-prescribing minimizes the likelihood that prescribers may submit an incomplete or inaccurate order. In the beginning step of the prescribing and dispensing process e-prescribing can prevent the occurrence of drug related issues. A reconciled, complete list of patient medication is another major benefit e-prescribing systems provide to prescribers. Third party payers, multiple pharmacies, multiple physicians the patient has seen other information from multiple sources are aggregated by e-prescribing and enable the physician to easily compile the exact drug list of all the drug patients are taking from multiply sources. E-system can help determine if a drug-drug interaction is present between the current drug and the drug which is going to be prescribing and allow physicians will know which medications a patient is taking. Electronic prescribing can also be an effective check system to alert a physician who not knows about a patient's allergies.

Lastly, drug safety can be improved through e-prescribing by minimizing medication errors caused by illegibility of physician's handwriting. The illegibility of prescribers handwriting is one the main factory causing medication errors. Its less likely in the e-prescribing process, that patient would be given an incorrect drug or wrong dosage because the prescription could not be interpreted correctly as compared to handwritten prescriptions. Also, errors in dosage and indications can be easily captured via e-prescribing. Electronic prescribing can address drug safety issues to a large extent.

Stakeholders in Electronic Prescribing System

To further understand that the electronic prescribing, we should consider the major stakeholders who are involved with it. This prescribing method affects physicians, pharmacist, and patients. So, we will analyze the roles of physicians, pharmacists, and patients who involved in e-prescribing debate to enhance our knowledge of this system.^[13]

Physician

Medical doctors have one of the longest training periods of all healthcare professionals. Physicians are significant decision makers in the health care system, deciding the medications that patients receive each year is one of the vital functions that these individuals play in the healthcare system.^[14] Hence, the e-prescribing issue that faces the healthcare system today is directly impacted by physicians.

In the e-prescribing system, physicians are the ones who prescribe the medications electronically. E-prescribing systems can provide physicians with pop-up alerts when potential errors occur with the prescribed medication. Physicians are the ones who prescribe the medications in the electronic prescribing system.^[5] Physicians can be provided with pop-up alerts when potential errors occur with the prescribed medication in E-prescribing systems. Some of these errors could be drug-drug interactions, wrong dosages and drug allergies. More clinical support at the time of prescribing medications will be provided to physicians by e-prescribing. The occurrence of drug related issues can be prevented at the very beginning step of the prescribing and dispensing process. It's critical to prevent the medication errors the very first step and then minimize errors from step to step.

On the other hand, there are some downsides to e-prescribing for physicians for physicians. There are some alerts that are not of good quality, such as those that show drug interactions when the patient has stopped talking the medication, but the system had not been updated. There are also some downsides for physicians in e-prescribing. The workflow of physicians can be interrupted by low priority or misleading alerts and may decrease the quality of patient care .Too many alerts might cause some physicians to override alerts or ignore

their messages possibly resulting in decreased patient safety.

E-prescribing can prevent the problems associated with stolen, fake or fraudulent prescription pads utilized for the purposes of medication abuse. As discussed earlier in this paper, e-prescribing system use password and username encrypted interfaces, so only authorized users can access patient data and electronically transmit prescriptions. In addition in e-prescribing system, physicians have access to data on whether the patient has filled the prescribed medications.^[4] Therefore, physicians can detect and act on possible patient non-adherence to medications.

Finally, another issue confronting physicians is the requirement for additional training in the requirement training in utilizing e-prescribing technology. To make the most out of what the software provides physicians need to be trained how efficiently and effectively use electronic prescribing. The software should be well designed and use friendly, run smoothly and be easily operated. Not all physicians may be comfortable or skilled with the use of advanced technology. If e-prescribing is thought of as more troublesome and not time saving as compared to the traditional handwriting method of prescribing that may inhibit adoption by some doctors.

Pharmacist

Pharmacists are another group of healthcare professionals who have an important role to play in e-prescribing who have an important role to play in prescribing.^[14] Pharmacists are responsible for delivering quality care to the patients. They fulfill this responsible while dispensing the prescription order received from the physicians by ensuring the appropriateness of the medication and assessing the impact of medication on patient health outcomes. From pharmacist's perspective, e-prescribing has important benefits and drawbacks which need to be considered.

E-prescribing many have many benefits and advantages for pharmacists.^[6] With this technological advancement, pharmacists can save a lot of time in many of their daily activities and also benefit from a more prompt transmission of prescriptions from the prescriber. These services can save significant time and money by providing efficient data exchange between physicians and pharmacists, thus giving them more time to spend on their other professional's duties. Recent study shows that the computerized prescribing, pharmacists spent 34 percent less time filling prescription and dispensing medications to patients. Also included in this study were statistics that illustrated that after the implementation of electronic prescribing, pharmacist spent 2.2 percent less time in discussions with others, and 3.4 percent less time in giving and taking information about the patient, including any professional consultation. Research showed that with the use of an electronic prescription

transmission systems, fewer telephone calls were placed between physicians and pharmacies. It's probably because the verbal communication of verifying prescriptions can be waived. Electronic prescribing can lead to smooth interaction between stakeholders in this way. E-prescribing, on a larger scale, may enhance the efficiency of the health system overall.

Improved prescription legibility is another big advantage of e-prescribing. One of the most frequently identified cause of medication errors is illegibility, the misinterpretation a prescription may potentially harm a patient by dispensing the wrong medication or wrong dosage and will be liable for negligence. The significance of preventable medical errors was outlined in a report from the US institute of medical errors are responsible for more deaths each year than highway crashes, breast cancer or AIDS according to the report. Therefore, implementation of an electronic system may be successful remedy for improve medication safety. Electronic prescribing has the potential to minimize medication error attributed to mistakes regarding drug identity, dosing, and scheduling as well.

A lessened sense of professional responsibility is one negative aspect that pharmacists may encounter with the extensive use of electronic prescribing system could transfer some of an e-prescribing system could transfer some of their duties of checking drug interactions and allergies to other professionals. The features of electronic systems might be beneficial to the overall health care system, but some pharmacists may worry that e-prescribing will slowly erode their responsibilities. Laws and regulations allow pharmacists in many case to substitute cost saving generic drug in place of brand name medications without authorization from prescribers. These traditional duties may not be necessary for the pharmacists to complete with the electronic prescribing because the system would send messages to physicians, alerting them that the medication they prescribed interact with each other medication or that a more cost effective medication could be requested.

The trend that not all pharmacies or pharmacists will be willing to keep their systems up to date is another negative characteristic of e-prescribing that could be imminent advancement in services. Implementing and updating the advanced systems that e-prescribing requires maybe beyond the resources of small independent community pharmacies. As e-prescribing becomes more widespread pharmacists will become major players in evaluating the pros and cons.

Patient

Patients are recipients of care and medications from the healthcare personnel with an insistence on or assurance about quality healthcare on a continual basis from the healthcare personnel. The positive impact of electronic prescribing on patient is reflected through improved communication between the physician and pharmacist by

eliminating unnecessary time spent in exchanging phone calls and faxing refill requests. Electronic prescribing can be a source of convenience for the patient since it will save their time by not having to wait in long queues for picking up their prescription while it is being filled by the pharmacist.

Third party payers now have increased influence in terms of cost-effective drug over the brand name drug requested. Patients may be given both least expensive and the most effective version. Cost does appear to have a large influence over the willingness of patient to receive care and necessary medications. The responsibility and decision to fill and purchase medication in the traditional system is placed on the patient. Many patients are less likely to take initiative to fill prescriptions because drugs are not affordable them

and would consequently be at risk for severe adverse health issues due to untreated conditions. A pharmacist in prescribing could identify this problem and have the option of making physicians aware of it. This would be an important strategy to improve overall patient care by alleviating this kind of health disparity.

Also the fact that the prescriptions undergo a double or triple check presents a source of relief and assurance to the patients that they are receiving quality care from different healthcare personnel at different levels of healthcare delivery.

From all these described above, the role of electronic prescribing from the stand point of the whole health care system is summarized as represented in Table-1.

Table 1: Advantages and disadvantages of electronic prescribing from the perspective of the health care system.

Sl. No.	Factors	Advantages	Disadvantages
1. Increase effectiveness of health care system		Improved appropriateness and accuracy of prescriptions Reduced prescribing errors due to pop-up alerts; reduced medication errors by eliminating mis-interpretation of illegible handwritten prescribing.	Costs High costs associated with the implementation and maintenance of the technology
		Decision making Facilitate prescriber's decision making process by accessing the cost and effectiveness information of the available treatment options.	Technology issues Problems related to the technology itself such as accidental or intentional system failure, slow speed, and security.
		Improved patient's safety Sharing of patient profiles among health care providers can minimize the medication related issue and easily identify patient compliance with medications.	Privacy violation Potential violation of patient's confidentiality and privacy.
		Improved patient's safety Sharing of patient profiles among health care provider can be minimize the related issues and easily identify patients compliance with medications.	Strained physician-pharmacist relationship Possibility of strained relationship if solution to the issue of fraud brought to the attention of health care providers by pharmacist like necessary training, motivation of using the system, possibility of treats made to some pharmacist or small retail pharmacies, pharmacist business might be in jeopardy.
2. Improved efficiency of health care system		Time saving Save time on verifying, filling and refilling prescribing.	
		Better communication Achieve smoother flow the delivery of health care, more efficient communication between prescribers and phone calls.	
		Short waiting times Waive patients from long waiting times during filing and picking up prescriptions, provision of more convenient health care service to the patient.	

The Future of E-Prescribing: Implementation and Potential Problem

We believe the use of e-prescribing will become prevalent and widespread in future. The increasing use of technology in the society suggests that the trend of moving towards e-prescribing is inevitable. Our review carefully weighed the benefits and costs of electronic prescribing. We believed that the benefits of electronic prescribing outweigh the drawbacks based on this evaluation. However, more time may be needed on this evaluation. However, more time may be needed to implement e-prescribing properly. If the implementation of e-prescribing is rushed without addressing major issues it may be as effective as it could be. In the future, electronic prescribing is likely to save the cost for both patient and health care system as a whole. When a physician knows the generic brands early on, their patient will be prescribed the best and most cost effective medication for his or her disease. Increases in safety due to the decrease in medication errors resulting from e-prescribing will also benefit patients.

Prescriber and pharmacist training and education can ensure effective and efficient working of electronic prescribing system. This can be achieved by either incorporating the training in the achieved by either incorporating the training in the school curriculum of the healthcare personnel enrolled in schools or by providing training through continuing education to healthcare personnel who are working.^[15]

There are many software companies are attempting to appeal to pharmacies, clinician offices, and other places within the health care system where electronic prescribing may be beneficial. Two software competitors, Rx Hub and superscripts are currently trying to promote e-prescribing systems. It's likely that the number of e-prescribing systems. It's likely that the number of e-prescribing software programs available will continue to rise with increased usage and popularity. Therefore, we propose that e-prescribing system or software can be limited to a small number of companies through patients and government regulation. We feel this will reduce compatibility complications between various health care providers and will decrease the confusion and stress associated with introducing new software into a pharmacy or clinician's office. Compatibility of systems and software are essential to transferring a prescription from the physician's office to a pharmacy.

We feel that further research examining which characteristics of software are most helpful should become mandatory and that survey of pharmacists and physicians who use e-prescribing is one of the most effective methods of performing this research. It will take some time to develop perfect e-prescribing software. We believe that with the cooperation of physicians, pharmacist and software company's e-prescribing systems more useful, intuitive, and easier to use.

Before the mass adoption of e-prescribing can take place security problems, such as fraudulent prescriptions and patient confidentiality will need to be addressed. One drawback of e-prescribing is that it makes fraudulent prescriptions harder to spot through handwriting analysis.^[16] Maintaining confidentiality is also a concern because of increased access to patient profiles and records by various healthcare professionals. In order to prevent problems with traditional handwritten prescribing methods from being carried into the electronic world they should be identified, studied, and resolved.

Currently there are no studies available, to our knowledge, which analyzes the feasibility of implementing the high cost associated with the development; implementation and maintenance of the technology may retard the utilization of electronic prescribing system in developing countries such as India with limited government budget which can be reallocated to where it is needed more.

CONCLUSION

Due to the novelty and popularity of electronic prescribing, it is important that more research is being conducted for evaluating the utilization of electronic prescribing in the health care system. There are still many issues with electronic prescribing, the information and the solution about which is not available. Healthcare organizations and institutions feel the need to be equipped with the latest technology available in the market. However, at the same time, it is necessary to ensure that the technology is being introduced in a way that the workforce has the correct information about its operation. If solutions for issues surrounding electronic prescribing are figured out, then it definitely has the potential to replace traditional paper prescribing and be part of the mainstream practice.

REFERENCES

1. Des Roches CMR, Agarwal CM, Fisher MA. Differences between integrated and stand alone e-prescribing systems have implications for future use. *Health Affairs*, 2010; 29(12): 2268-77.
2. Megan E. Keller, Sarah E. Kelling, Douglas C. Cornelius, Hafusat A. Oni, David R. Bright. Enhancing Practice Efficiency and Patient Care by Sharing Electronic Health Records. *Perspect Health Inf Manag*, 2015 Fall; 12(Fall): 1b. Published online: 2015 Nov 1. PMID: PMC4632871.
3. Amber Porterfield, Kate Engelbert, Alberto Coustasse. Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting. *Perspect Health Inf Manag*, 2014 Spring; 11(Spring): 1g. Published online: 2014 Apr 1. PMID: PMC3995494
4. Olufunmilola K. Odukoya, Michelle A. Chui. E-prescribing: Characterization of Patient Safety Hazards in Community Pharmacies Using a Socio-

- technical Systems Approach. *BMJ Qual Saf*, 2013 Oct; 22(10): 816-25. Published online: 2013 May 24. doi: 10.1136/bmjqs-2013-001834.PMCID: PMC3966066.
5. Cindy Parks Thomas, Meelee Kim, Ann McDonald, Peter Kreiner, Stephen J Kelleher, Jr, Michael B Blackman, Peter N Kaufman, Grant M Carrow. Prescribers' expectations and barriers to electronic prescribing of controlled substances. *J Am Med Inform Assoc*, 2012 May-Jun; 19(3): 375-81. Published online: 2011 Sep 21. doi: 10.1136/amiajnl-2011-000209. PMCID: PMC3341776.
 6. Randolph A. Miller, Reed M. Gardner, Kevin B. Johnson, George Hripcsak, Clinical Decision Support and Electronic Prescribing Systems: A Time for Responsible Thought and Action. *J Am Med Inform Assoc*, 2005 Jul-Aug; 12(4): 403-9. Published online: doi: 10.1197/jamia.M1830. PMCID: PMC1174885.
 7. June Forkner-Dunn. Internet-based Patient Self-care: The Next Generation of Health Care Delivery. *J Med Internet Res*, 2003 Apr-Jun; 5(2): e8. Published online: 2003 May 15. doi: 10.2196/jmir.5.2.e8. PMCID: PMC1550561.
 8. Rachel Czubak, Jasmine Tucker, Barbara J. Zarowitz. Optimizing Drug Prescribing in Managed Care Populations. *Disease Management & Health Outcomes*, March 2004; 12(3): 147-67. First online: 07 October 2012. DOI: 10.2165/00115677-200412030-00002.
 9. Abha Agrawal. Medication errors: prevention using information technology systems. *Br J Clin Pharmacol*, 2009 Jun; 67(6): 681-6. Published online: doi: 10.1111/j.1365-2125.2009.03427.x. PMCID: PMC2723209.
 10. Jesse C. Crosson, Rebecca S. Etz, Shinyi Wu, Susan G. Straus, David Eisenman, Douglas S. Bell. Meaningful Use of Electronic Prescribing in 5 Exemplar Primary Care Practices. *Ann Fam Med*, 2011 Sep; 9(5): 392-7. Published online: doi: 10.1370/afm.1261. PMCID: PMC3185481.
 11. Lee Ventola C. Direct-to-Consumer Pharmaceutical Advertising Therapeutic or Toxic? *P T*. 2011 Oct; 36(10): 669-674, 681-684. Published online: PMCID: PMC3278148.
 12. Mustaqeem Siddiqui and Vincent Rajkumar S. The High Cost of Cancer Drugs and What We Can Do About It. *Mayo Clin Proc*, 2012 Oct; 87(10): 935-943. Published online: doi: 10.1016/j.mayocp.2012.07.007. PMCID: PMC3538397.
 13. Stephen E. Wogen, George Fulop, Judith Heller. Improving the Efficiency of the prescription process and promoting plan Adherence. *MEDSCAPE News Today*. 11/03/2003; 2003 cliggott publishing, division of CMP Healthcare. [com/view article/462655](http://www.cmphealthcare.com/view/article/462655). ACCESSED.10/22/2011.
 14. Jennifer Fong Ha and Nancy Longnecker. Doctor-Patient Communication: A Review. *Ochsner J*, 2010 Spring; 10(1): 38-43. Published online: PMCID: PMC3096184.
 15. Randy P. McDonough and Marialice S. Bennett. Improving Communication Skills of Pharmacy Students through Effective Precepting. *Am J Pharm Educ*, 2006 Jun 15; 70(3): 58. Published online: PMCID: PMC1636963.
 16. Centers for medicare and Medicaid services(CMS)HHS.Medicareprogram;identification of backward compatible version of adopted standard for e-prescribing and the medicare prescription and the Medicare prescription drug program (NCPDP SCRIPT 10.6) Interim final rule comment period. *Fed Regist*, 2010 Jul 1; 75(126): 38026-30.