

SR 81 / HR 108 (2011)

Report

Legislative Workgroup on Electronic Prescribing (eRx) and Electronic Prior Authorization (ePA)

~~12/14/2011~~

1/4/2012

I) Senate Resolution 81 (Senator Mills) and House Resolution 108 (Representative LeBas)

A) Purpose ¹

To study and make recommendations to the legislature concerning electronic prescribing which at a minimum would accomplish and/ or address the following

- 1) Seek to limit marketing in electronic health record systems.
- 2) Seek to encourage the provision of evidence based information at the point of care for the prescriber and patient.
- 3) Standardize prior authorization to maximize administrative simplification and efficiency and adopt a universal prior authorization form to be made available for electronic use.
- 4) Provide for a patient's freedom of choice with respect to the selection of a pharmacy.
- 5) Provide for user authentication, audit, and physical security.
- 6) Best practices to maintain a neutral platform for the secure electronic transmission of health data including, but not limited to medication history, formulary status, and other patient information health professionals typically access when prescribing medication and other interventions.
- 7) Best practices to assure attempts to influence, through economic incentives or otherwise, the prescribing decisions of the practitioner at the point of care can be kept to a minimum and focused on patient safety and outcomes that maximize patient and provider freedom of choice.
- 8) Best practices to assure messages in electronic prescribing systems are substantially supported by scientific evidence, accurate, up to date, and fact based, including a fair and balanced presentation of risks and benefits, and support for better clinical decision making, such as alerts to adverse events and access to formulary information.
- 9) Best practices to establish a process to provide electronic prior authorization request and approval transactions between providers and group purchasers.

B) Membership ² - one representative each

- 1) Louisiana State Board of Pharmacy who will serve as co-chair
- 2) Louisiana State Board of Medical Examiners who will serve as co-chair
- 3) Department of Health and Hospitals
- 4) Department of Insurance
- 5) Louisiana State Medical Society
- 6) Louisiana Academy of Family Physicians
- 7) Louisiana Independent Pharmacies Association
- 8) Pharmaceutical Researchers and Manufacturers of America
- 9) Louisiana Association of Health Plans
- 10) Louisiana Health Care Quality Forum
- 11) Louisiana Hospital Association
- 12) Louisiana Worker's Compensation Corporation
- 13) Louisiana Association of Self Insured Employers
- 14) eQHealth Solutions
- 15) National Association of Chain Drug Stores
- 16) Louisiana Orthopedic Association
- 17) Louisiana State Board of Nursing
- 18) Louisiana Association of Nurse Practitioners
- 19) Medicine Louisiana, Inc
- 20) Louisiana Chapter of the American Academy of Pediatrics
- 21) Louisiana State Board of Optometry Examiners

C) Meeting

The workgroup met on August 19, 2011 at the Board of Pharmacy Offices in Baton Rouge. Background information on the evolution of e-prescribing ³ electronic prescribing of controlled substances ⁴ ⁵ electronic prior authorizations ⁶ and information relating to legislation in several states⁷ was discussed. Everyone present was invited to submit comments relating to their position on the issues for incorporation in the report⁸. ~~Committee staff offered to draft a report for consideration by all in advance of the submission deadline on January 1, 2012. Subsequently staff drafted the report inviting feedback from the participants which was incorporated in subsequent drafts. The Workgroup received permission to extend the submission deadline one month to facilitate participant review. A second meeting of the workgroup was held on January 18, 2012.~~

II) Background

A) Electronic prescribing (e-prescribing) ⁹ 10

- 1) The number of prescribers routing prescriptions electronically grew from 156,000 at the end of 2009 to 234,000 by the end of 2010—representing about 34 percent of all office-based prescribers.
- 2) Prescriptions routed electronically grew 72% from 191 million in 2009 to 326 million in 2010.
- 3) At the end of 2010, approximately 91 percent of community pharmacies in the U.S. were connected for prescription routing and six of the largest mail order pharmacies were able to receive prescriptions electronically
- 4) About 79 percent of e-prescribers used EMRs in 2010, up from 70 percent in 2009.
- 5) Electronic responses to requests for prescription benefit information grew 125% from 188 million in 2009 to 423 million in 2010.
- 6) At the end of 2010, Surescripts could provide access to prescription benefit and history information for more than 66 percent of patients in the U.S.
- 7) Prescription histories delivered to prescribers grew 184% from 81 million in 2009 to 230 million in 2010.

B) Prior authorization

- 1) Definition of Prescription Drug Prior Authorization and Current Prior Authorization Use and Process ¹¹ 12 13

A prescription drug prior authorization has been defined as "... the process of obtaining pre-approval from a payer for specified medications or quantities of medications, with the goals of: improving patient safety; and containing costs."

Prior Authorization programs are implemented by private and public (Medicaid and Medicare) insurers to reduce costs to payers (government, employers, patients) by ensuring that when appropriate patients are treated first with lower cost, first-line agents before progressing to newer, higher cost or experimental therapies.

These benefits however are associated with increased costs for providers due to the inefficiencies of the process and delays in obtaining medications for patients.

While prescription drugs requiring prior authorization make up only a small fraction of all medications, studies have also reported that prior authorization is a “widely adopted method of drug utilization management” and prior authorizations are “frequently used to manage the increasing costs of pharmacy benefits.” One large online survey found that nearly two-thirds of prescribers write prescriptions that require prior authorization. Over time, prescription drug prior authorizations have become an increasingly more frequent transaction. One study reported that “advances in MTM [medication therapy management], biotechnology, designer drugs, specialty pharmacy, and the cost of the pharmacy benefit, has increased the number of prior authorized medications.” As a result, “from 2000 to 2006, commercial plans doubled the number of medications requiring prior authorization,” and the number “increased steadily” among Medicaid programs.

~~However, the prior authorization process is often manual, nonstandard, and perceived as burdensome and costly. While some payers have instituted web portals for direct data entry of drug prior authorization requests, and vendors offer web-based solutions, the web portals are not standard across payers. In addition, drug prior authorization “often requires multiple telephone phone calls and facsimiles between pharmacy, practice, and a third party administrator to gain resolution.~~

2) Electronic e-prior authorizations ¹⁴

The federal government requires as a condition of certification (for the purposes of meaningful use) that electronic health record technology be capable of generating and transmitting electronic prescriptions. However, certification does not require that electronic health record technology also be capable of performing electronic prior authorization.

At the present time there are no industry transaction standards for real-time e-prior authorization nor is there an accepted electronic format that has been demonstrated to facilitate distribution of prior authorization forms. ¹⁵

The National Council for Prescription Drug Programs (NCPDP) has developed draft standards but these have not been formally approved or been finalized as American National Standards Institute (ANSI)-accredited standards.

Legislation that would establish minimum standards for e- prior authorization ~~requests are-is~~ under consideration in New Mexico¹⁶, California and elsewhere at the present time.

C) Regulatory framework ¹⁷

As a general rule, state laws govern the prescribing and dispensing of prescription drugs by licensed health care professionals as well as the practice of pharmacy. Federal law sets standards for prescribing, transmitting, and dispensing controlled substances. The federal government has ~~proposed amending~~amended its rules governing controlled substances to permit e-prescribing. However, state laws also regulate the transmission of prescriptions for controlled substances. Providers and pharmacists must comply with these state laws so long as the state provisions do not affirmatively conflict with federal law.

In addition to regulating the acceptable means by which prescriptions may be transmitted, states also have laws designed to curtail health care costs by encouraging the use of generic drugs. Virtually every state has a drug substitution law that generally permits or requires a pharmacist to dispense an equivalent lower-priced generic drug when a brand-name drug is prescribed. States also encourage prescribing generic drugs by capping Medicaid reimbursement payments for brand-name drugs where a generic equivalent is available, through the Federal Upper Limit program and state Maximum Allowable Cost programs.

State laws allow physicians to override these generic substitution or reimbursement caps by transmitting, along with the prescription, a message that the brand name is medically necessary in a means dictated by law, (e.g., handwriting "dispense as written" or "brand necessary" or a similar phrase on the face of a prescription). Federal Medicaid regulations, which used to require that brand necessary be handwritten on the face of a prescription, have recently been amended to expressly permit this certification to be electronically transmitted.

III) Findings

A) e-Prescribing

- 1) The benefits of e-prescribing are widely recognized and include ~~at least in theory~~
 - a) Improved quality and safety of care (more complete and accurate record of current medications and history of adverse drug reactions, real time decision support for best practices and drug-drug and drug-disease interactions, fewer errors associated with illegible handwriting)
 - b) Improved efficiency of care (more efficient production of prescriptions and maintenance of current medication lists and more efficient transmission of prescriptions to pharmacy)
 - c) Reduced costs (decision support for the selection of the most cost effective treatment option)
 - d) The benefits of e-prescribing have been recognized by the Federal Government which passed two pieces of legislation that provide prescribers incentives to adopt e-prescribing. Those laws are: The Health Information Technology for Economic and Clinical Health (HITECH) Act and the Medicare Improvements for Patients and Providers Act (MIPPA).
- 2) These benefits however are associated with significant costs for the provider due to
 - a) Lack of standardization with multiple systems/ platforms in use. One exception to this is the high degree of standardization of technical communication standards being used presently by the industry (Surescripts ¹⁸) and the National Council for Prescription Drug Programs
 - b) Limited integration with other components of the electronic health record
 - c) Changing federal and state regulations
- 3) ~~There are also concerns about~~ Other concerns have been identified ¹⁹

~~Errors associated with selecting the incorrect drug/ dose/ instruction from drop down lists. While there are benefits gained by preventing dispensing errors caused from incorrectly interpreting illegible handwriting, there are also new types of errors made by prescribers when selecting incorrect drugs, dosages or instructions from drop down boxes.~~

~~a) —~~

~~b) — Higher costs borne by the patient or insurer associated with the transaction or by means of the patient being directed to one or another pharmacy, or to a brand name when a generic or therapeutic equivalent costing less would have the same effect and~~

e)a) _____ Unfair competition by national and on line pharmacies to the disadvantage of local pharmacies and

e)b) _____ Conflicts of interest with pharmacy benefits managers or physicians ~~utilizing e Prescribing to direct or redirect directing or re-directing~~ prescriptions to pharmacies that they own

~~4) —~~ There is widespread and growing adoption of e-prescribing in Louisiana and elsewhere for non controlled substances with support from the federal government in the form of incentives and from the Louisiana Medicare Quality Improvement Organization (eQhealth Solutions) and the Louisiana Health Care Quality Forum²⁰

~~5)4) —~~ There is limited adoption of e-prescribing for controlled substances in Louisiana and elsewhere due to federal requirements that limit use to approved systems which are not yet widely available and/ or integrated into mainstream e-prescribing systems.

~~6)5) —~~ There is general agreement that

~~a) —~~ National standards/ solutions are an essential next step²¹.

~~(i) _____ So that computer systems used by different practitioners, dispensers, payers, vendors and others have a uniform technology platform on which to communicate.~~

~~(ii) _____ So as to ensure that the standards development process can continue to happen organically through organizations with expertise in this area such as the National Council of Prescription Drug Programs (NCPDP), without the pressures of~~

looming legislative mandates that could impede or otherwise create contradictory requirements.

(iii) _____ So that healthcare providers and entities are not faced with accommodating multiple and potentially conflicting technology standards depending upon the state that they are located.

a)_____ State initiatives should be limited to removing barriers to implementation, and maximizing opportunities for cost savings for payers including patients

b)_____ Advertising should not be permitted in e-prescribing systems. Prohibition on advertising however shall not interfere with a payer's ability to provide messaging that alerts the physician to lower cost alternatives or provides information on coverage requirements (e.g., prior authorization, step therapy, and/or quantity limit information)

c)_____ ~~Decision support should be provided to the prescriber at the point of care~~

B) e- Prior Authorization

1) There are no established standards ~~to support for~~ e-prior authorization. ~~Requiring the use of e-prior authorization would be counterproductive at the present time~~

2) There is general agreement that National standards/ solutions are an essential next step for same reasons given in the case of e-prescribing

III) Recommendations

A) Prohibit advertising in electronic medical records to include e-prescription and e-prior authorization systems. Prohibition on advertising however shall not interfere with a payer's ability to provide messaging that alerts the physician to lower cost alternatives or provides information on coverage requirements (e.g., prior authorization, step therapy, and/or quantity limit information) ~~(Resolution 1)~~

A)B)_____ Permit standards for e-prescribing and e-prior authorization and provisions for decision support to evolve nationally without imposition of standards at the state level ~~(Resolution 2)~~

~~B) Direct the Department of Insurance to establish standards and forms for use in the prior authorization process (paper and electronic) with the goal of maximizing efficiency for providers and payers and timeliness for patients (Resolution 3)~~

~~C) Prohibit referral of prescriptions to pharmacies owned by prescribers or intermediaries (Resolution 4)~~

~~D) Prohibit financial incentives for prescribers to select medications or pharmacies (Resolution 4)~~

C) Eliminate barriers to implementation of e-prescribing and e-prior authorization in state law and regulation such as inconsistencies, duplicative paper requirements, restrictions on the use of electronic data intermediaries, and restrictions on the use of electronic certification that a brand name is medically necessary²²

Appendices

Attached

A. SR 81 and HR 108 (2011)

B. Legislative Work Group participants

On line at <http://www.pharmacy.la.gov/assets/LegWkgrpE-Rx/SR81DrRpt.pdf>

C. National Progress Report on e-Prescribing; Surescripts 2010 (on line at

D. Electronic Prescribing of Controlled Substances (EPCS); HIMMS June 20, 2011

E. Electronic Prior Authorizations; HIMMS June 15, 2011

F. E-Prescribing and e-Authorization Legislation

G. Participants comments

H. E-Prescribing and e-Authorization Legislation

I. Report on State Prescribing Laws: Implications for e-Prescribing 2009

Endnotes

¹ SR 81 (2011) (Appendix A)

² Legislative Work Group [Participants](#) (Appendix B)

³ National Progress Report on e-Prescribing; Surescripts 2010 (Appendix C)

⁴ Electronic Prescribing of Controlled Substances (EPCS); HIMMS June 20, 2011 (Appendix D)

⁵ Electronic Prescriptions for Controlled Substances; Final Rule 21 CFR Parts 1300, 1304, 1306, and 1311 <http://edocket.access.gpo.gov/2010/pdf/2010-6687.pdf>

⁶ Electronic Prior Authorizations; HIMMS June 15, 2011 (Appendix E)

⁷ E-Prescribing and e-Authorization Legislation (Appendix F)

⁸ Participants comments (Appendix G)

⁹ National Progress Report on e-Prescribing; Surescripts 2010 (Appendix C)

¹⁰ Pharmaceutical Research and Manufacturers of America comment: Well-structured E-prescribing systems are tools that increase patient safety and efficiency. They should not be reduced to tools for arbitrary cost-cutting through limitations on a patient's access to needed medicines. Instead, E-prescribing standards should focus on patient access, an increase in efficiency and safety, and facilitating savings overall.

E-prescribing standards should promote a system design that serves to maximize all the potential savings available through the improvements in patient safety, quality of care, and cost-effectiveness. For example, using drug therapies more effectively will reduce inpatient admissions, which result in cost savings throughout the health care delivery system. Eliminating fraud and abuse likewise will reduce overall health care costs.

¹¹ Electronic Drug Prior Authorization Standardization and Transmission Report to the Minnesota Legislature 2010 Minnesota Department of Health [LINK](http://www.health.state.mn.us/asa/rxpa021510rpt.pdf)
<http://www.health.state.mn.us/asa/rxpa021510rpt.pdf>

¹² Louisiana Association of Health Plans comment: There are two market forces that are driving payers to increasingly adopt PA programs. First, in the last few years and looking forward through 2016 we have crossed a "patent cliff" where many heretofore blockbuster brand-name drugs are available as low cost generics for the first time because of expiring patents. On average, generic drugs cost 6-10 times less than the remaining brand products competing in that category and there is great competition being played out for physician influence between payers.

governments, and patients who want lower cost drugs and branded manufacturers that want physicians to prescribe higher cost medications.

The second market force that is driving payers to increasingly adopt PA programs is the shift from small molecule, mass produced compounds, to large molecule, "specialty" products made through biotechnology processes. For the foreseeable future, these specialty products will make up 50-75% of FDA approvals. These drugs cost an average of \$40,000 to \$100,000 per patient per year, have potential uses beyond their approved labels and the payer community, large group purchasers, and re-insurers are demanding that these costly agents are being used appropriately and for their intended uses.

¹³ Pharmaceutical Research and Manufacturers of America comment: Preserving the physician-patient decision-making authority should be the focal point for all decisions regarding drug treatment regimens and should be held at a premium when developing an E-prescribing system. States should establish a uniform form for plans to provide physicians seeking authorization for a covered drug, including a uniform, streamlined process for handling requests for expedited review for urgent or medical emergencies. It is essential to patient safety that necessary medicines are received in a quick and efficient manner.

¹⁴ E-Prescribing and Standards for E-Prior Authorization, DHHS [LINK](#) <http://www.healthit.gov/buzz-blog/from-the-one-desk/eprescribing-standards-eprior-authorization/#ixzz1VJR2YfI5>

¹⁵ RelayHealth (McKesson Corporation) comment: RelayHealth has a solution today that addresses this problem. RelayRx™ PriorAuthPlus is a real-time technology solution that automates the initiation of the PA process by using existing National Council for Prescription Drug Programs (NCPDP) pharmacy billing standards (i.e. NCPDP Telecommunication Standard). This solution minimally impacts workflows and enables our customers to: (1) Select the correct PA form based on existing claim data; (2) Auto-populate the patient, prescriber and drug information on the selected form thereby eliminating the need for a phone call or facsimile by the pharmacist to the prescriber. (3) Deliver the pre-populated form to the prescriber, who can add clinical information and sign electronically; (4) Submit the prior authorization to the plan and communicate the plan's response back to the pharmacy.

RelayHealth enables a more accurate and efficient process for prescribers, pharmacies, payers and patients. This nationwide solution currently improves the e-PA process for more than 14,000 pharmacies and 30,000 prescribers across the United States.

¹⁶ E-Prescribing and e-Authorization Legislation (Appendix H)

¹⁷ Report on State Prescribing Laws: Implications for e-Prescribing 2009 (Appendix I)

¹⁸ Surescripts comment: There are many types of standardization that come into play with HIT, such as technical communication standards, hardware standards, user-interface standards, workflow standards, etc. It would be very helpful to the industry for the workgroup to be more specific in terms of the type of e-prescribing standards it believes are lacking. If the workgroup is referring to technical communication standards for e-prescribing, we would share that there is a very high degree of standardization being used right now by the industry (in fact, the federal government has adopted e-prescribing standards for Medicare e-prescribing, and they have been used by the HIT industry for several years now. LINK

¹⁹ Surescripts comment: Patient choice of pharmacy and physician choice of medication are two of Surescripts' key guiding principles, which are reiterated for the record by the following statement made on page 2 of our 2010 National Progress Report (referenced in your report):

"Surescripts' commitment to collaborating with all healthcare participants to realize a neutral nationwide e-prescribing network—In addition to neutrality and collaboration, Surescripts' long-standing principles of transparency, open standards, protection of physician choice of therapy and patient choice of pharmacy, and privacy protection have created an ecosystem that enables the rapid growth of e-prescribing."

We believe similar principles are also observed by the other smaller e-prescribing networks in operation in the U.S. today. While there may be concerns about activities such as are mentioned above among some practitioners, there is no evidence that we are aware of that such activities are actually taking place, and if there was, we would take immediate steps to eliminate said activities on our network.

²⁰ Louisiana Health Care Quality Forum comment: The Louisiana Department of Health and Hospitals named the Forum in 2009 as the state-designated entity to lead the planning and implementation of health information technology grants made available by the American Recovery and Reinvestment Act of 2009. Since then, the U.S. Department of Health and Human Services, through the Office of the National Coordinator for Health Information Technology (ONC), has awarded approximately \$18.3 million in grant funds to the Forum for two major efforts: 1) to serve as the Regional Extension Center (REC) for Louisiana and assist providers and hospitals as they transition to electronic health records and 2) to implement a statewide health information exchange for the state.

As Louisiana's REC the Louisiana Health Information Technology (LHIT) Resource Center aims to assist providers and hospitals with the adoption, conversion and use of electronic health records

(EHRs). Currently, the LHIT Resource Center is working with more than 1,200 providers and 19 critical access and rural hospitals as they become meaningful users of EHRs.

The Louisiana Health Information Exchange, known as LaHIT, was launched in early November 2011. LaHIT is the mechanism that will allow for the secure exchange of health information among authorized providers and across Louisiana's health care system to help improve patient safety, quality of care and health outcomes. It is being piloted in the Acadiana region and will be rolled out statewide beginning in January 2012. To its credit, Louisiana is one of the first states in the country to accomplish this.

LaHIT recently developed a strategy for electronic prescribing for Louisiana that has been submitted to ONC. The strategy involves determining pharmacies in Louisiana that are not currently accepting electronic prescriptions and working with them to address barriers (e.g., cost, privacy of data, discoverability, accuracy of data, etc.). In addition, LaHIT staff members will conduct outreach for providers and hospitals to encourage electronic prescribing.

²¹ Surescripts comment: As was mentioned above, it is important to be specific about exactly what type of standards/solutions the workgroup believes have yet to be created. It will be very difficult for Surescripts and the HIT industry to address the workgroup's concerns without such explicit guidance.

²¹ Report on State Prescribing Laws: Conclusions and Recommendations page 4-1 ff