





HEALTHCARE COMPLIANCE AND BARRIERS TO THE IMPLEMENTATION OF HEALTHCARE IT INITIATIVES ACROSS THE CONTINUUM OF CARE

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Introduction

Small physician practices, rural health providers, and other non-acute providers of health services across the continuum of care face unique challenges when implementing and maintaining compliance programs. The complexity of the US healthcare system and recent initiatives to promote the quality and efficiency of healthcare through technology has presented new opportunities and problems. Providers of healthcare services must ensure that they stay up to date and in compliance with regulations and changing technological requirements in order to remain competitive in today's fast-changing healthcare delivery system.

The following article will explore various technology related compliance initiatives and the barriers to implementing them in small, rural, and non-acute care environments. Part I will provide an overview of the history of medicine, healthcare compliance and the ever-increasing effects of technology on healthcare compliance. Part II will introduce some standards and legislation that have, are, or will soon affect practice at the Federal level. Part III will focus on legislation in the state of Arkansas and the challenges specific to providing quality care in a rural, southern state. Part IV will explore the particulars of and implications of broad new initiatives to promote interoperability in healthcare information exchange. Part V will discuss how and why some areas of health care lag behind when it comes to implementing new requirements. Part VI will draw conclusions and make recommendations of how to solve some of the present barriers and how to better assimilate new practices into old systems to keep pace with the changing face of healthcare compliance and interoperability.

I. A Brief History of Medicine, Healthcare Compliance, and Healthcare IT

The history of medicine itself is a varied and robust school of thought, with PhD offerings on the subject from several prominent schools throughout the US and Europe. ¹ Studies range from the study of Hippocrates and Classical medicine, to the Colonial period, to focuses on a social approach to medicine, ³ such as the beginnings of epidemiology and the famous discovery of the origins of a Cholera epidemic near London, England by John Snow in 1854. ⁴ Florence Nightingale

¹ https://www.hopkinshistoryofmedicine.org/content/graduate-program

² https://www.ox.ac.uk/admissions/graduate/courses/dphil-history-history-science-and-medicine-economic-and-social-history?wssl=1

https://www.history.ac.uk/makinghistory/resources/articles/history of medicine.html

⁴ https://www.ph.ucla.edu/epi/snow/snowcricketarticle.html

wrote her <u>Notes on Nursing</u>: <u>What it is, and What it is Not</u> which was published in America in 1860⁵ and revolutionized the nursing profession.⁶

Although documentation of medical experiments, observations, outcomes, and theories date back to BCE times, keeping records for individual patients is a relatively new practice. Only about 100 years ago did physicians first decide to start keeping a patient record, on paper, for each individual person. Since that time, individual record keeping has become an expected and integral part of healthcare. It has evolved from paper records stored in a file cabinet, to computerized records, to vast databases containing an individual's entire health history.

The US government became more directly involved in the health of Americans with the introduction of Medicare and Medicaid in 1965. The prevention of healthcare fraud and abuse became a central focus of the US Attorney General's Office under Janet Reno during the 1990's. The Department of Justice (DOJ) announced in 1997 that there had been a 270% increase in the conviction rate for health care fraud and abuse cases during the Clinton Administration. Most of these convictions fell under the Anti-Kickback Statute (AKS), False Claims Act (FCA), and Stark law violations. Although the FCA was enacted in 1863 as a way to stop the abuse of fraudulent claims to the government during wartime, the FCA has remained relevant and has expanded to healthcare due to the advent of government funded healthcare institutions such as Medicare and Medicaid.

This time period of increased scrutiny on healthcare compliance paralleled the rapidly expanding world of technology. Although the first EMRs were invented in the 1970's, the technology was expensive and computers too cumbersome to be widely available for use in the medical field. These barriers began to be removed when the personal computer became widely available in the 1980's and the world wide web was established in 1990. 14

A need for standardization in the transmission of health records, along with concerns for the privacy and security of health information, prompted by the quickly expanding use of the internet and a new world of electronic health records led to the passing of the Health Insurance Portability and Accountability Act (HIPAA) on August 21, 1996. HIPAA mandated the Department of Health and Human Services (HHS) develop regulations designed to secure the privacy of health information. HHS began the development of what is now known as the HIPAA Privacy Rule; detailing permitted uses and disclosures of Protected Health Information (PHI).¹⁵

https://journals.lww.com/cancernursingonline/Fulltext/2014/11000/Florence Nightingale s Notes on Nursing a nd the.10.aspx

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⁶ https://ebn.bmj.com/content/4/3/68.short

https://www.rasmussen.edu/degrees/health-sciences/blog/health-information-management-history/

⁸ https://www.nursingtimes.net/roles/practice-nurses/the-importance-of-good-record-keeping-for-nurses-14-01-2003/

⁹ https://www.cms.gov/About-CMS/Agency-information/History/

¹⁰ Thomas E Bartrum & L.E. Bryant Jr. *The Brave New World Of Healthcare Compliance Programs,* 6 Annals Health L. 51 (1997). http://lawcommons.luc.edu/annals/vol6/iss1/4

¹¹ https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS FCA Primer.pdf

¹² https://oig.hhs.gov/compliance/physician-education/01laws.asp

¹³ http://library.ahima.org/doc?oid=105689#.XfFH-HdFxPY

¹⁴ https://www.vertitechit.com/history-healthcare-technology/

¹⁵ https://www.ncbi.nlm.nih.gov/books/NBK9576/

The rule evolved several times prior to the final rule being issued in 2002 and providers were expected to become compliant with the new rule by April 14, 2003. Small health plans were given one extra year to become compliant. ¹⁶

These changes led to the development of healthcare compliance programs. ¹⁷ These programs are designed to provide guidance to healthcare entities in order to help prevent violations of the various regulations. ¹⁸ Since the 1990's, additional legislation has expanded exponentially. ¹⁹ The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 expanded the scope of and penalties for HIPAA ²⁰ and implemented Meaningful Use (MU) standards which incentivized the implementation of electronic health records (EHR). ²¹

¹⁶ https://www.ncbi.nlm.nih.gov/books/NBK9576/

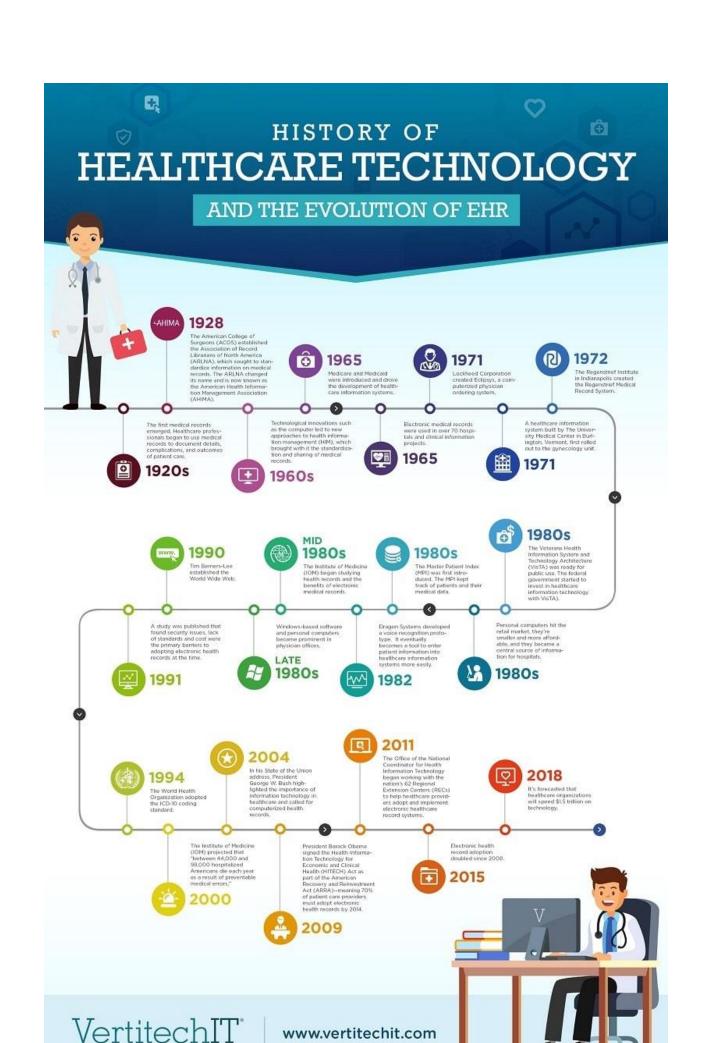
¹⁷ Thomas E Bartrum & L.E. Bryant Jr. *The Brave New World of Healthcare Compliance Programs,* 6 Annals Health L. 51 (1997). http://lawcommons.luc.edu/annals/vol6/iss1/4

¹⁸ https://www.corporatecompliance.com/faq.htm

¹⁹ https://pdfs.semanticscholar.org/c773/db44b60f5ed953d29e61793810308aa533f1.pdf (page 6)

https://www.hhs.gov/hipaa/for-professionals/special-topics/hitech-act-enforcement-interim-final-rule/index.html

https://www.himss.org/library/meaningful-use/what-is



Over the past decade or so technology has taken an ever more integral role in the lives of most Americans. Social media is a main source of communication and entertainment. Americans expect to have any information that they desire at their fingertips within a split second of typing a query into their smart phone. Healthcare is one exception that seems a little bit behind the times in this respect. The healthcare IT industry is struggling to shake off old ideas of how care is provided in order to integrate into a cohesive, technologically advanced system of care and to deliver the information at the fingertips model of care that more and more Americans are coming to expect.

II. Federal Regulations

In the 10 years since the passage of HITECH, EHR usage has expanded and Health IT has become more and more central to the way care is delivered in the United States. ²³ The Centers for Medicare and Medicaid Services (CMS) released their final rule for the EHR Incentive Program in 2010. This rule outlined the requirements for the implementation and "meaningful use" of electronic health records, designed to be implemented over a period of years, in 3 stages, with progressive measures to be met during each stage. The goal of MU was to increase the use of EHRs and to be able to quantify improvements through reporting in quality, safety, and patient access to their health information while maintaining privacy and security. ²⁴

The original Meaningful Use standards were successful in getting doctors and hospitals to adopt EHRs and further their use of health information technology. Those original standards have now been outgrown by newly emerging needs to facilitate more interoperability among the many different EHRs which presents an entirely new frontier with its own possibilities and challenges. Meaningful Use has been re-branded as "Promoting Interoperability" and new standards have been developed, with new incentives available through 2021. Heroperability Stages 1 and 2 encouraged the adoption and use of EHRs, the Promoting Interoperability Standards, Stage 3, expand on this usage to leverage technology and data capturing abilities to improve health outcomes, quality of care, interoperability, efficiency, and patient access to their health records.

In 2010 the Drug Enforcement Administration (DEA) published a final rule to go along with that year's other initiatives for increasing the use of EHR technology. The DEA authorized

²² https://www.hipaajournal.com/the-slow-pace-of-technology-adoption-in-healthcare-explained-8261/

²³ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4862057/

²⁴ https://www.cms.gov/Regulations-and-

Guidance/Legislation/EHRIncentivePrograms/downloads/MU Stage1 RegOverview.pdf

²⁵ https://healthcareinamerica.us/was-meaningful-use-a-failure-4f2c9f78820a

https://afmc.org/services/health-information-technology/

²⁷ https://www.cms.gov/Regulations-and-

Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms

the legal prescription of controlled substances through electronic means. This rule was not mandatory on the Federal level (but will be discussed later at the State level) but was made available as an option for providers who were using an EHR that complied with terms of the final rule.²⁸

On February 29, 2016, CMS issued an advisory letter to State Medicaid Directors, expanding the eligibility for funding for state expenditures under HITECH incentive payments. This expanded funding is intended to facilitate eligible professionals in meeting MU stage 2 or 3 requirements for information sharing and interoperability among all Medicaid eligible providers, even those who are not eligible for MU incentives. For example, an eligible professional may need to meet health information exchange requirements when coordinating a transfer of patient care to a long-term care facility, which is not an eligible facility. Under this new rule, the state can facilitate this capability with the non-eligible entity and be eligible for the 90% HITECH funding match meant to promote health information interoperability.²⁹

A new proposed rule released by the U.S. Department of Health and Human Services (HHS) on February 11, 2019 would implement several provisions of the 21st Century Cures Act with the purpose of increasing interoperability of and patient access to electronic health information. The proposed rule would require health care operations to standardize the format of their health information so that it may be easily shared in the format of a Health Information Exchange (HIE). It also provides that health care providers may not block the sharing of information, with seven exceptions including preventing patient harm and ensuring that information is kept private and secure within HIPAA guidelines. It also aims to reduce costs and burdens that have previously acted as barriers to health information interoperability. This proposed rule was publicized in the Office of the Federal Register on 3/4/2019 and was open for comments until 6/3/2019. The proposed rule received 1,923 public comments during this period. HHS has yet to release their final rule on these provisions. 30 31

III. The State of Arkansas

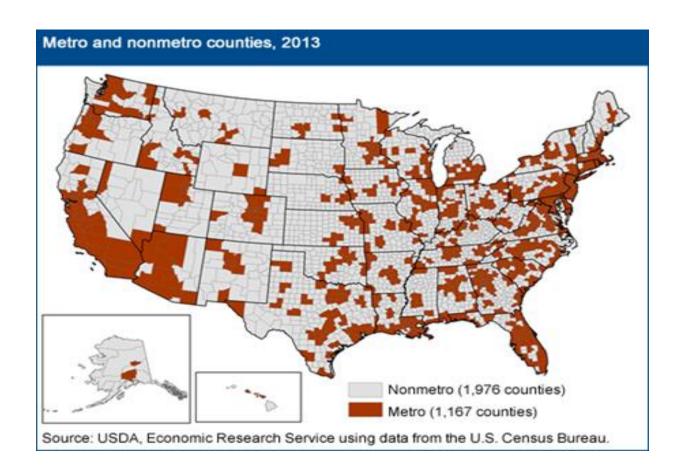
Arkansas is a very rural state, with a few "islands" of high-population areas, but much of the state is left to small, rural health systems and independent providers to meet the healthcare needs of rural Arkansans. This pattern is common in much of America, as illustrated by the following graph from the U.S. Census Bureau:

²⁸ https://www.deadiversion.usdoj.gov/ecomm/e rx/index.html

²⁹ https://www.medicaid.gov/federal-policy-guidance/downloads/smd16003.pdf

³⁰ https://www.cms.gov/Center/Special-Topic/Interoperability/CMS-9115-P.pdf

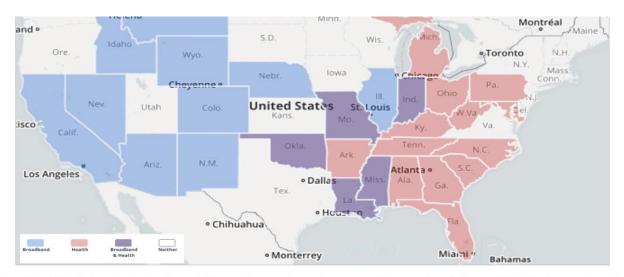
 $^{^{\}bf 31} \, \underline{\text{https://www.federalregister.gov/documents/2019/03/04/2019-02224/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification}$



Providers practicing outside these metropolitan centers may lack the resources taken for granted in metropolitan areas and are most in need of the support of educational programs and technological tools that prepare them to be successful owners as well as successful healthcare providers in underserved areas. Care delivery becomes more complicated in rural areas, with older, sicker, and poorer populations who may not have adequate insurance or other resources. It is difficult to attract and retain physicians to rural areas due to lower reimbursement rates and various quality of life issues.³² Consequently, meeting the needs of these patients while meeting regulatory requirements of improved quality outcomes, interoperability, and access to care can be a challenge. The lack of simple high-speed internet access is an obvious barrier to meeting these objectives. ³³

³² https://journalofethics.ama-assn.org/article/federal-and-state-initiatives-recruit-physicians-rural-areas/2011-05

³³ https://www.fcc.gov/health/maps



Broadband Health Double Burden Areas. This sample map shows the power of the mapping platform to identify clusters of need, potentially catalyze public-private partnerships and private sector collaborations, and focus policy efforts. The five states in purple—Indiana, Louisiana, Mississippi, Missouri, and Oklahoma—experience incidences of chronic disease above the national average. At the same time, fixed broadband access percentages in rural areas of these states are on average below 50%, and in some cases far below. (See also *Rural Broadband Access and Health* maps below showing "double burden" areas at the county level.)

A possible solution to begin closing this gap may include expanding the curriculum of medical schools and midlevel providers such as Advanced Practice Registered Nurses (APRN) to focus more on regulatory and IT education, especially in areas where there is a large rural population to serve and providers are more likely to find themselves isolated and in the position of being business owners as well as caregivers. State requirements to gain yearly Continuing Medical Education credits could include offerings for certain regulatory and technology issues. Schools could be encouraged to increase availability of dual degree programs for medical/APRN students such as master's in public policy (MPP), master's in healthcare administration (MHA) or master's in jurisprudence in health law (MJ).

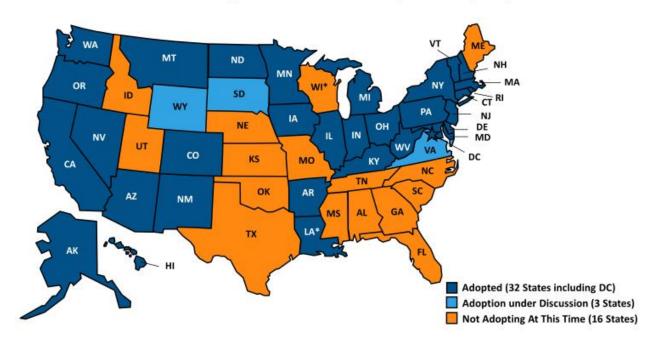
Arkansas, Alabama and other Southern states often rank at #48 or #49 in poor outcomes for education, healthcare, and crime, Mississippi often ranks #50. In the deep South, health disparities are significant and poor health indicators are statistically higher than in other regions. Obesity, diabetes, AIDS rates and infant mortality are higher here, and access to insurance coverage is lower than in other regions of the country. Although Arkansas is an exception, one reason for this access gap is that many Southern states did not choose to expand their Medicaid programs under the Affordable Care Act, as illustrated below: ³⁶

³⁴ https://www.fcc.gov/sites/default/files/broadband health sample maps 2017.pdf

³⁵ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1071163/

³⁶ https://www.kff.org/disparities-policy/issue-brief/health-and-health-coverage-in-the-south-a-data-update/

Figure 11
Status of Medicaid Expansion Decisions, January 12, 2016



Notes: Current status for each state is based on KCMU tracking and analysis of state executive activity. * LA's Governor signed an Executive Order to adopt the Medicaid expansion on 1/12/16, but coverage under the expansion is not yet in effect. WI covers adults up to 100% FPL in Medicaid, but did not adopt the ACA expansion. See source for more information on the states listed as "adoption under discussion." Source: "Status of State Action on the Medicaid Expansion Decision," KFF State Health Facts, updated January 12, 2016. http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/



37

On the technological side, innovative steps are already being taken to improve access to care for the neediest of rural populations in Arkansas, Mississippi, and other underserved areas. Although the terms "telehealth" and "telemedicine" are sometimes used interchangeably, telehealth is defined as a broad array of electronically delivered services to promote health, while telemedicine encompasses more of the clinical aspect of care delivery. The use of telehealth and telemedicine is expanding in rural areas, but there are barriers to these programs including infrastructure inadequacies and policy barriers. Reimbursement for telehealth services is one area that appears to be out of line with goals for a healthy population. Although insurers want to prevent poor outcomes and hospital readmissions, which can become expensive, many are not willing to cover telehealth services which may prevent some of these issues. The USDA and other agencies currently administer grant programs to support telehealth initiatives.

³⁷ https://www.kff.org/disparities-policy/issue-brief/health-and-health-coverage-in-the-south-a-data-update/

³⁸ https://www.aafp.org/media-center/kits/telemedicine-and-telehealth.html

³⁹ https://www.medicare.gov/coverage/telehealth

⁴⁰ https://www.americanbar.org/groups/health law/publications/aba health esource/2016-2017/december2017/telehealth/

⁴¹ https://www.ruralhealthinfo.org/topics/telehealth#challenges

Arkansas Statute

Some states including Arkansas have passed telemedicine parity laws. In April of 2015, Arkansas passed Act 887 which required Medicaid and private insurers to cover telemedicine services when certain requirements are met. Among these requirements are: the patient must be at an "originating site" which means at a provider's office or other healthcare facility. The consulting physician must be licensed to treat patients in Arkansas except in cases of periodic consultation. The telemedicine network must also be HIPAA compliant.⁴²

Legislation has been passed in many states to help combat the opioid epidemic. Health IT plays a large role in facilitating compliance with these laws, which include state mandated electronic transmittal of controlled substance prescriptions and state-wide tracking of controlled substance prescriptions. New York, Minnesota, and Maine were some of the earliest adopters of these regulations, with many other states following, including Arkansas. 43

The Arkansas Prescription Drug Management Program (PDMP) was put into place to help combat the opioid crisis. Known as Act 820 and approved on 4/3/2017, every time a Schedule II-V controlled substance is dispensed, the dispenser is required to provide the State Board of Health with certain information on both the prescriber and the recipient of the prescription. The State Board of Health uses this data to create a database of controlled substance prescriptions. Providers must obtain access to this database and are mandated to query a patient prior to writing a prescription for any schedule II or III controlled substance or for the first prescription of any benzodiazepine. If irregular prescribing or dispensing patterns are found, or signs of abuse are detected according to the guidelines set by the Director of the Department of Health and the PDMP Advisory Committee, prescribers will be sent a notice and if the pattern continues over a 12 month period, they will be referred to their respective State licensure committees for disciplinary action. The State unfortunately has had some funding deficits in this area and there is currently no way to monitor if providers have actually complied with the regulation to check the database prior to prescribing. The state unfortunated to the prior to prescribing.

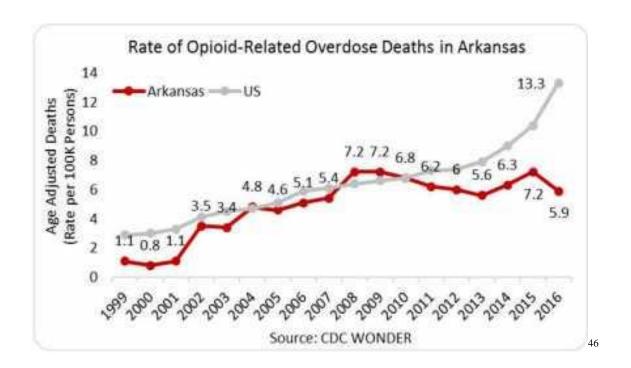
The Act states that the PDMP will provide real time data for all participants by January 1, 2019 if funding and technology are available. This real-time data would allow prescribers to see where their prescribing practices fall into the average and if they were an outlier and may need to change their practices. In Act 901, which took effect 4/1/2015, certain law enforcement officers were granted access to the PDMP database for law enforcement purposes. Since the initial Act was approved in 2011, opioid-related deaths have decreased significantly in Arkansas as compared to the rest of the United States.

⁴² https://legiscan.com/AR/bill/SB133/2015

⁴³ https://mdtoolbox.com/eprescribe-map.aspx?AspxAutoDetectCookieSupport=1

http://www.arkleg.state.ar.us/assembly/2017/2017R/Acts/Act820.pdf

⁴⁵ Interview with Thomas Holt, IT Director of Arkansas SHARE



An amendment to Arkansas Senate Bill 174 was recommended for passage by the Senate Judiciary Committee on February 13, 2019. The bill was signed into law as Act 447 of the Regular Session on 3/13/2019 entitled *An Act to Require Mandatory Electronic Prescribing for Controlled Substances; and for Other Purposes*.⁴⁷ This requirement will take effect on January 1, 2021. The Arkansas Office of Health Information Technology (OHIT), which houses the Arkansas State Health Information Exchange, the State Health Alliance for Records Exchange (SHARE) has received several calls from small practice providers who are concerned about the implications for their practice as they do not currently have the capability to prescribe via electronic means. ⁴⁸ Many nursing homes, dental offices, and other non-acute care providers who were not eligible professionals or hospitals under meaningful use also do not currently have the capability to prescribe electronically.

Arkansas is not alone in the underusage of the electronic prescribing capabilities available within EMRs. According to Surescripts, a highly interoperable network of pharmacies and providers and one of the largest clearinghouses for electronic prescribing nationwide, as of February 2019, 95.2% of pharmacies nationwide were Electronic Prescribing for Controlled Substances (EPCS) enabled, but only 33.4% of prescribers were EPCS enabled. With more and more states passing laws making electronic prescribing mandatory, more organizations will be forced to consider adopting new technologies and practices.

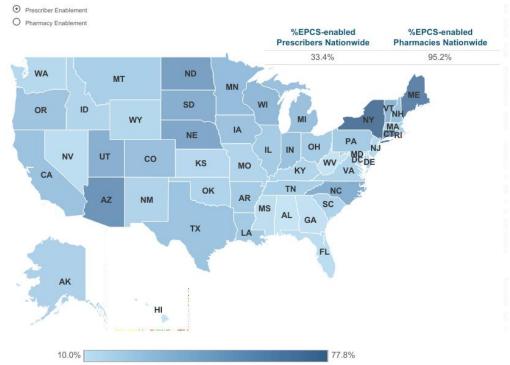
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⁴⁶ https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/arkansas-opioid-summary

⁴⁷ http://www.arkleg.state.ar.us/assembly/2019/2019R/Pages/BillInformation.aspx?measureno=SB174

⁴⁸ Interview with Thomas Holt, IT Director of Arkansas SHARE

EPCS Readiness: Which States Lead the Charge?



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49

IV. The Case for Health Information Interoperability

According to HealthIT.gov, "Electronic health information exchange (HIE) allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically—improving the speed, quality, safety and cost of patient care." HIE is not a new concept. It is an effort which has now been over three decades in the making. Only recently has the federal government begun to provide policies to support the adoption of HIE on a large scale.

In the early days of the HIE effort, in 1990, the availability of technology was an important barrier to achieving the goal of sharing health information on a large scale. Another common concern brought up when discussing the feasibility of HIE is information privacy and security, although studies show that the most common breach of privacy in hospitals involve paper

⁴⁹ https://surescripts.com/enhance-prescribing/e-prescribing/e-prescribing-for-controlled-substances/

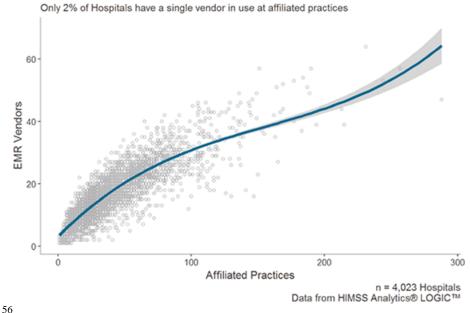
⁵⁰ https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/what-hie

records.⁵¹ Because of privacy concerns, early HIE efforts were resisted by providers who lobbied successfully against them in places like Iowa. Patients also have concerns about sharing their entire medical histories in this way.⁵² As we have moved forward into our new, technology-oriented age, and more legislation has been passed to protect privacy and security of health information, the opportunity to implement HIE has become more realistic. Arguments against it have changed, but still exist.⁵³

Many HIEs are in existence, with state government-funded programs and privately-operated competitors vying for market share.⁵⁴ Although several electronic health record (EHR) companies, such as Epic have joined in the HIE race,⁵⁵ many EHRs do not communicate with one another, and this is a problem not only on the larger scale of state-wide or nationwide information sharing but on an individual hospital or health system level, where many different EHR platforms may be in use within the same system.

The average hospital has 16 disparate EMR vendors in use at affiliated practices





The maturity of individual HIEs across the nation varies greatly as do the capabilities to collect and use data.⁵⁷ Approaches to creating these exchanges has not been standardized, and so while interoperability within one exchange may be excellent, that same exchange may not have the

 $[\]frac{\mathsf{51}}{\mathsf{https://www.beckershospitalreview.com/cybersecurity/the-most-common-type-of-data-breach-in-hospitals-paper-records-study-suggests.html}$

⁵² https://www.hipaajournal.com/patients-holding-back-health-information-over-fears-of-data-privacy-8634/

⁵³ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2995716/

⁵⁴ https://www.healthcareitnews.com/news/state-and-regional-hies-dont-count-us-out-just-yet

⁵⁵ https://www.epic.com/interoperability/ehr-interoperability-from-anywhere

⁵⁶ https://www.healthcareitnews.com/news/why-ehr-data-interoperability-such-mess-3-charts

⁵⁷ https://ehrintelligence.com/news/report-ranks-top-five-best-worst-states-for-ehr-adoption

capability to exchange information with another system, which defeats the purpose of the interoperability initiative. ⁵⁸

With all these barriers to implementing the HIE initiative, making a solid business case to encourage health systems to adopt this technology is difficult. There have been so many variable results in implementation and unmet goals so far, studies are questionable as to the value of HIE to customers and better research still must be conducted.⁵⁹ Various approaches have been proposed in order to further incentivize the adoption of HIE.

Although HITECH requires providers to "connect in a meaningful manner," further standards do not exist to encourage providers to maximize their participation in HIE. One organization that has the most power to make a difference in pushing providers into HIE use is CMS. By adopting more standards or requiring submission of quality measures that can only be met through the exchange of information with others as a condition of reimbursement, CMS holds enormous power over most providers. Another approach is to treat HIE as a public good, much like law enforcement or highways. An approach such as this, with a special emphasis on underserved and rural areas would allow everyone to participate without the individual costs associated with building interoperability one facility at a time. 61

A business case can be made, but it is often theoretical, based on long-term cost savings through efficiency, quality of care improvement, and improved reimbursement or lack of reimbursement penalties. Immediate outlay of cash in order to support an IT initiative that will lead to a theoretical return on investment over time in a rapidly changing healthcare environment can be a hard sell. In order to make this argument work, buy in must be gained from the highest executive and physician levels and careful consideration must be given to the selection and implementation of the project, with a focus on outcomes and transforming the way care is delivered within the system in which the HIE is being adopted.⁶²

V. Barriers to Implementation

The cost of implementing an EHR is a large barrier. Investment in Information Technology is only one part of the overhead in owning a small practice, ⁶³ and "Several studies estimate the cost of purchasing and installing an electronic health record (EHR) ranges from \$15,000 to \$70,000 per provider." Costs include 5 main components including the necessary hardware, software, implementation assistance, training, and ongoing support fees. ⁶⁴ This cost could significantly cut into the practice's ability to invest in other vital needs, such as updated equipment,

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⁵⁸ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5983050/

⁵⁹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5983050/

⁶⁰ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2995716/

⁶¹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2995716/

https://www.acc.org/~/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/Tools%20and%20Practice%20Support/Practice%20Solutions/Health-

IT/Data%20Harmony%20ACC 4%20Business%20Case%20for%20Interop Chaidez%202018 0504%20FINAL.pdf?la=en

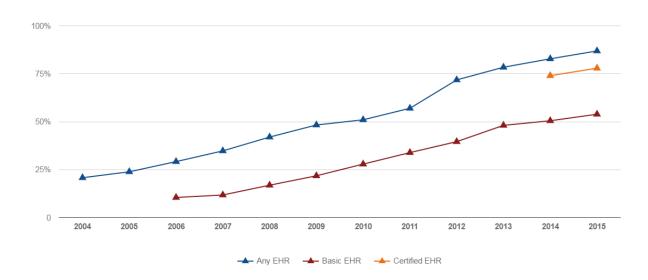
⁶³ https://www.99mgmt.com/blog/medical-practice-overhead-expenses

⁶⁴ https://www.healthit.gov/faq/how-much-going-cost-me

more personnel, or lead to a necessary tightening of an administrative budget which could mean less resources available for an effective overall compliance program. ⁶⁵

Eligible professionals under HITECH for the EHR Incentive Program, which were limited to physicians, dentists, nurse practitioners, and chiropractors who were not primarily hospital associated as well as acute care hospitals and critical access hospitals were eligible to participate in the EHR Incentive Program. These providers implemented EHRs at a much faster pace than providers who were not classified as MU eligible professionals, such as long-term care facilities, who have lagged behind in the implementation of EHRs. The graphics below demonstrate the adoption rate for physician offices, hospitals, and long-term care facilities:

As of 2017, nearly 9 in 10 (86%) of office-based physicians had adopted any EHR, and nearly 4 in 5 (80%) had adopted a certified EHR.⁶⁸



As of 2016, over 95 percent of all eligible and Critical Access hospitals have demonstrated meaningful use of certified health IT through participation in the Centers for Medicare & Medicaid Services (CMS) Electronic Health Record (EHR) Incentive Programs.⁶⁹

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https://www.acponline.org/system/files/documents/advocacy/current_policy_papers/assets/controlling_healthca_re_costs.pdf

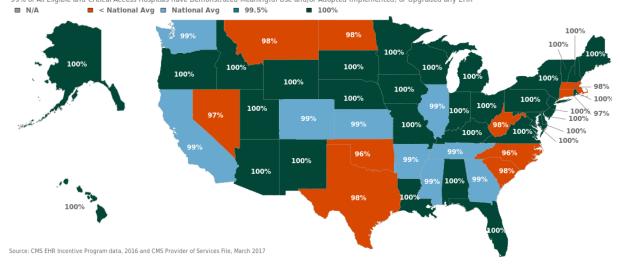
⁶⁶ https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/eligibility.html

⁶⁷ https://www.managedhealthcareconnect.com/article/impact-meaningful-use-and-macra-long-term-care

⁶⁸ https://dashboard.healthit.gov/quickstats/quickstats.php

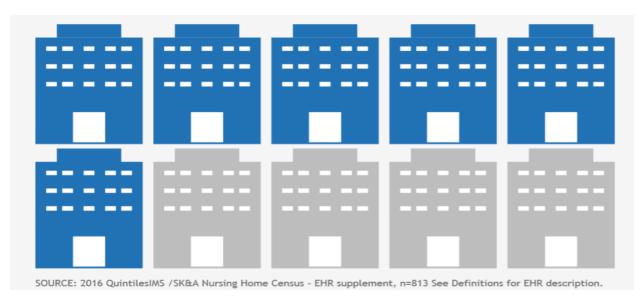
⁶⁹ https://dashboard.healthit.gov/quickstats/pages/FIG-Hospitals-EHR-Incentive-Programs.php





A majority of SNFs (64%) used an EHR in 2016.

Figure 1: Percent of SNFs that used an EHR, 2016⁷⁰

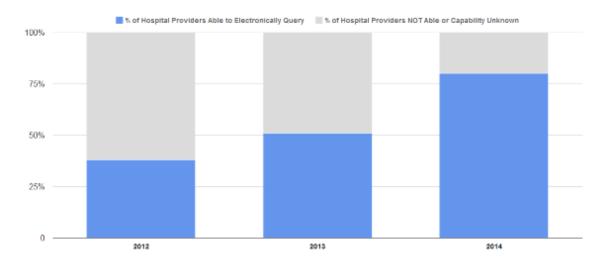


It is apparent from these statistics that nursing homes (also known as skilled nursing facilities, or SNFs) have less utilization of EHRs than physician's offices and hospitals at 64% as compared to 86% and 95%, respectively. As nursing homes were not considered eligible professionals or entities for MU, they did not receive incentive payments for the implementation of EHRs and were left behind.

 $^{^{70}\} https://dashboard.healthit.gov/evaluations/data-briefs/electronic-health-record-adoption-interoperability-nursing-facilities-2016.php\#figure1$

Once an EHR is implemented, the next stage in MU is to promote interoperability and exchange information electronically with other providers. This leads to its own set of costs. For many organizations with competing priorities, HIE just has not made it to the top of the "to-do" list, but compliance is growing. ⁷¹ Within the HIEs themselves, there are further barriers. One important barrier is that of patient identification. With the fragmented and inconsistent information being sent from hospitals and other providers to HIEs, it is very difficult to match records to a patient using typical patient identifiers. For example, many patients could share the same name, ethnicity, and birthdate. Zip code, payer source, phone number, and many other demographic identifiers could change and are unreliable. Medical record numbers are EHR specific. Not everyone has or wants to disclose a Social Security number. These small but important details can lead to big problems when working out how to make the correct information flow into the correct individual's health record.⁷²

U.S. Hospitals' Capability to Electronically Query Patient Health Information from Outside Their Organization or System



As of 2014, 80 percent of non-federal acute care hospitals have the capability to electronically query patient health information from external sources, an over 30 percentage point increase from 2013. In 2014, 48 percent of hospitals routinely queried patient health information from outside their organization or system. View Quick Stat.

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⁷¹ https://ehrintelligence.com/news/providers-still-facing-health-information-exchange-barriers

⁷² Interview with Thomas Holt, Director of Information and Technology, Arkansas SHARE

Constant change, limited resources, and complicated legislation can lead to lack of on-site expertise, ineffective employee training programs, and lead to physician burnout due to the ever-increasing burden of administrative tasks and paperwork.⁷³

In a constantly changing technology and regulatory filled world, the failure to keep up with or properly plan changes can make the difference between legal and illegal actions. Small improvements in technology can easily lead to a HIPAA Privacy breach if improperly installed or used without proper training. The failure to include a crucial element of the HIPAA Privacy rule, such as forgetting to make a Notice of Privacy Practices document easily accessible to patients when switching from in-person to electronic check in at the doctor's office can lead to a very costly regulatory infraction. ⁷⁴ ⁷⁵

A small physician practice, as with any other small business, has significant financial and human resource constraints and they face a disproportionate portion of regulatory costs when compared to larger corporate competitors. Whereas a large business entity may consider it a small and well-spent business expense to fund a compliance department to handle this type of issue for them, a small practice may have neither the available funds nor the office space to implement a program which provides no return on investment besides peace of mind. Hiring experts or certifying administrators to run an effective compliance program can strain an already tight budget. Taining employees in their role as stewards of a patient's health information or as to why it is important to avoid accepting gifts from vendors or patients takes more resources to develop, administer, and monitor the effectiveness of training, especially in light of today's shortage of healthcare workers leading to low retention and therefore frequent retraining. In light of these serious issues, small practices may choose to cut corners and hope for the best.

While federal HIPAA Privacy and Security law applies to everyone, several states have enacted legislation that is more restrictive. The language and consequences of bills effecting healthcare can be complicated and difficult to understand for someone who is not trained to interpret what they mean for their business. Issues such as the exchange of PHI via HIE will not be fully implemented until progress is made on getting different systems to overcome interoperability problems. Navigating the legalese of legislation and associated delays and frustrations in implementing complicated care models for a legally un-trained physician is like asking an English teacher to teach a Spanish class. A truly effective compliance program will incorporate people who understand both medical and legal terminology.

⁷³ https://www.ama-assn.org/practice-management/sustainability/do-you-spend-more-time-administrative-tasks-your-peers

⁷⁴ https://www.hhs.gov/sites/default/files/privacysummary.pdf

⁷⁵ http://www.physicianspractice.com/mgma-2016/low-cost-strategies-medical-practice-compliance

⁷⁶ https://www.sba.gov/advocacy/small-business-regulatory-enforcement-fairness-act-sbrefa

https://www.corporatecompliance.org/Portals/1/PDF/Resources/past_handouts/CEI/2017/P8_lane-vacca_2.pdf

⁷⁸ https://www.compliancecertification.org/AboutCCB.aspx? ga=2.139934003.1054537114.1543790470-1664946649.1543790470

⁷⁹ http://www.hcca-info.org/Portals/0/PDFs/Resources/Surveys/hcca-2015-hlthcr-cco-staff-salary-survey-report.pdf

⁸⁰ http://pages.stern.nyu.edu/~adamodar/New Home Page/datafile/margin.html

⁸¹ https://www.ruralhealthinfo.org/topics/health-care-workforce

⁸² https://www.sba.gov/advocacy/small-business-regulatory-enforcement-fairness-act-sbrefa

Even if an organization expends all the resources necessary to train their employees, they still must re-train periodically⁸³ and monitor whether or not the initial training was effective.⁸⁴ The work culture, values and ethics of an organization can have a lot to do with the effectiveness of the training.⁸⁵ There must be a balance between the focus on patient care and compliance in order to maintain the sustainability of a practice and protect patients from financial conflicts or privacy concerns arising from non-compliance, no matter how innocent the intent.⁸⁶

Current medical school curriculum is not set up to prepare physicians for business ownership, as it currently focuses primarily on clinical care. ⁸⁷ This leaves physicians at a disadvantage when they attempt to navigate the regulatory and business world associated with beginning or joining a small practice, where resources may not exist to launch a full-scale compliance program or department. ⁸⁸

Medical schools focus on training physicians to care for patients and are not usually set up to train business leaders, and dual degree programs are expensive and time consuming, especially when compounded by an already long and arduous undertaking such as medical school. Medical school entrance requirements generally include an undergraduate education in the natural sciences; biology, physics, or chemistry in the case of physicians or a biology based degree such as nursing for APRNs.

Due to training, priorities, knowledge deficits, and resource constraints, healthcare providers may harbor some resistance when told that they need to do certain things in order to maintain regulatory compliance. They may fear a loss of autonomy, or mourn for the way medicine used to be before it became so regulated. The Centers for Medicare and Medicaid Services (CMS) offers extensive guidance for small practices in the form of publications, open forums, special websites, and other communication methods intending to lessen the burden on providers in complying with regulations, but with over 7 million pages of documents this guidance may be time consuming for a provider already working long hours. Physicians who intentionally ignore compliance rules may find out that seemingly small infractions add up very quickly when facing health care fraud and abuse allegations and the possible resulting penalties of being disqualified from participation in CMS programs coupled with hefty fines and possibly even criminal charges can quickly put an end to their practice and possibly their career.

⁸³ https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ComplianceProgramPolicyandGuidance.html

⁸⁴ https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Compliance-Program-Effectiveness-Self-Assessment-Questionnaire.pdf

⁸⁵https://www.researchgate.net/publication/305390900 The Influence of Organizational Culture on Training Effectiveness

⁸⁶ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3555315/

⁸⁷ https://medschool.duke.edu/education/student-services/office-curricular-affairs/about-duke-curriculum

⁸⁸ https://www.sba.gov/advocacy/small-business-regulatory-enforcement-fairness-act-sbrefa

⁸⁹ https://www.hopkinsmedicine.org/som/admissions/md/application process/prerequisites requirements.html

⁹⁰ https://nurs.uark.edu/degrees-offered/dnp/admission-requirements.php

⁹¹ https://hbr.org/2014/06/engaging-doctors-in-the-health-care-revolution

⁹² https://www.cms.gov/Regulations-and-Guidance/Guidance/SmallEntity/index.html

⁹³ https://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf





VI. Conclusions and Recommendations

Healthcare Compliance is a constantly evolving industry and it is imperative that knowledgeable professionals are available to be employed in this field. The fast-paced world of healthcare IT is a large focus of many of the new regulations being pushed out today. As a new and evolving field in as complicated a healthcare environment as the United States, there have been failures, successes, lessons learned, and unintended consequences from past legislation. Moving forward with a focus on health care interoperability is essential to transforming the U.S. healthcare system into a more efficient, sustainable, and quality of care driven model.

CMS and other payers are already beginning to take steps to promote interoperability. This will most likely be the most significant motivator for organizations to buy into an HIE. The FY 2019 Medicare Promoting Interoperability Program has recently released their finalized performance-based scoring system, which effects eligible hospitals and critical access hospitals. Non-acute care providers and other ancillary providers such as long-term care are notably left out of many of these initiatives. In order to achieve true efficiency and completeness of information, all providers of health care across the spectrum will need to eventually participate in a robust information sharing network.

Information sharing is only as good as the information that is available to share. A standardized way to identify patients is needed, such as via a National Health Identification Number. Standards would have to be set for how these numbers are issued, maintained, and tracked for patients. Standards must also be achieved among the delivery of HIE among states and health systems nationwide.

A shift is taking place in the healthcare delivery system in the U.S. that will affect every stakeholder that provides, receives, legislates, or pays for care in our country. Promoting interoperability is a hard sell. It costs money. The benefits are difficult to quantify in real cost terms. Old habits die hard. The only reason providers and systems have been eager to adopt EHRs and other technology is because they have been incentivized to do so by their biggest payer source; CMS a.k.a: the U.S. government. Non-acute facilities have been much slower to adopt technology because they are not necessarily required to do so. Rural providers have found that they face access, socioeconomic, infrastructure, and other issues when attempting to implement these initiatives. The ultimate goal of promoting interoperability is to ensure that all healthcare related information is where it needs to be, when it needs to be there in order to facilitate efficiency and expedience in caring for patients. The public good is at stake.

There are many initiatives already in place to remove barriers in non-acute and rural care environments. The USDA is helping to expand broadband internet access in rural areas. ⁹⁴ In 2018, CMS announced their Rural Health Strategy program to focus on what is needed to increase quality of care in rural areas. ⁹⁵ However, more needs to be done. Non-acute care providers should be included in the incentives and requirements for participation in MU. Other incentives specific to providers, such as Public Service Loan Forgiveness (PSLF), a government program that promises to forgive the remaining balance on Federal student loans after 10 years of payments while working full time at a non-profit or government facility could entice more providers to a public service career. This program has been poorly administered and many applicants for PSLF have been denied loan forgiveness after meeting what they thought were all the requirements.

Dr. Stacy Zimmerman of Searcy, AR is the Director of a rural health medical residency program and states that "It is my passion to educate physicians to practice in the underserved areas of rural Arkansas." As the supervising physician in her residency program, rural Arkansans who come to her clinic are offered access to her services as an internal medicine physician, which is very unusual in a rural area. Dr. Zimmerman prides herself on preparing doctors to be leaders and to practice in a rural setting, where they are greatly needed. Passionate physicians such as her are perhaps the most valuable key to providing the ability to serve patients in the most efficient and high-quality way available. The most important stakeholders in making all of this happen are not the patients clamoring for better healthcare or better insurance, but healthcare providers themselves. Without properly trained, passionate, engaged, adaptable providers of healthcare, who make their life and livelihood about caring for and advancing the care of all patients, all these compliance regulations, IT initiatives, and public health initiatives would no longer need to exist.

 $^{^{94}\} https://www.usda.gov/media/press-releases/2018/11/13/usda-partners-communities-bring-high-speed-broadband-e-connectivity$

⁹⁵ https://www.cms.gov/newsroom/press-releases/cms-announces-agencys-first-rural-health-strategy

⁹⁶ https://www.arkansasonline.com/news/2018/jul/08/director-focuses-patient-centered-care