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SUPPORTING PHARMACY DATA INTEROPERABILITY: AN IMPERATIVE FOR PATIENT ACCESS AND OUTCOMES

Table of Contents

April 2023

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KEY FINDINGS

- Pharmacy provision of clinical services has been shown to improve health outcomes and is increasing at a time when patients need better access to services.
- It is imperative that the health care system achieve pharmacy data interoperability to preserve and enhance pharmacies' ability to help patients access the clinical services they need and to ensure that services pharmacies and other health care providers offer are based on complete and up-to-date clinical records.
- Significant progress has been made toward achieving pharmacy data interoperability, even though pharmacies have not had some of the advantages that have proven helpful in implementing data interoperability for other providers. Examples of progress include use of clinical documentation systems, increased data sharing during the COVID-19 pandemic, state Health Information Exchanges, vaccination registries, and prescription drug monitoring programs.
- However, challenges to pharmacy data interoperability remain that warrant action, and it behooves the entire health care system to collaboratively meet those challenges for the benefit of patient access and outcomes.
- There are steps that federal and state policymakers, technology and electronic health record companies, health plans, pharmacies, and other health care providers can take to further strengthen pharmacy data interoperability.

EXECUTIVE SUMMARY

Pharmacy provision of clinical services is important to patient access and outcomes. As patients access more services from pharmacies, the data interoperability of those pharmacies becomes more important to the health care system at-large. Pharmacy teams' ability to provide optimal care and meaningfully contribute to the value-based care transformation depends on their ability to access and contribute to patients' clinical records, just as hospitals, clinics, labs, and other providers need to know the information stored in pharmacies' systems if they are to appropriately serve their patients.

In this report, Leavitt Partners studies progress to date and remaining challenges in improving data interoperability for pharmacies, as well as measures that could help close the data interoperability gap for pharmacies. We summarize our findings and note that important progress toward pharmacy data interoperability includes use of clinical documentation systems, increased data sharing during the COVID-19 pandemic, state health information exchanges (HIEs), the Pharmacist eCare Plan, vaccination registries, prescription drug monitoring programs. and standardized data application programming interfaces (APIs). Useful as they are, we find that these tools are insufficient and incompletely implemented. Opportunities exist to address these gaps and promote broader pharmacy data interoperability that elevates the effectiveness and efficiency of the health care system.

This report finds that federal and state policymakers, technology and electronic health record (EHR) companies, health plans, pharmacies, and other health care providers can take steps to strengthen pharmacy data interoperability:

- **The Office of the National Coordinator for Health Information Technology (ONC)** can continue to include pharmacists and pharmacies in its definition of providers and encourage Qualified Health Information Networks (QHINs) to be ready to meet pharmacies' data exchange needs.
- **The ONC and the Office of the Inspector General (OIG)** can enforce implementation of the Cures Act, especially by holding Certified Electronic Health Record Technology (CEHRT) vendors and other health care system stakeholders accountable for sharing standardized data with pharmacies.
- **Federal lawmakers** can support ONC and OIG in this important work by ensuring that ONC is able to issue advisory opinions for information blocking and that the ONC and OIG have resources sufficient to support the enforcement authority that the Cures Act has granted them.[xxxvi]
- **The Centers for Medicare and Medicaid Services (CMS)** can encourage the inclusion of pharmacies in existing and emerging value-based care models, thereby incentivizing them to invest further in data interoperability.
- **State policymakers** can ensure pharmacies can access HIEs as an interim solution, while also supporting the development of more robust solutions, including cost-effective integration of HIE data into pharmacy and other clinical platforms for use at the point of care.[xxxviii] State

policymakers also can design their Medicaid plans to exercise the option to allow pharmacies to provide access to clinical services that patients need and pharmacy teams are trained to deliver.[xxxix]

- **Both state and federal policymakers** can ensure that statutes and regulations don't unnecessarily limit pharmacy-based provision of clinical services that patients need and can carefully weigh proposed mandates that require data reporting or adoption of certain technology against the risk of unintended consequences that ultimately could restrict patient access to clinical services.
- **Technology companies** can continue to prioritize the development and implementation of cost-effective data-sharing solutions for pharmacies that promote seamless integration with pharmacy dispensing systems and perform clinical interventions at the point of care.
- **Health plans** can work with technology companies and pharmacy system vendors to standardize processes to exchange data with pharmacies by leveraging sustainable infrastructure, rather than building and deploying unique and fragmented pharmacy data-sharing platforms or other workarounds.
- **Pharmacies** can use clinical documentation systems (where available and cost-effective), cloud-based data warehouses and applications, and single-user interfaces that support data interoperability. They can also maximize their use of HIEs where available as a transitional step toward greater data interoperability and ensure that their data exchange practices align with the information-sharing expectations established in the 21st Century Cures Act (Cures Act) Information Blocking Rule.
- **Other health care providers** can also ensure that their data exchange practices are aligned with the information-sharing expectations established in the Cures Act's Information Blocking Rule and embrace existing standards when exchanging data with pharmacies. This step will help ensure that services provided continue to be based on complete and current clinical records, especially as pharmacies provide increasing patient access to services.

These steps will support pharmacy data interoperability, which is critical to improving patient access and outcomes.

The research Leavitt Partners conducted to inform this report includes 22 interviews with 17 experts at 11 organizations including pharmacies, technology companies, standards development organizations, and other stakeholders. Our research also included a review of publicly available government reports, peer-reviewed journal articles, white papers, news articles, and other publicly available sources.

INTRODUCTION

Roughly 90 percent of the US population lives within five miles of a community pharmacy.[i] Visited 12 times more frequently than the average patient's primary care provider, pharmacies often are a touchpoint for individuals seeking care.[ii] Given estimates that the national physician shortage will reach 122,000 in less than 10 years,[iii] access to clinical services in pharmacies will be needed even more urgently in the years ahead.

Pharmacy teams are experts in pharmaceutical sciences and broader clinical patient care skillsets and increasingly are viewed as a critical component of the interprofessional primary care team—one that saves lives and resources.

Over the last two decades, pharmacies have become a top vaccination access point and increasingly provide various point-of-care tests, screenings, chronic care management programs, preventive care referrals, smoking cessation efforts, contraceptive care, transitions of care programs, medication adherence interventions, and other clinical services that have demonstrated improved outcomes and downstream cost savings.[iv]

Pharmacies' breadth of service offerings was further expanded through policies implemented to meet the needs of patients brought about by the COVID-19 pandemic. Retail pharmacies demonstrated their ability to provide needed clinical services with scale and speed during the COVID-19 response, administering more than 300 million vaccine doses in addition to testing and advancing access to treatments.[v,vi] As the US population ages and the demand for accessible clinical care continues to rise, it is important to enable pharmacies to build on the clinical services they can offer in alignment with the health needs of the communities they serve—from medication management to chronic care management.

Health plans and provider organizations involved in risk-based contracting have taken note of pharmacists' ability to contribute to the health of their communities by providing services that optimize medication use.[vi,vii] According to the National Academies of Science, Engineering, and Medicine, these organizations are increasingly recognizing the important role pharmacists play in chronic care management through direct payment strategies or value-based payment (VBP) arrangements.[viii]

The ability for pharmacies to expand access to care largely depends on states modernizing their policies to support increased access at pharmacies and at the same time is highly dependent on the ability for pharmacies to be reimbursed by health plans for the care delivered by pharmacy staff. Federal COVID-19 pandemic response policies have temporarily preempted the patchwork of state policies to support needed public access to critical services like COVID-19 vaccinations, testing, and antivirals by leveraging the nation's pharmacies without state-by-state restrictions. This increased access saved millions of lives and billions of dollars. As noted, pharmacists' teams provided more than 300 million doses of the COVID-19 vaccine.[v] Research shows that 70 percent of pharmacies providing expanded access to COVID-19 vaccines were located in communities with moderate to high social vulnerability.[ix]

To best deploy pharmacy teams' ability to serve patients and participate in value-based arrangements that maximize patient value, pharmacies need access to relevant patient information and the ability to share relevant patient information with other stakeholders, including health systems, primary care providers, and patients. In short, to capitalize on the clinical value of pharmacies to achieve broad goals related to access, equity, quality, and value, the health care system must achieve pharmacy data interoperability.

BACKGROUND

To understand the current pharmacy data interoperability landscape—the subject of the next section—it is useful to review some background on the dynamics that have shaped it, including policies that impact which services pharmacy teams are able to provide to patients, the extent to and method by which health plans cover and reimburse pharmacies for clinical services, and the fragmented nature of pharmacy data and systems.

Pharmacy Provision of Clinical Services

Pharmacies' ability to provide clinical services is subject to state and federal statutes and regulations. For instance, the Social Security Act's definition of a provider excludes pharmacists, prohibiting direct payment from Medicare Part B to pharmacists for services delivered to patients that go beyond incidental services linked directly to a covered provider.[x] State statutes vary but may feature similar limitations, and states' Medicaid state plans, which spell out how a state's Medicaid program will be run, are afforded more flexibility yet often limit pharmacy provision of clinical services, even if state statute allows it. Commercial insurers' plans are typically less encumbered and better able to take advantage of pharmacies' ability to provide access to clinical services.

As noted previously, federal action in response to the emergence of COVID-19 simplified rules allowing pharmacies to provide better access to clinical services. At the state level, states are viewing pharmacies as an effective way to increase access to quality clinical services. States like Arkansas,[xi] Iowa,[xii] Alaska,[xiii] Idaho,[xiv] and Kentucky[xv] have recently cleared the way for pharmacies to provide additional clinical services.

Coverage and Reimbursement

One factor contributing to gaps in pharmacy data interoperability is that historic payment models have stunted pharmacies' ability to receive proper reimbursement for clinical services, thus limiting incentives to engage in interoperability efforts. The traditional method of reimbursement for pharmacies is through a transactional payment system oriented toward dispensing drugs rather than administering clinical services. The historic dispensing model, while sufficient decades ago when pharmacies provided fewer clinical services, is an ineffective means of facilitating reimbursement for pharmacies today.

Further, as payers transition away from fee-for-service reimbursement and toward value-based payment (VBP) arrangements, pharmacy services will need to be recognized as integral components of patient care teams.

The lack of integrated clinical reimbursement affects data interoperability because pharmacies need financial incentives to help pay for the infrastructural cost of developing and implementing technology systems that allow clinical data to be easily and securely documented, analyzed, and exported. These systems, which require financial investment to support their integration into the pharmacy space, are discussed later in this report.

Fragmented Data and Systems

Pharmacies were excluded from early requirements and incentives related to EHR. As a result, unlike other parts of the health care system that are served by highly uniform, certified solutions offered by a handful of dominant vendors, pharmacy data and systems are relatively fragmented. For example, some pharmacies have developed their own proprietary systems to capture and store clinical information, and one pharmacy's "homegrown" clinical documentation system might look quite different from another's. More commonly, pharmacies use a clinical documentation system offered by a third-party vendor—typically the same company the pharmacy relies on for its prescription dispensing and/or pharmacy management system. Again, one vendor's system may look quite different from another's and different still from proprietary systems that are in use. As a result of this fragmented environment, while data and systems within a pharmacy organization or chain may be very fluid, links between organizations often require a degree of custom mapping and manipulation.

The fragmentation and lack of technological standardization in the pharmacy space hinder the furtherance of data interoperability. While there is no one singular system for storing dispensing pharmacy data, many industry professionals described an ecosystem that has lacked uniformity, thus limiting the pharmacy system's ability to transmit data between health care stakeholders. With incentives and infrastructure already formed in the clinical health system space, largely using HL7® FHIR®, health systems find themselves unable to communicate with retail pharmacies, which historically have used standards developed by the National Council for Prescription Drug Programs (NCPDP).

Leavitt Partners found that many pharmacy stakeholders have inconsistent capacities for importing clinical data to create patient profiles and analyze clinical documentation. While some pharmacies have found innovative solutions for viewing clinical data from other providers, other pharmacies have had to use outdated modalities such as email, fax, or mail. Because of these technical limitations in interoperability, pharmacists are hindered in their ability to deliver clinical care they were trained to provide, further frustrating data interoperability modernization.

PROGRESS ACHIEVED

Despite the headwinds described above, much work has been done to narrow the pharmacy data interoperability gap. Below we describe this work in technical and policy terms.

Technical Landscape

Interviews with pharmacy and interoperability leaders revealed several tools that are integral to the current pharmacy data interoperability landscape.

Clinical Documentation Systems

A clinical documentation system is a system that is able to utilize clinical data from other stakeholders as well as pharmacy workers during the delivery of clinical care. To address clinical data storage and usage, pharmacies have to integrate data solutions that allow for the importation, use, and exportation of clinical data to collaborate with health care stakeholders outside of the existing pharmacy system infrastructure. Hospitals have long used EHRs that have been subsidized and required by federal laws and regulations, which

has allowed for the proliferation of EHRs in many health care settings.

Pharmacy stakeholders that Leavitt Partners interviewed for this report indicated that EHRs optimized for hospital clinical service do not fit well into the pharmacy workflow and are not easily modifiable to adjust for implementation challenges. Therefore, some pharmacies have developed clinical documentation systems, used widely but not universally, to begin integrating clinical information into the pharmacy workflow.

According to interviewees, some of these documentation systems were developed proprietarily to account for clinical workflow, whereas other pharmacies are utilizing third-party vendors.

A limitation of the current ecosystem of clinical documentation systems is that there is little standardization of program utilization, and existing programs offer varying features, thus perpetuating the fragmented progress in pharmacy clinical data interoperability. While the progress to date is helping to modernize pharmacy clinical workflow and, thereby, improve patient experience, the pharmacy clinical documentation space has not received the same financial and regulatory support that other stakeholders have received and that aided their progress toward data interoperability.

Health Information Exchanges

HIEs offer the technology to allow digital access to and transfer of patient medical records to facilitate access to and retrieval of clinical data to provide safer and better care.[xvi–xviii] Almost every state and certain territories has at least one HIE, and according to Civitas Networks for Health (Civitas), the leading national association of HIEs, Civitas's membership is comprised of approximately 70 organizations at any given time.[xix] Although recent information on the breadth and degree of pharmacy use of HIEs is lacking—the need for research into the level of maturity and capabilities of the many state-based HIEs was noted in a Civitas study published in 2022—our interviews reveal that pharmacies often use HIEs to access patient health records in the course of providing clinical services. A 2022 report from the Pharmacy Health Information Technology Collaborative corroborates HIEs' usefulness to pharmacies that provide clinical services and concludes that "connecting pharmacy systems to HIEs is a critical component for test to treat programs"[xx] like the PAXLOVID antiviral therapy that pharmacists can prescribe for COVID-19 treatment under federal rules designed to increase patient access.[xxi] The Appendix includes an example of pharmacies using HIEs to improve patient care.

When pharmacies cannot access needed health records directly from providers or favor using a single HIE platform over connecting directly with multiple providers' EHRs, HIEs can be a useful option.

HIEs alone, however, are not the ideal solution to the data interoperability challenges pharmacies face. Although HIEs often partner to share data with their counterparts in neighboring states and regions, one important limitation of their usefulness to pharmacies today is HIEs' fragmented nature and representation of data contributed by users in particular geographic regions, such as the boundaries of the state they serve. For example, health information about the clinical services patients receive while traveling outside their home state may not be represented in their home state's HIE, creating a blind spot in their health records. Similarly, while HIEs often enjoy broad provider participation within the regions they serve, certain providers may not share health information with them, causing gaps in the data. Another limitation of HIE usefulness to pharmacies for data interoperability is their typical incompatibility with the pharmacy workflow. Rather than importing data feeds from HIEs into their clinical documentation systems, pharmacies typically retrieve and view data through HIEs' online portals, underscoring the importance of integrating HIE data into clinical documentation systems.

Pharmacist eCare Plan

The Pharmacist eCare Plan establishes an interoperable standard that pharmacies can use to export clinical data to other health care stakeholders. The Pharmacist eCare Plan can export data pertaining to patient demographics, encounter reason and type, lab results, interventions and outcomes, social history, active medications and prescription fill history, and payer information. The Pharmacist eCare Plan has been used as a viable option for some pharmacies, but uptake thus far across the industry has been modest. A limitation of the Pharmacist eCare Plan is that although the tool can be used to export clinical data, it does not allow pharmacies to import clinical data from other health care stakeholders.

Vaccination Registries

Immunization Information Systems (IIS) are population-based databases that encompass administered immunizations by various providers and practitioners. According to a national survey conducted by the American Immunization Registry Association (AIRA), pharmacies reported to IIS in 80 percent (36) of participating jurisdictions, although they were only required to report in 49 percent (22) of jurisdictions.[xxii:] Through this database, pertinent immunization information is consolidated into one platform for various immunization providers, including pharmacists, to access as they identify and address vaccination gaps for patients.[xxiii] Pharmacies continue to be effective contributors in terms of reporting vaccination information to IIS, and the COVID-19 pandemic may have strengthened vaccine registry reporting among some vaccinators given that all COVID-19 vaccinations were required to be reported to state IIS.

Notably, universal implementation of bidirectional registries would further enhance data sharing as today, while pharmacies contribute to vaccine registries in most states, they are not eligible to access the data in all states. [xxiv] Additionally, improved integration of IIS data into pharmacy platforms and clinical documentation systems could help to improve interoperability, as historically IIS have been standalone systems.

Prescription Drug Monitoring Programs (PDMPs)

Pharmacies have leveraged Prescription Drug Monitoring Programs (PDMPs) in response to the opioid epidemic as these systems document controlled substance prescriptions within a state and now more commonly between states. PDMPs can give health care providers useful information about patients' controlled substance prescription histories by alerting clinicians to individuals who may have multiple controlled substance prescriptions from various providers or who are otherwise at risk of a substance use disorder and require intervention.[xxv]

As of 2021, all 50 states now have laws establishing PDMPs to assist in the identification and prevention of drug abuse and misuse.[xxvi] Pharmacies must document required data in their state's PDMP for prescriptions dispensed for specified controlled substances. Pharmacies' bidirectional data exchange with PDMPs across states enhances data sharing and communication among the health care team to inform clinical decision making and patient care, helping to reduce opioid misuse and overdose.[xxvii] Similar to IIS, improved integration of PDMP data into pharmacy platforms and clinical documentation systems could help enhance interoperability, as PDMPs historically have been standalone systems.

Health Plan and Pharmacy Collaborations

Because no standardized or universally available data-sharing solution exists for pharmacies, health plans have implemented a number of workarounds. While pharmacy systems seamlessly share data related to prescription drug claims between pharmacies and health plans, the same infrastructure has not been applied for sharing clinical services or clinical patient data. Therefore, when health plans and pharmacies collaborate on clinical initiatives, such as transitions of care programs, chronic disease management or other initiatives, data-sharing workarounds must be relied upon.

These solutions are highly variable and may include a health plan-specific documentation platform outside of the pharmacy dispensing system, a clinical form for the pharmacy to complete and transmit to the plan, or even facsimiles or spreadsheets transferred between the plan and the pharmacy. These solutions may be workable for one-time projects or initiatives but lack scalability and contribute to fragmented data sharing. Consequently, a pharmacy collaborating with multiple plans on multiple patient care initiatives may have to document via various fragmented and disconnected systems that require varying types and formats of information to be entered, often manually.

Medication Therapy Management (MTM) platforms and a commercial vendor platform have sought to address these problems by coalescing information across multiple payers so pharmacies can address MTM needs or when plans engage pharmacies to achieve certain quality metrics. These systems, however, do not meet broader clinical data-sharing needs between pharmacies and health plans.

Additionally, it is important that pharmacies have systems and processes to document and bill for clinical services as a critical means of promoting data sharing between health plans and pharmacies. Aside from billing for vaccinations, prescription drugs, and MTM services, pharmacies have limited standards, systems, and infrastructure available to document and bill for clinical services. However, important progress is being made.

For example, while NCPDP continues working to develop standards for pharmacy service billing, important breakthroughs were made during the COVID-19 pandemic. For instance, NCPDP developed guidance to support pharmacist billing for patient assessments related to antivirals, irrespective of whether a product was dispensed.[xxviii] This was the first time NCPDP billing standards were used purely for pharmacy billing of a service without a medication product necessarily being dispensed. As states continue modernizing their policies to allow more care access at pharmacies and additional corresponding reimbursement opportunities become available, billing standards for pharmacy clinical services will become even more important and critically needed.

Standardization of Data Application Programming for Interface

A number of data standards are available to pharmacies for data exchange, and additional standards are in development. (See the call-out box to the right for the definition of some commonly used terms when discussing data standards.)

While many APIs in the clinical service space are not yet standardized, **SNOMED CT**,[xxix] a standard data set code does standardize value sets for a broad range of settings including pharmacies. SNOMED CT codes include drug therapy problems like dosages that are too low and direct interventions, such as comprehensive medication reviews.

A standardized coding system like SNOMED CT allows pharmacies to capture clinical information as discrete data points that can be shared with and used by other stakeholders using electronic standards. The Pharmacy HIT Collaborative has developed and published a guide for pharmacies to use in implementing SNOMED CT. Regardless of the tremendous progress toward data set standardization, because of low utilization and the challenges associated with implementing SNOMED CT in the pharmacy space, SNOMOD CT is not yet ubiquitous nor is it comprehensive enough to serve as a long-term solution to the pharmacy clinical data interoperability challenge.

Commonly Used Terms

Application Programming for Interface (API): An API is an interface code to exchange data between two systems or applications; that is, a code that bridges data sets, applications, or functionalities. APIs can be built or chosen.

Health Level Seven International (HL7®): The standards development organization that developed HL7® FHIR®.

Fast Healthcare Interoperability Resources (HL7® FHIR®): A medical data exchange standard - a language that can be used to translate data across systems, apps, organizations. HL7® FHIR® indicates how data should be transported and structured. HL7 FHIR® is one standard API.

Another form of standardized data is the **US Core Data for Interoperability (USCDI)** data standard. Adopted by the ONC as part of the Cures Act Final Rule, this standard serves as a foundation for sharing electronic health information by using uniform data inputs for clinical data that are transferable across API platforms. Because certified health IT developers must support the USCDI v1 standard as of January 1, 2023, this standard has had near complete implementation among health care stakeholders that exchange data with other parties. USCDI v1 comprises 15 data classes including Medications, Assessment and Plan of Treatment, and Clinical Notes. The ONC describes USCDI as "a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange."[xxx] Even though this standard helps control data classes so that providers can send uniform groupings of data, without standardized APIs and systems that can import and export this information seamlessly, USCDI alone cannot solve the challenges facing pharmacy clinical data interoperability.

Regulatory Advancements

In addition to the recent technical progress on interoperability that has taken place, recent regulatory advancements may prove useful in modernizing the clinical interoperability space, including pharmacy providers. The ONC is responsible for implementing the Trusted Exchange Framework and Common Agreement (TEFCA) established in the Cures Act. TEFCA focuses on establishing "a universal floor for interoperability across the country. The Common Agreement will establish the infrastructure model and governing approach for users in different networks to securely share basic clinical information with each other—all under commonly agreed-to expectations and rules, and regardless of which network they happen to be in. The Trusted Exchange Framework describes a common set of non-binding, foundational principles for trust policies and practices that can help facilitate exchange among Health Information Networks (HINs)."[xxxi]

The Cures Act Final Rule also obligates providers to support information sharing. In short, the Information Blocking Rule, as it is commonly known, prohibits a range of entities including hospitals from blocking access, exchange, and use of electronic health information (EHI) when it is technically feasible to share it. The effect of the rule is to prevent other health care stakeholders from intentionally blocking information from pharmacies when sharing the information is feasible. All health care providers could be subject to the information blocking requirements if they meet at least one of the "actor" categories (see call-out box).

Information Blocking Rule

Who: Defines "actors" as providers, including pharmacists and pharmacies.
What: Must enable access, exchange, or use of a patient's fully designated record set, which includes medical, billing, enrollment, claims records, and more.
When: When requested, without delay.
How: In the manner requested. Providers may enable access, exchange, or use in an alternative manner if certain conditions are met.
Why: To further one of the primary goals of the Cures Act, which was to put patients in command of their health information and prevent information blocking of the sort that the ONC described in its 2015 report to Congress, as well as avoid possible penalties.
Enforcement: The prohibition on information blocking took effect April 5, 2021. For some actors, the ONC will manage enforcement. For claims involving alleged information blocking by providers, the Act makes HHS responsible for enforcement through the OIG.

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Most pharmacists and pharmacies meet the definition of provider[xxxii] and could also meet the definition of a health information network.[xxxiii] Therefore, even though pharmacies may not use CEHRT, they still may fall under the Information Blocking provisions and may be required to share data with other members of the health care ecosystem.[xxxiv]

This rule may result in pharmacy stakeholders not currently obligated to have interoperable systems being obligated to reform those systems and create interoperable networks for clinical data. As such, pharmacy stakeholders will need to consider technical and policy-based advancements that allow for the free flow of interoperable clinical service data.

Recently, the Health Information Technology Advisory Committee (HITAC) that was established in the Cures

Act and recommends policies, standards, implementation specifications, and certification criteria to the ONC, announced it will create a taskforce on pharmacy interoperability. This taskforce could play a vital role in strengthening pharmacy data interoperability.

OPPORTUNITIES & RECOMMENDATIONS

Policy Recommendations

If the status quo is maintained, pharmacy data interoperability is likely to continue to progress at a modest pace through the significant voluntary efforts already under way. Thoughtful policy changes, however, could accelerate data interoperability and enable pharmacies to provide greater access to clinical services at a time when more access is seriously needed to support patient care. This section outlines key recommendations for policymakers to support pharmacy data interoperability and the patient access to clinical services that pharmacy data interoperability makes possible.

Federal Policymakers

The **ONC** is already taking a major step to support pharmacy data interoperability by creating and convening the HITAC task force on pharmacy interoperability. The ONC can further advance pharmacy data interoperability by maintaining fidelity to the broad definition of providers, including pharmacists and pharmacies, in implementing the Federal Health IT Strategic Plan.

Another way federal policymakers can help advance pharmacy data interoperability relates to the implementation of TEFCA. A key component of TEFCA is the designation of Qualified Health Information Networks (QHINs). It will be critical to pharmacy data interoperability that QHINs be fully prepared to meet the data exchange needs of pharmacies that contract with them and that provide clinical services.

As previously noted, the ONC and OIG are responsible for enforcing the 21st Century Cures Act's prohibition on information blocking. Although the ONC final rule has been published and implementation is under way, OIG rules are still expected. Those rules represent an opportunity for the OIG to support pharmacy data interoperability by holding CEHRT vendors and other health care system stakeholders accountable for sharing standardized data with pharmacies.[xxxv]

The ONC and OIG can support pharmacy data interoperability by enforcing implementation of the Cures Act, especially by holding CEHRT vendors and other health care system stakeholders accountable for sharing standardized data with pharmacies. **Federal lawmakers** can support ONC and OIG in this important work by ensuring that ONC is able to issue advisory opinions for information blocking and that the ONC and OIG have resources sufficient to support the enforcement authority that the Cures Act has granted them.[xxxvi]

The Centers for Medicare & Medicaid Services (CMS) can encourage the inclusion of pharmacies in existing and emerging value-based care models. In doing so CMS can incentivize pharmacies to invest further in data interoperability by enabling them to contribute to patient value and share in revenue as members of the interdisciplinary care team. This step could encourage pharmacy data interoperability within existing statutory definitions of "provider" (see additional discussion in "State and Federal Policymakers" below).

Furthermore, by including pharmacies as part of the interprofessional care team in value-based care models,

CMS can support the US Department of Health and Human Services' (HHS's) first stated goal in its five-year strategic plan: Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare.[xxxvii]

State Policymakers

State policymakers have the opportunity to support pharmacy data interoperability by advancing policies that support HIEs and their use by pharmacies, including cost-effective data integration of HIE data into pharmacy platforms for use at the point of care. A recent Civitas study showed that some states require certain organizations to use HIEs in varying ways. For example, New York requires general hospitals and health care facilities that use certified EHR technology to connect with the statewide HIE.[xxxviii] Short of requiring organizations to share data with HIEs, state policymakers inclined to support pharmacy data interoperability can do so simply by ensuring that pharmacies can access HIEs and the data they store. Taking this another step forward to cost-effectively integrate HIE data into pharmacy and other clinical platforms that are used at the point of care is essential to maximizing the clinical impact and usefulness of HIEs.

Similarly, and as noted previously, ensuring that vaccination registries and PDMPs in all states support bi-directional data exchange with pharmacies and the cost-effective integration of the data they hold into pharmacy and other clinical platforms for use at the point of care would advance pharmacy data interoperability. These policies are also commonly within the purview of state policymakers.

In addition to the foregoing opportunities for policymakers to support pharmacy data interoperability directly, they can encourage it indirectly by removing unnecessary limitations on the ability of pharmacy teams to provide clinical services that their patients need and that pharmacy teams are trained to provide. By clarifying and cementing pharmacies' ability to provide clinical services as appropriate, policymakers encourage pharmacies and their partners to continue to invest in pharmacy data interoperability. One way state policymakers can do this is through their Medicaid plans. As noted, states have the option to design their Medicaid plans to be more flexible than Medicare plans with regard to pharmacy provision of clinical services. Medicaid state plans that take advantage of this flexibility to support improved access to clinical care at pharmacies include those in the District of Columbia, Iowa, Maryland, North Carolina, and Montana.[xxxix]

State and Federal Policymakers

Both state and federal policymakers can ensure that statutes and regulations don't unnecessarily limit pharmacy-based provision of clinical services that patients need and should carefully weigh proposed mandates that require data reporting or adoption of certain technology against the risk of unintended consequences that ultimately could restrict patient access to clinical services.

State and federal policymakers should challenge themselves to ensure that statutes and regulations don't unnecessarily prevent pharmacy-based provision of clinical services to which patients need more access and that today's pharmacy teams are qualified to provide. This might take the form of permanently retaining flexibilities that were instituted as part of the federal COVID-19 response and have proven effective, reviewing statutory definitions of "provider" that categorically exclude pharmacy teams, or removing state-level barriers as several states recently have done. As noted, policies that support pharmacies' ability to provide access to needed clinical services as appropriate also indirectly encourage pharmacies and their partners to continue to invest in pharmacy data interoperability.

Finally, policymakers interested in supporting pharmacies in providing much needed access to clinical services

will want to carefully weigh proposals for mandates—especially unfunded mandates—compelling pharmacies to take actions such as reporting data or adopting technology against the risk of unintended consequences.

For example, mandates that require significant financial and human resources for compliance could unintentionally discourage pharmacies from providing clinical services or threaten their financial viability and thereby reduce access to clinical services.

Industry Recommendations

Just as Leavitt Partners' research identified steps that policymakers can take to advance pharmacy data interoperability, there are steps that various organizations in the health care industry can take as well. This section outlines key recommendations that can be taken by industry stakeholders to promote the pharmacy data interoperability that enables patients to access quality services at pharmacies as well as other providers.

Technology and EHR Companies

Technology companies can continue to prioritize the development and implementation of cost-effective data-sharing solutions for pharmacies that promote the ability to seamlessly integrate with pharmacy dispensing systems and make clinical interventions at the point of care.

Health Plans

Health plans can work with technology companies and pharmacy system vendors to standardize processes to share information to and from pharmacies by leveraging sustainable infrastructure rather than building and deploying unique and fragmented pharmacy data-sharing platforms or other workarounds.

Pharmacies

Pharmacies can use clinical documentation systems where available and cost-effective, cloud-based data warehouses and applications, and single-user interfaces that support data interoperability. They can also maximize their use of HIEs where available as a transitional step toward greater data interoperability and ensure that their data exchange practices are aligned with the information sharing expectations established in the Cures Act Information Blocking Rule.

Pharmacies can implement technical modernizations like those recommended in the Technical Recommendations section below, to ensure their teams are equipped to exchange data with other stakeholders.

Other Health Care Providers

Other health care providers like hospitals, clinics, and labs also can ensure their practices are in step with the information sharing obligations established in the Cures Act and embrace existing standards when exchanging data with pharmacies. This will help ensure that services provided continue to be based on complete and current clinical records, especially as pharmacies provide patients with increased access to services.

As pharmacies provide more clinical services, it becomes even more critical for hospitals, clinics, and other stakeholders to exchange data with pharmacies. Given the benefits for patients of pharmacy data interoperability across the health care system it is important for all providers to prioritize it.

Technical Recommendations

It is important to recognize that without policy change, the further development and investment in new technologies may be cost-prohibitive or otherwise untenable. However, for pharmacies to achieve data interoperability with other providers, certain technical modernizations need to be implemented and underpinned by policy changes that ensure pharmacy staff have the right interoperability tools. Pharmacies that provide clinical services to patients will need at least four unique pieces of a technology infrastructure in a modern, interoperable data exchange environment in addition to their pharmacy dispensing system, including:

- **A modernized clinical documentation system.** Pharmacists need to be able to capture the relevant USCDI clinical data that may come from various external sources. Additionally, pharmacies need to be able to digitally record clinical encounters. While pharmacists may be able to send that information via other systems, such as Pharmacist eCare Plans, fax, email, and mail; clinical documentation systems with the capacity to handle both dispensing transactional data and clinical service data, utilizing a standard API such as HL7® FHIR®, would allow pharmacies to perform clinical tasks and collaborate with other providers to create holistic care plans for patients.
- **Cloud storage (data warehouse).** To track the data and analytics necessary to operate a robust pharmacy clinical services infrastructure, a cloud-based data store is important to providing pharmacists with more real-time decision-making tools needed to provide the right care, at the right time, for the right patient. Some pharmacy dispensing systems currently have the ability to hold some variations of clinical data sent by other providers, but this capability is not ubiquitous in the industry, nor are all of the API variations currently collectible in many of these cloud storage systems. There needs to be an expansion of these cloud storage systems that can accept HL7® FHIR® APIs, in addition to other standards used by specific health care practices, in order for pharmacies to integrate more fully as members of the clinical care team. Practically speaking, these cloud-based solutions could run concurrently to existing locally stored documentation systems and pharmacy interfaces so pharmacies can utilize existing infrastructure while simultaneously receiving data through cloud-based means that their legacy systems are unable to import or export.
- **Cloud-based applications.** SMART on HL7® FHIR® allows a user-facing client application to connect to a FHIR® API based server.[xl] SMART-enabled applications[xli] are designed to plug into an HL7® FHIR® based infrastructure, potentially a clinical documentation system, and allow pharmacies to use those third-party applications to solve myriad workflow, interoperability, and functional use cases. For pharmacies seeking to modernize their interoperability infrastructure, ensuring that their systems utilize SMART on HL7® FHIR® will be imperative to working seamlessly with other health care stakeholders who are already using FHIR® enabled technology to transfer patient data among providers.
- **Single-user interface.** Though many of these recommendations listed will aid in the advancement of pharmacy interoperability, a single-user interface stands as one of the most critical pieces in ensuring pharmacy clinical service workflow ease of use. Pharmacies need to have a single-user interface they can use to visualize their most used daily functional workflows, applications that may help them with day-to-day tasks, data and analytics that

show how their pharmacy is tracking to organizational goals and objectives, and access to cloud-based data repositories that allow pharmacists to access data as needed. Having such a technical system will allow the pharmacy space to operate similarly to a full-service health system, operating with a full pharmacy dispensing and clinical service capacity.

As a transitional step toward greater data interoperability, pharmacies that are developing or acquiring the capabilities described herein can also ensure they are maximizing HIEs in their service areas when available and cost-effective. For example, pharmacies should both access information from and contribute to HIEs. If their clinical documentation systems are unable to import data feeds from HIEs, pharmacies can (partnering with their vendor, if applicable) update their systems to develop this capability, giving their teams the benefit of access to the information HIEs hold without the workflow disruption associated with logging into HIE portals to view clinical information. While importation of HIE data today may be cost-prohibitive in many instances, state policymakers advancing HIEs can promote solutions.

CONCLUSION

Pharmacy provision of clinical services is important to expanding patient access and improving outcomes, and data interoperability is critical to making the health care system more effective and efficient. Significant progress has been made toward pharmacy data interoperability, although opportunities remain. Federal and state policymakers, technology and EHR companies, health plans, pharmacies, and other providers can take steps to close the gap.

This report has identified specific recommendations across health care stakeholders as they relate to three overarching themes:

- State and federal policymakers can support pharmacy data interoperability by removing unnecessary barriers to pharmacy-based provision of clinical services to which patients need more access and that today's pharmacy teams are qualified to provide, by supporting bidirectional data exchange between existing systems like HIEs and pharmacies, and by continuing to support enforcement of existing policies.
- Collaboration across the health care ecosystem will be important to achieving pharmacy data interoperability that optimizes patient health outcomes, promotes quality and value, and improves efficiencies across the continuum.
- Standardized, cost-effective, and clinically actionable data storage and sharing solutions that are workable for pharmacies should be prioritized for development and implementation.

About Leavitt Partners Leavitt Partners, an HMA company, is a leading consulting firm at the forefront of navigating change in health care. We provide a holistic view of economic, market, delivery system, public policy, and political influences impacting health care, helping clients successfully navigate from today's uncertainty to tomorrow's prosperity. The firm provides clients federal insights and advocacy as well as member-based alliances, striving to make health care more accessible, effective, and sustainable.

Acknowledgments Leavitt Partners would like to thank the National Association of Chain Drug Stores (NACDS) for funding this report. None of the views or opinions expressed in this paper are attributable to NACDS. In addition, we want to thank Matthew Fleisher for his contributions to this white paper.

APPENDIX

Data Importation Opportunities

The recent interoperability rules that the ONC and CMS have either drafted or finalized provide a number of opportunities for pharmacies to access data from other health care sources:

- **Health Information Exchanges:** HIEs provide an important means for pharmacists to access data from multiple clinical and health care delivery entities on a local or regional basis. Each HIE currently provides this information to entities using Integrating the Healthcare Enterprise (IHE) profiles, and will eventually begin to provide the information to interested parties using HL7® FHIR®.[xlii, xliii]
- **USCDI/US Core:** Since January 1, 2023, all organizations that use CEHRT have been expected to provide USCDI information via the US Core Implementation Guide based on HL7® FHIR® Version R4.[xliv] This mandate will allow pharmacists to access physician notes, labs, medications, demographics, and other essential clinical and demographic information from multiple organization in a standardized and structured RESTful HL7® FHIR®API format, enabling pharmacies to access structured clinical data at the point of dispensing.
- **NCPDP SCRIPT Standard:** CMS recently proposed a rule that would update §423.160 to update the version of the SCRIPT standard for ePA for Medicare Part D. If finalized, this rule could make it easier for pharmacies to access prior authorization information.
- **Bulk Data Access (Flat HL7® FHIR®) HL7® FHIR® IG:** On December 13, 2022, CMS released its second interoperability rule (CMS-0057-P)[xlv] focused on providers and patients accessing an HL7® FHIR®API for bulk data access. Based on the proposed rule, after January 1, 2026, pharmacists will be able to access data on a roster of patients from payers to allow them to better manage a population and take on risk. The Bulk Data Access HL7® FHIR® IG[xlvi] allows pharmacists to make a single request for a roster of patients seeking pharmacy or other clinical services.
- **NCPDP Real-time Pharmacy Benefit Tool:** Already in production, this standard allows pharmacists and other providers to view patients' out-of-pocket costs, formulary and benefit information, and therapeutic alternatives. Accessing this information at the point of prescribing or dispensing empowers the pharmacist to better engage with patients based on patients' individual coverage situations.
- **CARIN Digital Insurance Card HL7® FHIR® IG:** This implementation guide provides all of the member's coverage information typically found on a member ID card to the pharmacist via an HL7® FHIR® IG.[xlvii] When patients select a preferred pharmacist, the provider or payer can send the insurance card information to the pharmacy via an HL7® FHIR® API. Once received, the pharmacy can run an eligibility check before patients pick up their medications. If that does not occur in advance, patients can provide digital membership card information via a third-party application or via SMART Health Cards/SMART Health Links.[xlviii]

Data Exportation Opportunities

Given the recent regulation and standards, pharmacy systems will be able to export more data than ever to external systems. Data exportation opportunities include:

- **USCDI/US Core:** As mentioned above, since January 1, 2023, all organizations that use CEHRT have been expected to provide USCDI information via the US Core Implementation Guide based on HL7® FHIR® Version R4.[xliv] Pharmacists can then send this information via an HL7® FHIR® API to physician EHRs, assuming providers have a way to consume this information in a SMART on HL7® FHIR® application, directly in their EHR, or through some other means.
- **NCPDP SCRIPT Standard:** CMS has recently issued a proposed rule that would update § 423.160 to include the SCRIPT standard for Medicare Part D. If the rule is finalized, pharmacies would have another tool for accessing prior authorization information.
- **CARIN Consumer Real-time Pharmacy Benefit Check (RTPBC) HL7® FHIR®IG:**[xlix] The CARIN RTPBC provides patients with access to their formulary and benefit information, out-of-pocket costs, therapeutic alternatives, and cash-price alternatives. Pharmacists have an opportunity to engage with patients who are accessing this information on an application of their choice and cross check that information against the patient benefit information stored in their own system.

South Dakota Health Link Success Story

HIEs can serve as an asset to pharmacies seeking the data they need to provide clinical services. For example, the following success story was recounted by a pharmacy using a state HIE:(Success Story | Health Link - Exchanging information. Changing lives. (sdhealthlink.org):

> *"A patient with multiple chronic disease states and medications was incurring high costs for brand name medication co-pays, per month, to manage her diabetes. [The HIE] allowed for a review of her previous medication regimen and recommendation for a less expensive, more effective medication therapy which provided a significant cost savings for the patient."*[xlx]

In this case, by accessing clinical records via the HIE, the pharmacy was able to perform a medication review for a patient with chronic conditions and recommend a more effective and affordable treatment.

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