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BUY VS BUILD: PHARMACY MANAGEMENT PLATFORM

**Key Considerations When Determining
How to Invest in Technology**

OVERVIEW - PHARMACY INDUSTRY & TECHNOLOGY

Pharmacies adapting to a rapidly evolving healthcare landscape will identify the need to update their supporting technology to compete in the marketplace. A key decision will be whether to build a new platform to support pharmacy operations, extend an existing platform to add new capabilities, or purchase a commercially available solution. The evaluation process is complex and requires careful consideration of many business and technology factors.

As pharmacies work to win new contracts, the underlying minimum expectations continue to expand while the pharmacy layers additional capabilities into their product offering to differentiate from competitors. Commonly, these key differentiators are centered around goals to improve patient outcomes, increase patient acquisition, optimize operations and efficiency, and secure patient data. As contracts change quickly, the ability to adapt is paramount to any technology solution as the time required to implement new capabilities is compressed. To accelerate the changes, the underlying product base must be robust enough to account for these future expansion needs, and nimble enough to be easily manipulated to support new differentiating offerings, new drugs and therapies and related clinical workflows, service level agreements (SLAs) and performance guarantees (PGs), and other contractual obligations.

Complex patient disease states often require supportive clinical programs to manage and improve outcomes. Pharmacies lacking the necessary clinical program workflows and supporting application tools - as well as real-time access to comprehensive, patient-specific healthcare data and analytical insights - have a difficult time providing optimal patient care. In a world where medical services are cannibalized and democratized by virtual events, neighborhood care clinics, large retail pharmacies, and small local mom-and-pop pharmacies, intimacy with the patient has become paramount.

Connectivity to health system and provider electronic health records, health information exchanges, laboratory diagnostic information, and payer claims data enables a pharmacy to make real-time, informed decisions related to a patient's holistic clinical presentation, optimize patient care, and enhance the patient experience and quality of life. Positively influencing patient outcomes through improved adherence rates, reduction in adverse events, and increased patient satisfaction are key differentiators pharmacies strive for, and should be an important requirement when developing a plan for any pharmacy management software.

With over 50% of the national drug spend on specialty pharmacy products, pharmacies must be able to gain access to payers' preferred pharmacy networks and limited distribution drugs (LDDs) to drive growth. To gain access to networks and drugs, a configurable, flexible and integrated pharmacy platform is critical.

Capabilities related to a specific drug, payer, or "program" workflow and data collection, contract management and reporting are necessary, and will exponentially improve a pharmacy's opportunity to increase patient acquisition and to meet the demands of payer and pharmaceutical contractual requirements.

For a pharmacy software solution to meet these contractual demands, the pharmacy management system should provide storage, tracking and automated alerting of specific manufacturer and payer contractual requirements. This allows for prioritization of operational activities based on real-time predictive analytics and identification of actionable data visualization with in-line alerts to ensure SLA and PG adherence. A key component of any pharmacy platform is the ability to capture and provide data extracts and/or reports to meet contractual requirements, earn the much-needed revenue associated with providing such data, and help with accreditation and audits.

Faced with margin compression and increased patient management activities, pharmacies need to continuously improve operational efficiencies. This is especially challenging in an environment with multiple sources of critical information often spread across disparate systems. In addition to the cost savings of an efficient operation, it is essential to streamline and automate processes to get patients onto therapy as quickly as possible. This helps pharmacies stay competitive in the marketplace and win patient referrals from physician offices and health system partners and maintain a high level of satisfaction from patients. Pharmacies require a sophisticated, rules-based, intelligent system to drive workflow to users, automate tasks, create necessary data collects and manage productivity effectively.

The ability to digitally engage with, and between, the patient and care team is also an important differentiator for pharmacies to consider. Patients, providers, field nurses, sales representatives, and other external stakeholders all benefit from real-time access to specific, controlled, integrated services and information from the pharmacy management system. An effective patient portal allows for secure login, reorder management, clinical assessment, education, alerting and communication between the pharmacy and patient based on patient preferences. A provider or healthcare partner portal, which can be extended to physicians, providers and other key external stakeholders, allows for reduced abrasion with referral sources, automated alerts, the exchange of clinical information and enhanced collaboration between providers and the pharmacy.

In addition to the critical points described above, this white paper identifies the Top 10 issues pharmacies must consider in a buy vs. build situation related to a pharmacy platform.

The Top 10 Pharmacy Buy vs. Build Considerations

(more fully described below):

1. Pharmacy Patient Safety and Outcomes
2. Pharmacy Complex Patient Disease and Therapy Management
3. Pharmacy Regulatory, Compliance and Data Security
4. Pharmacy User Experience and User Satisfaction
5. Pharmacy Industry Standards and Accreditation
6. Pharmacy Industry Knowledge and Expertise
7. Pharmacy Technology Planning and Build-out
8. Pharmacy Technology Implementation and Ongoing Support
9. Pharmacy Technology Interoperability and Flexibility
10. Pharmacy Technology Innovation

TOP 10 PHARMACY BUY VS. BUILD CONSIDERATIONS

While building any software can be complex, the unique requirements of healthcare, and more specifically, the pharmacy industry, present additional complexity beyond the technical aspects of the development process.

The Top 10 pharmacy buy vs. build considerations will present a more comprehensive picture of the effort required to define, design, build, deploy, support and enhance a pharmacy platform.

1. PHARMACY PATIENT SAFETY AND OUTCOMES

- Drug Utilization Review (DUR) - Drug Interactions, Dose Checking, etc.
- Clinical Management - Allergies, Diagnoses, Adherence, Interventions
- Prescription and Clinical Data Accuracy

When designing and building a pharmacy system, the patient must be at the forefront of all discussions. As patient information is obtained from the various sources (patient, prescriber, caregiver, etc.), it must not only be clearly and accurately entered and documented into the system, but it must also be easily visible, retrievable and/or used for interoperability.

For proper clinical tracking, there are industry standards and formats that must be used when capturing pharmacy and clinical information. For example, the entry of allergies is done in both text and “behind the scenes” codes for use in automated drug-allergy checking by the application. Likewise, entry of patient diagnosis is typically done using industry-standard ICD-10 codes and formatting for clinical management, automated drug-disease checking and proper billing and reimbursement.

Entry of prescription data elements must also follow industry and standardized requirements with respect to drug quantity, days’ supply, strength and dosing instructions, in part provided by external data sources for alignment. For example, the prescription may be dispensed in one quantity and billed as the metric decimal quantity, which are not always equal. As it may pertain to brand vs. generic dispensing, a prescription may also have restrictions based on prescriber direction, such as dispense as written (DAW) codes, which dictate what a pharmacy is permitted to do with drug substitution.

The risk associated with incorrect data entry, missing or invalid information, and inappropriate clinical management is more than significant. Patient harm is the primary concern. Without the proper pharmacy system automation and controls, there is a heavy reliance on manual processes and manual reviews by pharmacists or other clinicians. Manual processes are more error-prone than automated processes and are certainly less consistent across human-driven manual reviews. Less critical than patient harm, but certainly a key risk, is inappropriate dispensing related to contractual

or regulatory obligations or requirements. For example, filling prescriptions beyond the number of refills allowed, billing of payers without the appropriate information and approvals, etc., can lead to substantial fines and/or rejected reimbursement from payers.

2. PHARMACY COMPLEX PATIENT DISEASE AND THERAPY MANAGEMENT

- Appropriate and Timely Clinical Interventions
- Medication Dosing and Instructions/Administration
- Drug Storage and Handling Information
- Drug and Inventory Management (Package Size Quantities, Dispensing Rates)

As drug regimens become more complex, more demands are required of a pharmacy operation and its pharmacy application. Drug-specific clinical interventions, typically performed by a pharmacist or nurse, are required and must be documented for future reference, audits, billing, etc. A pharmacy system must have the ability to support these broadly varying yet critical interventions and identify when they are required to be completed, support related data entry, define the required pharmacy user role required, and escalate as needed based on clinical evaluation.

To properly manage new and complex drugs, the pharmacy inventory management system must have the ability to maintain drug storage and handling information, such as refrigerated drugs, solutions, and compounds. This, and related information, must be used by the pharmacy system during patient engagement, storage and shipping determination (*i.e.*, overnight shipping for refrigerated medications).

Likewise, the inventory and dispensing functions must align with respect to medication packages sizes, units of measure and route of administration. Medications may be provided to the patient as unit of use (pre-packaged) oral medications, injectable drugs in pen and syringe and needle formats, and even more complex therapies that require mixing or compounding of multiple medications. Medication dosing may range from simple, “take once daily” instructions to more complex subcutaneous injections at variable times over several weeks or months, or infused medications. Patient medication information and prescription labeling can be challenging in these more complex cases.

3. PHARMACY REGULATORY, COMPLIANCE AND DATA SECURITY

- Health Insurance Portability & Accountability Act (HIPAA) - Protected Health Information (PHI)
- HITRUST Certification
- Payment Card Industry (PCI) - Credit Card Processing
- State Boards of Pharmacy, State & Federal Laws

- Pharmacist vs. Non-Pharmacist Activities - Pharmacist Licensure
- Financial Controls - Sarbanes-Oxley (SOX)
- Prescription Drug Monitoring Program (PDMP) - Controlled Substances
- Payer Partners - CMS/Medicare, Medicaid
- Drug Manufacturer Partners

When developing a pharmacy management solution, pharmacies should expect an ongoing investment in staff time to manage frequent updates and keep informed on system compliance requirements. In addition, regulatory compliance needs can change as the pharmacy strategy requires the support of new offerings, such as the support for controlled substances. If controlled substance support features are not part of a minimum viable product (MVP), additional development investment will be required to capitalize on any new growth opportunities in this space. Regulatory agencies update their requirements frequently as new legislation is enacted. State pharmacy licensing regulations are constantly changing. Payer and pharmaceutical limited distribution drug requirements are becoming more stringent and demand service level agreement metrics and reporting capabilities to maintain contractual obligations. Managing and modifying the pharmacy system to accommodate these frequent changes requires considerable time and human capital to stay compliant.

Should a pharmacy be dispensing controlled substances, specific state-level reporting must be done under the PDMP. This requires the pharmacy system to capture specific patient and physician information for all dispenses qualifying as "controlled substances." This may require entry of a patient's driver's license number or other unique identifier, for example. Reporting must be done based on each state's requirements and data reporting formats. Additionally, while identification of controlled substances is typically driven by the drug schedule, some states classify drugs based on risk and usage. For example, growth hormone drugs would not be classified as a controlled substance based on their drug schedule, but are required by some states to be reported as a controlled substance.

The regulatory, compliance and data security landscape in the pharmacy industry is rather complicated and at times, seemingly overbearing. However, as this is driven by healthcare, patient data restrictions and patient safety, there are critical rules that must be followed. While HIPAA has been in place for many years, the requirements and restrictions apply in many ways to the pharmacy application and what controls are required, including storage of data, transmission of data, reporting of data and sharing of data. Depending on how data is used, deidentification may be required, which also has specific rules regarding how the deidentification must occur, likely including the validation of an expert.

HIPAA requires that all electronic PHI that is created, stored or transmitted in all work devices must be encrypted. Pharmacies today are challenged with ensuring their IT systems - which may include multiple systems or external documents - are both secure and highly available to meet operational, customer and patient requirements while protecting the privacy of their patients. Pharmacies will need to ensure their system fully meets HITRUST certification requirements and is assessed regularly for

vulnerabilities to optimize their security posture and avoid the associated fines, fees and penalties or inadvertent data disclosure.

As most pharmacies are billing patients for their medications, copays or other services, support for billing of credit cards is required. In this regard, pharmacies must meet specific PCI rules. In most, if not all cases, a patient's credit card information must be encrypted; in most current systems, credit cards are tokenized and only known by the specific credit card processor and not retained in any way in the pharmacy system.

Pharmacies must understand federal laws and not only the rules of the state in which they reside, but in many cases, the states in which they are servicing patients or interacting with prescribers. Each state has its own board of pharmacy with its own regulatory requirements. These requirements may range from prescription labeling to pharmacist-to-pharmacy technician ratios and restrictions. The pharmacy system must support the ability to restrict access to certain data and/or functions to meet regulatory requirements. For example, only a pharmacist is permitted to verify prescription information and they must also be licensed in the state in which the prescription is processed. In any event, routine board of pharmacy audits are completed and require a pharmacy system to support each state's requirements.

Understanding the financial considerations and/or restrictions are also critical for the pharmacy and should be supported by pharmacy system capabilities. Certain financial limitations should be aligned to specific users to ensure that financial information is reviewed and approved and cannot be manipulated inappropriately.

When contracting with other pharmacy stakeholders, such as payers and drug manufacturers, there are contractual requirements that must be met. These may be defined as specific PGs, SLAs, reporting specifications, pricing, etc.

As these contracts are executed, the pharmacy application needs to provide the proper support for each/all of these areas. Failure to meet PGs or SLAs may result in financial penalties or lost revenue.

4. PHARMACY USER EXPERIENCE AND USER SATISFACTION

- Application Usability
- Operational Workflow
- Patient and Prescriber Engagement
- New Product Rollout
- User Training
- Application Testing
- Single vs. Multiple System Usage

The pharmacy workforce and supporting applications and tools are critical to user satisfaction, which ultimately impacts patient satisfaction, employee turnover,

employee productivity and operational efficiencies and savings. Paramount to user satisfaction is the user experience (UX) and user interface (UI) of the pharmacy application. Pharmacy applications that require system users to struggle to find information, navigate to many screens, work based on standard operating procedures (SOPs) vs. system-driven automation, and do not force quality data entry, all result in a less-than-optimal user experience and lower user satisfaction. The design of the pharmacy application should pay particular attention to the roles that engage with external stakeholders such as patients and prescribers. Longer-than-desired phone interactions, multiple contacts, etc., all result in stakeholder dissatisfaction.

As a new product or new features and innovations are built and rolled out to the pharmacy system user community, change must be properly managed. New ways of doing things that are not intuitive create new and added stress to a workforce dealing with patients that range from mildly ill to requiring life-sustaining medications.

Training programs and related curriculum ensure the system is being used properly and is supporting patient and other stakeholder needs in a timely manner. A dedicated training resource or team is required to properly set up training data, maintain a training environment, update SOPs and evaluate personnel.

Equally important is pharmacy application testing. Testing requires the proper understanding of pharmacy operations, pharmacy data and all aspects of pharmacy intake, referral management, prescription management, clinical management, inventory management, dispensing/fulfillment, billing and reimbursement, reporting and configuration (user permissions, configuration, etc.). Detailed training plans are required, along with incident tracking and reporting, engagement with engineering, and prioritization based on pharmacy business risk and impact, to result in a “production-ready” pharmacy system.

As components of the pharmacy operation are built, it may require pharmacy users to access and navigate across multiple disparate systems. This not only increases the risk, but is very inefficient. Depending on the integration approach, this frequently requires dual entry of data, which is prone to error and extremely time-consuming. Ideally, all work should be done in a single, optimized, pharmacy platform. However, if ancillary systems are required, a higher level of integration is desirable to minimize risk and operational costs.

5. PHARMACY INDUSTRY STANDARDS AND ACCREDITATION

- National Council for Prescription Drug Programs (NCPDP) - Script Standard
- National Council for Prescription Drug Programs (NCPDP) - Telecommunications Standard D.0
- Prescription Drug Monitoring Program (PDMP) & American Society for Automation of Pharmacy (ASAP) Reporting
- Utilization Review Accreditation Commission (URAC)
- Accreditation Commission for Health Care (ACHC)

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Fast Healthcare Interoperability Resource (FHIR) & Health Level 7 (HL7)
- Electronic Data Interchange (EDI) - Inventory & Revenue Cycle Management

The healthcare industry, and pharmacy in particular, has many unique industry standards and accrediting bodies that must be supported by the pharmacy system. For the processing of electronic prescriptions to/from prescribers and pharmacies (referred to as ePrescriptions), the NCPDP Script Standard is required. As part of these standards, there are many different transactions that require different data. The pharmacy system not only needs to meet these specifications, but needs to support the optimal use of these transactions throughout the pharmacy operational workflow.

As referenced earlier, should the pharmacy dispense any drugs that require reporting under PDMP, there are many variations in the state-by-state reporting, typically using specifications administered by ASAP. These specifications, along with all the others, require pharmacy system changes and updates that require design, development, testing and deployment.

In the pharmacy industry, there are a few key accreditations that may be required, depending on the type of pharmacy and ability to win new business. Organizations such as URAC, ACHC and JCAO have specific requirements and associated reporting, both in and out of the pharmacy system. Additional routine audits are required where information must be pulled from the pharmacy system for review and validation.

As it pertains to healthcare interoperability, prevalent standards such as FHIR and HL7 are frequently needed to obtain and share information across partner stakeholders and other systems.

Most pharmacy systems will also require the use of EDI for inventory management and/or revenue cycle management. Inventory transactions for purchase orders, acknowledgements, shipping notifications, invoices, etc., require the use of EDI in communication with drug wholesaler or supplier(s). For revenue cycle management, certain billing requires EDI 837 transactions, and reimbursement/payments are done via EDI 835 transactions, along with other EDI transactions related to insurance coverage and benefits verification.

6. PHARMACY INDUSTRY KNOWLEDGE AND EXPERTISE

- Pharmacy and Healthcare Industry Expertise
- Pharmacy Application and Operational Design Expertise

One of the most challenging aspects of building a pharmacy application is finding individuals with the knowledge, expertise and experience to provide the needed input on pharmacy operations, workflow, regulatory requirements, user personas and breadth of areas from the receipt of the prescription to the final use by the patient. Personnel is also necessary to handle all of the back-office processes related to

configuration, licensure, inventory management, revenue cycle management, clinical management and reporting.

Individuals with this expertise are imperative to not only define the pharmacy system requirements, but also provide input on the system designs based on each individual pharmacy user persona.

The UI and UX are critical to a highly efficient, automated, intuitive pharmacy application that supports all internal and external stakeholders and allows the pharmacy to optimize patient acquisition and clinical patient outcomes. All of this must be done while also reducing the “cost to fill” or “cost to serve” for the patient.

Proper identification and definition of product features and capabilities is critical when building pharmacy software. Identifying and leveraging industry expert resources to drive requirements and feature definitions is difficult and is a distraction to business resources that run the pharmacy operation. The risk of sub-optimal product delivery is heightened unless dedicated experts are involved throughout all aspects of the product lifecycle.

For a single pharmacy, the opportunity to access market insights from other pharmacies does not exist, often resulting in a narrower set of product features than what is available from a commercial software provider. In addition, not all pharmacy operations experts can articulate business and technical needs sufficiently for a clear product definition. Without significant software expertise, the likelihood of converting the documented needs into a fully functional and efficient pharmacy management platform is low and fraught with risk. Many organizations that have attempted to build their own have spent millions of dollars only to later scrap the project all together.

7. PHARMACY TECHNOLOGY PLANNING AND BUILD-OUT

- **Technology Planning, Approach and Selection**

- Legal and Procurement Process
- Application Code
- Services - Microservices/APIs
- Database/Storage
- Connectivity
- Estimating Effort

- **Infrastructure Setup**

- Legal and Procurement Process
- Environmental/Hosting: Hardware and Third-party Software
- Source Code Repository, Tools and Management

- Monitoring
- Security Controls
- Disaster Recovery and Business Continuity
- **Human Resources & Expertise**
 - Hiring/Contracting/Training
 - Product
 - Engineering
 - Architecture
 - DevOps/Release Management
- **Application Testing**
- **Time to Market**
- **Operational Scalability**
 - User Growth
 - Transaction Growth

Obviously, there are many components for a pharmacy to consider and address when undertaking the build-out of a new pharmacy platform. Assuming the right technical expertise and leadership are in place; key underpinning decisions must be made at the onset regarding the desired technology (Microsoft, Oracle, etc.) as well as development methodology (waterfall, Agile, etc.). Analysis must be done to make a proper selection. Once decisions are made, a long and complex procurement process is required for licensing each component, and negotiating pricing and capabilities, along with implementing the needed development tools and repositories.

Another key part of the planning process is generating an estimated level of effort to determine the proper staffing based on the desired delivery of the pharmacy application. Determining the level of effort will largely be driven by the pharmacy system business and functional requirements, as defined by the pharmacy product expert(s). Estimating the build-out of a pharmacy system, even for only a few of the needed components, can be extremely challenging even with the most knowledgeable resources involved. As this effort leads into budgeting and finance requests for funding, there is a balance of under vs. overestimating. An estimation needs to account for all facets of the buildout, including data centers and hosting, infrastructure/ environments, third-party licensing, labor, etc.

Estimating the full cost to build software for the pharmacy market has proven difficult. The business requirements and resulting features set for a minimum viable product (MVP) and for a fully functioning system are complex to identify during a planning phase for estimates. Product management and architecture teams are required to

define key requirements, features and drive creation of the product. Developers and architects who are experts in cloud architecture, networking, compute/VM, database, workflow and UI design are also necessary. Pharmacy is highly regulated and therefore, product and compliance managers who are well-informed of regulatory compliance requirements will be needed. HIPAA security requirements demand a pharmacy to employ specialized resources and expertise to ensure patient data is managed and stored safely.

Likewise, internal integrations, infrastructure, and third-party solution partners may require procurement and ancillary licensing once defined. The needed infrastructure processes and internal systems must be identified and put into place to track all product feature sets, translation for development, build and unit execution and deployment. The creation of this ecosystem is costly, time-consuming and can be complex. Prior to deployment, testing, and related activities (documented test cases, automated testing, performance testing, release deployment/DevOps, etc.) will need to be in place along with tracing tools for issues, requests and more.

With respect to technical leadership and expertise, staffing all roles for a pharmacy build-out can be tedious and time-consuming. As pharmacy is a unique segment of healthcare, there are specific requirements to be met, specific terminology to be used and risk associated with patient care. While it may not be required to have a background in healthcare or pharmacy, this background is extremely beneficial in developing any pharmacy platform. Without some level of pharmacy knowledge and expertise on the technical team, full reliance is placed on the pharmacy product team to provide extremely detailed information with respect to requirements and testing to ensure high quality. In today's market, there is high demand and little supply of available technical talent. Obtaining resources can require salaries and benefits not seen historically, and to keep an employee, the work environment needs to be exemplary and possibly go beyond what may be deemed typically necessary.

If the pharmacy does not have an extensive software development team, the ramp-up of IT professionals is currently tremendously difficult. Both on-shore and off-shore availability are exceptionally low, resulting in substantial development delays, as well as lower-quality output and delivery. Using internal resources comes at a significant cost. Allocating existing resources to focus on the development of pharmacy software reduces the opportunity to develop differentiating capabilities and integrations that would allow the pharmacy to stay ahead of competition. Coordination between multiple high-value projects may be difficult and risks the loss of revenue opportunities.

Once the planning is aligned, technology determined, infrastructure in place and resources are onboard, the actual software development process can begin. The needed resources and processes must be in place to properly manage and track all aspects of the development lifecycle. This will include work assignment, status tracking, quality testing, incident reporting, documentation updates and ultimately, pharmacy system code releases.

Over time, as the pharmacy grows, so too, must the pharmacy application. The needed infrastructure scalability must be in place to support the pharmacy operations, ensure acceptable system performance, meet system uptime requirements and be prepared for disaster recovery and business continuity. The pharmacy market typically requires a much

higher level of standards than other markets that are not involved in patient care. Access to patient healthcare data needs to be real time and nearly 24/7, 365 days per year (*i.e.*, uptime). Maintaining a high-availability environment requires the proper monitoring of processes and integrations and will require much higher cost footprints.

A key metric with software is performance and the ability to support new business, including additional prescription volume, more system users, increasingly complex workflow and additional lines of business. All these complexities in the workflow and codebase, as well as the database, can impact platform performance.

The inclusion of the underlying architectural infrastructure is an additional effort beyond the time required to build all the features. As the product continues to grow, the expanding codebase requires ongoing performance monitoring and tasks to ensure product stability. Hosting in private data centers or in a commercial cloud solution should also include a fully built-out disaster recovery architecture that supports partial and full failure of any system or datacenter. The environments should be hosted in a burstable compute cluster allowing for immediate scalability based on load, including across tenants.

8. PHARMACY TECHNOLOGY IMPLEMENTATION AND ONGOING SUPPORT

- Product System Implementation
- Support Resources and Expertise
- Support Systems - Process and Tools
- Release Management and Communication

Implementation is time-consuming and requires careful planning and a disciplined, organized approach. Proper transition from the existing software to a new system includes the scrubbing and conversion of existing data, identifying and building necessary APIs for required integrations, and the development of multiple different environments to support testing, training, break-fix and production.

Each workstream of an implementation represents a unique risk to the transition that must be managed appropriately with potential to delay the overall timeline. System testing and training typically require key operational resources to provide time during operational hours to support these workstreams.

Once the pharmacy platform is built-out, implemented, and stabilized, ongoing support and maintenance with a team of resources, both business and technical, are required. Rapid response time is required for any critical issues as pharmacy organizations are providing patient care.

When purchasing a commercially available software solution, hosting, support, maintenance metrics and SLAs are typically provided in the statement of work (SOW) by the software provider in conjunction with the overall project and contractual agreements. As technology continues to rapidly change, frequent infrastructure

updates are required that typically span multiple system environments, integrations and partnerships. In healthcare, and more specifically, pharmacy, system access and availability are critical to providing timely care for patients. Critical issue response times are typically required to be completed within minutes and worked in an “all-hands” manner until resolved. Routine touchpoints and engagement need to be done for critical issues until resolution is provided. Depending on the nature of the issue, a failover may be done to a disaster recovery environment and site. Significant and frequent communication and interaction are required for any critical severity issues to minimize business impact and patient care. Support should be provided 24/7 using a predefined emergency support process for any after-hours requests.

9. TECHNOLOGY INTEROPERABILITY AND FLEXIBILITY

- Solution Configurability and Flexibility
- Changing of Integration Partners and API Gateways

In the current healthcare landscape and with general technology capabilities available, the need to maintain flexibility and interoperability is mandatory. As healthcare data can reside in many systems and organizations, there is certainly a push (including recent government regulations) to make patient healthcare data available to any provider at any time from any system.

To provide this capability, the pharmacy system needs to understand the overall healthcare ecosystem, potential partners and needed methods of integration. More and more integration capabilities and partners are coming into play rapidly. A pharmacy system must have the ability to quickly adapt and support new integration opportunities.

A robust API set is key to delivering value within an increasingly interconnected healthcare space. Integrations are critical for ePrescription processing, claims submission, credit card payments, master data file management, inventory replenishment and several other key functions within a pharmacy, as well as for a pharmacy platform that is part of a larger ecosystem. Additionally, regulations are mandating open access to patient data to allow providers and patients to advance patient care. Creating the connections to the various Health Information Exchanges (HIEs), as well as presenting the available data back to the pharmacy clinicians, can be a large lift. The cost to build, test and maintain those integrations is significant, as the platform must keep up with the pace of innovation and advancement across all integrated functions.

Furthermore, if the pharmacy management system is not an end-to-end pharmacy management platform, additional integrations are necessary to manage the business. Having separate systems for inventory management, order fulfillment and accounts receivable (A/R) is possible, but the effort to align those systems limits innovation, growth and other value-added opportunities. Getting accountability and support from multiple vendors to manage cross-app integration challenges can be difficult. This can result in longer lead times with problem resolution. The challenge of multiple

integration is not isolated to just the initial implementation, but extends to the ongoing release and upgrade process.

As new capabilities are launched, additional testing of integrations is needed and may require support from the development team and third-party partners to meet the evolving integration. A pharmacy should strive for a pharmacy management solution where all the pharmacy management functions operate together and support a vast network of interconnected solutions as necessary.

In tandem with the interoperability of the pharmacy platform is system configurability. For this purpose, configurability is defined as the ability to interoperate without coding updates and releases and to modify pharmacy workflow and processes, clinical management needs, collection of data, reporting, etc., through a permission-based pharmacy application user interface.

For a pharmacy to win new business, quick turnaround time to meet market demands is essential. Lengthy engineering development processes may not support the desired delivery timelines, even when working in an agile methodology. Within reason, as much as possible should be based on configuration vs. coding and allow the business to successfully differentiate and add new programs or offerings.

10. PHARMACY TECHNOLOGY INNOVATION

- New Feature/Function Identification and Development
- Market Analysis
- Total Cost of Ownership
- Time to Market

Software continues to evolve based on customer-driven needs, internal users, organizational opportunities, as well as industry, regulatory and compliance at a state and/or federal level. While prioritization of internal needs can be done and included based on available budget and value, regulatory and compliance (or other contractual) changes are ongoing and completed on a specific timeline or deadline. Some of these changes can be considerable and consume substantial resources, both labor and non-labor.

The pharmacy platform needs to continue to expand and provide new and beneficial features. The new feature/functions may be required solely to maintain parity with competitors, but ideally, they serve to differentiate the pharmacy capabilities. Market analysis is required to gain an understanding of what is happening in the pharmacy market, identify upcoming opportunities and determine how the software can allow the pharmacy to compete better, etc. Once identified, product features or new products need to be prioritized, defined and financial approval obtained. In a proprietary model, budget dollars are competing with other business areas and/or departments across the organization.

Depending on the pharmacy system design, new competitive advantages can be accomplished with configuration. This eliminates or minimizes the needs for architecture, engineering and release management to be involved, which requires substantially more time, cost and risk.

PHARMACY APPLICATION BUILD-OUT: EXAMPLE CASE STUDIES

Several current ScriptMed® customers who purchased ScriptMed® source code in years past have since come back to Inovalon for the ScriptMed® commercial product. In doing a gap analysis and comparison of capabilities completed by the pharmacy organization vs. Inovalon's ScriptMed®, the data was substantial in that the Inovalon commercial ScriptMed® product was substantially advanced both technically and functionally. A significant investment was made by the pharmacy in their proprietary application with little movement in business value and system capabilities over a multi-year period. Conversely, in the ScriptMed® commercial product, substantial capability advancements were made, resulting in the ability to win new business, reduce operating cost, and improve patient satisfaction, partner/provider satisfaction and user satisfaction.

In addition to those pharmacies that operated on ScriptMed® source code, several large pharmacy organizations with knowledgeable business and technical teams have attempted to build a proprietary pharmacy solution, investing tens of millions of dollars in the projects over several years, only to abandon the efforts and purchase a commercially available solution or remain on the current platform.

PHARMACY X:

Invest to Build New Pharmacy Platform - Project Canceled

The example below looks at Pharmacy X, that purchased source code from Inovalon for ScriptMed Enterprise (a legacy product). After hefty capital and resource investment, Pharmacy X concluded that at the end of the day, they are a healthcare company and not a software company. Although they were able to maintain the platform with heavy investment internally, they could not keep up on the innovation, regulatory compliance requirements, expansion of drug pipeline, payer and LDD (Limited Distribution Drug) requirements that Inovalon could offer as a dedicated global technology leader and pharmacy software provider.

PHARMACY Y:

Existing Proprietary Platform vs. Commercially Available Platform Decision

Pharmacy Y, a multi-location, national specialty pharmacy, performed an evaluation to decide whether to remain on their ScriptMed Enterprise source code software, where they were responsible for in-house development and support, or migrate to the commercially supported ScriptMed® specialty pharmacy software.

Pharmacy Y performed a functionality comparison between their in-house platform and the ScriptMed® commercial software. After many demonstrations and gap analysis sessions, the conclusion was that the Inovalon ScriptMed® commercial product had substantially richer functionality, enhancements, interoperability and scalability than the Pharmacy Y platform. In addition to software functionality, the cost of ownership and time to market in the fast-growing specialty segment further supported Pharmacy Y's decision to move to the commercial ScriptMed® product, maintained and advanced by Inovalon's pharmacy expertise. Other value drivers taken into consideration by Pharmacy Y when deciding to move to Inovalon's ScriptMed® commercial software included:

- ✓ ScriptMed® Configurable End-to-End Platform
- ✓ ScriptMed® Persona-driven User Experience & Configurable Workflows
- ✓ ScriptMed® Interoperability & Connectivity
- ✓ ScriptMed® Scalable, Secure Cloud-based Architecture
- ✓ ScriptMed® Real-time, Predictive Analytics
- ✓ ScriptMed® Healthcare Data Supplementation (DataStream™)
- ✓ ScriptMed® Actionable Data Visualization & Reporting
- ✓ ScriptMed® Team Expertise & Consultative Approach

CONCLUSION

With any software build vs. buy decision, there is much to analyze and consider. When it comes to pharmacy, the considerations are taken to a substantially higher level. There are many more considerations than those described in the Top 10, but the intent is to describe some of the key items that require careful thought and deliberation before undertaking the building of a complex pharmacy application.

The total cost of platform build-out and ongoing ownership must include all that's required for the initial planning and build-out, staffing, development, testing, releasing, hosting, etc. as well as ongoing support and needed future innovation and scalability.

While an in-house-built platform may deliver based on specifically identified needs or requests, the overall delivery of feature/functions are typically far less than with an off-the-shelf purchased platform. This is usually the case based on core competencies of the organizations developing the software. Pharmacies have a core competency around the practice of pharmacy and not software development, while software providers have a core competency of delivering software. If the software provider is focused on a specific market like pharmacy, the end result is a pharmacy platform with much richer feature/functions, much more automation and a better overall platform to serve the needs of the pharmacy.

As we have seen with other internal system build attempts, timelines are frequently extended well beyond what was planned, business opportunities are missed, cost of development and implementation efforts increase over budget and the risk of lost revenue is substantial. The push to get to a minimally viable product and then a “fully functional” system can drag on for months or years—or never be realized.

Once an MVP is in place, the urgency for enhancements and new features must be prioritized among competing needs with limited capacity, resulting in business impacts, increased costs and highly dissatisfied stakeholders and internal system users.

According to a study from The Standish Group in 2020, an estimated 66% of software projects fail.¹

Pharmacy software development and expertise is an Inovalon core competency, and the focus on continued improvement of the pharmacy application and related products is unparalleled. Conversely, the core competency of most pharmacy organizations is to dispense pharmaceutical products and services, provide service to their key stakeholders and provide clinical care to patients.

In Inovalon’s 25+ years of experience and the experience of its customers, the significant risk and cost associated with building a custom pharmacy management solution dramatically outweighs the benefits for the pharmacies that have undertaken that approach. Those that have decided to purchase a commercial product and focus on their core competency of pharmacy, have excelled from both a business perspective as well as a technology perspective, optimizing both. Those organizations that have taken a build approach made substantial investments with no delivery of software, or delivery of software with a far lower relative value than that of commercial software.

SOURCES

1. “Why Software Development Projects Fail,” 3 Pillar Global, January 28, 2021, <https://www.3pillarglobal.com/insights/why-software-development-projects-fail/>