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# Final Report

## Evaluation of the Electronic Prescribing of Controlled Substances Pilot

**Submitted To:**

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# Final Report: Evaluation of the Electronic Prescribing of Controlled Substances Pilot

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## EXECUTIVE SUMMARY

**Introduction.** In November 2012, two Federally Qualified Health Centers in California began prescribing controlled substances electronically in compliance with the Drug Enforcement Administration's (DEA) Interim Final Rule (IFR) number 21 CFR Parts 1300, 1304, 1306, and 1311. Over the 9-month pilot, the two sites completed the IFR's required steps to: implement certified functionality for the electronic prescribing of controlled substances (EPCS) within their electronic health record (EHR), identify-proof each of their prescribers (DEA-registered physicians and other providers); issue two-factor authentication credentials and train each prescriber on their use; and establish access to EPCS for each prescriber within the EHR. Several pharmacies with stores near the prescriber organizations also activated EPCS-certified pharmacy management software, allowing them to accept and fulfill the electronic prescriptions for controlled substances. An external project manager facilitated conversations and shared learning between the two prescriber organizations and communications with local and national representatives of the participating pharmacies. This evaluation chronicles the experiences of the pilot participants as they activated EPCS, identifying the impact of EPCS on prescriber and pharmacist workflows, the benefits of EPCS to the participants and the implementation challenges faced by pilot participants.

**Pilot outcomes.** Both sites succeeded in installing the EPCS software upgrade, in registering their individual prescribers and completing at least some EPCS transactions at EPCS-certified pharmacies. Mid-pilot, both sites experienced a system problem that brought EPCS down completely for their prescribers. Prescriber Organization 2 (PO2) was able to recover rapidly; this site also demonstrated a consistent upward trend in the percent of controlled substance (CS) prescriptions transmitted electronically. At PO2, EPCS usage peaked at 37% of CS prescriptions sent electronically across all local pharmacies; it sent about 70% of CS prescriptions electronically when considering only the pharmacies able to accept these scripts. Prescriber Organization One (PO1) struggled to get traction with EPCS, demonstrating some early acceptance by the prescribers, but then experiencing a rapid and consistent drop in usage. Only 44 of the 95 prescribers it registered ever sent a CS prescription electronically. Also, PO1 had much more difficulty recovering system functionality following the EPCS outage than PO2 experienced. In aggregate EPCS was down for two months at PO1; the outage spelled the effective end of its prescribers' use of EPCS.

**EPCS benefits.** All participants in the pilot accrued benefit from EPCS. Prescribers, staff and pharmacists interviewed for the evaluation described the EPCS workflows as "easy" and as requiring little extra effort over regular e-prescribing. Many welcomed the additional security they believe EPCS provides over current paper processes. Many appreciated the administrative efficiencies of EPCS over the current manual processes. Processes eliminated by EPCS included sending a prescription to a printer secured in a centralized locked location, distributing refill prescriptions securely (locked box, patient identification, charting pick-up), and the rekeying of paper prescription information at the pharmacy. Many believed that EPCS could improve patient safety in the same way that e-prescribing operates to reduce errors associated with paper prescriptions for other medications. Some called out the enhanced ability to trace

prescriptions for controlled substances and to include information about electronically prescribed controlled substances in internal patient acuity analyses and quality improvement initiatives.

**Facilitators.** Physicians working in an environment with a robust e-prescribing process may already be asking for relief from burdensome exception processing for CS prescriptions and eager to give EPCS a try. Prescribers' concerns about the security of paper prescriptions also pre-dispose them to appreciate the secure prescription transmissions offered by EPCS. Physician goodwill can be easily dissipated by negative experiences with the technology itself however. PO2 undertook specific actions to ensure that errors did not dilute physician demand for the technology, for example, running error reports up to four times per day and taking immediate steps to resolve errors with both local and national pharmacy representatives. Leadership commitment and applying the resources needed to ensure the system works smoothly for the physicians every time also appeared to be important facilitators of PO2's successful implementation. Similarly, a strong effort by PO2 to open lines of communication with the pharmacies and to coordinate business practices helped facilitate the rapid error resolution needed to keep prescribers engaged.

**Barriers.** The reliability of relatively new EPCS software proved to be a significant barrier to successful implementation. While the particular software glitch experienced by the two sites may not be repeated, the larger issue is how any negative experience with EPCS software may affect overall physician buy-in. The lack of critical mass of prescribers and pharmacies using the technology is an important current barrier to adoption as well. While the number of pharmacies that accept EPCS has grown rapidly, key independent pharmacies near the prescriber clinics were not able to participate in this pilot. At PO1, an in-house pharmacy—one that a significant portion of its patient population was required to use—could not obtain certification within the pilot period. The number of popular pharmacies that are EPCS certified defines the upper limit of electronic CS prescriptions that prescribers can send without requiring patients to change pharmacies, and forces the prescribers to maintain paper and fax processes even after embracing EPCS. For their part, the independent pharmacies may have little incentive to implement EPCS until many more physicians have adopted the technology and begun to encourage their patients to use certified pharmacies. Finally, the prescriber organizations found it difficult to interpret the IFR's requirements around identify-proofing and issuing prescriber authentication credentials, and the process of completing these steps was logistically challenging.

**Conclusion.** There is strong interest, high perceived value to users, technical capacity, societal benefit, and a business case to devote the resources needed to implement EPCS. Expansion is interdependent on prescribers and pharmacies; they must work collaboratively on implementation and incentives for expansion should address both sides of the EPCS equation. For pharmacies, addressing the cost of the DEA-required third party audits and uncertainty around the on-going costs of compliance might help induce smaller vendors working with independent pharmacies to bring the technology on board. Prescriber adoption might be encouraged by clarifying IFR requirements and by including CS prescriptions in meaningful use incentives. As for any new software, technology glitches are possible. With leadership commitment, adequate resources, and strong prescriber-pharmacy cooperation however, EPCS can work and work well.

## I. INTRODUCTION

Numerous studies have shown benefits to electronic prescribing (e-prescribing), such as improved patient safety and efficiency.[1,2,3,4,5] While adoption of e-prescribing technology continues to increase dramatically year over year, regulations imposed by the Drug Enforcement Administration (DEA) on the prescribing of controlled substances have required even those with robust e-prescribing protocols to maintain parallel paper and electronic faxing processes for controlled substance medications.

In 2010 the DEA published its Interim Final Ruling 21 CFR Parts 1300, 1304, 1306, and 1311 (the IFR). The IFR allows the electronic prescribing of controlled substances (EPCS) by DEA registrants (doctors, hospitals and other health professionals) when the software applications of both the e-prescribing organization and the recipient pharmacy are EPCS-certified pursuant to new security requirements.[6] The IFR legalized EPCS nationally; however, each state must separately integrate EPCS into its own regulatory rubric for monitoring the prescribing of controlled substances. California approved the use of EPCS in accordance with the IFR in June 2010.[7]

Although the IFR was published in 2010, implementing EPCS functionality has required significant programming changes to pharmacy management systems, to EHR technology, and to intermediary systems. The IFR requires those programming changes to be certified by independent auditors or DEA-approved certification organizations before EHR software vendors may deploy new EPCS software. As a result of these requirements, national pharmacies and EHR vendors were just beginning to bring EPCS online in 2012. And, while pharmacies are now implementing EPCS in large numbers—more than 40% of California pharmacies can now accept EPCS prescriptions—prescriber adoption remains very low.[8]

In the fall of 2012, the California HealthCare Foundation (CHCF) provided grants to incentivize prescriber organizations—in this case, two Federally Qualified Health Centers (FQHCs) with a robust e-prescribing culture—to choose the path of early EPCS adoption. For example, the grants helped the clinics purchase the technology needed to support the issuance of two-factor authentication credentials to prescribers that is required for EPCS.

By capturing both the successes and challenges of each of these pilot sites and their local pharmacy counterparts as they implemented EPCS, this evaluation seeks to inform the field on the benefits of EPCS, factors that may facilitate a successful EPCS roll-out, and potential barriers to success that organizations considering EPCS implementation should address in their planning processes.

## II. THE EPCS FRAMEWORK

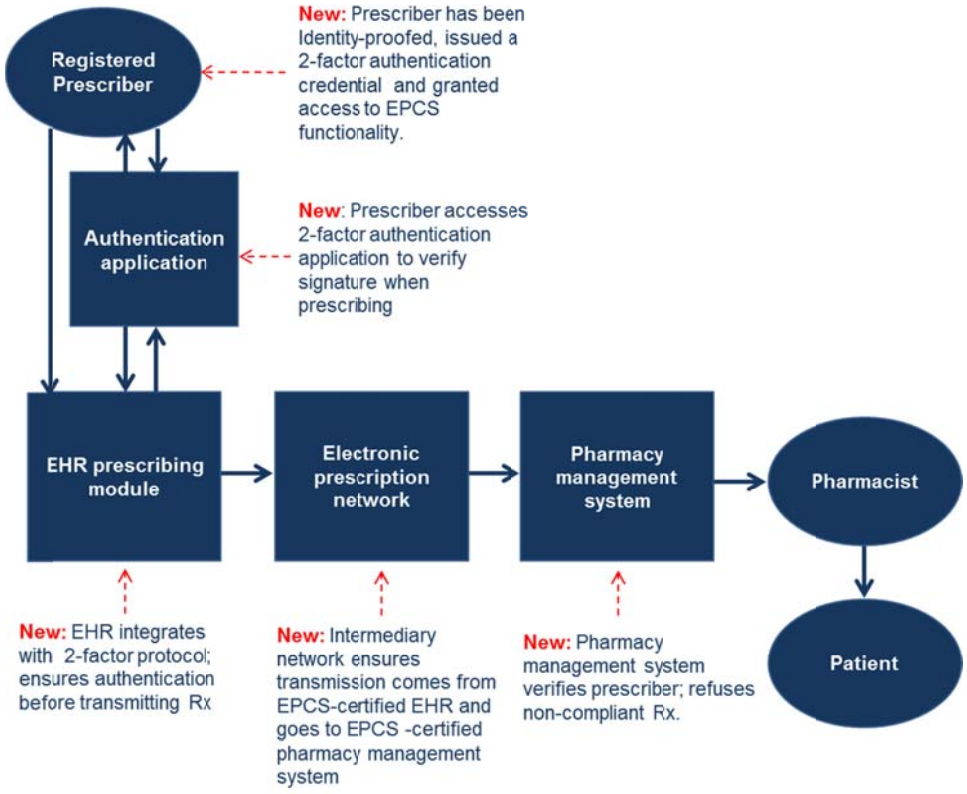
The purpose of the DEA's IFR is to ensure that electronic communications of prescriptions for controlled substances are both secure and auditable to reduce the risk for drug diversion and fraud. To accomplish these goals, the IFR establishes numerous new security requirements that apply to prescribers, pharmacies and to the several systems that support the exchange of information that comprises e-prescribing. An audit trail is created within prescriber and pharmacy applications "to document those instances in which a controlled substance prescription is received, annotated, modified

or deleted."[9] Modifications to both the EHR and the pharmacy's management software must be independently certified as compliant before its users can activate the EPCS functionality.

Prescriber organizations choosing to activate EPCS must also undertake certain required functions, including new reporting in the event of a security breach along with a registration process for its prescribers (described below).[10] Similarly, pharmacies must activate EPCS at their individual store locations, training their pharmacists and staff in how to use EPCS in compliance with both state and federal regulations regarding the dispensing of controlled substances.

Figure 1 provides a high-level overview of the security features that EPCS adds to standard e-prescribing.

**Figure 1: Overview of EPCS security features**




*Prescriber registration.* Before ever writing an electronic prescription for a controlled substance, the prescriber (who must be a DEA registrant) undergoes a set of processes this evaluation terms *registration*. Registration comprises: (1) identity proofing; (2) issuing a two-factor authentication credential; and (3) setting system controls to provide EPCS access to the prescriber.

*Two-factor authentication.* "Two factor authentication" means that the prescriber must provide two of three required authentication factors when signing a CS prescription. The prescriber enters something she knows (e.g., a password to use the EPCS software), then accesses an external authentication application to provide something she has (e.g., a "one time only" code generated by the credential) *or* something she is (e.g., a fingerprint or voice recognition). A key modification to the EHR is its integration with the authentication application to validate the prescriber-entered authentication factors.

*Electronic transmissions.* The EHR recognizes whether the pharmacy chosen by the prescriber uses an EPCS-certified pharmacy management system and rejects attempts to transmit an EPCS prescription to a non-certified pharmacy. Once transmitted, the prescription flows through the intermediary e-prescribing network, which ensures that each prescription meets its pre-established EPCS transmission

standards, including the requirement that both the transmitting and receiving systems be EPCS-certified. The pharmacy management system applies additional checks and flags scripts that do not arrive with an appropriate digital signature. Finally, the pharmacist has the option to reject an electronically prescribed CS prescription for non-compliance with state or federal regulation (e.g. an electronic refill for a Class II medication).

## III. ABOUT THE EPCS PROJECT

### A. SCOPE AND TIMELINE

The EPCS project officially began in November 2012 with a kick-off meeting bringing together the project leaders from the two pilot sites, the external project manager, the evaluation team and CHCF leadership. The two prescriber organizations each registered a few prescribers in December 2012 and had sent some initial prescriptions at the point of the first evaluation team site visits in that same month. The prescriber organizations completed the majority of their prescriber registrations over the first quarter of 2013 and encouraged their prescribers to begin sending CS prescriptions immediately. Both sites continue to use their EPCS functionality, although the official "pilot period" ended in July of 2013. Table 1 describes the pilot and evaluation timeline.

**Table 1: Pilot and evaluation timeline**

| | Sep-Oct 12 | Nov-12 | Dec-12 | Jan-13 | Feb-13 | Mar-13 | Apr-13 | May-13 | Jun-13 | Jul-13 | Aug-13 | Sep-13 | Oct-13 | Nov-13 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Sites implement EHR upgrade | ◆ | | | | | | | | | | | | | |
| Pilot kickoff meeting | | ◆ | | | | | | | | | | | | |
| First prescribers activated | | | ◆ | | | | | | | | | | | |
| Sites send 1st EPCS scripts | | | ◆ | | | | | | | | | | | |
| Pre evaluation site visits | | | ◆ | | | | | | | | | | | |
| Most prescribers activated | | | | | | | ◆ | | | | | | | |
| Interim evaluation interviews | | | | | | | ◆ | | | | | | | |
| Pilot period officially closes | | | | | | | | | | ◆ | | | | |
| Post evaluation site visits | | | | | | | | | | | ◆ | ◆ | | |
| Evaluation complete | | | | | | | | | | | | | | ◆ |

### B. PILOT PARTICIPANTS

The two pilot participants, hereafter Prescriber Organization One and Prescriber Organization Two, differ significantly in size and demographics. Prescriber Organization One (PO1) is located in urban Southern California, operates 23 clinic locations and has over 100 physicians who prescribe controlled substances. Prescriber Organization Two (PO2) operates six clinic sites with 39 employed physicians in a largely rural setting in Northern California.

Both prescriber organizations use the same electronic health record application, one of the first to achieve EPCS certification. Both pilot sites already had plans to implement a new version of their EHR that included the EPCS functionality and took the additional step of activating EPCS as part of this upgrade. The organizations expressed similar motives for choosing to activate EPCS within the context of this pilot, including a desire to create administrative efficiencies for prescribers, reduce medication errors associated with illegible or misinterpreted handwritten notes for regulated substances, and improve internal data for medication reconciliation and quality improvement initiatives.

Each pilot site identified pharmacy partners with whom they would implement EPCS. PO1 had planned to work with an external firm that manages on-site pharmacies at four of their clinic locations; unfortunately that firm's pharmacy management software vendor was not able to provide EPCS-certification in time for the pharmacies to participate. PO2 had planned to work with two independent local pharmacies; only one ultimately was able to participate but that organization brought 10 pharmacy sites to the pilot. Both PO1 and PO2 worked with the local stores of two national pharmacy retailers from the beginning of the pilot; a third national pharmacy also activated EPCS in its California stores early in the pilot period. A few other local pharmacies in PO1's region also began accepting EPCS. In effect, both prescriber sites could send prescriptions to any pharmacy that showed as EPCS certified within the EPCS module of their EHR. Table 2 provides additional information about the two pilot sites.

**Table 2. Prescriber organization environment**

| | Prescriber Organization 1 | Prescriber Organization 2 |
|---|---|---|
| Size/environment | • 23 clinics in two urban counties<br>• 119 medical staff providers and 68 per diem providers | • 6 clinics in one largely rural county<br>• 39 full-time providers and 16 contracted specialists |
| Demographics | 125,000 medically underserved patients; primarily Hispanic but ethnic mix is changing. | 36,000 low income patients; 3,650 homeless patients, 200 HIV-positive patients. Pre-dominantly white (81%) or Hispanic (9%). |
| Project leaders | Chief Medical Informatics Officer; IT Leader and Internal Consultant (also Project Manager). | Chief Executive Officer; Chief Information Officer (also Project Director); Chief Medical Officer; and Division Manager local pharmacy. |
| E-prescribing history | Implemented EHR in 2009; Meaningful Use Stage 1. | E-prescribing for 5 years. ~20% above Meaningful Use Stage 1. |
| Two-factor authentication approach | EHR password and one-time only code generated by token. | EHR password and one-time only code generated by smartphone application. |

## IV. PILOT OUTCOMES

In regular project status reports, the pilot participants self-reported their outcomes with EPCS in terms of the number of prescribers they registered, the number of those prescribers who used EPCS, their approach to addressing the EPCS outage that both experienced in May 2013, and the volume of CS prescriptions that they transmitted electronically. EPCS volume for the two prescriber organizations was also reported by the local stores of one national pharmacy retailer cooperating with the pilot. PO2 also provided information about their EPCS error rates over time. Evaluation interviews captured the actual changes in workflow imposed by EPCS at the prescriber organizations and pharmacies. This section summarizes these recorded outcomes.

### A. EPCS ROLL-OUT

***Both prescriber organizations rolled out EPCS successfully; pharmacies were able to accept the prescriptions.***

At the time of the kick-off meeting in November, both prescriber organizations had completed the upgrade of their EHRs as required to activate EPCS. The prescriber organizations each registered a few providers with high volumes of CS scripts in December. Both had planned to quickly register successive waves of prescribers beginning in January. Both organizations found the requirements of the IFR around registration difficult to interpret however, and their original plan for registering prescribers was logistically challenging to implement. While both organizations immediately fell behind on their provider registration schedule, by early spring each had succeeded in registering the majority of their prescribers and each had prescribers who were actively using the EPCS functionality.

National pharmacy retailers and an independent, family-owned group of pharmacies were all able to receive and fulfill the prescriptions they received without major difficulty.

**Table 3. Prescriber organization registration results**

| | Prescriber Organization 1 | Prescriber Organization 2 |
|---|---|---|
| Planned prescriber registrations | 119 | 39 |
| Number of actual prescriber registrations | 95 (80%); 44 prescribers have used token at least once. | 39 (100%) |

### B. EPCS RELIABILITY

***Both prescriber organizations experienced a serious EPCS outage; only one recovered fully.***

Both sites experienced a failure or “EPCS outage” in early May of 2013, when their EHR suddenly stopped accepting provider authentication credentials. The problem resulted from the expiration of an

embedded security certificate within the EHR. The EHR vendor issued a Hot Fix (a patch for operational software) in May 2013 to correct the problem with the expired security certificate, and PO2 was able to recover functionality in about one week.

PO1 was not able to install the patch until they had first implemented a number of earlier modifications issued by the vendor. PO1 sought a solution that would install only the security certificate correction to minimize the IT resource drain but the vendor was not able to supply a limited fix. In late June 2013, PO1 decided to implement all required modifications to reboot EPCS. Unfortunately, these changes did not resolve the issue for PO1 prescribers, who continued to report that the system would not accept their credentials. Research showed the new problem was related to a conflict with security protocols within the PO1 network. This problem was resolved in early July. In aggregate, at PO1 the EPCS functionality was out of commission from May 6-July 9, 2013.

## C. EPCS VOLUME

### *PO2 achieved significant EPCS volume; PO1 had limited success.*

PO2 rapidly expanded their EPCS volume over the course of the pilot period. PO1 struggled to convince their prescribers to use the functionality and their difficulty restoring the EPCS functionality following the outage substantially diminished prescriber use of EPCS within the pilot period.

At pharmacies that had activated EPCS, PO2 was sending 65-75% of their prescriptions for controlled substances electronically by the end of the pilot period. While this volume had begun to approach their e-prescribing rate for non-controlled substances (85%), they still faced the constraint that about 50% of their prescriptions were sent to pharmacies that had not yet activated EPCS. Looking across all pharmacies, PO2 achieved a peak EPCS rate of 37% of all CS prescriptions written by their prescribers.

PO1 had only just begun using the EPCS functionality again at the time of the post-pilot interviews. According the final progress report submitted by PO1, only 14 prescribers have used EPCS since the functionality was restored in July. PO1 self-reported a peak of 3.32% of controlled substances prescribed electronically across all pharmacies.

**Table 4. Prescriber organization volume results**

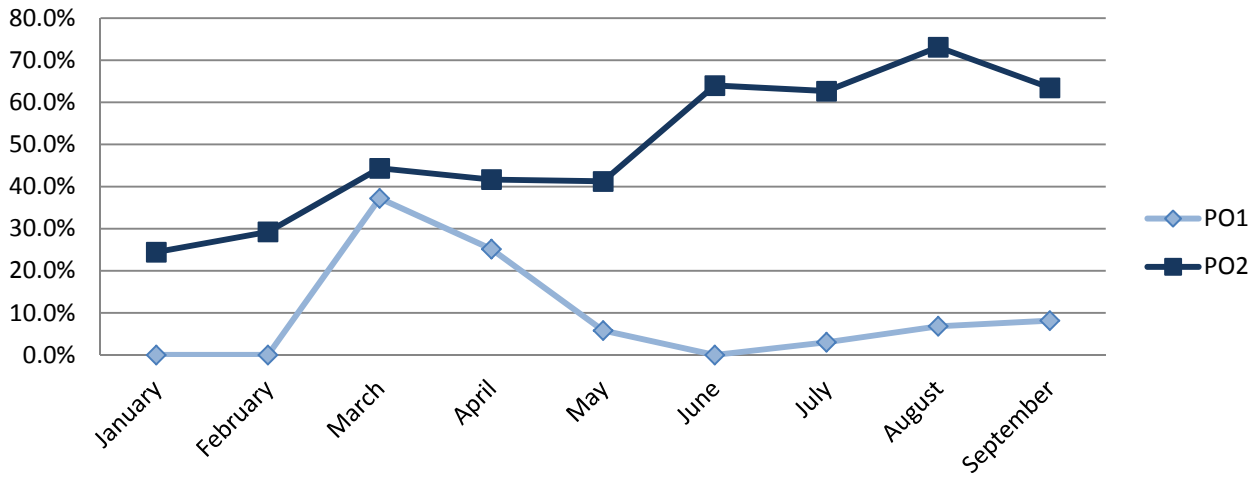
| | Prescriber Organization 1 | Prescriber Organization 2 |
|---|---|---|
| Number activated pharmacies | >350 area locations of 3 national pharmacies across the two counties served, plus a few other local pharmacies | 19 total: 10 locations of independent local pharmacy; all area locations of 3 national pharmacies |
| Pre-pilot % of CS volume at activated pharmacies | Not reported. | ~50% |

**Table 4. Prescriber organization volume results**

| | Prescriber Organization 1 | Prescriber Organization 2 |
|---|---|---|
| Highest self-reported EPCS as % of total CS (all pharmacies) | <3.5 % (July 2013) | 37% (August 2013) |
| Highest volume EPCS as % total CS (one certified national pharmacy) | 8% (September 2013) | 73% (August 2013) |
| Error rates for EPCS | Not reported | ~3.5% first month, 1.35% overall |

Figure 2 displays data provided by one national pharmacy that reported EPCS volume at their stores near PO1 and PO2 locations. While these data are from only one of the participating national pharmacies, they provide an interesting view of how EPCS volume varied over the course of the pilot for the two prescriber organizations, when considering only EPCS-certified pharmacies. Note that the sites registered physicians in waves; some of the increases displayed in the graph can be explained by the sites having added registered prescribers. The dip in May (for PO2) and the nadir in May and June (for PO1) correspond to the periods when EPCS was out of commission at their respective sites.

**Figure 2: Percentage EPCS of total CS prescriptions, one EPCS-certified national pharmacy retailer, January 2013 - September 2013**




## D. IMPACT ON PRESCRIBER AND PHARMACY WORKFLOWS

### *For new prescriptions, post-EPCS processes were nearly the same as for other e-prescribing.*

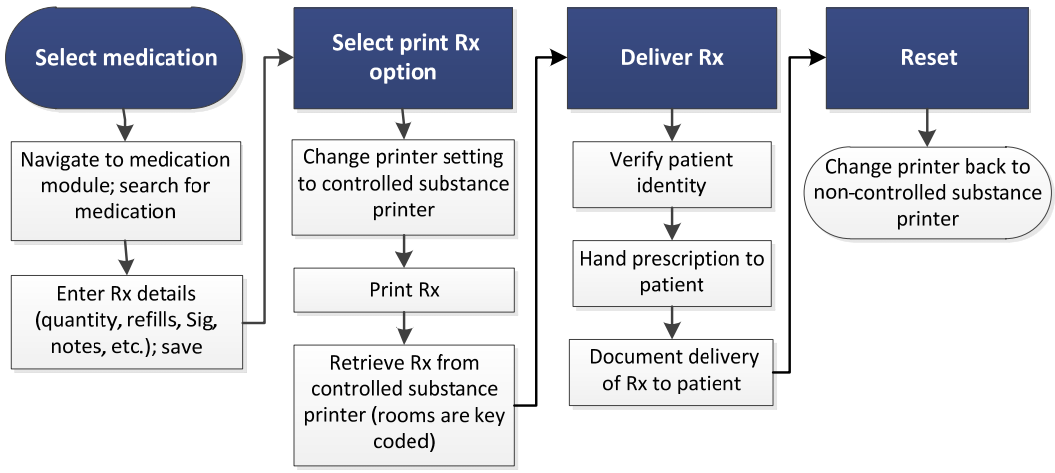
The pre- and post-EPCS processes for new and refill prescriptions were very similar for the two sites, given that both sites operate under California regulation and both use the same vendor for their EHR. This section highlights key impacts of EPCS on workflows at the prescriber sites and local pharmacies.

**EPCS eliminates secure printer, secure paper and "wet signature" steps for prescribers.** In the absence of EPCS, prescribers must use DEA-certified prescription paper for controlled substances. This paper includes features that can help a pharmacist distinguish a legitimate prescription from a fraudulent one; for example, a reflective watermark that shows as "VOID" when copied and a prescription logo that disappears or changes colors when breathed on or used. Prescriber sites typically stock this paper in a separate printer in a secure location; for example in a separate room with a keypad entry lock. Prescribers may send the prescription to print and pick it up themselves to sign and then hand to the patient, or may have procedures in which a medical assistant retrieves the prescription and brings it to the physician for signature before giving it to the patient.

To manage security when the patient is not handed a prescription directly by the physician, the clinics store printed and signed prescriptions (primarily refills) in a locked box. Staff members perform additional patient identification checks before giving the prescription to the patient and also note in the patient's medical record when the prescription has been delivered and to whom.

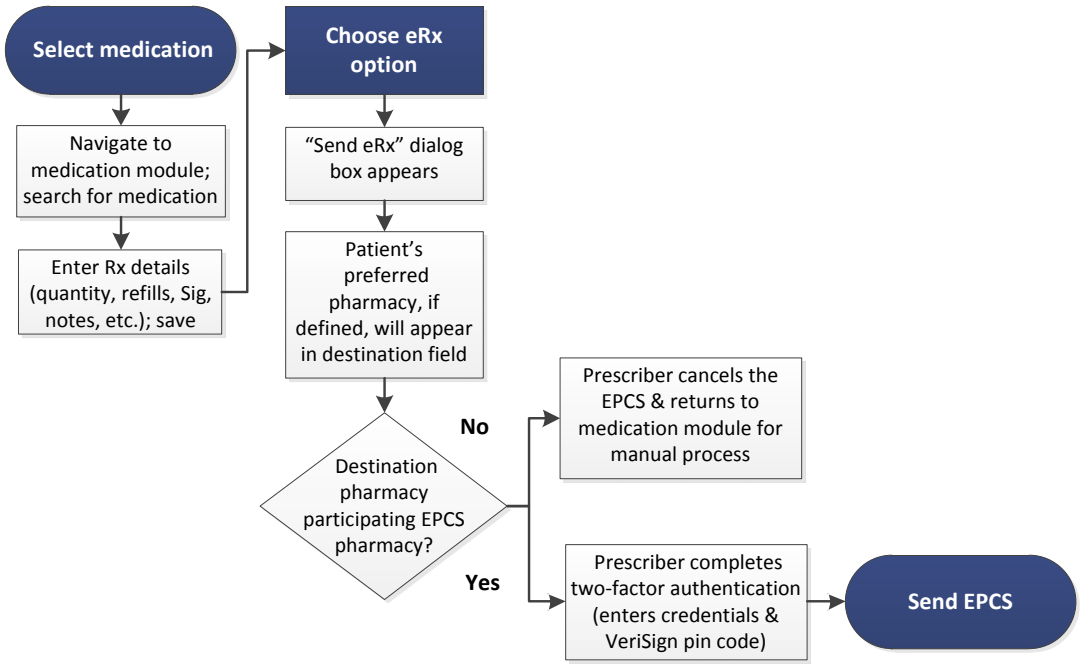
Figure 3 displays PO2's description of the steps for filling a new prescription for a controlled substance without EPCS.

**Figure 3: Pre-EPCS prescriber workflow for new CS prescriptions**



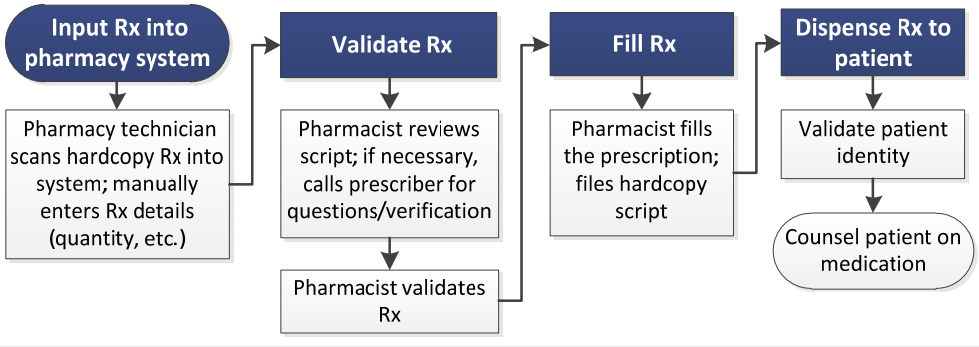

As shown in Figure 4, EPCS eliminates the printing and manual distribution steps for prescriptions that may be sent electronically—that is, those going to an EPCS-certified pharmacy. In comparison to the standard e-prescribing steps (not shown), EPCS adds two steps, selecting an EPCS-certified pharmacy and completing the two-factor authentication protocol before transmission.

**Figure 4: EPCS prescriber workflow for new CS prescriptions**




**Pharmacies also eliminate manual processes.** Pharmacies receiving paper prescriptions first apply manual security protocols designed to help identify signs of fraudulent scripts. Examples include: verifying the features embedded in the water-marked paper; verifying a patient's information against the information on the prescription; and looking out for certain combinations of medications that may flag prescription drug abuse. Then, they must type the prescription into their pharmacy management system. Figure 5 displays the typical workflow for a pharmacy receiving a paper or faxed controlled substance prescription according to interviews with pharmacists near both PO1 and PO2.

**Figure 5: Pharmacy workflow for paper CS prescriptions**




How pharmacists receive an EPCS prescription varies slightly based on their individual pharmacy software. In general, the prescriptions arrive in almost exactly the same format as other e-prescriptions and no longer require any manual entry before dispensing the medication.

Two pharmacists described security features within the pharmacy's certified system that detect whether a physician properly signed the script with their digital signature and is authorized to send controlled substance scripts electronically; if the requirements are not met, the system will instruct the pharmacist to generate a printout, after which the prescription deletes from the system.

> ***"But if it doesn't have the digital signature, it self-deletes from my computer. It will actually make it through typing, the tech will type it, it'll show up on my computer, I will review it and then it'll pop up with a box that says this does not have a digital signature and it will delete and it will print out. So if somebody tries to send us one and they are not authorized to do so, on their end it deletes itself. My computer somehow knows."***
>
> ***(Pharmacist, PO2)***

### *EPCS simplifies refill processes; but special issues also affect refills.*

In the absence of EPCS functionality, front-line staff members typically handle the first step of processing the refill request, abstracting information from the chart and typing it manually into a prescription refill template. They then send a task with the template to the prescribing physician. The prescriber must accept the task, open the template, and approve or deny the request. If the request is approved, the written prescription must be printed securely and then faxed to the pharmacy or printed and given back to staff to call the patient for pickup. If the request is denied, support staff will notify the pharmacy, typically by phone.

> ***"Every little thing, even if it's an easy step, it's still time consuming. You've got to go into the chart. You've got to verify everything. You've got to get up, unlock the drawer, get it out, go to the patient, get ID, go back and document it."***
>
> ***(Front-line staff member, PO2)***

Front-line staff store written refill prescriptions in a locked drawer for patient pickup. Patients need to come to the clinic for the prescription, sign in, and wait their turn to talk to staff. Staff members check the patient ID and note in the chart who picked up the prescription.

With EPCS, refill requests for Class III, IV, and IV substances come directly into the provider's task queue, eliminating the front-end step of manually creating the refill request and also the back-end process to securely distribute the refill prescriptions.

A practice PO2 had adopted to expedite refills for CS prescriptions before EPCS caused problems for them after implementing EPCS. To avoid working from faxed requests from the pharmacies, PO2 had requested that pharmacies send electronic refill requests for all controlled substances (Class II-V). The physicians receive these requests as refill tasks in their respective work queues. Before EPCS, the standard process was for the physician to immediately decline the electronic request but use this task as the reminder to speak to the patient if denying the refill or to create a paper prescription to fax or hand to the patient if approving it. Implementing EPCS meant the physician could now accept the electronic requests for Class III-V substances but not for Class II medications because no refills—paper or electronic—are allowed for Class II drugs. Once physicians began responding to refill requests electronically for Class III-V medications however, they sometimes attempted to authorize electronic refill requests for Class II substances as well. These requests would then be denied at the pharmacy. One pharmacist remarked that he disliked PO2's process and thought it should be discontinued. Even

though the refill request is appropriately denied, it still counts as an error and requires a call back to obtain the new prescription for the patient.

Some interviewees also described a limitation of electronic prescribing related to storing "pending" refill prescriptions. Before EPCS, a physician wishing to prescribe three months of a medication with a 30-day prescription limit might write three paper prescriptions simultaneously and give the future prescriptions to the staff to store for pick-up when each new prescription is due. When prescribers tried this same approach for electronic prescriptions they found that some of the pharmacy systems are able to store future prescriptions while others cannot.

## V. EVALUATION FINDINGS

### A. EPCS BENEFITS

***When the technology works as planned, prescribers and pharmacists alike found that EPCS offers significant benefits.***

**Participants reported high satisfaction and positive impacts on productivity.** Staff and providers commented that they and their teams were satisfied with EPCS. While PO1 prescribers had concerns about the technology problems and long delays to get to smooth operations, for the most part they still believed that EPCS was more efficient than manual processes.

PO2 prescribers and staff cited the ease and efficiency of the system and reported that improvements in workflow contributed to staff satisfaction. Several providers and pharmacists reported the integration of EPCS with the electronic prescribing system made it easy for them to learn and use. Participants did not formally measure changes in productivity as a result of EPCS. Most believed however that EPCS had enhanced productivity through: saving physician time to print and retrieve prescriptions; allowing physicians to prescribe from anywhere; reducing pharmacy time to enter a prescription; and avoiding clarification callbacks. Several physicians and pharmacists commented that EPCS

**EPCS Benefits**

EPCS pilot participants—including physicians, pharmacists and their parent organizations—described many benefits from adopting EPCS.

**Benefits for physicians and clinic staff**

- ✓ Easy to use; prescribe from any secure computer (not tied to secure printer).
- ✓ Saves physician and staff time on both new and refill prescriptions.
- ✓ Reduces use of expensive watermarked prescription paper.
- ✓ Direct communication channel between prescriber and pharmacy improves ability to track prescriptions and eases prescriber concerns about security.
- ✓ Provides robust data on CS prescribing patterns for quality improvement.

**Benefits for pharmacies**

- ✓ Easy to use; close to regular e-prescribing.
- ✓ Saves time by eliminating rekeying of Rx information.
- ✓ More accurate prescriptions, potentially improving patient safety.
- ✓ Stronger security reduces the opportunity for fraudulent prescriptions to escape detection.

allowed them to spend more time seeing or counseling patients. Prescribers and front-line staff reported that EPCS reduced their work handling refill pick-ups and pharmacy call-backs.

**Improved patient safety.** Participants across all roles—managers, providers, pharmacists, and front-line staff—believed that electronic prescribing would avoid errors that might harm patients, for example, those caused by illegible prescriptions.

**Potential cost savings.** Many participants cited cost savings stemming from eliminating the use of costly watermarked prescription paper and time spent by staff on controlled substance prescriptions. One senior manager stated there was an $8,000-10,000 savings just from reduction in the use of the secure prescription paper, but most could only assume that EPCS reduced costs.

> ***"I hate printing … because I'm always nervous, like are these people legit, or is it just a drug seeker? I don't know, and sometimes it's a gamble, especially because I'm not the primary so I don't know these people well enough. I hate … printing prescriptions, and oh and on our prescriptions actually if you flip it over it has everybody's DEA number, so when you pass that out, I mean it's like a gold ticket to somebody that knows how to use that stuff."***
>
> ***(Prescriber, PO1)***

**Stronger security.** Nearly half of respondents across sites reported that improving security for prescribing controlled substances was a primary driver behind implementing EPCS. Participant concerns with fraudulent or tampered written prescriptions were common in pre-EPCS interviews; post-pilot, few noted security concerns or worries about using EPCS. One prescriber mentioned that EPCS caused leadership to revisit how to handle sensitive prescribing issues around drug-seeking patients and communicating with the primary provider. With EPCS, an on-call provider could choose whether or not to prescribe a controlled substance to a patient just as before (i.e., paper or electronic fax), or exercise the option to delegate the CS prescribing decision to the primary care physician.

**Increased ability to track prescriptions and analyze physician prescribing habits.** A few physicians called out the ability to track where the prescription was sent and whether it was picked up. Representatives from both sites valued the potential for new EPCS data on physician prescribing habits to enhance quality improvement initiatives.

### B. IMPACT ON WORKFLOW

***EPCS imposed only minor modifications to prescriber and pharmacist workflows (compared to standard e-prescribing) and those modifications were well-received.***

**Concerns about provider reaction to the two-factor identification process are largely unwarranted.** Early in the project, some senior leaders expressed concerns that the physicians would not like the two-factor authentication process. As has been reported in other studies however, prescribers in this pilot seemed unfazed by the need to carry a token (PO1) or use their smartphone application (PO2) to obtain the one-time only code they used to sign electronic CS prescriptions.[11] Prescribers saw the additional security as adding value, given their worries about the security of current paper processes.

**Pharmacists, physicians and staff called post-EPCS workflows "easy."** Prescribers noted the new processes were extremely similar to existing e-prescribing processes, adding only the steps to obtain and enter the PIN. The physicians appreciated that EPCS freed them to write a prescription from anywhere, not just when they were down the hall from a secure printer. One spoke in the pre-interviews about how he hated having to physically go to the clinic to access the secured printer and special paper in the evening or on the weekend because he had forgotten an urgent prescription. Post-pilot, he particularly appreciated the ability to prescribe from home.

> ***"Like what if it's Friday night and I remember that I didn't do a morphine script? I really have to drive in the following morning, take my kids, because I have to take my kids, take my kids into urgent care … sign in, print it out [on the urgent care printer], then sign it, then tell the urgent care person that it's there. I mean, what a waste of time and energy for a stupid piece of paper. Come on. We got computers. So that's why I want this e-prescribing thing immediately."***
>
> ***(Prescriber, PO2)***

Front-line staff at PO2 valued how EPCS diminished the effort to distribute paper refills for controlled substances—a process that involved several extra steps and many phone calls from patients about whether the refill was ready.

> ***"It's actually smoother because we don't have the 45 minutes of the angry patient having to wait to pick up the prescription."***
>
> ***"Or them calling, is my prescription ready to be picked up yet?"***
>
> ***"[Or asking] did the doctor print it out yet?"***
>
> ***"That happens a lot. That is very good. That happens a lot. I'll get 3 or 4 calls a day with that on the hard copies."***
>
> ***(Three front-line staff members, PO2)***

**Behind the scenes, prescriber organizations and pharmacies will need new processes and policies.** Prescriber organizations needed to determine: how to register and train new physicians; how to address lost tokens or phones; and whether and how to educate or encourage patients to use EPCS-certified pharmacies. Senior leaders at PO1 mentioned they had concerns with new liabilities imposed by EPCS, including how to ensure compliance with new reporting requirements related to security breaches, as they debated whether to participate in the pilot. Pharmacies must also prepare their pharmacists to accept EPCS, and must develop procedures to ensure substitute or "floater" pharmacists are made aware of the availability of EPCS when they take a shift at an EPCS-certified store.

## C. FACILITATORS

***Facilitators for successful EPCS implementation include physician demand, leadership commitment and prescriber-pharmacy partnerships.***

**Physician demand and a strong e-prescribing culture.** At both sites, prescribers had previously expressed a desire to enhance security over the prescribing of controlled substances. Given the strong e-prescribing history at both organizations, physicians also looked forward to relief from the administrative burden of manual processes for ordering controlled substances.

PO2 took active steps to nurture physician acceptance and usage through immediate error resolution—including monitoring errors up to four times per day at the start of the pilot—and through regular interactions with the physicians to celebrate milestones and communicate timelines for fixing any problems. The close relationships that PO2 developed with the local pharmacies and with their national representatives during the pilot also helped to facilitate immediate error resolution. For example, when faced with the problem of a substitute (or floater) pharmacist denying EPCS prescriptions because he was unfamiliar with the new processes, PO2 could pick up the phone and have a pharmacy manager or national pharmacy representative immediately contact the pharmacist to say it was okay to accept the prescription.

**Tactics for Success**

There's more to EPCS implementation than ensuring the technology works reliably. The evaluation identified several tactics that might improve the likelihood of successfully implementing EPCS.

- ✓ Nurture physician and staff demand. Current processes are a pain-point for prescribers and staff alike. Identify those feeling the most pain for early adoption; let them spread the positive word.
- ✓ Develop the pharmacy relationships before you begin. Find partners that want to work with you. Put their problem solvers on speed dial and let them know how they can quickly reach you to resolve their issues.
- ✓ Consciously create positive first experiences for prescribers. Jump on errors and other problems. Let the physician know when the problem will be resolved and then deliver.
- ✓ Pave the way for patients to demand EPCS from their physicians:
  - Highlight service in patient newsletters.
  - Develop handouts for physicians and staff to explain EPCS and identify EPCS certified pharmacies.
  - Train staff to explain EPCS in response to refill requests. If prepared, this group can sincerely promote the convenience of EPCS refills.

**Leadership support and adequate internal resources to address problems before they negatively affect user experience of EPCS.** EPCS is not yet at a point where implementation is routine. Leadership commitment must include the internal resources needed to address unexpected issues. PO1's outage was much longer and deeper than that of PO2, in part because they had not anticipated the need to implement a large backlog of noncritical system fixes before rebooting EPCS.

**Implementation as a prescriber organization-pharmacy partnership.** EPCS is not an initiative that is implemented solely within any one organization. A successfully filled prescription for a controlled

substance represents a complex interplay of manual and electronic processes, the transfer of information across several independent systems, coordinated business processes between prescribers and pharmacies and a common interpretation of the mix of state and federal regulations surrounding controlled substances. PO2 included the Division Manager of a large local pharmacy on the pilot implementation team and worked closely with the manageable number (19) of pharmacy partners to install EPCS—a set of integrated systems and processes—as an integrated team. Both the pharmacies and the clinic found value in the new or stronger relationships that resulted from their joint effort and in working collaboratively with the local pharmacies to resolve early issues with EPCS.

> ***"…as soon as we went live, [the project director] sent us an email and we did a lot of test claims to make sure we were receiving them and it was fine…We've had a lot of communication keeping each other informed as to what is going [on]…I think that has been very helpful."***
>
> ***Pharmacist, PO2***

The pharmacy with which PO1 had the closest existing relationship—their in-house group—was unable to participate in the pilot. While PO1 had contacts at the regional level for each of the national pharmacies, they did not try the one-to-one communications and testing strategies with individual stores that PO2 employed with apparent success. These tactics might have proven more difficult to implement in a large urban area; however, they might also have facilitated quick responses to any process or communication blips between the pharmacies and PO1 prescribers and thus helped to ensure that physicians' critical first experiences with EPCS were positive.

## D. BARRIERS

### *Key barriers to wide-spread use of EPCS include: lack of critical mass; cost of pharmacy entry; reliability of new technology; and challenging prescriber registration processes.*

**Lack of critical mass.** In both pre- and post-interviews, pharmacists wished more physicians would use EPCS and physicians wished more pharmacies were certified so EPCS could become the norm rather than an exception process. The maximum potential EPCS volume at each of the pilot sites was significantly constrained by the inability of key pharmacies to participate in the pilot. At PO1, an in-house pharmacy—one that a significant portion of its patient population was required to use—could not obtain certification within the pilot period. At PO2, a pharmacy located onsite—and one to which prescribers felt patients were particularly loyal—was similarly unable to participate. Each of these pharmacies asked their pharmacy system vendor to quickly complete EPCS certification and participate in the pilot, but these overtures were rebuffed. While the critical mass issue will likely resolve itself over time, the current state remains a significant barrier to the rapid expansion of EPCS and to realizing the benefits it promises to provide.

**Cost as a barrier to pharmacy entry.** Several interviewees cited cost as a barrier to entry for the pharmacies. While the DEA's economic impact report for EPCS assumed a cost of about $15,000 per audit for both practices and pharmacies, participants interviewed were hearing anecdotally that actual costs were much higher—from $30,000 to $100,000 and up.[12] Since audit costs are borne by the

pharmacy system vendors, each vendor makes its own decision as to how to allocate the expense across their customer base. For large national pharmacies with in-house systems, the cost of the audit is a cost for the pharmacy system, spread over a great number of stores nationally. A smaller vendor might have more difficulty recovering costs from its customer base; on the other hand, one of the independent pharmacies participating in the pilot reported that their vendor had not assessed any specific expense for the EPCS functionality. This issue intersects with the critical mass barrier described above. That is, more physicians and physician organizations need to implement EPCS before the pharmacy management system vendors that supply smaller pharmacies will perceive a clear mandate to initiate the effort and expense of EPCS certification.

**Reliability issues.** EPCS technology is new and relies on multiple systems interfacing around complex security requirements. Glitches can occur and starts and stops may damage physician receptivity. Both sites experienced a problem where prescribers were suddenly unable to e-prescribe, receiving a message that the system would not accept their credentials. In addition, one of the pilot sites discovered a serious problem with all incoming refill requests—including non-EPCS refills. This problem was not captured by vendor monitoring reports, pointing out the need for strong internal testing and monitoring for the unexpected. Staff members at PO1 reported ongoing problems following the EPCS outage. One, they discovered an issue involving proxy settings of their internal system that was blocking EPCS prescriptions and had to be reprogrammed. Two, a couple providers reported problems with the functionality of their tokens that PO1 was in the process of addressing at the time of the post-pilot interviews; these negative experiences affected prescriber ongoing willingness to use EPCS.

***"… it was a small group of us, maybe 5 or 6 of us trying it first and then it was supposed to get bigger and eventually it got bigger but then, you know… if you get burned, so to speak a couple times, you just stop using it. So like Dr. --- hasn't, I told him, hey, it should be working, try it. So he finally tried it again yesterday after a month or whatever and his still didn't work. So he's like, really?"***

***(IT staff member, PO1)***

**Challenge of initial registration effort.** Both sites found it challenging to interpret the registration requirements, that is, the required steps to identify-proof prescribers, issue two-factor authentication credentials and to set system access controls to allow prescriber access to the EPCS functionality. Both sites found that the registration effort went more slowly than expected. Their initial plan to register prescribers en masse at clinical meetings did not work well. Attendance was low and the physicians did not like waiting in line for others to be credentialed. Both sites subsequently decided to send the two registrars to the clinicians at their respective locations and to register them individually according to a schedule. Registration was combined with training on how to use EPCS, including how to obtain the one-time only code. The registrars estimated the combined process took about 15 minutes to complete.

Along the way, PO2 discovered that both registrars did not need to meet in person with each physician prescriber. The project director met with each physician to authenticate the physician's network user ID, to load and authenticate the device, and to provide the training. Later, the IT representative and the second registrar would meet separately to complete the final step—authenticating the user in the EHR.

This approach saved significant time for the DEA-licensed registrar, a senior physician leader, and PO2 shared it with PO1. Even after making the change however, PO1 continued to find that their original team of two registrars was insufficient to register so many prescribers. They added a second registration team late in the pilot.

**Substitute or "floater" pharmacists were not ready for EPCS.** Both sites experienced problems where a substitute pharmacist coming in to cover a shift would be unaware of EPCS and begin denying electronic prescriptions for controlled substances. The sites reported that the problem occurred most frequently at the national pharmacy retailers, pointing to a need for these pharmacies to develop procedures for just in time communications about EPCS and training for their contingent workforce.

**Many prescribers are reluctant to ask patients to change pharmacies.** While a few physicians reported that they actively encouraged their patients to use EPCS-certified pharmacies, several commented that they were unwilling to mention EPCS to their patients. This reluctance may derive from several factors; one that was mentioned was a desire not to interfere with the patient's ability to price-shop prescriptions or to choose a more conveniently-located pharmacy. This barrier may become less salient as patients become more familiar with the availability of EPCS and the conveniences it offers them.

## E. EPCS AND PATIENTS

### *Prescriber and staff opinions on patient reaction to EPCS were mixed.*

The evaluation did not include any direct contact or interviews with patients, however the evaluation queried participants about patient reactions to EPCS they had observed and how their organizations were handling the question of whether to encourage patients to choose an EPCS-certified pharmacy.

> ***"I think the patients like it, the ones that are using it. I think they enjoy not having to come back here and stand in line and wait and pick their prescription up and then go to the pharmacy…We hear about I can't come in because I don't have gas or I don't have a ride or my caregiver can't get there and I'm due today…"***
>
> ***(Front-line staff member, PO2)***

Participant perspectives on the impact of EPCS on patient experience were mixed. Clinic staff generally believed that patients had not been significantly impacted by EPCS or that patients took the change for granted because they were used to other electronic prescriptions. Several pilot participants noted that the patients who had previously complained about the distance from the clinic to their home or the wait time for refills were most likely to comment about EPCS benefits.

### *Encouraging patients to choose EPCS pharmacies was neither the policy nor the norm, but some physicians did so.*

Neither PO1 nor PO2 established a specific policy to encourage patients to use EPCS-certified pharmacies. At PO1, a senior leader said that at the beginning of EPCS they actively told patients they could send their prescriptions electronically, but some patients were vocal about wanting to use their same pharmacy (that may not be EPCS-certified).

> ***"In the beginning we were putting [on] a little pressure. You know, why don't you go next door and get it, but now we are not. We just, you want to use this pharmacy, fine. If that pharmacy doesn't do it, then we'll [give you paper]. And the computer knows. The system knows if that pharmacy allows [EPCS] or not … we saw so much pushback from the patient that they want to use only one pharmacy or their pharmacy that we said … continue. You know, even asking, it doesn't make sense."***
>
> ***(Senior leader, PO1)***

The project director at PO2 noted that some physicians were apprehensive about directing patients to use EPCS-certified pharmacies. To address this discomfort, PO2 published information about EPCS and the participating pharmacies in their patient newsletter. The organization's role was to inform the patients of the option; the patients retained the choice of pharmacy. Physicians determined individually whether to suggest EPCS.

Prescribers were free to communicate the potential advantages to the patient if they desired, and it appeared that a good number of physicians were taking this step. PO2 physicians seemed to be more comfortable making a suggestion to the patient, perhaps because EPCS was more firmly established there by the end of the pilot. A few physicians there reported that they now inform patients that they have the ability to send controlled substance scripts electronically and that only some pharmacies accept controlled medications in this fashion. Two front-line staff members at PO2 concurred that some physicians now encourage EPCS. They've been asked by the physicians they support to educate patients about the EPCS option; one of the physicians had developed a handout for the staff member to provide to the patient after the physician had verbally advised the patient about the EPCS process. She added that many patients have become familiar with the ability to send their prescriptions via EPCS and are now using pharmacies with EPCS capability; others continue to ask for paper prescriptions.

> ***"Like if they call and ask for a refill, I know through Dr. ---, he's asked us to always ask them do you want … this on a paper script or would you like me to send it via the computer to one of these three pharmacies? And like I said, educate them that that's a possibility."***
>
> ***(Front-line staff member, PO2)***

While PO2 physicians appeared farther along with the idea of suggesting a patient choose an EPCS-certified pharmacy, the practice was not unknown at PO1. A PO1 staff member also remarked that the physician she supports explains EPCS to his patients; her role is to reinforce the explanation.

## VI. POLICY IMPLICATIONS

Participants called current lack of critical mass the most significant barrier to widespread EPCS adoption. Because many physicians are reluctant to suggest patients change pharmacies, the independent pharmacies most often used by clinic patients must participate to achieve high EPCS volumes. To encourage pharmacy adoption, policymakers might take steps to address the frequency and cost of the required third-party audits. Greater clarity on the type of system changes that would require an EPCS re-audit might allay pharmacy vendor concerns about ongoing compliance costs.

Physician organizations are only just beginning to adopt EPCS and may need stronger incentives since the market share incentive that encourages pharmacy adoption does not apply. Previous research suggested that physician adoption of regular e-prescribing was accelerated in response to federal incentive programs under the Medicare Improvements for Patients and Providers Act.[13] For EPCS, policymakers might consider adding EPCS to federal meaningful use incentives, for example by including CS prescriptions in the calculation for the e-prescribing measure.

## VII. AREAS FOR ADDITIONAL RESEARCH

Although many interviewed participants believed that EPCS has the potential to improve care quality and patient experience while simultaneously producing efficiency gains, additional research is needed to test these perceptions. Studies might address:

- Whether perceived improvements in prescriber and staff workflows translate into measurable changes in staff productivity and savings that exceed the costs of implementation.

- The impact on patient experience. The evaluation did not include direct feedback from patients on their experience with EPCS. Participants had mixed views on how EPCS impacted patient experience. Further research might address whether EPCS—which should increase patient convenience—has any unintended consequences on their experience of care.

- The relative security of EPCS over current manual processes. Nearly all interviewed participants felt that EPCS is more secure than current processes, and since a desire for increased security is a key driver of physician demand, research confirming this belief might incentivize physician adoption.

- The possibility that EPCS might improve care coordination. One prescriber suggested this intriguing idea, noting that EPCS allows an on-call provider to delegate the decision to prescribe a controlled substance to the primary care physician. Research into the impact of EPCS on prescribing habits and the use of EPCS data in internal analyses might answer these and other care quality questions.

## VIII. CONCLUSION

EPCS is an innovation that appears here to stay. There is strong interest, high perceived value to users, technical capacity, societal benefit, and a business case to devote the resources needed to implement this functionality. Expansion is interdependent on prescriber and pharmacy adoption; society will not realize the full potential of EPCS until both groups decide jointly to make the effort and work cooperatively on implementation. Incentives to accelerate wide-spread adoption should address both physician groups (e.g., include EPCS in meaningful use standards) and pharmacies (e.g., address the timing and cost of third party audits).

> ***"You know, as a culture here we have embraced technology and this is such, this component of our practice is such a big one, a large one, that it just seemed it was ripe for solution, and why not us? You know, why not us? We have good partners, we have good technology, we have great leadership, we have a medical staff buy-in.... So that, I mean, all those conditions, all right. I think it's a culture issue for us. I think it was a leadership issue for us."***
>
> ***(Senior leader/project director, PO2)***

EPCS also presents implementation challenges that must be carefully addressed. The failure to devote adequate attention or resources to both systemic problems and episodic errors may erode physician support and cause the effort—which should enhance physician and staff satisfaction—to create physician resistance instead. With leadership support, adequate resources, and strong prescriber-pharmacy cooperation, EPCS can work and work well.

## APPENDIX A: RESEARCH METHODS

AIR used qualitative research methods to address the following research questions:

1. Did participants perceive operational efficiencies and benefits that exceeded burden as a result of implementing EPCS? What data are available to support these perceptions?

2. How were prescribing and pharmacy fulfillment workflows affected by the implementation of EPCS compliant with current national and state regulatory requirements? What facilitators and what barriers did each pilot site experience during implementation?

3. What lessons can provider organizations and pharmacies considering EPCS learn from these early adopters?

4. What are the implications of the implementation pilot for policymakers and regulators, such as the DEA and the California Board of Pharmacy? Can opportunities be identified to streamline requirements for EPCS while maintaining adequate security protections?

Research activities included pre- and post-pilot site visits with in-person interviews and observations, interim telephonic interviews with project leaders, and document collection. AIR's Institutional Review Board approved all data collection protocols, recruitment, and interview procedures before contact and data collection. In total, AIR conducted 55 individual and small group interviews with 42 key stakeholders involved in the EPCS pilot. Both in-person and telephonic interviews were transcribed verbatim and systematically coded in NVivo 10.0. Table A-1 categorizes participant interviews.

**Table A–1. Interviewed participants by organizational role**

| Position in organization | PO1 | PO2 | Total |
|---|---|---|---|
| Senior leaders/project directors | 3 | 2 | 5 |
| Physicians | 4 | 5 | 9 |
| Front-line staff (nurse and nonclinical) | 1 | 3 | 4 |
| Pharmacists | 8 | 5 | 13 |
| Information technology staff | 3 | 0 | 3 |
| External individuals/vendors (both local and national) | -- | -- | 8 |
| Total participants | 19 | 15 | 42 |
| Total interviews | 25 | 23 | 55 |

Quantitative data used in the report were self-reported or provided by the external project manager and have not been validated.

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