Part 1: A National Patient Identifier: An Idea Whose Time Has Come Again

Part 2: Taking ePrescribing to the Next Level with the Structured and Codified Sig

Part 3: Legislative Changes to I-STOP: Are They a Good Thing?
1

Part 1: A National Patient Identifier: An Idea Whose Time Has Come Again

By Michael Burger, Senior Consultant

From an interoperability perspective, identifying patients so their clinical records across multiple care providers can be collated in a comprehensive and complete care record is an important but difficult task. The challenge is that there is currently no single way to identify individual patients within and across the health care ecosystem. In response, stakeholders use a variety of patient data and complicated algorithms to try to link patient records. Despite the sophistication of the methodologies, matching remains imprecise. The result is expensive overhead to manually sort things out as well as costs related to poor care quality, patient safety and potential liability.

Recognizing the need, the industry has developed solutions with varying levels of sophistication. A recent strategic alliance between Experian Health and the National Council for Prescription Drug Programs (NCPDP) is the latest entrant into the space. In the meantime, stakeholders are calling for the end of a Congressionally imposed ban on the creation of a national patient identifier standard by the government that has existed since the late 1990s.

Why is it so hard to identify patients and their records? A national patient identifier sounds like a pretty simple concept. It’s not. The complexities of creating one are extensive. There are people with the same names and birthdates; people who go by a nickname, alias, initials, hyphenated names or multiple names, such as their birth and married names; and people with the same name who live at one address. There are additional challenges posed by clerical errors and data discrepancies introduced during diagnosis, treatment and billing. Plus, the size of the health care delivery system and fragmentation of paper- and computer-based record-keeping enormously complicate things. Cumulatively, these issues make accurately identifying patients and associating them with their records a colossal undertaking.

The Social Security number (SSN) used to be the “gold standard” of patient identification, but even that is fraught with challenges. For one thing, the SSN is no longer a sacrosanct, unique number; a single SSN has been seen as being used by multiple people without the government’s knowledge. Providers and payers have no way to verify the authenticity of SSNs presented by patients. Patients are unwilling to share SSNs in response to the rise in identity theft. As a result, medical practices, hospitals and insurers increasingly are discarding the SSN in favor of their own identifiers. In fact, the government is getting ready to remove SSNs from Medicare cards in response to a provision tucked away in the Medicare Access and CHIP Reauthorization Act.

Then, there is legislation. In 1996, Congress mandated the creation of a patient identifier as part of the administrative simplification portion of the Health Insurance Portability and Accountability Act. Patient advocates objected and pressured Congress. As a result, federal appropriations legislation for fiscal year 1999, passed in 1998, prohibited
Part 1: A National Patient Identifier: An Idea Whose Time Has Come Again

the Department of Health and Human Services (HHS) from spending any funds to create a unique patient identifier standard, unless authorized by Congress.

Industry efforts. Until recently, there has been no appetite for repealing the ban on a federal patient identifier standard. To fill the gap, the industry has responded with a variety of solutions. Available commercial solutions vary along a number of parameters. These include the sophistication of the matching algorithms, kinds of data needed, price, platform, scalability and the abilities to correctly match patients and cleanse duplicate records.

Some organizations, like Surescripts, have created internal methodologies for matching patients with their records. Surescripts initially created this service to facilitate electronic prescribing. Leveraging that expertise, the company recently launched its National Record Locator Services (NRLS). According to Surescripts’ press release, the NRLS went live this year with 140 million patients and more than 2 billion interactions between those patients and members of their care teams — regardless of where care was delivered. The new service will be offered without charge until 2019 to electronic health record system (EHR) vendors.

The CommonWell Health Alliance provides members with a patient matching service. It supplements demographic data in participants’ EHRs with other identifiers, such as government-issued identification (ID). As of June 2016, CommonWell has more than 8,000 provider sites committed to using the services, including 4,700 in production, in all 50 states, the District of Columbia and Puerto Rico.

The Experian Health and NCPDP alliance addresses the challenge from a slightly different direction. As announced, Experian Health’s Universal Identity Manager will be leveraged to accurately identify patients and match records within and across disparate health care organizations (pharmacy, lab, payer, provider etc.) to create a unique, universal patient identifier. The new approach benefits from Experian’s success in matching, managing and protecting identities across various industries and NCPDP’s extensive knowledge of pharmacy claims and standards. Both organizations have witnessed firsthand the challenges associated with the lack of a universal patient identifier. They believe their solution will be easy to append within clients’ systems.

Moving forward. A number of drivers have spurred the development and use of a patient identifier. They include:

• **Stakeholders want a national patient ID.** Stakeholders are becoming vocal about the need for correct patient identification and removal of the ban on a national identifier standard. In a recent paper, the influential National Academy of Sciences called for a reset of the 2004 federal health goals, including creation of a national patient identifier. The American Health Information Management Association (AHIMA) initiated a petition aimed at the White House to address a voluntary patient safety identifier solution to patient matching. In January, the College of Healthcare Information Management Executives (CHIME) launched a $1 million contest to accelerate creation and adoption of a solution for ensuring 100% accuracy in identifying patients in the United States. If that isn’t enough, nearly two dozen stakeholders recently sent a letter urging Congress to allow HHS to create a unique patient identifier. Signatories read like a Who’s Who, including AHIMA, America’s Health Insurance Plans, American Medical Informatics Association, Blue Cross Blue Shield Association, CHIME, Health Information and Management Systems Society, IMS Health Intermountain Healthcare, Long Term and Post Acute Care (LTPAC) Health IT Collaborative, National Community Pharmacists Association (NCPA), Pharmaceutical Care Management Association (PCMA) and Surescripts.

• **The business case is compelling.** Disparate and disconnected patient records cost a lot of time and money to sort out. Duplicate records alone account for 5% to 15% of all patient records or about 15,000 duplications for every 100,000 records. Addressing the challenge is expensive. According to one report, each case of misidentification at the Mayo Clinic costs at least $1,200 to fix. Intermountain Healthcare spends between $4 million and $5 million per year on technologies and processes intended to ensure correct patient identification. That’s not even counting the costs associated with duplicative testing and potential adverse outcomes due to comprehensive patient records not being available.
Part 1: A National Patient Identifier: An Idea Whose Time Has Come Again

- Need for interoperable data exchange. The world has changed significantly since the late 1990s, when the Congressional ban on a national standard was put in place. We have the technological means to exchange large volumes of patient data. EHRs are used in nearly all hospitals and 80% of physician offices. There are government mandates, such as meaningful use, that increase the need for electronic creation and exchange of patient data. The rise of integrated delivery systems also creates additional demand for sharing of patient records and data. Many, including the RAND Corporation, believe that true interoperability in health care cannot achieved without a national patient identifier.

Of course, there will be challenges to implementing any national patient identifier. They include:

- Privacy and security. Some privacy advocates argue that a system built on patient-specific identification numbers could lead to the disclosure of confidential information or the misuse of patient information. Advocates didn't like the idea in 1998, and they aren't likely to be more receptive nearly two decades later. While some would argue that health information technology and related infrastructures are more secure than ever, that argument is undercut by the data breaches that seem to happen on a daily basis. Medical identity theft is on the rise, which potentially could be facilitated by a single number for every patient. All of this throws cold water on the desire for a national patient identifier — at least for some.

- Practicality. Numerous changes would be needed to implement a national patient identifier. For example, there likely would be a new government structure to issue them and manage their creation and use. It will take some doing to correctly identify patients and merge duplicate ID numbers for existing records within and across organizational boundaries — and then reassign the new identifier. Then, there are large-scale system changes for everyone. It’s a huge undertaking, considering it would involve all patients and every single provider, payer and vendor. And it would take time to implement, especially if government rulemaking is involved.

- Costs. It could be expensive to change existing systems and records to add a patient’s identifier, both retrospectively and prospectively. There also are administrative and governance issues, including opt in/opt out, which will add to implementation costs.

- Business case for vendors. EHR vendors are aware that patient matching is an issue for their customers but a business case is needed. Even if a national patient identifier is created, it is likely that individual stakeholders will request additional and varying data elements and formats. Such customization is expensive and time consuming. Moreover, EHR vendors are reluctant to make any changes without user demand, which traditionally has been driven by legislation. Interestingly, Surescripts’ NLRS has been introduced to the EHR vendor market without government mandate for a patient identifier.

What do we think? We will be watching with interest the sudden competition among various patient identifier offerings. We also will be watching to see how these industry-generated identifiers will shape the accuracy of — and access to — patient records. We think stakeholders will be making a run at the new Congress to repeal the ban on the patient identifier standard, in addition to the stakeholder letter that was just delivered to the lame duck session. If the ban is lifted, it will be interesting to see which standards will be mandated by the government (we presume by the Centers for Medicare and Medicaid Services), and how that affects what’s already happened in the industry. Even if a new national identifier standard is permitted, its development and implementation could take years. Regardless of what happens, we think there will be pushback from advocates. We certainly haven’t seen the last of this topic. Stay tuned.
Part 2: Taking ePrescribing to the Next Level with the Structured and Codified Sig

By Michael Burger and Keith Fisher, Senior Consultants

Electronic prescribing (ePrescribing) is no longer in its infancy. Today, 80% of ambulatory physicians use this method to prescribe medications for their patients and send that information electronically to the pharmacy. However, ePrescribing’s patient safety benefits and efficiencies cannot be fully realized without increased use of functionalities that already exist in the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard v. 10.6. An example is the Structured and Codified Sig (short for Signatura). This part of the prescription communicates dosing instructions to the pharmacy that will then be conveyed to the patient. However, the Structured and Codified Sig is not used to its full potential. In fact, it is seldom used at all.

Work on the Structured and Codified Sig has been ongoing for more than a decade. With impetus from the government and a federal advisory group, a task group was convened to address the issue by NCPDP, which develops and maintains the SCRIPT standard. The idea was to standardize communication of dosing instructions within the ePrescribing process to create unambiguous and complete directions for the pharmacy filling the ePrescription. Other benefits include decreased opportunities for transcription errors and improved efficiencies and work flows for both prescribers and pharmacists.

Despite the progress that has been made, the Structured and Codified Sig is rarely used by prescribers or supported by many electronic health records (EHRs) enabled for ePrescribing. Reasons include work-flow and technical challenges, as well as lack of user demand.

Workflow challenges. Work-flow challenges that serve as barriers to adoption still exist for the prescriber and pharmacy. Currently, there are two ways for prescribers to indicate their dosing directions in ePrescribing using NCPDP SCRIPT v. 10.6. The first is a mandatory 140-byte free text field. The second is the additional optional use of separate fields that provide coded data for the various components of the instructions: the verb, route, dosage form, indication, vehicle, site, timing and duration. Most users simply prefer to enter whatever they want in the free text field.

Manually entering dosing instructions into the free text field is an efficiency issue for prescribers as well as for pharmacists, who must rekey the information from free text Sig into the pharmacy system once an ePrescription is received. This creates the potential for numerous time-consuming calls for clarification between pharmacists and physicians. All this manual entry and rework additionally open the door to errors and have implications for the quality and safety of patient care.

Technical challenges. Several technical challenges limit adoption of the Structured and Codified Sig. For example: There is the complexity of the mandatory standardized, interoperable code sets for many of the Sig segment fields. SNOMED-CT was selected for all fields except one. The remaining field must be populated using federal medication terminologies and National Cancer Institute code set. Needless to say, this is a lot for vendors to understand and complex to program.

Sig builders are available in most ePrescribing-enabled EHRs. These include drop-down menus for common terms and favorites the prescriber can add. Once selected, however, this information is populated into the free text field, which can never be left blank. Even though the data are
already being created by the prescriber in individual fields, most EHRs lack the ability to transfer the same data into the codified Sig segment.

Vendors must create behind-the-scenes tables to map the various elements of the dosing instructions into the ePrescription — or the reverse when the pharmacist receives the ePrescription. These changes are costly to develop and release, and vendors prioritize their enhancements based on user demand and mandate. Tepid demand and lack of a mandate have caused support of Structured and Codified Sig to be a low priority for EHR vendors.

We also hear, anecdotally, that pharmacies are wired to accept data but don’t yet “process” or use the information in the Structured and Codified Sig segment. Since few prescribers are using it, pharmacies have been slow to adapt their systems to support it.

Opportunities. The groundwork for the Structured and Codified Sig has been laid. Opportunities exist to make it more valuable and usable to prescribers, as well as enhance vendor offerings. These include:

- Develop a commonly used subset of codes for each Sig field. This is something that perhaps an NCPDP task group could address. A good start has been made by providing a lot of this information in the standard’s implementation guide.
- Identify gaps and usability challenges. Now that ePrescribing is commonplace, it is time to revisit the barriers and opportunities that exist for use of the Structured and Codified Sig in both the ambulatory and inpatient settings.
- Continue enhancements to NCPDP SCRIPT. According to experts, enhancements incorporated in SCRIPT version 2012+ include a more robust Structured Sig Segment, which supports a text field size of 1000, as well as other enhancements and recommendations from a pilot. As use of the Sig becomes more commonplace, we expect that NCPDP will receive more requests for enhancements.
- Develop additional pilots. Once gaps and challenges have been identified, stakeholders could develop pilots to test potential solutions.

- User improvements. Vendors should continue to seek ways of implementing the Structured and Codified Sig to make its use easier for prescribers. This could create competitive advantage. For example, vendors could improve Sig favorites capabilities by including the most commonly used Sigs. Many of these have already been identified by NCPDP. As a best practice, Surescripts recommends that vendors should determine the 100 most commonly prescribed Sig concepts and make sure the system can fully accommodate construction and transmission of these Sig strings.
- Training is needed. Physicians will have to be educated about the need for — and use of — the Structured and Codified Sig so it can be used to its full potential. Although it is part of a technical transaction and should be invisible to the user, prescribers must be educated about functionalities available in the electronic Sig and their importance to quality and safety of patient care.
- Work with the government on rule making. Currently, the Structured and Codified Sig is optional for use in certified EHRs. At some point, the government will consider the standard mature enough to be made mandatory for EHR certification. We have learned from previous standards adoption efforts that early involvement in the rule-making process is crucial for outcomes that are acceptable and workable for stakeholders.

Moving forward. The value of ePrescribing cannot be fully realized without enhancements to — and use of — the Structured and Codified Sig. We hope stakeholders can find a way to stimulate user adoption and move the ball up the field. We are hopeful the industry and users can continue to work together to make measurable progress in addressing some of the barriers and challenges surrounding its use. The quality and safety of health care demand it.

Point-of-Care Partners are experts in ePrescribing and the Structured and Codified Sig. Send us an email or give us a call. We’d be happy to give you a deeper dive into the issues and potential solutions.

The authors thank NCPDP member Laura Topor, who has led NCPDP’s Structured and Codified Sig efforts, for her review and comment on a draft of this article.
Part 3: Legislative Changes to I-STOP: Are They a Good Thing?

By Connie Sinclair, Senior Consultant

New York’s I-STOP (Internet System for Tracking Over-Prescribing) Act went into effect March 27. This tough law requires that most state physicians use electronic prescribing (ePrescribing) for both non controlled and almost all controlled substances (EPCS).

Now that the mandate has been in place for more than six months, prescribers and pharmacists have identified workflow problems caused by the all-electronic requirement. Several pieces of legislation have been introduced to address such concerns raised by prescribers. Are these proposed changes needed refinements or are they a form of prescriber pushback? It depends.

The first bill, NY A 9335B, was signed into law September 29. It abolishes a rule requiring doctors to file reports with the state Health Department each time they issue verbal or written prescriptions when ePrescribing is not technically possible. Now, doctors can simply make a note in a patient’s record when such a circumstance occurs. We support the concept of this slight change to I-STOP. Doctors who are trying to do the right thing need the ability to make exceptions from time to time without being burdened by unnecessary red tape. For example, it can take weeks to months for a newly launched drug product to be added to the drug file in a prescriber site’s electronic health record. This is an instance for which a written prescription might be the only option. However, we are concerned it could create a loophole for those prescribers who might abuse the less restrictive scenario. Our bet is that New York will be monitoring for prescribers having a disproportionate amount of written or verbal prescriptions.

Two other bills were vetoed and we agree with Governor Cuomo that they should not have been enacted. Here’s why:

NY A 9837 would have authorized physicians to send electronic prescriptions to a website accessible by pharmacies. If a patient’s pharmacy is unable to access an electronic prescription, the prescriber may issue a hard copy of the prescription to the patient. In fact, this vaguely described prescription site in the cloud doesn’t exist and there are no industry standards or plans to create it, so this bill would have created a huge loophole for avoiding the mandate.

The other piece of proposed legislation, NY S 6778, would have created an exception to the ePrescribing mandate for nursing homes by allowing verbal prescribing if deemed in the best interest of a patient. The authors explained that such an ePrescribing exemption is needed because nursing home doctors often work off site or part time. As a result, they may need to phone in prescription orders to nurses,
who can quickly administer medications to residents. They apparently have not read I-STOP, which already contains provisions allowing doctors to phone in prescriptions on an emergency basis. Reading between the lines, this is yet another attempt to circumvent the law by those who wish to avoid or delay ePrescribing.

One more piece of legislation that is in the governor’s hands, NY A 10448, proposes what we believe is a good solution to a problematic situation. In the old world of paper prescriptions, whenever a patient went to his or her chosen pharmacy and found the prescribed drug to be out of stock, that patient would simply carry the paper prescription to another pharmacy. As is the case in most states, pharmacists may transfer a prescription to another pharmacy for subsequent refills, upon patient request, if the prescription has already been filled at least once by the transferring pharmacy. However, this creates a gap if an electronic prescription is delivered to the patient’s preferred pharmacy but that pharmacy is unable to fill it. The current law does not allow transfer of that new prescription because only refills may be transferred. This proposed change would fix that. The key to any modification of the original mandate is to take great care to reduce unnecessary work-flow burdens that might inadvertently be introduced, while maintaining the integrity of the mandate. Unintended consequences of getting this wrong are:

1. **Weakening the I-STOP statute.** Creating exemptions to a tough law generally is a bad idea. Exemptions start to weaken a law, as well as create implementation and enforcement challenges. It also creates discontent among those who have been compliant and made necessary technology and implementation investments only to learn they could have saved a lot of time and effort like the laggards to adoption.

2. **Creating an appetite for more exemptions.** Legislative success breeds legislative success. It is, however, a slippery slope. Once an interest group starts chipping away at legislative requirements, the momentum increases for it do more of the same. NY A 9837 and S 6778 were steps in that direction. Fortunately, they were vetoed. But now that the legislative ice has been broken, what other I-STOP provisions will face the legislative chopping block down the line?

3. **Sending the wrong message to other states looking to follow New York’s lead.** I-STOP is considered a national legislative model to prevent fraud and drug diversion by requiring mandatory ePrescribing for both non controlled and controlled substances. States play “follow the leader” in terms of legislation. Other states might get cold feet if they think the New York law has been watered down or enact similarly watered-down versions themselves. This could lead to lesser ePrescribing and EPCS requirements in other states, as well as weaken efforts to address fraud and drug diversion. We think this is a suboptimal result and bet law enforcement would agree.

Point-of-Care Partners is closely monitoring the impact of I-STOP in New York and the rise of similar legislation in other states. Our ePrescribing State Law Review was created to keep companies current with federal and state regulatory changes so they can proactively identify opportunities and modifications that may be needed. Subscribers receive ongoing, in-depth analyses of relevant prescribing rules and have access to our regulatory experts. An abbreviated summary, the ePrescribing State Law Capsule, is available on a complimentary basis.

Ms. Sinclair is director of the Point-of-Care Partners Regulatory Resource Center. She can be reached at connie.sinclair@pocp.com.