Perspectives and Updates on
Health Care Information Technology

HIT Perspectives

1

2

3

June 2015

POINT-OF-CARE PARTNERS
Health IT Management Consultants

By Tony Schueth, Editor-in-Chief, and Michael Burger, Senior Consultant

Alleged "information blocking" by vendors of electronic health records (EHRs) continues to be a hot topic in Washington. It first arose as part of the broader conversation about the need for interoperability in the health information technology (healthIT) space. Now it appears to be taking on a life of its own: the focus of a new draft congressional bill, the recently released *Report to Congress on Health Information Blocking* from the Office of the National Coordinator for Health Information Technology (ONC), meaningful use (MU) draft stage 3 certification processes and a discussion topic at the May meeting of the Health Information Technology Policy Committee (HITPC).

Taken individually, these events are interesting. Taken together, they add up to a trend that is likely to be around for some time and bears close scrutiny. Point-of-Care Partners (POCP) is monitoring this issue, and here is where it stands at the moment.

Proposed legislation. Rep. Michael Burgess, MD, recently released a draft bill, "Ensuring Interoperability of Qualified Electronic Health Records." Language from the finalized bill will become part of the "21st Century Cures initiative," which the powerful House Energy and Commerce (E&C) Committee — of which Burgess is a member — will use as a vehicle to develop ways to accelerate the discovery, development and delivery of promising new treatments to patients.

The Burgess bill does several things. It specifies that an EHR can be considered interoperable if it provides open access, complete access to health data and does not block access to other qualified EHRs. Those criteria would be fleshed out by a 12-member, congressionally appointed "charter organization" — yet another federal advisory committee that would supercede existing ones. It would recommend EHR interoperability measures to ONC and submit a report in 2017 on interoperability progress. The legislation also allows for vendors to be decertified by the Department of Health and Human Services if they are unable to meet the interoperability criteria.

What's missing here is anything related to the likely cost to make this happen. It's technically possible, but not

inexpensive. That is why EHR vendors should be interested in the Burgess bill: it could have a potentially bigger impact on product planning than meaningful use. The bill also is important as yet another symbol of congressional disillusion with the progress of EHRs and healthIT in the face of the $44 billion already paid as incentives to eligible providers. It also is a harbinger of things to come as it probably will not be the only bill of its kind to hit the Hill in coming months. This kind of issue will likely resonate with powerful constituent groups, so lawmakers are likely to pile on to better position themselves in upcoming elections.

We expect Burgess will submit finalized language this summer, following analysis of stakeholder comments submitted earlier this spring. The E&C Committee is very powerful, so it is possible that the 21st Century Cures initiative will have some traction. In addition to his seat on that committee, Burgess is one of the few physicians in Congress and a member of the Republican Doctors Caucus. As a result, we anticipate healthIT will continue to be of interest to him.

ONC Report to Congress. ONC recently released its Report to Congress on Health Information Blocking, which responds to a Congressional request that was included as part of a spending bill to keep the government running for the first three quarters of 2015 (aka the "CRomnibus"). The legislation directs ONC to assess the extent of health information blocking and recommend a comprehensive strategy to address it.

The Report begins with a balanced and thoughtful analysis of the issue, acknowledging that "many actions that prevent information from being exchanged may be inadvertent, resulting primarily from economic, technological and practical challenges that have long prevented widespread and effective information sharing." Information blocking is defined as occurring when "persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information."

Not surprisingly, the Report is sharply critical of EHR vendors. It alleges that certain vendors create a climate ripe for information blocking through business practices and pricing. It contends the information blocking

phenomenon largely is due to business practices of "certain EHR developers [who] refuse to establish interfaces with certain technologies or entities, or will only do so on terms so onerous that they amount to a refusal for all practical purposes." This seems harsh, especially since it is based mostly on anecdotal evidence. Little actual data could be obtained because ONC does not have the authority to require vendors and others to produce such information.

What is missing is a counterweighting explanation of why such business practices might occur. The answer is that there is insufficient justification for information sharing relative to the costs of creating the interface. This is the central issue. For example, the report cites an instance in which an integrated delivery network (IDN) restricts the ability to exchange secure messages among only providers who are members of its care network. However, in doing so, the IDN is protecting its business interests (and in turn managing costs) by using technology to ensure that referrals stay "in network." It is not that the EHR vendor and IDN "collude" to block information. In reality, there is no economic incentive to refer patients out of network; the IDN simply is taking advantage of a smartly designed piece of software that enables an ability to address a business need.

There are also pricing issues. Prices for interfaces could be considered "comparatively high," but compared to what? Interfaces between any disparate computer software are complex, with many potential points of failure. EHR software is no different. And interfaces often represent the single most costly feature for EHR vendors to support. Interfaces are priced relative to what they cost to build and maintain; of course, margin is built in. The answer proposed by ONC is free or low-cost application interfaces (APIs). We believe further study is needed to address a number of issues, including the use of standards, governance, privacy and security. What protections for vendors and users are needed if API developers cease supporting their software or substantially increase prices? What processes will be put in place to ensure that an API functions correctly to ensure patient safety?

MU stage 3 certification. Information blocking is a topic for comment in the MU stage 3 certification rule. It asks for examples of information blocking and ideas for criteria and processes for decertifying EHRs of vendors who engage in the practice. We expect stakeholder feedback on this issue to be incorporated in the final rule.

HITPC. The CRomnibus also directs the HITPC to submit a report on the state of interoperability to the House and Senate Committees on Appropriations and the appropriate authorizing committees before the end of 2015. The report is to cover the technical, operational and financial barriers to interoperability, the role of certification in advancing or hindering interoperability across various providers, as well as identification of any other barriers. As part of the report development, information blocking was a topic of discussion at a recent HITPC meeting. According to news reports, a

HITPC work group declined to endorse the information-blocking restrictions in ONC's MU stage 3 certification standards, calling for additional study of this complex issue. It also concluded that EHR decertification, as proposed in Burgess' draft bill and discussed in ONC's Report to Congress, would place an undue burden on providers and patients (not to mention vendors).

So, what's the answer? It's clear that information blocking is a hot potato that is not going to be dropped anytime soon.

It's easy to point the finger at EHR vendors and claim they are engaging in "opportunistic pricing practices," which generally are not illegal. It's not as easy to target IDNs and force them to share information about patients when they've invested millions to keep such data within their "walled garden." It's also easy to point the finger at Congress and the government for creating legislation and multiple (and potentially overlapping) programs that would regulate — and perhaps stifle, as some suggest — the business of healthIT and health information exchange.

At the heart of the matter is that healthIT is a business. HealthIT responds to market-based demand. The transition from quantity-based reimbursement to quality-based reimbursement will create business reasons to share patient data — better outcomes, reduced costs and elimination of duplicative testing. At that point, a $20,000 interface moves from "nice to have" to a valuable business tool. Health care is not a normal market — it is composed of very different entities that don't necessarily respond to traditional market drivers. Truth be told, the health care system sometimes does not work in favor of consumers (providers and patients) and requires oversight to work more effectively. Striking an effective balance across traditional drivers, market realities, user needs and government oversight will be vital.

We also need to have some up-front harmonization among the requirements for any new healthIT legislation and those for existing federal programs, advisory committees and related processes. There already has been pushback from the Brookings Institution about the Burgess bill, which essentially says that more congressional action is not the answer to stimulate innovation and eliminate barriers to better healthIT and better health care.

Nonetheless, congressional action is where the ball rests at the moment. ONC's Report essentially punted the ball back to the Hill. Dr. Burgess should introduce his revised language soon. The HITPC has to draft its Report to Congress following near-term deliberations. It will then be up to Congress to decide what to do next. POCP is monitoring the action, so let us know if we can provide further details.

# **2** Part 2: DERF-a-Palooza at May NCPDP Meeting Yields Results

By Michael Burger, Senior Consultant

The May quarterly meeting of the National Council for Prescription Drug Programs (NCPDP) was a DERF-a-Palooza with lively discussion, debate and action on 25 DERFs that proposed changes to the NCPDP SCRIPT standard and the Formulary and Benefit (F&B) standard.

DERF is the acronym for Data Element Request Form, which is used as part of the process to recommend and approve modifications to NCPDP standards. The large number of DERFs considered in May were the result of the industry's desire to get proposed changes nailed down and approved so they could be incorporated into the next round of Medicare Part D standards adoption (see the timeline below). An irregular update schedule by standards development organizations (SDOs) has long been a pain point for many government regulators, not just the Centers

for Medicare and Medicaid Services (CMS), which runs the Medicare program. As a result, regulations often were out of sync with the latest version of a standard.

NCPDP listened, and activities at the past several meetings represent a first step toward bringing regularity to the process. Kudos to NCPDP for taking the initiative and making this happen. While the timing of the May quarterly meeting may not get all the desired changes into the DERF queue in time for the upcoming release of NCPDP standards, this should be a temporary situation as the idea of a schedule irons itself out. We expect other SDOs will follow suit. After all, it is in everyone's best interests to have the most up-to-date standards available for timely adoption by Medicare and other programs.

www.pocp.com **POINT-OF-CARE PARTNERS**
Health IT Management Consultants
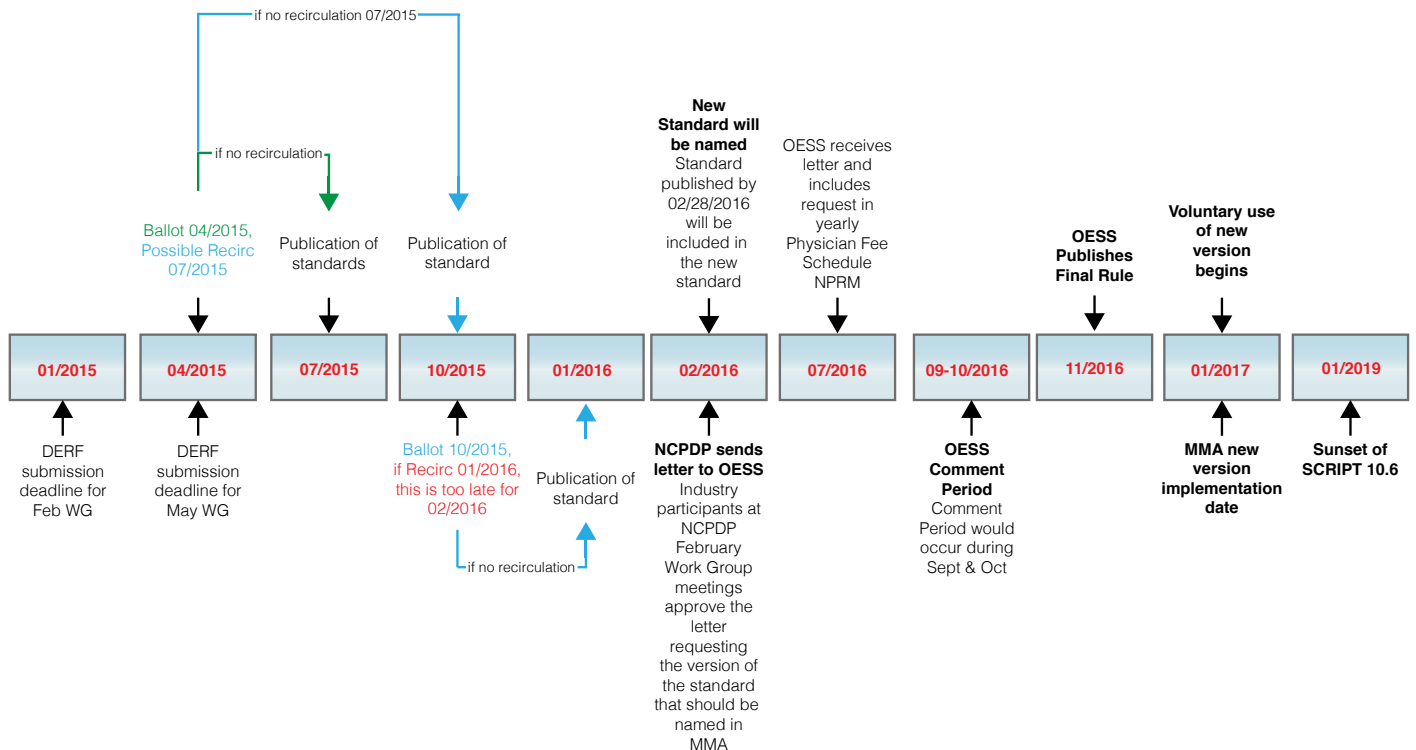
Here are some of the highlights of the NCPDP meeting.

Real-time benefit information in electronic health records (EHRs). The real-time benefit verification transaction is still a work in progress, with several related DERFS passed or pending at the May meeting. Use of this transaction would replace the downloaded data files that are used today, which have limitations due to latency of the update process and the quantity and quality of data. Real-time benefit verification will greatly improve the breadth, accuracy and effectiveness of formulary data available to the prescriber at the point of care. This will address the perception of many prescribers that currently available formulary and benefit data are either incorrect or incomplete, which has resulted in the current F&B transaction being sparsely used by prescribers. Having real-time benefit information in the EHR will enable prescribers to see dollar copay amounts for individual patients at the point of prescribing. This will help with formulary compliance and medication adherence because prescribers can see what drugs are on formulary and what they will cost out-of-pocket. As a result, they can prescribe a medication that will be covered by the patient's insurance plan with the least out-of-pocket expenditures. Research shows that patients will abandon prescriptions if they are too expensive, or not take them correctly to save money.

Some proposed versions of the transaction give payers the ability to mention specific alternatives to a requested drug. This information was popular in retail and mail-order pharmacy messaging in the past and used to switch patients to preferred drugs, including generic alternatives.

As part of proposed real-time benefit verification, savings program offers could be displayed along with copay amounts. We are monitoring some early activity by payers to develop pilots. After initially slowing down the process, a few payers are moving forward with pilots to demonstrate its value. Although it may be some time before a standard is approved, the impact will be far reaching once use gains traction. It could also become a distraction and excuse for not fixing the systems and processes that exist today.

Mandatory inclusion of diagnosis. Adding the diagnosis to electronic prescriptions (ePrescriptions) was proposed to go from optional to mandatory in the SCRIPT transaction with the passage of DERF 1264. The workgroup stopped short of a mandatory designation, instead passing the DERF with language to make diagnosis "strongly recommended." Diagnosis is among the many key pieces of clinical and administrative information that are needed,

especially for prescriptions for specialty medications and now for biosimilars. Systematically adding the diagnosis to ePrescriptions would eliminate the need for manual entry, reduce opportunities for error, improve patient safety, expedite processing of prior authorization (PA) requests and make it easier and less costly to manage specialty medications throughout the continuum of care. The challenge will be integrating capture and inclusion of diagnosis into the ePrescribing work flow.

Electronic prescribing of biosimilars. A DERF was passed that adds manufacturer name and dispensed drug lot number to the medication history and Rx fill transactions. Biosimilars are becoming available in the United States, so having the manufacturer and lot number of a dispensed drug will be necessary to identify and track positive outcomes and potential adverse events (AEs). This information also will be needed as part of state substitution regulations. So far, interchangeable biosimilars may be substituted for reference products without prior notification in Colorado, Georgia, Tennessee, Utah and Washington State. While inclusion of these data is not mandatory, we expect pharmacies will start populating such data in the transactions and transmit them back to physician EHRs, ultimately making it easier to track outcomes and AEs at the point of care and complying with state substitution regulations.

Attachments. DERF 1292 introduced an indicator in the SCRIPT transaction to let the prescriber know an attachment is required for electronic prior authorization (ePA). It was ultimately approved, but a lively discussion ensued over a related but larger issue: the concept of an "attachment" in the age of ePA. EHR vendors would prefer to have information requested in the form of specific questions, which can be responded to with discrete data. In reality, attachments are outside the work flow of a paperless EHR. In order to create one, the prescriber must print something based on data already in the EHR, save it as a PDF file and then append that file as the attachment.

Industry pressure to utilize the SCRIPT standard to transact ePA, rather than attachments, will streamline the process for prescribers. The ultimate goal is to push the ePA transaction into the background in the EHR, with the data required for PA transferred to the payer without requiring prescriber data reentry.

Point-of-Care Partners is an active participant in NCPDP work group meetings as well as many task groups. Let us know how we can put that knowledge to work for you.

③ Part 3: Surescripts Issues 2014 National Progress Report

By Tony Schueth, Editor-in-Chief

Surescripts just released its *2014 National Progress Report*, which always shines a national spotlight on electronic prescribing (ePrescribing).

The theme this year could be "ambulatory ePrescribing: game over, what's next," as it celebrates the industry's success with ePrescribing, paints a picture of what's still to be done and begins to make the case for how successful ePrescribing can translate to other areas of health information technology (healthIT).

Interestingly, the title doesn't even mention "ePrescribing," which also is not called out as a specific section this year. The contents fall into three categories: company highlights, brief summaries of the status of a handful of transactions, and an appendix that contains a summary chart for selected transactions and a chart for rankings by state of their percentage of ePrescribing of controlled substances (EPCS). The format is a slick chart book with a marketing brochure feel, replete with graphics and brief rundowns of selected accomplishments.

Company highlights. A good bit of this year's report is devoted to Surescripts' promotional highlights. In fact, its very first section emphasizes the breadth of the company's connectedness among a long list of stakeholders. Other sections address:

 • **Optimization.** Surescripts touts moving from "adoption to optimization" in 2014. This is depicted by a chart characterizing growth in transaction volume as adoption and utilization from 2005 to 2013 and optimization going forward. (It looks awfully familiar to one we've used for years.) Optimization is defined as adding new functionality and improving data quality. We agree that such value-adds as interoperability, new transactions and improved prescription quality will continue to drive transaction volume. We expect such efforts to intensify industrywide due to individual activities by vendors, intermediaries and standards development organizations to create value and innovation. Bigger-picture initiatives created by industry associations and the government — such as meaningful use (MU) and the new interoperability program launched by the Office of the National Coordinator for Health Information Technology (ONC) — also will contribute to making ePrescribing an increasingly integral and valuable part of patient care.

 • **Clinical messaging.** The growth of clinical messaging — one of Surescripts' expanding lines of business — is highlighted. According to a separate data set chart, the company processed a total of 7.4 million clinical messages in 2014 and 974 hospitals were users. Ambulatory providers obviously contributed to the total, but they are not mentioned. Clinical messaging is a valuable transaction to some stakeholders. However, it is one of a host of new or improved transactions and tools, such as clinical decision support, that will create value and become a must-have for value-based care.

 • **Improving "public health through fraud prevention."** ePrescribing's potential to reduce fraud and prescription drug abuse has been acknowledged as early as 2005. This is important and still true today. Now that technology and infrastructure have advanced, policy makers are taking advantage of ePrescribing's potential to help address the nation's opioid drug abuse epidemic through such programs as New York's Internet Systems for Tracking Over-Prescribing (I-STOP). It mandates that all prescriptions be sent electronically beginning March 2016 (the implementation date was moved back). We expect to see similar programs springing up nationwide. The promise of ePrescribing to improve public health is a topic that merits its own write-up, but was not covered

in this year's report, even though public health is given as a subtitle.

Selected Transactions. The report's real meat lies in write-ups about three specific transactions.

• **Medication history.** The section on medication history is an example of the report's change in focus. The narrative suggests a benefit of ePrescribing lies in making available access to real-time prescription data at the point of care — especially for hospitals' use in medication reconciliation. The savings to hospitals from medication reconciliation are estimated for a range of facilities, such as $11,704 for a small (100-bed) hospital to $1.1 million for a very large (1,000+ bed) facility. Such figures are guaranteed to get hospitals' attention, especially the bigger ones with deeper pockets. It is not clear how the estimates were derived as many factors must be taken into account to conduct such an analysis. For example, pharmacy claims data are more robust that medical claims data, but it's unclear how many pharmacies contributed to the analysis.

In terms of transaction volume, Surescripts concentrated on the hospital side of the equation. The chart in the appendix indicated that the number of hospitals conducting medication history transactions more than doubled in 2014. However, hospital volume accounted for approximately 11% of the 764 million total medication history transactions.

The report also does not discuss improving prescription quality by addressing problems associated with medication history, including data accuracy and availability. The first step toward optimizing ePrescribing's value for medication reconciliation is an analysis of how to overcome such data and process deficiencies. Then, the brains behind healthIT can figure out ways to better conduct electronic medication reconciliation and tackle transitions of care.

• **Electronic prior authorization.** Surescripts also sets the stage for electronic prior authorization (ePA) of medications as a value-add. The write-up briefly discusses some of the problems with manual PA and offers estimates of ePA savings: 4 hours per pharmacist per week or $11,000 per pharmacist per year; 5 to 8 hours per physician each week, translating to $14,000 per physician per year.

Regardless of how they are computed, those savings

can make such an ePA product attractive to big chains and large group practices. Everyone needs to wring out efficiencies from the overhead, so the report shines a light on this often overlooked opportunity to save money. The patient safety aspect of ePA was mentioned in passing, with ePA cited as a means to minimize abandoned prescriptions resulting from the hassles associated with the manual PA process.

• **Electronic Prescribing for Controlled Substances (EPCS).** New this year is a report out on EPCS, which is a good news-bad news story. The good news is that EPCS is now legal in 50 states and the District of Columbia (Missouri very recently adopted rules in support of EPCS that will become effective in July). Transaction volume rose 400% in 2014 to 1.6 million controlled substance ePrescriptions routed through the Surescripts network. The bad news is that only roughly three-quarters of pharmacies can receive EPCS (although that number increased since 2013) and only 1.4% of providers were enabled.

Interestingly, Surescripts just announced at the 2015 HealthDataPalooza (May 31 – June 3) that 3% of providers are now enabled to send electronic prescriptions for controlled substances. While this is still only 3%, we're encouraged — and not surprised — to see this start to take off due to mandatory use of such programs as with New York's I-STOP. We think the future for EPCS is bright as physicians will have to prescribe controlled substances electronically if they are to meet the higher ePrescribing thresholds that will be required for MU stage 3 (the current proposal is 80%). EPCS also will be key for providers in certain specialties, such as oncology, which have many patients using controlled substances. By the way, Point-of-Care Partners offers several regulatory updates on a subscription basis to help you keep current with the ever-changing landscape of state laws and regulations for ePrescribing, including EPCS. Visit our website for a demonstration and more information.

Transaction data. The appendix is divided into two sets of summary charts, one of which provides data for selected transactions. This is the only place to find data regarding traditional ambulatory ePrescribing per se. Surescripts routed 1.2 billion ePrescriptions in 2014 and more than two-thirds were new prescriptions.

(continued)

Perspectives and Updates on
Health Care Information Technology

www.pocp.com

Point-of-Care Partners
Health IT Management Consultants

© 2015 Point-of-Care Partners, LLC

This chart also contains a confusing statistic about percentage of ePrescribers. Surescripts claims the percentage inched upward to 56% in 2014 from 55% the previous year. According to our copy of last year's report, roughly three-quarters of ambulatory providers were ePrescribing in 2013. We suspect the discrepancy is likely due to the inclusion of all prescribers — acute and ambulatory — this year, but "chart book" format has precious little explanation, unlike in past years. To those of us who pay attention, it makes it appear as though we have gone significantly backward when, in fact, progress continues to be made. Moreover, we understand from sources outside the report that nearly 80% of ambulatory providers are ePrescribing.

State rankings based on EPCS. The second summary chart in the appendix shows state rankings on the basis of EPCS — the percentage of prescribers enabled to conduct EPCS, the percentage of pharmacies enabled to receive EPCS and the percentage of EPCS prescriptions. This stands in contrast to last year, when the rankings recognized utilization of ePrescribing based on volume of use of Surescripts' prescription benefit, medication history and prescription routing services.

The top 10 states using EPCS include many of those adopting ePrescribing early, such as Delaware, Massachusetts and Rhode Island. However, Nebraska was in the middle of the pack on traditional ePrescribing but topped the EPCS list this year (we understand largely because of a large integrated delivery network), followed by California (which, ironically, has been near the bottom of the traditional ePrescribing state rankings). Both have nearly 9% of prescribers and more than 70% of pharmacies enabled. Nebraska has 6.9% EPCS transaction volume, with California a distant second at 4.3%. New York ranks 21st, with 1.9% of prescribers and 70.3% of pharmacies enabled, but less than 1% of EPCS transactions. Obviously, New York has a long way to go in the way of EPCS if providers are going to meet I-STOP's March 2016 go-live date. Surescripts has done a huge service by shining a light on the embryonic state of EPCS, which will be useful to vendors and policy makers going forward.

What's missing. It strikes us that several pieces are missing or not specifically called out. They include:

Formulary and benefit. Precious little about the critically important aggregate flat file that Surescripts distributes using the NCPDP Formulary and Benefit (F&B) standard is

found in this year's report despite concerns from prescribers about the accuracy of formulary data. We understand it may be hard to measure, but have heard anecdotally that the file is bigger and better. One deficient area that could be tracked is the PA flag.

There is also nothing about the real-time benefit check (RTBC), which promises to add accuracy and clarity to the group-level F&B paradigm. Both have implications for curbing costs and, arguably, improving health care by increasing formulary compliance and medication adherence. Research has shown that high out-of-pocket costs are a main reason why patients abandon prescriptions.

Specialty pharmacy. Specialty prescribing also is not covered, but that is not surprising because these prescriptions are low in volume in the overall scheme of things and the prescription process is not yet automated enough to merit a mention in Surescripts' report. However, that is due to change in the near future because of the importance of specialty medications as high-cost drivers of the nation's drug spend, with specialty medication outlays expected to quadruple to $402 billion by 2020, and the strides being made in the industry to bring specialty prescribing into the electronic age.

Specialty prescription drugs — those used to treat chronic, complex diseases such as cancer, multiple sclerosis and rheumatoid arthritis — have historically been associated with rare medical conditions. However, they are being used more frequently for the treatment of such common chronic conditions as rheumatoid arthritis and multiple sclerosis. According to a recent study, specialty drugs in 2013 accounted for less than 1% of US prescriptions but for more than 25% of prescription spending. Specialty drugs also are associated with greater costs — with a $12,238 median over a treatment period versus $784 for traditional drugs. In actual terms, some specialty therapies can easily exceed $10,000 per patient per year.

As a result, specialty prescribing is on the radar of payers, patients and policy makers who are looking for a balance between the high costs of specialty medications and their many benefits related to health and quality of life. Moreover, it is ripe for automation. People tend to view specialty prescribing as a single transaction while it is, in fact, a series

(continued)

 of transactions done mostly by paper, phone and fax. Enter ePrescribing. Standards and ePrescribing infrastructure already are available to handle the basic prescription process. Other necessary pieces, such as ePA, are emerging that will facilitate automation of other specialty prescribing processes. The industry is working to fill in the gaps, which will put specialty ePrescribing on the map in the near future.

Perspectives and Updates on
Health Care Information Technology

www.pocp.com

Point-of-Care Partners
Health IT Management Consultants

© 2015 Point-of-Care Partners, LLC