Perspectives and Updates on
Health Care Information Technology

HIT Perspectives

Biopharma Insights

1. **Part 1:** Automation of Specialty Pharmacy Gains Momentum
2. **Part 2:** The Time Is Right for Electronic Medical Prior Authorization
3. **Part 3:** Improving Drug Price Transparency: Progress and Opportunities

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Point-of-Care Partners helps Life Science and Biopharmaceutical companies develop EHR and Health IT strategies to increase product adoption, drive growth, and help their healthcare customers succeed in the world of value based care.

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1 Part 1: Automation of Specialty Pharmacy Gains Momentum

By Brian Bamberger, Life Sciences Practice Lead

Heads up, brand teams, automation of specialty pharmacy is rapidly gaining momentum. Results will have implications for a drug's selection, approval mechanisms and distribution. Hubs ultimately will be impacted, including their role in patient education and companies' investments in them. Manufacturers have the opportunity to join in on the ground floor and affect the outcomes.

Drivers for change. Specialty pharmacy has come on everyone's radar these days, for a variety of reasons. Costs are a big factor. The rise of chronic illnesses and the expensive medications needed to treat them have made specialty the **fastest growing** segment of medications.

Growing digitization of health care is another driver. Specialty pharmacy processes still remain largely paper based and dependent on phone and fax. This stands in contrast to nonspecialty medications, nearly all of which are prescribed electronically. Everyone is interested in getting rid of paper and fax, including Seema Verma, who heads the Centers for Medicare and Medicaid Services. **She recently challenged developers** to "help us make every doctor's office in America a fax-free zone by 2020."

Addressing the hassle of prior authorization (PA) is yet another factor. Most specialty medications require PA, which is a pain point that creates delays to therapy and prescription abandonment. The industry has responded with automation. Electronic PA (ePA) rapidly is becoming deployed for medications covered under the patient's pharmacy benefit, in response to state legislation and payer mandates. Now there are growing efforts for ePA of drugs covered under the patient's medical benefit, or mPA. (**Read more about mPA in the September issue of *HIT Perspectives*.**)

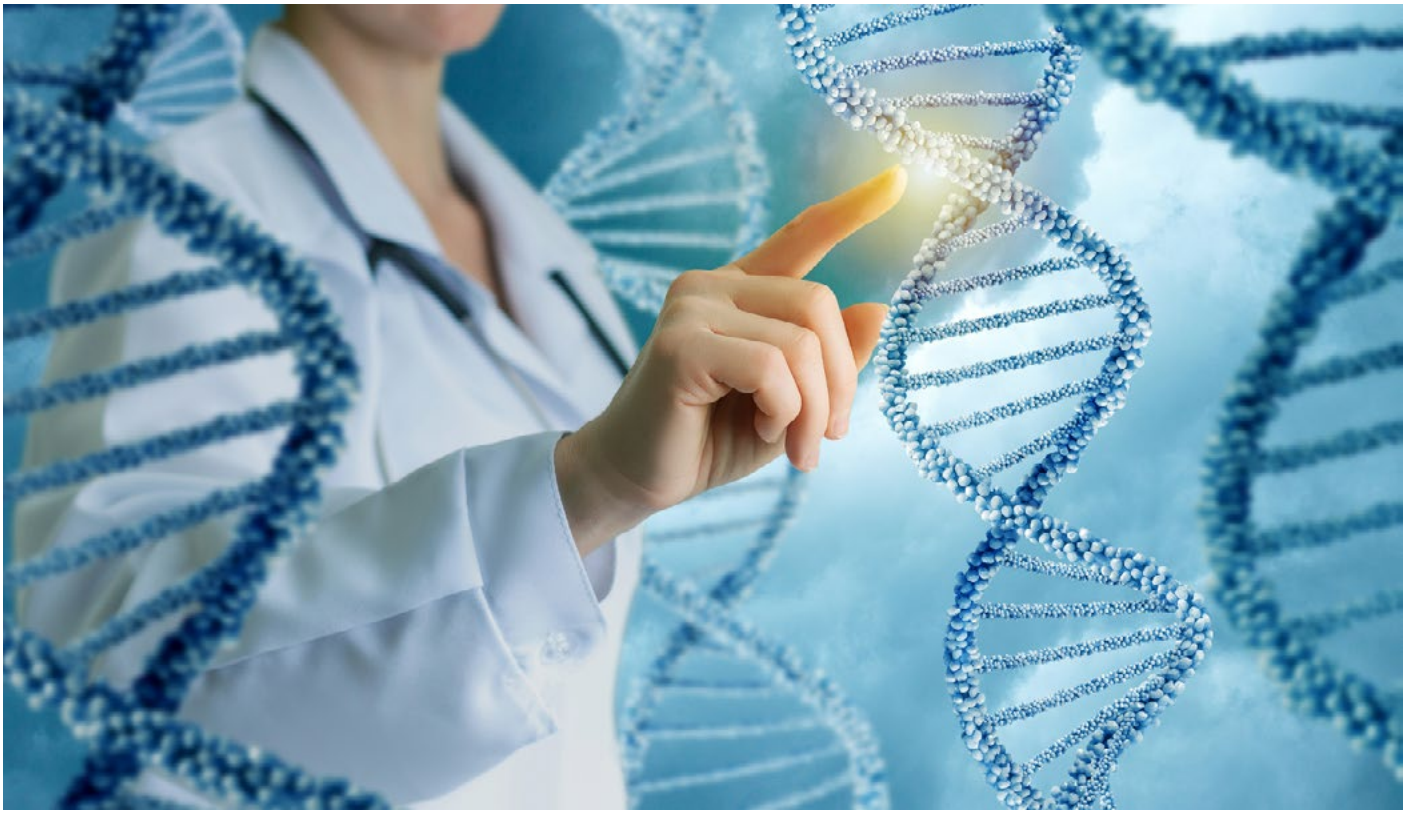
If that isn't enough, information about specialty drugs that are prescribed — and related information, such as adverse drug events — needs to be incorporated into electronic health records (EHRs). The capturing and sharing of such information via EHRs is essential for the growing trend toward outcomes-based reimbursement, as well as for various safety-related requirements.

Efforts for change. Initial efforts for specialty pharmacy computerization are being undertaken by the National Council for Prescription Drug Programs (NCPDP), which recently convened a Specialty Prescribing Workgroup whose expressed purpose is to improve the automation of specialty workflows. It is co-chaired by my colleague at Point-of-Care Partners (POCP), Pooja Babbrah. Brand team participation is sought to represent the needs of your patients and their prescribing physicians.

"The workgroup will become the focal point for industry stakeholders involved in specialty medications," explained Ms. Babbrah. "We have already identified a number of processes — from enrollment and benefit verification to prior authorization, patient consent and outcomes reporting —that can benefit from standardization to improve speed to therapy.

"We need to have pharmaceutical manufacturers involved. It is critically important to understand their requirements and points of view," she added.

The workgroup is kicking off with two focused efforts. The first is computerizing patient enrollment for a new therapy. This will



allow the physician to send required information electronically to a pharmacy. Currently, NCPDP SCRIPT — the main standard used for electronic prescribing (ePrescribing) — is insufficient for the needs of specialty pharmacy. Additional detailed information along with the prescription will assist with automation. Brand team input is needed to help the workgroup understand what information is needed for specific specialty medications.

The second effort focuses on benefit identification, which is spearheaded by a task group. This group will evaluate how to begin the process of automating determination of whether a drug is covered under a patient's medical or pharmacy benefit or both. This varies by payer, so having this information will help the prescriber know where to go for approval as well as improve speed to therapy.

These efforts will affect both parts of specialty pharmacy: the drugs themselves and distribution. Brand teams will have to figure out how their brands will be impacted by electronic approvals and extensive PA. How will brand investment in hubs be affected, since some traditional patient education and support will become electronic? How will distribution change?

These are some of the reasons why manufacturer representation is needed in the workgroup and in specific task group calls in which important issues are explored. It's an opportunity to make your voice heard. In fact, an outreach task group will be added, which would benefit from manufacturer participation to strengthen business cases. I'd be happy to put you in touch. In the meantime, POCP is monitoring these developments. Let me keep you in the loop. You can reach me at **brian.bamberger@pocp.com**. •

2 Part 2: The Time Is Right for Electronic Medical Prior Authorization

By Michael Solomon, PhD, MBA, Senior Consultant and Jocelyn Keegan, Payer Practice Lead

To be sure, prior authorization (PA) is a pain point for payers, providers and patients. The process of obtaining permission from an insurance company before a covered drug, procedure or device can be provided is complex, involving the exchange of voluminous medical and other information between the patient's insurance company and the provider. Until recently, nearly all PA required paper submissions by phone and fax. This delayed speed to therapy and frustrated everyone involved.

This is changing for drugs covered under a patient's pharmacy benefit with the advent of an electronic, standards-based process called electronic PA (ePA). With it, handling PA requests can be done as part of the electronic prescribing (ePrescribing) process at the point of care through the electronic health record (EHR). However, this is not the case for the hundreds of drugs, devices and procedures covered under the patient's medical benefit.

They include:

- Drugs covered under Medicare Part B
- Procedures such as radiology, magnetic resonance imaging, endoscopy and chemotherapy
- Devices such as pacemakers, nebulizers, glucometers and infusion pumps

Prior authorization for these drugs, devices and procedures is still mired in the time-consuming, antiquated paper-phone-fax processes. It is time to bring PA for them into the digital age.

The need for mPA. A number of factors are converging to stimulate the development and adoption of electronic medical prior authorization (mPA). They include:

- **The chronic disease crisis.** The prevalence of chronic diseases is rising at an alarming rate. **According to the federal government**, half of the American population will have at least one chronic disease by 2025. One in four adults currently has multiple chronic conditions. Treatments for chronic conditions often are complex and may require expensive specialty medications.
- **The growing demand for specialty medications.** Due to the rise in complex, chronic illnesses, there is a growing need for expensive specialty medications, most of which require PA. Specialty is the **fastest growing** segment of medications.
- **Administrative burdens.** Three-quarters of physicians (specialists and primary care) report the burden of PA is high. According to the **American Medical Association**, doctors spend the equivalent of 40% of their time navigating PA. Because this administrative burden is so great, about a third of physicians maintain staff members who exclusively deal with PAs. It usually takes days — or even weeks — **for an insurance company to decide** whether it will approve a PA request. Needless to say, this leads to delays in therapy and frustration for both patients and providers. These factors are increasing the demand by provider associations for an mPA solution.
- **The shift to value-based care.** Health plans and integrated delivery networks are entering into a growing number of value-based care arrangements. These increases the focus on evidence-based guidelines and utilization management. PA becomes a shared tool to support both provider and payer cost and quality goals. As the volume and complexity of PAs increase, pressure is growing to reduce the administrative burden with automation.
- **State legislation.** States recognize the burden PA places on providers and are responding by working to improve the quality and use of medical PA. Nine states have passed mPA legislation and more are expected to do so. That said, these laws are a patchwork of requirements. This lack of uniformity leads to adoption challenges by users and EHR developers.
- **Federal legislation.** The House recently passed a bundle of 50 bills (**H.R. 6**) aimed at addressing the opioid epidemic. One is **H.R. 5773**, the Preventing Addiction for Susceptible Seniors Act of 2018. It contains provisions to require ePA for drugs covered under Medicare Part D.
- **Interest by Medicare.** Medicare, the nation's largest payer, is becoming interested in mPA. For example, all durable medical equipment Medicare administrative contractors now accept PA requests electronically through **esMD**, the Electronic Submission of Medical Documentation program. This starting point is likely to lead to mPA requirements for other devices and procedures covered by Medicare. In addition, adoption of mPA by Medicare is likely to spur private payers to follow suit.

The current state of mPA. Electronic medical prior authorization is still in its early phases. There are many challenges that must be addressed. For example:

- In contrast to ePA, PAs for drugs covered under the medical benefit still rely heavily on phone calls and faxes for the documentation to support a PA request. Use of unstructured data is commonplace. Providers must use more than one channel — that is, phone, fax and portal — to complete most mPA submissions. Requests for specialty medications are especially paper intensive. Not only are portals outside of the prescriber's workflow, they inhibit the automated extraction of clinical data that reside in the EHR and are required for many mPA submissions.

- Many proprietary solutions for mPA have developed due to deficiencies in the current ASC X12N 278/279 standards and the lack of a claims attachment standard. Although mandated by the Health Insurance Portability and Accountability Act (HIPAA), the ASC X12N 278/279 standards fall short of stakeholders' current needs. A standardized attachment of structured clinical data would be helpful. HIPAA has also mandated the creation of a claims attachment standard; however, there does not seem to be any desire on the part of the government or industry to produce one as no action has been taken for decades.
- Payers' systems are limited when it comes to supporting benefit and PA checks. They also have deficiencies in handling the voluminous documentation that often is required.
- There is no standard for how best to transport the supporting clinical data for mPA that is needed. It will have to be embraced by stakeholders — Medicare and system vendors in particular.
- EHR systems today are just beginning to grapple with workflows to support electronic mPA. In addition, there is virtually no support for PA attachments, either using the ASC X12N 275 transaction or alternative formats. These deficiencies and information gaps in existing EHR workflows are related to similar issues involving lack of computerization for specialty medications.
- There is a lack of empirical evidence of return on investment on mPA workflow investments for both payers and providers.
- Significant portions of today's manual workflows rely on utilization managers' knowledge and expertise, which are not codified in a single place in payers' systems.

Looking to the future. While it may seem like a daunting task to address the complexities of computerizing mPA, there are lessons learned and opportunities that can be leveraged. For example:

- We do not have to "boil the ocean." Not everything needs to be done at once. Significant progress can be made incrementally, such as targeting high-volume/high-cost therapy areas. Staging and timing are critically important.
- Key stakeholders must drive the process. Both facilitation and leadership are essential. Industry leaders must step up, but the process must be facilitated by knowledgeable experts whose only "skin in the game" is success. The role of stakeholder politics should not be underestimated because it impacts the content and timing of the development of standardized solutions.
- Existing standards must be adapted to meet the needs of today's stakeholders. They need to be critically evaluated and revised as necessary and as expediently as possible to support the complexities of PA requirements and the electronic flow of information between providers, payers and patients.
- The Real-Time Benefit Check (RTBC) format must be adapted for use with drugs, devices and procedures covered under the patient's medical benefit. This new ePrescribing transaction provides accurate patient-specific, real-time data and coverage information at point of prescribing. There is a critical need for member-specific benefit checks and indications of PA requirements for mPA – following the path of RTBC for ePA.
- Computerization of specialty medication processes will accelerate, as will their seamless integration into EHRs.
- Medicare and Medicaid will increasingly require ePA for drugs covered under the pharmacy and medical benefits. These will continue to drive progress.

While realization of the benefits of integrated medical/pharmacy benefit management will take time, there is huge potential on the horizon to avoid suboptimal care and improve the patient's experience. Those health systems and payers that can make good on this potential can dramatically improve the health outcomes/cost equation and become established market leaders in the new era of value-based care.

*Point-of-Care Partners (POCP) is heavily involved in various aspects of mPA development. We are monitoring growth in this technology and soon will be unveiling a value model based on adoption horizons. Our Regulatory Resource Center is tracking mPA legislation and regulations at the state and federal levels. Send the staff an email (***regulatory@pocp.com***) for a consultation.*

POCP is uniquely positioned to help your organization better understand mPA and make it work for you. Let us know how we can help. Reach out to us: **michael.solomon@pocp.com** *and* **jocelyn.keegan@pocp.com**. •

3 Part 3: Improving Drug Price Transparency: Progress and Opportunities

By Tony Schueth, Editor-in-Cheif

This is part 2 of a two-part series on drug price transparency. The **first article** *focused on drivers for change and the information gaps inherent in the current prescribing process.*

A new revolution is coming to the point of care. First was the advent of electronic prescribing (ePrescribing). This revolution leverages ePrescribing to provide accurate, patient-specific information on medication prices and related out-of-pocket (OOP) costs for the patient at the point of prescribing. Such actionable information will help reduce costs, improve medication adherence and outcomes and enhance patient and provider satisfaction. While improving drug price transparency is a work in progress, considerable headway has been made. This article describes some of those advances and six opportunities for improvement.

Progress. Leveraging improvements in technology and a perceived value proposition for key stakeholders, the industry is moving forward rapidly and aggressively with transparency. Several developments are worth noting:

- **Transaction Standards.** While some stakeholders are using application programming interfaces, transaction standards are building blocks for implementations that can be used successfully on a uniform, broad scale. Standards development organizations are developing transaction standards that can be used to address price transparency. For example, the National Council for Prescription Drug Programs (NCPDP) has worked over the past several years with payers, pharmacy benefit managers (PBMs), vendors and pharmacies to create consensus-based industry standards. NCPDP workgroups currently are working on developing two standards for the Real-Time Benefit Check (RTBC) formats as well as an implementation guide. RTBC enables data access in real time and directly from the payer, providing accurate and detailed patient-level benefit information about medication coverage, copays and plan restrictions. Use of RTBC will help improve formulary compliance and medication adherence by ensuring

that the patient knows OOP costs before arriving at the pharmacy and can receive the most effective, least expensive, approved drug.

- **Implementations.** Recognizing the need for and value of drug price transparency at the point of prescribing, the industry has forged ahead despite the absence of a finalized standard. Major players, such as Surescripts, CoverMyMeds and DrFirst, have built solutions. Startups are popping up, including RxRevu and Gemini Health. There were 3.1 million RTBC transactions in 2018 **through the Surescripts network alone**, indicating a value proposition for RTBC.

  So far, three different implementation models for RTBC have emerged: direct connection between the electronic health record (EHR) and payer, connection through an intermediary or a combination of both. This menu of options creates challenges for the hundreds of EHR vendors in the market. Which model should they select and how should that choice be integrated into their EHR solution? This is especially challenging for the direct connection option. In this model, prescription benefit information comes directly from the PBM/payer to the EHR. The EHR needs to connect directly to multiple PBMs, which would require each EHR to contract with all payers and for each payer to develop, maintain and support connectivity to every EHR. Such issues may sort themselves out in the future with the rollout of an NCPDP standard and as the market matures; however, it seems likely that the direct connectivity model will be used primarily by the largest vendors and others will leverage intermediaries.

Opportunities. While much progress has been made, there are still many opportunities for improvements and innovative solutions. Six come to mind.

1. **Developing RTBC for drugs covered under the medical benefit.** The current RTBC transaction focuses on medications covered under the pharmacy benefit. However, there is a need for RTBC for specialty drugs covered under the medical benefit. There are several reasons. For one, the use of specialty medications is rapidly growing and roughly half of the specialty drugs prescribed today are covered under the medical benefit. Use of RTBC could help identify under which benefit the drug is covered and address long-standing issues of transparency and access for these expensive medications. It could also help providers understand benefit restrictions, find less expensive alternatives and identify the appropriate specialty pharmacy to fill the prescription. This will help lower costs and improve speed to therapy, outcomes and patient satisfaction while reducing hassles for the prescriber. However, RTBC for medical benefit drugs is on a longer-term horizon. Specialty pharmacy is in the very early days of automation. NCPDP recently has formed a Specialty Workgroup that is working to address specialty medication and network restrictions during prescribing. **(See the article in this issue of HIT Perspectives** addressing the need for a related transaction, the electronic medical prior authorization).

2. **Improving formulary and benefit (F&B) files.** The need for F&B files will not go away with the advent of RTBC. Rather, F&B will evolve to support RTBC by consistently alerting prescribers of the need to perform a RTBC due to mitigating factors, such as noncovered drugs. Thus, eligibility-informed formulary is still important because it helps determine whether an RTBC is needed. As a result, payers must address the shortcomings in F&B data. For example, data regarding individual patients' insurance coverage, coverage restrictions, therapeutic class guidelines, deductibles and other information are not always complete or accurate. Whether or not prior authorization is required will migrate to the RTBC response transaction, where it can more accurately reflect member-specific benefits.

3. **Fixing the prescription rework challenge.** ePrescribing vendors need to be innovative to address a challenge related to prescription rework when using the RTBC. **One study confirms** that prescribers using the RTBC frequently change the drug prescribed when provided with information regarding a patient's insurance coverage and OOP costs. When that happens, the prescriber is faced with extra steps when selecting an alternative, whether it's for an entirely different medication or just a change in packaging and strength. This is a hassle and one reason why so many prescribers just say, "Let the pharmacist sort it out." How does that happen today? It's often resolved by phone; many physicians perceive it as easier to have a nurse answer the phone than to rewrite a prescription. In any case, any rework takes precious time away from the patient visit and adds to physician dissatisfaction. To ensure broad adoption and sustained use of RTBC, interoperability between the EHR system's ePrescribing system and RTBC ap-

plication must be carefully designed and implemented to pass RTBC results as a new prescription to eliminate clinician rework.

4. Settling on a pricing model. Because of the way RTBC has evolved, there are varying pricing models for use of the transaction. Pricing may be outcomes based for those payers engaging in significant numbers of value-based contracts. Our research shows multiple pricing models will likely be in place for quite some time and the reimbursement models will support key objectives. These include getting patients on the appropriate, on-formulary drug; avoiding drugs requiring prior authorization when an alternative is available and improving medication adherence.

5. Integrating information on payment assistance programs. Another information gap affecting patients' potential OOP liability is the unavailability of information on payment assistance programs offered by manufacturers and others. Having this information at the point of prescribing can help the physician identify more cost-effective options for the patient. This ultimately improves outcomes and medication adherence and reduces costs. There are plenty of assistance programs available, but the physician must know about them before they can acted upon. For example, many manufacturers fund coupon and copay card programs to offset the costs of drugs for consumers. In fact, **manufacturers offer coupons for nearly half of the top 200 drugs**, creating billions of dollars in potential savings opportunities. They also fund financial assistance for patients' drug copays or other medical expenses through nonprofit foundations. **Many states have similar programs**, although details vary as to for whom and what conditions may be covered. Several payers also offer drug assistance programs, such as **CVS Health** and Express Scripts' **InsideRx**.

Currently, the prescriber must hunt for information about these programs, taking valuable visit time for research. However, things are changing with the digital age and such information can be incorporated into the ePrescribing workflow so it is available at the point of prescribing. While this is an opportunity, there are challenges for EHR vendors. They must identify such programs, figure out how to integrate the information into their EHR and keep the information updated.

6. Understanding the patient's financial picture. The prescriber is likely to lack understanding of a patient's financial obligations, which influence whether a patient can afford a medication at a point in time. Factors include coinsurance, other insurance copayments, and drug deductibles, as well as the patient's finances. The RTBC only provides part of the picture: a snapshot of a patient's potential OOP cost for a particular drug at a particular time. This varies because payers do not calculate the patient's OOP costs the same way and there is no standard for presenting OOP costs. In addition, the RTBC may not aggregate OOP costs for all drugs prescribed for an individual patient, so the problem is exacerbated when multiple drugs are prescribed at the same time.

Other unknown financial factors may affect whether a medication is affordable. Examples include income and various responsibilities, such as rent or funding a child's education. These can change dramatically from visit to visit.

All of this is unknown to the provider at the point of care, who may have to ask about such very personal information — especially if the patient needs a very expensive drug with a very large copay, such as an oncology medication. Providers may be reluctant to have this discussion and patients likewise may be reluctant to provide such information and keep it available in the EHR. Some hospitals and integrated delivery systems maintain staff to assist with this matter, but it is beyond the purview of most ambulatory prescribers.

These kinds of sensitive financial issues must be addressed going forward if drug price transparency at the point of care is to become an optimal tool for providers and consumers.

Moving forward. Considerable headway has been made to streamline processes, reduce costs and improve speed to therapy through advancements in drug price transparency at the point of prescribing. The RTBC will become a valuable tool to help ensure that patients will get the right, most cost-effective approved drug before they get to the pharmacy.

Keep current with Point-of-Care Partners. We are monitoring these developments and are active in the development of — and enhancements to – these and other standards related to ePrescribing. Drop me an email at **tonys@pocp.com**. *I'd be happy to fill you in.* •