Perspectives and Updates on
Health Care Information Technology

HIT Perspectives

Biopharma Insights

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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: New Federal Opioid Legislation Has Potential Impacts for All Pharmaceuticals

By Brian Bamberger, Life Sciences Practice Lead

Sweeping new legislation was signed into law on October 24, pulling together 70 bills from both sides of the aisle to address various aspects of the opioid epidemic. The new law is the "Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" or the "SUPPORT for Patients and Communities Act" (aka **HR6 and Public Law 115-271**).

about 15% of all prescriptions. Roughly one fifth were prescribed electronically in 2017, representing 77.33 million ePrescriptions for controlled substances. Most of that was due to mandates in New York, Connecticut, Maine and Minnesota.

We expect prescribers who are required to use EPCS for Part D prescriptions will ePrescribe for all prescriptions. Physicians will

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The SUPPORT Act contains provisions that directly impact how drugs will be prescribed through mandates concerning electronic prescribing (ePrescribing), electronic prior authorization (ePA) and prescription drug monitoring programs (PDMPs).

ePrescribing. Section 2003 mandates that prescriptions for all controlled substances covered under Medicare Part D must be transmitted electronically beginning on January 1, 2021, with a few exceptions.

The impacts: Requiring electronic prescribing of controlled substances (EPCS) will give a needed shot in the arm to use of this transaction. Controlled substance prescriptions account for

want to have one workflow for all prescriptions because nearly 80% of noncontrolled substances are already being ePrescribed. In addition, private payers and states are likely to follow suit and require EPCS for all controlled substance prescriptions, not just a subset related to opioids.

Now physicians (the vast majority of whom treat Medicare patients) will have to get on board. The impact of adoption should be minimal. Virtually all electronic health records (EHRs) — the most frequently used method for ePrescribing — are already compliant with EPCS standards required by the **Drug Enforcement Administration (DEA)**.

Electronic prior authorization. ePA has been around for a while but has not experienced the adoption uptick originally expected. The new law should change that. Section 6062 mandates that all covered Part D drugs requiring prior authorization (PA) must be electronically submitted to Part D sponsors and processors electronically — and responded to electronically — by January 1, 2021. Those ePA transactions must use an as yet-to-be named standard specified by the Secretary of the Department of Health and Human Services (DHHS). In addition, facsimiles, proprietary payer portals that do not meet standards specified by the Secretary, or electronic forms don't count as complying with the law.

The impacts: We think the Act's provisions will have far-reaching impacts on how prior authorizations are obtained.

- Of the three health IT-related provisions in the SUPPORT Act, this has the biggest impact on all pharmaceutical products. Currently, ePA adoption is lagging. Mandated use of a standards-based ePA transaction by Medicare Part D pushes others to follow suit, including private payers and states. This will bring more electronic health records and physician users into the fold.
- The Act spells the death knell for faxes and portals, which still are heavily used today for requesting prior authorizations. States will want to revisit their legislation to eliminate use of standardized paper forms, faxes and portals.
- Payers and pharmaceutical benefit managers (PBMs) will have to fill data gaps and fix inaccuracies in formulary and benefit (F&B) files, as described below. Prescribers often do not trust the F&B information, which has been a barrier to ePA adoption.
- In the near term, the standards vacuum will lead to more retrospective PA. Retrospective PA is better than fax, phone and

paper but nonetheless a burdensome, usually proprietary process in which PA is sought after the prescription has been rejected at the pharmacy by the payer. Retrospective PA frequently results from missing or incomplete data in the current ePrescribing process. In an electronic health record, ePA is triggered based upon an indicator, or flag, in the formulary and benefit (F&B) file provided by the payers and PBMs. However, the PA flag is frequently not populated by commercial payers. Even when the flag is provided, the need for PA is not always accurately presented. These inaccuracies, plus the traditional manual paper and fax-based PA process, result in delays and frustration.

- The Act's provisions will accelerate innovative solutions. Several are on the horizon. Artificial intelligence (AI) is one that some organizations are testing to predict if a PA will be required. Another is the real-time pharmacy benefit check (RTPBC), which provides real-time patient-level information at the point of prescribing, pulled directly from the payer's claims system, which is where the most accurate and timely information is stored. It enables the prescriber to see patient-specific plan restrictions (such as PA and step therapy), true out-of-pocket costs for a medication (specific copay/coinsurance amount) and specific deductible information. This will prevent dispensing delays caused by inadvertent prescribing of a drug that is not covered by the patient's insurance or requires an expensive copayment. Even with these innovations, the need for F&B files will not go away with the advent of RTPBC. Rather, they will evolve to support RTPBC by consistently alerting prescribers of the need to perform a PA due to mitigating factors, such as noncovered drugs. Thus, eligibility-informed formulary is still important because it helps determine whether a PA is needed. The bottom line is that payers must address the shortcomings in F&B data at the same time as they are innovating with AI and RTPBC.

PDMPs. PDMPs are state-specific databases of controlled substance prescriptions. Electronic consultation of PDMPs before the prescriber "writes" the prescription is viewed as an effective way to prevent drug diversion, overprescribing and doctor shopping.

The SUPPORT for Patients and Communities Act has numerous provisions related to making PDMPs more interoperable. Grants are in the offing to states and other jurisdictions to implement, enhance, and improve various PDMP functionalities. These include improved and interoperable sharing and accessing of controlled substance prescribing data across the states; integration of PDMP data into EHRs and the "health IT infrastructure" workflow; and "integration of automated queries into clinical workflow to improve the use of such data analytics by practitioners and dispensers." Other interoperability-related provisions include sharing dispensing data across state lines in real time and linking PDMP data to other data systems within the states, such as those for coroners, the Department of Veterans Affairs and the Department of Indian Affairs. The statute also allows the DHHS Secretary to issue guidelines specifying a uniform electronic format for the reporting, sharing, and disclosure of information pursuant to PDMPs.

The impacts: Receipt of the grant money requires that a state must have a PDMP program in place, which likely puts additional pressure on Missouri as the sole state without a true state-wide PDMP program. These provisions will require states to revisit their legislation to sync up with the requirements in the SUPPORT for Patients and Communities Act. We expect that states will also revisit legislation due to Section 1016. This addresses PDMP data sharing for Medicaid, granting authority for state laws to permit sharing of data among providers, as permitted by state law. •

Want to know more? *The SUPPORT for Patients and Communities Act has numerous other provisions of interest to stakeholders, including expanding use of telehealth in Medicare for substance abuse treatment and expanding eligibility for medication therapy management for beneficiaries at risk for substance abuse. Contact Keith Fisher (keith.fisher@pocp.com), who co-leads our Regulatory Resource Center (RRC). We can provide a complete look at the act's provisions, as well as explain the depth of information available from the RRC on laws and regulations pertaining to ePrescribing, ePA, and other topics of interest. Drop me a line (brian.bamberger@pocp.com) if you'd like to know more about the changing health IT landscape and what it means for your company.*

2 Part 2: Connecting Patients With the Costs of Their Medications

By Jocelyn Keegan, Payer Practice Lead, and Pooja Babbrah, PBM Services Practice Lead

The soaring cost of specialty medications and the increasing complexity of health benefits means that consumers are asked to bear a larger share of the cost of their medications, yet most don't know how that will affect their pocketbook or their health care. More than ever, consumers need to know upfront about drug prices, payer requirements, pharmacy options and potential out-of-pocket costs. At the same time, connecting patients with the costs of their medications is part of consumer-directed care and price transparency at the point of prescribing.

But that's easier said than done. Physicians may be unaware of the need for prior authorization (PA) when prescribing expensive specialty medications, often because of data-related issues in the formulary and benefit (F&B) file used for electronic prescribing (ePrescribing). Since they don't have all the facts at their fingertips — and don't really trust what they do have — prescribers frequently order medications that are not on formulary, have higher copayments or generally are unaffordable. Patients' out-of-pocket costs are often unknown until they are hit with sticker shock at the pharmacy.

All of this often results in a variety of problems related to unaffordable medications, including reduced speed to therapy, abandoned prescriptions, disruptions in care, medication nonadherence, and unnecessary doctor visits and emergency department and hospital admissions.

The industry response. The industry is aware of these issues and is taking action through the development of two new transactions: the real-time pharmacy benefit check (RTPBC) and the real-time medical benefit check (RTMBC). They represent continued forward movement toward connecting patients with the costs of care.

- **RTPBC.** The real-time pharmacy benefit check is an emerging transaction that focuses on pricing transparency for the patient at the point of prescribing, which is driving adoption.

  With the RTPBC, the prescriber and patient can have up-to-date information about a drug that is being prescribed as part of the ePrescribing process at the point of care through the electronic health record. The RTPBC lets the prescriber know in real time if the drug is covered, the copay amount for the drug and any plan restrictions. Potential alternatives can be provided if the drug is not covered. The prescriber also will know whether the drug requires PA, helping the physician obtain faster approval and improve speed to therapy.

  At the same time, all this information helps the consumer better understand the potential out-of-pocket financial obligations associated with certain drug choices. It also can help direct the consumer to a specific site of care — or site of administration, in the case of many specialty medications — that is covered by insurance. This dialog between the prescriber and patient, facilitated by the RTPBC, is an important way to engage patients in their care and improve outcomes.

  An RTPBC standard is under development by the National Council for Prescription Drug Programs (NCPDP). Even though the federal government has not yet adopted an RTPBC standard, several vendors are offering RTPBC connectivity due to the value of the transaction. For example, there were 3.1 million RTPBC transactions in 2017 through Surescripts. This growing transaction volume indicates the RTPBC's value to patients, payers and prescribers in better connecting consumers with the costs of their medications.

- **RTMBC.** Work on a related transaction area that Point-of-Care Partners is calling the real-time medical benefit check is just getting off the ground. It is needed because roughly half of prescriptions today are for drugs, devices and procedures covered under patients' medical benefit. These can also be a huge hit to consumers' pocketbooks if their costs are not known at the point of the prescribing. That said, the development and widespread adoption of the functionality required to support RTMBC is on a longer horizon due to the nascent efforts to expose medical payer systems to support specialty pharmacy.

Connecting patients with the costs of their prescriptions.

In addition to development of the RTPBC and RTMBC, what else can be done to better inform patients about the costs of their prescriptions? Here are some thoughts.

1. **Accelerating specialty pharmacy automation.** Specialty pharmacy is largely not yet computerized, relying heavily on antiquated phone-, fax- and paper-based processes. Work is underway to change that. The industry is taking steps to automate the complex processes used for filling specialty prescriptions, building on standards and implementations for ePrescribing. These also complement other efforts to automate various aspects of specialty pharmacy, such as patient enrollment. NCPDP has a new specialty pharmacy workgroup to identify issues that can be addressed through standards development. These efforts should increase momentum to accelerate specialty pharmacy automation, which in turn will drive adoption of the RTPBC and development of the RTMBC. It also will drive adoption of electronic prior authorization (ePA).

2. **Adoption of the ePA standard.** The time is right for adoption of the ePA standard from NCPDP. ePA is a tightly related, complementary transaction to the RTPBC and RTMBC. ePA allows the prescriber to electronically request a PA from the payer, a process that takes seconds versus the time-consuming manual method. The payer's response also is received in seconds, benefiting patient costs and speed to therapy depending on whether the drug is covered. It is already being used by many in the industry and increasingly is becoming mandated by states. The newly enacted **SUPPORT for Patients and Communities Act (HR6)** calls for the government to adopt an ePA standard. Its use will be required for drugs covered under Medicare Part D beginning on January 1, 2021. This needs to be done sooner rather than later so an implementing regulation can be issued with enough time for stakeholders to comply. Adoption of this standard will help improve the patient experience and speed to therapy, as well as help drive the use case for the RTMBC and medical prior authorization.

3. **Enhanced consumer communications.** Paying attention to the consumer and providing high-quality experiences are parts of payers' business models, especially those transitioning to value-based care. They are metrics on which providers are rated by payers and how certain public payers, such as Medicare Advantage plans, are rated as well. As a result, consumers must be given meaningful and transparent pricing information for their costs of care. Payers must evaluate and improve how they communicate drug pricing information to consumers. The same goes for pharmaceutical manufacturers.

4. **Improved data quality.** Payers also must improve their data quality so patients and providers can make informed decisions about which medications will work best and what affordable alternatives may be available. As mentioned previously, there are problems with the quality and accuracy of the F&B files used in ePrescribing. These data quality issues must be fixed if the information is to be used — and trusted — by prescribers.

Payers must evaluate and improve how they communicate drug pricing information to consumers. The same goes for pharmaceutical manufacturers.

Development of the RTPBC and RTMBC represents a beginning of the end of the decades-long disconnect in drug costs for patients. Realization of the benefits of integrating these transactions into ePrescribing will take time but there is a huge potential on the horizon to improve the patient's experience and avoid cost-related disruptions in care. •

Want to know more? Reach out to us at **jocelyn.keegan@pocp.com** *and* **pooja.babbrah@pocp.com**