Electronic Prescribing Regulations Expand in 2019

e-Prescribing Regulation Affecting Stakeholders Across Healthcare

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Patients today are behaving more like consumers, demanding the same degree of information transparency and competition from healthcare product and service providers that they get in their day to day lives as consumers of anything else. eBay, spothero, kayak, uber—everywhere we turn in our lives as consumers, disintermediation and freedom of information are giving consumers more relative power control vs companies than ever before.

This evolution is happening because patients are bearing a greater share of the cost for their own care than ever before. Many factors have contributed to this state, including the growth of high-deductible insurance plans that have an increasing number of patients paying from "dollar one" for their medical and prescription drug care. As a result, patients are increasingly committed to driving their own outcomes while optimizing their healthcare spend.

This demand is manifesting itself in two primary ways—1) New and increasingly demanding legislative and regulatory requirements, and 2) Evolved technologies to enable providers to meet the needs of the patient-as-consumer. This report provides an overview of several key areas in which ePrescribing regulations have emerged in recent years, how those requirements are changing, and the technological capabilities currently available to assist healthcare providers (HCPs), and the electronic health record (EHR) companies who serve them, in meeting these.

Prescription Medication Data Regulation— Driving Change Across Healthcare In 2019 and Beyond

CONTROLLED SUBSTANCES

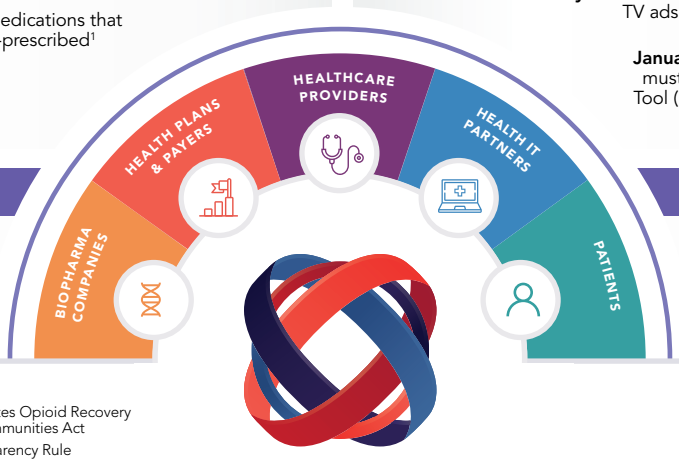
January 2021 – All controlled medications billed to Medicare Part D must be e-prescribed[1]

January 2021 – All covered Part D medications that require prior authorization must be e-prescribed[1]

REAL-TIME BENEFIT AND PRESCRIPTION PRICE TRANSPARENCY

July 2019 – Drug companies must disclose pricing in TV ads under the Know the Lowest Price Act (May 2019)[2]

January 2021 – Each Medicare Part D plan must adopt at least one Real Time Benefit Tool (RTBT) effective in integrating with the ePrescribing or EHR system[3]



ePRESCRIBING

January 2020 – All e-prescribing software must comply with CMS-NCPDP SCRIPT 2017071

SPECIALTY PRESCRIBING

August 2018 – NCPDP forms Work Group 18 Specialty to develop standards and address gaps in care across Specialty Prescribing

1. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act
2. HHS Direct-to-Consumer Ad Drug Price Transparency Rule
3. Medicare Advantage and Part D Pricing Final Rule

PRESCRIPTION PRICE TRANSPARENCY REGULATION

HHS, CMS , Congress Toughen Requirements for Prescription Price Transparency

HHS Requires Price Transparency in TV Ads for Prescription Drugs (May 8, 2019)

HHS' new direct-to-consumer Ad Drug Price Transparency Rule, effective July 9, 2019, is intended to improve price transparency and tack high out-of-pocket patient drug costs and mandates that advertisements disclose the following statement:

"The list price for a [30-day supply of] [typical course of treatment with] [name of prescription medication or biological product] is [insert list price]. If you have health insurance that covers prescription medications, your cost may be different."[6]

The law applies to direct-to-consumer television advertisements for prescription pharmaceuticals covered by Medicare or Medicaid to include the list price-Wholesale Acquisition Cost-if that price is equal to or greater than $35 for a month's supply or the usual course of therapy.

Know the Lowest Price Act (May 10, 2019)

This act was signed into law with an effective date on or after January 1, 2020. Implemented to increase price transparency for consumers covered under Medicare or Medicare Advantage, it blocks Medicare Advantage plan providers or providers of a Medicare Part D prescription drug plan from using gag clauses to prohibit pharmacists from alerting Medicare customers of differences between their insurance copay and what the patient would pay without using health insurance coverage.[8]

Medicare Advantage and Part D Pricing Final Rule (May 16, 2019)

CMS issued the Medicare Advantage and Part D Pricing Final Rule to help ensure patients have greater transparency into the cost of prescription drugs in part D with the ability to compare options and demand value. Each Part D plan must adopt at least one Real Time Benefit Tool (RTBT). This Real Time Benefit Tool must prove effective in integrating with, at a minimum, the ePrescribing system or electronic health record (EHR) of one prescriber no later than January 1, 2021.

What Does it Mean?

The increasing availability or real-time, patient specific pricing data on prescription medications is intended to empower patients—be it on TV, at the pharmacy counter, or in the exam room. While greater information is a good thing, patients and drug manufacturers alike will be relying on healthcare providers to help the patient make the most appropriate decision for their care, which may not always be the least expensive.

How Technology Can Help

These new regulations place significant responsibility on providers. The challenge of meeting that responsibility without adding an undue burden on providers has fallen on the healthcare IT companies, particularly EHR and e-prescribing software providers.

Adoption of technologies which can meet this challenge has been rapid. Veradigm RxTruePrice, accessible by 200,000 HCPs, provides discounted health plan or pharmacy benefit manager (PBM) pricing, cash pricing, therapeutic alternatives and competitive prices at different pharmacies. All information is specific to the patient and all passively displayed their usual clinical workflow. Ultimately, such solutions are only as valuable as the scope and accuracy of the data behind it. Unlike other solutions who may only connect to a single source for prescription data, Veradigm RxTruePrice integrates data from a broad range of partners to cover a more complete range of insurance and cash pricing, as prior authorizations, helping HCPs to effectively use the solution with as many patients as possible.

E-PRESCRIBING REGULATION

NCPDP Leads Standards Initiative on Specialty Medication Communication

Specialty medications are high-cost, complex drugs with special handling and delivery requirements.[2] Unfortunately, while these medications can have essential benefits for patients with rare or chronic conditions, they are often hard to obtain.

The National Council for Prescription Drug Programs (NCPDP) creates and promotes standards for electronic healthcare transactions. Their solutions help address industry challenges such as real-time claims adjudication, eligibility and benefit verification, real-time ordering by the physician, and sharing of medication history. The NCPDP has created the new Task Group for Specialty Prescribing to develop standards and address gaps in care. This group is made up of representatives from pharmacies, payer health organizations, prescribing solution vendors, pharmacy wholesalers, consulting firms, and others.

The task group has 4 main initiatives planned for 2019 that should help automate specialty pharmacy to impact the quality and safety of care:

1. Automated methods for enrolling patients in specialty programs will emerge
2. Stakeholders will accelerate automating various facets of specialty prescribing
3. The industry will finally grapple with solutions to ultimately identify who owns coverage for a patient at the point of prescribing
4. Conduct a baseline study of speed to therapy[2]

The NCPDP defines the standard for data transmitted as part of an electronic prescription through the current SCRIPT Standard 10.6. In April 2018, the Centers for Medicare and Medicaid (CMS) mandated NCPDP SCRIPT 2017071—the new standard for ePrescribing software, for which compliance must be demonstrated to reimbursement within the Medicare Advantage and Part D programs in January 2020. This regulatory requirement will require major development effort for every ePrescribing application on the market.

What Does it Mean?

As Specialty Medications grow in number and frequency of prescription, the challenges of ensuring fulfillment of these prescriptions by patients will be magnified even further. Without the widespread automation of manual processes and adoption of ePrescribing standards that the NCPDP is working to develop and promote, the healthcare system will remain constrained in its ability to effectively deliver specialty medication therapy to patients.

How Technology Can Help

There remains significant upside for improvement in process by which patients obtain specialty medications. Prior Authorizations, Specialty Pharmacy price data, and patient-specific benefit and cash pricing are already capable of being electronically delivered by Veradigm ePrescribe as part of the EHR workflow of 200,000 health-care professionals. At the same time, advancements in automating the acquisition, formatting and transmission of patient, payer, and provider data throughout the specialty medication fulfillment process are showing great promise, and should be expected to reap significant reductions in time-to-therapy in the coming years. Lastly, the ability to effectively integrate specialty medication prescribing data with outcomes data remains an obstacle for health systems and BioPharma companies alike, but one which appears likely to be addressed as well as interoperability and industry consolidation continue to accelerate.

CONTROLLED SUBSTANCES REGULATION

CMS and ONC Change Rules for Benefit Checks, Electronic Prescribing of Controlled Substances (EPCS)

On October 24, 2018 a new law was signed under Medicare Part D that will have legislation changes concerning the opioid epidemic.

Here is a brief summary of this new law:

1. The legislation 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).
2. This act is also referred to as the HR6 that includes Medicaid, Medicare, and public health reforms to combat the opioid epidemic.
    a. Starting January 1,2021, all controlled medications billed to Medicare Part D must be electronically prescribed.
    b. Starting January 1, 2021, all covered Part D medications that require a prior authorization must be electronically prescribed.
    c. Electronic prescribing is a way to help deter prescription fraud and diversion.
3. Physicians should understand the new law aims to improve prevention and protect against deadly synthetic drugs, help patient's recover quicker and more effectively, and educate communities on the dangers of the opioid crisis.[8]

Prescription Drug Monitoring Programs (PDMP) Proliferate

A prescription drug monitoring program (PDMP) is an electronic database that tracks controlled substance prescriptions in a state. In the US, 49 states have implemented a statewide prescription drug monitoring program. While PDMPs do not eliminate the ability for drug abusers to acquire opioids, they can help control their exposure to them. The federal Centers for Disease Control and Prevention has called such statewide patient monitoring databases "among the most promising state-level interventions" to improve opioid prescribing and protect at-risk patients."[14]

What Does it Mean?

Electronic prescribing is safer, faster, and far more traceable than paper prescribing. These benefits only grow when applied to controlled substances. As the next generation of controlled substance e-prescribing technologies arise, expect an even greater impact on the ability to achieve effective oversight of controlled substance prescribing and usage.

How Technology Can Help

EPCS and PDMP integration are already available through solutions like Veradigm ePrescribe. As PDMPs become more universal and start to standardize, an increasing share of healthcare professionals will be empowered to execute and report their controlled substances prescribing electronically, helping to ensure safer, more efficient fulfillment of controlled substances prescriptions for patients.

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