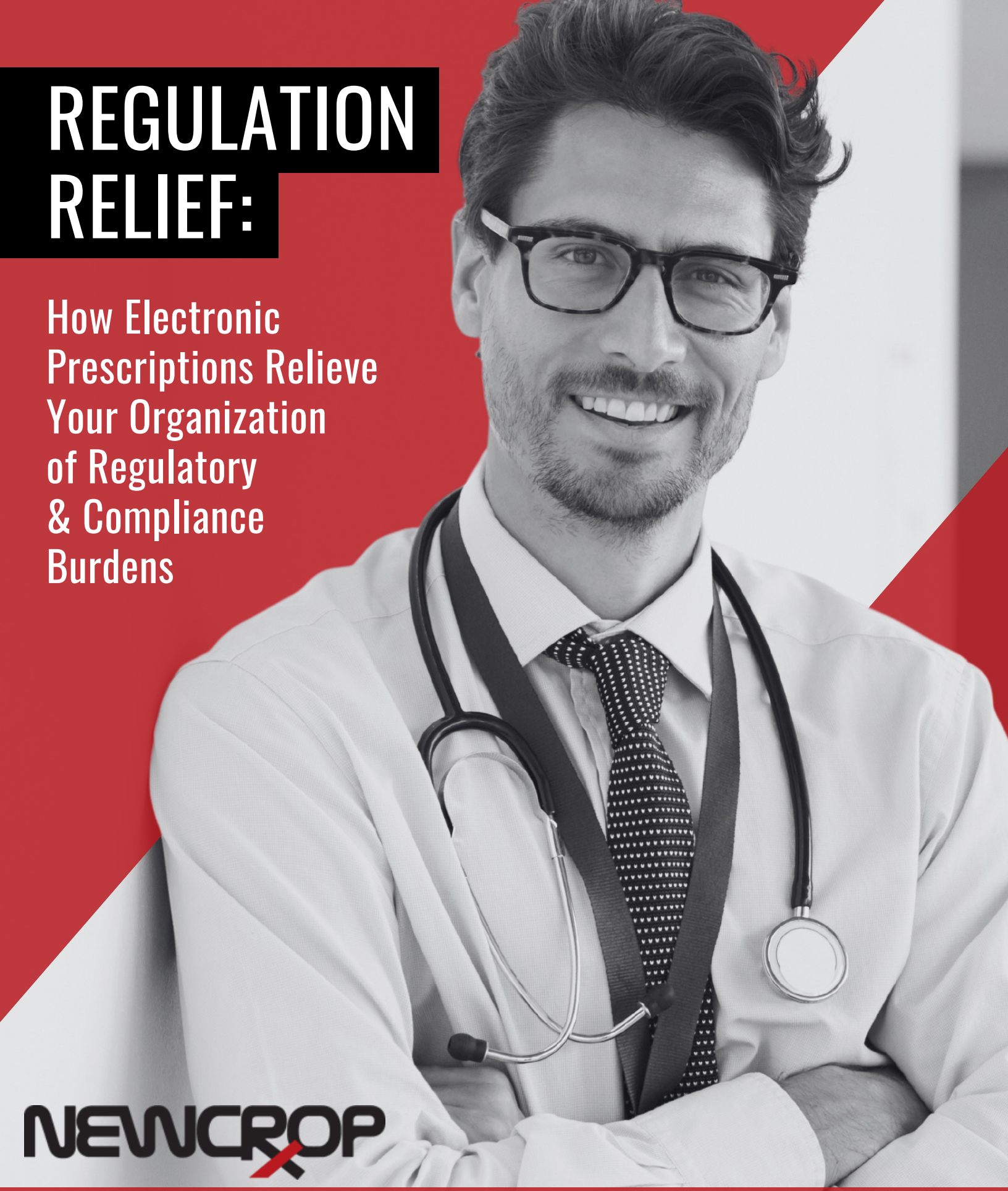
REGULATION RELIEF:

How Electronic Prescriptions Relieve Your Organization of Regulatory & Compliance Burdens



NEWCROP

A deep dive into the complicated and ever-changing regulatory landscape of prescribing physicians and healthcare IT and the e-prescribe accountability measures that ensure compliance and quality of care.

Introduction

Every day, healthcare providers and their staff face a formidable number of federal regulations. These regulatory measures are meant to protect patients from risks while they receive medical care. The main issue faced by providers and the software systems that support them when it comes to federal mandates is the immense regulatory burden. In order to manage the ever-shifting regulatory landscape and maintain compliance, clinical staff and EHR systems across the country are being pulled in a hundred different directions, each one taking valuable time away from what matters post. Patient care in the case of physicians. And improving their technology solutions in the case of the practice management systems that help those physicians do their good work.

According to an American Hospital Association (AHA) report "Regulatory Overload: Assessing the Regulatory Burden on Health Systems, Hospitals, and Post-Acute Care Providers," these clinical staff members "must comply with 629 discrete regulatory requirements across nine domains." This same report continued to detail that providers spend nearly $39 billion a year on administrative tasks and compliance.

In terms of electronic prescribing, federal, state, and DEA (Drug Enforcement Administration) requirements are all putting undue stress on organizations across the nation.

The concern is that electronic health systems have yet another tool to implement and another list of regulatory measures that they must adhere to on top of the hundreds they already have to follow. The solution to this problem is partnering with the right vendor of an electronic prescribing system. The best partnership can relieve the regulatory burdens associated with electronic prescribing for your organization.

Electronic Prescriptions for Controlled Substances (EPCS)

When it comes to the regulation of prescription drugs in the US, there are no lack of compliance measures in place. A recent study revealed that more than 131 million people, or 66 percent of adults in the United States are using at least one prescription drug. The National Institute on Drug Abuse reported that over 70,000 people died in the United States from a drug overdose in 2019. More than 36,000 of those deaths involved synthetic opioids.

Due to the growing overuse of controlled substances in the US, many states are putting mandates in place for electronic prescribing. As of January of 2021, Medicare is mandating that prescriptions for all controlled substances under Part D be transmitted electronically. At this same time, 36 US States have current, future, or pending mandates on the implementation of e-prescribing. The hope and intention of these orders are to limit the abuse of controlled substances by creating a direct digital line form prescribers to pharmacies.

Drugs, substances, and certain chemicals used to make drugs are classified within 5 categories or "schedules" depending on their medical use and level of dependency potential. The reason for these categories is that they help set the parameters for federal regulation, schedule 1 facing the strictest regulation and schedule 5 being the least regulated. Schedule 1 drugs have little to no medical use and are considered extremely dangerous (unable to be prescribed at all) where schedule 5 drugs are commonly used by doctors and only have a slight potential for abuse. Per the SUPPORT for Patients and Communities Act, as of January 1st, 2021 all drugs that fall somewhere within schedules 2-4 are required to be prescribed electronically.

The DEA regulatory requirements for EPCS include Application Certification, Identity Proofing, Two-Factor Identification, Logical Access Controls, Audit Trails & Reporting, and Timely Transmission. You can learn more about the regulatory requirements for EPCS by reading our Complete Guide to EPCS.

The best way to remain compliant with DEA standards is to form a strong partnership with an experienced vendor. They are primarily responsible for ensuring your organization remains compliant with all EPCS regulatory mandates. In fact, they should, at the time of implementation, have already simplified the process for Clinical access.

Pre-certified services allow for an expedited certification review and the completion of an EPCS DEA-mandated external audit. The solution should provide an identity infrastructure, offer an integrated suite of data services, and integrate with EHRs at a low cost.

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Prior Authorization & Real Time Benefit Tools

According to the National Council for Prescription Drug Programs (NCPDP), a prior authorization (PA) is "the process that is used to request coverage of specific medication for a specific patient."The payer is in charge of determining whether or not it will pay for the prescription. Up to this point, the PA has been primarily completed through the exchange of paper documentation. The NCPDP goes on to define an electronic prior authorization (ePA) as "the electronic transmission of information between the prescriber, and payer to determine whether or not the PA is granted."

In the past, should a patient give a prescription to their pharmacist and that prescription required prior authorization, the pharmacist would tell the patient, the patient would then notify their provider, the provider would then completed forms to send to the patient's insurance payer, and the prescription is either approved or denied for coverage. This created an extremely time-consuming process for patients who are in need of their medications.

Electronic prescribing and prior authorizations have the capability to greatly abate the regulatory burden by eliminating a few unnecessary steps.

As of December 29, 2020, CMS named an e-prescribing standard to reduce regulatory burden and speed up patient access to medications. This final rule requires that Part D prescription drug plans have a prior authorization transaction standard for their Part D programs. This feature will enable providers to see that a certain drug requires prior authorization during the prescribing process rather than after it has already been sent to the pharmacy. This final rule will not be enforced until January 1st, 2022 due to COVID-19.

This rule requires that providers implement at least one real-time benefit tool (RTBT) that integrates directly into their electronic prescribing and EHR systems. It also requires that under the ONC Health IT Certification Program, providers must include a real-time benefit tool that conveys patient-specific cost and coverage information. The new electronic prior authorization standard enables providers to initiate and manage Part D Drug approvals within their own system, rather than have the patient complete an unnecessary number of steps outside of the visit.

Now, the provider can receive prior authorization approval before sending the prescription to the pharmacist electronically, eliminating the need for the patient to run back and forth and allowing them to access their medications much easier.

The key to all of this is finding the right electronic prescribing solution for your EHR. Fully integrated electronic prescribing and EHR systems will enable providers to offer accurate, up-to-date prescription prices and authorization information. When searching for a software partner that can relieve regulatory burden, search for one that offers an integrated system and which makes accessing prior authorization tools simple and efficient.

With this ability, your prescribers can help their patients finally access the prescriptions they need safely and efficiently without having to jump through hoops.

Meaningful Use

According to The Office of the National Coordinator for Health Information Technology (ONC), in order to qualify for incentive payments through the EHR incentive programs created by CMS, eligible providers and organizations must demonstrate "meaningful use" of an electronic health record (for example electronic prescribing). Meaningful use is a list of objectives or goals that clinicians must achieve in order to benefit from the EHR incentive program. First enacted by the US Federal Government in 2009, its intent was to motivate medical professionals to adopt electronic health record technology through the use of financial incentives.

There are three stages within meaningful use which are: 1) Data Capture and Sharing, 2) Advanced Clinical Processes, and 3) Improved Outcomes. Once a voluntary opportunity, providers now face penalty should they not engage in the program. While there are many objectives that providers must adhere to, electronic prescribing is an important component of each stage. The overall goal of this program is to improve the quality of patient care through the use of health IT. The CDC has listed five goals on which the meaningful use program depends on. These goals are:

1. Reducing health care disparity by improving efficiency, safety, and quality
2. Engaging with patients and their families in their health care
3. Improving Health care coordination
4. Improving public Health
5. Protecting Patient's Personal Health Information

Stage 1

Stage one of this program focuses on the appropriate sharing and communication of data through a quality EHR. Providers must adhere to all 15 core requirements should they wish to benefit from the program and avoid penalties. Stage 1 requires physicians to prescribe 40% of medications electronically.

Stage 2

Stage 2 of meaningful use concentrates on the advanced clinical process, stressing the importance of properly exchanged patient information and care coordination. Eligible providers must meet the requirements of stage one in order to qualify for stage two. This stage has an additional 17 core objectives and 6 menu objectives. Providers must adhere to all 17 core objectives and meet at least 3 of the 6 menu objectives in order to qualify. The initiation of Stage Two is when electronic prescribing really started to rise, requiring more than 50% of prescriptions to be sent electronically.

Stage 3

The third stage, and arguably the most relevant stage when it comes to patient care is focused on the realized improvement of patient outcomes. Stage 3 has 8 required objectives that eligible clinicians must adhere to in order to avoid penalty. These 8 objectives are in addition to the objectives included in both Stages 1 and 2.

These 8 objectives are:

- Protective Health Information
- Electronic Prescribing
- Clinical Decision Support (CDS)
- Computerized Provider Order Entry (CPOE)
- Patient Electronic Access
- Coordination of Care Through Patient Engagement
- Health Information Exchange
- Public Health and Clinical Data Registry Reporting

Out of these 8 Stage 3 objectives, electronic prescribing is one that we will highlight. This objective requires eligible providers to have more than 80% of their permissible prescriptions assessed for their composition and transmitted electronically to pharmacies.

> E-prescribing allows EHRs and providers achieve meaningful use more easily by setting the necessary foundation for success. It enables organizations to easily meet the threshold of this program while also taking other steps to achieve meaningful use.

E-prescribe helps EHRs achieve meaningful use by:

- Enabling the simple prescription of controlled substances with minimal risk.
- Reduces readmission risk
- Full Insights/Alerts for Previous Medication and History
- Managing After Hours Interruptions
- Reduce Callbacks from Pharmacies
- Reduce Patient Return Visits
- Enable the Prescription of Medications Covered by Insurance
- Minimized Prescription Drug Errors

While implementing an Electronic Prescribing solution is a necessary requirement of meaningful use, providers have options when it comes to who they actually work with. Partnering with the right vendor of software can enable your practice to truly reap the benefits that come with a top-tier program. One of the biggest benefits of electronic prescribing is that it can enable providers insight into the patient's health and history, offer added safety with addictive substances, and increase security, all leading to better patient outcomes.

Interoperability

Interoperability, sometimes referred to as Health Information Exchange, is one of those terms that has boomed in healthcare over the last few years. It is defined as the ability of separate information systems, devices, or applications to access, exchange, integrate, and use data in a coordinated sense. This exchange of data should be possible across different organizations, regions, and national boundaries, making it simple to communicate information in a time-sensitive and seamless manner.

The goal of interoperability within health systems is to optimize the care that patients receive across organizations by making their PHI more accessible to authorized users. For example, if a patient's general practitioner (GP) is a part of one organization, but the patient ends up in the ER of a different one, the ER providers can still request the patient's relevant medical history should they need it.

When implemented effectively, interoperability can play an important role in the reduction of regulatory burden and administrative processes.

Interoperability in healthcare settings has three levels.

Foundational: This level enables two IT systems to communicate clearly and securely with one another. This communication is limited to pure data sharing with no advanced analysis or interpretation.

Structural: This level allows two IT systems to follow a set of requirements for format, syntax, and order of data sharing. This enables the receiving IT system to interpret the data and find the right place for it in their own system.

Semantic: The third, and highest level of interoperability in healthcare settings allows two systems to communicate information, interpret it, and use it.

As time progresses, the industry as a whole is realizing the valuable role interoperability plays in the future of healthcare.

The Interoperability Standards Advisory (ISA) process is the model in which the ONC has determined the standards and specifications for interoperability implementation across the industry. It is essentially a coordinated catalog of standards and specifications to help providers, health IT developers, and others meet their interoperability needs.

While the ISA covers a wide range of interoperability standards, one that it highlights is electronic prescribing.

There are 18 standards and specifications for electronic prescribing set by the ISA. These standards cover a broad spectrum of requirements that are intended to make the e-prescribing process uniform in nature and beneficial to providers, patients, and payers.

- Allows a Long Term or Post-Acute Care to Request to Send an Additional Supply of Medication:
- Allows a Pharmacy to Notify a Prescriber of Prescription Fill Status
- Allows a Pharmacy to Request a Change to a Prescription
- Allows a Pharmacy to Request a New Prescription For a New Course of Therapy or to Continue Therapy
- Allows a Pharmacy to Request Additional Refills
- Allows a Pharmacy to Request, Respond to, or Confirm a Prescription Transfer
- Allows a Prescriber or a Pharmacy to Request a Patient's Medication History
- Allows a Prescriber to Cancel a Prescription
- Allows a Prescriber to Communicate Drug Administration Events

- Allows a Prescriber to Communicate with a REMS Administrator
- Allows a Prescriber to Prescribe Medication Using Weight-Based Dosing
- Allows a Prescriber to Recertify the Continued Administration of a Medication Order
- Allows a Prescriber to Request, Cancel or Appeal Prior Authorization for Medications
- Allows a Prescriber to Send a New Prescription to a Pharmacy
- Allows a Prescriber to Send a Prescription to a Pharmacy for a Controlled Substance
- Allows a Provider to Request a Patient's Medication History from a State Prescription Drug Monitoring Program (PDMP)
- Allows for Communication of Prescription Information Between Prescribers and Dispensers
- Allows for the Exchange of State Prescription Drug Monitoring Program (PDMP) Data

Interconnectivity between electronic prescription and EHR technologies enables providers to monitor and track patient prescription refills, medication adherence, and usage. It helps to eliminate the risk associated with electronic prescribing.

Implementing an interoperable electronic prescribing system can also greatly reduce the regulatory burden within your organization. The right program can check off each standard and specification set by the ISA and offer even more to simplify your prescribing workflow. Interoperability does and will continue to play a vital role in the future of healthcare as a whole. Providers should find a system vendor that is both experienced in the regulatory requirements of electronic prescribing but knows how to alleviate the burden off of the shoulders of healthcare providers.

Cost Savings of Partnering with an e-Prescribe Vendor

When weighing whether or not to onboard an e-prescribe vendor, there are some valuable factors to take into consideration.

Compliance Members

Some providers invest a ton of money into staffing chief compliance officers that help to ensure their organization is adhering to every law, regulatory requirement, guideline, and best practice. This is too big a job for one individual and providers usually have to staff more than one person to cover multiple different areas of importance. By onboarding an e-prescribe vendor, your organization can bypass the need for this role as it pertains to electronic prescribing.

Penalties for Noncompliance:

As mentioned earlier, should your organization fail to adhere to the regulatory requirements, laws, guidelines, and best practices associated with e-prescribing, you may face costly financial penalties. The only way to avoid these costs is to remain 100% compliant. By onboarding an e-prescribe vendor, your organization will not have to question whether or not it is remaining compliant and will never have to worry about penalty costs.

Certified systems that do a great job of remaining up to date on all e-prescribing regulatory requirements from meaningful use to interoperability can relieve the regulatory burden from your organization. The vendor takes on the responsibility of keeping your organization compliant while your team focuses their energy on what matters most, patient care.

To learn more about an e-prescribe system vendor that can help relieve regulatory burden in your organization, click here.

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About NewCrop

NewCrop LLC provides electronic prescribing systems, delivered over the Internet and designed for incorporation into electronic medical records. All features are available as a comprehensive user interface or, via data services, as individual components. EPCS is available, as well as all interconnectivity requirements for Meaningful Use Stage 2.

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