Trends in ePrescribing Regulation & Legislation

Trends Impacting Near-Term Product Road Maps

September 17, 2019

Point•of•Care PARTNERS | HEALTH IT MANAGEMENT CONSULTANTS

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Agenda

✓ Understand How Prescribing is Regulated

✓ Major Federal Legislation and Impacts

✓ Key State Legislative Activities

✓ Overview of Long-Term, Post-Acute Care Regulations

✓ Key Trends Impacting EHR Design

✓ What does the future hold?

How well do you stay on top of state regulations?

❑ I do a great job staying on top of state regulations on my own

❑ I sort of stay on top of things

❑ I have a team that monitors state regulations

❑ I wait until providers tell me of changes

❑ I purchase a service that helps me stay on top of things

Presenters

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Governance of Prescribing Processes

- **States** govern prescriptions with many agencies, statutes and rules
- DEA only governs controlled substance prescriptions

State Board of Pharmacy

State Board of Medicine

State Board of Nursing

State Controlled Substances Authority

State Medicaid Agency

DEA
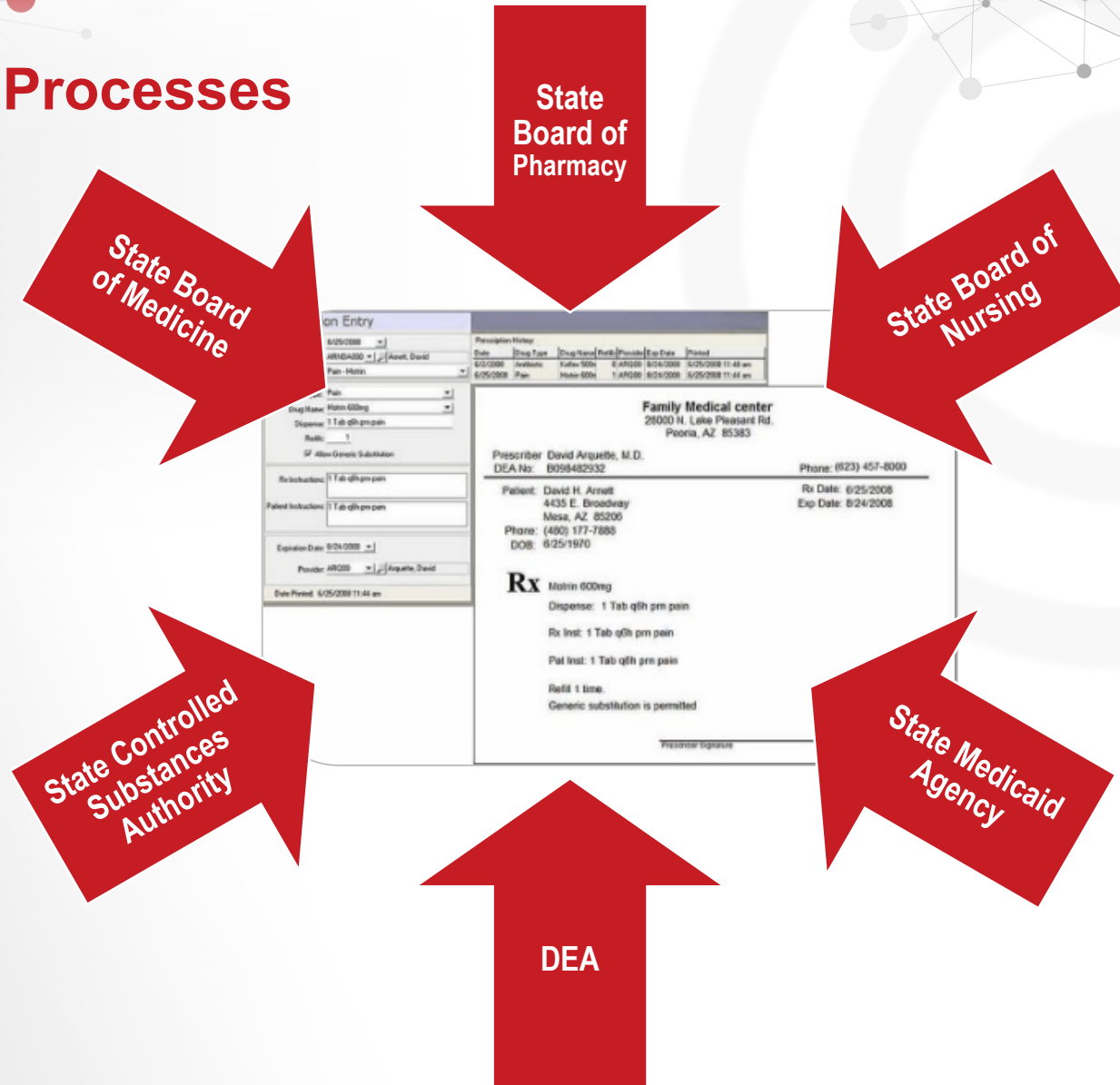
Prescriber challenges

Because there are so many variables, it's challenging for prescribers to keep up to date on the state and federal mandates

- Providers tend to interpret laws themselves, or ask a friend

Calls come to the EHR vendor after a call, letter or visit from the pharmacy board

Noncompliant ePrescribing

Risks

Dissatisfied customers and reduced confidence in your solution

Lost opportunity to use development staff to create new value for customers

Staff time expense – help desk calls, routine software updates, emergency "hot fixes"

Stakes are getting higher as new mandates have significant impact on EHRs and prescribers due to penalties for noncompliance

Estimated Cost of Missed Regulatory Changes

Based on costs incurred by representative mid-size EHR company

Help Desk Calls

$18,000

- 1 call/month for each customer
- 1% (5) are related to missed regulatory issues
- Each regulatory call requires 3 hours of staff time for call time, triage and research

Hot Fixes

$50,000

Each hot fix to address major missed regulatory changes takes *5 hours per customer* and involves:

- Product Management Team
- Development Team
- Q/A
- Distribution
- Installation

Intangible Costs

$$$

Cannot be quantified

- ***Customer Satisfaction:*** Physicians are legally liable for their prescriptions. If their software is not current, vendors risk customer dissatisfaction and possible loss
- ***Opportunity Cost for Hot Fixes:*** EHR staff not involved in hot fixes can allocate their time to other essential, revenue-generating work

*Assumptions: 500 customers nationwide. A blended stall costs of $100/hour is used for all calculations.

Up-to-Date Compliant ePrescribing

Benefits

Proactive vs. reactive

Improved brand reputation

Higher degree of customer confidence

Eliminate the last minute scramble to meet unexpected regulatory requirements

Incorporate regulatory changes as part of normal product development

Poll Question

In the last 2 years, has your company had to roll out a patch or hot fix in order to comply with an enacted regulation or rule?

❏ Yes

❏ No

Traditional Regulatory Trends Affecting EHRs

There are 485+ federal and state requirements that impact EHR prescribing compliance

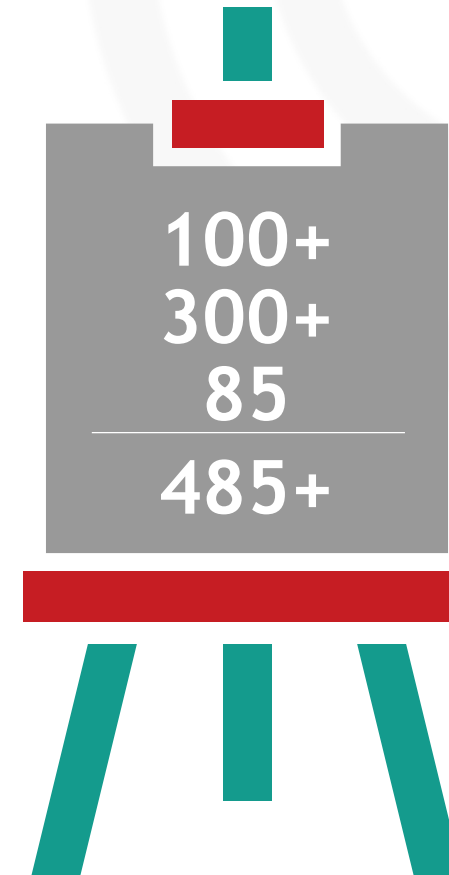**PRESCRIBING**

100+

Who can
prescribe what?

FORMATTING

300+

Printing
Specifics

DELIVERY

85

How does it get
there?

100+
300+
85
485+

Federal Legislation Highlights

ENACTED

H.R .6, SUPPORT for Patients and Communities Act
- Effective **1/1/2021**
- Mandates EPCS and ePA for Part D covered drugs

 CMS-4180-F Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses
- Effective **1/1/2020 and 1/1/2021**
- Final rule requires use of the real-time benefit check for Part D Sponsors by 1/1/2021

PROPOSED

CMS 4189-P Medicare Program; Secure Electronic Prior Authorization for Medicare Part D
- If finalized, will require ePA, based on the NCPDP SCRIPT 20170701, beginning on **1/1/2021**

PROPOSED

21st Century Cures Act: Interoperability, Information Blocking, ONC Health IT Certification (ONC Cures Act)
- Requires use of APIs, FHIR and Standards for health IT certification

CMS-9115-P CMS Interoperability and Patient Access Proposed Rule
- Comments through early June
- Requires payers to share claims data through APIs and support electronic exchange of data for transitions of care

CMS-1718-P FY 2020 SNF Payment & Policy Changes
- Focused on meaningful use quality measures
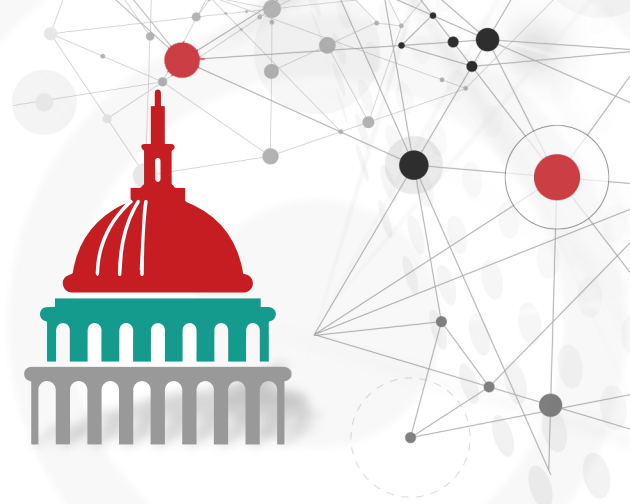
State Action (As of August 2019)

ELECTRONIC PRESCRIBING of CONTROLLED SUBSTANCES (EPCS)

28 states have current or pending **EPCS LEGISLATION**

ELECTRONIC PRIOR AUTHORIZATION

32 states have current or pending **ePA LEGISLATION**

14 require support for ePA transaction

15 specify NCPDP standard

PRESCRIPTION DRUG MONITORING (PDMP)

44 states require prescribers access their PDMP before prescribing **CONTROLLED SUBSTANCES**

Some states are sponsoring or requiring access via EHRs and others are sponsoring access via their HIE

44 states have controlled substance (CS) **SCHEDULE VARIANCES**

37 states have **CS LIMITATIONS**

States are ramping up on rules governing controlled substance prescribing including new limits on prescribing e.g. days' supply maximums; limits by prescriber type

States are requiring additional data, such as diagnosis, on the prescription

OPIOID CRISIS

State Action: Technology Solution

Prescription Drug Monitoring Programs

- State-run databases of dispensing records for Controlled Substances
  - Pharmacies and dispensing prescribers submit records
- Historically, PDMP utilization has been optional for clinicians

Challenge for compliance is clinicians exiting EHR workflow to access web-based PDMP

State Prescription Drug Database

Dispensing Prescriber

Pharmacy

Profile → Pharmacy Prescriber

Profile → State Board Law Enforcement
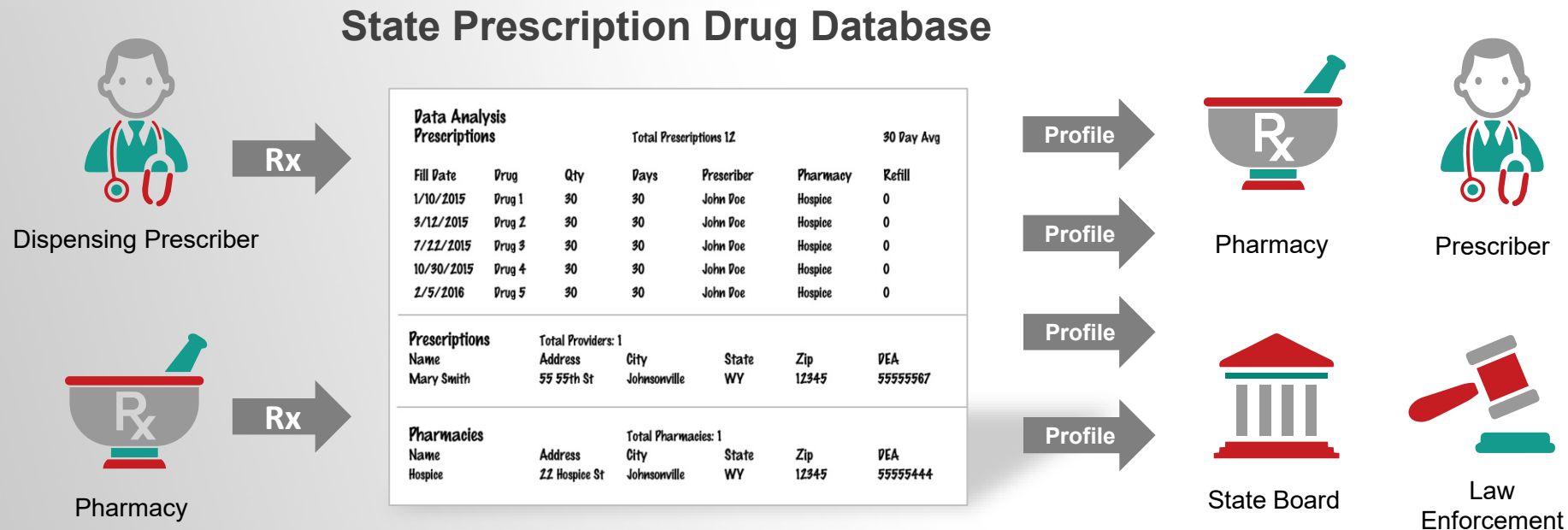
Regulatory Trend:
States Addressing PDMP EHR Workflow Integration

44 states require PDMP access prior to prescribing of some or all controlled substances.

To improve access, states are requiring **PDMP Integration** through EHRs and/or HIEs supporting

- Allowing data sharing with EHRs
- Encouraging integration into prescriber workflow
- Interface from EHR to PDMP required
- Certification that EHR displays PDMP data in prominent manner required
- Documentation of PDMP review in Medical Record

Prescriber PDMP Access Required

July 2019

All Controlled Substances

Some Controlled Substances

Not Required
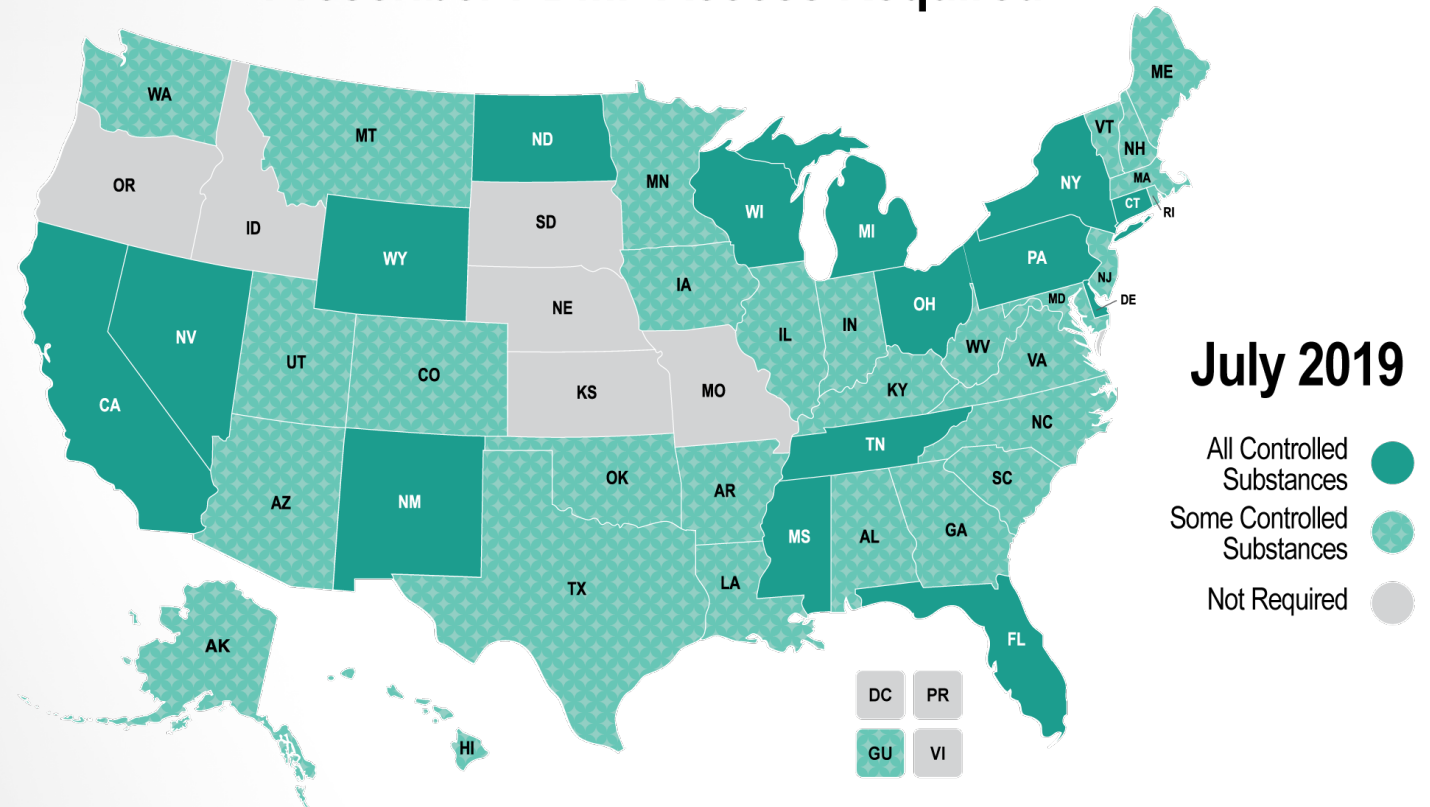
Regulatory Trend: Pharmacy Electronic Prior Authorization

Rx ePA specified in 32 states
- 14 Require/mandate payers to support ePA
- 15 specify NCPDP standard

Only NJ, IA and IL have pending ePA bills now

Pharmacy ePrior Authorization Laws

July 2019

Required ● (Red)
Allowed ● (Teal)
Proposed ● (Gray hatched)
No Information ● (Light gray)

Regulatory Trend: Medical Electronic Prior Authorization
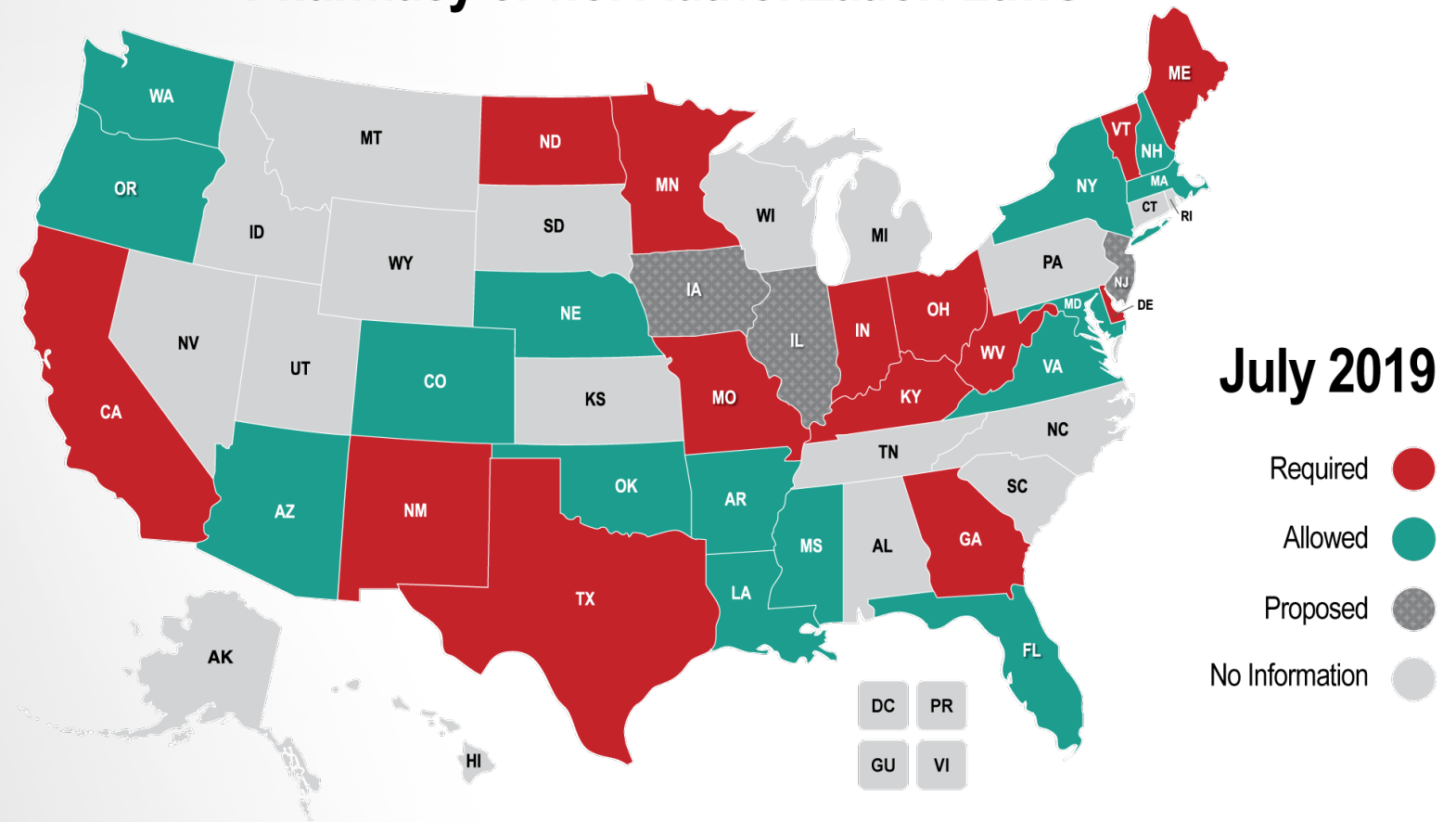
Medical Prior Authorization Laws

July 2019

Required — 🔴

Allowed — 🟢

Proposed — ⬤

No Information — ⬜

Upcoming State and Federal Deadlines: Mandatory ePrescribing

5/1/2019
1 State:
EHR vendor must comply

1/1/2020
6 States, including
1 for all CS &
Legend Drugs

7/1/2021
1 State: All Opioids;
1 State: All CII - IV

1/1/2022
1 State: All CS &
Legend Drugs

Currently 5 states have mandatory ePrescribing rules in effect.

10/24/2019
1 State; All CS

7/1/2020
1 state, requires EPCS

1/1/2021
H.R. 6 mandates
EPCS for Part D
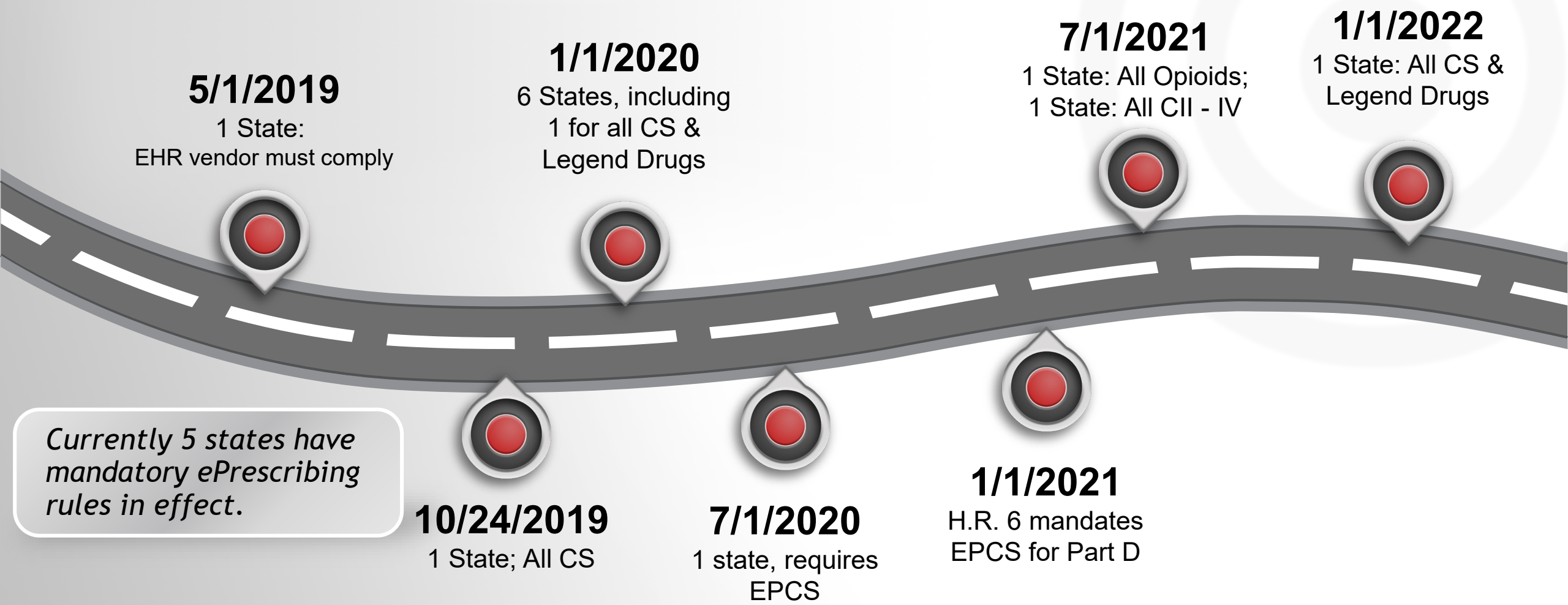
EHR Impacts:

Each Trend Has An Impact On EHR Design

- Mandated EPCS
- Mandated PDMP
- Mandated ePA

EHR

- SCRIPT 2017071 – January 1, 2020
- Real-Time Pharmacy Benefit Check
- RxChange
- RxFill

EHR Value

Poll Question

Would your organization be affected if existing exemptions for non-hospital care settings such as long-term post-acute care environments if they were rescinded?

❑ Yes

❑ No

Long-Term, Post-Acute Care

Highlights from POCP's LTPAC State Navigator issued in July 2019

- Exceptions and exemptions for long-term, post-acute care environments:
  - Prescription Drug Monitoring Programs
    - Some states do not require controlled substance prescriptions for residents of nursing homes to be reported to the PDMP
  - Electronic Prescribing of Controlled Substances
  - CS Limitations
    - Hospice patients and those with terminal illnesses have relaxed rules on prescribing and dispensing opioid quantities and partial fills
  - Prescribing Authority

POCP is monitoring and documenting wherever there are LTPAC deviations and developments at the NCPDP LTPAC Work Group.

What's Next?

Ongoing whirlwind of legislation, state and federal

- ePrescribing & ePA mandates
- Stronger PDMPs with mandated utilization
- Restrictions on opioid prescriptions
- Opioid and Benzodiazepines coadministration

Interoperability

- PDMP
- Real Time Benefit Inquiry
- 30 day medication reconciliation (Da Vinci Project)
- Medication reconciliation in transitions of care

Specialty Medication prescribing increases

ePrior Authorization gains traction

Trending

- Artificial Intelligence (AI)
- ePrescribing in Long Term Care & Post Acute Care
- Privacy & Security

Conclusions

- Prescribers are dependent upon their EHR vendors to proactively support regulatory requirements

- States will continue to regulate in different ways than Federal requirements

- EHR compliance in a rapidly changing regulatory environment is critical

- Anticipating regulatory impact enables concise product planning to enable cost effective EHR enhancements

Persistent Monitoring Ensures Compliance

ePrescribing solutions providers must diligently monitor legislative activities at state and federal levels to avoid non-compliance risks

Persistent Monitoring Ensures Compliance

Regulatory Resource Center Solutions:

- ePrescribing State Law Review
- ePA State Navigator
- LTPAC State Navigator
- ePrescribing State Law On-Demand

INDUSTRY REPORT
ePA's Real Benefits

https://www.pocp.com/downloads/ePAReport

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- Point-of-Care Partners can help
- Contact us at regulatory@pocp.com

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ePRIOR AUTHORIZATION'S REAL BENEFITS:
Reducing Frictional Costs and Speeding Time to Therapy

May 2019

A Point-of-Care Partners
Analysis, Trends, and
Action (ATA) Report

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Thank You

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