Keeping Pace with ePrescribing Regulatory Compliance

Trends Impacting Near-Term Product Road Maps

February 20, 2019

Point·of·Care PARTNERS | HEALTH IT MANAGEMENT CONSULTANTS

GoToWebinar Logistics

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

✓ Crystal Ball – What Might be Next?

Poll Question

Does responsibility for ePrescribing regulatory compliance fall on an individual or a department?

❑ Individual

❑ Department

Presenters

Keith Fisher, R.Ph.

Co-Editor, Regulatory
Resource Center
Point-of-Care Partners

Michael Burger

Practice Lead,
EHRs and EDI
Point-of-Care Partners

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
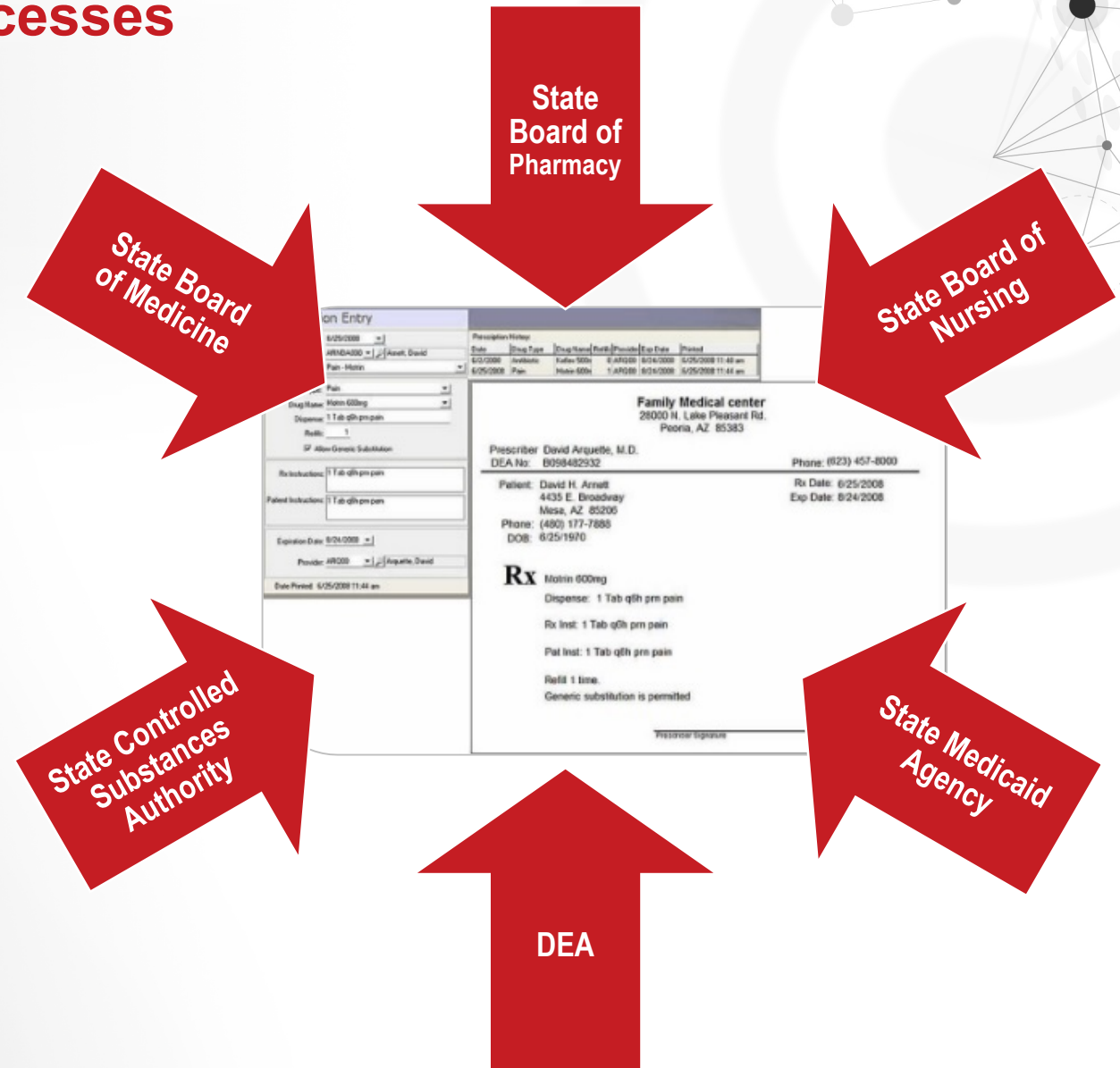
Noncompliant ePrescribing

Risks
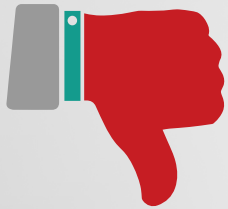
Dissatisfied customers and reduced confidence in your solution
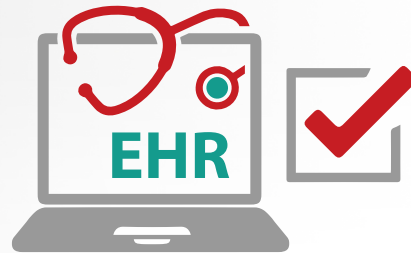
Lost opportunity to use development staff to create new value for customers

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 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

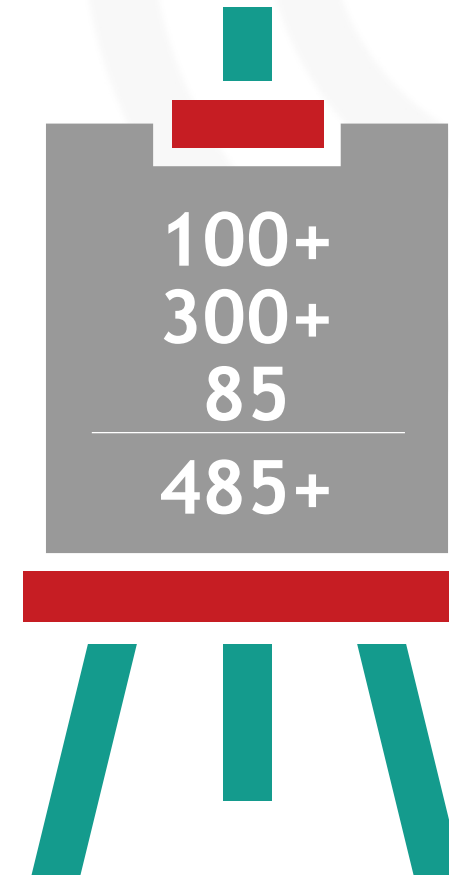**PRESCRIBING**

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

Indications-Based Formulary Design
Effective **CY2020**
CMS Action for Part D Sponsors

PROPOSED

Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses
- Effective **1/1/2020**
- Proposed rule to require use of the real-time benefit check for Part D Sponsors
- POCP Comments

PROPOSED

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

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

State Action (As of December 2018)

ELECTRONIC PRESCRIBING of CONTROLLED SUBSTANCES (EPCS)

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

ELECTRONIC PRIOR AUTHORIZATION

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

14 require support for ePA transaction

11 specify NCPDP standard

PRESCRIPTION DRUG MONITORING (PDMP)

41 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

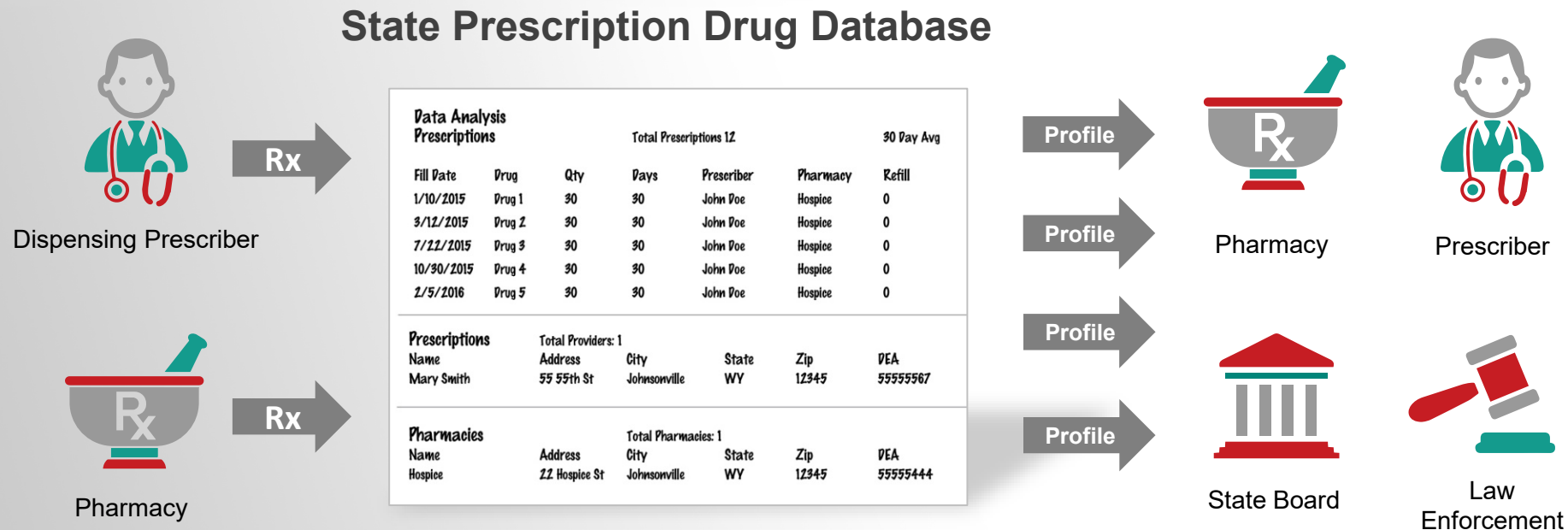States are requiring additional data, such as diagnosis, on the prescription

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 → Rx

Pharmacy → Rx

Data Analysis
Prescriptions   Total Prescriptions 12   30 Day Avg

Fill Date	Drug	Qty	Days	Prescriber	Pharmacy	Refill
1/10/2015	Drug 1	30	30	John Doe	Hospice	0
3/12/2015	Drug 2	30	30	John Doe	Hospice	0
7/22/2015	Drug 3	30	30	John Doe	Hospice	0
10/30/2015	Drug 4	30	30	John Doe	Hospice	0
2/5/2016	Drug 5	30	30	John Doe	Hospice	0

Prescriptions   Total Providers: 1
Name	Address	City	State	Zip	DEA
Mary Smith	55 55th St	Johnsonville	WY	12345	55555567

Pharmacies   Total Pharmacies: 1
Name	Address	City	State	Zip	DEA
Hospice	22 Hospice St	Johnsonville	WY	12345	55555444

Profile → **Pharmacy**   **Prescriber**

Profile → **State Board**   **Law Enforcement**

Regulatory Trend:

States Addressing PDMP EHR Workflow Integration

- Removing barriers
  to access
  - Allowing data sharing with EHRs
  - Encouraging integration into prescriber workflow
  - Interface from EHR to PDMP required by 1/1/2021 in one state
  - Another state requires EHR to be approved and to display PDMP data in prominent manner
  - In 3 states, prescribers must document viewing of PDMP in Medical Record

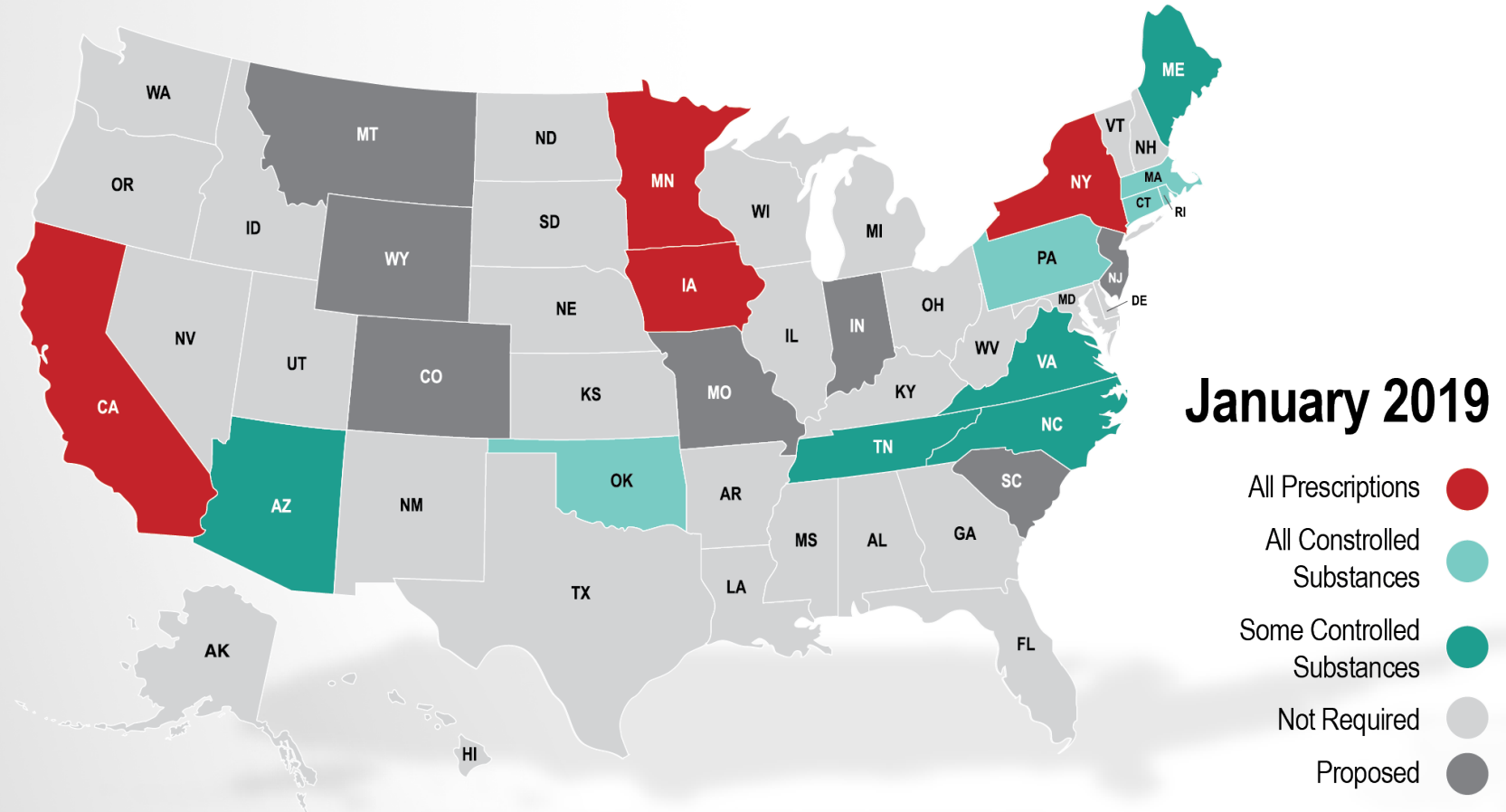*As of January 2019, 25 states supported or required PDMP Integration through EHRs and/or HIEs*

Prescriber PDMP Access Required
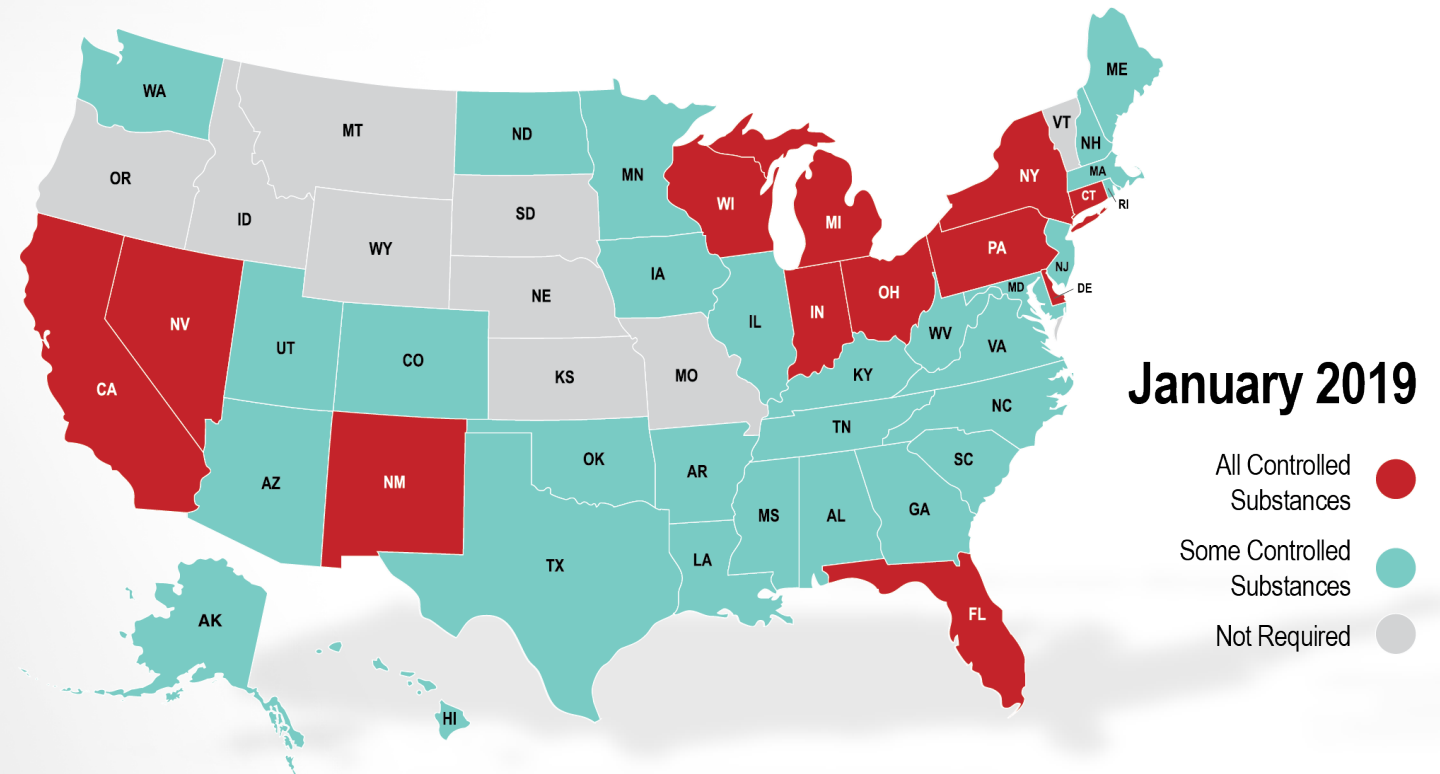
January 2019

All Controlled Substances

Some Controlled Substances

Not Required

Upcoming State and Federal Deadlines: Mandatory ePrescribing

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

10/24/2019
1 State

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

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

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

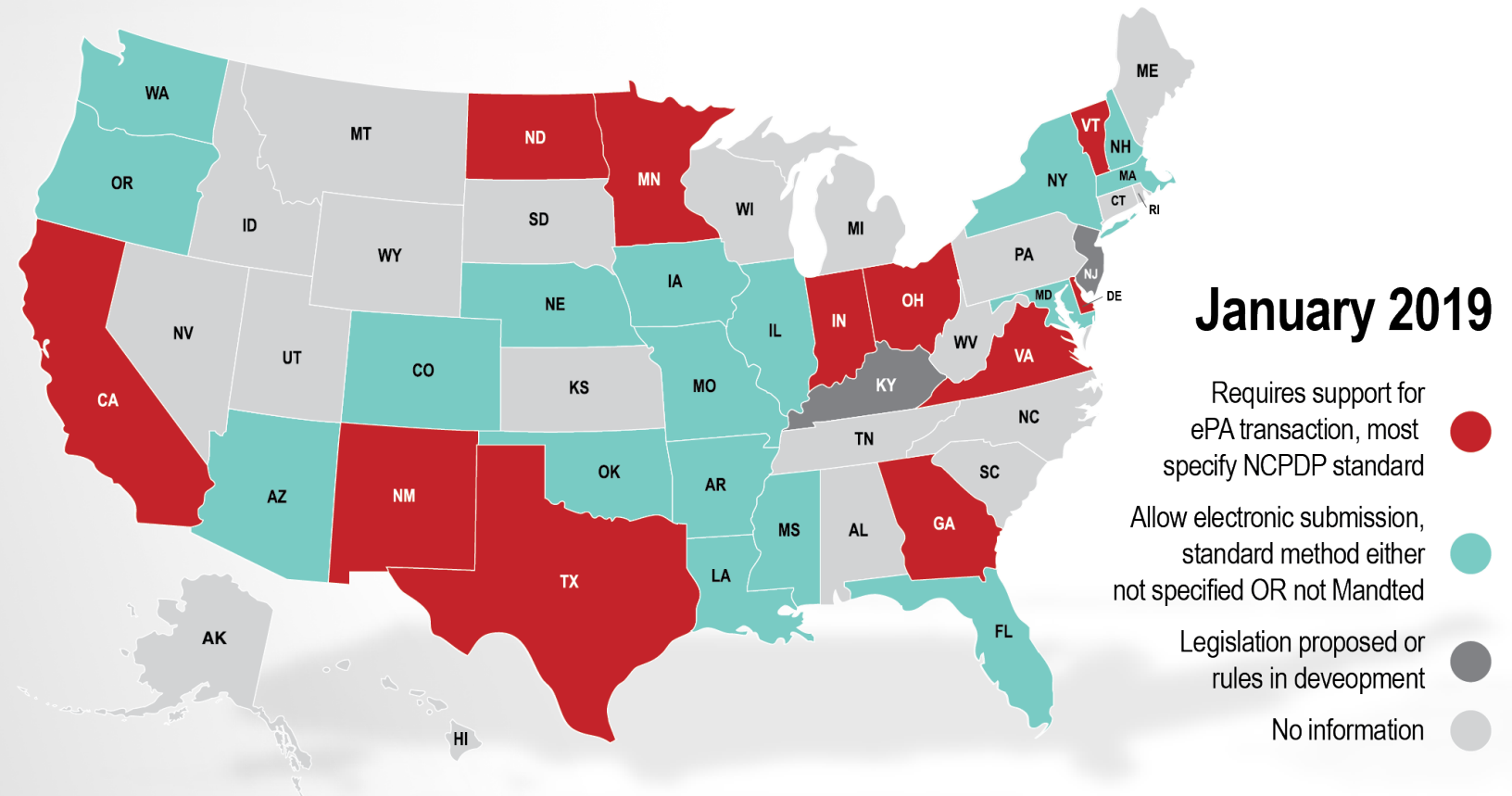*In addition, 5 states have mandatory ePrescribing rules in effect.*

Regulatory Trend: Pharmacy Electronic Prior Authorization

Rx ePA specified in 11 states
- Require payers to support ePA
- 1 state requires providers to use ePA

Renewed focus on Medical PA – specialty medications

Pharmacy ePrior Authorization Laws

January 2019

Requires support for ePA transaction, most specify NCPDP standard ●

Allow electronic submission, standard method either not specified OR not Mandted ●

Legislation proposed or rules in deveopment ●

No information ●

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

Does your organization have plans to offer software solutions in non-hospital care settings such as long-term, post-acute care environments?

❑ Yes

❑ No

Long-Term, Post-Acute Care

Highlights from POCP's LTPAC State Navigator issued in January 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
- Price Transparency at point of care
- Real Time Benefit Inquiry
- 30 day medication reconciliation (Da Vinci Project)

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

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

Thank You

Keith Fisher, R.Ph.

keith.fisher@pocp.com

Michael Burger

michael.burger@pocp.com

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www.pocp.com

@pocpHIT

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