EHR Game Changers: New ePrescribing Regs On Horizon!

Trends Impacting Near-Term Product Road Maps

Point•of•Care PARTNERS | HEALTH IT MANAGEMENT CONSULTANTS

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Presenters

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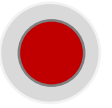Director, Regulatory Resource Center
Point-of-Care Partners

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Objectives

- Understand How Prescribing is Regulated

- Identify Key Trends that Impact EHR Design
  - Historical and Ongoing Trends
  - Opioid Crisis
  - Biosimilar Substitution Laws
  - Electronic Prior Authorization

- Crystal Ball – What Might be Next?

Governance of Prescribing Processes

- States govern prescriptions with many agencies, statutes and rules.

- DEA only governs controlled substance prescriptions
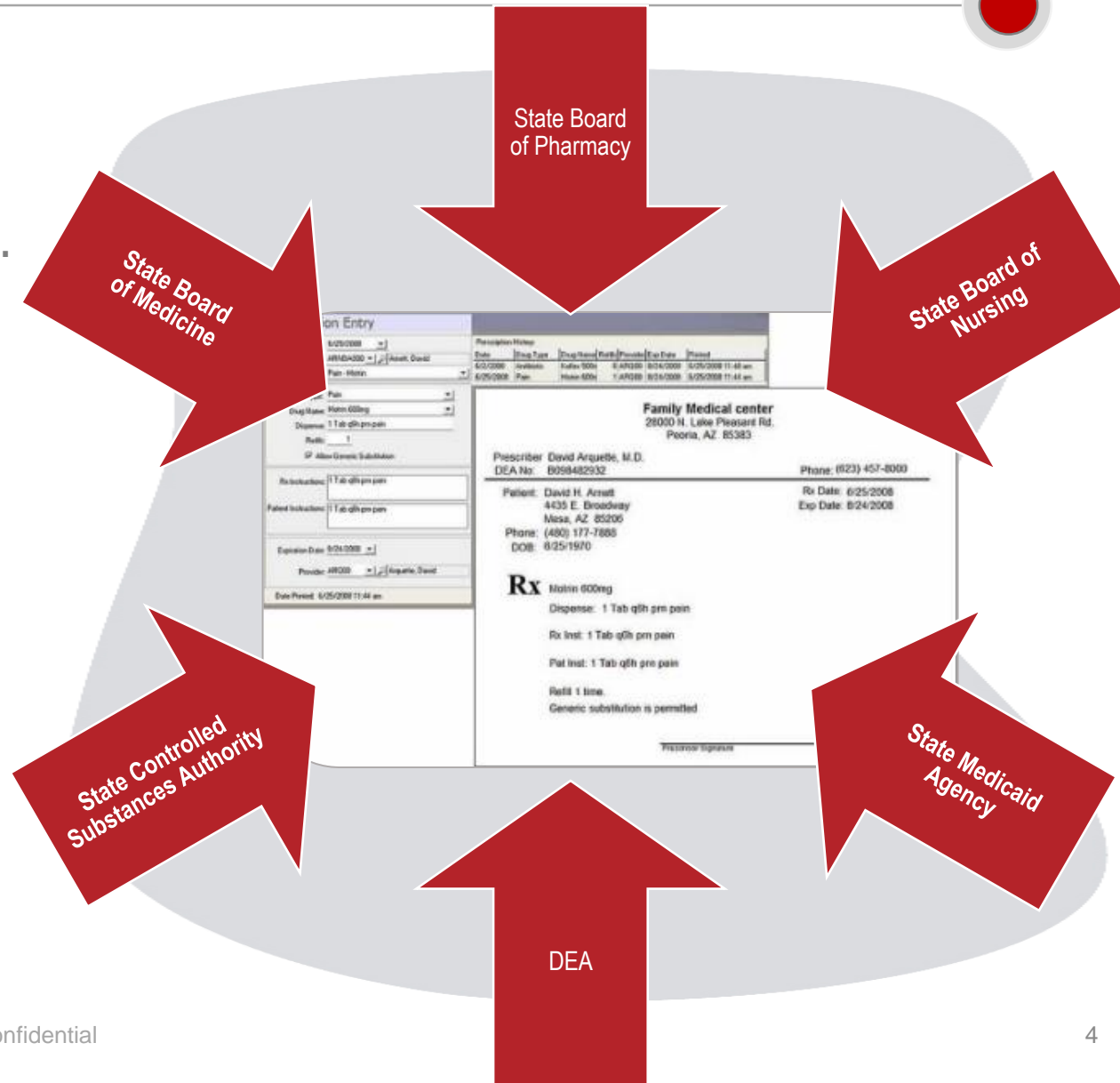
Noncompliant ePrescribing

Risks

- Dissatisfied customers and reduced confidence in your solution

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

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

Stakes are getting higher as new mandates have significant impact on EHRs, and penalties for prescriber noncompliance

Up-to-Date Compliant ePrescribing
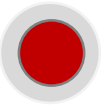
Benefits

- 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

Traditional Regulatory Trends Affecting EHRs

- There are 417+ federal and state requirements that impact EHR prescribing compliance

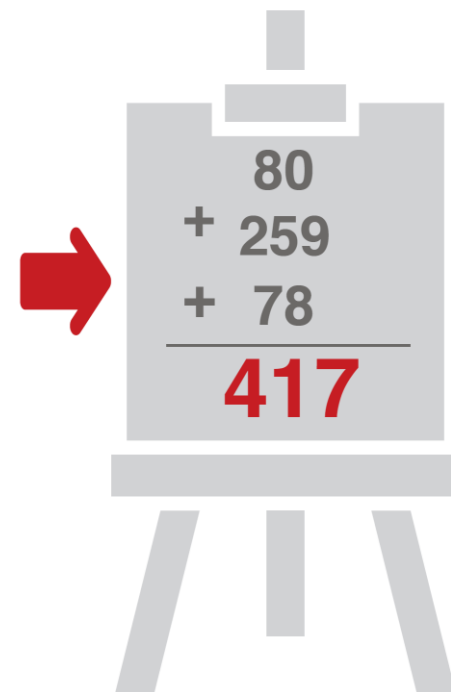## PRESCRIBING
80

Who can prescribe what?

FORMATTING
259
Rx

Printing specifics

DELIVERY
78

How does it get there?

$$80 + 259 + 78 = 417$$

States Respond to Recent Trends

Evolving Technology

- EHR
- HIE
- Telemedicine
- Security
- Mobility

Opiate Crisis

- Diversion prevention methods
- Prescriber mandates

Prior Authorization Reform

- Electronic PA
- Standard forms
- Formulary PA requirements

Biosimilar Substitutions

- Prescriber notification via EHR

Each state independently enacts laws and rules to address state-specific and federal demands.

Trend:
The Explosive Opioid Abuse Crisis

- Since 1999, the following statistics have *quadrupled*:

  - Prescription opioids sales but without an overall change in the amount of pain reported.

  - Deaths from prescription opioids – drugs like oxycodone, hydrocodone, and methadone.

  - 165,000 people have died from *prescription* opioid overdoses.[1]

On an average day in the U.S.:

650,000+

opioid prescriptions are dispensed

78

people die from an opioid-related overdose

Source: FACT SHEET: The Opioid Epidemic - By The Numbers. HHS.gov. http://www.hhs.gov/opioids/about-the-epidemic/index.html#. Published June 15, 2016. Accessed August 1, 2016.
[1] Centers for Disease Control and Prevention. http://www.cdc.gov/drugoverdose/data/overdose.html. Accessed August 10, 2016.

Opioid Epidemic: The Economic Impact

Perspective

The cost of opioid abuse is greater than the state budgets for Alaska, Delaware, Idaho, Iowa, Maine, Mississippi, New Hampshire, Oklahoma, Rhode Island, South Dakota, and *combined.*[1]

$55 billion in health and social costs related to prescription opioid abuse each year.

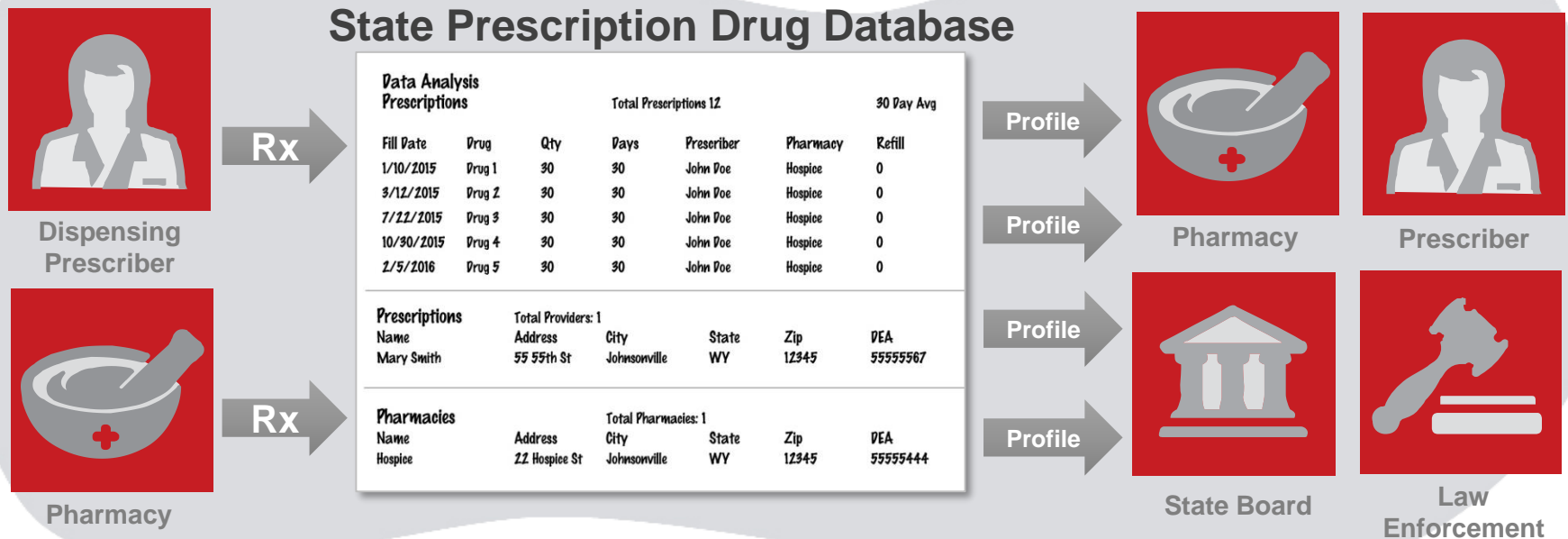**$20 billion** in emergency department and inpatient care for opioid poisonings.

Technology Success Story:
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

State Prescription Drug Database

Dispensing Prescriber

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

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

Profile

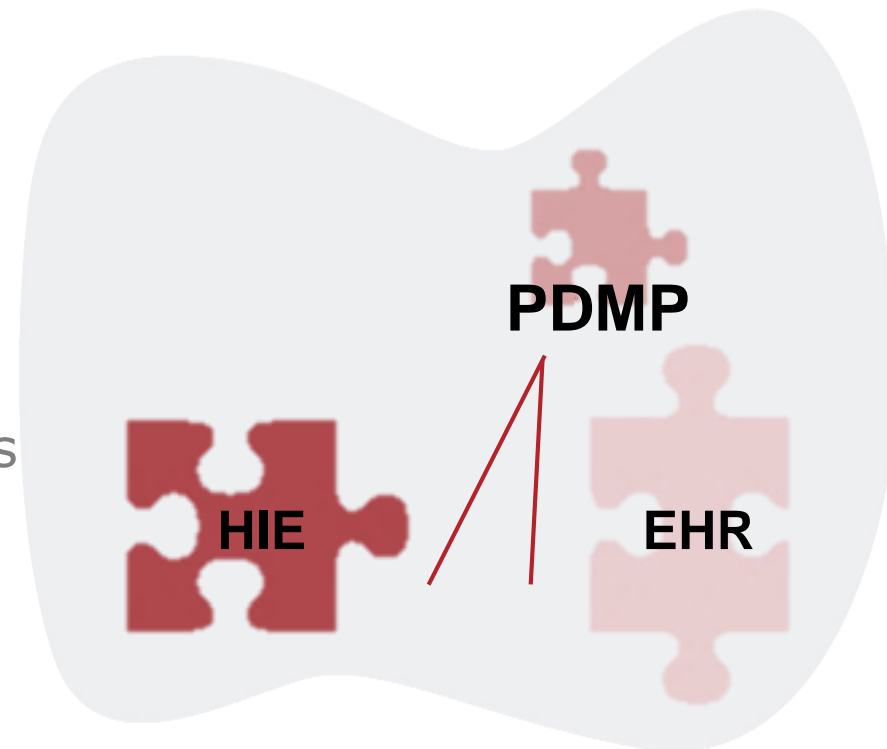# Federal Action:
Comprehensive Addiction and Recovery Act (CARA)

- Enacted 7/22/2016

- Reauthorizes National All Schedules Prescription Electronic Reporting Act (NASPER)
  - Grants to state PDMPs
  - New focus on Interoperability, ePrescribing, HIEs, EHRs
  - PDMP into the workflow

- Mandates VA facility prescribers to query the PDMP

PDMP

HIE

EHR

Federal Action:
Prescription Drug Monitoring Act of 2016 - PENDING

- Senate Bill 3209 Introduced 7/13/2016

- Within 2 years of enactment, all states to

  - Mandate pharmacists and prescribers to access the PDMP

  - Require dispense records to be reported to PDMP within 24 hours

  - Share data between states via a single hub
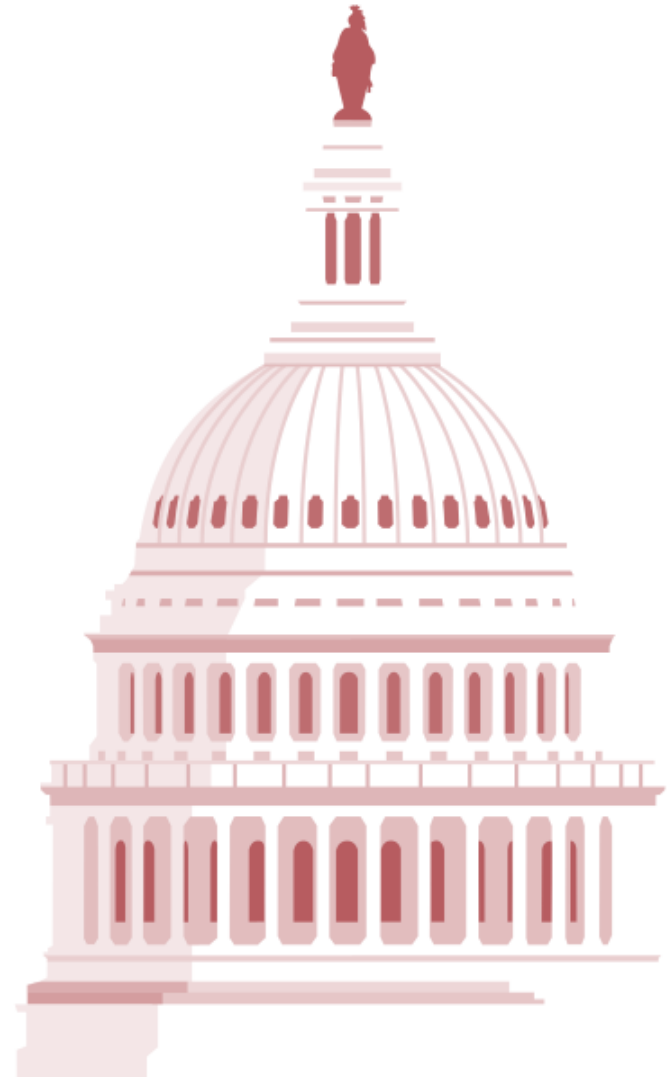
Regulatory Trend:
States Addressing PDMP EHR Workflow Integration

- States are removing barriers to access
  - Allowing data sharing with EHRs
  - Encouraging integration into prescriber workflow

- States are mandating prescriber utilization
  - Requiring registration for PDMP access
  - Requiring access before prescribing

Missouri

- For all Controlled Substances
- For Some Controlled Substance Prescriptions
- Not Required
- No PDMP
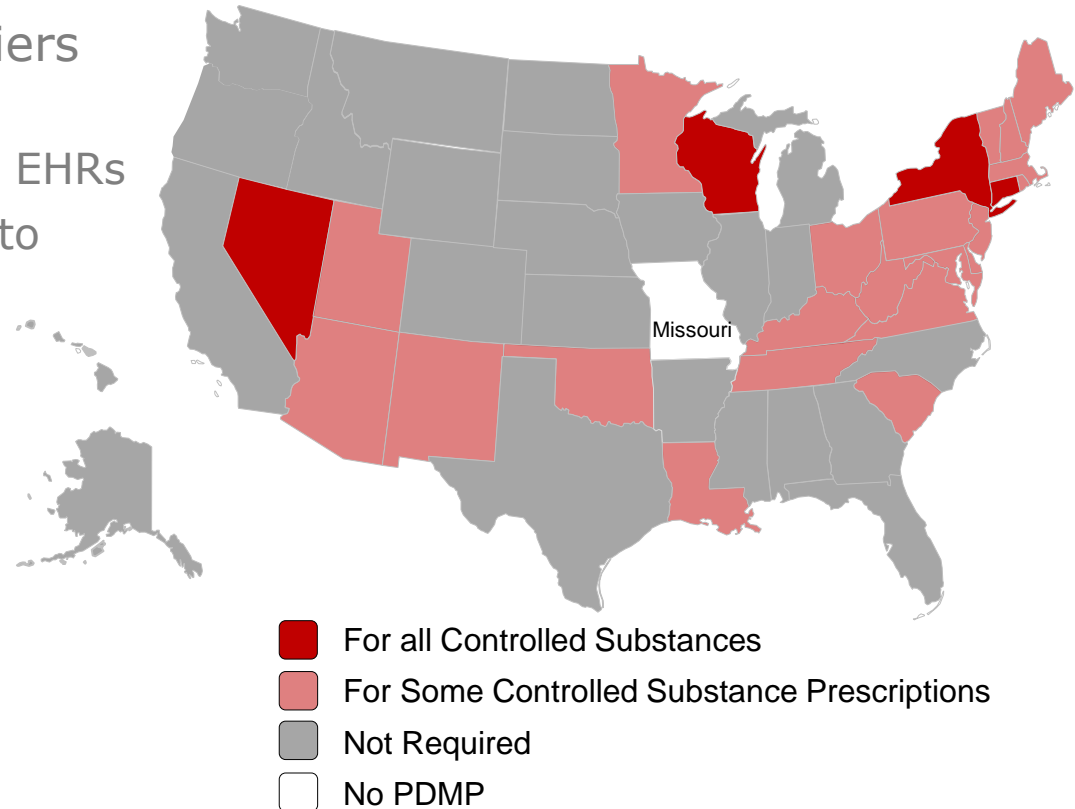
25 states now require prescribers to view the PDMP when prescribing specified controlled substances

EHRs Can Be Part of the Solution

- Improving Prescriber access to PDMP is a key strategy to reduce abuse

- Access outside the prescribing workflow is a hindrance to utilization

"Most primary care physicians are aware of PDMPs, but many find the data difficult to access." Health Affairs March 2015

Integrated PDMP Access:
Successfully Piloted

- ONC PDMP and Health IT Integration Pilot Programs
  - Chartered to identify and resolve barriers to interoperability
  - Executed use cases for integrated access to PDMPs via EHRs in pilot setting
  - Used NCPDP SCRIPT
  - Connected to States and Hubs

- EHRs participants include Epic, NextGen and Dr. First

- Wrapping up and reporting out now
  - Tweaks identified
  - Some are production ready

The Office of the National Coordinator for
Health Information Technology

The S&I Framework is a collaborative community of participants from the public and private sectors who are focused on providing the tools, services and guidance to facilitate the functional exchange of health information.
Learn more at www.siframework.org

Regulatory Trend:
States Mandating New Prescribing Methods and Limits

- ePrescribing Mandates such as New York, Minnesota and Maine

- Widely varying prescribing limits

C-II Expiration

New York

< 7 Days Supply

Minnesota

eRX Required

Maine

EHR defaults
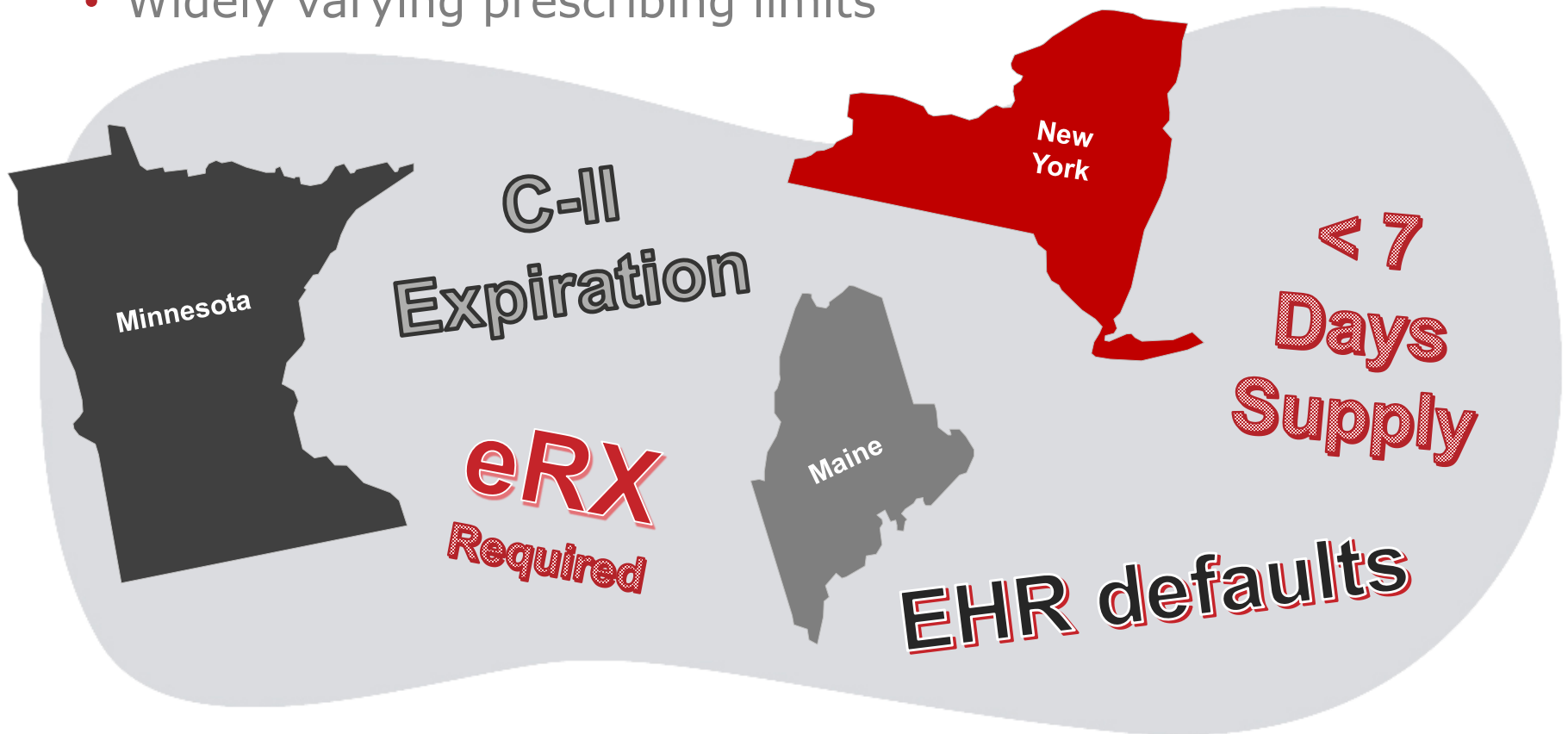
Regulatory Trend:
States Mandating New Prescribing Limits and Methods

STATES ≠ DEA

30 = ✉

🚫 **OPIATES**

- State schedule variances
  - States placing drugs in different schedules than DEA
  - Impacts EPCS pathway for drugs not scheduled by DEA

- Partial filling of C-II's allowed, with electronic notification back to prescriber (enacted)

- Requiring Non-Opiate Directive forms to be stored in the "interoperable EHR" (enacted, rules TBD)

Regulatory Trend: Biosimilar Substitution

At state level:

- New laws/regulations for biosimilar substitutions
  - Amending generic substitution rules to accommodate biosimilars

- 26 states are considering or have passed legislation establishing standards

It's all about patient safety

Physician notification of pharmacist substitution is required.

The EHR Challenge:
Pharmacy Notification to Prescriber
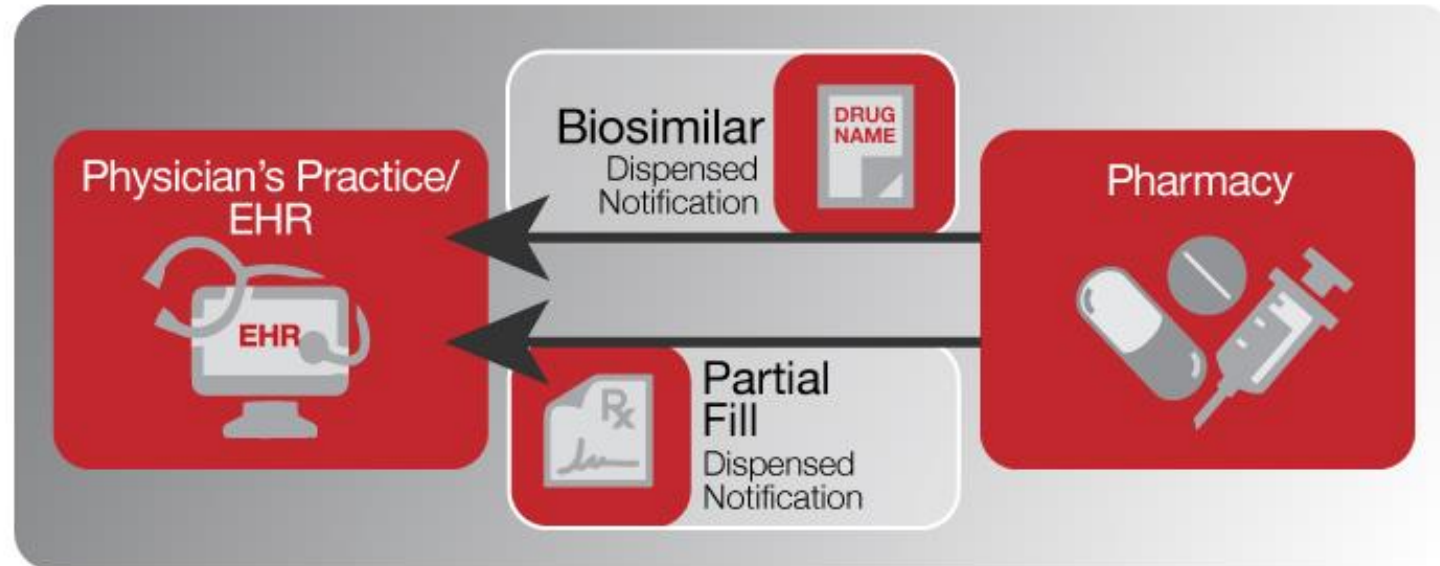
Biosimilars

- 22 states require physician to be notified of biologic dispensed via "interoperable EHR"

Controlled Substances

- Massachusetts allows patients to request partial dispensing of opioid prescription
  - Remainder of the prescription voided
  - Pharmacist must notify prescriber of amount actually dispensed

Potential Solutions:
Pharmacy-to-Prescriber Notification

Medication History

Pros:

- Supported today by all EHRs, EDI Networks, most payers and *some* pharmacies (for cash prescriptions)

- Financial model (for transactions) established

Cons:

- Delivered on demand, generally at time of visit

- Contains snapshot of active medications; may not include all fills

- Primary data source is payer; may not include cash prescriptions. Does not include drugs covered by medical benefit or info from non-participating payers or pharmacies

Potential Solutions:
Pharmacy-to-Prescriber Notification

Rx Fill

Pros:

- Delivered unsolicited at each fill
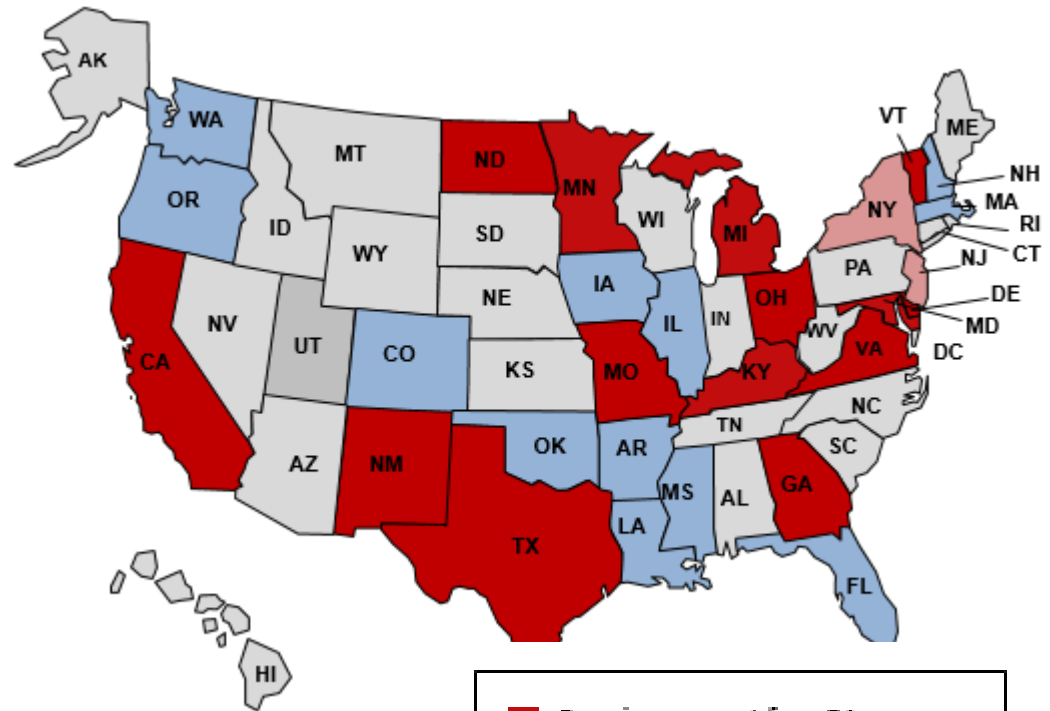
- Data source is pharmacy; every fill is captured

Cons:

- Not supported today by EHRs, Pharmacies or EDI Networks

- Financial model (for transactions) TBD

Regulatory Trend: Electronic Prior Authorization

- ePA specified in many states
  - 14 states require payers to support ePA
  - 1 state requires providers to use ePA

14 States Have ePA Mandates

Legend:
- **Require support for ePA transaction, most specify NDPDP standard**
- **Require electronic submission, standard method either not specified OR not mandated**
- **Legislation proposed or rules in development**

Poll Question

WHICH OF THE FOLLOWING REGULATORY TRENDS ARE ON YOUR PRODUCT ROAD MAPS?

❑ PDMP Access Integration

❑ Electronic Prior Authorization

❑ Controlled Substance Prescribing Limits

❑ Biosimilar Substitution

What's Next?

Ongoing whirlwind of Opiate legislation, state and federal

- ePrescribing mandates
- Stronger PDMPs with mandated utilization
- Restrictions on opiate prescriptions

Interoperability mandates

- PDMP
- HIE

Biosimilar trend continues

ePrior Authorization gains traction

Other trends unrelated to ePrescribing

- Telemedicine
- Privacy

Conclusions

✓ EHR regulatory support is critical for EHR success

✓ Prescribers are dependent upon their EHR vendors and trust them to support their requirements

✓ States will continue to regulate in different ways

✓ EHRs must anticipate regulatory impact and plan accordingly

Persistent Monitoring Ensures Compliance

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

- Point-of-Care Partners can help.

- Contact Bill Hein bill.hein@pocp.com or visit www.pocp.com/statelawreview

ePrescribing State Law Review