



THE OPIOID CRISIS AND COMPLIANCE

2019 Healthcare Enforcement Compliance Conference

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1

INTRODUCTION AND OBJECTIVES

1

Compliance Requirements and Beyond - Start the discussion with the regulatory and practice guidelines and guardrails for the Professions. Providers, Pharmacists, Healthcare IT and Accountable Care Organizations have all earned a seat at the table.



2

Systems Controls - Provide which buttons and levers can be pulled and protected to achieve 100% compliance for each team of Stakeholders while retaining the individual decision-making authority of the clinicians.



3

Response Plan - Share examples of RACI roles (Responsible, Accountable, Communicated, Informed) in a multidisciplinary project plan to address vulnerabilities and improve the coordinated response of the Program.

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INTRODUCE THE AUDIENCE - POLLING QUESTION

Which role best describes you?

- | | |
|------------------------------------|--|
| 1. Compliance Officer/Director | 5. Government, Regulatory, or Enforcement Role |
| 2. Quality/Regulatory Risk Officer | 6. General Counsel/Compliance attorney |
| 3. President/CEO | 7. Other |
| 4. Internal Auditor | |

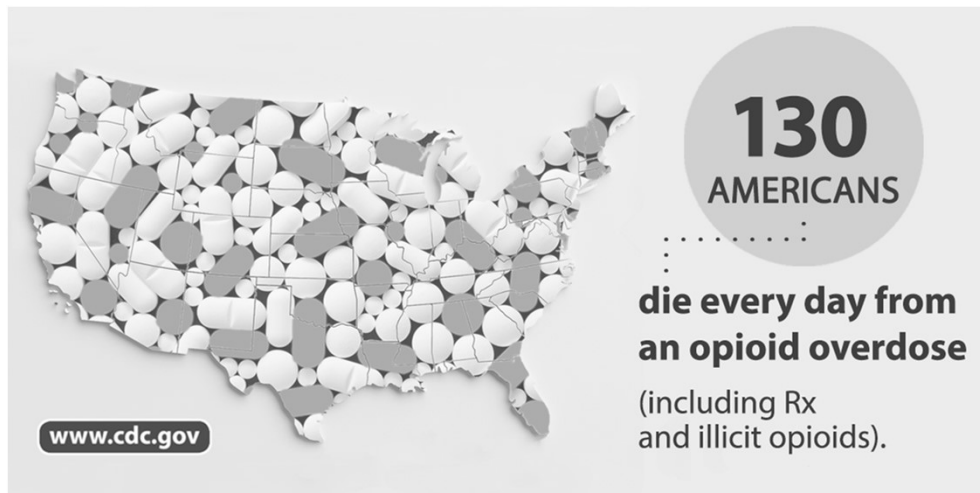
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CURRENT STATS



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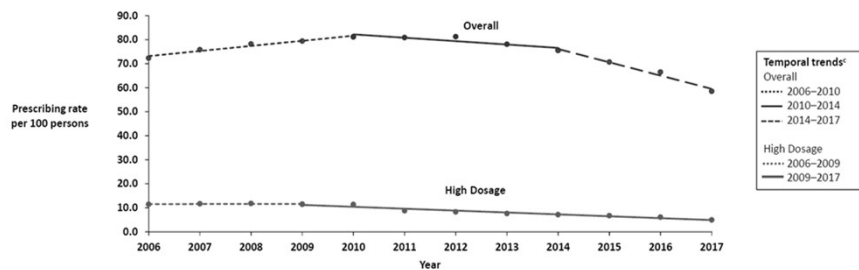
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CURRENT STATS – MAKING PROGRESS

Opioid Prescribing Practices

Annual opioid^a prescribing rates overall and for high dosage prescriptions^b (≥ 90 MME/day)^c — United States, 2006–2017



Source: IQVIA[®] Transactional Data Warehouse.

^aOpioid prescriptions, including codeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxycodone, propoxyphene, tapentadol, tramadol and Butrans[®] and Belbuca[®] (buprenorphine), were identified using the National Drug Code.

^bHigh dosage prescriptions were defined as opioid prescriptions resulting in a daily dosage of ≥ 90 morphine milligram equivalents.

^cTemporal trends from 2006 to 2017 were evaluated by applying joinpoint regression methodology. This modeling approach simultaneously identified statistically significant trends as well as shifts in trends that occurred within a time series. A maximum of two joinpoints was allowed. Different dash types correspond to year groupings as determined by joinpoint regression.

Centers for Disease Control and Prevention. 2018 Annual Surveillance Report of Drug-Related Risks and Outcomes — United States. Surveillance Special Report. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Published August 31, 2018. Accessed 9/19/2019 from www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf

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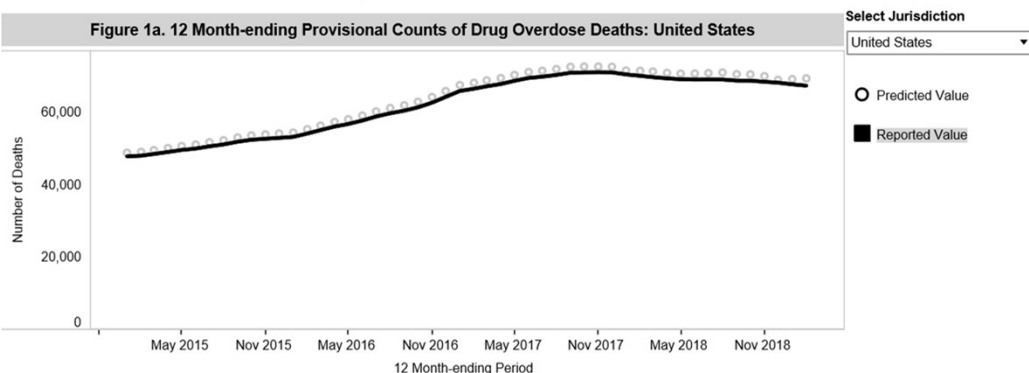
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CURRENT STATS – MAKING PROGRESS

12 Month–ending Provisional Number of Drug Overdose Deaths

Based on data available for analysis on: 9/1/2019



<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

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• “ •

You get no bonus points for having a compliance program.”

*HHS Inspector General Daniel R. Levinson
Remarks at the Health Care Compliance Association's
Annual Compliance Institute (Apr. 18, 2016)*

• ” •

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Accounting for the Opioid Epidemic in Compliance Programs

Opioid crisis has been declared an emergency both nationally and in most states.

In October 2017, President Trump declared the opioid epidemic a public health emergency.

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THE CONTROLLED SUBSTANCES ACT

The Controlled Substances Act (“CSA”)

- Regulates the manufacture and distribution of controlled substances.

Penalties for violating the CSA include:

- Criminal penalties
- Significant civil monetary fines
- Administrative action

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DOJ’S FUNDAMENTAL QUESTIONS

Is the corporation’s compliance program well designed?

Is the program being applied earnestly and in good faith?

Does the corporation’s compliance program work in practice?

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I. ASPECTS OF A WELL-DESIGNED COMPLIANCE PROGRAM

Risk Assessment

- Has the company analyzed and addressed varying risks presented by its role in the sale, distribution, handling, etc. of controlled substances?

Consolidation and Formalization

- This component includes a clear organizational structure and the dedication of sufficient employee and monetary resources.
 - A formal Controlled Substance Diversion Program
 - 7 Areas of Controlled Substance Compliance

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I. ASPECTS OF A WELL-DESIGNED COMPLIANCE PROGRAM

Comprehensive Scope

- Program must address the entire life cycle of controlled substances within the facility, including ordering, receiving, storing, dispensing, administering, and wasting.

Storage and Physical Security

- Security controls should include the utilization of automation and technology to reduce opportunities for diversion and maintain clear records of chain of custody for controlled substances.

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I. ASPECTS OF A WELL-DESIGNED COMPLIANCE PROGRAM

Stakeholder Buy-In and Coordination

- Must involve key stakeholders, all of whom must buy-in and communicate effectively for a compliance program to succeed.

Procedural Controls

- Include policies and procedures designed to ensure compliance with regulatory requirements and protect patients and employees from the potential risks of diversion.

Training

- Appropriate training for new employees and training for current employees on at least an annual basis.

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I. ASPECTS OF A WELL-DESIGNED COMPLIANCE PROGRAM

Monitoring

- Routine auditing and monitoring necessary to ensure compliance with controlled substance laws and policies. Also, proactive monitoring of ordering, dispensing, administering, and wastage records should be conducted to look for patterns and trends that suggest diversion.

Investigations

- Need well-defined and consistent investigation processes. Potential abuse and diversion should be investigated promptly, preferably by dedicated staff that have adequate training and expertise to conduct an effective investigation.

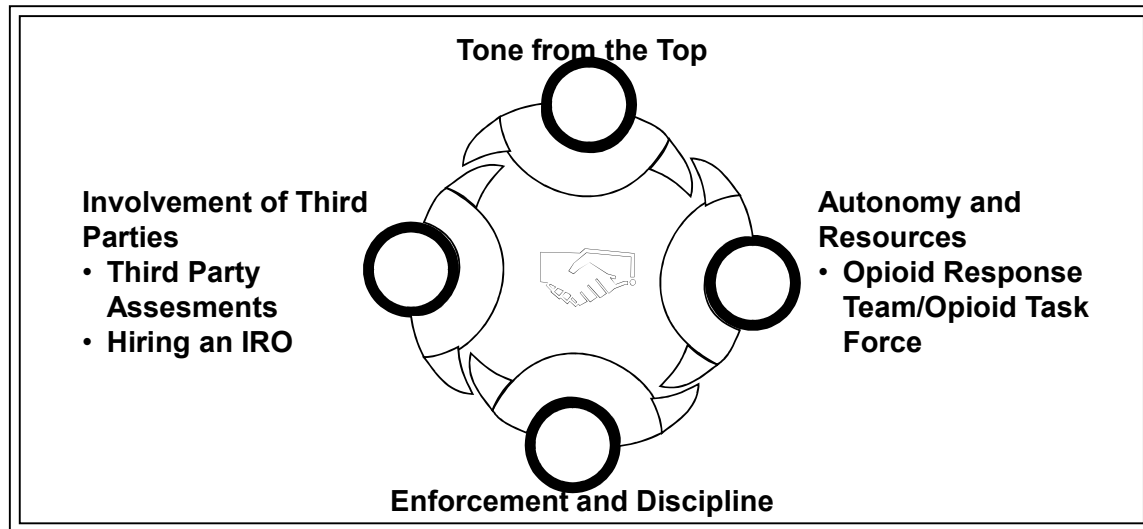
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II. EFFECTIVE IMPLEMENTATION



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III. COMPLIANCE THAT WORKS IN PRACTICE

Continuous Improvement, Periodic Testing, and Review

- Proactive v. Reactive

Investigations and Response to Investigations

Analysis and Remediation of Underlying Misconduct

- Root Cause Analysis
- Remediation
- Accountability

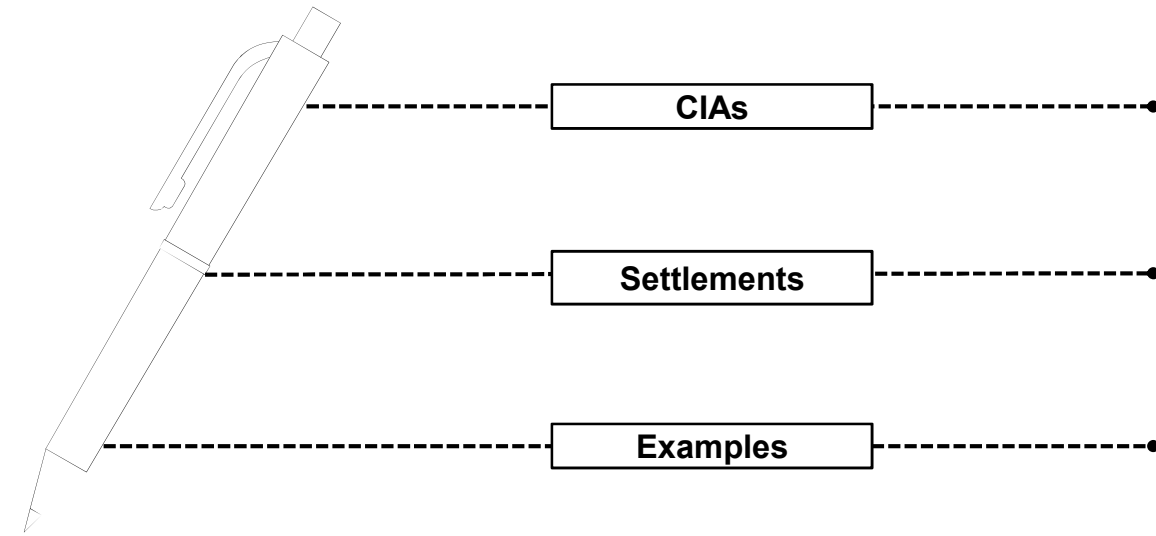
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CONSEQUENCES OF NON-COMPLIANCE



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POLLING QUESTION

Are you confident that your facility has a robust Opioid Risk Compliance Program?

a) Yes



b) No



c) Not sure



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STANDARDS AND STIGMAS

1 Industry Guidelines <ul style="list-style-type: none"> • CDC – Opioid Prescribing Guidelines • CMS – Limits Conditions of Payment • TJC – Updated Pain Management and Assessment Guidelines • AMA – National and State Medical Boards & Associations • SAMSHA 	2 Regulatory Requirements <ul style="list-style-type: none"> • DEA, BOP, BOM,(ISMA), MLB, PDMP, SOM • Key Performance Indicators of Organization (DOJ) • States' Limits on Days Supply and Max Daily Dose, Partial Fills • State Medical Board Prescribing and Dispensing Regulations, if applicable • State Controlled Substances Act, if applicable 	3 Neutralize the Terminology to remove stigma <ul style="list-style-type: none"> • Substance Use Disorder > Addiction, Dependence and Abuse • Acute vs Chronic Pain
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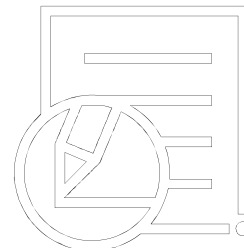
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KEY AREAS TO AUDIT

Data Analytics/Monitoring

- A** Compliance Metrics (Opioid Risk Screening, Urine Screen, PDMP check)
- B** Prescribing Habits/Outliers
- C** Suspicious Order Monitoring (SOM)
- D** Predictive Modeling / Analytics
- E** Drug Diversion Monitoring Reports



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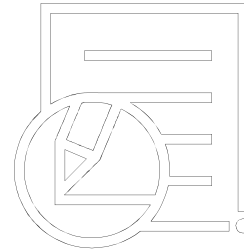
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KEY AREAS TO AUDIT

Licensing

- A** DEA Facility License
- B** APRN Licenses and User Templates
- C** Notification/Removal of DEA or state CSR Licenses monitoring



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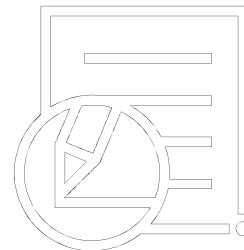
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KEY AREAS TO AUDIT

On September 4th, 2019, HHS announced \$1.8 billion in grants available to states to combat the opioid crisis by expanding access to treatment and supporting near real-time data.

Monitoring for Compliance with Grant Requirements:

- A** Inpatient/ED identification of SUD
- B** Treatment referrals
- C** Peer recovery
- D** MAT availability



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KEY AREAS TO AUDIT

TJC Pain Management And Assessment Guidelines



Discharge Instructions



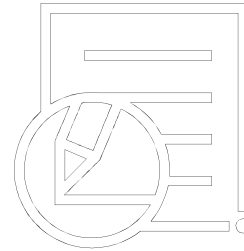
Data Monitoring for Progress



Monitoring for Respiratory Depression



Appropriate Referrals



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KEY AREAS TO AUDIT FOR DIVERSION

Procurement	<ul style="list-style-type: none"> Authorized Orderer – Utilization of CSOS SOD between Ordering and Receiving
Receiving	<ul style="list-style-type: none"> Security upon Receipt Two individuals count received drugs and compare to invoice and sign
Inventory Management (including Storage and Security)	<ul style="list-style-type: none"> Utilize Automated Dispensing Machine (Pyxis, Omnicell, etc.) Perpetual Inventory
Transfers / Restocking	<ul style="list-style-type: none"> Secure carts Inventory count and retrieval of returned drugs
Ordering / Prescribing	<ul style="list-style-type: none"> Authorized order required for dispense (and review of overrides)
Preparation and Dispensing	<ul style="list-style-type: none"> Controlled substances in single pockets Blind counts and review of discrepancy reports
Administration (including Waste and Return)	<ul style="list-style-type: none"> Retrieve one patient at a time, and as close to administration time as possible Return / Waste Witness required for CS
Monitoring	<ul style="list-style-type: none"> Testing of wasted CS Utilization of ADM CS reports
Investigation and Response	<ul style="list-style-type: none"> Hotline for reporting suspected diversion Multidisciplinary Drug Diversion Response Team
Education	<ul style="list-style-type: none"> Diversion education is given to all staff and is ongoing Education signage in Med Rooms for what to look for and how to report diversion

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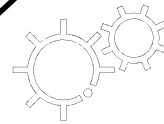
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TECHNOLOGIES / REPORTING CAPABILITIES

- RxAuditor
 - Commonly used tool to monitor for diversion.
- Buddy Waste Reports / Not Involved in Wasting
- Timing (Dispense to Admin to Waste)
- Security Cameras over ADM / Waste stations
- Smart Sinks / Disposal Systems
- Testing waste returned from OR/procedural areas
- Interface your ADM and MAR
 - Significant reduction in manual audit time, 100% review of dispense to administration / waste / return and any discrepancies, instead of needle in a haystack.



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COMMON OBSERVATIONS IDENTIFIED

01 Inappropriate Waste Procedures and Virtual Witnessing

02 Lack of Monitoring Reports or Action Taken

03 Lack of physical security from when drugs are received to when they are checked into inventory

04 Inappropriate classification of drug in Pyxis / Omnicell that results in blind count or waste / return witness not being required

05 Lack of system-wide education on what to look for and how to report potential diversion

06 Utilization of single use vials for multiple doses or patients and not securing medication in between doses (Can also lead to inappropriate billing)

07 Inappropriate user access to Automated Dispensing System / Med Rooms



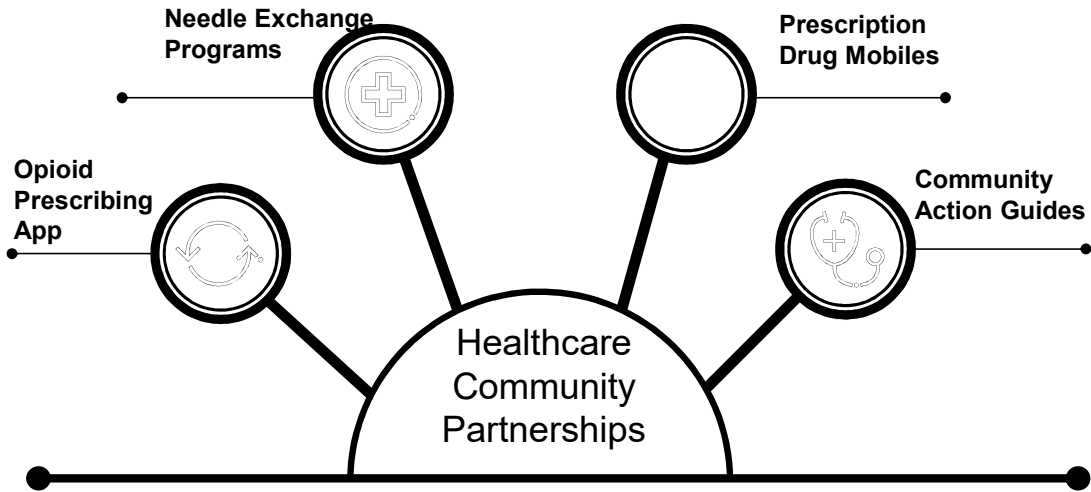
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ABOVE AND BEYOND THE REQUIREMENTS.... HEALTHCARE COMMUNITY PARTNERSHIPS



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RESPONSE PLAN

RACI Model – who is doing what?

RESPONSIBLE	ACCOUNTABLE
<ul style="list-style-type: none"> People or stakeholders who do the work. They must complete the task or objective or make the decision. Several people can be jointly Responsible. 	<ul style="list-style-type: none"> Person or stakeholder who is the "owner" of the work. He or she must sign off or approve when the task, objective or decision is complete. This person must make sure that responsibilities are assigned in the matrix for all related activities. Success requires that there is only one person Accountable, which means that "the buck stops there."
<ul style="list-style-type: none"> People or stakeholders who need to give input before the work can be done and signed-off on. These people are "in the loop" and active participants. 	<ul style="list-style-type: none"> People or stakeholders who need to be kept "in the picture." They need updates on progress or decisions, but they do not need to be formally consulted, nor do they contribute directly to the task or decision.
CONSULTED	INFORMED


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RESPONSE PLAN - EVALUATE


		Roles	RACI
 Evaluate	Support clinical review and evaluation of Patient Records in order to provide evidence of all factors considered in selecting an appropriate agent and making therapeutic decisions specific to each patient's individual condition.	Providers HCO HIT Regulators	R A C I
	Historical patient data and current visit summary are assessed using clinical data modeling tools; such as, a morphine equivalent dosing calculator, titration guide and the CDCs current professional dosing standards.	HIT Providers HCO Regulators	R A C I
	Concurrent medications, additional prescribers, disease state and diagnosis codes, and refill histories are all pertinent chart information presented for use in decision making regarding the appropriateness of care in the prescribers usual course of practice. (Predictive Modeling)	HIT Providers HCO Regulators	R A C I

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RESPONSE PLAN - QUANTIFY


		Roles	RACI
 Quantify	Individual prescribing events objectively quantify Provider decision making following a standard algorithm and provide supporting documentation for deviations from standards.	HIT Providers Regulators HCO	R A C I
	Outlier prescribing and patient factors are assigned values for comparative studies and inter-rater reliability reporting capabilities which are easily translated across Professional and Stakeholder groups.	HIT Providers HCO Regulators	R A C I

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RESPONSE PLAN - AGGREGATE


		Roles	RACI
 Aggregate	Collection and assembly of the multitude of factors which contribute to prescribing behaviors provides relevant datasets across many professional practice settings never before collectively considered in the solutioning of controlled substance diversion and abuse epidemic.	HIT Providers HCO Regulators	R A C I
	Monitoring and trending of data at each 'level' (local, state, federal, regulatory, law enforcement, professional, patient) provides a wealth of interest specific trends and indicators to enable both independent, as well as sweeping global intervention.	HIT Providers HCO Regulators	R A C I

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RESPONSE PLAN - DEFEND

		Roles	RACI
 Defend	Prevents illegitimate or inappropriate controlled substance prescriptions from being purported, circulated and dispensed.	Providers Pharmacists Regulators/HIT HCO	R A C I
	Eliminates manual loopholes by which controlled substance medications end up in the hands of known diverters.	Providers Pharmacists Regulators/HIT HCO	R A C I
	Combines the resources of many Stakeholder groups to combat and solve the diversion crisis instead of litigating, penalizing and incarcerating.	Providers Pharmacists Regulators/HIT HCO	R A C I
	Supports Prescribers and Pharmacists in their role in providing the highest level of quality clinical Health Care to their Patients.	Providers Pharmacists Regulators/HIT HCO	R A C I

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COMMON MONITORING REPORTS

01	Missing Medication - Ordered and Dispensed, but not Administered, Wasted, and/or Returned	05	Dispense after discharge (or too close to discharge)
02	Discrepancy Reports and Trending	06	Removal after death or transfer
03	Outlier Reports by drug / area	07	Pain scale linked to the quantity and dosage of medication dispensed
04	Override Trending Report		



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Slide 34

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Just here for reference, dont plan to present on this slide unless questions come up.

Russell, Julia (10300), 9/19/2019