# Insights

*A fact based approach to managing risk and compliance*

**Rx Data Driven Compliance Monitoring: Controlled Substance Prescribing, Dispensing, and Utilization**
January 2020

pwc

scan HEALTH PLAN

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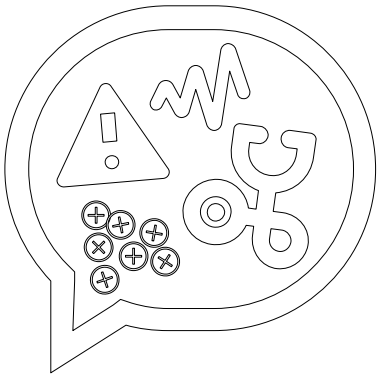
## Agenda



1. Introductions
2. Risks and compliance considerations
3. Fact based approach
4. Network analysis example
5. Benchmarking example
6. Questions and answers/discussion



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# 1

# Introductions

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## About Sandhi

Sandhi is a fan of David Bowie and the Manager of Risk Management Analytics at SCAN Health Plan, in that order.

He received his B.A. in Sociology from the University of California at Riverside in 2008 and is a Certified Scrum Master (CSM).

His passion for data has allowed him to **understand and leverage technology in new and innovative ways.** For the last 8 years he has applied this knowledge to develop digital risk solutions to help identify and manage risk using **machine learning and artificial intelligence** techniques . This includes detecting Fraud, Waste and Abuse, Compliance, and Operational risks.

# About Fran

**Fran Grabowski**
Director, Digital Risk Solutions
#TeamPwC
AIDS/LifeCycle Global Captain

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Fran has 16 years of experience focusing on developing effective data analytics to identify relevant **organizational risks**, **operational inefficiencies**, and **data integrity issues**. He helps healthcare organizations leverage data to address risks related to **regulatory compliance**, **complex processes**, and **sensitive personal health information**. Fran assists clients in building the people, process, and technology capabilities to support **analytics-based decision-making, automation, and data governance strategies.**

Fran's primary focus is on Rx Analytics, including operational and compliance monitoring capabilities for controlled substances, drug diversion, and 340B. Fran is a member of ISACA and is a Certified Information Systems Auditor (CISA).


Author of "Prescribing Practices & Drug Utilization - Attack the Opioid Crisis with Facts"


Fran is the Global Captain of *#TeamPwC* for **AIDS/LifeCycle**, which over the past four years has raised over **$1.2 million** towards HIV/AIDS related services, advocacy and research.




# About Ben

**Ben Wright**
Director
Healthcare Compliance

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Ben is a director with PwC's Healthcare Compliance practice. He has over 9 years of industry experience in healthcare compliance to include being a **Compliance and Privacy Officer**, successfully managing a Corporate Integrity Agreement, and **remediating compliance risks** for a variety of organizations facing significant regulatory and brand risk. His experience includes working with payers, providers, PBM's, pharmacy, and medical technology organizations.

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## Risk & compliance considerations

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## Evolving risk - Scrutiny expanding to payers and providers

**Yesterday's challenges**

1. Provider overprescribing
2. Member drug seekers "Doctor Shopping"
3. Diversion

**Lack of, or ineffective**

- **Visibility into processes and across systems**
- **Comprehensive policies, guidelines, & controls**
- **Comprehensive care (mental + physical)**
- **Training and education**

**Today's news**

1. Increasing state PDMP requirements
2. **CMS & state prescribing limits**
3. **Increasing criminal & civil actions**
4. Proposed opioid production reduction
5. More dangerous elicit supply (fentanyl)

**Is being compounded by new risks**

- **PDMP data used for investigations**
- **Increased attention on payers and providers**
- **Drug diversion costs & potential shortages**
- **Legal/settlement costs**



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# The Multi-pronged enforcement approach

### Setting the stage

- August 2017 – President Trump declares opioid crisis a national emergency, allowing additional resources to states and federal agencies.
- October 2017 – Acting HHS Secretary Eric D. Hargan declares the opioid crisis a public health emergency, implements "Five-Point Strategy"
- November 2017 – Presidential commission issues report recommending funding for treatment, recovery, research, and enforcement. Updated May 2019.
- Enforcement is only one prong of a nationwide multi-pronged approach, and enforcement itself consists of multiple prongs – administrative actions, civil actions, and criminal actions, each of which can proceed in parallel

### Approach

- **Administrative actions** – Drug Enforcement Agency revocations of registration and immediate suspension orders
- **Civil actions** – Civil claims under the CSA or the False Claims Act, state law claims brought by state Attorneys General or others
- **Criminal actions** – State Attorneys General, the DOJ, and U.S. Attorneys have stepped up criminal actions against entities and individuals for opioid-related offenses
- **Parallel proceedings** – Administrative, Civil, and Criminal actions may proceed simultaneously

**Examples of criminal cases charging doctors with death - Resulting sentencing enhancement**

In March 2019, a Kansas doctor was sentenced to life in prison for conspiracy to distribute prescription drugs outside the course of medical practice; unlawfully prescribing opioids and other medications; obstruction; and money laundering

In April 2019, a New York doctor was indicted on 16 counts of distributing oxycodone, fentanyl, and other controlled substances to a particular patient, including one count for distributing fentanyl that caused the patient's death

In May 2019, a Virginia doctor was convicted at trial of 861 federal drug charges: one count of maintaining a place for the purpose of illegal distributing controlled substances, one count of possession with intent to distribute controlled substances, and 859 counts of illegal prescribing Schedule II controlled substances, including opioids that caused a patient's death



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# Regulators taking action

How are you preparing for this new, emboldened enforcement strategy?

The **Department of Health & Human Services** is beginning to hold accountable those parties engaging in illegal prescribing practices by **better investigating fraud and through regulatory changes** in the guidelines that govern opioid distribution.

The **Centers for Medicare & Medicaid Services** is also **sharpening its focus on the issue** by pressuring its Part D sponsors to better manage drug overutilization within their plans and by proposing new limits for opioid prescriptions.




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# Not just a "clinical issue" for your contracted providers

**Clinical**

Identification of provider training opportunities

Tailored treatment plans to address opioid naive, chronic, and other at risk populations

Expanded requirements for Drug Screenings

New ways and places to engage at risk members and communities

**Financial**

Increased cost of Fraud, Waste, and Abuse schemes

Increased long term cost of care for those with Substance Use Disorder

Increased funds for treatment

Growing number of lawsuits over negligent prescribing practices and diversion oversight is growing

Provider incentive programs: utilization of the PDMPs, MIPS, Grant dollars, State programs

**Compliance, Regulatory**

Federal Controlled Substance Act, the False Claims Act, and specific State reporting/PDMP requirements

DEA/DOJ has hired new federal prosecutors who focus exclusively on providers and pharmacies who improperly prescribe/distribute opioids and other controlled substances

Increased scrutiny on FWA programs

**Brand Impact**

Increased investigation and publicity of diversion activities, over-prescribing, and access to comprehensive care

**18.7M**

pills diverted from healthcare organizations in 2018

Source: Protenus, DRUG DIVERSION DIGEST: 2018 SIX MONTH RETROSPECTIVE, June 2018.



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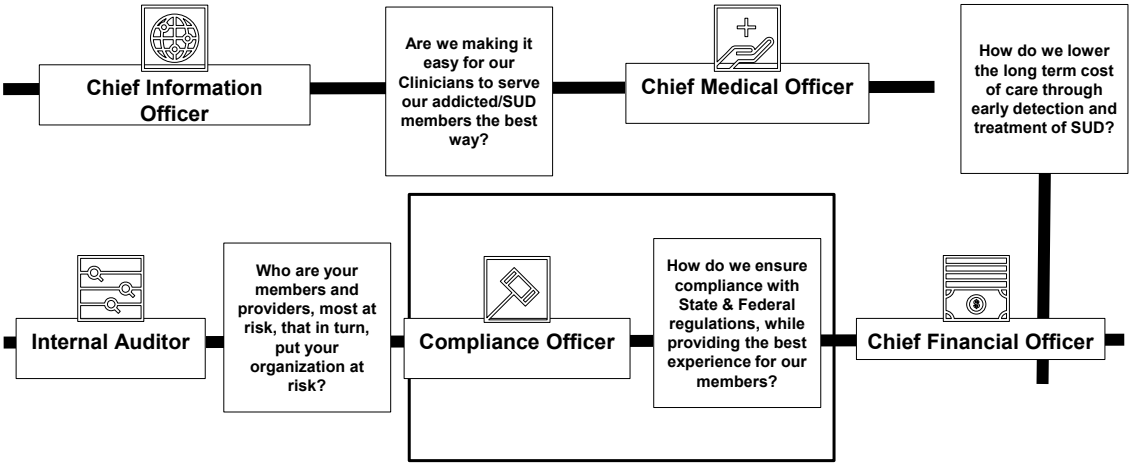
# What's **my role** in our controlled substances strategy?



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# Controlled substance prescribing & diversion considerations

**Assess the policies, standards, processes, procedures and controls related to prescribing and diversion**

- FWA analytics & monitoring capabilities
- Changing standards of care; clinical guidelines
- Provider and Pharmacy authorizations, limits, and overrides
- Internal documents referencing opioids
- Mental health / trauma screening
- Opioid alternatives
- Informed consent
- Formulary management
- Identification of high-risk co-prescriptions
- Pain contracts / controlled substance agreements
- Medication assisted treatment
- Opioid prescription volume, strength, and frequency above Federal and State guidelines and/or above provider/member cohorts
- Provider compliance over utilization of State PDMPs
- Training & education
- Notification to regulatory bodies, such as States or the U.S. Drug Enforcement Administration, as necessary

**Are we measuring and mitigating risks effectively?**

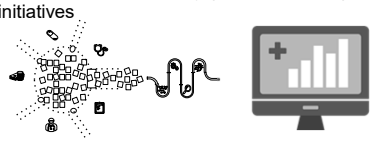
**Do we know all the regulations and are we compliant?**

**Are we putting our clinicians in a position to better identify, treat, and prevent Substance Use Disorder and Overdose?**

**Are we leveraging all of our data assets to prevent and identify FWA and drug diversion?**

**Leverage facts to drive productive conversations**

- Identify trends and outliers among cohorts
- Identify provider's that require commendation, monitoring, education, and investigation
- Identify members at risk for Substance Use Disorder and/or overdose for provider outreach, education, treatment
- Monitor compliance
- Measure impact of policy/guidelines changes and initiatives





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# Controlled substance financial impacts

**How are we lowering costs of care?** ↘

**How will new laws impact our members?** ↗

**Assess the financial impact of controlled substances**

**Direct & Indirect Cost Impact**

- **Benchmark costs** of top MDCs, DRGs, and ICD-10 Codes with and without the presence of Opioid
- Identify **potential cost savings** of addressing opioid related member encounters
- Analyse potentially **avoidable hospital admissions and ED visits**
- Leverage **new programs / innovations to reduce costs** (i.e. Project Engage at Christiana Care Health System; Alternative to Opioids Program ("ALTO") at St. Joseph's Health)
- Diversion schemes

**Expanded coverage and requirements**

Understand potential revenue opportunities related to **H.R.6**:

- Mandatory Medicare Opioid Screenings
- **Expansion of Medicare coverage**, the number of members seen by a physician (100), and the number of practitioners eligible to prescribe buprenorphine
- The 100% bundled payment for newly eligible treatments significantly **increases coverage for MAT treatment** and promotes treatment expansion in the covered categories
- **New grant incentives** ($10M for each of FY 2019 - 2023) for hospitals and other entities to develop robust opioid overdose member protocols.
- HHS to award grants to establish or operate comprehensive **opioid recovery centers**.

**66%**
of opioid-abuse related members relied on public health insurance (33% Medicare, 33% Medicaid)

**~$1.9B**
is the low estimate of annual hospital costs attributable to members who with an opioid overdose between Oct. 2017 and Oct. 2018

**40%**
of overdose members admitted have organ failure

**$11,731**
is the average hospital cost for a overdose member admitted and treated

Source: *Morgan Guthrie, Premier Inc.;"Opioid Overdoses Costing U.S. Hospitals an Estimated $11 Billion Annually"*, January 2019



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## Fact based approach

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## Fundamentals: Definitions and measures

**Most of the following can be used in reference to both members and providers**

| | | | | |
|---|---|---|---|---|
| **Prescriptions** | **Active prescription/order**<br>The period between when the drug was prescribed, and when it runs out based on suggested dosage | **Co-prescription(s)**<br>Two or more active prescriptions for a member at any point in time, such as multiple opioids or opioids and other high risk drugs | | |
| **Measures** | **Days supply**<br>Dispense amount divided by maximum prescribed amount of the medication used in 1 day | **Opioid rate**<br>% of total Prescriptions that are Opioids | **Morphine equivalent dose**<br>The period between when the drug was prescribed, and when it runs out based on suggested dosage | **Morphine equivalent daily dose**<br>The period between when the drug was prescribed, and when it runs out based on suggested dosage |
| **Status/ Conditions** | **Opioid naive**<br>No opiates prescribed within previous 60 days. | **Chronic opioid**<br>>=60 Days Supply within past 90 days | **High dose chronic**<br>>=60 Days Supply of >=90 MED within past 90 days | **Substance Use Disorder (SUD)**<br>Medical condition in which the use of one or more substances leads to a clinically significant impairment or distress. |
| **Treatments** | **Controlled substance/pain agreement**<br>Agreement between a member and their provider to help ensure members understand their role and responsibilities regarding their treatment (e.g., how to obtain refills, conditions of medication use), the conditions under which their treatment may be terminated, and the responsibilities of the health care provider. | **Medication assisted treatment**<br>Use of FDA-approved medications to treat opioid addiction. Coupled with counselling, MAT treats the whole person and significantly reduces the rate of relapse. Medi-Cal, Medicare, and many private insurance plans cover MAT. | | |



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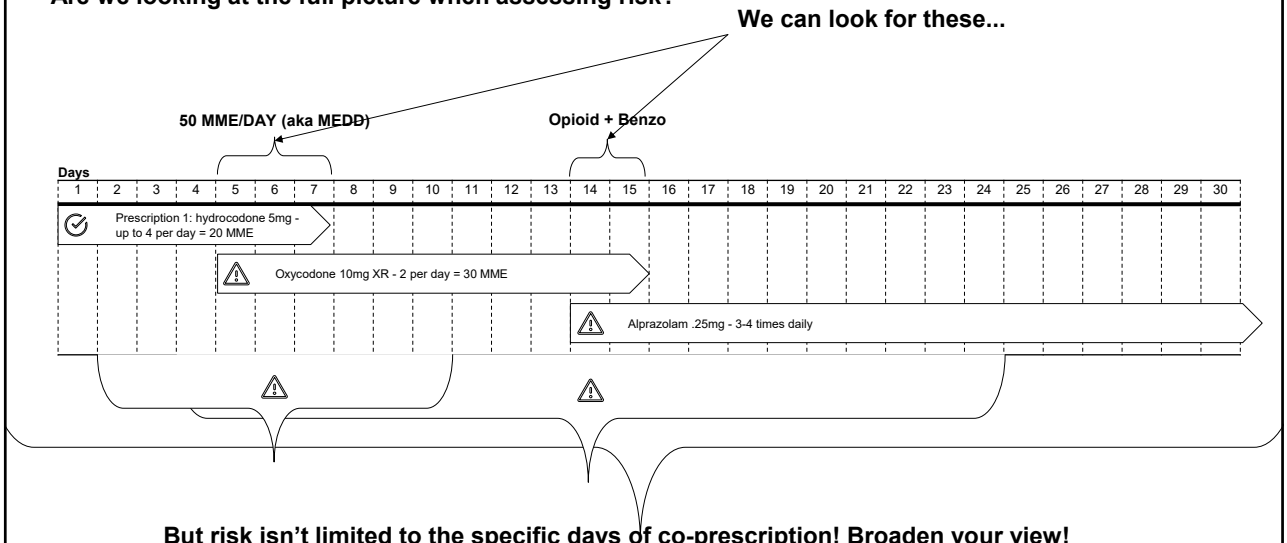
# Drug utilization within the longitudinal health record

**Are we looking at the full picture when assessing risk?**




**But risk isn't limited to the specific days of co-prescription! Broaden your view!**



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# Key metrics to monitor and the questions they answer

**The following are example analytics, however a tailored approach by cohort should be considered**

| Measure/metric | Description | Value/questions to Ask |
|---|---|---|
| **% of members with active opioids** | Members with active opioid prescriptions | How do providers and locations compare to their peers? |
| **% of members over MEDD threshold** | Threshold applied to the sum of the Morphine Equivalent Daily Dose for all of a member's active prescriptions. Calculated for each day. | Regulators have set various thresholds with which providers must comply in regards to treatment and reporting activities. Are providers compliant? How do providers, locations, and members compare to their peers? |
| **% of chronic members** | members who have an active opioid prescription for six weeks or longer | How do providers and locations compare to their peers? How do providers, locations, and members compare to their peers?<br>Are there alternative treatments or actions that can be taken to reduce these members' reliance on opioids? |
| **% of native members** | members who haven't had an active opioid prescription for ninety days | How do providers, locations, and members compare to their peers? Are there actions, such as education opportunities, that can be taken to help prevent long term reliance? |
| **% of co-prescribed members** | members that are prescribed an opioid and at least one other high risk drug such as Barbiturates, Benzodiazepines, Carisoprodols, Gabapentinoids, Sedative Hypnotics, or Stimulants | There are clinical risks to certain drug combinations and some combinations are popular among the addicted. How do providers, locations, and members compare to their peers?<br>Are there alternative treatments or actions that can be taken to reduce potential harm by the co-prescribed drugs? |
| **% of member cohort still active** | Naive members that receive their opioid prescription around the same time, and for similar medical necessities, should have a similar reduction of MEDD over time | Do we see the expected trend? How do providers, locations, and members compare to their peers? |
| **% of members with pain contracts** | members that are required to sign a Controlled-substance Agreement with their provider | Regulators and organizations have various requirements for contracts between the member and their provider surrounding controlled substances. Are providers compliant? Are members compliant? |
| **# of providers and locations per member** | Distinct providers and locations per member over a specified time period | members with drug seeking behaviors often visit multiple providers and locations. While data is limited to just one system's data, there are still opportunities to identify outliers. How do members compare to their peers? |



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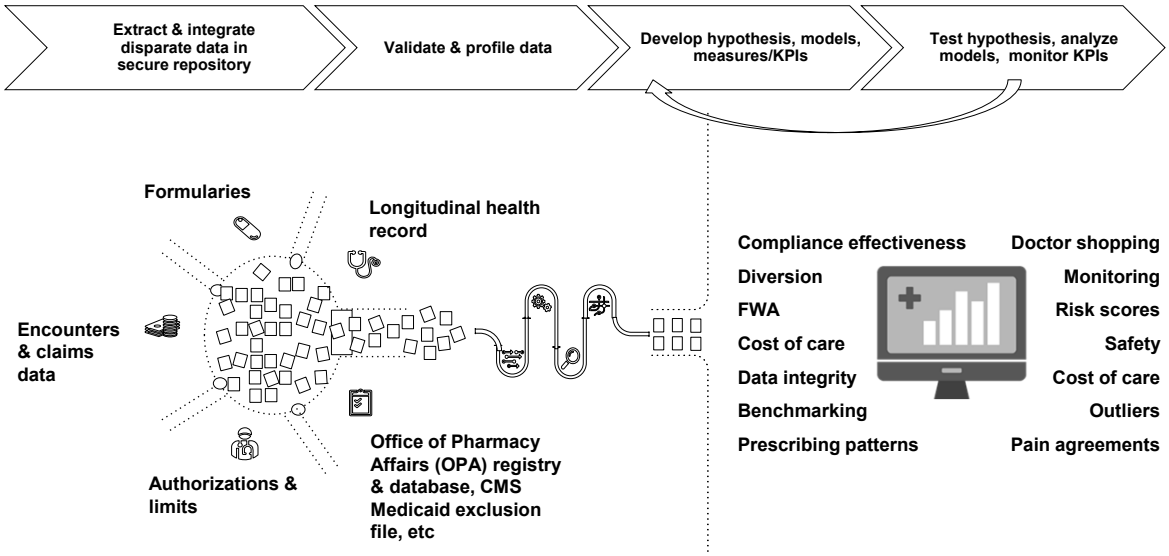
# Example data analytics project approach



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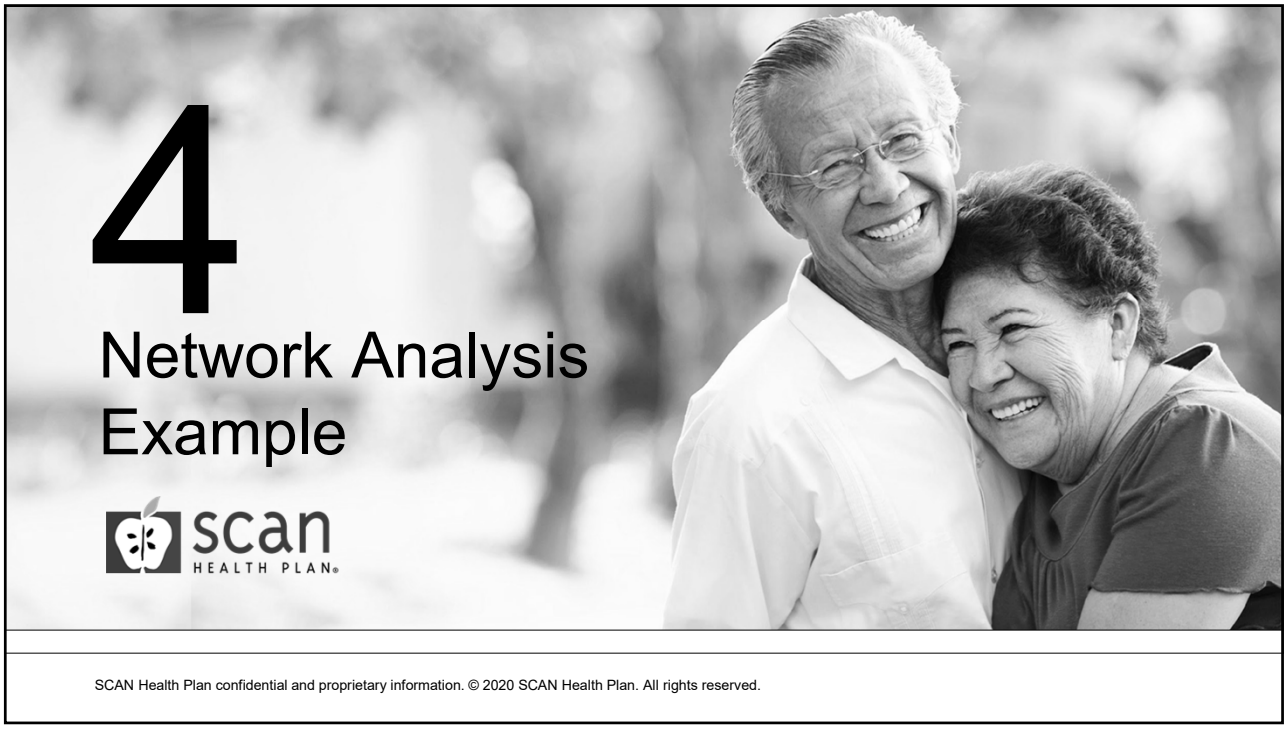




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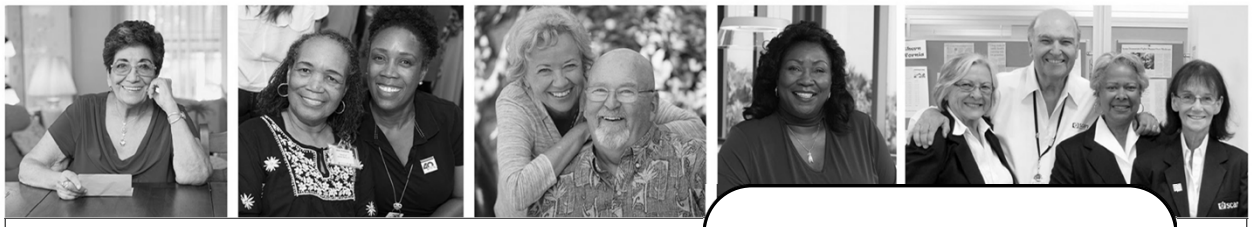

## About SCAN Health Plan

- Non-profit Medicare Advantage organization serving California
- SCAN serves approximately 200,000 members, largely in the Southern California region
- *Keeping Seniors Healthy & Independent*




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## Fraud scheme background

- In early 2017, members reported receiving **unwanted** Lidocaine ointments by mail.
- Scheme started hitting the industry in 2015, but had not yet affected SCAN at scale.

**OVER THE COUNTER**


Numb 520 (1.35oz / 38g) 5% Lidocaine, Liposomal Technology for Deeper Penetration, Topical Numbing
$17.99 ($13.33/Ounce)

**PRESCRIPTION**


- Lidocaine 5% average AWP of about $355 per prescription in 2017.
- Diclofenac Sodium has an AWP of about $1,100 per prescription in 2017.

**EXTRA CREAMS**

**$**




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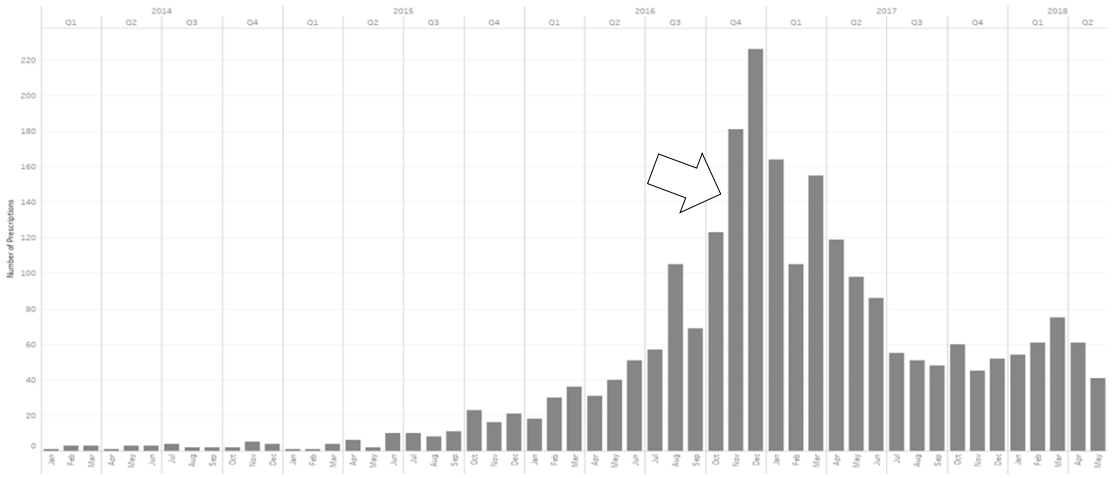
## Anomaly identified by trend analysis








## What are the chances?

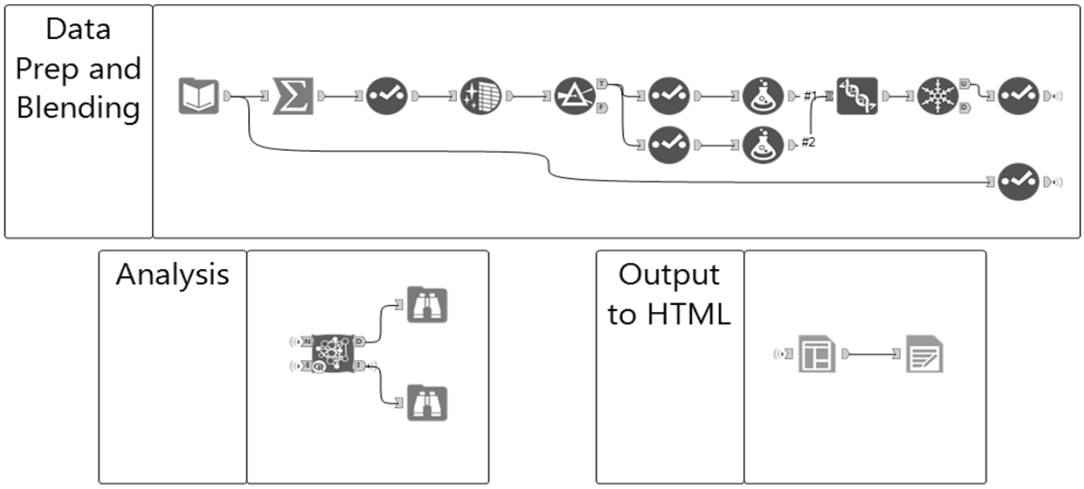
One member would be served by **many pharmacies?**

Every member got the **same high quality?**

Dozens of members go to the *same pharmacy* **outside California?**

Several pharmacies shared the **same address?**

## Cracking the case







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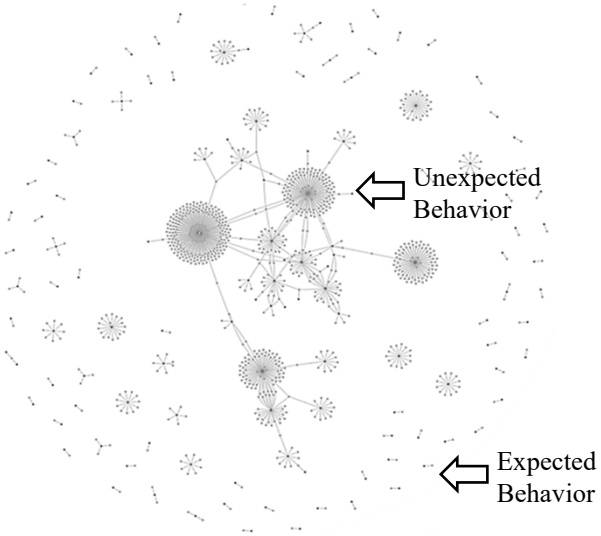
## Investigation - Network Analysis




- Analysed full population of members
- Identified members with high quantity of prescriptions
- Assessed pharmacies for % of members with high-quantify fills
- Relationships and weighting considerations key to analysis

○ **PHARMACY**
○ **MEMBER**

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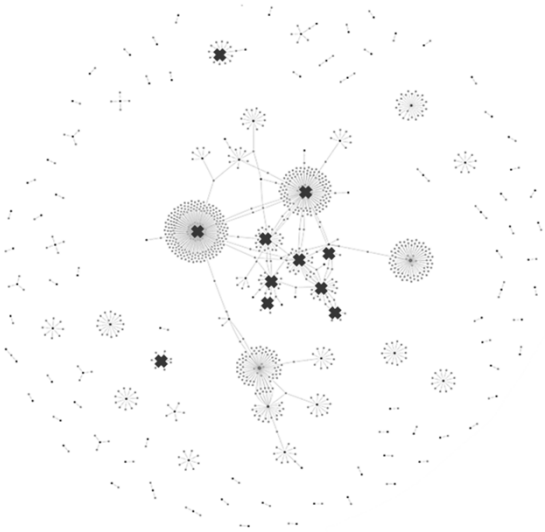
## Investigation - Network Analysis



- Red "**X**" indicates a pharmacy that we were able to take action against, typically as termination from our network.

◯ **PHARMACY**

◯ **MEMBER**





## Impact

Financial

- Helped to "stop the bleeding."
- 2 year projected potential cost avoidance in the millions.

Business:

- Demonstrated issue to business partners
- Clearly visualized normal behavior versus abnormal behavior
- Prioritized resources and investigations
- Identified more pharmacies with similar practices

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# Benchmarking example

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## Medicare Part D opioid analysis

- Analysis developed from data published by CMS **to give health plans and systems their first look at how their providers' prescribing patterns compare to their peers**
- **The data is limited** in that it only includes providers that prescribed drugs paid for by the Medicare Part D program between 2013 and 2017
- While this does not provide you the complete picture of prescribing practices or drug utilization, it does provide a **unique, and first of its kind, peer comparison*** not available within your own data

*PwC has exercised reasonable care in the collecting, processing, and reporting of this information but has not independently verified, validated, or audited the data to verify the accuracy or completeness of the information. PwC gives no express or implied warranties, including but not limited to any warranties of merchantability or fitness for a particular purpose or use and shall not be liable to any entity or person using this document, or have any liability with respect to this document. This information is for general purposes only, and is not a substitute for consultation with professional advisors.

**Data sources**

**Provider Affiliations Source**
**For Provider Systems:** Compiled by Definitive Healthcare from the Centers for Medicare and Medicaid Services (CMS) Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (PUF).

**For Health Plans:** Health Plan Provided Data

**Opioid data source**
The Centers for Medicare & Medicaid Services (CMS) has prepared a public data set, the Medicare Part D Opioid Prescriber Summary File, which presents information on the individual opioid prescribing rates of health providers that participate in Medicare Part D program. This file is a prescriber-level data set that provides data on the number and percentage of prescription claims (includes new prescriptions and refills) for opioid drugs, and contains information on each provider's name, specialty, state, and ZIP code. This summary file was derived from the 2017 Part D Prescriber Summary Table.

Documentation available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Prescriber_Methods.pdf)



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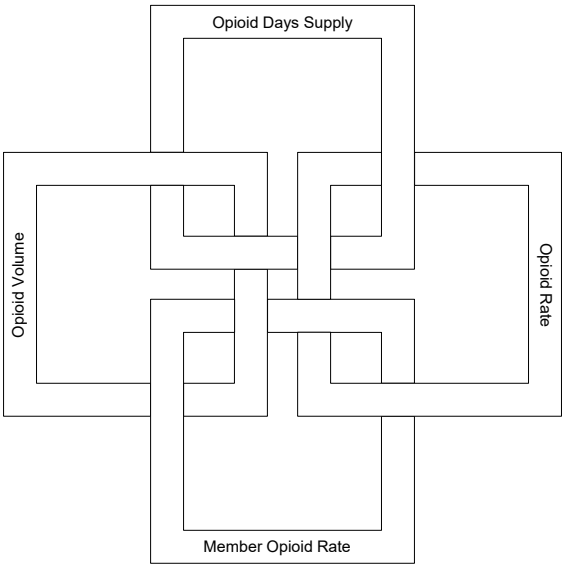
# Medicare Part D opioid analysis - Key measures




- **Opioid rate**
  Percentage of prescriptions made by a provider and reimbursed by Medicare that are opioids. Drop down on upper right corner allows you to view this measure for "All opioids" or "Long Acting Opioids."
- **Opioid days supply**
  The average days supply of the opioid prescriptions ordered by a provider.
- **Opioid volume**
  Count of opioid claims. Combine with above measures to assess risk. For example, if a provider's opioid rate is high, but they prescribed a low volume of opioids, their risk level is low.
- **Member opioid rate**
  Percentage of Medicare beneficiaries that receive prescriptions from a provider that were prescribed an opioid



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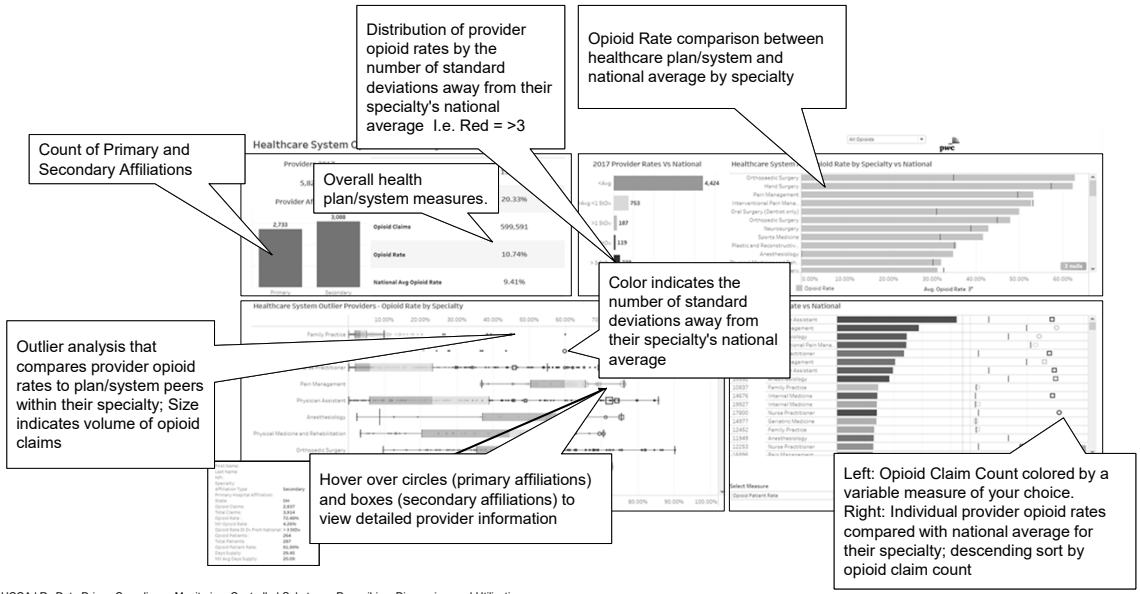
# Opioid prescribing rate analysis



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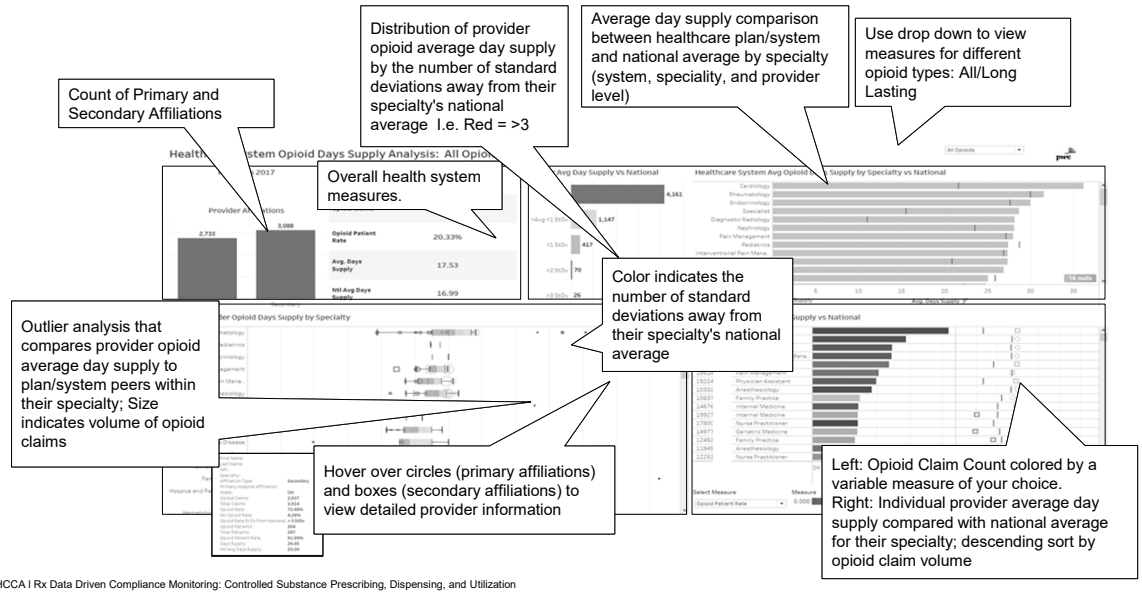
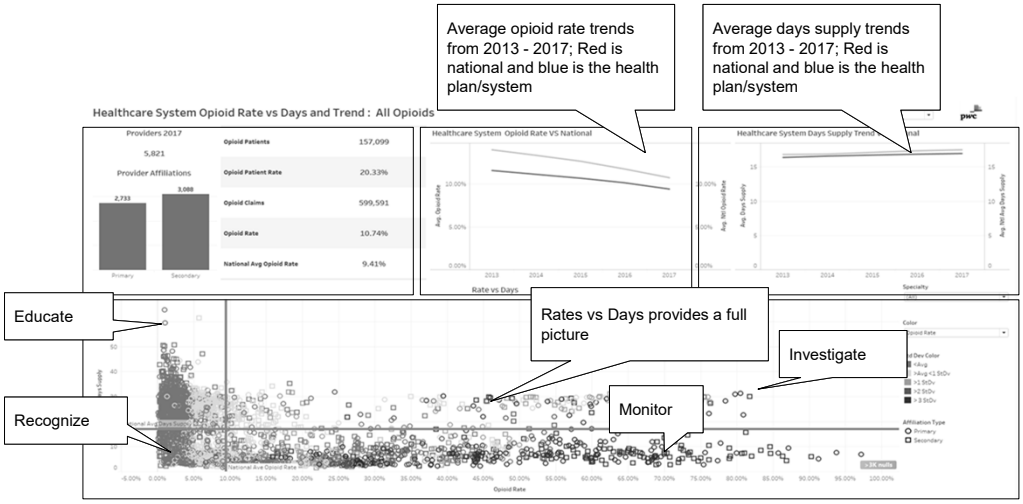
# Opioid days supply analysis








# 5 year trend analysis & provider mapping



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## Questions & answers

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# Thank you

https://www.pwc.com/us/controlledsubstancesolutions



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