

# Enforcement and the Opioid Crisis

Health Care Enforcement Compliance Conference  
November 2019



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## Consumer Protection Branch

<h3>Food, Drug, and Consumer Products</h3> <ul style="list-style-type: none"><li>□ Criminal and Civil Enforcement<ul style="list-style-type: none"><li>▪ Pharmaceuticals and Medical Devices</li><li>▪ Food and Dietary Supplements</li><li>▪ Compounding Pharmacies</li><li>▪ Consumer Products</li></ul></li><li>□ Justice Manual § 4-8.000 Requirements</li><li>□ Defense of FDA/CPSC</li></ul> 	<h3>Opioids</h3> <ul style="list-style-type: none"><li>□ PIL Task Force</li><li>□ Criminal and Civil Enforcement<ul style="list-style-type: none"><li>▪ Manufacturers</li><li>▪ Distributors</li><li>▪ Pharmacies/Prescribers</li></ul></li><li>□ CSA Injunctions – 21 U.S.C. § 843(f)</li><li>□ National Prescription Opiate MDL</li><li>□ Injection Site Litigation</li><li>□ Data Analytics/Leads</li></ul> 
<h3>Complex Consumer Fraud</h3> <ul style="list-style-type: none"><li>□ Transnational Elder Fraud Strike Force</li><li>□ Criminal Enforcement<ul style="list-style-type: none"><li>▪ Telemarketing Fraud</li><li>▪ Mass-Mailing Fraud</li><li>▪ Tech-Support Scams</li></ul></li><li>□ Civil Fraud Injunctions – 18 U.S.C. § 1345</li><li>□ Interagency Coordination</li><li>□ Data Analytics/Leads</li></ul>  	<h3>Deceptive Practices/ Identity Integrity</h3> <ul style="list-style-type: none"><li>□ Unfair/Deceptive Practices</li><li>□ Privacy/Data Breaches</li><li>□ Robocalls/Do Not Call Violations</li><li>□ U.S. Servicemember Fraud</li></ul> 

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[www.justice.gov/civil/consumer-protection-branch](http://www.justice.gov/civil/consumer-protection-branch)

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# Consumer Protection Branch

- Civil and criminal litigation – health and safety mandate
- Experience with pharmaceutical investigations
- USAO and agency partnerships
- Embedded investigative and analytical support
- PIL Task Force / Opioid Enforcement Initiatives

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# Civil Remedies for CSA Violation



**Injunctions**



**Civil Monetary Penalties**



**Civil Asset Forfeiture**

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## CSA Remedies - Injunctions

- Forward-looking relief
- Court ordered
- Additional sanctions for violations of court order
- Middle ground between DEA administrative sanction and criminal prosecution
- Focused on stopping unlawful prescribing/dispensing

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## CSA Injunctions

- **Statutory Authority**
  - Injunction “tailored to restrain violations” of sections 842 and 856 (21 U.S.C. § 843(f)(3))
  - Catchall authority to enjoin CSA violations (21 U.S.C. § 882(a))
- **Wide range of available injunctive relief**
  - Complete or selective prohibition on prescribing / dispensing controlled substance
  - Countersign / monitoring / reporting requirements
  - Obey the law
- **Discovery**
  - Pre-indictment / Independent action – Civil rules apply
  - Post-indictment – Criminal rules apply (21 U.S.C. § 843(f)(4))

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## Advantages of Civil Injunction

- Temporary restraining order/Preliminary injunction may provide faster relief
- Injunctive relief is more flexible and can be narrowly tailored
- Injunction action may be coupled with civil penalties and other causes of action (ex. False Claims Act)
- Efficient use of DOJ/DEA resources
- Can apply to pharmacists and other individuals even if not registrants

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## Case Studies

### US v. Pena-Rodriguez & Mendez Northern District of Texas

- Dr. Cesar B. Pena-Rodriguez & Dr. Leovares Antonio Mendez were operating as family physicians for the Cumbre Medical Center in Garland since 2011.



#### § 842(a)(1) Illegal Prescribing Proof:

- Mendez and Pena-Rodriguez sold medically unjustified prescriptions to undercover agents in all but one of 25 undercover visits.
- Undercover agents paid \$250 and in exchange received prescriptions for controlled substances with minimal to no examination.
- PMP data shows that both doctors prescribed a high volume of "holy trinity" prescriptions.
- Pena-Rodriguez prescribed the trinity a total of 221 times to 19 individuals, and prescribed 2 of the 3 drugs 835 times to 127 individuals
- Mendez prescribed the trinity 193 times to 16 individuals, and prescribed 2 of the 3 drugs 1,928 times to 218 individuals.

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## Case Studies

### US v. Pena Rodriguez & Mendez Northern District of Texas

- Motion for Temporary Restraining Order filed *ex parte* and under seal.
- TRO enjoined both doctors from distributing or dispensing opiates or opioids. Also required record preservation.
- TRO served on Pena Rodriguez and Mendez when the search warrant had been executed.
- Case is stayed for both defendants for 180 days, until 2/3/2020

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## Case Studies

### U.S. v. Tricaso & Gerber Northern District of Ohio

#### U.S. v. Gerber

- Solo practitioner specializing in pain management
- 842(a)(1): Illegal Prescribing Proof
  - Undercover agent for Ohio Board of Pharmacy (19 total Rx)
  - Expert witness review of Medicare claims data for 81 patients (~4800 Rx)

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- Motion for TRO/PI filed *ex parte* and under seal
- TRO Granted
  - Dr. Gerber restrained from prescribing any CS in Schedules II, III, and IV
  - Record preservation provision
- TRO converted to PI- Dr. Gerber filed Answer

#### U.S. v. Tricaso

- Operated Better Living Clinic & gym doctor
- 841(a)(1): Illegal Distribution Proof
  - DEA confidential source (wire)
  - Cash for pills in hotel parking lot
- 842(a)(1): Illegal Prescribing Proof
  - Cash for Rx to DEA source (wire)
  - Steroid Rx to local police source (wire)

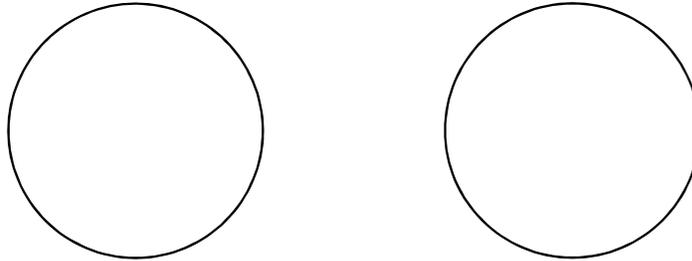
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- Motion for TRO/PI filed *ex parte* and under seal
- TRO Granted
  - Restrained from distributing or dispensing any CS
  - Record preservation provision
  - Surrendered DEA registration and medical license
  - TRO extended
  - Permanent injunction entered

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## Corresponding Responsibility



“The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, **but a corresponding responsibility rests with the pharmacist who fills the prescription.**”

“An order purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription within the meaning and intent of [section 829] **and the person knowingly filling such a purported prescription**, as well as the person issuing it, **shall be subject to the penalties provided** for violations of the provisions of law relating to controlled substances.”

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## 21 C.F.R. § 1306.06

“A prescription for a controlled substance may only be filled by a pharmacist, **acting in the usual course of his professional practice** and either registered individually or employed in a registered pharmacy ...”



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- “Indicia” that prescription was not issued for legitimate medical purpose
- “Create a level of concern” that might cause pharmacist to not fill prescription or conduct further investigation.
- Gives pharmacist “reason to know” that presented Rx is not legitimate.
- Willful blindness / deliberate ignorance could establish pharmacist’s knowledge.

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- ⚠ “Pattern or Factory Prescribing” Rx for same drugs/quantities from same MD
- ⚠ Combinations or “cocktails” of frequently abused controlled substances
- ⚠ Geographic anomalies (distances between MD, patient and pharmacy)
- ⚠ Shared addresses by customers presenting on same day or with same Rxs
- ⚠ Quantity and strengths don’t make sense or at maximum levels
- ⚠ Paying cash (esp. when they have insurance)
- ⚠ Customers with same diagnosis code from same MD
- ⚠ Rx written by MDs outside their area of specialty
- ⚠ Fraud on face of Rx
- ⚠ Early refills

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# Celina, Tennessee

Population	Median Age	Median Household Income
<b>1,493</b>	<b>42.8</b>	<b>\$21,202</b>
Poverty Rate	Number of Employees	Median Property Value
<b>35.2%</b>	<b>411</b>	<b>\$89,600</b>

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**Dale Hollow Pharmacy:**

- Enough opioids purchased to provide 1 1/2 max-strength Vicodin tabs for every man, woman, child in Clay County every single day between 2015 and 2018.

**Xpress Pharmacy of Clay County:**

- 40% of all 90-day supply of max-strength Percocet every day
- 20% of all 90-day supply of max-strength Percocet every day in Clay County at more than 3X the national rate
- Dale Hollow #3; Xpress #11 in 90-day opioid purchases per capita
- 83-96% of buprenorphine = non-therapy formulation
- 30-50% Cash payments
- 50% of sales = Controlled Substances (bunkos = 15-25%)
- 20% related to Rx's obtained from Xpress

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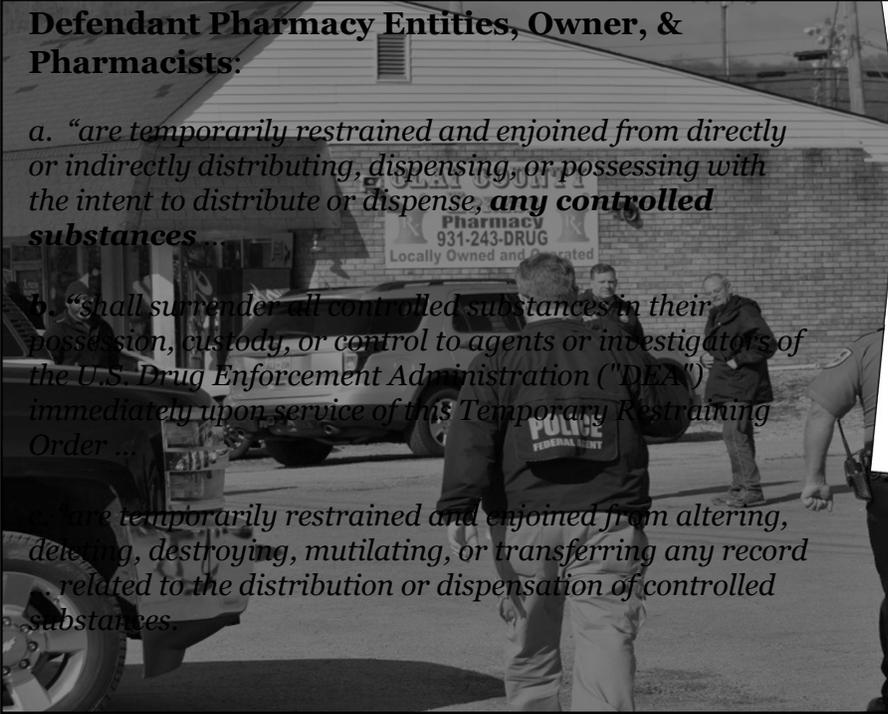

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**Defendant Pharmacy Entities, Owner, & Pharmacists:**

a. *“are temporarily restrained and enjoined from directly or indirectly distributing, dispensing, or possessing with the intent to distribute or dispense, **any controlled substances** ...*

b. *“shall surrender all controlled substances in their possession, custody, or control to agents or investigators of the U.S. Drug Enforcement Administration (“DEA”) immediately upon service of this Temporary Restraining Order ...*

*... are temporarily restrained and enjoined from altering, deleting, destroying, mutilating, or transferring any record related to the distribution or dispensation of controlled substances.*




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# The Appalachian Regional Prescription Opioid Strike Force (ARPO SF)

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## ARPO SF Launch

FOR IMMEDIATE RELEASE

Thursday, October 25, 2018

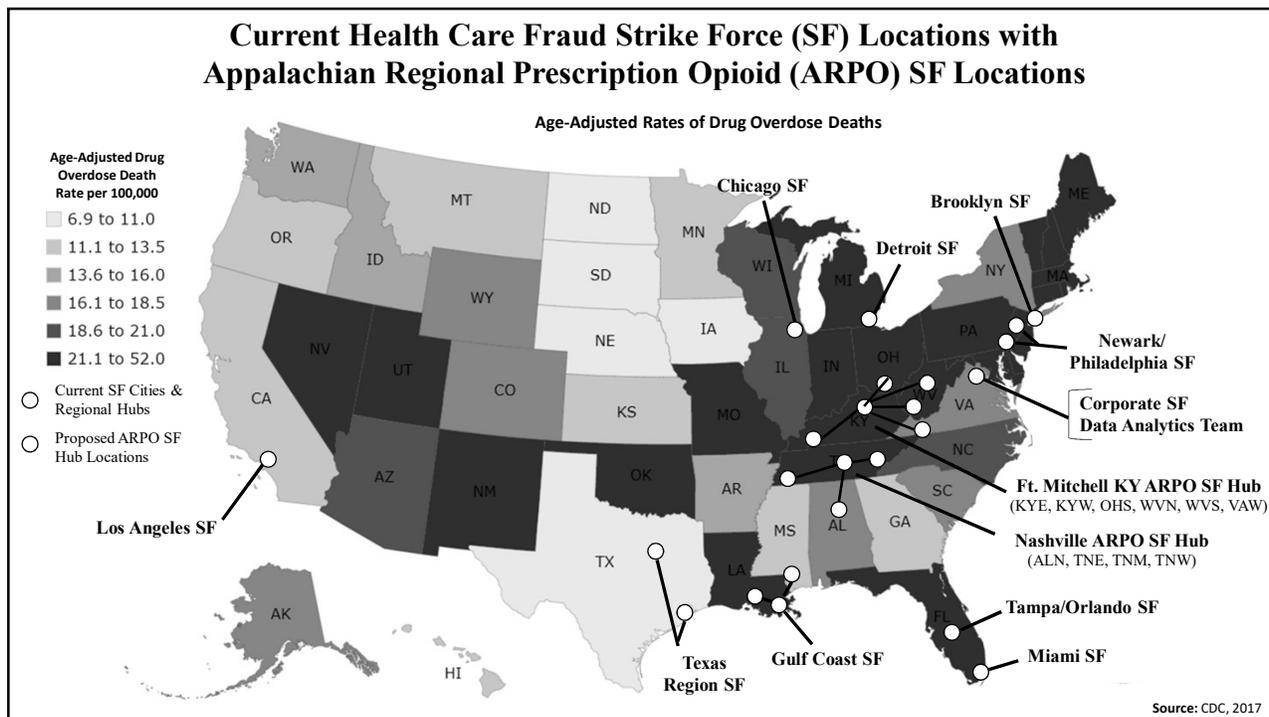
### **Justice Department's Criminal Division Creates Appalachian Regional Prescription Opioid Strike Force to Focus on Illegal Opioid Prescriptions**

Assistant Attorney General Brian A. Benzckowski of the Justice Department's Criminal Division today announced the formation of the Appalachian Regional Prescription Opioid Strike Force (ARPO Strike Force), a joint law enforcement effort that brings together the resources and expertise of the Health Care Fraud Unit in the Criminal Division's Fraud Section (HCF Unit), the U.S. Attorney's Offices for nine federal districts in five states, as well as law enforcement partners at the FBI, U.S. Department of Health and Human Services Office of the Inspector General (HHS-OIG) and U.S. Drug Enforcement Administration (DEA). The mission of the ARPO Strike Force is to identify and investigate health care fraud schemes in the Appalachian region and surrounding areas, and to effectively and efficiently prosecute medical professionals and others involved in the illegal prescription and distribution of opioids.

Assistant Attorney General Benzckowski was joined in the announcement by U.S. Attorney Robert M. Duncan Jr. for the Eastern District of Kentucky; U.S. Attorney Russell M. Coleman for the Western District of Kentucky; U.S. Attorney Benjamin C. Glassman for the Southern District of Ohio; U.S. Attorney William J. Powell for the Northern District of West Virginia; U.S. Attorney Michael B. Stuart for the Southern District of West Virginia; U.S. Attorney J. Douglas Overbey for the Eastern District of Tennessee; U.S. Attorney Donald Q. Cochran for the Middle District of Tennessee; U.S. Attorney D. Michael Dunavant for the Western District of Tennessee; U.S. Attorney Jay E. Town for the Northern District of Alabama; Assistant Director Robert Johnson of the FBI's Criminal Investigative Division; Deputy Inspector General for Investigations Gary L. Cantrell of the Department of Health and Human Services Office of Inspector General (HHS-OIG) and Assistant Administrator John J. Martin of the DEA Diversion Control Division.

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## ARPO SF: Program Goals

- **Applying the SF Model to the Appalachian Region To Partner with the USAOs and Focus on Opioids**
- **Focus** Prosecutorial Resources
- **Target** Very Worst Prescribers
- **Harness** Our Agency Relationships
- **Deploy Data Analytics** to the Region
- **Deploy Financial Resources**, Such As experts, scanning/processing
- **Deterrent Effect** By Prosecuting Doctors and other Medical Professionals

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# Opioid Fraud & Abuse Investigations

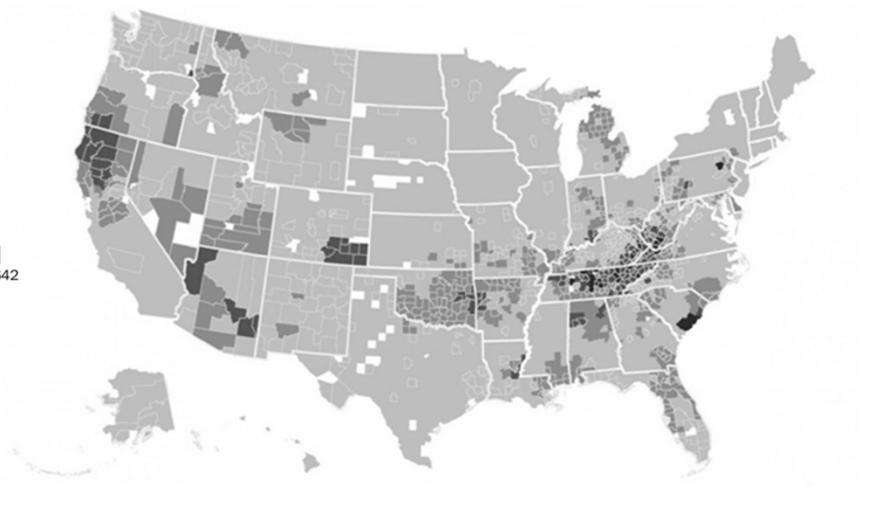
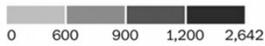
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## *The Opioid Overdose Epidemic*

Highest Quarter of Overdose Rates  
(by County)

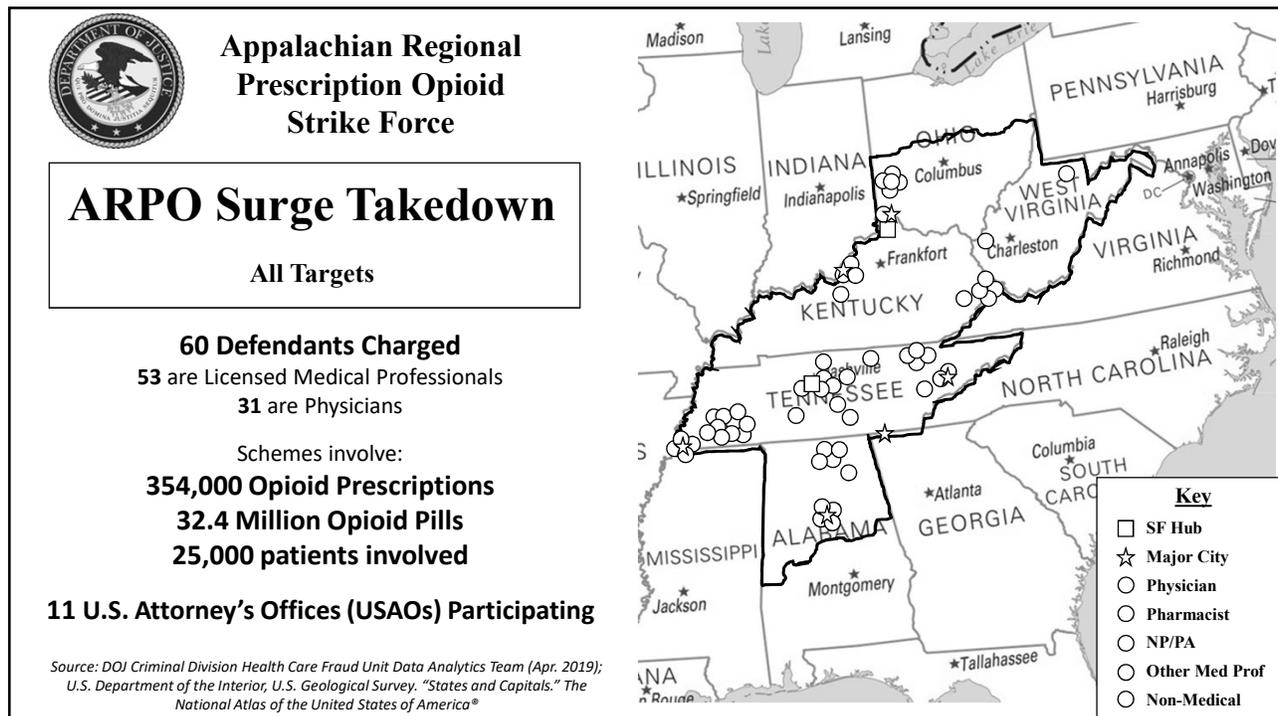
Grams of Prescription Opioids Delivered  
(per 1,000 People)



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# The ARPO SF “Surge”

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## Appalachian Regional Prescription Opioid Strike Force

### Second ARPO Strikeforce Takedown

**13 Defendants Charged**

11 are Licensed Medical Professionals  
11 are Physicians

Schemes involve:

**17.5 Million Opioid Pills**

**6 U.S. Attorney's Offices (USAOs) Participated:**

KYE, OHS, TNE, TNW, VAW, WVS



Source: DOJ Criminal Division Health Care Fraud Unit Data Analysis Team (Apr. 2025); U.S. Department of the Interior, U.S. Geological Survey, "States and Capitals," The National Atlas of the United States of America

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# ARPO SF: Community Outreach Plan

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# ARPO SF: Community Outreach Plan



- **Goals**
  - Prevent Overdose Deaths
  - Provide Continued Access to Care
  - Mitigate Turn To Street Drugs
- **5-Step Plan (Months of Coordination)**
  - Pre-Surge Coordination: CDC, Fraud Section, FBI, DEA, SAMSHA, HHS-OIG
  - Law enforcement officers will have Narcan, an anti-overdose medication, on site;
  - Law enforcement and health officials present at all operating sites on the day of arrest;
  - CDC and state public health officials will have literature directing patients to peer professionals, treatment facilities, and other public health resources; and
  - The Department's national press release will also include information, provided by the states, identifying where patients can seek additional help.

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## Public Health Coordination - Opportunities

Pre-Takedown	During Takedown	Post Takedown
<ul style="list-style-type: none"> <li>• Connect law enforcement with state health/opioid POCs:                             <ul style="list-style-type: none"> <li>• Establish trusted network in 50 states</li> </ul> </li> <li>• Conduct rapid State/Local needs assessment prior to takedown:                             <ul style="list-style-type: none"> <li>• Epi support:                                     <ul style="list-style-type: none"> <li>• Data sharing</li> <li>• Identify high-risk patients</li> <li>• Patient contact information</li> </ul> </li> <li>• Identify/Address barriers</li> <li>• Support development of local clinician list</li> <li>• Assess need for clinical support                                     <ul style="list-style-type: none"> <li>• Takedown day</li> <li>• Gap care</li> </ul> </li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Coordinate with local health authorities</li> <li>• Support law enforcement</li> <li>• Assist patients on day of takedown                             <ul style="list-style-type: none"> <li>• Patient education</li> <li>• Naloxone distribution</li> <li>• Prescriptions</li> </ul> </li> <li>• Warm hand off/ referral coordination:                             <ul style="list-style-type: none"> <li>• Local health leads</li> <li>• Local providers</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Conduct outreach to identified high-risk patients and connect to care</li> <li>• Provide gap care</li> </ul>

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# ARPO SF: Community

District	Case Name	# of Targets	Defendant(s) Name	Target Type?	Doctor? (Y/N)	DATA Waived?	Prescriber NPI	Still Practicing?	Clinic Name(s)
EDTN	██████████	1	██████████	Physician	Y	N	██████████	Y	██████████
EDTN	██████████	1	██████████	Physician	Y	N	██████████	Y	██████████
EDTN	██████████	2	██████████	Physician	Y	N	██████████	Y	██████████
EDTN	██████████		Nurse Practitioner	Y	N	██████████	Y		
MDTN	██████████	3	██████████	Nurse Practitioner	Y	N	██████████	Y	██████████
MDTN	██████████		Nurse Practitioner	Y	N	██████████	Y		
MDTN	██████████		Nurse Practitioner	Y	N	██████████	Y		
MDTN	██████████	1	██████████	Physician	Y	N	██████████	Y	██████████
WDTN	██████████	2	██████████	Nurse Practitioner	Y	N	██████████	Y	██████████
WDTN	██████████		1	██████████	Physician	Y	N	██████████	
WDTN	██████████	1	██████████	Physician	Y	Y	██████████	Y	██████████
WDTN	██████████	1	██████████	Physician	Y	Y	██████████	Y	██████████

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# ARPO SF: Community Outreach Plan

**TN REDLINE**  
800-889-9798  
**Statewide Crisis Line**  
855-CRISIS-1  
**TN Dept. of Mental Health and Substance Abuse Services**

**Alabama Department of Mental Health**  
844-307-1760

For any patients impacted by the law enforcement operations, DOJ, DEA, HHS-OIG, HHS' Substance Abuse and Mental Health Services Administration, Centers for Disease Control and Prevention, and all five State Departments of Health are deploying federal and state-level strategies to address patient harm and insure continuity of care. Additional information regarding available treatment programs and where patients can turn for assistance is available as follows:

**Alabama:** The Alabama Department of Mental Health has a dedicated telephone number to connect those affected by the closure. The toll-free substance abuse number is 1-844-307-1760. Information about substance abuse and opioids is available at the following websites:

<http://www.alabamapublichealth.gov/pharmacy/opioid-and-heroin.html>

<https://mh.alabama.gov/understanding-the-opioid-crisis/>

**Kentucky:** If you are in Kentucky and are suffering with addiction you can find help by calling 833-8KY-HELP or logging in at [Findhelpnowky.org](http://Findhelpnowky.org)

**Ohio:** If you are seeking help in Ohio, please call the OhioMHAS patient helpline, at 1-877-275-6364

**Tennessee:** If you are seeking help in Tennessee:

- For a referral to addiction treatment services, call the Tennessee REDLINE: 800-889-9789.
- In a mental health crisis, call the Statewide Crisis Line: 855-CRISIS-1 (855-274-7471).
- For help accessing substance abuse or mental health services call the Tennessee Department of Mental Health and Substance Abuse Services Helpline: 800-560-5767 or 615-532-6700. This line is staffed Monday-Friday, 8 a.m. - 4:30 p.m. CT.

**West Virginia:** If you are in West Virginia and are suffering with addiction you can find help by calling 1-844-HELP-4WV or logging in at <https://HelpandHopeWV.org>

For individuals seeking help in **other states**, please call 1-800-662-HELP

**OhioMHSA Patient Helpline**  
877-275-6364

**HelpAndHopeWV.org**  
844-HELP-4WV



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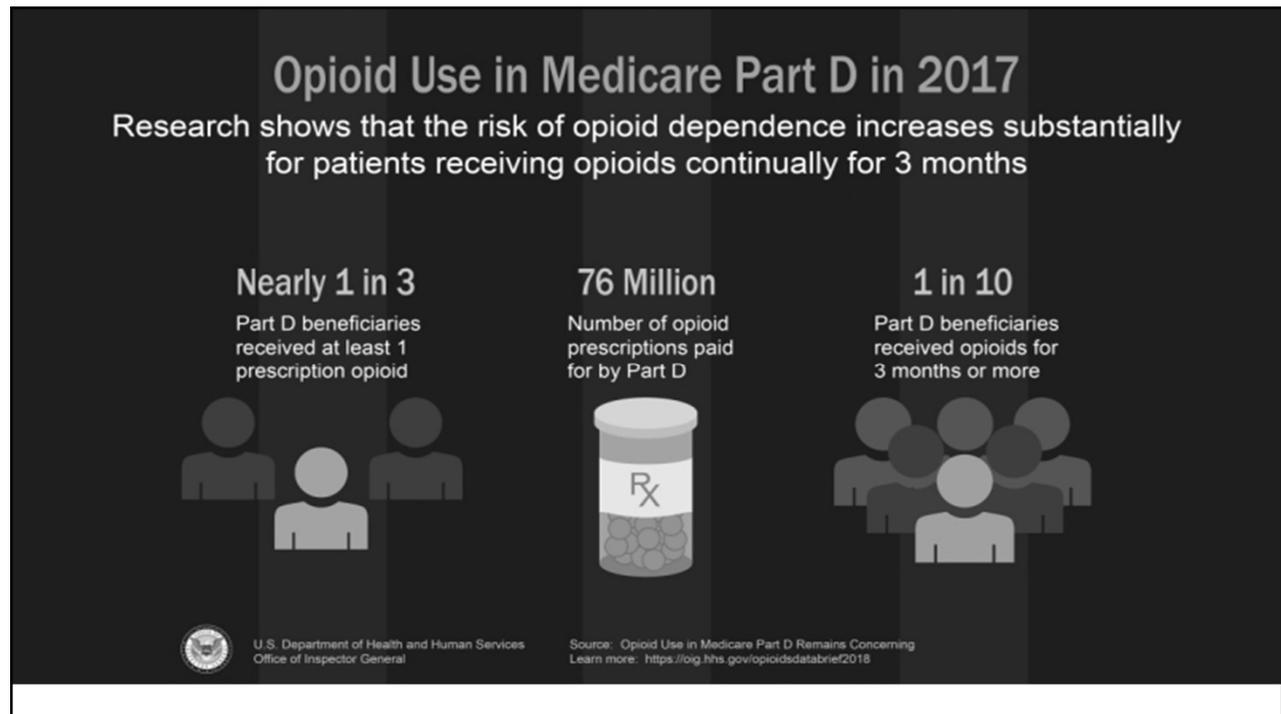
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# Impact

- Technical assistance to state and local health departments
  - Ex: AK, AL, GA, KY, NYC, PA, TN, UT
  - ORRT personnel deployed to TN and NYC for clinic actions
- Project ECHO
- Established trusted contact networks in 13 states
- 1,025 CDC staff members and Commissioned Corps officers trained
- 2019 Lung Injury Response participation

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## Opioid Use in Medicare Part D in 2017

Almost  
**460,000**

Part D beneficiaries received  
high amounts of opioids

About  
**71,000**

Beneficiaries are at serious risk  
of opioid misuse or overdose



U.S. Department of Health and Human Services  
Office of Inspector General

Source: Opioid Use in Medicare Part D Remains Concerning  
Learn more: <https://oig.hhs.gov/opioidsdatabrief2018>

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## Opioid Use in Medicare Part D in 2017

Almost 300 prescribers had  
questionable opioid prescribing  
patterns for the 71,000  
beneficiaries at serious risk



U.S. Department of Health and Human Services  
Office of Inspector General

Source: Opioid Use in Medicare Part D Remains Concerning  
Learn more: <https://oig.hhs.gov/opioidsdatabrief2018>

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## Opioid Use in Medicare Part D in 2017

OIG continues to support our State and private sector partners through the Healthcare Fraud Prevention Partnership and our shared commitment to reducing the harm of opioids



U.S. Department of Health and Human Services  
Office of Inspector General

Source: Opioid Use in Medicare Part D Remains Concerning  
Learn more: <https://oig.hhs.gov/opioidsdata/brief2018>

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## Opioid Use in Medicare Part D in 2017

The severity of the opioid crisis makes it imperative that OIG and its HHS partners continue working together to develop new strategies to address the epidemic



U.S. Department of Health and Human Services  
Office of Inspector General

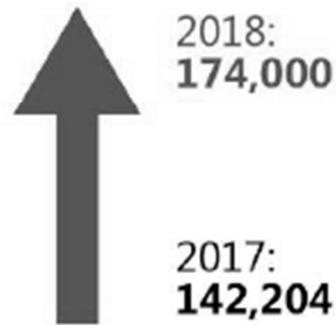
Source: Opioid Use in Medicare Part D Remains Concerning  
Learn more: <https://oig.hhs.gov/opioidsdata/brief2018>

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The number of Part D beneficiaries receiving opioids continues to decrease.



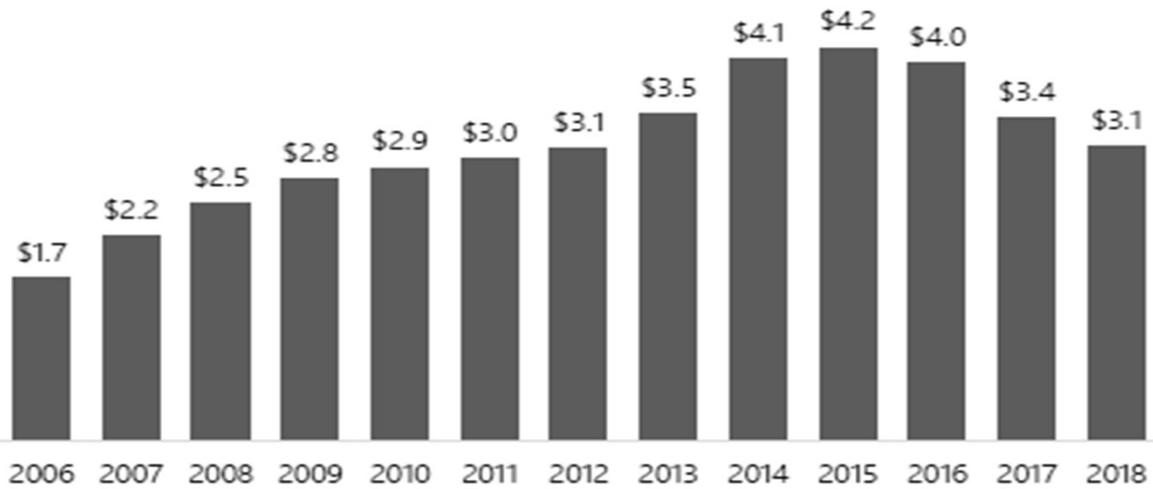
Meanwhile, the number of beneficiaries receiving drugs for medication-assisted treatment has increased.



Source: OIG analysis of Medicare Part D data, 2019.

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**Exhibit 1: Spending for opioids in Part D has continued to decrease, but remained at over \$3 billion in 2018**

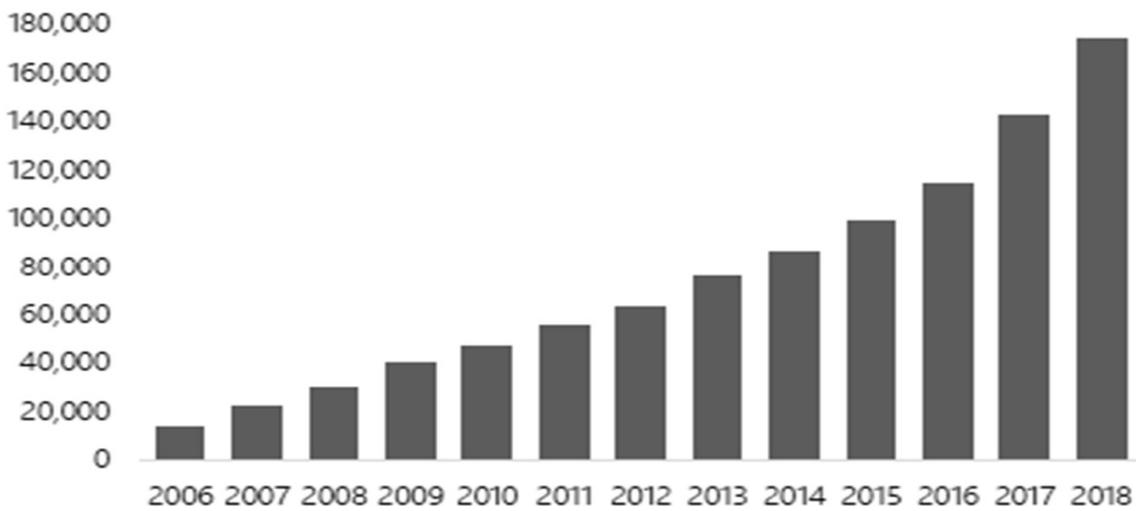


Source: OIG analysis of Medicare Part D data, 2019.

\*Spending in billions

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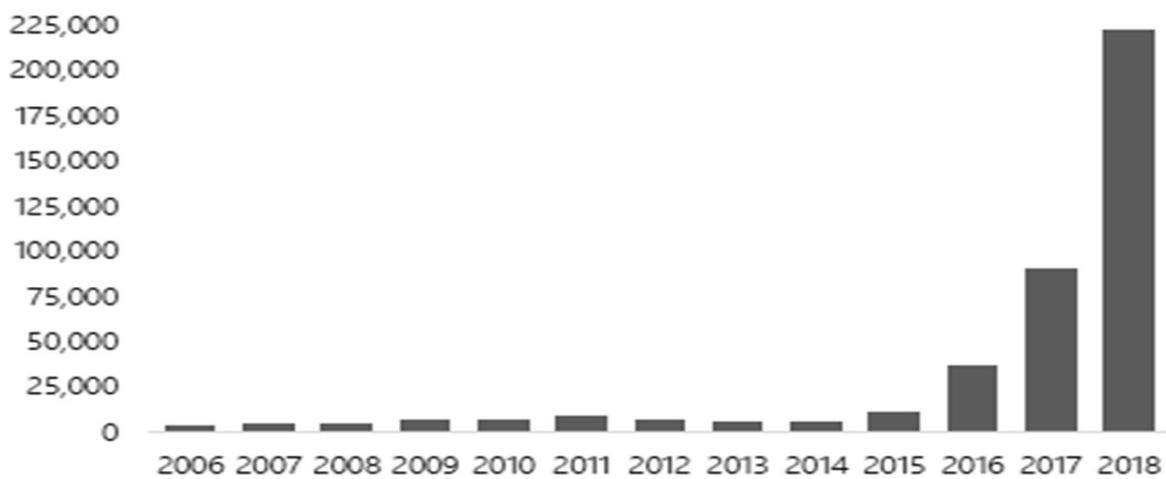
**Exhibit 2: The number of beneficiaries receiving MAT drugs through Part D has increased each year**



Source: OIG analysis of Medicare Part D data, 2019.

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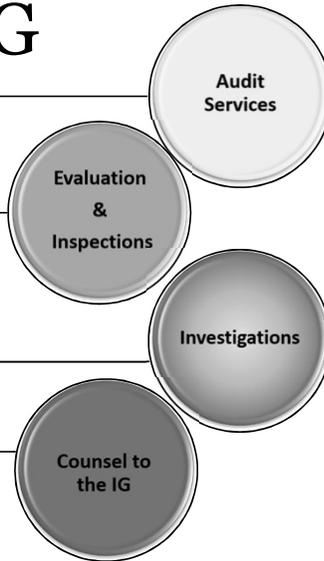
**Exhibit 3: The number of beneficiaries receiving prescriptions for naloxone—a drug that can reverse an opioid overdose—more than doubled from 2017 to 2018**



Source: OIG analysis of Medicare Part D data, 2019.

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# HHS OIG



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## OIG Outputs – 2014-2018

- \$24.4 Billion in Expected Investigative and Audit Recoveries
- 1,607 Audit and Evaluation Reports
- 4,385 Criminal Actions
- 3,562 Civil Actions
- 17,720 Exclusions

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## Desired Outcomes

- Healthier People
- Lower Costs/Trust Fund Solvency
- Better Care
- More Efficient System

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## Identifying Risk Areas

- Program Vulnerabilities
- Data Analytics
- Hotline, Qui Tams, Tips
- OIG Collaboration



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## OIG-Identified Risks

- HHS Top Management Challenges
- Work Plan
- Semi-Annual Report, HCFAC Report
- Audits, Evaluations, Investigative Results
- Website -- [oig.hhs.gov](http://oig.hhs.gov)

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# Questions?

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