DEADIVERSION CONTROL DIVISION





Silvia N. Colón

Diversion Program Manager

DEA Caribbean Division

1

The Mission of the **DIVERSION CONTROL DIVISION**

Prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources



While ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.





Regulatory Authority

Title 21, Code of Federal Regulations, Sec. 1300 et seq. (21 CFR § 1300 et seq.)

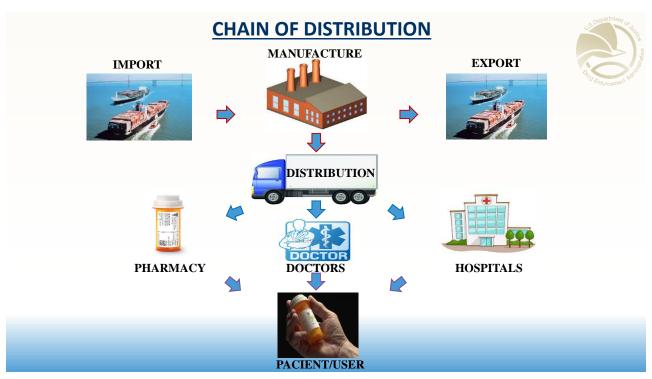




Every person who manufactures, distributes, dispenses, imports or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance, shall obtain a registration, (unless exempted by law), as one of the following:

21 CFR § 1301.11 (a); 1301.13

3



DEA Registration Entails Several Requirements



RECORDKEEPING REQUIREMENTS 21 CFR Section 1304 et al

Keep records of Controlled Substances:

- Schedules I and II separately from Schedules III, IV, and V and from all other records
- Available for inspection for a minimum of two years
- Complete and accurate records

INVENTORY REQUIREMENTS 21 CFR Section 1304.11

- Complete and accurate record of all CS on hand
- Date inventory was conducted
- Maintain inventory for at least two years
- Biennial Inventory within two years of previous inventory

5

DEA Registration Entails Several Requirements



SECURITY REQUIREMENTS 21 CFR Section 1301.71(a)

Requires that all registrants provide effective controls and procedures to guard against theft and diversion of controlled substances.

PRESCRIPTION REQUIREMENTS 21 CFR Section 1306 et al.

- Dated and signed on the date when issued
- > Patient's full name and address
- Practitioner's full name, address, and DEA registration number
- Drug name
- > Strength
- Dosage form
- Quantity prescribed
- Directions for use
- Number of refills (if any) authorized

DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the registrant has:



- 1.Materially falsified any application filed
- 2.Been convicted of a felony relating to a controlled substance or a List I chemical
- 3.Had their state license or registration suspended, revoked, or denied
- 4.Committed an act which would render the DEA registration inconsistent with the public interest
- 5.Been excluded from participation in a Medicaid or Medicare program

7

THE DIVERSION CONTROL PROGRAM CONSISTS OF:



- DIVERSION INVESTIGATORS
- SPECIAL AGENTS
- TASK FORCE OFFICERS
- INTELLIGENCE RESEARCH SPECIALISTS



Punitive Authority

Title 21, United States Code, Sec. 841 (21 USC § 841)



It shall be unlawful, for any person knowingly of intentionaly--

- To manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense a controlled substance; or
- To create distribute, or dispense or possess with intent to distribute, or dispense a counterfeit substance;



21 USC § 841

9

What is DIVERSION?





Diversion is the transfer of a pharmaceutical prescribed controlled substance, from its licit medical purpose to an illicit purpose





July 13, 2017: National Health Care Fraud Takedown **Results in Charges Against Over** 412 individuals

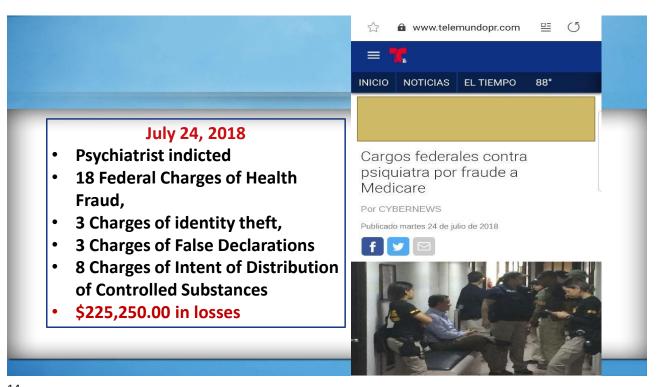
- \$1.3 billion in fraud losses
- Counts of Health Fraud and Prescription Fraud in 41 Districts
- **Including 13 Health Practitioners in Puerto Rico**



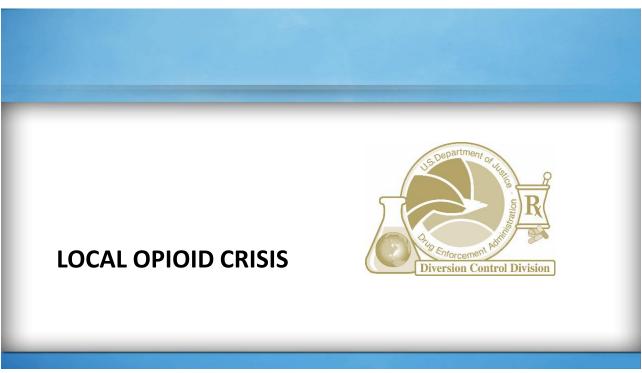
June 28, 2018: National Health Care Fraud Takedown **Results in Charges Against Over** 601 individuals

- \$2 billion in fraud losses
- Counts of Health Fraud and Prescription Fraud in 58 **Districts**
- Including 165 doctors, nurses and other licensed medical professionals.

endi Noticias

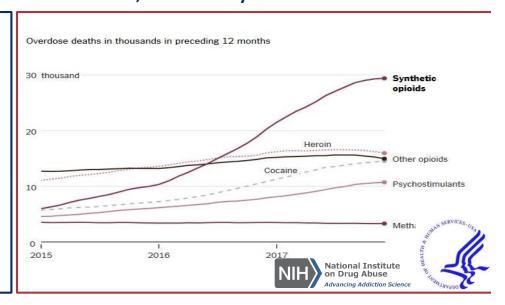




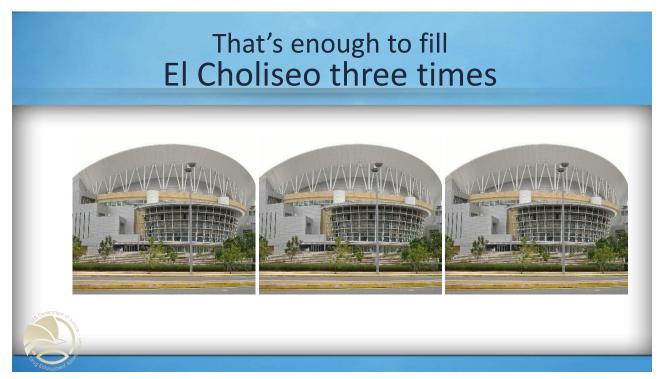


On 2017 Over 72 thousand overdose deaths on 2017. In USA, Puerto Rico y USVI

- 66 thousand deaths by October 2018 (CDC)
- 598 people in PR (ASSMCA)
- 130 Deaths per Day.
- 66% involved the misuse or abuse of an opioid.



17



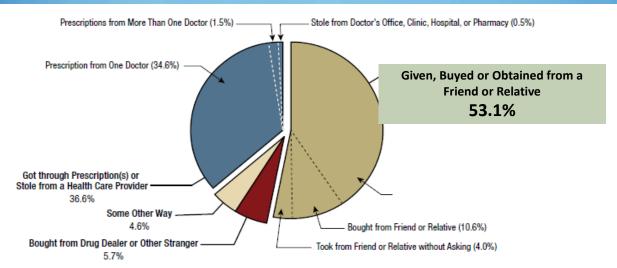


drugabuse.gov

19

SAMHSA Report from September 2017:

53.1% of misused prescriptions come from a friend or relative



11.1 Million People Aged 12 or Older Who Misused Prescription Pain Relievers in the Past Year











