

American Pain Foundation
A United Voice of Hope and Power over Pain

**"Who Do You First Protect?
Your Practice or Your Patient?"**


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Section of DEA
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Directors
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Objectives

- Review the legal influence of the DEA on the practice of pain management
- Examine common practice policies created to shield prescribers from law enforcement investigation and their impact on the person living with pain
- Explore what actions a pain management nurse can take when she/he experiences, witnesses, or unwittingly perpetuates unjust treatment of the person with pain

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Cathy Gallagher BS



See Separate Slide Deck

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Mary Vargas JD



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There are Questions That Need To Be Answered

- Where is the fine line between:
 - Discrimination or safety?
 - Safe clinical practice or violations of federal protected rights?
- Opioid Contracts/Agreements
- Urine/Blood Testing
- "3 Strikes You Are Out" Policies
- Process Used with Accepting of New Patients
- Limited "menu" of available treatment options

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Micke Brown BSN, RN



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Mega Question:

How do we provide dignified care for people living with pain while honoring legitimate safety concerns?

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Share Your Dilemma



Open Discussion

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Stand up for the rights of people with pain to receive timely and appropriate pain care!!



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Drug Enforcement Administration



DEA Overview

Cathy A. Gallagher
Associate Section Chief
Liaison and Policy Section
Office of Diversion Control

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September 2010
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Office of Diversion Control Mission

To prevent, detect, and investigate the diversion of controlled substances from legitimate sources

while



Ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes

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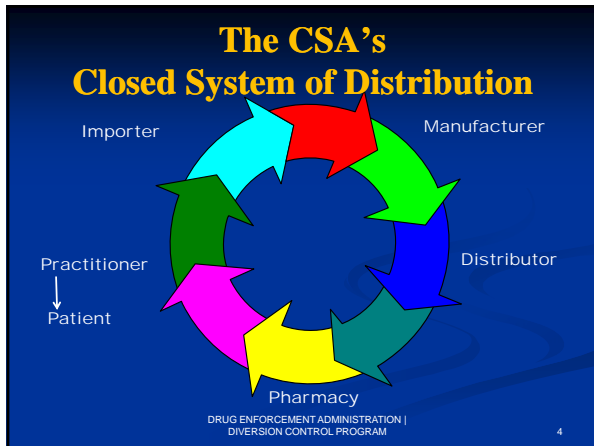
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Controlled Substances Act of 1970

- Established system for U.S. compliance with international treaties.
- Serves as the legal foundation of the Federal government's authority over controlled substances and listed chemicals.
- Consolidated over 50 laws regulating the manufacture, distribution, import / export, and dispensing of controlled substances and listed chemicals.

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Active DEA Registrants

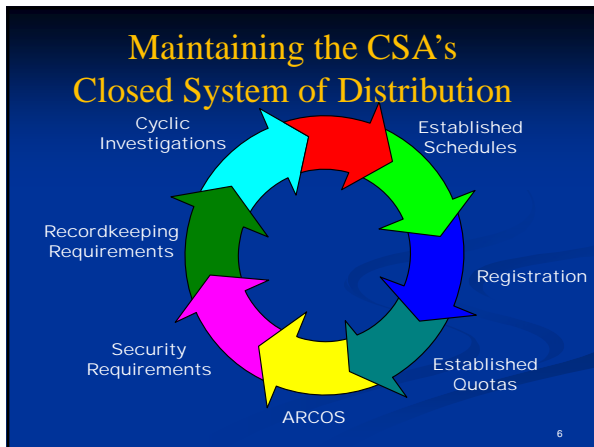
as of 6/8/10

- Practitioners 1,045,080
- MLP – Nurse Practitioners 92,107
- MLP – Physician Assistants 54,255
- Pharmacies 65,863
- Hospitals/Clinics 15,606
- Researchers 6,147
- All Others 5,676

- Approximate Total: 1.3 million - 2010
- Approximate Total: 480,000 - 1973

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Prescription Requirements

In order to be legal, a prescription must:

- Be issued by a registered practitioner.
- For a legitimate medical purpose.
- In the usual course of professional practice.



21 CFR §1306.04(a)

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Prescription Requirements

- DEA does **NOT** define nor regulate medical practice standards.
- There are no federal laws or regulations that put limits on the quantity of controlled substances that may be prescribed.
- Some states or insurance providers may limit the quantities of controlled substances prescribed or dispensed.

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Pharmacist's Corresponding Responsibility

- Corresponding responsibility rests with the pharmacist who fills the prescription.

21 C.F.R. § 1306.04 (a)

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Pain Management DEA's Policy Statement

- Dispensing Controlled Substances for the Treatment of Pain.
- Policy Statement published 09/06/2006.
- Reiterates DEA policy to prevent abuse and diversion without adversely impacting the legitimate need of patients to have full access to pain relief prescribed by their physician.

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Pain Management DEA's Policy Statement

- To reassure physicians that DEA does *not* apply a greater scrutiny to the prescribing of controlled substances to treat pain.
- Discussed the phrase “legitimate medical purpose.”
- Addressed requests for a guidance document on treating patients for pain.

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Comments / Questions?



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Position Statement on Access to Pain Care August 2010

Pain is a serious and costly public health issue — together, acute and chronic pain significantly and negatively affects the lives of an estimated one out of every four Americans, costing more than \$100 billion each year in medical claims, disability payments, lost wages and lost productivity.¹ This figure does not begin to cover the physical, emotional and economic strain of pain on the individual and his or her family members and friends.

Unfortunately, many barriers exist in our society and culture that place access to pain management out of reach for many Americans. Barriers are multifaceted and entrenched, ranging from a lack of pain providers who are knowledgeable and willing to provide appropriate pain care, to financial affordability, disparities and discrimination, and unnecessarily restrictive regulation. Furthermore, unintended consequences exist in policy, third-party payer rulings and professional conduct based on fear and stigma that continue to erode access to effective pain management among those who are suffering.

The effects of pain on the individual and society can be alleviated or managed with proper medical attention. Early intervention can reduce health care costs, limit disability and dramatically improve the lives of people living with pain and their loved ones.

Position

The American Pain Foundation (APF) advocates for improved access to effective pain care as a guiding principle and integral part of its mission. People experiencing pain have a basic human right to timely, appropriate and effective treatment of pain.

Access to care is a difficult and burdensome barrier for people with pain in receiving appropriate pain care and for our society at large, and requires an elevated collaborative effort to overcome.

APF views the goal of access to care as:

- Timely and appropriate pain care that includes access to the full range of legal, safe and effective treatment options for all individuals, regardless of race, ethnicity, gender, age, socioeconomic or insurance status, to lessen pain, promote recovery, restore function and improve quality of life.
- Individual comprehensive multimodal pain management plans devised by the person with pain and his/her health care team. Such plans will address complex factors, such as the patient's health status, clinical and social circumstances, pain condition, severity and functional impact of pain, patient preference, provider experience and availability.

- Use of multimodal treatment approaches tailored to the individual living with pain, including reasonable access to medically appropriate options such as pharmacotherapy, psychosocial intervention, physical rehabilitation, integration of complementary and alternative medicine (CAM), injection and infusion therapies, implantable devices and surgical intervention. Treatment options must include access to medications, including controlled substances, as necessary for an individual's pain treatment. Such medications should be used according to FDA-approved indications or other uses justified by research and clinical experience.

It is a moral imperative to help people living with pain achieve a standard of life deemed worthy of living — one that permits individuals to enjoy their family members and friends, as well as contribute to our society and economy. To this end, all people in pain have a right to timely, appropriate and effective pain care.

APF believes access to care can be improved by

- Educating the medical community and the public that chronic persistent pain is a disease state that requires medical attention and expertise.
- Adapting disease management principles to guide primary care and appropriate specialty referral.
- Implementing standards and monitoring practices within all health care systems and ensuring that transparency of pain care is an indicator in satisfaction surveys and other institutional quality ratings (e.g., National Committee for Quality Assurance, Joint Commission on Accreditation of Healthcare Organizations).
- Developing and implementing state specific report cards on practice and access using the Pain & Policy Studies Group (www.painpolicy.wisc.edu) model for state policy report cards.
- Identifying and eliminating regulatory and third-party payer policies and medical practices that usurp the “doctor-patient” relationship or deny pain care access to vulnerable groups or those policies that are primarily developed for cost savings that may supersede the best interest of patient care and serve as an inappropriate and unacceptable form of health care rationing.
- Ensuring that reimbursement is compatible with the time required for effective pain assessment and treatment and that it includes multi-disciplinary/multimodal practice of care.

APF calls on the professional medical community, regulators and all concerned stakeholders to partner with people living with pain in taking action. Organizational leaders and members alike must reaffirm the ethical commitment to the care of people living with pain and re-energize collaborative efforts to strategically address the problems related to accessing pain care and the barriers preventing care. Medical, governmental, non-profit and private sector parties must work together to improve clinical and economic outcomes associated with acute and chronic pain. The overwhelming evidence of harm resulting from inaction serves as an irrefutable call to action.

i National Centers for Health Statistics, Chartbook on Trends in the Health of Americans 2006, Special Feature: Pain. Page 70. <http://www.cdc.gov/nchs/data/hus/hus06.pdf>. Accessed August 24, 2010. National Institutes of Health. NIH Guide: New Directions in Pain Research I. September 4, 1998. Available <http://grants.nih.gov/grants/guide/pa-files/PA-98-102.html>. Accessed August 24, 2010.