

Criminal and Civil Enforcement Trends: Focus on Federal Enforcement of Fraud and Abuse Involving Hospice Programs and Opioid Abuse

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1

Speakers

Christine Anusbigian, MBA - Specialist Leader

- Deloitte & Touche LLP

Sean Bosack, JD

- Godfrey & Kahn, S.C.

Michelle Frazier, JD, SVP Chief Compliance Officer

- Aurora Health Care

Stacy Gerber Ward, JD

- von Briesen & Roper, S.C.
- Former Assistant United States Attorney

2

Outline

- **Background**
 - HCF Statutes
 - Hospice care in the U.S.
 - Opioid abuse in the U.S.
- **Agency involvement and enforcement tools**
- **Fraud Schemes and cases**
- **Compliance/audit recommendations**

3

Health Care Fraud Statute: 18 U.S.C. § 1347

- Punishes anyone who knowingly and willfully executes or attempts to execute any scheme to defraud “*any health care benefit program,*” in connection with delivery of or payment for health care benefits, items or services, or anyone who uses or attempts to use false or fraudulent pretenses, representations, or promises in connection with delivery of or payment for health care benefits, items, or services to gain control of any money or property owned by “*any health care benefit program.*”

4

Health Care Fraud Statute Penalties

- Violators shall be fined and/or imprisoned for up to **10 years**.
- If serious bodily injury results, the violator shall be fined and/or imprisoned for **up to 20 years**.
- If death results, the violator shall be fined or imprisoned for **any term of years or for life**.
- Actual knowledge of the statute or specific intent to violate is *not required*.
- Applies to both government-sponsored programs *and* private insurance.

5

False Claims Act 31 U.S.C. § 3729

- Federal law that imposes liability on people who defraud governmental programs like Medicare and Medicaid.
- Violators are subject to civil monetary penalties of \$10,500 to \$20,000 per false claim and three times the actual damages the government sustains due to the fraud.
- **Providers have been sued under the False Claims Act for issuing medically unnecessary prescriptions.**

6

Federal Program Exclusion Statute: 42 U.S.C. § 1320a-7

- The “Exclusion Statute” requires that physicians convicted of crimes related to federal healthcare programs, neglect or abuse of patients, or felony violations relating to controlled substances be excluded from participation in federal health care programs.



- Physicians may also be excluded if convicted of a misdemeanor related to a controlled substance, subject to suspension or revocation of license.

7

Yates Memorandum: Individual and Corporate Liability

September 9, 2015:

- U.S. Deputy Attorney General issued to all DOJ attorneys policy changes regarding treatment of corporate civil and criminal prosecutions.
- **Reason** ...too many individuals escaped punishment for wrongdoing associated with the financial crisis.
- **Outcome** ...an enhanced focus on pursuing civil and criminal cases against individuals.

8

Yates Memorandum: Health Care Providers

- Reference to the False Claims Act is one of the DOJ's primary tools.
- Providers and systems need to monitor the conduct of physicians, nurses and mid-levels.
- Commit to updating compliance policies and procedures.
- Commit to educating individuals on best practices to mitigate institutional and individual risk.

9

Hospice care in the U.S.

Increasing Scrutiny of Hospice Care

Why Focus on Hospice?

- In 2013, **Medicare paid \$15.1 billion** for hospice care for 1.3 million beneficiaries.
- Between 2005 and 2009, hospice payments **increased 53%**.
- Payments for hospice care in nursing facilities rose even faster: nearly a **70% increase** over the same years.

What is the Medicare Hospice Benefit?

To be eligible for Medicare hospice care, a beneficiary must be:

- Entitled to Part A of Medicare
- Certified as having a terminal illness with a life expectancy of 6 months or less.
- Care may be provided in various settings, including the home or a nursing facility.

Source: <https://oig.hhs.gov>

Increasing Scrutiny of Hospice Care (cont'd)

Hospice care has been a focus of the Office of Inspector General (OIG), United States Department of Health and Human Services (DHHS).

OIG Work Plan 2017

- Medicare Hospice Benefit Vulnerabilities and Recommendations for Improvement: A Portfolio
- Review of Hospices' Compliance with Medicare Requirements
- Hospice Home Care — Frequency of Nurse On-Site Visits to Assess Quality of Care and Services

OIG Reports

- Hospices Should Improve their Election Statements and Certifications of Terminal Illness (September 2016)
- Hospices Inappropriately Billed Medicare Over \$250 million for General Inpatient Care (March 2016)
- Medicare Hospice Care For Beneficiaries in Nursing Facilities: Compliance With Medicare Coverage Requirements (September 2009)

Source: <https://oig.hhs.gov>

Hospice benefit

The Medicare Hospice Benefit

- Medicare pays for health services for palliative care that is related to a terminal illness.
- Terminal Illness: One in which the patient's life expectancy is 6 months or less if the terminal illness runs its normal course. 42C.F.R. § 418.3.
- Palliative care is designed to relieve the pain, symptoms, or stress of terminal illness. 42CFR § 418.3.
- Palliative care does not treat the underlying condition.

Medicare Hospice Conditions

- Beneficiary must be terminally ill.
- The treating physician and hospice medical director must both sign the initial certification of terminal illness (90 days).
 - Subsequent certifications must only be signed by one physician.
- Beneficiary must sign an election form.
- A plan of care must be established by the hospice.

15

Care Related to Patient's Terminal Illness

- By signing the election form, the beneficiary waives his/her rights to other Medicare benefits (i.e., curative care) related to the terminal illness.
- Electing the hospice benefit will not alter traditional Medicare benefits for medical conditions not related to his/her terminal illness.

16

Physician Certifications

- For the initial certification period of 90 days, two physicians – the treating physician and the hospice medical director – must certify that the patient has a prognosis of less than 6 months. 42 C.F.R. § 418.20.
- The certification must be accompanied by clinical information and other documentation that support the medical prognosis of less than 6 months. 42 C.F.R. § 418.22.
- “A signed certification, absent a medically sound basis that supports the clinical judgment, is not sufficient for application of the hospice benefit under Medicare.” 70 Fed. Reg. 70,532, 70,534-35 (Nov. 22, 2005).

17

Hospice Levels of Care

Routine Care

- Paid on a daily rate.
- Paid for every day when the beneficiary is on the service, regardless of whether a service was rendered on a particular day.
- Same rate no matter how many disciplines provided care.
- Not paid if another level of hospice care is provided.

18

Hospice Levels of Care (cont'd)

Continuous Care

- Paid on an hourly basis.
- Beneficiary experiences an acute medical crisis requiring more intensive hospice care.
- Care provided with the intent to maintain the beneficiary at home.
- Minimum of 8 hours of care a day required.
- At least half the hours of care must be provided by a nurse (RN or LPN).

19

Hospice Levels of Care (cont'd)

General Inpatient Care

- Inpatient hospitalization specifically to address care related to the terminal illness.
 - Pain control/symptom management.
 - Breakdown of caregiver support system.

Respite Care

- Short-term inpatient care specifically to relieve caregivers.
- Expected to be provided on an occasional basis.
- Duration is limited to 5 days.

20

Hospice Levels of Care (cont'd)

Rev. Code	Level of Care	2016 Reimbursement
651	Routine Home Care (days 1-60)	\$186.85/day
651	Routine Home Care (days 61+)	\$146.83/day
652	Continuous Care	\$944.79 (\$39.37/hour)
655	Inpatient Respite Care	\$167.45/day
656	General Inpatient Care	\$720.11/day

Source: Medicare Learning Network Matters No. MM9301 (9/4/15)

21

Hospice Cap

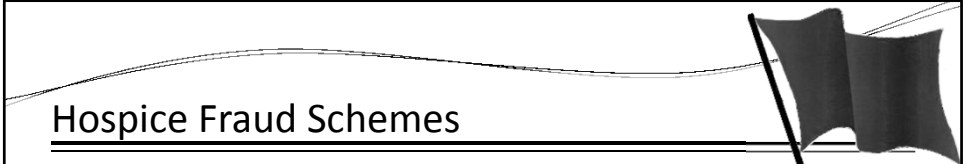
- There is a cap on the amount that a hospice can be paid annually.
- The cap amount for 2016 was **\$27,820.75**.
- To determine a hospice's aggregate cap, multiply the number of Medicare beneficiaries by the hospice cap amount.
- So, if a hospice has 100 beneficiaries, the aggregate cap calculation is:
 - $100 \times \$27,820.75 = \$2,782,000$
- If the hospice has received more than that amount from Medicare during the year, the hospice must pay back the overage.

Source: CMS Fact Sheet, Final Fiscal Year 2017 Payment and Policy Changes for the Medicare Hospice Benefit (CMS-1652-F).

22

Hospice fraud schemes

13

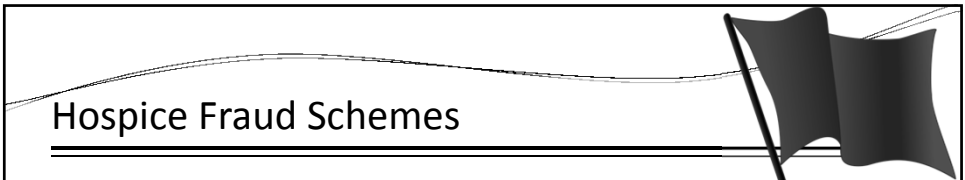


Hospice Fraud Schemes

- Admitting and retaining beneficiaries that do not have a prognosis of 6 months or less.
 - Local Coverage Determinations (LCDs) are used to determine prognosis.
- Red Flags
 - High percentage of beneficiaries with “suspect” diagnosis such as dementia and failure to thrive.
 - High percentage of beneficiaries that have long lengths of stay (more than one year).
 - Discharging beneficiaries to avoid “cap exposure.”

24

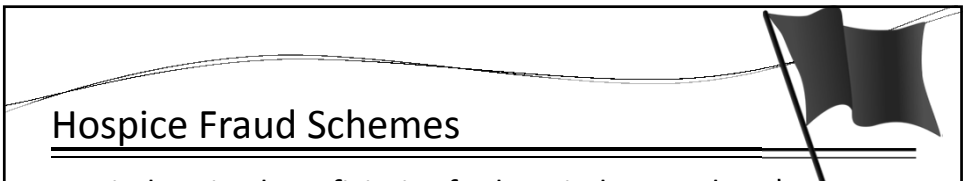
Hospice Fraud Schemes



- Billing for a higher level of care than necessary
 - Billing for general inpatient care or continuous care when the patient does not need elevated levels of care.
- DOJ complaint against national hospice company:
 - The company marketed crisis care services to patients and their families as “intensive comfort care” services, without mentioning that, in order to bill Medicare for these services at the higher rates, a patient had to be experiencing a short-term crisis and have acute medical symptoms.
 - One company nurse stated that, on more than one occasion, when the company sent her to the homes of patients whom she was told needed crisis care, she arrived only to find that the patients were at church, playing bingo, or having their hair done, and not in crisis.

25

Hospice Fraud Schemes




- Discharging beneficiaries for hospital care related to terminal illness and then readmitting them.
- Hiring medical directors who also serve as medical directors for nursing homes in an effort to obtain referrals.
- Offering kickbacks to nursing homes for referrals.
 - Hospice nursing staff providing care to non-hospice residents.
 - Supplying the nursing home with equipment allegedly for the residents on hospice.

26

Hospice Cases

Hospice care has been a focus of the OIG and the DHHS.

- ❖ SouthernCare Inc. ¹⁸, an Alabama-based company, and its shareholders allegedly submitted false claims to the Government for hospice patients who were not eligible for such care. In 2009, SouthernCare Inc. agreed to pay a total of \$24.7 million to settle allegations and enter into a corporate integrity agreement (CIA) with OIG.
- ❖  Roberto Ruiz, M.D., and his company, Southwest Internal Medicine Group, P.C., entered into an integrity agreement with OIG in 2009 to resolve charges of submitting false claims to Medicare for hospice services. The agreement requires written policies, employee education, and annual audits. He also paid \$525,000 to resolve his civil liability.
- ❖ In 2008, Solaris Hospice, Inc. ¹⁹, formerly Home Hospice of North Texas, and its two owners agreed to pay \$500,000 plus interest to resolve allegations that Solaris submitted improper claims for hospice-related items and services. The improper claims included, for example, alleged misrepresentation to Medicare of the medical conditions of patients to ensure that they would be or continue to be hospice patients. Also, Solaris Healthcare, the parent company of Solaris, agreed to enter a 5-year CIA with OIG.

<https://oig.hhs.gov/newsroom/news-releases/2011/hospice.asp>

Hospice compliance assessment

Hospice Claims Assessment

The following activities are completed during a hospice medical record assessment:

1. Confirm sampling parameters

- Confirm the sampling parameters such as:
 - Sample size,
 - Number of hospice claims,
 - Payor mix (e.g., Medicare, Medicaid, and commercial payors),
 - Dates of service,
 - Random or focused sample, and
 - A focused sample may include selections based on certain facilities, geographies or potential high risk claims.

2. Obtain data & select samples

- Obtain a report of claims billed for the specified period of time.
- Based on the agreed upon criteria select a sample.

3. Obtain records

- Claim form
- Remittance advice.
- Physician certification and/or recertification that the beneficiary meets the hospice criteria of a terminal prognosis.
- Documentation of face-to-face encounters.
- Completion of the hospice election notices.
- Other
 - Billing documents (AOB, MSP, ABN, contract notes etc.)
 - Licensure

Hospice Claims Assessments (cont'd)

The following activities are completed during a hospice claims assessment:

4. Evaluate Claims & Medical Records

- Compare each record to the payor billing requirements at the time of service.
- Hospice claims and medical records are evaluated for the following:
 - A preliminary assessment and/or plan of care was developed and signed within 48 hours of admission
 - If the physician certification / recertification that the beneficiary meets the hospice criteria of a terminal prognosis was completed within the required timeframes, and that appropriate signature and dates are present
 - If the patient's clinical documentation meets LCD criteria
 - If the physician's "face-to-face" requirement was met as required for recertification of the terminal illness prior to 180th day recertification period and each subsequent recertification period thereafter. Whether the document was signed by the physician and the narrative contains a summary of patient's continual eligibility for hospice
 - If the appropriate level of service, as supported by the documentation, was charged and reported on the claim
 - If the hospice election forms were completed within the required time frame and whether the election forms contain the content required by Medicare.

Hospice Claims Assessments

Compliance with the following guidelines are assessed during hospice claims assessments:

Guidelines

- CMS Pub 100-4 Chapter 11
- CMS Pub 100-2 Chapter 9
- Title 42, Part 418
- Medicare LCDs - These policies contain clinical criteria that should be documented by the physician to demonstrate the terminal status of the patient.
 - Home health & hospice Medicare Administrative Contractors:
 - National Government Services, Inc.
 - CGS Administrators, LLC
 - Palmetto GBA
- OIG Compliance Program Guidance Hospices – published 1999

Hospice Claims Assessments (cont'd)

CMS Published an example election statement in December 2016.

MLN Matters® Number: SE1631 Related Change Request Number: N/A

Medicare Hospice Election Statement

Draft Sample

I, _____ choose to elect the Medicare hospice benefit and receive
(Beneficiary Name)

Hospice services from _____
(Hospice Agency)

Hospice Philosophy
I acknowledge that I have been given a full explanation and have an understanding of the purpose of hospice care. Hospice care is to relieve pain and other symptoms related to my terminal illness and related conditions and such care will not be directed toward cure. The focus of hospice care is to provide comfort and support to both me and my family/caregivers.

Effects of a Medicare Hospice Election
I understand that by electing hospice care under the Medicare Hospice Benefit, I am waiving (give up) all rights to Medicare payments for services related to my terminal illness and related conditions and I understand that while this election is in force, Medicare will make payments for care related to my terminal illness and related conditions only to the designated hospice and attending physician that I have selected. I understand that services not related to my terminal illness or related conditions will continue to be eligible for coverage by Medicare.

Right to choose an attending physician
I understand that I have a right to choose my attending physician to oversee my care. My attending physician will work in collaboration with the hospice agency to provide care related to my terminal illness and related conditions.
☐ I do not wish to choose an attending physician

I acknowledge that my choice for an attending physician is: _____ NPI (if known) _____
Physician Full name: _____
Office Address: _____

I acknowledge and understand the above, and authorize Medicare hospice coverage to be provided by _____ to begin on _____
(Hospice Agency) (Effective Date of Election)

Note: The effective date of the election, which may be the first day of hospice care or a later date, but may be no earlier than the date of the election statement. An individual may not designate an effective date that is retroactive.

Signature of Beneficiary/Representative _____ (Date) _____
☐ Beneficiary is unable to sign -
Reason: _____

Witness signature (Date)

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1631.pdf>

Hospice Claims Assessments (cont'd)

The following illustrative examples display the tools that can be utilized when conducting a hospice claims assessment:

Document Checklist	Complete	N/A	Comments
1. UB-04 Claim Form	<input type="checkbox"/>	<input type="checkbox"/>	
2. Remittance Advice	<input type="checkbox"/>	<input type="checkbox"/>	
3. Physician Certification of Terminal Illness from hospice physician and attending physician (if any)	<input type="checkbox"/>	<input type="checkbox"/>	
4. Patient referral information	<input type="checkbox"/>	<input type="checkbox"/>	
5. All Other Applicable Physician Orders (arranged in date order, earliest date first)	<input type="checkbox"/>	<input type="checkbox"/>	
6. Other supporting documentation to support terminal prognosis	<input type="checkbox"/>	<input type="checkbox"/>	
7. Level of care determination form	<input type="checkbox"/>	<input type="checkbox"/>	
8. Face-to-Face Documentation related each certification or recertification period	<input type="checkbox"/>	<input type="checkbox"/>	
9. Patient Consent for treatment	<input type="checkbox"/>	<input type="checkbox"/>	
10. Skilled Nursing Progress Notes	<input type="checkbox"/>	<input type="checkbox"/>	
11. Home Health Aide Notes	<input type="checkbox"/>	<input type="checkbox"/>	
12. Home Health Aide Supervision Notes	<input type="checkbox"/>	<input type="checkbox"/>	
13. Interdisciplinary Team Care Plan(s)	<input type="checkbox"/>	<input type="checkbox"/>	
14. Other supporting documentation, if any List:	<input type="checkbox"/>	<input type="checkbox"/>	

Record information										Record review									
Sample #	Medical Record #	Patient ID	DOB/Age	Date of Death	DC Date	Home Hospice	Insurance	Chart Form	Thru Date	Date of birth released	Order Referral	Notice of Election	Documentation by Physician	Documentation by Physician	Certified as Terminal Illness (CTI) by hospice physician or physician?	Certified as Terminal Illness (CTI) by hospice physician or physician?	Documentation Requirements met to recertify prior to 3rd month of certification?	Documentation Requirements met to recertify prior to 3rd month of certification?	Comments (see detailed checklist)

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Hospice Claims Assessments (cont'd)

During a hospice claims assessment, it is important to consider additional review areas:

Other Review Areas:

- Hospice cap
- Quality reporting
 - 2% reduction in payment for not reporting
- Potential data analytic examples:
 - Referral patterns
 - Diagnoses
 - Utilization / length of stay

Interviews:

- Interview and other document review to assess both controls in place and improper practices, for example:
 - Processes for auditing and monitoring and/or quality assurance checks
 - Systems, tools or prompts that serve as checklists and/or reminders to complete required tasks
 - Inappropriate referrals
 - Selection of patients that are lower cost and longer term

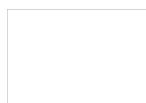
Hospice Claims Assessments (cont'd)

Look for risks identified in OIG Compliance Program Guidance specifically for hospice care.

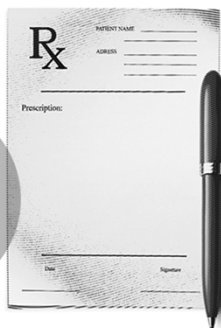
- Uninformed consent to elect the Medicare Hospice Benefit.
- Admitting patients to hospice care who are not terminally ill.
- Arrangement with another health care provider who a hospice knows is submitting claims for services already covered by the Medicare Hospice Benefit.
- Under-utilization.
- Falsified medical records or plans of care.
- Untimely and/ or forged physician certifications on plans of care.
- Inadequate or incomplete services rendered by the Interdisciplinary Group.
- Insufficient oversight of patients, in particular, those patients receiving more than six consecutive months of hospice care.
- Hospice incentives to actual or potential referral sources (e.g., physicians, nursing homes, hospitals, patients, etc.) that may violate the anti-kickback statute or other similar Federal or State statute or regulation including improper arrangements with nursing homes.
- Overlap in the services that a nursing home provides, which results in insufficient care provided by a hospice to a nursing home resident.
- Improper relinquishment of core services and professional management responsibilities to nursing homes, volunteers and privately-paid professionals.
- Providing hospice services in a nursing home before a written agreement has been finalized, if required.
- Billing for a higher level of care than was necessary.
- Knowingly billing for inadequate or substandard care.
- Pressure on a patient to revoke the Medicare Hospice Benefit when the patient is still eligible for and desires care, but the care has become too expensive for the hospice to deliver.
- Billing for hospice care provided by unqualified or unlicensed clinical personnel.
- False dating of amendments to medical records.
- High-pressure marketing of hospice care to ineligible beneficiaries.
- Improper patient solicitation activities, such as "patient charting".
- Inadequate management and oversight of subcontracted services, which results in improper billing.
- Sales commissions based up on length of stay in hospice.
- Deficient coordination of volunteers.
- Improper indication of the location where hospice services were delivered.
- Failure to comply with applicable requirements for verbal orders for hospice services.
- Non-response to late hospice referrals by physicians.
- Knowing misuse of provider certification numbers, which results in improper billing.
- Failure to adhere to hospice licensing requirements and Medicare conditions of participation.

Opioid abuse in the U.S.

Opioid Overdoses the United States (2000-2014)



of all opioid overdose deaths involve a **prescription opioid.**



- From 2000 to 2014 nearly half a million people died from drug overdoses.
- Since 1999, the number of overdose deaths involving opioids nearly quadrupled.

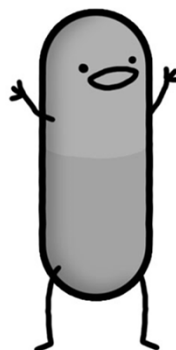
Centers for Disease Control and Prevention. [Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014](#). MMWR 2015; 64:1-5.

37

Opioid Overdose Deaths in the U.S.

In 2014, opioids were involved in 47,000 deaths in the U.S.

Approximately 129 people die every day from drug poisoning, 61% of them are pharmaceutical opioids or heroin related.



Side effects may include death!

SOURCE: Office of the Attorney General Memorandum, September 21, 2016. Subject: Department of Justice Strategy to Combat Opioid Epidemic

38

Economic Impact of the Opioid Epidemic

- \$55 billion in health and social costs related to prescription opioid abuse each year.
- \$20 billion in emergency department and inpatient care for opioid poisonings.



Source: Pain Med. 2011;12(4):657-67. 2013;14(10):1534-47.

Each day, more than
1,000
PEOPLE

are treated in
emergency
departments for
not using prescription
opioids as directed.



39

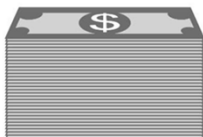
Part D Drug Spending, 2015

- From 2006 to 2015, total spending for Part D drugs increased by 167%, growing from \$51.3 billion to \$137 billion.
- Part D spending for opioids was highest for OxyContin, hydrocodone-acetaminophen (Vicodin), oxycodone-acetaminophen (Percocet), and fentanyl.
- Part D spending for commonly abused opioids reached \$4.1 billion in 2015.

NEARLY 1 IN 3 beneficiaries received a commonly abused opioid



These opioids accounted for **OVER \$4 BILLION** in Part D spending



The commonly abused opioids with the **HIGHEST PART D SPENDING** were:



OxyContin
Hydrocodone-
Acetaminophen
Oxycodone-
Acetaminophen
Fentanyl

Source: HHS OIG Data Brief, June 2016, OEI-02-00290, "High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns."

40

Agency involvement

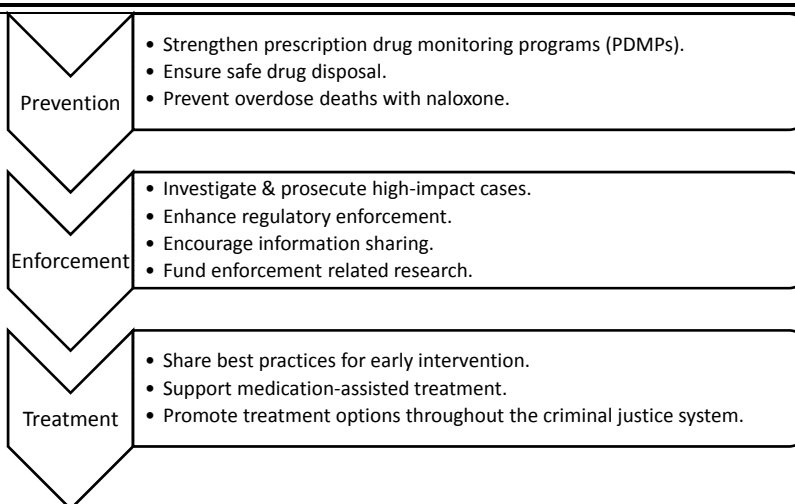
Agency Involvement CDC and DOJ

1. Guidelines for Prescribing Opioids for Chronic Pain
Information for Patients
Information for Providers
CDC and Prevention (1/6/2017)
2. 3 Pillars of Engagement Memo
Office of Attorney General (9/21/2016)
3. New Actions to combat opioid epidemic.
Health and Human Services Actions (7/6/2016)
4. Prescription Drug Monitoring Programs (PDMPs)
5. Outlines actions for Improving Pain Care in America
National Pain Strategy (3/2016)

42

3 Pillars of Engagement Memo

From the Office of Attorney General (9/2016)



Source: OAG Memo distributed 9/21/2016 – Subject: Department of Justice Strategy to Combat Opioid Epidemic

43

HHS - New Actions to Combat Opioid Epidemic

- A proposal to eliminate any potential financial incentive for doctors to prescribe opioids based on patient experience.
- Expanding access to buprenorphine.
- Launch of more than a dozen new research studies on opioid misuse and pain treatment.
- A requirement for Indian Health Service prescribers and pharmacists to check state PDMP databases before prescribing or dispensing opioids.

Source: Burwell, S. (7/2016) "HHS announces new actions to combat opioid epidemic. HHS.gov.

44

Prescription Drug Monitoring Programs (PDMPs)

PDMPs are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs to patients, to monitor for suspected abuse or diversion.



Source: Centers for Disease Control and Prevention, (3/23/2016) Injury Prevention & Control: Opioid Overdose. Available at: <https://www.cdc.gov/overdose/pdmp/index.html>

45

PDMPs (cont'd)

- 29 states are receiving funding through the *Prevention for States* program.
- Through 2019, CDC plans to give selected states annual awards between \$750,000 and \$1 million to advance prevention in four key areas.
- PDMPs continue to be among the most promising state-level interventions to improve painkiller prescribing, inform clinical practice, and protect patients at risk.

Source: Centers for Disease Control and Prevention, (8/30/2016) National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention. Prevention for States, Available at: https://www.cdc.gov/drugoverdose/states/state_prevention.html

46

Federal enforcement tools

47

Controlled Substances Act (CSA)

21 U.S.C. § 801, *et seq.*

- The CSA is the framework through which the federal government regulates the lawful production and distribution of controlled substances.
- The CSA places certain drugs and chemicals into one of five schedules.
- Schedule 1 has no accepted medical use.
- Schedules 2 through 5 include substances that have accepted medical uses and the schedules reflect substances that are progressively less dangerous and addictive.

48

Controlled Substances Act (cont'd)

- The CSA requires that any person or entity who handles a controlled substance must register with the Drug Enforcement Administration (DEA).
- The CSA requires registrants to maintain accurate records of all transactions involving controlled substances and accurate inventories.
- The CSA provides criminal sanctions for the illicit possession, manufacture, or distribution of controlled substances.
- The CSA also contains civil penalties for violations, including violations of the record keeping provisions.

49

Controlled Substance Act Enforcement

Schedule	Example	Prison Time	Fines
II	Oxycodone Fentanyl	Up to 20 Yrs.	Up to \$1M
III	Tylenol w/Codeine Ketamine	Up to 10 Yrs.	Up to \$500,000
IV	Valium Ambien Darvocet	Up to 5 Yrs.	Up to \$250,000

- Prison terms and fines double for distribution to persons under 21.
- Persons convicted can be subject to forfeiture of personal property and real estate

50

DEA Registration & Licensure Actions



- Under 21 U.S.C. § 822, Physicians must register in order to prescribe or dispense controlled substances.
- Medical licensure loss or limitation and loss of DEA registration often go hand-in-hand.
- Where physicians are charged with prescription-related criminal violations or civil violations, voluntary surrender of DEA registration is often part of a plea or settlement.

51

Civil Enforcement of the CSA

- *U.S. ex rel. Denk v. PharMerica Corp.*, E.D. Wisconsin
- PharMerica is a closed-door pharmacy that provides pharmaceuticals to long-term care facilities.
- The relator was a pharmacy manager in the Wisconsin pharmacy.
- Initially reported to the DEA that the pharmacy was not obtaining prescriptions for controlled substances dispensed to nursing homes.
 - Staff contacted the pharmacy and asked that a drug be dispensed for the resident.
 - Pharmacy dispensed the drug and simultaneously created a document with some of the information necessary for a prescription and faxed it to the resident's physician.

52

Civil Enforcement of the CSA (cont'd)

- CSA requires that Schedule II drugs (narcotics) be dispensed only after receiving an original written prescription (21 C.F.R. § 1306.11(a)).
- The CII written prescription requirement has two exceptions:
 - Prescriptions for nursing home residents can be faxed.
 - In an emergency situation, the practitioner may give an oral prescription to the pharmacy, followed within 7 days by a written prescription.
 - 21 C.F.R. § 1306.11(d) and (f)
- Schedule II prescriptions cannot be “refilled” – a new prescription must be given (21 C.F.R. § 1306.12(a)).

53

Civil Enforcement of the CSA (cont'd)

- The DEA executed administrative warrants at several PharMerica pharmacies.
- Concluded that PharMerica dispensed Schedule II narcotics without first having an original written prescription and, in some instances, never received a prescription.

54

Civil Enforcement of CSA (cont'd)

- The relator alleged that many of these inappropriately filled medication requests were reimbursed by the Medicare Part D program and, therefore, the claims for these drugs to Part D were false and violated the False Claims Act.
- The United States intervened and filed a complaint (Case No. 09-CV-720, E.D. Wisconsin).
- Case settled for \$31.5 million to resolve both violations of the CSA and the FCA.

55

Mass General Hospital (Civil case)

- Time Frame:** From October 2011 to April 2015
- Issue:** Lax controls and procedures to guard against theft and diversion of controlled substances.
- Examples:** 2 nurses stole +17,000 pills from automated drug-dispensing machines. MGH failed to report to DEA.
- A 2-month audit (2013) found +25,000 missing or extra pills at the inpatient and outpatient pharmacies.
- Medical personnel often took controlled substances with them to lunch at the on-site hospital cafeteria.
- Outcome:** \$2.3M violations of the Controlled Substance Act (21 C.F.R.).

56

Potential fraud schemes

37

Courting Disaster

Physician Behavior that Invites Liability and Investigation:

- Operating like a “Pill Mill”
 - High-volume pain clinics that prescribe large quantities of painkillers to people who don’t need them medically.
 - Investigators are on the lookout for high-turnover practices.
- Failure to “trust but verify”
 - Failure to physically examine patients.
 - Failure to notice drug dependence.
 - Prescribing drugs without legitimate medical need.
 - Failure to monitor patients on state PDMPs.
 - Failure to adhere to pain contracts.
 - Failure to require urine testing where appropriate.

58

Fraud Schemes

Examples of opioid fraud schemes:

- Diversion through automated drug-dispensing machine
- Forged prescriptions
- Bedside diversion
- Operating room diversion
- Prescribing professionals – “pill mill”

59

Supporting compliance

60

Centers for Disease Control Guidelines for Prescribing Opioids

Encourage providers to implement leading practices for responsible prescribing which includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients.

1. Identify and treat the cause of the pain, use non-opioid therapies.
2. Start low and go slow.
3. Close follow-up.
4. Conduct a physical exam, pain history, past medical history, and family/social history.



Source: CDC Guidelines for Prescribing Opioids for Chronic Pain, 2016

61

CDC Guidelines to Avoid Liability (cont'd)

5. Conduct urine drug test.
6. Consider all treatment options.
7. Implement pain treatment agreements.
8. Monitor progress with documentation.
9. Use safe and effective methods of discontinuing opioids.
10. Use PDMP data to identify past and present opioid prescriptions throughout treatment.



Source: CDC Guidelines for Prescribing Opioids for Chronic Pain, 2016

62

Compliance Assessment - Diversion Prevention Program

- Create Diversion Prevention Program
 - Overseen by multidisciplinary Steering Committee that includes Medical Staff, Pharmacy, Nursing, Loss Prevention/Security, Human Resources, Compliance, Patient Safety/Clinical Risk Management, Legal Services, Operations.
- Develop control standards
 - Include comprehensive background investigations of employment candidates & mandatory pre-employment and periodic drug testing.
- Solidify incident response and reporting processes.
- Ensure effective and consistent training for signs of diversion and drug-seeking behavior.
- Automated drug-dispensing machine/Pyxis – location – in sight of other professionals or camera.

63

Compliance Assessment - Regular Auditing

- Conduct risk assessment through Diversion Prevention Committee to prioritize audits, including scope and location/department.
- Review storage and security processes to ensure that controlled substances and prescription pads/paper are secured.
- Identify high risk areas where waste diversion may occur (i.e., surgical, anesthesia, procedural) and develop regular audit process to monitor these areas.
- Ensure effective investigation and reporting processes are in place to address suspected diversions.

64

Compliance Assessment Using Analytics To Detect Diversion

Opioid Data Mining Project

- Identify prescribing time period (ex. April 11, 2016 - April 17, 2016).
- Develop filter protocol to identify common indicators of improper prescribing:
 - 10 or more prescriptions for opioids within a week,
 - prescriptions with a count of 60 or more pills,
 - immediate releasing, including 20-30 mg IR opioids and all medications with Oxycodone, Methadone and Fentanyl in title.
- Run opioid prescribing report out of Epic (or other system) and filter as described above.
- Based on results, work with leadership to review physician prescribing practices.
- Develop opioid prescribing tool kit and other materials to facilitate discussion.
- Coordinate with leadership and Human Resources to develop corrective action plan, as appropriate.

65

Thank You

Christine Anusbigian
Deloitte & Touche LLP
200 Renaissance Center
#3900
Detroit, MI 48243
canusbigian@deloitte.com
(313) 396-5857

Sean O'D. Bosack
833 E Michigan St
Suite 1800
Godfrey & Kahn, S.C.
Milwaukee, WI 53202
sbosack@gklaw.com
(414) 273-5431

Michelle Frazier
Senior Compliance Officer
Aurora Health Center
3000 W. Montana St.
Milwaukee, WI 53215
Michelle.Frazier@aurora.org
(414) 299-1711

Stacy Gerber Ward
von Briesen & Roper
411 E. Wisconsin Ave.
Suite 1000
Milwaukee, WI 53202
(414) 276-1122

66

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