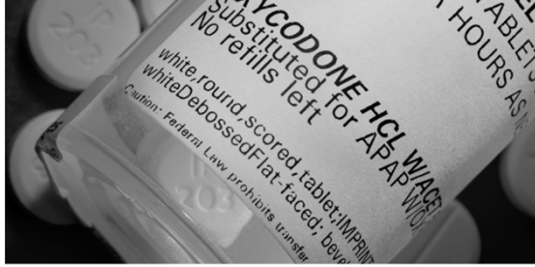


Navigating the Changing Regulatory Enforcement Landscape Relating to Opioids



BASS BERRY + SIMS

Panel

Chris Covington
Assistant Special Agent in Charge, HHS OIG
Nashville, Tennessee

Alicia Davis
President and CEO
ALN Consulting
Nashville, Tennessee

Lisa S. Rivera
Member, Bass Berry Sims
Nashville, Tennessee

BASS BERRY + SIMS

Presentation Overview

- ✦ Genesis of the Opioid Crisis/Statistics
- ✦ Recent Enforcement Actions
- ✦ Legislative Changes
- ✦ Tips for Auditing Provider Prescribing Habits
- ✦ Responding to an Enforcement Action

BASS BERRY + SIMS

THE GENESIS OF THE OPIOID CRISIS?

“Addiction Rare in Patients Treated with Narcotics”

To the Editor

Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one.

We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

Jane Porter

Hershel Jick, M.D.

Boston Collaborative Drug Surveillance Program Boston University Medical Center,

Waltham, MA 0

January 10, 1980

N Engl J Med 1980; 302:123

BASS BERRY + SIMS

CONTRIBUTING FACTORS

1. In 2001, the Joint Commission issued its Pain Management Standards, which led to classifying pain as the "fifth vital sign."
2. Government ordered patient satisfaction survey's - physicians issue unnecessary opioid prescriptions for pain relief to achieve better patient satisfaction scores.
3. Purdue Pharmaceuticals.

Health | Local News | Northwest

Ferguson lawsuit says OxyContin maker Purdue Pharma partnered with Washington state doctors to boost use of addictive painkiller

Originally published January 5, 2018 at 8:06 pm | Updated January 6, 2018 at 12:11 am

BASS BERRY + SIMS

SURVEY

Table 2

Questionnaire

Questions	No pain	Mild	Moderate	Less than severe	Severe
What type of pain did you expect in the post-operative period?	1	2	3	4	5
What type of pain did you experience in the post-operative period?	1	2	3	4	5
	Within 1 h	Within 1 h	Within 2 h	After 2 h	Never
When you were in pain, APMS responded	1	2	3	4	5
	Excellent	Very good	Good	Fair	Poor
What was the quality of pain relief after APMS management?	1	2	3	4	5
How would you rate the effectiveness and sensitivity of APMS staff?	1	2	3	4	5
How was your overall experience with your pain management service?	1	2	3	4	5

Questions

Would you use the same analgesia modality again if you recommended the same modality to your friend?
How the APMS team courteous and professional during interactions?
Are you aware that a team of specialist pain doctors your pain relief that is a part of anesthesia department (APMS - Acute pain management service)?

What type of pain did you expect in the post-operative period?
What type of pain did you experience in the post-operative period?
When you were in pain, APMS responded
What was the quality of pain relief after APMS management?

BASS BERRY + SIMS

PURDUE PHARMA'S MARKETING CAMPAIGN

- ✦ Purdue bought more than \$18 million worth of advertising in major medical journals that touted OxyContin. Some of the ads, federal officials said grossly overstated the drug's safety.
- ✦ Purdue aggressively pursued doctors and other health workers with literature and sales calls.
- ✦ OxyContin contains oxycodone, an opioid as potent as morphine and abusers learned they could crush the pills and snort or inject the dust.
- ✦ The company pleaded guilty in 2007 to felony charges of "misbranding" OxyContin "with the intent to defraud or mislead." The company paid \$600 million in fines and other penalties. Among the deceptions it confessed to directing its salespeople to tell doctors the drug was less addictive than other opioids.

BASS BERRY + SIMS

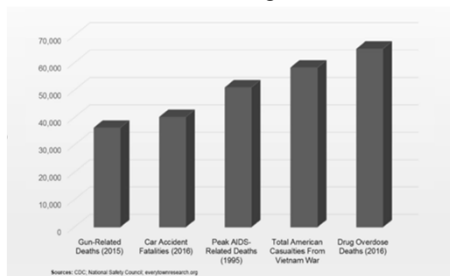
A Few Statistics

- ✦ HHS Secretary declared a public health emergency in response to the growing use and abuse of prescription opioids
 - ▶ 4x sales of prescription opioids and 2x opioid-related deaths in past 2 decades
 - ▶ Drug overdoses are the leading cause of accidental deaths
 - ~90 deaths from opioid overdoses/day; ½ involve prescription opioids
 - In 2016, ~64,000 drug overdose deaths; 42,000 opioid related
 - ▶ 75% of heroin users began their drug abuse by misusing prescription opioids

BASS BERRY + SIMS

Perspective

More deaths caused by overdose than car accidents and gun violence



BASS BERRY + SIMS

Perspective

The New York Times
TheUpshot

Bleak New Estimates in Drug Epidemic: A Record 72,000 Overdose Deaths in 2017

Aug. 15, 2018



Drug overdoses killed about 72,000 Americans last year, a record number that reflects a rise of around 10 percent, according to new preliminary estimates from the Centers for Disease Control. The death toll is higher than the peak yearly death totals from [H.I.V.](#), [car crashes](#) or [gun deaths](#).

Peak deaths for:

Car crashes - 1972
53,000

HIV - 1993
46,000

Gun - 1993
39,000

BASS BERRY + SIMS

Additional impact



POLITICS

WHITE HOUSE | POLICY | DEFENSE | CONGRESS | ELECTIONS | EUROPE | CHINA

Economic cost of the opioid crisis: \$1 trillion and growing faster



- The economic toll of the opioid crisis is estimated to have topped \$1 trillion from 2001 through 2017, a new report says.
- The economic fallout from the epidemic of heroin and prescription painkiller abuse is on track to cost \$500 billion from 2018 to 2020 alone.
- More than 62,000 Americans are believed to have fatally overdosed from opioids in 2017.

Dan Mangan | @DanMangan
Published 6:01 AM ET Tue, 13 Feb 2018



BASS BERRY + SIMS

Recent Enforcement Actions

✦ Increased Enforcement:

- ▶ Professional licensing boards
- ▶ Federal agencies
- ▶ Local law enforcement

✦ Since July 2017:

- ▶ 600 individuals excluded for opioid diversion and abuse

✦ Some investigation and enforcement tools:

- ▶ Opioid Fraud and Abuse Unit
- ▶ Prescription Interdiction & Litigation (PIL) Task Force
- ▶ Data Analytics

BASS BERRY + SIMS

Federal Enforcement Actions: Recent Actions Against Healthcare Facilities

- + University of Michigan Health System (August 2018)
 - ▶ \$4.3 million settlement
 - Failed to obtain DEA registrations
 - Failed to maintain complete and accurate records
 - Failed to timely notify the DEA of theft or loss of controlled substances
- + Effingham Health System (May 2018)
 - ▶ \$4.1 million settlement
 - Failed to provide effective controls and procedures
 - Failed to timely notify the DEA of suspected diversion
- + Nantucket Cottage Hospital (May 2018)
 - ▶ \$50,000 settlement
 - Failed to properly maintain controlled substances records
 - Failed to maintain effective controls against diversion

BASS BERRY + SIMS

Federal Enforcement Actions: Recent Actions Against Individual Providers

- + Physician and addiction treatment clinic entered into a \$23,000 settlement agreement (August 2018)
 - ▶ Directed another physician to pre-sign hundreds of blank prescriptions
- + DOJ announced the "largest ever health care fraud enforcement action" (June 2018)
 - ▶ Focused on allegations of billing for medically unnecessary opioid prescriptions
 - ▶ Charged 601 individuals across 58 federal districts for schemes involving over \$2 billion
- + Chiropractor entered into a \$1.45 million settlement agreement (December 2017; January 2018)
 - ▶ Operated 4 pain clinics as "pill mills"
- + 2 pharmacists paid \$5 million in restitution for victims' assistance (October 2017)
 - ▶ Dispensed opioids to "pill mill" customers

BASS BERRY + SIMS

Federal Enforcement Actions: Recent Actions Against Pharmacies

- + Leo's Lakeside Pharmacy (June 2018)
 - ▶ \$75,000 settlement
 - Failed to account for and keep accurate records of frequently abused opioids
- + CVS
 - ▶ \$1.5 million settlement
 - Failed to timely report the loss or theft of certain controlled substances

BASS BERRY + SIMS

State Enforcement Actions

✦ Lawsuits by state Attorney Generals

▶ Typical Allegations:

- Overstating benefits
- Downplaying risks
- Failure to monitor
- Failure to identify suspicious orders

▶ Typical Defenses:

- No private right of action under the CSA
- Prescribers break the chain of causation
- Free Public Service Doctrine

✦ Criminal prosecutions

✦ Lawsuits by family members

BASS BERRY ✦ SIMS

Enforcement Actions: Takeaways

✦ Increased investigations of healthcare professionals and entities

▶ Targets throughout the distribution chain

✦ Wide range of settlement amounts

▶ Less likely that small violations will fall through the cracks

✦ Penalties/settlements of millions of dollars even for individuals

✦ Civil state law claims

BASS BERRY ✦ SIMS

**Every Morning When You Arrive at Work
There is A Line Waiting For The Doors to
Open**



BASS BERRY ✦ SIMS

Federal Legislative Changes to Address Opioid Challenges

- ✦ **Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, H.R. 6, 115th Cong. (2018)**
 - ▶ Improves grants for treatment programs and expands Medicaid coverage for inpatient rehab
 - ▶ Requires USPS to screen international packages for fentanyl
 - ▶ Requires Medicaid programs to identify and flag at-risk beneficiaries
 - ▶ Instructs CMS to evaluate the use of telehealth services to treat substance use disorder
 - ▶ E-prescribing for coverage of Part D prescription controlled substances Requires prescription drug plan sponsors to establish drug management programs for at-risk beneficiaries
 - ▶ Creates an online portal for information sharing
 - ▶ Requires providers to screen for opioid use disorders during the initial Medicare physical

BASS BERRY ✦ SIMS

Federal Legislative Changes to Address Opioid Challenges

- ✦ **Sharing Health Information**
 - ▶ When certain health information can be disclosed without a patient's consent:
 - A provider can share information with a patient's family and close friends when sharing the information is in the best interests of an incapacitated or unconscious patient **and** the information is directly related to the family or friend's involvement in the patient's care or payment for the care
 - A provider can share information with individuals in a position to prevent or lessen a serious and imminent threat to the patient's health or safety

BASS BERRY ✦ SIMS

Federal Legislative Changes to Address Opioid Challenges

- ✦ **Sharing Health Information: Overdose Prevention and Patient Safety Act, H.R. 6082, 115th Cong. 2018**
 - Better aligns HIPAA with 42 C.F.R. Part 2
 - Allows more sharing of substance use disorder records
 - Increases penalties for unlawful disclosure of substance use treatment records
 - Prohibits discrimination based on data revealed in treatment records

BASS BERRY ✦ SIMS

Federal Legislative Changes to Address Opioid Challenges

✦ Medicare Drug Management Programs

- ▶ 1 in 10 Part D beneficiaries regularly receive prescription opioids
- ▶ CMS issued a Final Rule allowing Part D plan sponsors to establish drug management programs for at-risk beneficiaries
- ▶ CMS proposed to permit Medicare Part D plans to limit at-risk beneficiaries' access to opioids
- ▶ CMS announced creation of an Opioid Prescription Drug Monitoring Tool

BASS BERRY ✦ SIMS

Federal Legislative Changes to Address Opioid Challenges: Other Proposed Legislation

✦ Opioid Crisis Response Act of 2018, S. 2680, 115th Cong. (2018)

- ▶ Authorizes/improves grants for prevention and treatment
- ▶ Provides support for states to improve their PDMPs and promote data sharing
- ▶ Clarifies FDA's authority to require manufacturers to package opioids as "blister packs"

BASS BERRY ✦ SIMS

Federal Legislative Changes to Address Opioid Challenges: Other Proposed Legislation

✦ Preventing Overdoses While in Emergency Rooms Act of 2018, H.R. 5176, 115th Cong. (2018)

- ▶ Requires HHS to establish a grant program for hospitals to develop protocols for discharging patients treated for drug overdoses
- ▶ Improves integration and coordination of post-discharge care of patients with substance use disorder

BASS BERRY ✦ SIMS

State Legislative Changes to Address Opioid Challenges

+ Opioid Prescribing Limits

- ▶ Limits on timing of prescriptions (e.g. MA, NC, FL, CT, LA, NJ, PA)
 - Often 3-7 days
- ▶ Limits on amount of opioids prescribed (e.g. MD, AZ, CT, DE, MA, NJ, NY, PA, RI, VT)
 - Daily supply limits
 - Morphine milligram equivalents (MME)/day limits
- ▶ Some pharmacies and payors are joining in (e.g. CVS, Blue Cross)

BASS BERRY + SIMS

State Legislative Changes to Address Opioid Challenges

+ Prescription Drug Monitoring Programs (PDMPs)

- ▶ Allow providers to analyze patients' past prescription drug use before prescribing opioids
- ▶ Correlated with decreases in opioid prescribing and in opioid-related deaths

+ PDMP Use by State Licensing Boards

- ▶ Alaska: BOP may give reports to prescribers on their opioid prescribing practices
- ▶ North Carolina: Allows for notification to licensing board if prescriber's behavior increases risk of diversion
- ▶ Maine: Allows release of data on opioid prescribing practices to hospital's chief medical officer

+ Mandatory PDMP Use

- ▶ California: prescribers will be required to consult PDMP before prescribing Schedule II-IV controlled substances
- ▶ Georgia and Mississippi: tie PDMP registration to ability to secure/renew DEA registration
- ▶ Georgia and South Carolina: penalize practitioners who fail to query the PDMP
- ▶ Kentucky and North Carolina: penalize pharmacies for improper reporting

BASS BERRY + SIMS

State Legislative Changes to Address Opioid Challenges

+ Integrating PDMPs and EHR

- ▶ Ochsner Health System: first health system to implement an integrated system
 - Reduced the time it takes to search for prescription data
 - Increased providers' use of prescription data in their practices
 - Reduced the incidence of opioid abuse
- ▶ Deaconess Health System: first Indiana hospital system to integrate prescription data with its EHR

+ Limitations of PDMPs

- ▶ Use isn't always mandatory
- ▶ Many practitioners oppose change to a mandatory system
 - UC Davis survey: indicated most physicians and pharmacists think practitioners *should* check the PDMP before prescribing, but only about 23% of physicians and 38% of pharmacists think it should be required
- ▶ Mandatory use may be restricted to certain contexts
- ▶ No national system

BASS BERRY + SIMS

State Legislative Changes to Address Opioid Challenges

+ Redesigning Treatment and Discharge of Patients with Opioid Disorders

- ▶ Virginia: conduct H&P, review the PDMP, assess patient's risk for abuse, and document that all of these actions have been taken
- ▶ New York: proposed requiring hospitals to develop policies and procedures to identify and refer patients with substance abuse disorders and assist patients in coordinating appropriate services after discharge
- ▶ New Jersey: requires practitioners to discuss when prescribing opioids the risks of addiction and dependence and the availability of alternative treatment programs

BASS BERRY + SIMS

State Legislative Changes to Address Opioid Challenges: Other Approaches

- + Requiring wholesalers to report "suspicious" opioid orders (e.g. WV, OR)
- + Revising drug formularies (e.g. TX)
- + Requiring pain management facilities to be registered/certified (e.g. LA)
- + Revising Certificate of Need (CON) statutes (e.g. KY)
- + Expanding availability of telemedicine care (e.g. KY)

BASS BERRY + SIMS

Potential Risks for Physicians and Other Providers and Facilities

+ Staffing

- ▶ It is estimated that by 2025, there will be a shortage of 250,000 substance abuse and mental health providers
- ▶ **Some Federal Staffing Requirements**
 - Medicare Conditions of Participation
 - Requires enough physicians on staff to handle complications from opioid overdoses
 - The Emergency Medical Treatment and Labor Act (EMTALA)
 - Requires hospitals to stabilize patients and treat emergency medical conditions
 - Requires that services provided to the public be available through on-call coverage

BASS BERRY + SIMS

Potential Risks for Physicians and Other Providers and Facilities

- ✦ Urine drug testing
- ✦ Working with contractors
- ✦ Vicarious liability

BASS BERRY + SIMS

Opioid Overdoses Nationwide

Highest Quarter of Overdose Rates
(by County)

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

0 600 900 1,200 2,642



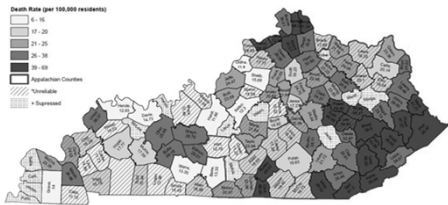
BASS BERRY + SIMS

12-District Opioid Initiative

- ✦ On August 2, 2017, Attorney General Jeff Sessions announced the formation of the Opioid Fraud and Abuse Detection Unit.
 - ✦ Dedicated opioid prosecutors were assigned to combat prescription opioid “pill mill” schemes.
 - ✦ Joint effort by FBI, DEA, HHS-OIG and various state MFCUs.
- ▶ Middle District of Florida
 - ▶ Eastern District of Michigan
 - ▶ Northern District of Alabama
 - ▶ Eastern District of Tennessee
 - ▶ District of Nevada
 - ▶ Eastern District of Kentucky
 - ▶ District of Maryland
 - ▶ Western District of Pennsylvania
 - ▶ Southern District of Ohio
 - ▶ Eastern District of California
 - ▶ Middle District of North Carolina
 - ▶ Southern District of West Virginia

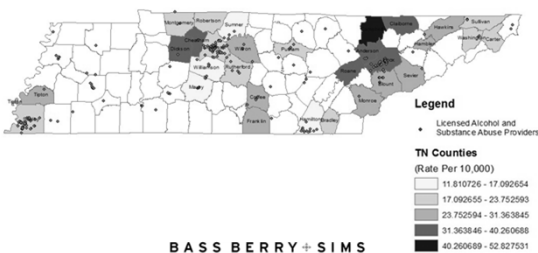
BASS BERRY + SIMS

KY Overdoses by County (2012-2015)



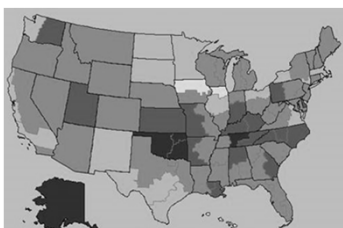
BASS BERRY + SIMS

TN Opioid Deaths By County (2015)

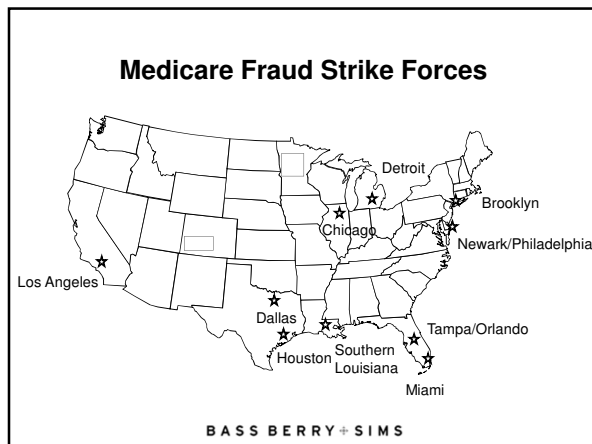


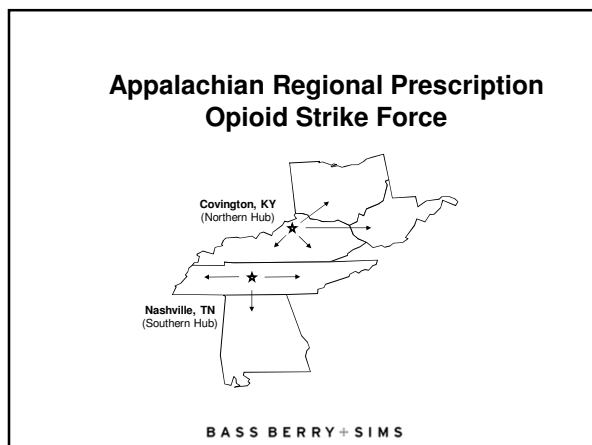
BASS BERRY + SIMS

Medicare Part D: Opioids per capita



BASS BERRY + SIMS





Navigating the Enforcement Minefield

Compliance program → audit → review findings → act!

Maintain a comprehensive compliance program

- ▶ Consider guidelines for safe opioid prescribing for patients with chronic non-cancer pain (CDC)
 - What to do PRIOR to prescribing opioids
 - How to f/u & monitor patients on long term opioids
 - How to monitor opioid doses (MED)
 - What do to with concerns of addiction/diversion
 - When to consider a specialty referral

BASS BERRY + SIMS

Navigating the Enforcement Minefield

Compliance program → *audit* → *review findings* → *act!*

- ▶ Review prescribing habits to proactively identify potential concerns
- ▶ Sufficiently demonstrate analysis of audit findings
- ▶ Demonstrate remediation of underlying misconduct

BASS BERRY + SIMS

Navigating the Enforcement Minefield: Auditing Red Flags – Provider

• Top 50 list – writing opioid Rx at rate far exceeding peers	• Patient overdose/death within 60 days of opioid Rx
• How many of the provider's patients are doctor shopping (3-5 providers)	• Overutilization of ancillary services (referrals)
• High patient volume	• Inadequate/non-existent exams
• High percentage of provider's patients prescribed a CS	• Lack of meaningful diagnostic testing OR medically unnecessary/excessive testing (UDS, x-ray)
• Prescribing multiple CS at the same time (opioid & benzodiazepine)	• Failure to follow diversion prevention measures - UDS, check CSMD/PDMP
• Morphine mg Equivalents (MME) > 90-120 per patient per day	• Out of state patients/group travel

BASS BERRY + SIMS

Navigating the Enforcement Minefield: Auditing Red Flags - Pharmacy

• High % of pharmacies' CS patients from a single MD	• High dosage CS/quantity compared to ailment
• High volumes of CS compared to peer pharmacies	• Multiple patients present identical sets of Rx
• Dispensing multiple CS at the same time (opioid & benzodiazepine)	• Out of state patients/group travel
• Charging high cash prices	• Failure to utilize PDMP

BASS BERRY + SIMS

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
OFFICE OF GENERAL COUNSEL

JOHN DREYZEHNER, M.D. MPH
COMMISSIONER

4. You prescribed combinations of controlled substances without appropriately documenting a clear objective finding of a chronic condition to justify the ongoing and increasing prescribing.
5. You insufficiently attempted to identify the etiology of reported pain.
6. You prescribed controlled substances and other medication without appropriately documenting a thorough history or adequately inquiring into potential drug history.
7. You prescribed controlled substances and other medication without conducting physical examinations focused on the source of reported pain or appropriately documenting a written treatment plan with regard to the use of controlled substances and other medication.
8. You prescribed controlled substances without consulting the Controlled Substance Monitoring Database (CSMD).

BASS BERRY + SIMS

DATE	DIAGNOSIS/HISTORY OF PRESENT ILLNESS	DOCUMENTED ETIOLOGY OF PAIN	OBJECTIVE FINDINGS OF PAIN	RIS & PHYSICAL EXAM	MEDICATION PRESCRIBED (S)	ASSESSMENT & PLAN
------	--------------------------------------	-----------------------------	----------------------------	---------------------	---------------------------	-------------------

[illegible]

Patient	Diagnosis	Medication(s) Prescribed	MME
Doe-Jane	Cervicalgia, C. DDD, Osteoarthritis, MPS	Paracet 10325mg 1 po q 12 hours	30

[illegible]

BASS BERRY + SIMS

Conclusions

- + No one is immune from addiction including the educated, the affluent, and those who had no intention of acquiring a drug habit.
- + Opioid medications do have a legitimate medical use to help alleviate pain and physicians are not blind to the dangers of opioid abuse.
- + Clinicians today are more cautious when prescribing opioids and other prescription pain medications, closely observing their patients for signs of abuse and addiction.
- + It is important for clinicians and their organizations to stay well informed of current laws, and any pending legislation regarding opioid prescribing.

BASS BERRY + SIMS

Questions?

Chris Covington
Assistant Special Agent in Charge, HHS OIG
Nashville, Tennessee
Chris.Covington@oig.hhs.gov
615-736-5206

Alicia Davis
President and CEO, ALN Consulting
Nashville, Tennessee
alicia@alnconsulting.com
615-988-9125

Lisa S. Rivera
Member, Bass Berry Sims
Nashville, Tennessee
lrivera@bassberry.com
615-742-7707

BASS BERRY + SIMS
