

# THRIVE ALABAMA

## COMPLIANCE HOT TOPICS



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# TELEHEALTH

## Current Lay of the Land

Providers must work through evolving state and federal regulations to remain compliant. Providers are responsible for knowing what care can and cannot be provided via telehealth and even where they can provide telehealth and be reimbursed.

Federal regulations are outlined by Centers for Medicare and Medicaid Services (CMS) while states have their own laws and guidelines for telehealth (telemedicine).

HIPAA and state privacy laws still control information sharing.

The provision of healthcare remotely by means of telecommunications technology

## The Shifting Landscape

CMS is continually expanding reimbursement for telehealth services thereby increasing the acceptable use of telehealth.

Several bills moving through Congress that seek to expand the authority of the Veterans Health Administration to allow physicians to treat patients across state lines. Would be a policy expansion that signals the beginning of a bigger move towards allowing the treatment of patients across state lines.

State licensing issues are a key hurdle to the expansion of telehealth. Physicians currently required to be licensed in the state where the patient is being treated. Supporters of the expansion of telehealth feel licensing laws do not reflect the changing nature of the practice of medicine.

Substantial factors and regulatory issues to consider with regard to licensing and telehealth (i.e. conflicts between states regarding discipline and acceptable medical practice).

# 340B DRUG PROGRAM

**The 340B Program** enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

**Manufacturers participating in Medicaid**, agree to provide outpatient drugs to covered entities at significantly reduced prices.

**Eligible health care organizations/covered entities** are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. [See the full list of eligible organizations/covered entities.](#)

**Participants in the 340B Program** have the opportunity to capture cost savings from the purchase of prescription drugs and use those cost savings to reinvest in patient care.

The 340B Drug Discount Program is a US federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices.

## The Compliance Conundrum

HRSA's Office of Pharmacy Affairs is the regulatory oversight for the 340B Program.

OPA has extensive requirements for the development of compliance programs for the various types of covered entities. Interestingly, much of what program participants have come to accept as required regulation is not found anywhere in the actual 340B regulations.

Increasing OIG pressure on HRSA and OPA has resulted in increased pressure on 340B covered entities to meet standards and requirements that are not in regulation and unclear.

Increasing and evolving "regulation" creates extensive costs for covered entities that could be spent in offering more expansive care, but legal challenges to these "regulations" would be expensive and could put an entities 340B program in jeopardy in the interim.

Growing legislative attention is being directed at that 340B program's usefulness, potential for abuse and misuse, and economic impact.

# OPIOID EPIDEMIC

**Inappropriate prescribing, misuse, and abuse of opioid drugs is an increasing problem in Alabama and the nation.**

## **Blue Cross Blue Shield Study Showed:**

**Alabama ranked highest** in the nation having more opioid prescriptions than most people.

Alabama physicians estimated to have **written 5.8 million prescriptions** for opioids in 2015.

Alabama ranked as **number one prescriber of opioid pain reliever prescriptions.**

BCBS Health Index identified substance use disorder as the 5<sup>th</sup> most impactful condition affecting the health of commercially insured members in the U.S. and, in Alabama, results also showed substance use disorder as the 5<sup>th</sup> most prevailing health condition.

Impact of the opioid epidemic becomes evident in all walks of life and the law.

A term that generally refers to the rapid increase in the use of prescription and non-prescription opioid drugs, in the United States, beginning in the late 1990s.

## Legal Crackdown on Opioids

During an April 17, 2019 press conference, Jay Town, U.S. Attorney for the Northern District of Alabama, and members of Appalachian Regional Prescription Opioid Strike Force, announced that 60 people, including 31 doctors, had been charged for their roles in illegal prescribing and distributing millions of pills with opioids and other dangerous drugs.

The national opioid crackdown lead to the arrest of 8 Alabama a doctors including:

D1: Authorities had been called to physician's home 35 times since October 2015, including once for an overdose and authorities found drug paraphernalia at his home and office;

D2: Physician who has been sued for wrongful death in the passing of a 30 year old. Lawsuit claims patient died from mixed drug toxicity. Federal court records alleged that physician prescribed dangerous combinations of drugs known to heighten the risk of overdose and death;

D3: Spouses in medical practice first raided in August 2017 are named in 15 count indictment alleging conspiracy to distribute a controlled substance, maintaining a drug-involved premises, 5 counts of unlawful distribution of a controlled substance, conspiracy to commit healthcare fraud, and 7 counts of healthcare fraud.