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FINAL REPORT OF THE OPIOID ABUSE SENATE STUDY COMMITTEE

COMMITTEE MEMBERS

Senator Renee Unterman – Chair
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Senator Butch Miller
District 49

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Department of Public Health

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Prepared by the Senate Research Office
2016

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COMMITTEE FOCUS, CREATION, AND DUTIES

The Senate Study Committee on Opioid Abuse (Committee) was created with the adoption of Senate Resolution 1165 during the 2016 Legislative Session. The Committee was charged with undertaking a study of opioid abuse and issues surrounding the rise in overdose deaths involving opioids.

The following individuals were appointed by the President of the Senate to serve as members of this Committee:

- Senator Renee Unterman of the 45th, Chair
- Senator Butch Miller of the 49th
- Commissioner Brenda Fitzgerald, Department of Public Health
- Rick Allen, RPh, Georgia Drugs and Narcotics Agency
- Dr. Allen Butts, The Longstreet Clinic
- Cecil Cordle, PharmD, CVS Pharmacy, Tifton
- Dr. Rafael Pascual, Northeast Georgia Medical Center

The following legislative staff members were assigned to this Committee: Jared Evans and Elton Davis of the Senate Budget & Evaluation Office; Ines Owens of the Senate Press Office; Elizabeth Holcomb and Koko Lewis of the Senate Research Office; Lynn Whitten of the Office of Legislative Counsel; and Avi'el Bland, Senate Health and Human Services Committee Secretary and Legislative Assistant to Senator Unterman.

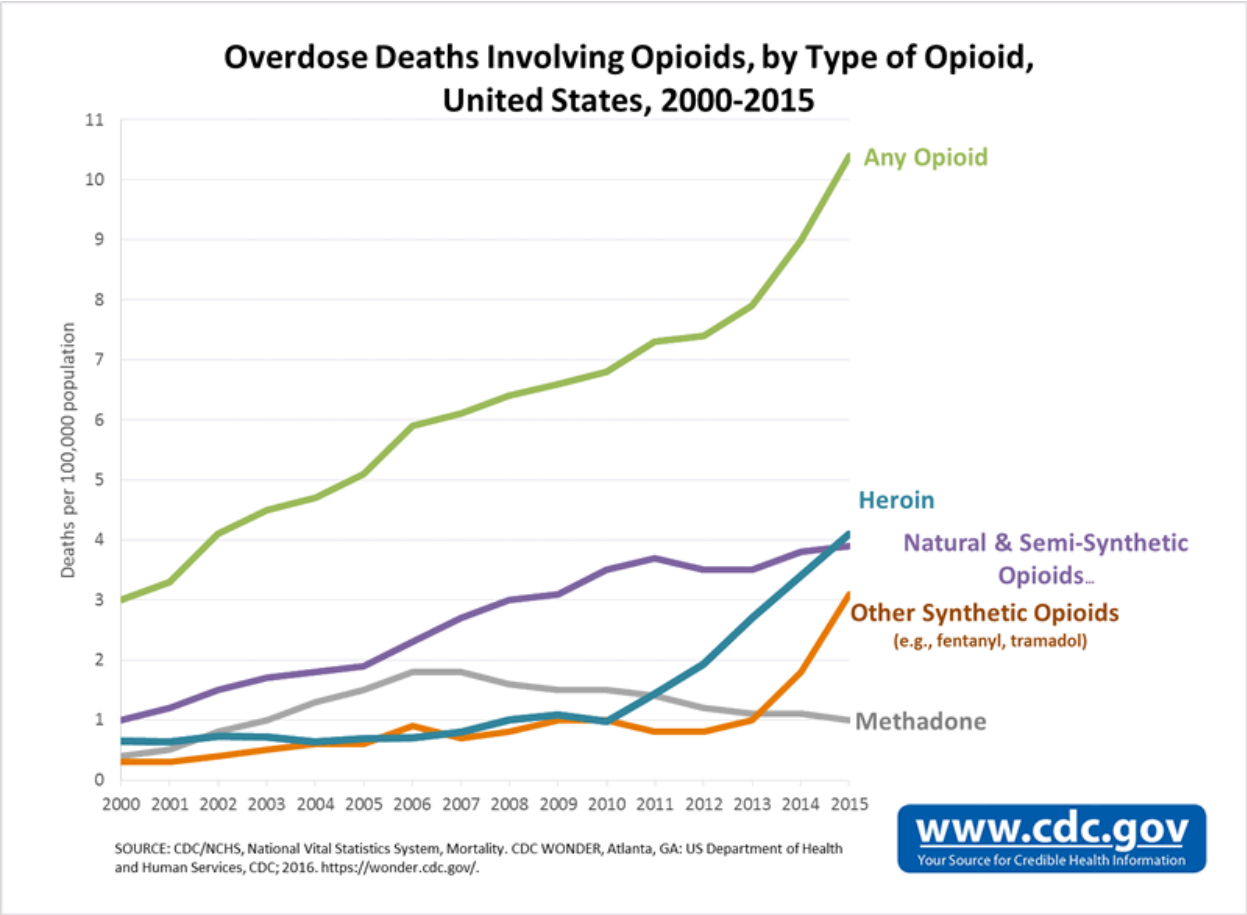
BACKGROUND

The Opioid Epidemic

According to the Centers for Disease Control and Prevention (CDC), two distinct but interconnected trends are driving America's opioid overdose epidemic: (1) a 15-year increase in deaths from prescription opioid overdoses; and (2) a recent surge in illicit opioid overdoses driven mainly by heroin and illegally-made fentanyl.

The CDC's National Center for Health Statistics found that the number of overdose deaths involving opioids rose from 28,647 in 2014 to 33,091 in 2015. This figure and the data below on the number of deaths involving opioids in 2015 were released in December of 2016.

- Heroin overdose deaths rose from 10,574 in 2014 to 12,990 in 2015, an increase of 23 percent.
- Overdose deaths involving synthetic opioids other than methadone rose from 5,544 in 2014 to 9,580 in 2015, an increase of 73 percent. This category of opioids is dominated by fentanyl-related overdoses, and recent research indicates the fentanyl involved in these deaths is illicitly manufactured, not from medications containing fentanyl.
- Taken together, 19,885 Americans lost their lives in 2015 to deaths involving primarily illicit opioids: heroin, synthetic opioids other than methadone (e.g., fentanyl), or a mixture of the two.
- Overdose deaths involving prescription opioids, excluding the category predominated by illicit fentanyl, rose only slightly from 16,941 in 2014 to 17,536 in 2015, a 4 percent increase.



The figure above shows the rise of overdose deaths involving all opioids as well as four categories of opioids considered by the CDC. These categories of opioids are outlined below and were referred to throughout the Committee's study.

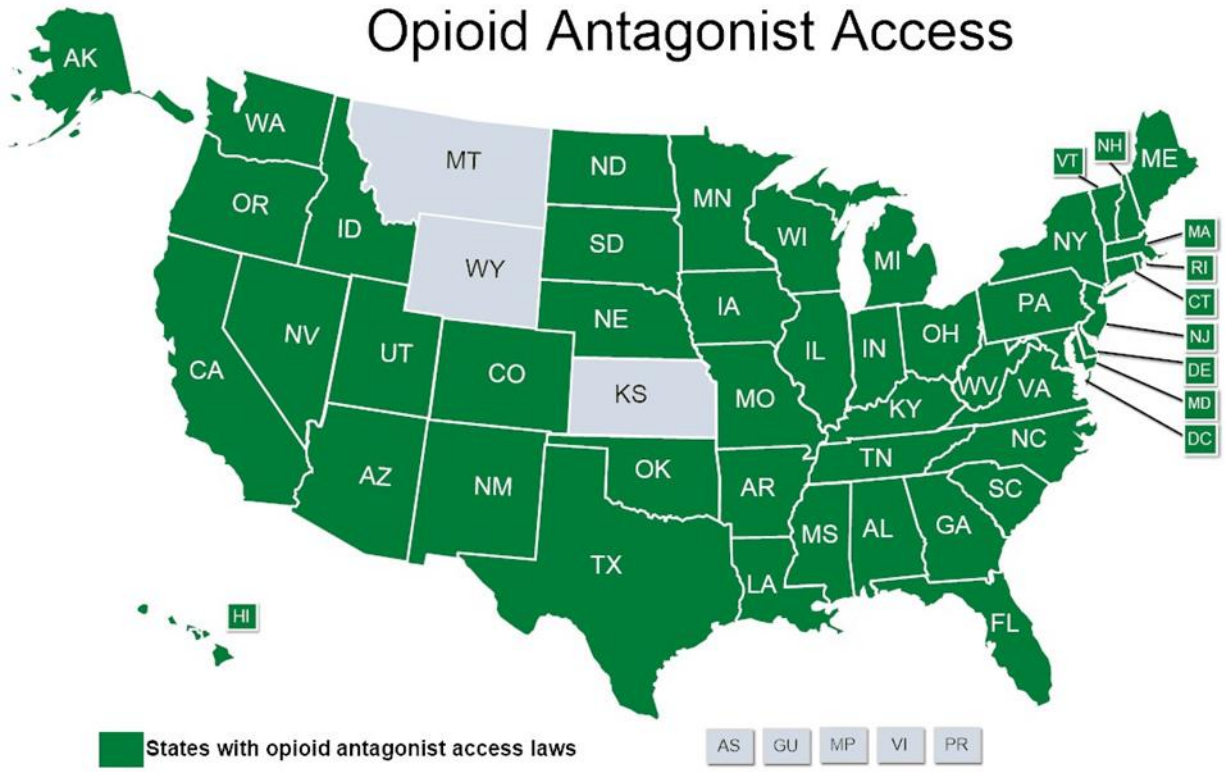
- **Natural opioid analgesics,** including morphine and codeine, and **semi-synthetic opioid analgesics,** including drugs such as oxycodone, hydrocodone, hydromorphone, and oxymorphone;
- **Methadone,** a synthetic opioid;
- **Synthetic opioid analgesics** other than methadone, including drugs such as tramadol and fentanyl; and
- **Heroin,** an illicit (illegally-made) opioid synthesized from morphine that can be a white or brown powder, or a black sticky substance.

Access to Naloxone by Third Party Prescription and First Responders

Almost every state has enacted legislation in response to increased opioid use. The laws passed by a majority of states fall into two categories, outlined below.

Laws Providing Access to Opioid Antagonist Naloxone

As of August 2016, 47 states have passed laws providing immunity to medical professionals who prescribe or dispense naloxone or persons who administer naloxone. Previously, laws required a doctor-patient relationship to be established prior to issuing a direct prescription to an at-risk drug user and third party prescriptions were prohibited.[1]

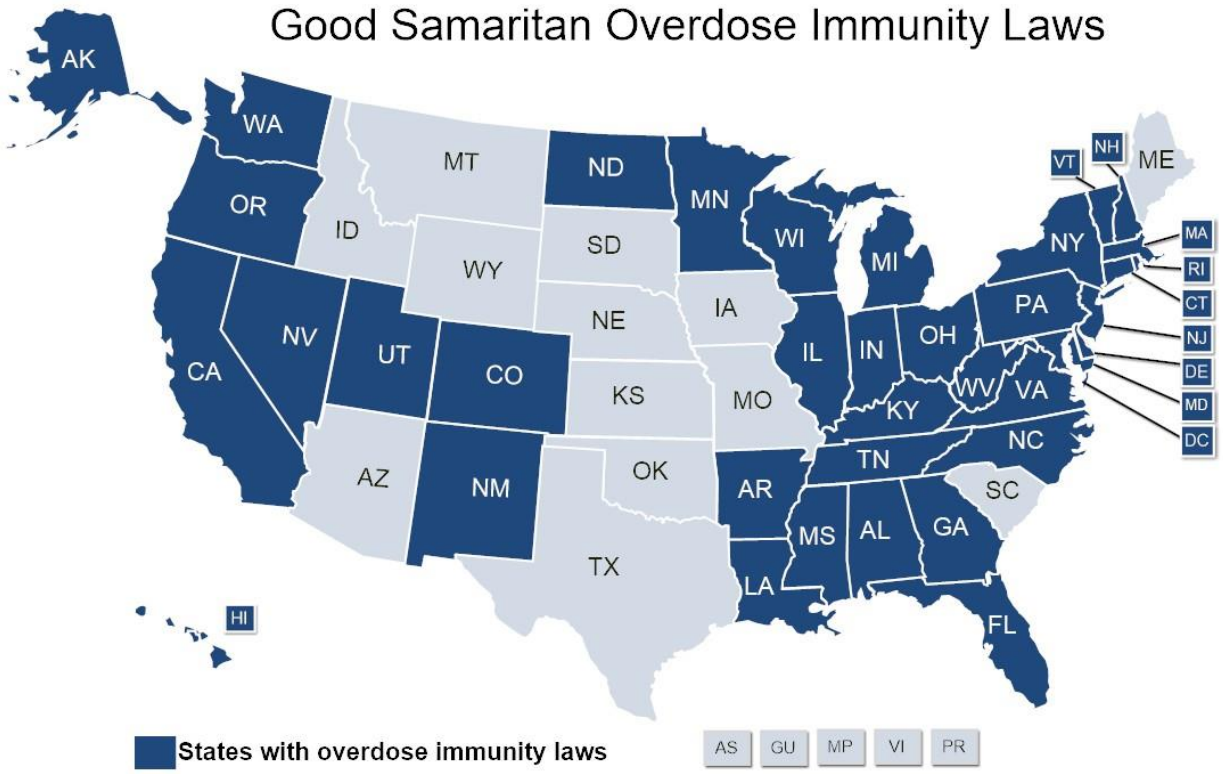


Source: NCSL, 2016

Good Samaritan Laws

The figure below shows that 37 states and the District of Columbia have enacted some form of a Good Samaritan or 9-1-1 drug immunity law to encourage people to seek medical attention for a drug overdose. In general, these laws provide immunity from supervision violations and low level drug possession and use offenses when a person seeks medical attention for himself/herself or another for a drug overdose. Immunity is extended to persons who have a reasonable belief that someone is experiencing an overdose emergency and makes a report of such belief in good faith.

[1] A third-party prescription is an order written for medication dispensed to one person with the intention that it will be administered to another person.



Source: NCSL, 2016

As you can see from the figures above, many states have laws addressing both categories and Georgia's law has been in effect since 2014 with the passage of House Bill 965. This bill was introduced as the Georgia 9-1-1 Medical Amnesty Law by Representative Sharon Cooper and reached final passage with the language of House Bill 966 through a committee substitute passed by the Senate Health and Human Services Committee. Specifically, the law authorizes practitioners to prescribe opioid antagonists to certain individuals and entities pursuant to a protocol, allowing pharmacists to dispense and opioid antagonist pursuant to a physician's prescription. Such prescriptions may be made by a physician to a third party individual or entity for another person at risk of experiencing an opioid related overdose, to be used by the third party under physician's protocol. Third party individuals and entities include: a pain management clinic, first responder, harm reduction organization, family member, friend, or other person in the position to assist the person at risk of overdosing. The law also authorizes first responders, EMS personnel, and paramedics to carry and administer opioid antagonists pursuant to a licensed physician's order.

Naloxone Access and Over-the-Counter Sale Barriers

The interest in laws that allow individuals to bypass a doctor's office and obtain naloxone from pharmacies has increased in 2016 after Walgreens and CVS began selling naloxone. Although a variety of sources and individuals describe this type of access as OTC, this is technically incorrect since naloxone is a prescription-only drug that has not been designated by the FDA for OTC sale. Still, other states have employed a variety of approaches to allow individuals to access naloxone at a pharmacy without first seeing a prescriber and getting a traditional prescription. The primary objective of this study committee was to gain a better understanding of these approaches and identify a model approach for Georgia.

MEETING TESTIMONY

This section provides a brief summary of topics covered at each meeting, including the names and affiliations of individuals who were asked to provide testimony to the Committee. Although testimony has been condensed to ensure the report could be timely submitted, copies of all presentations and materials submitted to the Committee are kept on file in the Senate Research Office.

Meeting 1 – September 30, 2016

The first meeting was held at Northeast Georgia Medical Center in Gainesville, Georgia, and consisted of an overview of the issues related to opioid abuse. The individuals who provided testimony and the titles of each presentation are listed below.

- "Opioid Drug Abuse Today – Trends and Implications in Georgia"
  - Kay Hall, MBA, RN, Northeast Georgia Medical Center
- "Opiates: The New Epidemic"
  - Joni B. Powell, CACH, Support Services Supervisory, Laurelwood
  - Trisha Ziem, MACL, LPC, Assessment Coordinator , Laurelwood
- "Opiates: Neonatal Abstinence Syndrome"
  - Brittany Smith, RN, MSNEd, Unit Manager, Neonatal Intensive Care Unit, Northeast Georgia Medical Center
- "Advantages and Disadvantages of Narcan Sold Over the Counter"
  - Melissa Frank, Director of Pharmacy, Northeast Georgia Medical Center

Meeting 2 – October 17, 2016

Meeting 2 was held on October 27th at the Capitol and continued the discussions from the previous meeting on neonatal abstinence syndrome, prescription drug policies for pain medications, and efforts to prevent substance abuse. The Committee expanded the scope of this study to include the ramifications of addiction and examine how neonatal abstinence syndrome impacts social services and Georgia's foster care system. The following individuals provided testimony:

- Tom Fitzgerald, MD, Emergency Medicine, Tanner Medical Center
- Jane E. Ellis, MD, PhD, Associate Professor of Maternal-Fetal Medicine, Medical Director, Emory Regional Perinatal Center; Grady Memorial Hospital; Vice Chair, Georgia Maternal Mortality Review Committee
- Paul Browne, MD, Section Chief, Associate Professor of Maternal Fetal Medicine, Augusta University
- Karen Dudley, MD, Neonatalogist, Northside Hospital
- Trish Witcher, RN, MSN, Labor and Delivery Unit Nurse, Northside Hospital
- Lee Biggar and Andy Kogerma: Georgia Department of Family and Children Services (DFCS)
- Jim Langford, Georgia Prevention Project

In addition to providing oral testimony, Mr. Langford distributed a summary of a white paper by the Substance Abuse Research Alliance (SARA). A final copy of SARA's "Prescription Opioids and Heroin Epidemic in Georgia" was distributed to the Committee shortly after the December meeting and is provided in Exhibit A of the Appendix.

Meeting 3 – November 9, 2016

The Committee held a third hearing on November 9th at the Capitol. Testimony was provided to the Committee by the following individuals:

- John Horn, U.S. Attorney, Heroin Working Group
- Lt. William Ricker, Zone 1 Crime Suppression Unit Commander, Atlanta Police Department
- Sarah B. Flack, Director of the Community Prosecution Unit for the Atlanta Judicial Circuit
- Kathleen O'Connor, Public Policy and Regulatory Affairs, Shatterproof
- Dr. Michael Fishman, Director of Young Adult Program at Talbott Recovery Atlanta;
- Laurisa Barthen, Outreach and Communications Coordinator, Georgia Council on Substance Abuse;
- Jim Langford, Georgia Prevention Project

Meeting 4 – December 13, 2016

The Committee returned to the Capitol for a fourth meeting on December 13, 2016. Testimony was provided by the following individuals:

- Cassandra Price—Director of the Office of Addictive Diseases at DBHDD
- Virginia Pryor—Deputy Director of Child Welfare at DFCS within DHS
- Brook Etherington—Vice President of the Opioid Treatment Providers of Georgia; CEO of Alliance Recovery Center

After hearing testimony, Mr. Allen provided an update on Georgia's PDMP to his fellow Committee members.

COMMITTEE FINDINGS

Access to Naloxone

The Committee was created to increase access to naloxone in Georgia by identifying a legislative mechanism to allow pharmacists to independently dispense naloxone to an individual without a physician's prescription. At Meeting 4, Senators Renee Unterman and Butch Miller shared background information on this topic with the Committee, which was previously provided to them by the Senate Research Office. The Georgia Retail Association submitted written materials to the Committee but did not provide oral testimony.

Other states have employed a variety of approaches to bypass the need for a physician to issue a prescription, including: collaborate practice agreements (CPAs), pharmacist-as-prescriber models, and standing order legislation.

1. Legislation allowing **collaborative practice agreements (CPAs)**: where a practitioner delegates medication management authority to a pharmacist, where the pharmacist can prescribe the drug and offer front-line medical advice to the purchaser;
2. Legislation for a **Pharmacist-as-Prescriber** model: allowing pharmacists to furnish medication to a patient without the involvement of a physician;
3. **Standing Order** Legislation**:** which allows for the dispensing of naloxone under standing orders, where prescribers are given the authority to prescribe the medication via such an order, and are granted limited immunity with regard to such prescriptions so long as they act in good faith.

At Meeting 4, Commissioner Fitzgerald and Mr. Allen agreed that a standing order would be feasible in Georgia. The next day, the Board of Pharmacy adopted Emergency Rule 480-34-0.31-.11 (Naloxone) to allow pharmacists to dispense naloxone to individuals pursuant to a statewide standing order issued by Commissioner Fitzgerald. According to the rule, the steady and sharp increase in the number of overdoses and deaths due to prescription and illegal forms of opioid drugs poses an imminent threat to the public health, safety, and welfare; and naloxone is critical in assisting persons at risk of overdose.

Synthetic Opioids

The Committee heard testimony from law enforcement officials on the dangers of handling fentanyl and carfentanil in the field at Meeting 3. On September 22, 2016, the DEA issued a warning to the public and law enforcement regarding the dangers of carfentanil, a drug linked to a significant number of overdose deaths in the nation.[2] Carfentanil is a synthetic opioid analgesic that is 10,000 times more potent than morphine and 100 times more potent than fentanyl, which itself is 50 times more potent than heroin.

Law enforcement officers told the Committee that access to more than one dose of naloxone is extremely important in overdose cases involving fentanyl or carfentanil.

[2] https://www.dea.gov/divisions/hq/2016/hq092216.shtml

Georgia's Prescription Drug Monitoring Program

Georgia's Prescription Drug Monitoring Program (PDMP) was established in 2011 to assist in the reduction of the abuse of controlled substances; to improve, enhance, and encourage a better quality of healthcare by promoting the proper use of medications to treat pain and terminal illness; and to reduce duplicative prescribing and overprescribing of controlled substances practices. The Georgia Drugs and Narcotics Agency maintains the PDMP through a program known as PMPAware. All Georgia licensed Dispensers (pharmacies and dispensing prescribers) are required to submit information for dispensed Schedule II, III, IV and V controlled substance prescriptions to PMPAware on a weekly basis.

Under Georgia's PDMP law, only physicians owning or practicing in pain management clinics are required to query the PDMP before prescribing any Schedule II through IV Controlled Substance. Additionally, only physicians owning or practicing in pain management clinics are required to register with the PDMP. As Ms. O'Connor of Shatterproof explained at Meeting 3, Georgia law allows access to information for review or investigation but it does not require the PDMP to proactively analyze and distribute data in cases where high-risk behavior is most probable.

Mr. Allen provided a detailed report and update on Georgia's PDMP, which is available in Appendix C. The Committee agreed that physicians would have a greater incentive to participate in the PDMP if the system was updated more often. The cost to upgrade the system to update every 24 hours was estimated to be between $20,000 to $30,000 per year.

Neonatal Abstinence Syndrome

The Committee heard testimony at Meetings 1 and 2 on the prevalence of neonatal abstinence syndrome (NAS) in the U.S., where a baby is born with NAS every 25 seconds. Testimony at Northeast Georgia Medical Center provided the Committee with detailed information on the various symptoms associated with NAS. The medical costs associated with each child born with NAS are estimated at roughly $93,400, and the long-term effects of NAS may include learning disabilities and delayed motor skills. Dr. Karen Dudley, a neonatologist at Northside Hospital, emphasized the importance of a system-wide approach and home intervention to the Committee. Additionally, Northside has a "Quality Improvement Initiative" that uses a protocol-based approach that has led to a decreased average stay for infants born with NAS.

The Department of Family and Children Services (DFCS) provided testimony at Meeting 2 on how increased opioid abuse has affected the delivery of social services in recent years. According to DFCS, cases involving opioid abuse or other drug addiction can be very challenging for caseworkers who already face high volume caseloads.

The Committee also heard testimony on the best practices for treating addiction in pregnant women, including detox programs that use methadone as a treatment approach. Dr. Paul Browne, an associate professor of maternal fetal medicine at GRU, provided testimony on Augusta University's addiction program for pregnant mothers. Dr. Ellis of Augusta University told the Committee that the best strategy in achieving neonatal and fetal outcomes is to make sure the mother's needs are met, which may include appointment reminders and transportation to treatment sites. While there is no detox program at Northside, Dr.Dudley believes that having the conversation about NAS with parents beforehand is very helpful.

Heroin Working Groups

Additional testimony was provided by prosecutors and law enforcement officers who have first-hand knowledge and experience with the opioid crisis in Georgia. As Mr. Horn described at Meeting 3, Georgia is part of the opioid crisis but has not reached a catastrophic point like some states (e.g. West Virginia and Ohio). The Fulton County Heroin Working Group discussed at Meeting 3 was modeled after programs in Pittsburgh, Pennsylvania and Cleveland, Ohio. The Committee was encouraged to hear testimony on the effectiveness of the heroin working groups in Georgia and the opportunity to expand these efforts in other areas of the state.

Prescription Drug Policies in Emergency Departments

As Ms. Hall explained at Meeting 1, the Emergency Department (ED) is the largest source for opioid analgesics and is estimated by the National Center for Health Statistics to generate roughly 39 percent of all opioids prescribed in the U.S. Unlike other vital signs, pain is subjective and more difficult to assess since it cannot be proven through a medical test. ED physicians are faced with the burden of carefully assessing each patient presenting with pain while also achieving high patient satisfaction scores regardless of whether a prescription for pain medication is issued. Concerns over whether the push for patient satisfaction contributes to provider prescribing habits are significant, leading some EDs to implement a prescription drug policy. Northeast Georgia Medical Center (NGMC)'s ED Controlled Substance Policy was approved in 2012 and consists of a uniform policy that educates patients on adherence to the policy and redirects patients to community resources for the management of chronic pain, which should occur by one non-emergency provider. Dr. Tom Fitzgerald provided testimony at Meeting 2 on the development of a similar policy by Tanner Medical's ED.

Medication Assisted Treatment Sites for Opioid Addiction

Brooke Etherington, Vice President of the Opioid Treatment Providers of Georgia, provided testimony at Meeting 4 on how Medication Assisted Treatment Sites (MATs) in Georgia vary by facility size and services. This variance explains why those who work in the MAT industry tend to shy away from calling these facilities "methadone clinics." Committee members expressed concerns regarding certain facilities that reportedly dispense methadone like a vending machine and made several references to "pill mills." According to Mr. Etherington, all MATs in Georgia should be regulated and subject to inspections.

Approaches to Address Substance Abuse in Georgia

Jim Langford of the Georgia Prevention Project distributed a summary of a white paper by the Substance Abuse Research Alliance (SARA), which was later finalized in December 2016. In addition to the SARA white paper, Mr. Langford provided testimony on outreach prevention and education programs.

COMMITTEE RECOMMENDATIONS

Based on the foregoing findings, the Committee makes the following recommendations:

- Legislation should be introduced in 2017 to codify the effect of Emergency Rule 480-34-0.31-.11 (Naloxone) that was adopted by the Georgia Board of Pharmacy on December 14, 2016. This rule increases access to naloxone to individuals by allowing pharmacists to independently dispense naloxone in cases where a patient-specific prescription has not been issued by a physician. The Committee agrees that O.C.G.A. § 24-6-116.2 should be amended to authorize the State Health Officer (Commissioner Brenda Fitzgerald) to issue a statewide "standing order," which would function as a prescription for opioid antagonists/naloxone for any persons or entities she chooses to name in the order.
- The Committee agrees that first responders need additional funding sources for naloxone, especially with the increased use of synthetic opioids that often require more than one dose to achieve an effective reversal. Funding for naloxone should be increased to ensure first responders are equipped with adequate supplies.
- The Committee supports efforts to improve the utility of Georgia's Prescription Drug Monitoring Program by: mandating reporting by all prescribing physicians; increasing funding to expand the ability of GDNA to review and make data available; and developing an application that will allow the system to update its information every 24 hours. An exception to physician reporting requirements should be considered for prescriptions of five pills or less, which would decrease workload related to minor procedures or some acute pain treatments. Additionally, continuing medical education should be developed for physicians and other prescribers on narcotics, proper prescribing, and the use of alternative medications. Narcotic prescriptions should be tracked by DEA and anyone writing over a decided number should be looked at to verify legitimacy of practice.
- The Committee agrees that medication assisted treatment sites (MATs) should be regulated in Georgia and intends to share its findings with the Commission on Narcotic Treatment Programs to formulate a legislative solution to this issue.
- The progress of the heroin working groups should be closely monitored in hopes that a statewide model can be developed in the future.
- The Committee recommends a continuance of state funds for DBHDD to support addiction treatment and recovery services. Additional funding resources should be explored to support early intervention efforts and coordination with DFCS for children born to drug addicted mothers.
- There should be a consistent approach to chronic pain management across our health systems in Georgia. The Committee supports bringing experts together in a future study to develop a uniform system that can implemented on a state level.
- Finally, Georgia needs to be proactive in its effort to address the opioid epidemic and explore funding opportunities to ramp up outreach prevention and education programs on school campuses.

CONCCURING REPORT BY DR. RAFAEL PASCUAL

Regarding the PDMP and mandating prescriber participation:

Participation should not be required if prescriber writes for a prescription duration of under 7 days. Additionally, the PDMP website should be updated for ease of use and allow physician assistants, techs or nurses be allowed to access site for the physician.

Respectfully Submitted,

FINAL REPORT OF THE OPIOID ABUSE SENATE STUDY COMMITTEE

Renée S. Unterman

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Honorable Renee Unterman, Chair
Senator, District 45