



Responding to the NAS Epidemic: Tennessee State-Level Efforts

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The Center for Children's Justice | Philadelphia, PA
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Disclosure

- Michael Warren, MD MPH, has disclosed no relevant, real or apparent personal or professional financial relationships with proprietary entities that produce health care goods and services.



Objectives

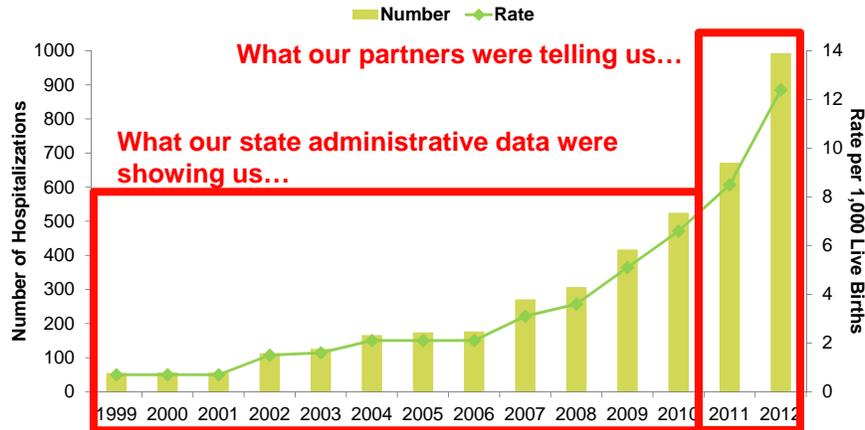
- Describe Tennessee's Neonatal Abstinence Syndrome (NAS) subcabinet
- Discuss the implementation and utilization of a real-time surveillance system for neonatal abstinence syndrome (NAS) in Tennessee
- Identify state-level program, policy, and legal efforts to address neonatal abstinence syndrome in the broader context of an opioid epidemic



**Tennessee's NAS
Subcabinet**

NAS in Tennessee: 2012

NAS Hospitalizations in Tennessee, 1999-2012



Data sources: Tennessee Department of Health; Office of Health Statistics; Hospital Discharge Data System (HDDS) and Birth Statistical System. Analysis includes inpatient hospitalizations with age less than 1 and any diagnosis of drug withdrawal syndrome of newborn (ICD-9-CM 779.5). HDDS records may contain up to 18 diagnoses. Infants were included if any of these diagnosis fields were coded 779.5.



TennCare NAS Costs, CY2011

Metric	TennCare Paid Live Births ¹	TennCare non-LBWT Births	TennCare Live LBWT Births ²	NAS Infants
Number of Births	45,205	40,437	4,768	528
Cost for Infant in first year of life	\$350,936,293	\$171,336,964	\$179,599,329	\$33,249,612
Average Cost per child	\$7,763	\$4,237	\$37,668	\$62,973
Average length of stay (days)	4.8	3.2	18.3	32.5

1.1% of infants

9.5% of costs

Data source: Division of Health Care Finance and Administration, Bureau of TennCare.
 1. This sample contains only children that were directly matched to TennCare's records based on Social Security Number.
 2. Any infant weighing under 2,500g at the time of birth was considered low birth weight (LBWT).



Infants in DCS Custody, TennCare, CY2011

	Infants born in CY 2011	NAS infants
Total # of Infants	55,578	528
Total # infants in DCS	767	120
% in DCS	1.4%	22.7%

Data source: Division of Health Care Finance and Administration, Bureau of TennCare.
 This sample contains only children that were directly matched to TennCare's records based on Social Security Number.



NAS Impacting Multiple State Agencies



NAS Subcabinet Working Group

- Convened in late Spring 2012
- Committed to meeting every 3-4 weeks
- Modeled after successful Safety Subcabinet convened by Governor Haslam
- Cabinet-level representation from Departments:
 - Public Health (TDH)
 - Children's Services (DCS)
 - Human Services (DHS)
 - Mental Health and Substance Abuse Services (DMHSAS)
 - Medicaid (TennCare)
 - Safety
 - Children's Cabinet



NAS Subcabinet Working Group

- Working principles:
 - Multi-pronged approach
 - Best strategy is primary prevention but clearly must address secondary and tertiary prevention
 - Each department progresses independently, keep group informed of efforts
 - Supportive rather than punitive approach



Other Key Partnerships

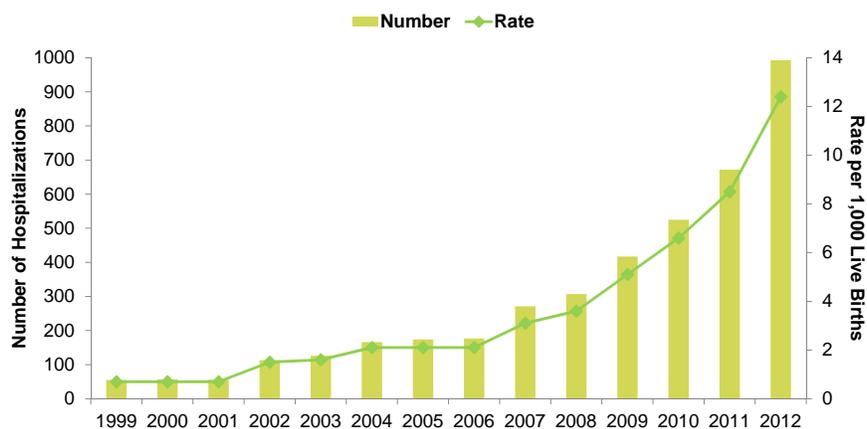
- **Local anti-drug coalitions**
 - Awareness campaigns
 - Count It! Lock It! Drop It!
 - Advocacy
- **Law enforcement**
 - Drop-off boxes/Take-back events
- **Courts/Correctional system**
 - Drug courts/educational programs
 - Jail-based education
- **Academic partners**
 - Data analysis/research projects
 - Subject matter expertise
- **Insurance payers**
 - Pilot funding
- **Professional medical organizations**
 - Continuing education
 - Advocacy
- **Community agencies**
 - Wrap-around/recovery support
 - Home visiting
- **Elected officials**
 - Local, state, national policy efforts



**Generating Data for
Action**

NAS in Tennessee: 2012

NAS Hospitalizations in Tennessee, 1999-2012



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NAS in Tennessee: 2012

- What we knew in 2012...
 - Hospital discharge data through 2010 showed sharp increase in NAS cases
 - Feedback from hospitals (particularly in East TN): “Busting at the seams” with NAS babies
 - Increase in drug overdose deaths
 - **We have a problem**
- What we **didn't** know in 2012...
 - 2011 or 2012 case numbers
 - State rules re: release of hospital discharge data
 - Source of prenatal exposure
 - Not easily identifiable via administrative claims



NAS as a Reportable Disease

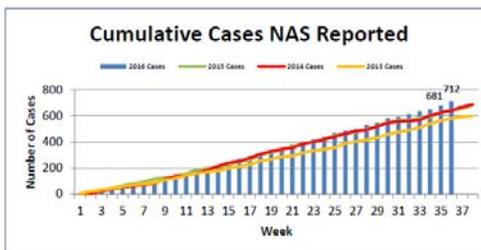
- Add NAS to state’s Reportable Diseases and Events list
 - State Health Officer (Commissioner) has authority to add conditions to list as appropriate
 - Effective January 1, 2013
- Reporting hospitals/providers submit electronic report
- Reporting Elements
 - Case Information
 - Diagnostic Information
 - Source of Maternal Exposure
- Initially, reporting done through SurveyMonkey® and SurveyGizmo®
 - Now use REDCap™



Neonatal Abstinence Syndrome Surveillance Summary Week 36: September 4– September 10, 2016

Year to Date Reporting Summary		
Total Cases Reported:		712
Sex	Male	377
	Female	335

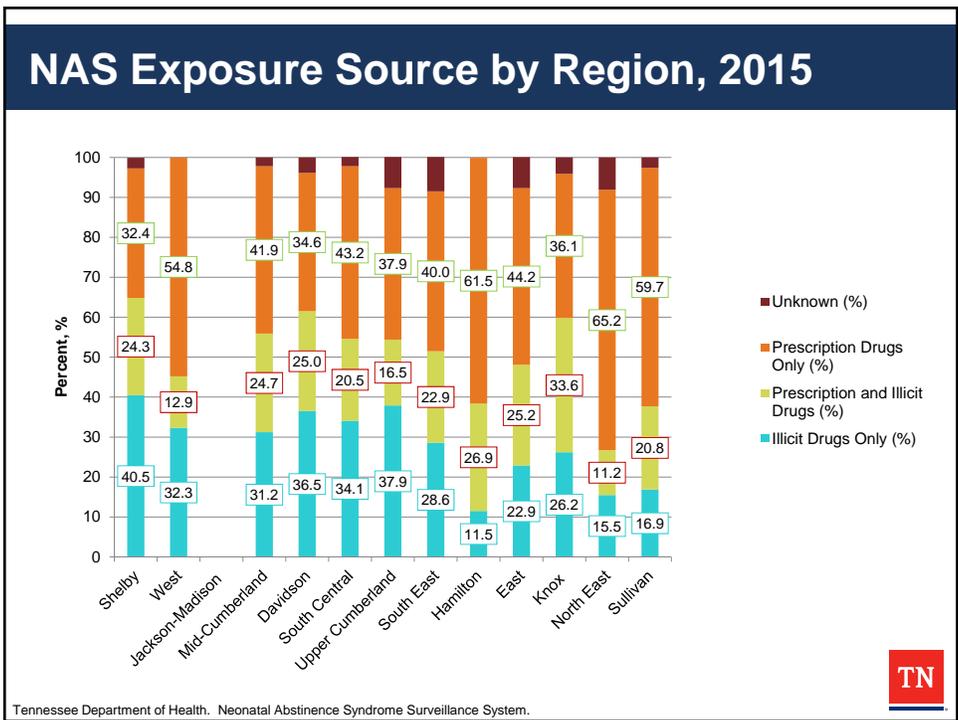
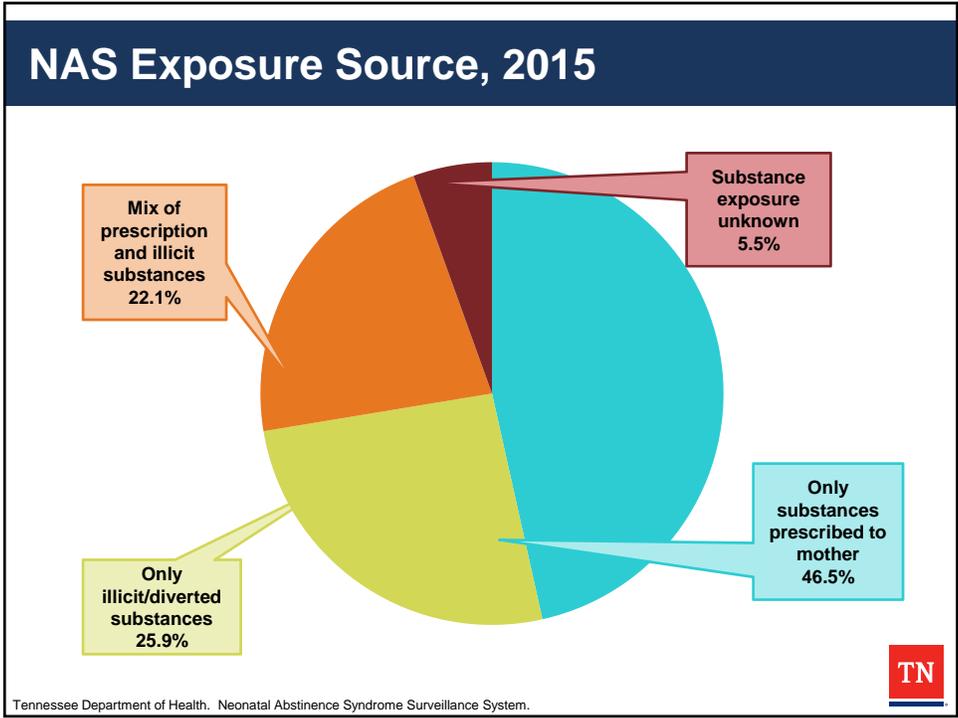
Maternal County of Residence	# Cases	% Cases ²
Davidson	50	7.0
East	154	21.6
Hamilton	11	1.5
Jackson/Madison	3	0.4
Knox	64	9.0
Mid-Cumberland	80	11.2
North East	131	18.4
Shelby	2	0.3
South Central	39	5.5
South East	25	3.5
Sullivan	52	7.3
Upper Cumberland	76	10.7
West	25	3.5
TOTAL	712	99.9



Source of Exposure	# Cases ¹	% Cases
Medication assisted treatment	483	67.8
Legal prescription of an opioid pain reliever	79	11.1
Legal prescription of a non-opioid	54	7.6
Prescription opioid obtained without a prescription	190	26.7
Non-opioid prescription substance obtained without a prescription	84	11.8
Heroin	18	2.5
Other non-prescription substance	114	16.0
No known exposure	8	1.1
Other ⁴	38	5.3

1. Summary reports are archived weekly at: <http://tn.gov/health/articles/nas-summary-archive>
 2. Total percentage may not equal 100.0% due to rounding.
 3. Multiple maternal substances may be reported; therefore the total number of cases in this table may not match the total number of cases reported.
 4. Other exposure may include cases reported to the archived surveillance system with classifications not captured in the current system.







NAS: Levels of Prevention			
	PRIMARY Prevention	SECONDARY Prevention	TERTIARY Prevention
Definition	An intervention implemented before there is evidence of a disease or injury	An intervention implemented after a disease has begun, but before it is symptomatic.	An intervention implemented after a disease or injury is established
Intent	Reduce or eliminate causative risk factors (risk reduction)	Early identification (through screening) and treatment	Prevent sequelae (stop bad things from getting worse)
NAS Example	Prevent addiction from occurring Prevent pregnancy	Screen pregnant women for substance use during prenatal visits and refer for treatment	Treat addicted women Treat babies with NAS

Adapted from: Centers for Disease Control and Prevention. A Framework for Assessing the Effectiveness of Disease and Injury Prevention. MMWR. 1992; 41(RR-3): 001. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml00016403.htm>



Narcotics/Contraceptive Use, TennCare, 2014

Demographics	TennCare Women	Women Prescribed Narcotics (>30 days supplied)	Narcotic Users Rate per 1,000	Women Prescribed Contraceptives and Narcotics	% of Women on Narcotics and Contraceptives	Women Prescribed Narcotics without Contraceptives	% of Women on Narcotics Not on Contraceptives
All Women	320,327	38,210	119	5,625	15%	32,585	85%
15-20	85,174	1,333	16	541	41%	792	59%
21-24	48,169	2,787	58	814	29%	1,973	71%
25-29	59,165	6,998	118	1,561	22%	5,437	78%
30-34	53,614	9,483	177	1,459	15%	8,024	85%
35-39	42,963	9,281	216	804	9%	8,477	91%
40-44	31,241	8,328	267	446	5%	7,882	95%

Data source: Division of Health Care Finance and Administration, Bureau of TennCare. CY2014 data. Available at: <http://www.tn.gov/assets/entities/tenncare/attachments/TennCareNASData2014.pdf>



East TN NAS Primary Prevention Project

- **Primary Prevention Initiative (PPI):**
 - Department-wide initiative
 - Vision by State Health Officer
 - Focus upstream
 - Engage community partners to address local issues

- **East TN PPI Project:**
 - Started in Cocke and Sevier counties
 - Partnership with local jails
 - Health education sessions
 - Focus on NAS prevention
 - Information on effective contraception
 - Partnerships with jails to refer inmates to local health department for family planning



East TN NAS Primary Prevention Project

- All services are **voluntary**
- Any patient referred to health department for family planning services is offered a **variety of acceptable and effective contraceptive methods**
- Selected results from East TN PPI project:
 - **442 referrals** in 2014-15
 - **88%** with **history of drug use**
 - **30%** reported **drug use during pregnancy**
 - **19%** had delivered **infant with NAS**
 - **73%** reported **no contraceptive method**
 - Among referred patients:
 - **94%** received a contraceptive method (N=406)
 - **84%** chose a **voluntary reversible long-acting contraceptive** (N=361)



**Data to Action:
State Level**

Request for Black Box Warning



STATE OF TENNESSEE
DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH
COMMISSIONER

BILL HASLAM
GOVERNOR

November 1, 2012

Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write out of grave concern for the health, developmental and life course consequences for babies whose antenatal environment includes substantial opioid analgesic exposure. We believe that a "black box warning" for these medications would help assure that women of childbearing age and their health care providers are aware of the serious risks associated with narcotic use during pregnancy. Possible content for the warning may be as follows:

WARNING: USE OF NARCOTIC ANALGESICS IN WOMEN OF CHILD BEARING AGE MAY CAUSE NEONATAL ABSTINENCE SYNDROME

This message would also promote a critical dialog between the patient and provider regarding considerations in planning for pregnancy or prevention of unintended pregnancy for women who are benefiting therapeutically from these powerful medications or who may be at risk for abusing them. This



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FDA NEWS RELEASE

For Immediate Release: Sept. 10, 2013
Media Inquiries: Morgan Liscinsky, 301-796-0397, morgan.liscinsky@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

En Español

FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics

New boxed warning to include neonatal opioid withdrawal syndrome

The U.S. Food and Drug Administration today announced class-wide safety labeling changes and new postmarket study requirements for all extended-release and long-acting (ER/LA) opioid analgesics intended to treat pain.

"The FDA is invoking its authority to require safety labeling changes and postmarket studies to combat the crisis of misuse, abuse, addiction, overdose, and death from these potent drugs that have harmed too many patients and devastated too many families and communities," said FDA Commissioner Margaret A. Hamburg, M.D. "Today's action demonstrates the FDA's resolve to reduce the serious risks of long-acting and extended release opioids while still seeking to preserve appropriate access for those patients who rely on these medications to manage their pain."

The FDA is also requiring a new boxed warning on ER/LA opioid analgesics to caution that chronic maternal use of these products during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening and require management according to protocols developed by neonatology experts. NOWS can occur in a newborn exposed to opioid drugs while in the mother's womb. Symptoms may include poor feeding, rapid breathing, trembling, and excessive or high-pitched crying.

The updated indication further clarifies that, because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, these drugs should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain; ER/LA opioid analgesics are not indicated for as-needed pain relief.

"The FDA's primary tool for informing prescribers about the approved uses of medications is the product labeling," said Douglas Throckmorton, M.D., deputy director for regulatory programs in the FDA's Center for Drug Evaluation and Research. "These labeling changes describe more clearly the risks and safety concerns associated with ER/LA opioids and will encourage better, more appropriate, prescribing, monitoring and patient counseling practices involving these drugs."

Recognizing that more information is needed to assess the serious risks associated with long-term use of ER/LA opioids, the FDA is requiring the drug companies that make these products to conduct further studies and clinical trials. The goals of these postmarket requirements are to further assess the known serious risks of misuse

TennCare Prior Authorization Form



**Prior Authorization Form
Long Acting Narcotics**

All PA forms may be found by accessing <https://tnm.providerportal.sxc.com/rxclaim/TNM/PAs.htm>

If the following information is not complete, correct, or legible the PA process can be delayed. **Use one form per r**

Member Information											
Last Name						First Name					
ID Number						Date of Birth					
Prescriber Information											

For female patients between the ages of 18 & 45, please complete questions 10 -12

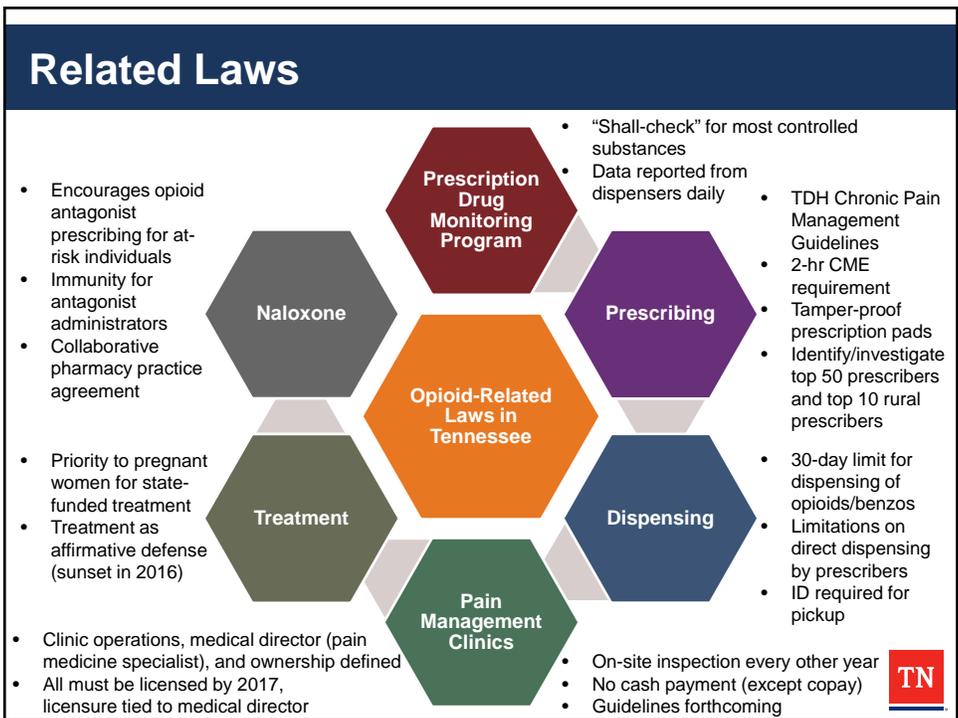
10. The use of opioid analgesics during pregnancy has been associated with **neonatal abstinence syndrome**. Has this patient been counseled regarding the risks of becoming pregnant while receiving this medication, including the risk of neonatal abstinence syndrome? Yes No

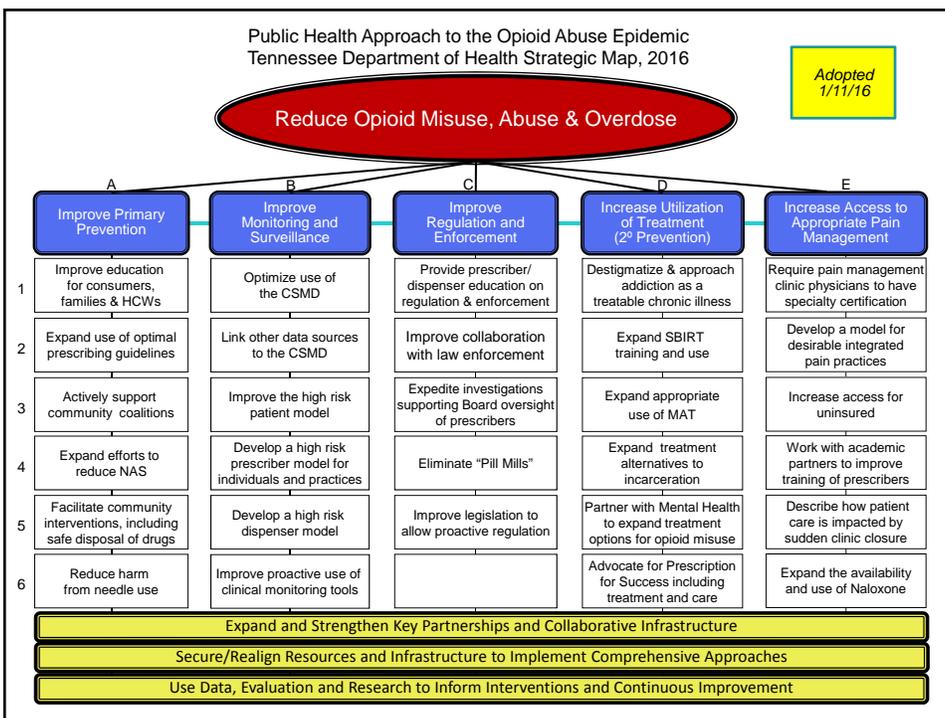
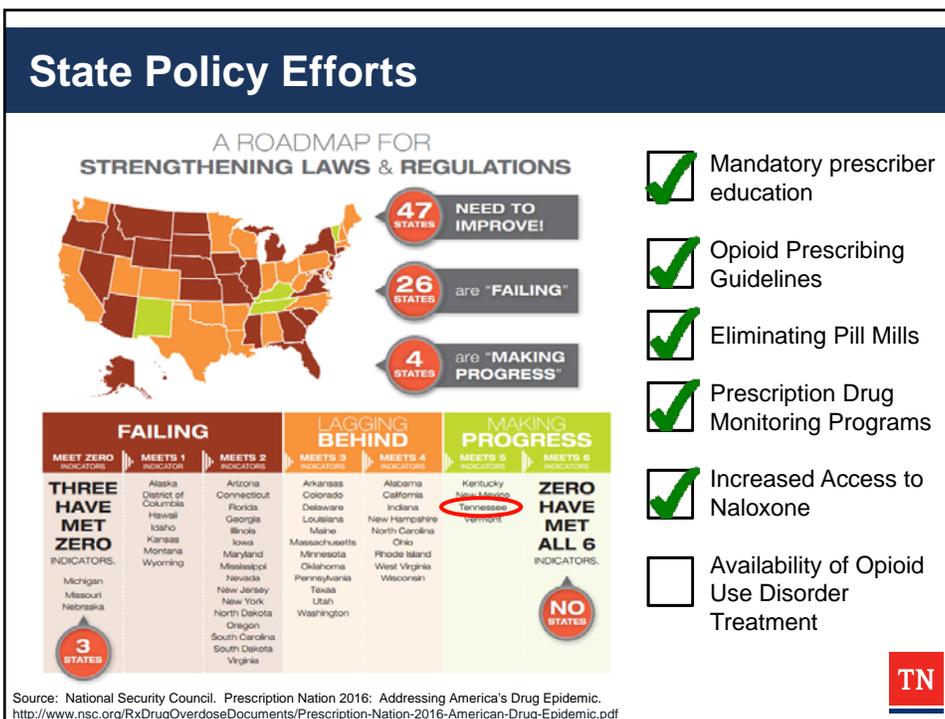
11. Is this patient currently **utilizing a form of contraception**? Yes No

12. Has **access to contraceptive services** been offered to this patient? Yes No



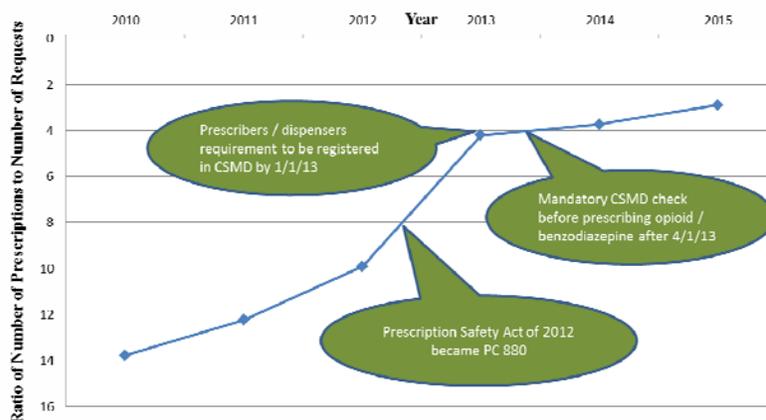
Form available at:
[https://tnm.providerportal.sxc.com/rxclaim/TNM/TC%20PA%20Request%20Form%20\(Long%20Acting%20Narcotics\).pdf](https://tnm.providerportal.sxc.com/rxclaim/TNM/TC%20PA%20Request%20Form%20(Long%20Acting%20Narcotics).pdf)





Process Impact: PDMP Law

Figure 3. Ratio of Number of Prescriptions to Number of Requests in the CSMD, 2010-2015*



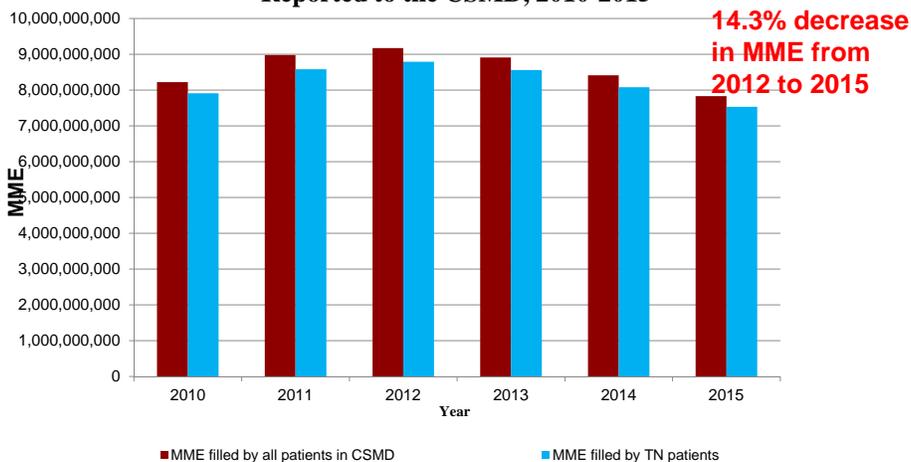
* Includes all Prescriptions and all requests

Tennessee Department of Health. Controlled Substance Monitoring Database. 2016 Report to the 109th General Assembly. http://www.tn.gov/assets/entities/health/attachments/CSMD_AnnualReport_2016.pdf



Outcome Impact: MME Dispensed

Opioid MMEs and Prescriptions Dispensed to TN Patients and Reported to the CSMD, 2010-2015*



*Excluding prescriptions reported from VA pharmacies.

Tennessee Department of Health. Controlled Substance Monitoring Database.



Collaborative Research Projects

- 5 grants awarded to collaborative research partnerships
 - Address key NAS research questions
 - Answerable:
 - With TN data and expertise
 - Within one year
 - Funded with MCH Block Grant funds and Medicaid Infant Mortality/Women's Health grant

RESEARCH TOPICS

- Development of a predictive model for NAS
- Barriers to contraception in women attending substance abuse programs
- Optimal management of the pregnant woman taking opioids
- Understanding and improving provider knowledge and behavior
- Understanding optimal management of the infant with NAS

<http://www.tn.gov/health/article/nas-research-projects>



Summary

- A **collaborative approach** (the NAS Subcabinet) was utilized to address a **complex problem impacting multiple state agencies**
- NAS surveillance in TN has allowed for more **robust description of exposure sources**
- **Utilization of data from multiple sources** allows for targeting of local prevention efforts as well as state programs and policies
- Addressing NAS and the broader opioid epidemic requires a **multi-faceted, long-term approach**



For More Information

- Weekly NAS Surveillance Archive
 - <http://www.tn.gov/health/article/nas-summary-archive>
- Monthly and Annual NAS Reports
 - <http://www.tn.gov/health/article/nas-update-archive>



Contact Information

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