

STATEWIDE TASK FORCE  
ON  
PRESCRIPTION DRUG ABUSE  
&  
NEWBORNS

2014 Progress Report



ATTORNEY GENERAL  
**PAM BONDI**  
FLORIDA OFFICE OF THE ATTORNEY GENERAL



**Statewide Task Force on Prescription Drug Abuse & Newborns  
October 7, 2013**

**Statewide Task Force on Prescription Drug Abuse & Newborns**

**Task Force Membership**

The Honorable Pam Bondi  
Florida Attorney General  
Task Force Chairwoman

State Surgeon General Dr. John H. Armstrong  
Department of Health  
Task Force Vice-Chairman

Interim Secretary Esther Jacobo  
Department of Children and Families

Secretary Elizabeth Dudek  
Agency for Health Care Administration

Assistant Commissioner Jim Madden  
Florida Department of Law Enforcement

The Honorable Joe Negron  
Florida Senate

The Honorable Dana Young  
Florida House of Representatives

Dr. Stephanie Haridopolos  
Attorney General Appointment

Dr. Robert Yelverton  
Florida Medical Association

Dr. Kenneth Solomon  
Pediatrix Medical Group & St. Joseph's Women's Hospital  
Florida Hospital Association

Dr. David Dixon  
North Florida Women's Care  
Florida Osteopathic Medical Association

Willa Fuller  
Executive Director  
Florida Nurses Association

Jane Murphy  
Executive Director  
Florida Association of Healthy Start Coalitions

Keith Nash  
Associate State Director  
March of Dimes Florida Chapter

Doug Leonardo  
Executive Director  
BayCare Behavioral Health

Office of the Attorney General

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**Executive Summary**

Prescription drug abuse during pregnancy creates adverse health effects in newborns termed Neonatal Abstinence Syndrome (NAS). The national prescription drug abuse epidemic afflicts increasing numbers of pregnant women, fueling an explosion in cases of NAS in Florida’s newborns. NAS babies suffer terribly from withdrawal symptoms such as tremors, abdominal pain, incessant crying, rapid breathing, and sometimes seizures. Meanwhile, providing drug prevention and treatment for pregnant women and mothers pose significant policy and practice challenges both to the health care community and our social welfare agencies.

The 2012 Florida Legislature created the *Statewide Task Force on Prescription Drug Abuse and Newborns* to begin addressing the growing problem of NAS. Attorney General Pam Bondi chaired the Task Force and State Surgeon General John Armstrong was Vice-Chair. The 15-member Task Force consisted of medical professionals, law enforcement, prevention experts and state legislators. The Florida Legislature charged this Task Force with examining the scope of NAS in Florida, its long-term effects as well as the costs associated with caring for drug exposed babies, and which drug prevention and intervention strategies work best with pregnant mothers.

The Task Force fulfilled its mission by publishing its *Final Report* in February 2013. The *Final Report* outlined the problem of NAS, examined the costs to Florida from NAS, and identified strategies to reduce the problem of prescription drug addiction among pregnant women. The following are the Task Forces’ 15 policy recommendations along with a brief status update:

Policy Recommendation	Assignment	Status Update
<p>1. Develop and implement a coordinated statewide public awareness initiative, using existing community resources, that is intended to educate the public about the dangers of prescription drug abuse during pregnancy.</p>	<ul style="list-style-type: none"> <li>• Attorney General</li> <li>• Department of Children &amp; Families</li> <li>• Department of Health</li> <li>• Florida Association of Healthy Start Coalitions</li> <li>• March of Dimes</li> </ul>	<p>Attorney General Bondi, DCF, the DOH and members of the Task Force launched “Born Drug-Free Florida” - a statewide prevention campaign that educates expectant mothers about the importance of discussing prescription drug use with their doctors.</p> <p>The Born Drug-Free Florida initiative includes:</p> <ul style="list-style-type: none"> <li>• Helpline</li> <li>• Billboards</li> <li>• Radio spots</li> <li>• Website</li> </ul> <p>This prevention initiative has helped at least 60 pregnant women begin substance abuse treatment.</p>
<p>2. Ensure that all school-based prescription-drug-specific primary prevention efforts are properly developed, evidence-based, rigorously evaluated, and sustainable.</p>	<ul style="list-style-type: none"> <li>• Drug Policy Advisory Council</li> </ul>	<p>Review is ongoing.</p>

Policy Recommendation	Assignment	Status Update
3. Make drug screening pregnant patients a voluntary, best practice policy for obstetricians. Screening would occur via the most appropriate methods determined by obstetricians as part of their patient standard of care.	<ul style="list-style-type: none"> <li>• Florida Osteopathic Medical Association</li> <li>• Florida Medical Association</li> <li>• Department of Health</li> </ul>	Associations are advocating for voluntary screening of pregnant patients.
4. Develop curricula for Florida nursing and medical schools addressing addiction as a brain disease; develop continuing education credits for medical professionals to enhance their knowledge and skills to more effectively manage chronic pain, treat substance abuse disorders, and better prevent prescription drug diversion.	<ul style="list-style-type: none"> <li>• Department of Health</li> <li>• Florida's Medical Schools</li> <li>• Board of Governors</li> <li>• Florida Medical Association</li> <li>• Florida Osteopathic Medical Association</li> <li>• Florida Nurses Association</li> </ul>	Recommendation is ongoing.
5. Create a toolkit of "best practices" for nurses caring for Neonatal Abstinence Syndrome (NAS) newborns and their families.	<ul style="list-style-type: none"> <li>• Florida Nurses Association</li> </ul>	A toolkit is being developed by a workgroup of nurses established by the FNA; toolkit will be launched later in 2014.
6. Collaborate with communities (hospital staff, medical personnel, Healthy Start, Early Steps) to implement a system of "case conferencing" for NAS infants so as to better coordinate services before discharge from a hospital.	<ul style="list-style-type: none"> <li>• Department of Health</li> <li>• Department of Children &amp; Families</li> <li>• Florida Hospital Association</li> <li>• Florida Medical Association</li> <li>• Florida Association of Healthy Start Coalitions</li> </ul>	
7. Find innovative ways to increase the voluntary use of Florida's Prescription Drug Monitoring Program (PDMP) among medical professionals.	<ul style="list-style-type: none"> <li>• Department of Health</li> <li>• Florida Medical Association</li> <li>• Florida Osteopathic Medical Association</li> </ul>	DOH has conducted numerous outreach efforts to encourage greater utilization of the PDMP. This past year, health care practitioner registration increased 28 percent, and utilization increased 61 percent.
8. Create an immunity provision in Florida law for pregnant woman seeking prenatal care or substance abuse treatment.	<ul style="list-style-type: none"> <li>• Task Force Members</li> </ul>	
9. Create a toolkit to help communities establish and maintain Substance Exposed Newborn Workgroups.	<ul style="list-style-type: none"> <li>• Florida Association of Healthy Start Coalitions</li> <li>• Florida Perinatal Quality Collaborative</li> <li>• Department of Health</li> <li>• Department of Children &amp; Families</li> <li>• Attorney General</li> </ul>	
10. Ensure appropriate adoption procedures and support exists for families wishing to adopt a drug exposed newborn.	<ul style="list-style-type: none"> <li>• Governor's Office of Adoption &amp; Child Protection</li> <li>• Department of Children &amp; Families</li> </ul>	This initiative is continuing.

Policy Recommendation	Assignment	Status Update
<p>11. Work with federal agencies to fund research projects in Florida aimed at: (1) understanding the full economic costs associated with NAS in Florida; (2) enhancing our understanding of effective treatment methods for NAS infants and mothers with opioid dependence; (3) understanding the long-term consequences of maternal opioid pain reliever abuse on children; and (4) funding expanded access to evidence-based behavioral interventions for at-risk mothers (such as electronic-therapy and nonresidential community-based care).</p>	<ul style="list-style-type: none"> <li>• Department of Health</li> <li>• Department of Children &amp; Families</li> <li>• Agency for Healthcare Administration</li> <li>• Attorney General</li> </ul>	<p>State agencies continue to monitor opportunities to apply for grant funding.</p>
<p>12. The Agency for Health Care Administration will create a workgroup to assess the viability of expanding the Screening Brief Intervention and Referral to Treatment (SBIRT) model beyond health care settings to other settings where at-risk mothers can be reached.</p>	<ul style="list-style-type: none"> <li>• Agency for Health Care Administration</li> <li>• Department of Children &amp; Families</li> <li>• Department of Health</li> <li>• Florida Alcohol &amp; Drug Abuse Association</li> </ul>	<p>The Florida Medicaid Program has developed a guide that Medicaid Practitioners and Medicaid Managed Care Health Plans can use in developing the SBIRT model.</p>
<p>13. Develop treatment protocols for drug-exposed newborns as well as recommendations for alternatives to narcotics for pain management in pregnant women.</p>	<ul style="list-style-type: none"> <li>• Florida Medical Association</li> <li>• Florida Osteopathic Medical Association</li> <li>• Florida Perinatal Quality Collaborative</li> </ul>	<p>The development of treatment protocols for drug-exposed newborns is ongoing.</p>
<p>14. Enhance the capacity of the behavioral health system to ensure that pregnant women and mothers have immediate access to the appropriate level of care, through a continuum of services that-at a minimum- includes:</p> <ul style="list-style-type: none"> <li>• Expand residential treatment capacity</li> <li>• Expand intensive outpatient treatment capacity</li> <li>• Fund case management services to assist women leaving treatment</li> </ul>	<ul style="list-style-type: none"> <li>• Department of Children &amp; Families</li> <li>• Florida Alcohol and Drug Abuse Association</li> </ul>	<p>Florida Legislature funded \$8.9M in new substance abuse treatment funding for pregnant women and mothers with children.</p>
<p>15. Add Neonatal Abstinence Syndrome to the list of Reportable Diseases and Events.</p>	<ul style="list-style-type: none"> <li>• Department of Health</li> </ul>	<p>The Florida Department of Health convened an NAS Ad Hoc Advisory Committee and created a standardized NAS case definition. The Department intends to develop NAS disease reporting requirements through rule making and has been noticed in the Florida Administrative Weekly.</p>

## 1. Background: Resolving Florida's Rx Drug Abuse Epidemic

Until recently, Florida was known as the “OxyContin Express,” a major source for powerful, diverted pharmaceuticals (such as oxycodone and hydrocodone) for addicts and criminal distribution rings throughout the nation. Florida became the epicenter of prescription drug diversion because of a proliferation of unscrupulous pain management clinics called “pill mills.” These pill mills flourished in Florida during the past decade because of weak regulatory oversight of these “clinics,” limited oversight of physician dispensing habits, as well as Florida being one of the last states to implement a Prescription Drug Monitoring Program (PDMP).

A critical step forward in organizing Florida's balanced attack on “pill mills” began in March 2011, when Governor Rick Scott and Attorney General Bondi created *Florida's Regional Drug Enforcement Strike Forces*. The Strike Force model was organized by utilizing Florida's seven domestic security regions and to then have the region co-led by a Sheriff and a Police Chief. Strike Force operations sought to reduce the supply of diverted prescription drugs through intelligence driven, multi-jurisdictional operations against the whole spectrum of the pill mill phenomenon: corrupt wholesalers, unscrupulous “physicians”, rogue pharmacies and the “doctor-shopping” “patients” supporting their addiction. The salutary effects of Florida's crackdown has resulted in 3,742 arrests (including 67 doctors), and the seizure of 848,037 pharmaceutical pills, 121 vehicles, 538 weapons, and \$10,073,807 as of December 2013. Additionally, 254 pain clinics have been closed.

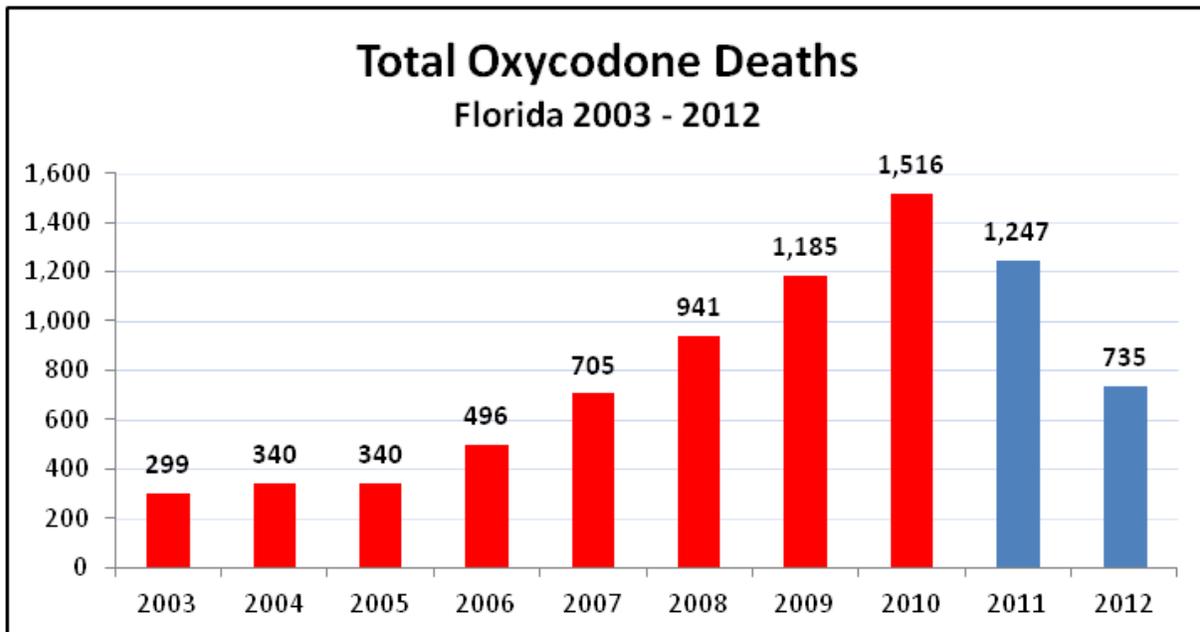
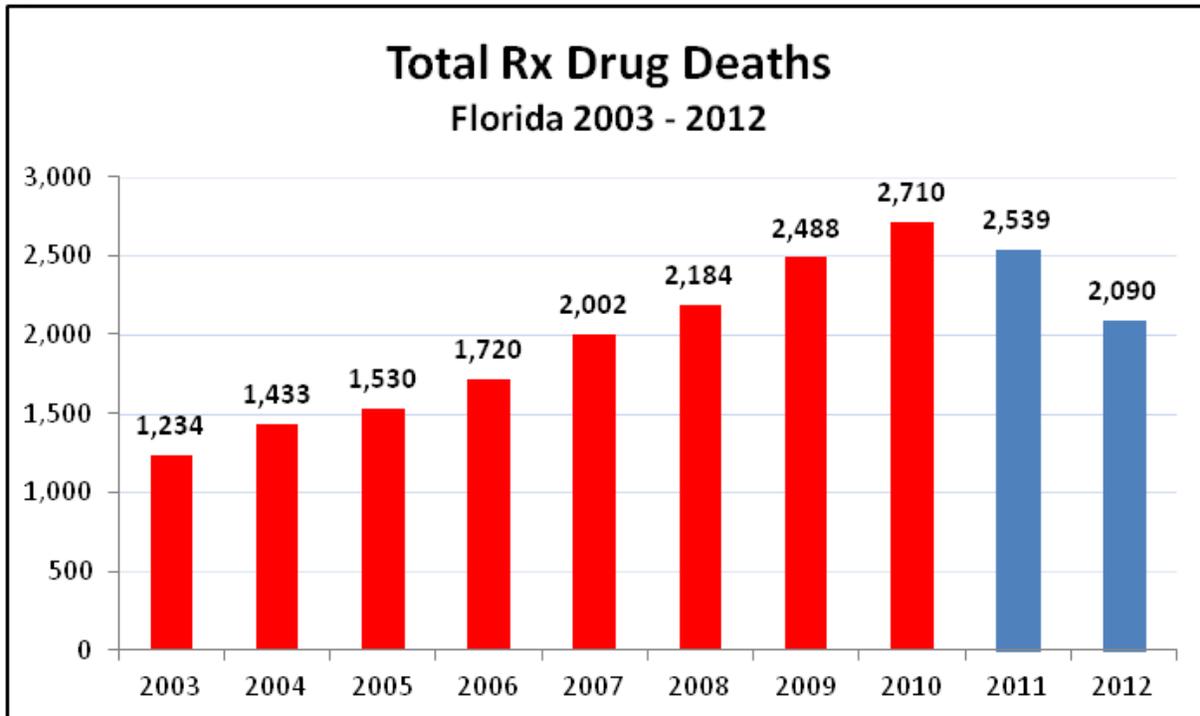
As the Strike Force model began to take hold, the Florida Legislature enacted HB 7095 to support both law enforcement and health care professionals. HB 7095 was a tough new law to combat prescription drug diversion that:

- Banned dispensing of Schedule II and Schedule III controlled substances by physicians and made a violation of the ban both a third degree felony and grounds for licensure discipline.
- Created a standard of care for all physicians prescribing controlled substances to treat chronic pain.
- Required physicians to either electronically prescribe controlled substances or use counterfeit-proof prescription pads.
- Added new criminal penalties.
- Improved reporting to the state's PDMP from 15 to 7 days.
- Required wholesale distributors to credential customers and report on distribution of controlled substances.
- Required pharmacies dispensing Schedule IIs and IIIs to be re-permitted with the state.
- Provided \$3 million to fund the *Regional Drug Enforcement Strike Forces*.

While any one of these legislative enhancements on their own would have helped reduce prescription drug diversion and abuse, all of these statutory changes implemented together created dramatic results. For example, thanks to the Florida Legislature's dispensing ban coupled with aggressive regulatory efforts to close pill mills, the number of Florida doctors dispensing the most oxycodone within a given year has declined dramatically. In 2010, 98 of the top 100 oxycodone pill dispensing physicians nationally resided in Florida. In 2011, after the passage of HB 7095, only 13 of the top 100 resided in Florida, and by the end of 2012, not one Florida doctor appeared on the top 100 list.<sup>i</sup>

The most important result of Florida's turnaround on prescription drug diversion has been the dramatic lowering of prescription drug overdose deaths. The significance of this decline in overdose deaths cannot be overstated: during the previous six years (2005-2010), prescription drug deaths were increasing in Florida on average by 12 percent each year, *with oxycodone specific deaths increasing an average of 35 percent each year*. Since the successful implementation of Florida's holistic strategy to combat this epidemic, there has been:

- A 52 percent decline in the number of oxycodone overdose deaths;
- A 23 percent decline in hydrocodone overdose deaths; and
- A 23 percent decline in prescription drug overdose deaths.<sup>ii</sup>



Florida has not completely resolved its prescription drug epidemic, but thanks to the dedicated work of law enforcement, the medical community, health regulators, and local community leaders throughout the state, Florida is now making significant progress. Meanwhile, a sad outcome of this epidemic has been a surge in the number of child bearing age woman misusing or abusing prescription drugs, with the inevitable rise in hospitals across Florida having to treat more drug exposed newborns.

## **Intent of the Progress Report**

The 2012 Florida Legislature created the *Statewide Task Force on Prescription Drug Abuse and Newborns* to begin addressing the growing problem of prescription drug exposed newborns. This Task Force was charged by the Legislature with examining the scope of prescription drug abuse and drug exposed newborns in Florida, its long-term effects and the costs associated with caring for drug exposed babies, and which drug prevention and intervention strategies work best with pregnant mothers. Attorney General Pam Bondi chaired the Task Force and State Surgeon General John Armstrong was the Vice-Chair. The 15-member Task Force consisted of medical professionals, law enforcement, prevention experts and state legislators.

The Task Force concluded early on that reducing the number of drug exposed newborns must be done collaboratively, because in Florida no one state agency is solely responsible for addressing the problem of drug addiction. Collaboration is always more difficult in practice than concept given that relevant resources and data are spread across various public and private sector entities. As was clearly stated in the *Final Report*, it is important to note that a task force is not the vehicle to solve the problems it was created to examine. A task force is rather a catalyst to bring together multiple stakeholders and guide them to agree on a way forward.

The Task Force fulfilled its mission by publishing its *Final Report* in February 2013. The intent of this *Progress Report* is to update the Florida Legislature, as well as the public, about the status of the Task Force's policy recommendations and to highlight those initiatives that will need to be sustained after the task force sunsets in 2014.

## **Key Takeaways from the Final Report:**

- Florida has been the epicenter of prescription drug diversion, resulting in more women using or abusing prescription opioid drugs.
- More women abusing prescription drugs translates to an increase in more cases of Neonatal Abstinence Syndrome (NAS).
- NAS refers to medical complications newborns typically experience if their mothers abused illicit or prescription drugs during pregnancy.
- NAS is a treatable disease.
- Determining the exact number of cases of NAS in Florida is difficult because there is significant variability in hospital policies and practices used to determine both the diagnosis and reporting of NAS.
- Nevertheless, in 2011 there were 1,563 NAS cases reported in Florida. This category includes all classes of drugs abused during pregnancy. Updated totals from 2012 are located in Appendix A.
- A recent national study determined that between 2000 and 2009 average hospital charges for newborns diagnosed with NAS increased from \$39,400 to \$53,400 per baby, about a 35 percent increase.
- The Task Force determined that NAS costs are concentrated in Neonatal Intensive Care Unit expenses, and are typically paid by Medicaid.

## 2. Prevention

### Key Prevention Takeaways from the Final Report:

- Prevention should be viewed as a process, grounded in science, and not as a one-time event.
- Prevention programs that focus on providing education and awareness of the risks of prescription drug abuse to pregnant women are cost-effective and can be life-saving.
- Doctors and nurses well trained in drug addiction are the keystone to both preventing and alleviating NAS.
- Some prescription drug addicted women-fearing the involvement of child welfare agencies-avoid prenatal care. Florida’s prevention messaging needs to ease these concerns, encouraging women to seek prenatal care and substance abuse treatment.
- The Task Force agreed to not advocate for mandatory prenatal drug screenings, but rather to advance substance abuse screening as a component of a complete obstetric standard of care; screening should also be done with the consent of the pregnant woman.
- The Task Force recommended that the SBIRT program be expanded outside the primary care setting in order to reach more pregnant women needing an intervention and referral to treatment. (Screening Brief Intervention and Referral to Treatment-SBIRT-is a public health approach to delivering early intervention to anyone using alcohol and/or drugs in unhealthy ways).

### Prevention Policy Recommendations:

Policy Recommendation	Assignment
1. Develop and implement a coordinated statewide public awareness initiative, through existing community resources, to educate the public about the dangers of prescription drug abuse during pregnancy.	Attorney General Department of Children & Families Department of Health Florida Association of Healthy Start Coalitions March of Dimes
2. Find innovative ways to increase the voluntary use of Florida’s Prescription Drug Monitoring Program (PDMP) among medical professionals.	Department of Health Florida Medical Association Florida Osteopathic Medical Association
3. The Agency for Health Care Administration will create a workgroup to assess the viability of expanding the Screening Brief Intervention and Referral to Treatment (SBIRT) model beyond health care settings to other settings where at-risk mothers can be reached.	Agency for Health Care Administration Department of Children & Families Department of Health Florida Alcohol & Drug Abuse Association
4. Create a toolkit of “best practices” for nurses caring for Neonatal Abstinence Syndrome (NAS) newborns and their families.	Florida Nurses Association The University of South Florida College of Nursing

### **Creating Public Awareness: Born Drug-Free Florida Campaign**

A frequently discussed topic at task force meetings was the general lack of awareness among both the public, and even with some in the medical community, as to the dangers of prescription drug abuse. The Task Force agreed that healthcare providers, physicians, pharmacists, and patients must all play important roles in identifying and preventing prescription drug abuse by pregnant women if Florida is to make substantial progress in stopping

NAS. The most cost-effective way to address prescription drug abuse is to make certain it never happens in the first place. However, preventing prescription drug abuse poses unique challenges. Prevention strategies must walk the fine line that informs women of the benefits of properly prescribed controlled substances, while at the same time instilling the message that when prescription drugs are misused or abused the consequences can be costly.

The fundamental goal of any anti-NAS drug abuse prevention campaign must be to shift women’s perceptions and attitudes regarding the harm that comes from misusing prescription drugs. To that end, the Task Force put forward a specific policy recommendation to develop and implement a coordinated statewide public awareness initiative, using existing funds, to educate the public about the dangers of prescription drug abuse during pregnancy. On May 10, 2013, Attorney General Pam Bondi, the Department of Children and Families, the Department of Health and members of the Task Force launched “Born Drug-Free Florida.” This statewide prevention campaign educates expectant mothers about the importance of discussing prescription drug use with their doctors, and it provides ways to assist women. The campaign includes a helpline at 1-877-233-5656, a website at BornDrugFreeFL.com, video and radio spots, and billboards.

As of November 2013, the Born Drug-Free Florida hotline had received 332 calls. This hotline screens callers, refers them to appropriate facilities in their area and provides other informational resources. It has helped at least 60 pregnant women begin substance abuse treatment. The Department of Children & Families also reports that there has been at least a 300 percent increase per month in calls compared to before the Born Drug-Free Florida campaign started.

The initiative’s ad campaign began April 2013 and ended June 30, 2013, but still gets additional free spots and placement provided by media partners. A total of twenty-two billboards were posted in Pensacola, Tallahassee, Orlando, Tampa, Jacksonville and Gainesville. More than 22,000 local, network affiliate radio and iHeart radio spots ran statewide. The BornDrugFreeFL.com website has received 7,510 page views, and the average duration of each visit has been about five and a half minutes. The length of these visits shows visitors are spending time reviewing information on the site. Printed prevention materials were also distributed to regional DCF offices, Healthy Start Coalitions, County Health Departments, Healthy Families and other local organizations. The materials included 74,400 postcard-size fliers and 2,720 posters.

The Born Drug-Free Florida campaign has been so successful that the Tennessee Metropolitan Drug Commission is duplicating the initiative in an effort to address the drug exposed baby epidemic in their state; Born Drug-Free Tennessee will use Florida’s materials as templates.





In addition to the prevention campaign, Attorney General Bondi joined with 42 other State Attorneys General to send a letter to the Food and Drug Administration (FDA) urging them to adopt new 'Black Box' Warning Labels for certain prescription pain medications. The FDA responded by announcing in September 2013, a new requirement for a boxed warning on Extended Release/Long-Acting opioid analgesics, cautioning that chronic maternal use of these products during pregnancy could result in neonatal opioid withdrawal syndrome. A copy of the letter and the FDA's response are included in Appendix B.

#### **Florida's PDMP: A Cost-effective Tool for Screening Drug Use**

Perhaps the best opportunity to intervene with women at risk of delivering a drug exposed newborn is during the early stages of their pregnancy. Prenatal screening by health care providers can result in early identification, referral for a comprehensive drug and alcohol assessment, and an appropriate link to treatment services. Screening should therefore occur as early in the pregnancy as possible to minimize risk of exposure for the developing infant. The Task Force agreed to not advocate for mandatory screenings, but to simply advance the notion of screening for substance abuse as a part of complete obstetric standard of care, and that it should be done with the consent of the pregnant woman.<sup>iii</sup>

Screening methods include self-report, interviews, clinical observation and the use of Patient Advisory Reports from Florida's Prescription Drug Monitoring Program (PDMP). Medical professionals can access Florida's PDMP (called E-FORCSE) to screen their patients to determine what controlled substances they are currently prescribed or have been prescribed in the past. Florida's PDMP is a state-level resource operated by the Department of Health (DOH) that helps improve patient standard of care by getting prescription drug information to medical professionals in a free and timely manner. The goals of the PDMP are integrally aligned with DOH's mission to protect, promote and improve the health of all Floridians. Florida's PDMP is saving lives by improving clinical decision-making by medical professionals who utilize the system.

The Task Force therefore recommended increasing the voluntary use of Florida's PDMP among medical professionals. The Department of Health has already conducted numerous outreach efforts encouraging more PDMP usage; over the past year, health care practitioner registration increased 28 percent, and system utilization increased 61 percent. Furthermore, 71 percent of the prescribers registered to use the database have queried 2,859,105 times. Physician assistants have the highest utilization rate at 79 percent and have queried the database 160,823 times. Overall, 80 percent or 23,084 health care practitioners registered to use the database have queried the database 6,484,624 times since it was launched in 2011.

Increasing utilization rates of the PDMP by medical professionals is a good sign, but Florida has room to improve. The Department of Health will continue to conduct outreach efforts to urge more medical professionals to make the most of Florida's PDMP data. Doctors who regularly use the PDMP have testified that they cannot think

about practicing effective medicine without it. As advocates of the PDMP continue to increase, it is incumbent upon them to spread the positive news about this database to their colleagues to help attain maximum utilization of this valuable healthcare tool and thereby improving patient standard of care.

### **Screening, Brief Intervention, and Referral to Treatment**

The Screening, Brief Intervention, and Referral to Treatment (SBIRT) model is a public health approach to delivering early intervention to anyone abusing alcohol and/or drugs. SBIRT is a succinct, proactive process for identifying substance abuse, thereby better helping those with the disease of addiction to enter treatment. Research has shown that large numbers of individuals at risk of developing serious alcohol or other drug problems can be identified through primary care screening. Interventions such as SBIRT have been found to reduce healthcare costs, and decrease the frequency and severity of drug and alcohol use.

The Task Force recommended that SBIRT be expanded outside the primary care setting in order to reach more pregnant women needing an intervention and referral to treatment. Several states are now in the process of determining how SBIRT billing codes should be utilized in their respective Medicaid plans. While a few states have activated codes allowing non-physician professionals to conduct SBIRT, other states limit SBIRT to physicians only. In order to determine the best approach for Florida, the Agency for Health Care Administration set-up a workgroup to assess the viability of expanding SBIRT. This workgroup included the Department of Children & Families, the Department of Health, the Attorney General's Office, Healthy Start, substance abuse treatment providers and the Florida Alcohol and Drug Abuse Association.

In 2013, the workgroup held three meetings in Tallahassee (October 28th, November 13th and December 11th). Discussions were organized around how to operationalize the SBIRT model for both medical and in non-healthcare settings. In order to make SBIRT effective in a medical environment, the model will have to be reimbursable. Encouragingly, the Centers for Medicare and Medicaid Services have already approved Medicaid codes for healthcare practitioners to use for reimbursable SBIRT services. The Florida Medicaid Program meanwhile has developed a guide that Medicaid Practitioners and Medicaid Managed Care Health Plans can use in developing the SBIRT model. Florida Medicaid will also provide codes and fees to Medicaid practitioners and to Medicaid Managed Health Care Plans to utilize. The guide to utilizing the SBIRT model for Medicaid Practitioners, which includes the codes and fees, is included in Appendix C.

The workgroup also recommended that the following groups attempt to directly reach out to expectant mothers - no matter their socioeconomic status - to discuss the dangers of all types of substance abuse: Healthy Families, Healthy Start, Faith-Based Communities, Early Head Start Home Visiting, Women Infant Children (WIC), Community Centers and Teen Programs, and High School and Middle School Based Programs. Educating women through these organizations will allow for better education and hopefully better pregnancy outcomes.

### **Toolkit for Nurses**

Nurses play an important role in supporting families of NAS infants. However, neonatal nurses can experience a heavy emotional toll when caring for NAS infants. Hospital administrators, perinatal social workers, and doctors therefore need to be aware of the concerns their nurses have when treating NAS infants and their families. The Task Force's *Final Report* encouraged hospital leaders and physicians to support nurses and help promote stress relieving strategies to improve nursing satisfaction and retention.

The Florida Nurses Association (FNA) is now in the process of fulfilling this policy recommendation by creating a NAS toolkit for nurses. The FNA created a NAS work group of twenty-four nurses from various aspects of nursing, from bedside care providers to nurse educators in Florida's colleges and universities. Members are working on an ongoing educational initiative which includes the aforementioned toolkit to the specialized support and care needed for pregnant, drug abusing women and their families. The toolkit will contain resources for nurses to

assist them with client care - from the direct care phase to follow-up and support throughout the pregnancy and birth. There will also be resources for a Community Education and Prevention aspect of the program that will include a package addressing community education and public speaking.

### 3. Treatment

#### Key Treatment Takeaways from the Final Report:

- Successful outcomes in treating NAS infants are greatly aided when an opioid abusing pregnant woman receives medical care early in her pregnancy.
- There are two approaches to treating an opioid drug abusing pregnant woman: either a Medicated Assisted Treatment (MAT) program or detoxification; then followed by substance abuse treatment.
- A MAT program-using either methadone or buprenorphine-prevents drug withdrawal in a pregnant woman, thereby protecting the fetus from repeated withdrawal episodes.
- Effective pharmacological treatment of prescription drug abusing pregnant women also requires the use of evidence-based behavioral interventions (substance abuse counseling, routine drug testing, and additional recovery support services).
- A substance abuse treatment program for pregnant women should include:
  - (1) coordinated physical and behavioral health care;
  - (2) collaboration with child welfare and community services;
  - (3) gender specific evidence-based practices, and
  - (4) a ‘whole family’ approach (including outreach to fathers and relatives to get them involved in treatment services)

#### Treatment Policy Recommendations:

Policy Recommendation	Assignment
1. Enhance the capacity of the behavioral health system to ensure that pregnant women and mothers have immediate access to the appropriate level of care through a continuum of services that, at a minimum, includes: <ul style="list-style-type: none"> <li>• Expand residential treatment capacity</li> <li>• Expand intensive outpatient treatment capacity</li> <li>• Fund case management services to assist women leaving treatment</li> </ul>	Department of Children & Families Florida Alcohol and Drug Abuse Association
2. Add Neonatal Abstinence Syndrome to the list of Reportable Diseases and Events.	Department of Health

#### **Introduction**

The Task Force confirmed that the most effective response to prescription drug abuse by a pregnant woman was to have doctors develop a diagnostic framework capable of rapidly determining the nature of their pregnant patient’s drug use or abuse to establish the appropriate level of care. This framework would require a health care professional to first distinguish between illicit and legitimate prescription opioid use. Illicit prescription opioid use is taking drugs like methadone, buprenorphine, oxycodone and hydrocodone without a prescription, whereas appropriate use means taking these same prescription drugs under the guidance of a reputable physician. Appropriate use can also include medical professionals using methadone and buprenorphine to treat opioid dependent pregnant women; these opioid agonists help prevent erratic maternal opioid levels, thereby better protecting the opioid dependent woman’s fetus from experiencing repeated withdrawal episodes.<sup>iv</sup>

Effective pharmacological treatment of prescription drug abusing pregnant women also requires the use of evidence-based behavioral interventions. To achieve this superior standard of care, there is a need for more and better education and training on substance abuse addiction for all professionals encountering pregnant women. Unfortunately, many prescription drug abusing women go unnoticed simply by not self-reporting their drug use during pregnancy. The Task Force therefore recommended enhanced drug addiction education and training for the medical community, establishing best practice treatment protocols for drug exposed newborns, and enhancing the ability of pregnant women to access substance abuse treatment.

Substance abusing pregnant women need comprehensive treatment services. Simply linking a drug abusing woman to a MAT program will not solve her addiction problem. A complete system of care must be instituted to support and improve her chances of sustaining a drug-free lifestyle enabling her to care for her child. A woman who births a drug exposed newborn will experience many barriers, including possible interruption of her relationship with her child, feelings of guilt over the adverse effects her addiction has had on her newborn child, and changes to the family dynamic when a newborn has to stay for an extended period in a NICU. In addition, the mother may experience financial difficulties that can become overwhelming during the process of recovery. That is why a substance abuse treatment program for pregnant woman should include: (1) coordinated physical and behavioral health care; (2) collaboration with child welfare and community services (including courts and schools); (3) gender specific evidence-based practices, and (4) a whole-family approach (including outreach to fathers and relatives to get them involved in treatment services).<sup>v</sup>

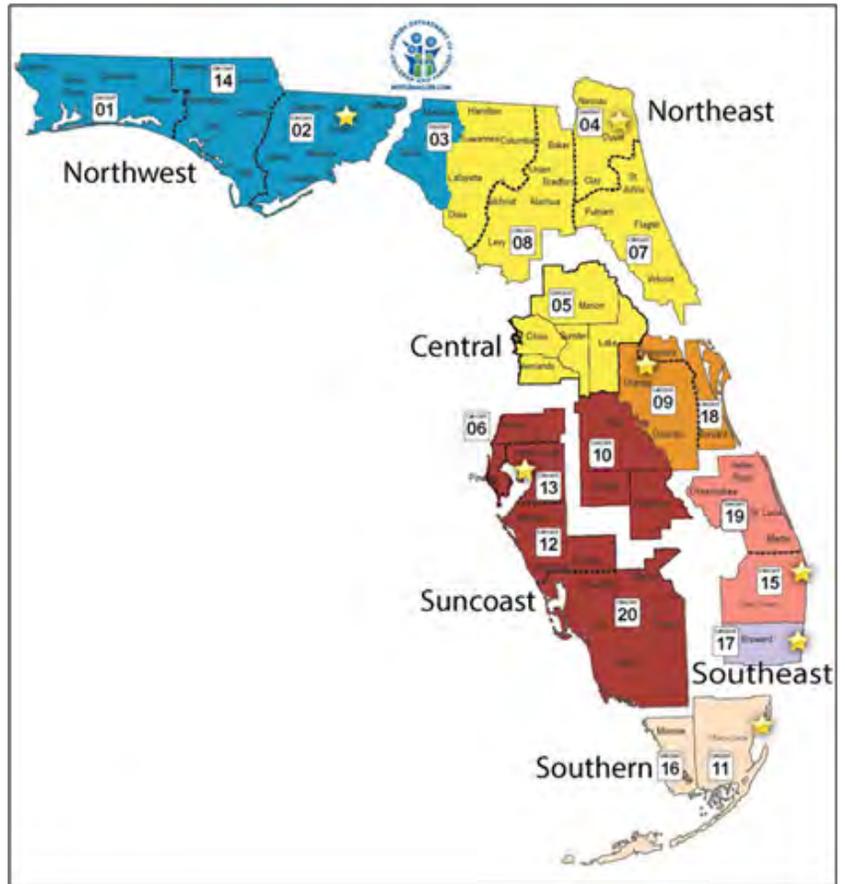
Comprehensive treatment services should address all of these issues, and should encourage women to stay with their treatment program until they are drug free. Unfortunately, many of these women are in need of services that Medicaid does not cover, such as residential substance abuse treatment. Although Florida grants pregnant women priority access to drug treatment, some treatment locations may not be immediately available, especially for women who already have children. That is why the Task Force recommended an enhancement in Florida's behavioral health system to ensure that pregnant women and mothers have immediate access to the appropriate level of care through a continuum of services.

**Increasing Substance Abuse Treatment for Women**

The Task Force's *Final Report* advocated for the closing of the treatment gap and for providing comprehensive treatment services to more women in need. The Florida Legislature responded by allocating DCF with \$8,967,700 of nonrecurring funds from the General Revenue fund for the expansion of substance abuse services for pregnant women and their affected families. These enhanced services were made possible thanks to the leadership of Chairwoman Denise Grimsley in the Senate and Chairman Matt Hudson in the House of Representatives, as well as Task Force members Senator Joe Negron and Representative Dana Young.

The Department of Children and Families channeled these funds into the seven behavioral health Managing Entity (MEs) contracts (Chart I). These MEs do not provide direct services; rather, they allow the department's funding to be tailored to the specific behavioral health needs in the various regions of the State. The MEs worked with community providers to increase access to care for pregnant women as well as women with children (Chart II).

**Chart I**



**Chart II**

Managing Entity	FY 13-14 Allocation <sup>vi</sup>
Big Bend Community Based Care	\$725,807
Broward Behavioral Health Coalition	\$935,500
Central Florida Behavioral Health Network	\$1,821,721
Central Florida Cares Health System	\$1,689,000
Lutheran Services Florida	\$1,278,352
South Florida Behavioral Health Network	\$1,625,596
Southeast Florida Behavioral Health Network	\$891,724
<b>Total</b>	<b>\$8,967,700</b>

This new funding stream also created an opportunity to enhance data collection for this specific population. For the first half of FY 2013-14, more than 350 women received residential treatment, outpatient treatment with housing support, post-partum case management, or a combination of these services.

## **Making NAS a Reportable Disease**

To make NAS reportable per the recommendations of the Task Force, the Florida Department of Health convened an NAS Ad Hoc Advisory Committee. Based on their expertise and guidance, a standardized NAS case definition was developed to ensure that comparable data are collected across the state. The Department's intent to develop NAS disease reporting requirements through rule making has been noticed in the Florida Administrative Weekly (FAW) and a draft rule has been developed. It is currently undergoing review by the Governor's Office of Fiscal Accountability and Regulatory Reform. The approved rule proposal will be posted in the FAW. If stakeholder concerns are limited and the rule is approved by the Florida Joint Administrative Procedures Committee, the rule has a projected implementation date of May 1, 2014.

The Department will use hospital discharge diagnosis data to calculate statewide NAS rates. The Department plans to distribute educational materials about the rule change to health care providers and other pertinent hospital staff shortly after the rule takes effect; this outreach will help to facilitate accurate reporting. The first data summary with NAS incidence estimates for the January-June 2014 will be published in January 2015. A more comprehensive report on NAS incidence and maternal risk factors for the 2014 calendar year is scheduled to be released in October 2015.

A pilot study (Epi Aid) with reviews of NAS patient medical records at three hospitals in the Tampa Bay area will be performed this spring. The purpose of this data validation study is to learn how well the hospital discharge diagnosis data set represents the true number of NAS cases meeting the DOH case definition diagnosed in Florida. The draft report will be available by June 30, 2014 and the findings will further inform how we can ensure the quality and accuracy of NAS reporting.

## 4. The Way Forward

Florida’s fight to end its prescription drug abuse epidemic continues. This ongoing struggle is exemplified by the initiatives outlined in this report highlighting improvements in preventing and treating cases of NAS. But these positive steps against the scourge of NAS must be sustained. The following chart outlines a series of initiatives that will need the continued support of our state’s leaders.

<b>Sustainment of Key Task Force Policy Recommendations</b>
<p>1. Maintain the “Born Drug-Free Florida” prevention campaign.</p> <p>a. This campaign has been successful in raising awareness about the issue of prescription drug abuse by pregnant women and drug exposed newborns.</p> <p>b. The hotline number has been an effective resource for pregnant women, helping link at least 60 women to treatment.</p>
<p>2. Continue funding the expansion of substance abuse treatment for pregnant women and mothers with children.</p> <p>a. The \$8.9M in non-recurring funding has been effective in beginning to address the treatment needs for pregnant women and mothers with children.</p> <p>b. There are still too many NAS cases; reports indicate unmet needs for pregnant women seeking substance abuse treatment.</p> <p>c. State funding for NAS related services should be made a priority during the 2014 legislative session.</p>
<p>3. Ensure hospital staff are either trained or at least informed on new NAS reporting requirements, and that information is accurately reported to the Department of Health.</p>
<p>4. Follow-up with Medicaid Managed Care Health Plans to ensure these plans are aware of the cost-effectiveness of the SBIRT model; and also inform medical professionals that services associated with SBIRT are reimbursable.</p>
<p>5. Continue outreach efforts to increase the voluntary use of Florida’s Prescription Drug Monitoring Program (PDMP) among medical professionals.</p> <p>a. Efforts by DOH, the Florida Medical Association and others have led to substantial increases in the number of medical professionals utilizing the PDMP to treat their patients.</p> <p>b. The PDMP is still not being accessed enough; medical training and additional public awareness efforts should help convince more medical professionals that the PDMP is a cost-effective tool to screen patients while protecting patient confidentiality.</p>

As this task force sunsets in 2014, the coordinated efforts begun by this task force will need to continue and Florida’s Drug Policy Advisory Council (DPAC) offers an opportunity to sustain these NAS efforts beyond 2014. DPAC can be the organizational force ensuring the Task Force’s policy recommendations are continually assessed, redeveloped and sustained.

Florida’s Drug Policy Advisory Council is housed within the Department of Health and is chaired by the State Surgeon General. DPAC membership consists of:

- The Attorney General, or her designee.
- The Executive Director of the Department of Law Enforcement, or his designee.
- The Secretary of Children and Family Services, or her designee.
- The Director of the Office of Planning and Budgeting in the Executive Office of the Governor, or his or her designee.
- The Secretary of Corrections, or his designee.
- The Secretary of Juvenile Justice, or her designee.
- The Commissioner of Education, or her designee.
- The Executive Director of the Department of Highway Safety and Motor Vehicles, or her designee.
- The Adjutant General of the state as the Chief of the Department of Military Affairs, or his designee.
- In addition, the Governor appoints 7 members of the public to serve on the council.

The Council meets on a quarterly basis to conduct comprehensive analyses of issues relating to the problem of substance abuse, and makes recommendations to the Governor and Legislature for developing and implementing a state drug control strategy. The addition of issues such as the fifteen NAS recommendations would be a natural fit to the great drug policy efforts the Drug Policy Advisory Council is already undertaking. Finally, since there are several vacancies currently on the DPAC, there is an opportunity for Neonatal Task Force members to be appointed to DPAC.

**Appendix A**  
County Level Newborn Drug Withdrawal Data

FACILITY COUNTY	CY 2007	CY 2008	CY 2009	CY 2010	CY 2011	CY 2012
<b>GRAND TOTALS (Based on Livebirths w/779.5 and/or 760.72)</b>	<b>536</b>	<b>694</b>	<b>1,019</b>	<b>1,336</b>	<b>1,563</b>	<b>1,630</b>
<i>Alachua</i>	21	32	63	87	96	77
<i>Bay</i>	1	6	10	5	17	15
<i>Brevard</i>	27	56	53	78	86	82
<i>Broward</i>	29	35	48	73	55	69
<i>Charlotte</i>	2	5	15	19	23	21
<i>Citrus</i>	1	1	2	8	5	10
<i>Clay</i>	16	8	19	26	35	48
<i>Collier</i>	17	27	25	28	35	36
<i>Columbia</i>		2	5	8	9	5
<i>Dade</i>	14	13	23	18	25	35
<i>DeSoto</i>	1		2	5	3	4
<i>Duval</i>	80	62	118	153	154	215
<i>Escambia</i>	51	52	61	52	61	49
<i>Hernando</i>	34	39	59	79	74	95
<i>Highlands</i>	3	1	5	2	2	6
<i>Hillsborough</i>	24	41	61	90	124	125
<i>Indian River</i>	1	4	7	7	4	1
<i>Jackson</i>	1			2	3	3
<i>Lake</i>	5	1	4	7	18	10
<i>Lee</i>	22	26	56	69	75	52
<i>Leon</i>	4	7	3	10	11	15
<i>Manatee</i>	6	13	16	20	51	46
<i>Marion</i>	12	11	6	13	15	20
<i>Martin</i>	4	4	2	3	5	3
<i>Monroe</i>					1	1
<i>Nassau</i>	1	1	2	3	7	16
<i>Okaloosa</i>	3	5	10	12	14	15
<i>Orange</i>	36	61	66	100	129	134
<i>Osceola</i>	3	5	6	2	4	3
<i>Palm Beach</i>	26	35	45	40	31	42
<i>Pasco</i>	6	7	16	20	33	34
<i>Pinellas</i>	43	67	92	107	155	140
<i>Polk</i>	10	11	13	16	31	24
<i>Putnam</i>		1	2	3	1	5
<i>St. Johns</i>	3	2	7	7	5	15
<i>St. Lucie</i>	3	1	8	8	7	19
<i>Santa Rosa</i>		3	1	2	3	2
<i>Sarasota</i>	9	25	43	74	78	53
<i>Seminole</i>		3	5	2	2	5
<i>Volusia</i>	16	18	34	67	61	76
<i>Walton</i>	1	3	6	11	15	4

**Appendix B - 1**

National Association  
of Attorneys General

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2030 M Street, NW  
Eighth Floor  
Washington, DC 20036  
Phone: (202) 326-6000  
<http://www.naag.org/>

May 13, 2013

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

Dear Dr. Hamburg:

We write to you today out of concern for the health and well-being of newborn children. The opioid epidemic has taken the lives of many of our citizens and has affected nearly everyone in this nation, including newborn children. Neonatal Abstinence Syndrome (“NAS”) caused by maternal opiate use has increased at alarming levels. As you are aware, NAS is caused when infants suddenly lose their opioid drug supply at birth.

NAS includes the malfunction of the autonomic nervous system, respiratory system and gastrointestinal tract. Signs of withdrawal usually present from within 24 hours to several days after delivery and may include: abnormal sleep patterns, tremors, vomiting, high-pitch crying, irritability, hyperactivity, seizures, weight loss and failure to gain weight. Onset, duration and severity of the manifestations vary with the substance or substances used, the amount and timing of the mother’s last dose, and the rate at which the drug is eliminated from the infant’s body.

As the use of prescription opioid analgesics increases, so do the instances of NAS. We therefore believe that a “black box warning” for these medications would help ensure that women of childbearing age – as well as their health care providers – are aware of the serious risks associated with narcotic use during pregnancy. Possible content for the warning might be as follows:

**WARNING: USE OF NARCOTIC ANALGESICS IN PREGNANT WOMEN MAY CAUSE NEONATAL ABSTINENCE SYNDROME**

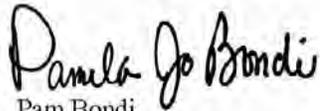
Both the human and financial costs of NAS are alarming. In a 2012 Journal of American Medical Association article, a group of physicians determined that treating a single newborn with NAS in 2009 cost approximately \$53,400, with a total estimated cost to the Nation in that year of \$720 million; Medicaid paid for 77.6% of these treatment costs. This study also found that approximately 1 infant was born every hour in the United States with NAS.

While there are NAS treatment protocols, there is still sparse scientific data as to optimal treatments for NAS in either the ante or post-partum

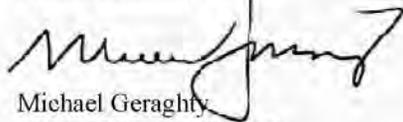
settings. The best course of action therefore is prevention. Appropriate clinical awareness and protocol would be enhanced by a “black box” warning.

Thank you for your consideration. We look forward to your response.

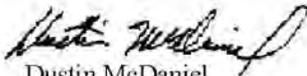
Sincerely,



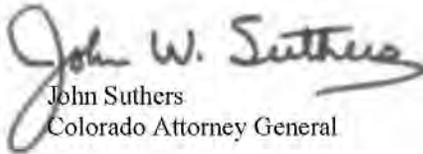
Pam Bondi  
Florida Attorney General



Michael Geraghty  
Alaska Attorney General



Dustin McDaniel  
Arkansas Attorney General



John Suthers  
Colorado Attorney General



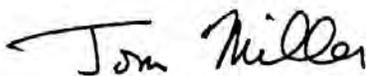
Joseph R. “Beau” Biden III  
Delaware Attorney General



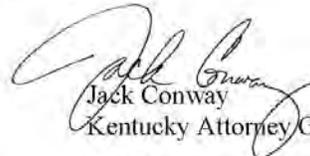
Lenny Rapadas  
Guam Attorney General



Lisa Madigan  
Illinois Attorney General



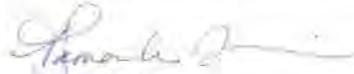
Tom Miller  
Iowa Attorney General



Jack Conway  
Kentucky Attorney General



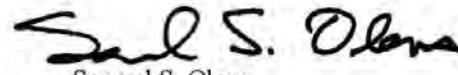
Tom Horne  
Arizona Attorney General



Kamala Harris  
California Attorney General



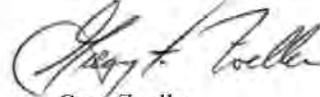
George Jepsen  
Connecticut Attorney General



Samuel S. Olens  
Georgia Attorney General



David Louie  
Hawaii Attorney General

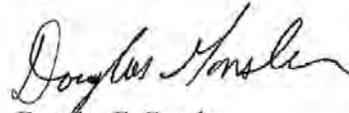


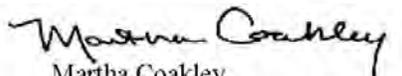
Greg Zoeller  
Indiana Attorney General



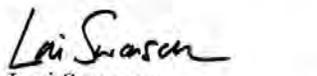
James “Buddy” Caldwell  
Louisiana Attorney General

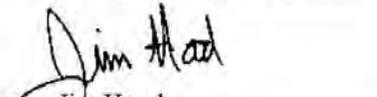
  
Janet Mills  
Maine Attorney General

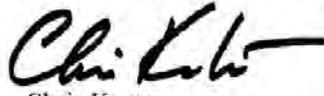
  
Douglas F. Gansler  
Maryland Attorney General

  
Martha Coakley  
Massachusetts Attorney General

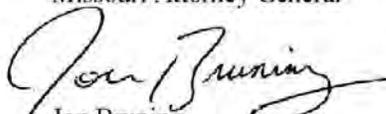
  
Bill Schuette  
Michigan Attorney General

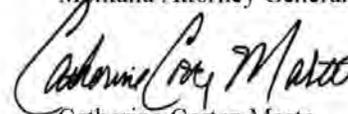
  
Lori Swanson  
Minnesota Attorney General

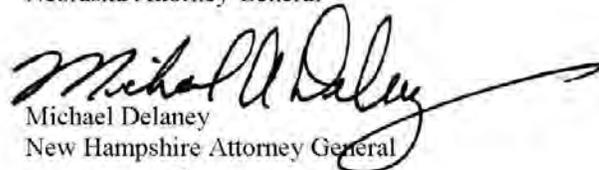
  
Jim Hood  
Mississippi Attorney General

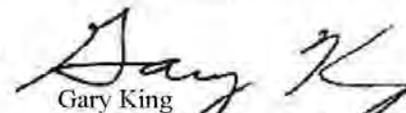
  
Chris Koster  
Missouri Attorney General

  
Tim Fox  
Montana Attorney General

  
Jon Bruning  
Nebraska Attorney General

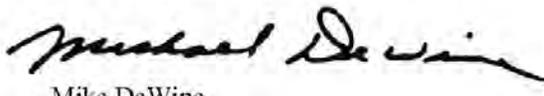
  
Catherine Cortez Masto  
Nevada Attorney General

  
Michael Delaney  
New Hampshire Attorney General

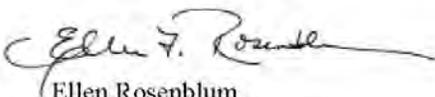
  
Gary King  
New Mexico Attorney General

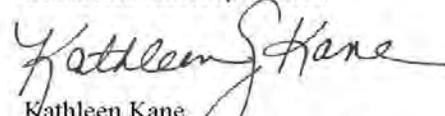
  
Roy Cooper  
North Carolina Attorney General

  
Wayne Stenehjem  
North Dakota Attorney General

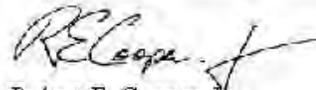
  
Mike DeWine  
Ohio Attorney General

  
Scott Pruitt  
Oklahoma Attorney General

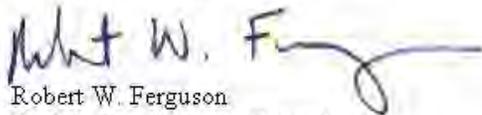
  
Ellen Rosenblum  
Oregon Attorney General

  
Kathleen Kane  
Pennsylvania Attorney General

  
Peter Kilmartin  
Rhode Island Attorney General

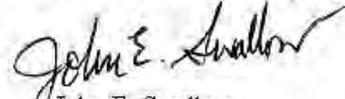
  
Robert E. Cooper, Jr.  
Tennessee Attorney General

  
William H. Sorrell  
Vermont Attorney General

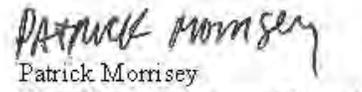
  
Robert W. Ferguson  
Washington Attorney General

  
Gregory A. Phillips  
Wyoming Attorney General

  
Marty J. Jackley  
South Dakota Attorney General

  
John E. Swallow  
Utah Attorney General

  
Vincent Frazer  
Virgin Islands Attorney General

  
Patrick Morrissey  
West Virginia Attorney General

## Appendix B - 2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

June 7, 2013

James McPherson  
Executive Director, National Association of Attorneys General  
2030 M Street, NW  
Eighth Floor  
Washington, DC 20036

Dear Mr. McPherson:

Thank you for the letter from the National Association of Attorneys General, signed by 43 members, expressing concern about the growing incidence of neonatal abstinence syndrome (NAS) and requesting that the Food and Drug Administration (FDA) consider the inclusion of a "black box warning" (formally known as a boxed warning) in the labeling of opioids to ensure that women of child bearing age and their healthcare providers are aware of the risk of NAS.

You raise an important public health issue, and FDA agrees that opioid exposure from misuse or abuse can create significant problems for mothers and infants. Current FDA-approved labeling for opioid analgesics addresses the effects of *in utero* exposure on neonates and advises against the use of opioids in women during and immediately prior to labor and delivery. The labeling also addresses the effects of opioid exposure on newborns of mothers who continue to use opioids while nursing.

Please be assured that FDA recognizes the significant public health implications that an additional warning may have for both appropriate use and misuse of these products. The agency is actively reviewing the labeling of opioids to assess the need for the inclusion of a black box warning regarding the risk of NAS.

In addition to considering labeling modifications, FDA has taken a number of actions to address this problem. Among these actions is the July 2012 approval of Risk Evaluation and Mitigation Strategies (REMS) for long-acting (LA) and extended-release (ER) prescription opioids. The REMS requires sponsors of these products to make available training on proper prescribing practices and to distribute educational materials to prescribers and patients on the safe use of these medications. Additional information about this can be found on the FDA website at: <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm>.

FDA believes that healthcare professionals who prescribe opioid analgesics have a responsibility to help ensure the safe and effective use of these products. These healthcare professionals are in a key position to balance the benefits of prescribing opioids against the risks of serious adverse events, including opioid abuse resulting in NAS. The intent of the REMS is to reduce serious outcomes resulting from inappropriate prescribing, misuse, and abuse of LA and ER opioids while maintaining patient access to pain medications.

More generally, FDA has proposed changes to the regulations concerning the content and format of pregnancy and lactation labeling for human prescription drug and biological products. The proposed changes are designed to provide a framework to clearly communicate information on the benefits and risks of drug and biological product use during pregnancy and lactation to help facilitate prescribing decisions. The proposed *Pregnancy and Lactation Labeling Rule* was published for public comment (73 FR 30831) and the agency is currently in the process of preparing the final rule. Additionally, FDA, along with other federal agencies, is partnering with the Centers for Disease Control and Prevention's efforts to understand the risks of medication use in pregnancy through the *Treating for Two: Safe Medication Use in Pregnancy Initiative*.

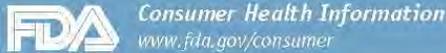
Thank you again for your interest in this matter. Please contact me if you have further thoughts or concerns.

Sincerely,



Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs

## Appendix B - 3



# Goal of Labeling Changes: Better Prescribing, Safer Use of Opioids

Consumers and health care professionals will soon find updated labeling for extended-release and long-acting opioid pain relievers to help ensure their safe and appropriate use.

In addition to requiring new labeling on these prescription medications, the Food and Drug Administration (FDA) is also requiring manufacturers to study certain known serious risks when these drugs are used long-term.

"The new labeling requirements and other actions are intended to help prescribers and patients make better decisions about who benefits from the use of these medications. They also are meant to reduce problems associated with their use," says Douglas Throckmorton, M.D., deputy director of regulatory programs in FDA's Center for Drug Evaluation and Research. "Altogether, the actions we're now announcing are part of FDA's efforts to make opioids as safe as possible for those who need them," Throckmorton adds.

He noted that the actions come after careful analysis of new safety information, including reviews of medical literature, and consideration of input from patients, experts and many other interested parties.



## How Labeling Will Change

Opioids work by changing the way the brain perceives pain. They are available by prescription as pills, liquids, and skin patches. Extended-release and long-acting (ER/LA) forms pose a greater safety concern because—as their names suggest—they produce

their effects for a longer period, and many contain higher doses compared with immediate release or opioid/non-opioid combination products. They include, to name a few, long acting versions of opioids such as morphine, oxycodone, and fentanyl. Currently, labeling on these ER/

*“This is not the first or last initiative, and we will continue supporting broader efforts to solve the serious public health problems associated with the misuse and abuse of opioids.”*

LA opioids indicate they are for “the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.”

However, the updated indication for when to prescribe and take these medicines will, when finalized, emphasize that other, less potentially addictive, treatment options should be considered first.

FDA is requiring labeling that says the drugs are “indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.”

The “limitations of use” portion of the new labeling retains language indicating that the drugs are not intended for use as an “as-needed” pain reliever. Furthermore, the new labeling adds: “Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve [Tradename] 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.”

This new labeling language emphasizes that patients in pain should be assessed not only by their rating on a pain intensity scale, but also based on a more thoughtful determination that their pain — however it may be defined — is severe enough to require daily, around-the-clock, long-term opioid treatment, and for

which alternative treatment options are inadequate.

This framework better enables prescribers to make decisions based on a patient’s individual needs, given the serious risks associated with ER/LA opioids, against a backdrop of alternatives such as immediate release (IR) opioids and non-opioid pain relievers. It allows prescribers to make an assessment of pain relative to a patient’s ability to perform daily activities or enjoy a reasonable quality of life.

FDA-approved labeling of these pain relievers already describes the effects on newborns of exposure to these drugs while in the mother’s womb and warns against use by women during pregnancy and labor and while nursing. The new labeling, however, will provide more detail and will elevate the risk of neonatal opioid withdrawal syndrome (NOWS) to the most prominent position in labeling—a boxed warning. Symptoms of NOWS may include poor feeding, rapid breathing, trembling, and excessive or high-pitched crying.

#### Postmarket Studies

Recognizing the need for more scientific data about the benefits and risks of ER/LA opioids when used over long periods, FDA also decided to require drug companies to conduct longer term studies and trials of ER/LA opioid pain relievers on the market.

The companies must evaluate long-term use, with the goal of assessing a variety of known serious risks, including misuse, abuse, addiction, overdose, and death, as well as the risks of developing increasing sensitivity to pain.

#### Education to Reduce Risk

Following implementation of the safety labeling changes, certain educational materials for patients and health care professionals will be modified to reflect the new labeling for the ER/LA opioid pain relievers. As part of the new labeling changes, opioid manufacturers also must revise a paper handout patients receive with their prescription.

The ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) will also be updated after the labeling changes are finalized. The ER/LA Opioid Analgesics REMS requires manufacturers to make available continuing education courses for health care professionals who prescribe these drugs. The courses, from accredited sources, teach about risks and safe prescribing and safe use practices of these medications.

“By improving information about the risks of ER/LA opioid pain relievers and by clarifying the populations for whom the benefits outweigh the risks, we aim to improve the safe and appropriate use of these products,” says Throckmorton.

He adds: “This is not the first or last initiative, and we will continue supporting broader efforts to solve the serious public health problems associated with the misuse and abuse of opioids.” 

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## Appendix C



RICK SCOTT  
GOVERNOR

*Better Health Care for all Floridians*

ELIZABETH DUDEK  
SECRETARY

December 9, 2013

### Guide to utilizing the Screening, Brief Intervention and Referral to Treatment Model for Medicaid Practitioners

This manual has been developed to guide Medicaid practitioners in using the Screening, Brief Intervention and Referral to Treatment (SBIRT) model. SBIRT is a public health approach to treatment which supports preventative care and the identification of health concerns early in treatment before they become chronic, acute or require deep end medical treatment, such as emergency services or hospital care. The Agency for Health Care Administration is interested in facilitating the use of this model by Medicaid providers in physicians' offices, and non-traditional settings. Medicaid has existing procedure codes for physicians, County Health Departments, Rural Health Clinics and Federally Qualified Health Care Centers that can be used to follow the steps of the model. The SBIRT model is a four-part process:

1. Universal screening globally assesses the health status of recipients seen by a practitioner for medical, mental health, or substance use conditions.
2. Brief intervention is provided when a screening indicates a moderate level of risk. Brief intervention can utilize motivational interviewing techniques focused on raising awareness of the identified health concern and its consequences and motivating the recipient toward positive behavioral change.
3. Brief therapy continues the motivational discussion for recipients needing more than a brief intervention. Brief therapy is more comprehensive and includes further assessment, education, problem solving, coping mechanisms, and building a supportive social environment.
4. Referral to treatment provides referral to a specialty care provider for persons deemed to be at high level of risk.

The attached is a listing of procedure codes by provider type which will allow practitioners to bill Medicaid for these services at the appropriate stage within the model for recipients of any age.

References:

① [http://www.whitehouse.gov/sites/default/files/page/files/sbirt\\_fact\\_sheet\\_ondcp-samhsa\\_7-25-111.pdf](http://www.whitehouse.gov/sites/default/files/page/files/sbirt_fact_sheet_ondcp-samhsa_7-25-111.pdf)

Other resource material:

1. <http://www.samhsa.gov/prevention/sbirt/>
2. [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT\\_Factsheet\\_ICN904084.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf)

2727 Mahan Drive • Mail Stop #1  
Tallahassee, FL 32308



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Providers can access Florida Medicaid’s Coverage and Limitations Handbooks at the Agency for Health Care Administration’s website or at the following link: [http://portal.flmmis.com/FLPublic/Provider\\_ProviderSupport/Provider\\_ProviderSupport\\_ProviderHandbooks/tabId/42/Default.aspx](http://portal.flmmis.com/FLPublic/Provider_ProviderSupport/Provider_ProviderSupport_ProviderHandbooks/tabId/42/Default.aspx). The codes and fee’s referred to in this guide are subject to revision periodically. The electronic version of the coverage and limitations handbooks listed below should be consulted at the time services are being rendered for the most accurate codes and fees.

**Medicaid County Health Department Certified  
Match Program Coverage and Limitations Handbook**

Code	Mod	Code Descriptions	Max Fee
96150	HO	W1182 Social Worker (LCSW or Master's Level)— Individual Evaluations/Assessments	8.97 (per 15 minute unit)
96152	HO	W1182 Social Worker (LCSW or Master's Level)— Individual Service Treatment	8.97 (per 15 minute unit)
96153	HO	W1183 Social Worker (LCSW or Master's Level)— Group Service Treatment	4.25 (per 15 minute unit)

**FQHC Handbook**

*Adult Health Screening Codes*

**Adult Screening**

Code	Mod	Code Descriptions	Max Fee
99385		Adult Health Screening, new patient, age 21-39 years	Cost based
99386		Adult Health Screening, new patient, age 40-64 years	Cost based
99387		Adult Health Screening, new patient, age 65 years and over	Cost based
99395		Adult Health Screening, established patient, age 21-39 years	Cost based
99396		Adult Health Screening, established patient, age 40-64 years	Cost based
99397		Adult Health Screening, established patient, age 65 years and over	Cost based

**Child Health Check-up screening**

Code	Mod	Code Descriptions	Max Fee
99381		Child Health Check-Up Screening – new patient <1year	Cost based
99382		Child Health Check-Up Screening – new patient 1 through 4 years	Cost based
99383		Child Health Check-Up Screening – new patient 5 through 11 years	Cost based
99384		Child Health Check-Up Screening – new patient 12 through 17 years	Cost based
99385	EP	Child Health Check-Up Screening – new patient 18 through 20 years	Cost based
99391		Child Health Check-Up Screening – established patient <1 year	Cost based
99392		Child Health Check-Up Screening – established patient 1 through 4 years	Cost based
99393		Child Health Check-Up Screening – established patient 5 through 11 years	Cost based
99394		Child Health Check-Up Screening – established patient 12 through 17 years	Cost based
99395	EP	Child Health Check-Up Screening – established patient 18 through 20 years	Cost based
H0004		Individual and/or Group Therapy by Mental Health Practitioner (45--50 minutes)	Cost based

Clinic services are reimbursed on an “all inclusive” encounter rate that is determined yearly for each RHC and FQHC.

**Rural Health Clinic**

**Adult Screening**

Code	Mod	Code Descriptions	Max Fee
99385		Adult Health Screening, new patient, age 21-39 years	Cost based
99386		Adult Health Screening, new patient, age 40-64 years	Cost based
99387		Adult Health Screening, new patient, age 65 years and over	Cost based
99395		Adult Health Screening, established patient, age 21-39 years	Cost

Code	Mod	Code Descriptions	Max Fee
			based
99396		Adult Health Screening, established patient, age 40-64 years	Cost based
99397		Adult Health Screening, established patient, age 65 years and over	Cost based

**Child Health Check- up Screening**

Code	Mod	Code Descriptions	Max Fee
99381		Child Health Check-Up Screening – new patient <1year	Cost based
99382		Child Health Check-Up Screening – new patient 1 through 4 years	Cost based
99383		Child Health Check-Up Screening – new patient 5 through 11 years.	Cost based
99384		Child Health Check-Up Screening – new patient 12 through 17 years	Cost based
99385	EP	Child Health Check-Up Screening – new patient 18 through 20 years	Cost based
99391		Child Health Check-Up Screening – established patient <1 year	Cost based
99392		Child Health Check-Up Screening – established patient 1 through 4 years	Cost based
99393		Child Health Check-Up Screening – established patient 5 through 11 years	Cost based
99394		Child Health Check-Up Screening – established patient 12 through 17 years	Cost based
99395	EP	Child Health Check-Up Screening – established patient 18 through 20 years	Cost based
H0004		Individual and/or Group Therapy by Mental Health Practitioner (45--50 minutes)	Cost based

Clinic services are reimbursed on an “all inclusive” encounter rate that is determined yearly for each RHC and FQHC.

**Physician Services**

**Services for Recipients under the Age of 21**

Code	Mod	Code Descriptions	Max Fee
99381		Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; infant (age younger than 1 year)	71.47
99382		Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; early childhood (age 1 through 4 years)	71.47
99383		Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; late childhood (age 5 through 11 years)	71.47
99384		Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; adolescent (age 12 through 17 years)	71.47
99385	EP	Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; 0-20 years	71.47
99391		Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; early childhood (age 1 through 4 years)	57.17
99392		Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; early childhood (age 1 through 4 years)	57.17
99393		Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; late childhood (age 5 through 11 years)	57.17

Code	Mod	Code Descriptions	Max Fee
99394		Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; adolescent (age 12 through 17 years)	57.17
99395	EP	Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; 18-20 years	57.17

**Services for Recipients Age 21 and Older**

Code	Mod	Code Descriptions	Max Fee
99211		Office Outpatient Visit 5 Minutes	12.48
99385		Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; 21-39 years	68.84
99386		Initial comprehensive preventive medicine evaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, new patient; 40-64 years	79.50
99395		Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; 21-39 years	68.84
99396		Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; 40-64 years	65.71
99397		Periodic comprehensive preventive medicine reevaluation and management of an individual including an age and gender appropriate history, examination, counseling/anticipatory guidance/risk factor reduction interventions, and the ordering of laboratory/diagnostic procedures, established patient; 65 years and older	70.90

<sup>i</sup>Drug Enforcement Administration. (2013) Automation of Reports and Consolidated Orders System (ARCOS) Data. Retrieved: January 2013.

<sup>ii</sup>Florida Department of Law Enforcement. (2013). Drugs Identified in Deceased Persons by Florida Medical Examiners: 2012 Report. September 2013. Retrieved from: <http://www.fdle.state.fl.us/Content/getdoc/0f1f79c0-d251-4904-97c0-2c6fd4cb3c9f/MEC-Publications-and-Forms.aspx>.

<sup>iii</sup>The American College of Obstetricians and Gynecologists. (2012). Committee Opinion: Opioid Abuse, Dependence and Addiction in Pregnancy. Number 524, May 2012.

<sup>iv</sup>Kaltenbach, Karol Dr. (2012). Neonatal Abstinence Syndrome: Consequences and Context. Presentation at the Office of National Drug Control Policy's Leadership Meeting on Maternal Addiction, Opioid Exposed Infants and Neonatal Abstinence Syndrome. August 30, 2012.

<sup>v</sup>Hamilton, Nancy. (2012). Operation PAR Presentation for Statewide Task Force on Prescription Drug Abuse & Newborns. October 12, 2012, Pembroke Pines, FL.

<sup>vi</sup>FY 13-14 Department of Children and Families Approved Operating Budget: [http://www.dcf.state.fl.us/asb/datafiles/fy14/aob/ME\\_Allocation.xls](http://www.dcf.state.fl.us/asb/datafiles/fy14/aob/ME_Allocation.xls).



*PL-01 The Capitol  
Tallahassee, Florida 32399-1050  
(850) 414-3300  
<http://myfloridalegal.com>*