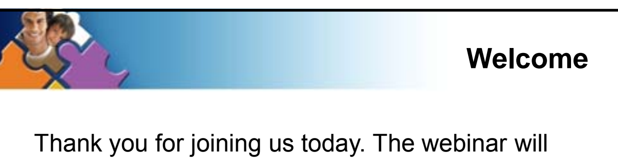

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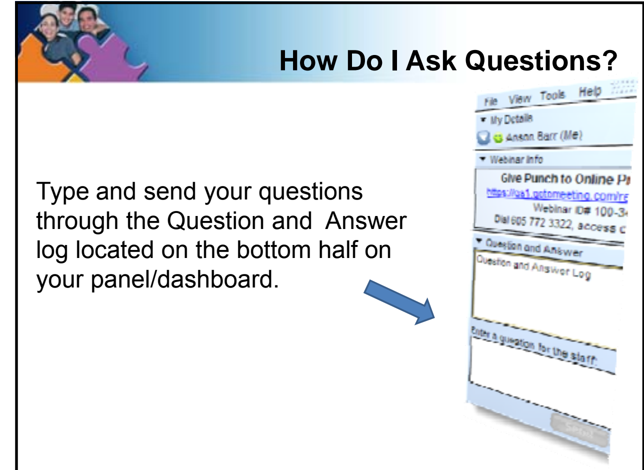

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Medication Assisted Treatment (MAT) Series, Part II of II: Medication Assisted Treatment During Pregnancy, Post-natal and Beyond

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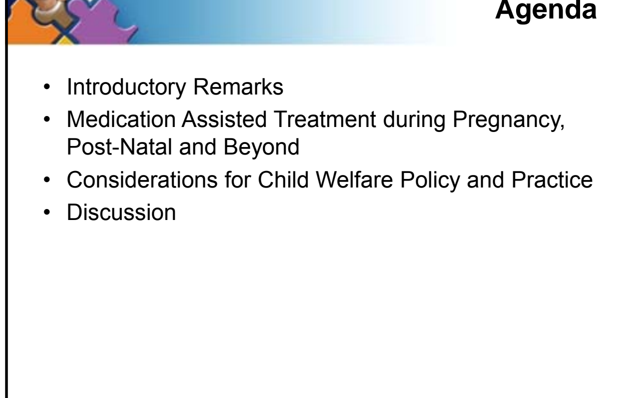
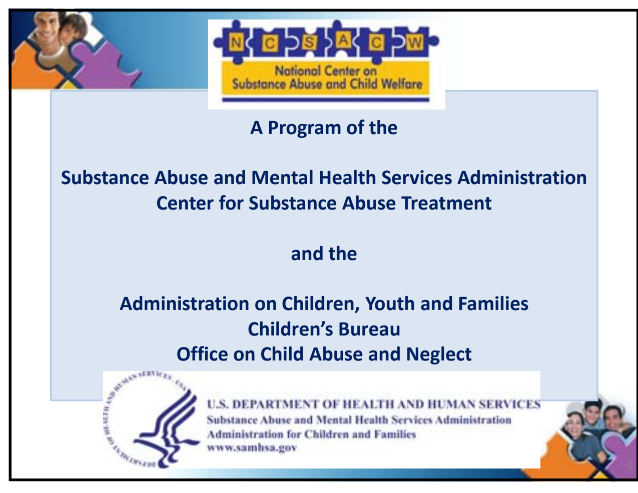


Agenda

- Introductory Remarks
- Medication Assisted Treatment during Pregnancy, Post-Natal and Beyond
- Considerations for Child Welfare Policy and Practice
- Discussion



Let's Hear About You

- Registrants identified as:
  - Substance Abuse Treatment Providers (45%)
  - Child Welfare (30%)
  - Other (24%)
  - Dependency Court or Family Drug Court (6%)
- Most attended Part I, Understanding MAT for Families Affected by Substance Use Disorders (88%)

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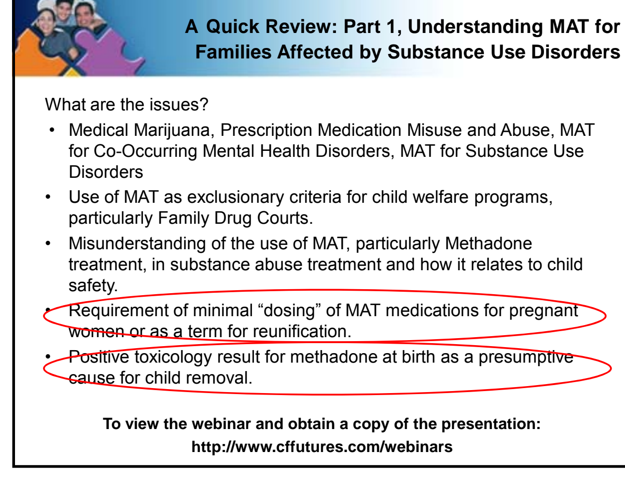
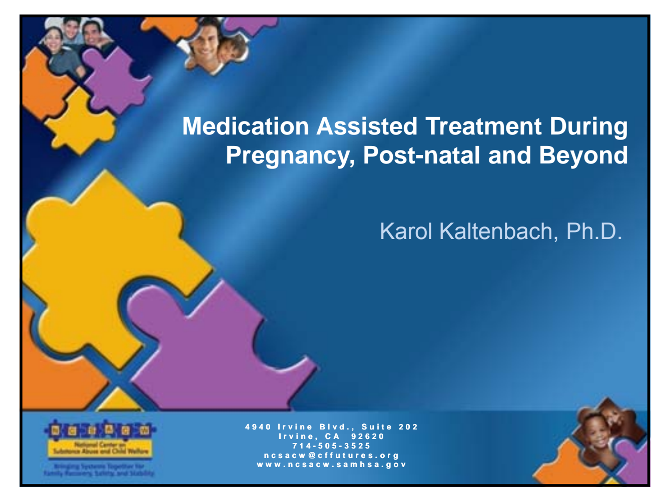




Overview

- MAT and Pregnancy
- Neonatal Abstinence Syndrome (NAS)
- Illicit Drug Use and Prescription Misuse
- Co-Occurring Psychiatric Disorders
- Breastfeeding

Medication Assisted Treatment

- In USA, methadone maintenance has been recommended for opioid dependent pregnant women since the early 1970's
- 1997 NIH Consensus Panel recommended as standard of care
- Buprenorphine has been used in Europe since the mid 1990's. In the USA, it is not yet formally approved for use with pregnant patients

  but it's use in the USA is increasing

Medication Assisted Treatment and Pregnancy

- Effective maintenance
  - Prevents the onset of withdrawal for at least 24 hours
  - Reduces or eliminates drug craving
  - Blocks the euphoric effects of other narcotics

Kaltenbach et al., Obstetrics and Gynecology Clinics of North America,1998

Medication Assisted Treatment and Pregnancy

Benefits of MAT during pregnancy:

- Direct Effect
  - PREVENTS ERRATIC MATERNAL OPIOID LEVELS AND PROTECTS THE FETUS FROM REPEATED EPISODES OF WITHDRAWAL

Medication Assisted Treatment and Pregnancy

- Indirect Effects

DECREASES RISKS TO FETUS OF INFECTION FROM HIV, HEPATITIS AND SEXUALLY TRANSMITTED DISEASE

REDUCES THE INCIDENCE OF OBSTETRICAL AND FETAL COMPLICATIONS

Medication Assisted Treatment and Pregnancy

- Withdrawal Procedures

Withdrawal Procedures

- Medication assisted withdrawal used to provide transition from illicit opioid to drug free state
- Taper – Transition from maintenance to drug free state

Withdrawal Procedures

- Medication assisted withdrawal:
  Need to provide counseling and education on risk/benefits of maintenance.
- Taper:
  A thorough assessment is essential to determine if woman is appropriate candidate
- Should be conducted under supervision by physician accompanied by fetal monitoring

Withdrawal Procedures

- Long term recommendations have been for withdrawal (taper) to be conducted within the second trimester
- However, there are no systematic studies on whether withdrawal should only be initiated during this time period
- Some evidence that rates of spontaneous abortion and prematurity do not differ from rates in the general population.

Withdrawal Procedures

- Outpatient: Slow decrease of methadone by 2- 2.5mg per week
- Inpatient: Can be more rapid (2-2.5mg per day)
- Fetal movement monitored and non-stress tests performed
- Withdrawal should be discontinued if it causes fetal stress or threatens to cause preterm labor

Center for Substance Abuse Treatment, 2005

Withdrawal Procedures

- Women can be safely withdrawn during pregnancy
- Question is whether it should be done
  - Very high rate of relapse in opioid dependent women
  - Places fetus at additional risk

Withdrawal Procedures

- Retrospective study of maternal and neonatal consequences of withdrawal during pregnancy
  - 3 day methadone assisted withdrawal/ no maintenance
  - 3 day methadone assisted withdrawal with maintenance
  - 7 day methadone assisted withdrawal/no maintenance
  - 7 day methadone assisted withdrawal with maintenance
  - Received methadone maintenance from treatment entry

Jones et al, American Journal on Addictions, 2008

Withdrawal Procedures

- Summary of Results

  Maintained women remained in treatment longer, attended more prenatal care appointments and delivered at the program hospital

Jones et al, American Journal on Addictions, 2008

Withdrawal Procedures

- No one would dispute that the delivery of an infant free of drug exposure is a universal goal – when possible
- In the case of opioid dependence this must be balanced within the risk/benefits of continued medication

Medication Assisted Treatment

- Induction to Methadone Maintenance

Induction to Methadone

- USA Regulatory Issues (42CFR 8.12)

  Documented opioid dependence for a minimum of 1 year (pregnant women are exempt but must certify pregnancy)

  First dose ≤ 30mg

  If withdrawal symptoms persist after 2-4 hours, initial dose can be supplemented with another 5-10mg

  Maximum first day total dose 40mg unless documented by physician that dose was insufficient to control withdrawal

Methadone Induction

- Difference in outpatient and hospital induction Induction

Inpatient allows for medical monitoring and comprehensive approach

Outpatient often practical necessity

Twice daily observation should occur until patient is stabilized

Methadone: Issues of Dose

- Areas of concern regarding maternal dose during pregnancy
  - Effective dose
  - Relationship of dose and NAS

Methadone: Issues of Dose

- Dose should be based on the same criteria used for non-pregnant patients

Prevent the onset of withdrawal for 24 hours

Reduce or eliminate drug craving

Block the euphoric effects of other Narcotics

Center for Substance Abuse Treatment 2005

Methadone: Issues of Dose

- ***Optimal dose is therapeutic dose.*** Original work by Dole and Nyswander suggests that effective dose is usually in the range of 80-120mg
- Current data indicate that most patients are maintained on doses between 100-200mg.
- However, others may require significantly higher doses

Methadone: Issues of Dose

- Opioid dependent women who become pregnant while receiving methadone should initially be maintained on their pre-pregnancy dose

Methadone: Issue of Relationship of Maternal Dose to NAS

- Continued debate regarding relationship between maternal dose and NAS
- Evidence is inconsistent
- Often recommended to reduce maternal methadone dose to avoid NAS
- A non-therapeutic maternal dose may promote supplemental drug use and increase risk to the fetus

Medication Assisted Treatment

- Buprenorphine

Buprenorphine

- Approved by the FDA in October 2002
- Two sublingual formulations
  - Subutex (buprenorphine
  - Suboxone (buprenorphine/naloxone)

May 2003 approved for use in OTP’s

Buprenorphine and DATA 2000

- Drug Addiction Treatment Act of 2000
  Qualifying physicians in medical offices outside the OTP system may prescribe and/or dispense

  Schedule III, IV and V opioid medications for the treatment of opioid addiction if such medications have been specifically approved by the FDA for that indication

  Subutex and Suboxone are eligible for use under DATA 2000

Buprenorphine

- Current guidelines recommend that buprenorphine be prescribed to pregnant women only when the benefits outweigh the risks and the patent has refused methadone.

CSAT, 2004

Buprenorphine Induction

- INDUCTION
  - Issue for buprenorphine is dependence on short-acting opioids or long-acting opioids.
    - Short-acting: minimum of 12-24 hours between use and buprenorphine administration and exhibit early signs of withdrawal.
    - Long-acting: taper to <30mg for a minimum of 1 week. Last dose of methadone must be at least 24 hours before administration of buprenorphine.

Buprenorphine Induction

- Transition from methadone to buprenorphine especially difficult in pregnancy.
- Methadone dose must be tapered to ≤ 30mg and/or patient should already be experiencing withdrawal before induction onto buprenorphine

Buprenorphine Induction

- Does not have the same regulatory restrictions as methadone
- Typical first dose is 2 mg, with initial dose supplemented up to 4mg on first day.
- Most patients stabilized on 12-24mg per day

Medication Assisted Treatment

- Neonatal Abstinence Syndrome

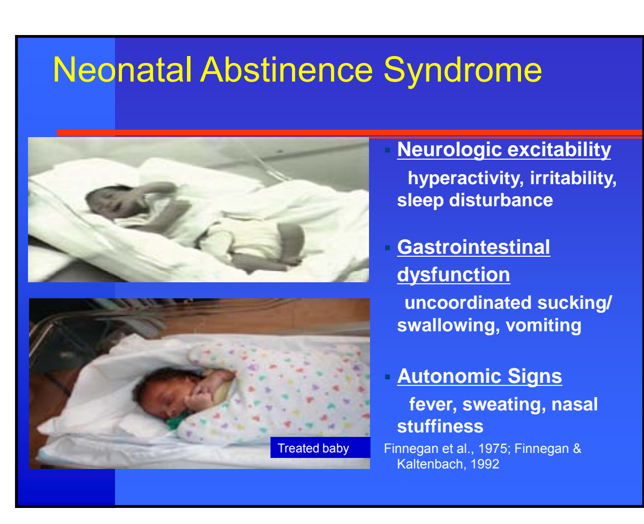
Neonatal Abstinence Syndrome

- NAS and Maternal Drug Use

  Neonatal Opioid Abstinence
  Heroin/Oxycodone and Buprenorphine

  Other non-opioid drugs that cause behaviors consistent with withdrawal
  Benzodiazepine
  *Cocaine
  *Alcohol
  *Methamphetamine
  *Usually does not require treatment

  Poly-drug exposure



Neonatal Opioid Abstinence

- The majority of infants exposed to opioids undergo withdrawal
- Issue of severity and the need for pharmacological intervention

Neonatal Abstinence Syndrome

- *MOTHER Study:*

Jones HE, Kaltenbach K, Heil SH, et al., Neonatal abstinence syndrome after methadone or buprenorphine exposure.

N Engl J Med 2010:363: 2330-31

- Evaluate the possible differential impact of buprenorphine and methadone, given to opioid-dependent pregnant women, on both neonatal and maternal outcomes

Neonatal Abstinence Syndrome

- **57% of methadone-exposed and 47% of buprenorphine-exposed babies were treated for NAS.**
- **In comparison to methadone-exposed neonates, buprenorphine-exposed neonates:**
  - **Required 89% less morphine to treat NAS**
  - **Spent 43% less time in the hospital**
  - **Spent 58% less time in the hospital being medicated for NAS**
- **Both medications in the context of comprehensive care produced similar maternal treatment and delivery outcomes.**

Unanswered Questions

- **What is the best induction procedure for pregnant women onto buprenorphine?**
- **What is maternal and infant safety and efficacy of Suboxone exposure during pregnancy?**
- **In what ways does the maternal and infant safety and efficacy of methadone and buprenorphine change in the presence of co-morbid alcohol and/or benzodiazepine exposure?**

Medication Assisted Treatment and Pregnancy

- Illicit drug use and prescription misuse

Illicit Drug Use and Prescription Misuse

- Concomitant drug use
  - Methadone has no direct pharmacological effect on non-opioids
  - Abuse of other drugs such as cocaine, marijuana, alcohol, and/or benzodiazepine must be treated as a separate problem
  - Benzodiazepine misuse the most difficult problem

Medication Assisted Treatment and Pregnancy

- Co-Occurring Psychiatric Disorders

Prevalence of Psychiatric Disorders and Substance Use Disorders in Pregnant Women

- Prevalence of depression among substance abusing pregnant women is extremely high
  - For non- abusing pregnant women rates have been reported between 9%-16%.
  - For substance abusing women in treatment rates usually between 40%- 70%.

Prevalence of Psychiatric Disorders and Substance Use Disorders in Pregnant Women

- Center for Substance Abuse Treatment funded 50 treatment programs in the mid 1990's
  - Residential women and children's program
  - Pregnant and post-partum program
  - Published evaluation results in 2001
    - 5,110 women received services
    - 50% had mental health disorders

Prevalence of Psychiatric Disorders and Substance Use Disorders in Pregnant Women

- Fitzsimons et al., *Journal of Substance Treatment,* 2007
  - Study included 106 opioid dependent pregnant women
    - 37% had primary mood disorder
      - Of those, 44% also had anxiety disorder
    - 36% had primary anxiety disorder
      - Of those, 37% also had a mood disorder

Use of SSRIs in Pregnancy

- Over the past decade, there have been reports describing neonatal complications in newborns of mothers using SSRIs
- In 2004, the US FDA required warnings of perinatal complications. Physicians were advised to taper dosage during the last trimester so that the fetus is not exposed for at least 7-10 days before delivery.

Use of SSRIs in Pregnancy

- Pattern of neonatal symptoms referred to as Poor Neonatal Adaptation (PNA)
  - Jitteriness
  - Poor muscle tone
  - Weak or absent cry
  - Respiratory distress
  - Hypoglycemia
  - Low Apgar score
  - Seizures

Koren et al, CMAJ 2005

Use of SSRIs in Pregnancy

- PNA symptoms may result from a SSRI withdrawal or a serotonin toxicity
- Neonatal serum SSRI concentrations needed to distinguish between the two
- PNA symptoms should not be confused with NAS symptoms

Use of SSRIs in Pregnancy

- Limited amount of data
  - Number of studies is small
  - Across studies, occurrence of PNA is variable but no higher than 30%
  - Paroxetine (Paxil) and fluoxetine (Prozac) are the SSRI's most commonly reported with PNA
    - May be related to pharmacology or to the fact that they are the most widely used

Use of SSRIs in Pregnancy

- Risk associated with use of SSRIs during pregnancy must be weighed against the risk associated with untreated disease

Use of SSRIs in Pregnancy

- Adverse effects of untreated depression during pregnancy
  - Increased risk of:

Suicidal ideation	Spontaneous abortion
Hypertension	Intrauterine growth retardation
Low-birth weight	Depressive-like behavior in infant
Pre-eclampsia	Neurobehavioral changes in infant
Pre-term birth	Postpartum depression
Hospitalization	Substance abuse

Medication Assisted Treatment

- Breastfeeding

Breastfeeding

- Opioid maintained mothers can breast feed if:
  - They are not HIV positive
  - They are not using illicit drugs
  - They do not have a disease or infection in which breastfeeding s contraindicated

Breastfeeding

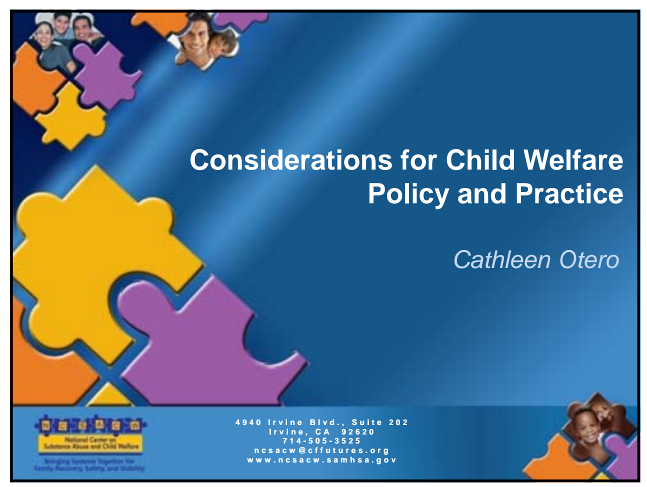
- In 2001, the American Academy of Pediatrics eliminated the dose restriction of methadone, making methadone maintenance compatible with breastfeeding regardless of dose.
- There are limited date on buprenorphine but evidence indicates only small amounts of buprenorphine pass into breast milk.
- Consensus Panels support breastfeeding for buprenorphine maintained mothers (CSAT, 2004; CSAT 2005)

Medication Assisted Treatment is Most Effective

- Provided in appropriate doses
- Provided in the context of prenatal care
- Provided as a part of women-centered treatment

Summary

- The use of medication assisted treatment must be evaluated with a risk/benefit model that takes into account what is best for both mother and child
- Treatment programs must continue to strive to better understand the complex needs of opioid dependent pregnant women and employ models of care that address their multiple issues.



Child Abuse Prevention and Treatment Reauthorization Act (CAPTA) of 2010

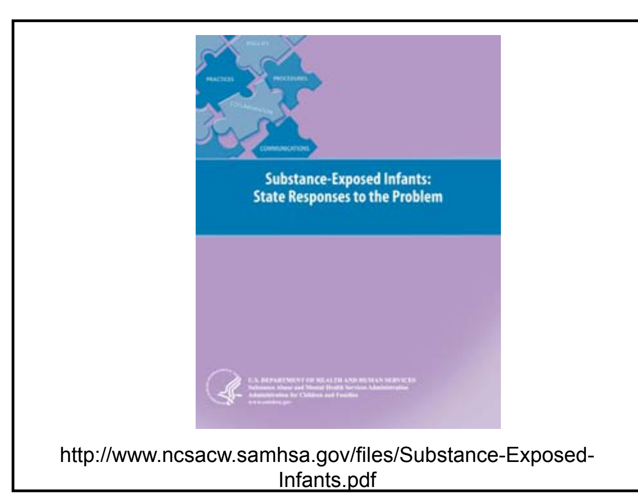
- An assurance in the form of a certification by the Governor that the State has in effect and is enforcing a State law, or has in effect and is operating a Statewide program that includes provisions and procedures for:
  - Reporting of child abuse and neglect, including a State law for mandatory reporting on child abuse and neglect by certain individuals required to report such instances (section 106(b)(2)(B)(i))
  - Addressing the needs of infants born with and identified as being affected by a Fetal Alcohol Spectrum Disorder (including appropriate referrals to child protection service systems and for other appropriate services) (section 106(b)(2)(B)(ii));

Child Abuse Prevention and Treatment Reauthorization Act (CAPTA) of 2010

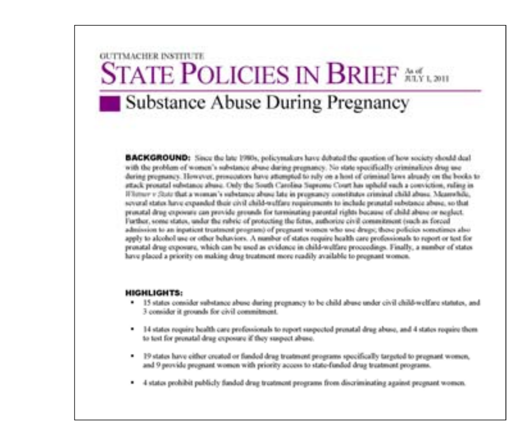
- A description of policies and procedures:
  - Promoting and enhancing collaboration among child protective services, domestic violence, substance abuse, and other agencies in investigations, interventions and service delivery to children and families affected by child abuse or neglect (including children exposed to domestic violence) (section 106(b)(2)(D)(v));

Policy and Practice Considerations

- Collaboration with multiple stakeholders – primary care providers, substance abuse treatment/ MAT providers and the courts – is essential.
- Cross systems release of information
- Cross systems role clarification
- Clearly written policies and guidelines for clients
- Clearly written policies and guidelines for staff



http://www.ncsacw.samhsa.gov/files/Substance-Exposed-Infants.pdf



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STATE POLICIES IN BRIEF As of JULY 1, 2011

Substance Abuse During Pregnancy

BACKGROUND: Since the late 1980s, policymakers have debated the question of how society should deal with the problem of women's substance abuse during pregnancy. No state specifically criminalizes drug use during pregnancy. However, prosecutors have attempted to rely on a host of criminal laws already on the books to attack prenatal substance abuse. Only the South Carolina Supreme Court has upheld such a conviction, ruling in *Whitner v State* that a woman's substance abuse late in pregnancy constitutes criminal child abuse. Meanwhile, several states have expanded their civil child-welfare requirements to include prenatal substance abuse, so that prenatal drug exposure can provide grounds for terminating parental rights because of child abuse or neglect. Further, some states, under the rubric of protecting the fetus, authorize civil commitment (such as forced admission to an inpatient treatment program) of pregnant women who use drugs; these policies sometimes also apply to alcohol use or other behaviors. A number of states require health care professionals to report or test for prenatal drug exposure, which can be used as evidence in child-welfare proceedings. Finally, a number of states have placed a priority on making drug treatment more readily available to pregnant women.

HIGHLIGHTS:

- 15 states consider substance abuse during pregnancy to be child abuse under civil child-welfare statutes, and 3 consider it grounds for civil commitment.
- 14 states require health care professionals to report suspected prenatal drug abuse, and 4 states require them to test for prenatal drug exposure if they suspect abuse.
- 19 states have either created or funded drug treatment programs specifically targeted to pregnant women, and 9 provide pregnant women with priority access to state-funded drug treatment programs.
- 4 states prohibit publicly funded drug treatment programs from discriminating against pregnant women.

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