



Treatment of Opioid Dependence in Pregnancy

VERMONT GUIDELINES

November 2010

These best practice guidelines were written as a collaborative effort between the division of Alcohol and Drug Abuse Programming at the Vermont Department of Health, the Maternal Fetal Medicine Department at Fletcher Allen Health Care and the Neonatal Follow-up Department at Fletcher Allen Health Care.

The obstetrical and pediatric guidelines were written for use at our institution after a decade of work with the population of substance dependent pregnant women and their children. They are intended for clinical providers to review and use as a template, if desired.

It is our hope you find some benefit in the forms and protocols that we utilize. We recognize that the most important feature of our work is having a system to communicate between the providers of care for the family in recovery.

We offer thanks to the March of Dimes and to the Vermont Child Health Improvement Program for their support in the completion of this document.

There are unique challenges in working with the substance dependent pregnant population and there are unique rewards to be found there as well.

Anne Johnston, MD
Director Neonatal Medical Follow-up Clinic, Fletcher Allen Health Care

Todd W. Mandell, MD
Medical Director, Division of Alcohol and Drug Abuse Programs

Marjorie Meyer, MD
Director, Maternal Fetal Medicine Fletcher Allen Health Care



SECTION 1

Vermont Buprenorphine Practice Guidelines

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Vermont Guidelines for Medication-Assisted Treatment (MAT) for Pregnant Women

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Services for Opioid-Dependent Pregnant Women in Vermont

Data current as of July 2010

Vermont 2-1-1 is a resource that provides information about available services in your area. It is a toll-free call for Vermonters or you may visit their website at www.vermont211.org

STATEWIDE RESOURCES	
Methadone	The Chittenden Clinic Habit OpCo* Lebanon, Brattleboro and BAART in Berlin
Residential Treatment	Serenity House* 98 Church Street P.O. Box 207 Wallingford, VT 05773 802-446-2640
	Maple Leaf Farm* 10 Maple Leaf Road Underhill, VT 05489 802-899-2911
	Valley Vista* 23 Upper Plain Bradford, VT 05032 802-222-5201

BARRE DISTRICT OFFICE: WASHINGTON & ORANGE COUNTIES	
Children's Integrated Services Intake Coordinator	Family Center of Washington County 383 Sherwood Drive, Montpelier, VT 05602 802-262-3292
Home Health Agency	Central Vermont Home Health & Hospice 600 Granger Road, Barre, VT 05641 802-223-1878
Maternal Child Health Coordinator	Vermont Department of Health McFarland Office Building 5 Perry Street, Suite 250, Barre, VT 05641 802-479-4200 888-253-8786 (Toll-free within VT)
Hospital	Central Vermont Medical Center
Methadone	BAART Behavioral Health Services* 300 Granger Road, Berlin, VT 05641 802-223-2003
Buprenorphine	Central VT Substance Abuse Services* PO Box 1468, Montpelier, VT 05601 802-223-4156
	Treatment Associates 73 Main Street, Suite 27 Montpelier, VT 05602 802-225-8355
	Synergy Counseling Group 542 US Route 302, Suite C Berlin, VT 05641 802-477-5021
For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator/provider_search.process_query?alternative=CHOICE&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Treatment Associates 73 Main Street, Suite 27, Montpelier, VT 05602 802-225-8355
	Fletcher Allen Health Care Comprehensive Obstetric and Gynecologic Services (COGS)** 802-847-1400
Buprenorphine prescribed only during pregnancy and 6-8 weeks postpartum	
Substance Abuse Counseling	Central VT Substance Abuse Services* PO Box 1468, Montpelier, VT 05601 802-223-4156
	Treatment Associates 73 Main Street, Suite 27, Montpelier, VT 05602 802-225-8355
	Synergy Counseling Group 542 US Route 302, Suite C, Berlin, VT 05641 802-477-5021
	Washington County Youth Services Bureau* PO Box 627, 38 Elm Street Montpelier, VT 05601 802-229-9151
OB: Antepartum and postpartum care are available in the Barre area. Do not prescribe treatment for opioid dependence. Delivery at CVMC.	
Pediatrics: Pediatric care is available for antenatal consultation and newborn care in the Barre area. Assessment and treatment of the opioid exposed newborn is available at CVMC. Follow-up of newborns treated at Fletcher Allen Health Care and discharged on methadone is available through Neonatal Medical Follow-up Program, Vermont Children's Hospital at Fletcher Allen, 802-847-9809.	
NAS Scoring: Modified Finnegan – trained by Fletcher Allen.	
NAS Rx: Morphine in hospital.	

* Vermont State-Approved Programs

** Only patients planning on receiving all care through FAHC/COGS will be started on medication.

BENNINGTON DISTRICT OFFICE: BENNINGTON COUNTY	
Children's Integrated Services Intake Coordinator	Agency of Human Services 150 Veteran's Memorial Drive Bennington, VT 05201 802-447-2887
Home Health Agency	VNA & Hospice of Southwestern Vermont Healthcare Services 160 Benmont Avenue, Suite 17 Bennington, VT 05201 802-442-5502
	Manchester Health Services 5468 Main Street Manchester Center, VT 05255 802-362-2126
Maternal Child Health Coordinator	Vermont Department of Health 324 Main Street, Suite 2 Bennington, VT 05201 802-447-3531 800-637-7347 (Toll-free within VT)
Hospital	Southwestern Vermont Medical Center
Methadone	Brattleboro Retreat* (for detox only) PO Box 803, Anna Marsh Lane Brattleboro, VT 05302 800-738-7328 The Chittenden Clinic Habit OpCo* Lebanon, Brattleboro and BAART in Berlin
Buprenorphine	Brattleboro Retreat* (for detox only) PO Box 803, Anna Marsh Lane Brattleboro, VT 05302 800-738-7328
For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator/provider_search.process_query?alternative=CHOICE&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Brattleboro Retreat* PO Box 803, Anna Marsh Lane Brattleboro, VT 05302 800-738-7328 Several private providers in the area.
Substance Abuse Counseling	Northshire UCS* PO Box 815, 5312 Main Street Stephen C. Lundy Building Manchester Center, VT 05255 802-362-3950 United Counseling Services* 100 Ledge Hill Drive Bennington, VT 05201 802-442-5491
OB: Antepartum and postpartum care are available in the Bennington area. MFM consult early in pregnancy. Do not prescribe treatment for opioid dependence.	
Pediatrics: Pediatric care is available for antenatal consultation and newborn care in the Bennington area. Assessment of the opioid-exposed newborn is available at SVMC. SVMC will accept back transfers from Albany.	
NAS Scoring: Modified Finnegan – trained by Fletcher Allen Health Care.	
NAS Rx: Transfer to Fletcher Allen or Albany if NAS requires medication management.	

BRATTLEBORO DISTRICT OFFICE: WINDHAM COUNTY	
Children's Integrated Services Intake Coordinator	Winston Prouty Center Brattleboro, VT 05301 802-257-7852
Home Health Agency	Visiting Nurse & Hospice of Vermont and New Hampshire 1 Hospice Court, Bellows Falls, VT 05101 888-300-8853
Maternal Child Health Coordinator	Vermont Department of Health 232 Main Street, Suite 3 Brattleboro, VT 05301 802-257-2880 888-253-8805 (Toll-free within VT)
Hospital	Brattleboro Memorial Hospital
Methadone	Brattleboro Retreat (for detox only) PO Box 803, Anna Marsh Lane Brattleboro, VT 05302 800-738-7328 Habit OpCo* PO Box 8417, 16 Town Crier Drive Brattleboro, VT 05301 802-258-4624
Buprenorphine	Brattleboro Retreat (for detox only) PO Box 803, Anna Marsh Lane Brattleboro, VT 05302 1-800-738-7328
For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator/provider_search.process_query?alternative=CHOICE&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Brattleboro Retreat PO Box 803, Anna Marsh Lane Brattleboro, VT 05302 800-738-7328
Substance Abuse Counseling	Brattleboro Retreat PO Box 803, Anna Marsh Lane Brattleboro, VT 05302 800-738-7328 Health Care & Rehabilitation Services* Brattleboro Region Offices 51 Fairview Street, Brattleboro, VT 05301 802-254-6028 Rise Program* 435 Western Avenue, Brattleboro, VT 05301 802-257-5654 Rise II* 11 Underhill Avenue, Bellows Falls, VT 05101 802-463-9851
OB: Antepartum and postpartum care is available in the Brattleboro area. Do not prescribe treatment for opioid dependence. Delivery at BMH.	
Pediatrics: Pediatric care is available for antenatal consultation and newborn care. Assessment and treatment of the opioid-exposed newborn is available at BMH.	
NAS Scoring: Yes – trained by DHMC.	
NAS Rx: Morphine in hospital.	

* Vermont State-Approved Programs

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BURLINGTON DISTRICT OFFICE: CHITTENDEN COUNTY			
Children's Integrated Services Intake Coordinator	Visiting Nurse Association of Chittenden & Grand Isle Counties 1110 Prim Road Colchester, VT 05446 802-860-4426	Substance Abuse Counseling	The Chittenden Clinic* 1 South Prospect Street, Room 1420 Burlington, VT 05401 802-656-3700 or 800-413-2272
Home Health Agency	Visiting Nurse Association of Chittenden & Grand Isle Counties 1110 Prim Road Colchester, VT 05446 802-860-4420		Day One* UHC Campus, 3rd floor, St. Joseph's 1 South Prospect Street Burlington, VT 05401 802-847-3333
Maternal Child Health Coordinator	Vermont Department of Health 108 Cherry Street, Burlington, VT 05402 PO Box 70, Suite 101, Burlington, VT 05446 802-863-7323 888-253-8803 (Toll-free within VT)		HowardCenter Mental Health & Substance Abuse Services* 855 Pine Street Burlington, VT 05401 802-488-6100
Hospital	Fletcher Allen Health Care		HowardCenter Act 1/Bridge Program* 184 Pearl Street Burlington, VT 05401 802-488-6425
Methadone	The Chittenden Clinic* 1 South Prospect Street, Room 1420 Burlington, VT 05401 802-656-3700 or 800-413-2272		HowardCenter Centerpoint Adolescent Treatment Services 1025 Airport Drive South Burlington, VT 05403 802-488-7711
Buprenorphine	Synergy Counseling Group 56 West Twin Oak Terrace, Suite 5 South Burlington, VT 05403 802-651-9880		Lund Family Center* Cornerstone Drug Treatment Program 76 Glen Road P.O. Box 4009 Burlington, VT 05406 802-864-7467 / 800-639-1741
For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator/!provider_search.process_query?alternative=CHOICEG&one_state=VT			Spectrum Youth & Family Services* 177 Pearl Street Burlington, VT 05401 802-862-5396
Initiation of Buprenorphine During Pregnancy	Fletcher Allen Health Care Comprehensive Obstetric and Gynecologic Services (COGS)** 802-847-1400		Synergy Counseling Group 56 West Twin Oak Terrace, Suite 5 South Burlington, VT 05403 802-651-9880
Buprenorphine prescribed only during pregnancy and 6–8 weeks post-partum.			
		OB: Flether Allen Health Care Comprehensive Obstetric and Gynecological Service (COGS), 802-847-1400.	
		Pediatrics: Follow-up of newborns treated at Fletcher Allen and discharged on methadone is available through Neonatal Medical Follow-up Clinic, Vermont Children's Hospital at Fletcher Allen, 802-847-9809.	
		NAS Scoring: Modified Finnegan	
		NAS Rx: Methadone initiated in hospital, once stable discharge to home on methadone.	

MIDDLEBURY DISTRICT OFFICE: ADDISON COUNTY	
Children's Integrated Services Intake Coordinator	Addison County Parent/Child Center PO Box 646 Middlebury, VT 05753 802-388-3171
Home Health Agency	Addison County Home Health and Hospice PO Box 754, 254 Ethan Allen Highway Middlebury, VT 05753 802-388-7259
Maternal Child Health Coordinator	Vermont Department of Health 700 Exchange Street, Suite 101 Middlebury, VT 05753 802-388-4644 888-253-8804 (Toll-free within VT)
Hospital	Porter Hospital
Methadone	The Chittenden Clinic Habit OpCo* Lebanon, Brattleboro and BAART in Berlin
Buprenorphine: For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator!/provider_search.process_query?alternative=CHOICE&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Fletcher Allen Health Care Comprehensive Obstetric and Gynecologic Services (COGS)** 802-847-1400
Substance Abuse Counseling	Counseling Service of Addison County* 89 Main Street Middlebury, VT 05753 802-388-6751
OB: Antenatal and postpartum care is available. Refer for MFM consult early in pregnancy, and transfer care to Fletcher Allen COGS at 36 weeks for delivery. Do not prescribe treatment for opioid dependence.	
Pediatrics: Follow-up of newborns treated at Fletcher Allen Health Care and discharged on methadone is available through Neonatal Medical Follow-up Clinic, Vermont Children's Hospital at Fletcher Allen, 802-847-9809.	
NAS Scoring: Modified Finnegan – trained by Fletcher Allen.	
NAS Rx: No treatment available at Porter, transfer to Fletcher Allen if NAS requires medication management.	

MORRISVILLE DISTRICT OFFICE: LAMOILLE, ORLEANS, CALEDONIA & WASHINGTON COUNTIES	
Children's Integrated Services Intake Coordinator	Agency of Human Services 63 Professional Drive Morrisville, VT 05661 802-888-0539
Home Health Agency	Lamoille Home Health Agency 54 Farr Avenue Morrisville, VT 05661 802-888-4651
Maternal Child Health Coordinator	Vermont Department of Health 63 Professional Drive, Suite 1 Morrisville, VT 05661 802-888-7447 888-253-8804 (Toll-free within VT)
Hospital	Copley Hospital
Methadone	BAART Behavioral Health Services* 475 Union Street Newport, VT 05855 802-334-0110
	BAART Behavioral Health Services* 300 Granger Road Berlin, VT 05641 802-223-2003
	The Chittenden Clinic Habit OpCo* Lebanon, Brattleboro and BAART in Berlin
Buprenorphine: For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator!/provider_search.process_query?alternative=CHOICE&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Fletcher Allen Health Care Comprehensive Obstetric and Gynecologic Services (COGS)** 802-847-1400
Buprenorphine prescribed only during pregnancy and 6-8 weeks postpartum	
Substance Abuse Counseling	Behavioral Health and Wellness Center* 530 Washington Highway, Suite 10 Morrisville, VT 05661 802-888-8320
OB: Antepartum and postpartum care is available locally. Do not prescribe treatment for opioid dependence.	
Pediatrics: Pediatric care is available for antenatal consultation and newborn care in Morrisville area. Follow-up of newborns treated at Fletcher Allen Health Care and discharged on methadone is available through Neonatal Medical Follow-up Clinic, Vermont Children's Hospital at Fletcher Allen, 802-847-9809.	
NAS Scoring: Modified Finnegan – trained by Fletcher Allen.	
NAS Rx: No treatment available at Copley, transfer to Fletcher Allen if NAS requires medication management.	

* Vermont State-Approved Programs

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NEWPORT DISTRICT OFFICE: ORLEANS & ESSEX COUNTY	
Children's Integrated Services Intake Coordinator	Northeast Kingdom Learning Services PO Box 27 West Glover, VT 05875 802-525-3012 or 800-209-0121
Home Health Agency	Orleans/Essex VNA & Hospice, Inc. 46 Lakemont Road Newport, VT 05855 802-334-5213
Maternal Child Health Coordinator	Vermont Department of Health 100 Main Street, Suite 220 Newport, VT 05855 802-334-6707 800-952-2945 (Toll-free within VT)
Hospital	North Country Hospital
Methadone	BAART Behavioral Health Services* 475 Union Street Newport, VT 05855 802-334-0110
Buprenorphine	BAART Behavioral Health Services* 475 Union Street Newport, VT 05855 802-334-0110
For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator/provider_search.process_query?alternative=CHOICEG&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Fletcher Allen Health Care Comprehensive Obstetric and Gynecologic Services (COGS)** 802-847-1400
Buprenorphine prescribed only during pregnancy and 6-8 weeks post-partum	
Substance Abuse Counseling	BAART Behavioral Health Services* 475 Union Street Newport, VT 05855 802-334-0110
	Tri-County Substance Abuse* 154 Duchess Avenue PO Box 724 Newport, VT 05855 802-334-5246
OB: Refer to Fletcher Allen Health Care Comprehensive Obstetric and Gynecological Service (COGS) for antenatal care, 802-847-1400. Will consider "shared care" with Fletcher Allen for women already in treatment. MFM consult early in pregnancy. Transfer care at 36 weeks.	
Pediatrics: Follow-up of newborns treated at Fletcher Allen Health Care and discharged on methadone is available through Neonatal Medical Follow-up Clinic, Vermont Children's Hospital at Fletcher Allen, 802-847-9809.	
NAS Scoring: Modified Finnegan – trained by Fletcher Allen.	
NAS Rx: Refer to Fletcher Allen Health Care – Methadone initiated in hospital, once stable discharge to home on methadone. On rare occasion treat tincture of opium at North Country Hospital.	

RUTLAND DISTRICT OFFICE: RUTLAND COUNTY	
Children's Integrated Services Intake Coordinator	Rutland Area Visiting Nurse Association & Hospice PO Box 787, 7 Albert Cree Drive Rutland, VT 05702 802-770-1621
Home Health Agency	Rutland Area Visiting Nurse Association & Hospice PO Box 787 Rutland, VT 05702 802-775-0568 or 800-244-0568
Maternal Child Health Coordinator	Vermont Department of Health 300 Asa Bloomer State Office Building Rutland, VT 05701 802-786-5811 888-253-8802 (Toll-free within VT)
Hospital	Rutland Regional Medical Center
Methadone	The Chittenden Clinic Habit OpCo* Lebanon, Brattleboro and BAART in Berlin
Buprenorphine: For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator/provider_search.process_query?alternative=CHOICEG&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Several private providers in the area.
Substance Abuse Counseling	Evergreen Services* 135 Granger Street Rutland, VT 05701 802-747-3588
OB: Antenatal and postpartum care is available in the Rutland area. Do not prescribe treatment for opioid dependence. Delivery at RRMCC.	
Pediatrics: Pediatric care is available for antenatal consultation and newborn care locally. Assessment and treatment for the opioid-exposed newborn is available at RRMCC.	
NAS Scoring: Modified Finnegan – trained by Fletcher Allen Health Care.	
NAS Rx: Morphine in hospital.	

ST. ALBANS DISTRICT OFFICE: FRANKLIN & GRAND ISLE COUNTIES	
Children's Integrated Services Intake Coordinator	Northwestern Counseling & Support Services/The Family Center of Northwestern Vermont 30 Fisher Pond Road St. Albans, VT 05478 802-393-6597
Home Health Agency	Franklin County Home Health Agency 3 Home Health Circle, Suite 1 St. Albans, VT 05478 802-527-7531
Maternal Child Health Coordinator	Vermont Department of Health 20 Houghton Street, Suite 312 St. Albans, VT 05478 802 524-7970 888-253-8801 (Toll-free within VT)
Hospital	Northwestern Medical Center
Methadone	The Chittenden Clinic Habit OpCo* Lebanon, Brattleboro and BAART in Berlin
Buprenorphine: For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator/provider_search.process_query?alternative=CHOICE&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Fletcher Allen Health Care Comprehensive Obstetric and Gynecologic Services (COGS)** 802-847-1400
Buprenorphine prescribed only during pregnancy and 6-8 weeks postpartum.	
Substance Abuse Counseling	Howard Center* 172 Fairfield Street St. Albans, VT 05478 802-524-7265
OB	Fletcher Allen Health Care Comprehensive Obstetric and Gynecological Service (COGS) 802-847-1400
Pediatrics: Follow-up of newborns treated at Fletcher Allen Health Care and discharged on methadone is available through Neonatal Medical Follow-up Clinic, Vermont Children's Hospital at Fletcher Allen, 802-847-9809.	
NAS Scoring: Modified Finnegan – trained by Fletcher Allen	
NAS Rx: No treatment available at NMC, transfer to Fletcher Allen if NAS requires medication management.	

ST. JOHNSBURY DISTRICT OFFICE: CALEDONIA, ESSEX & ORANGE COUNTIES	
Children's Integrated Services Intake Coordinator	Northeast Kingdom Learning Services PO Box 27, West Glover, VT 05875 802-525-3012 or 800-209-0121
Home Health Agency	Caledonia Home Health Care & Hospice PO Box 383, 161 Sherman Drive St. Johnsbury, VT 05819 802-748-8116
Maternal Child Health Coordinator	Vermont Department of Health 107 Eastern Avenue, Suite 9 St. Johnsbury, VT 05819 802-748-5151 800-952-2936 (Toll-free within VT)
Hospital	Northeastern Vermont Regional Hospital
Methadone	BAART Behavioral Health Services* 445 Portland Street St Johnsbury, VT 05819 802-748-6166
Buprenorphine: For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator/provider_search.process_query?alternative=CHOICE&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Fletcher Allen Health Care Comprehensive Obstetric and Gynecologic Services (COGS)** 802-847-1400
Buprenorphine prescribed only during pregnancy and 6–8 weeks postpartum.	
Substance Abuse Counseling	Tri-County Substance Abuse Services* 2225 Portland Street St. Johnsbury, VT 05819 802-748-1682
	BAART Behavioral Health Services* 445 Portland Street St. Johnsbury, VT 05819 802-748-6166
OB	Fletcher Allen Health Care Comprehensive Obstetric and Gynecological Service (COGS) 802-847-1400
	Dartmouth Hitchcock Medical Center (DHMC)
Pediatrics: Follow-up of newborns treated at Fletcher Allen Health Care and discharged on methadone is available through Neonatal Medical Follow-up Clinic, Vermont Children's Hospital at Fletcher Allen, 802-847-9809 or DMHC.	
NAS Scoring: Modified Finnegan – trained by DMHC.	
NAS Rx: No treatment available at NVRH, transfer to either DHMC or Fletcher Allen – family choice – if NAS requires medication management.	

* Vermont State-Approved Programs

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SPRINGFIELD DISTRICT OFFICE: WINDSOR & WINDHAM COUNTIES	
Children's Integrated Services Intake Coordinator	Springfield Area Parent Child Center 2 Main Street North Springfield, VT 05150 802-886-5242
Home Health Agency	Visiting Nurse & Hospice of Vermont and New Hampshire 66 Benning Street, Suite 6 West Lebanon, NH 03784 800-575-5162
Maternal Child Health Coordinator	Vermont Department of Health 100 Mineral Street, Suite 104 Springfield, VT 05156 802-885-5778 888-296-8151 (Toll-free within VT)
Hospital	Springfield Hospital Holly Trail, Nurse Manager
Methadone	Habit OpCo* PO Box 8417, 16 Town Crier Drive Brattleboro, VT 05301 802-258-4624
	Habit OpCo* 8 Interchange Drive West Lebanon, NH 03784 603-298-2146
Buprenorphine: For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator!/provider_search.process_query?alternative=CHOICEG&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Brattleboro Retreat PO Box 803, Anna Marsh Lane Brattleboro, VT 05302 800-738-7328
Substance Abuse Counseling	Health Care and Rehabilitation Services* 390 River Street Springfield, VT 05156 802-886-4500
OB: Antenatal and postpartum care is available. Do not prescribe treatment for opioid dependence.	
Pediatrics: Pediatric care is available for antenatal consultation, and newborn care is available locally. Assessment of the opioid-exposed newborn is available at Springfield Hospital. Transfer to DHMC for NAS treatment according to DMHC guidelines or Fletcher Allen Health Care Neonatal Medical Follow-up Clinic, Vermont Children's Hospital at Fletcher Allen, 802-847-9809.	
NAS Scoring: Modified Finnegan – trained by DHMC.	
NAS Rx: Transfer to DHMC	

WHITE RIVER JUNCTION DISTRICT OFFICE: WINDSOR & ORANGE COUNTIES	
Children's Integrated Services Intake Coordinator	Orange County Parent Child Center 361 VT Route 110 Chelsea, VT 05038 802-685-2264
Home Health Agency	The Family Place 319 US Route 5 South Norwich, VT 05055 802-649-3268
	Visiting Nurse & Hospice of Vermont and New Hampshire 66 Benning Street, Suite 6 West Lebanon, NH 03784 800-575-5162
Maternal Child Health Coordinator	Vermont Department of Health 226 Holiday Drive, Suite 22 White River Junction, VT 05001 802-295-8820 888-253-8799 (Toll-free within VT)
Hospital	Gifford Medical Center
Methadone	BAART Behavioral Health Services* 300 Granger Road Berlin, VT 05641 802-223-2003
	Habit OpCo* 8 Interchange Drive West Lebanon, NH 03784 603-298-2146
Buprenorphine: For private providers in your area visit: http://buprenorphine.samhsa.gov/pls/bwns_locator!/provider_search.process_query?alternative=CHOICEG&one_state=VT	
Initiation of Buprenorphine During Pregnancy	Fletcher Allen Health Care Comprehensive Obstetric and Gynecologic Services (COGS)** 802-847-1400
Buprenorphine prescribed only during pregnancy and 6–8 weeks postpartum.	
Substance Abuse Counseling	Health Care and Rehabilitation Services* PO Box 816, 49 School Street Hartford, VT 05047 802-295-3031
	Clara Martin Center* Box G Randolph, VT 05060 802-728-4466
	Clara Martin Center* P.O. Box 278 Bradford, VT 05033 802-222-4477
OB: Fletcher Allen Health Care Comprehensive Obstetric and Gynecological Service (COGS) 802-847-1400. Dartmouth Hitchcock Medical Center (DHMC) for antepartum and postpartum care.	
Pediatrics: Follow-up of newborns treated at Fletcher Allen Health Care and discharged on methadone is available through Neonatal Medical Follow-up Clinic, Vermont Children's Hospital at Fletcher Allen, 802-847-9809 or DMHC.	
NAS Scoring: Not scoring – not trained.	
NAS Rx: No treatment available at Gifford, transfer to Fletcher Allen Health Care or DMHC if NAS requires medication management.	



Case Studies & Frequently Asked Questions

Together with our partners at Fletcher Allen Health Care, we drafted a list of the most frequently asked questions about this topic.

A woman presents for prenatal care. She is dependent on illicit opiates. What do we do?

There are three options to explore:

1. Deliver at your local institution with close coordination amongst substance abuse counseling, opiate agonist medication prescriber, obstetrics, and pediatrics to ensure seamless delivery of care.
2. Refer to Fletcher Allen Health Care for consultation or care. This might include a woman being followed by her local OB provider who is seen at Fletcher Allen Health Care for a consult with planned delivery at that facility.
3. Refer to nearby regional hospital that delivers newborns exposed to opiates for prenatal consult, delivery and newborn management.

A pregnant woman is in treatment for opiate dependence and plans to deliver at her local hospital. What do we need to know?

DURING PREGNANCY: Coordinate care amongst all providers, watch fetal growth, pediatrics consultation, home health referral, ensure compliance with substance abuse counseling and treatment. Consider anesthesia consultation if at high risk for caesarean delivery. Refer to local Children's Integrated Services (CIS) team through your local Vermont Department of Health office.

DURING LABOR: Continue opioid-agonist medication as indicated. Nubain® (nalbuphine hydrochloride) and Stadol should be avoided. It is a synthetic opioid-agonist – antagonist and can precipitate acute withdrawal in an opioid-dependent individual. Epidural and spinal analgesia are effective: expect approximately 70% increase in opiate dosage following caesarean delivery for adequate pain control.

For more information, go to www.annals.org/content/144/2/127.abstract for an article from "Annals of Internal Medicine" on pain management strategies in patients on methadone or buprenorphine. Morphine sulfate or hydromorphone (Dilaudid) are reasonable options for pain management.

What about the baby?

The delivery hospital should be prepared to assess and treat infants for neonatal abstinence syndrome. This should be established prior to planning the delivery.

What is neonatal abstinence syndrome?

Neonatal abstinence syndrome (NAS) is a generalized disorder characterized by signs and symptoms of nervous system irritability, gastrointestinal signs, respiratory distress and autonomic nervous system dysfunction. It is most commonly due to infants exposed to opioids *in utero*. Some examples of opioids are methadone, buprenorphine, Oxycontin, oxycodone, hydrocodone and heroin

How frequently does NAS occur in infants born to women on methadone maintenance therapy?

While all infants need to be monitored for NAS, approximately 50% of newborns born to a woman on methadone maintenance therapy will require pharmacologic treatment for NAS.

How frequently does NAS occur in infants born to women on Buprenorphine maintenance therapy?

Early studies suggest that approximately 30% of newborns born to a woman on maintenance therapy will require pharmacologic treatment for NAS.

Does the dose of methadone predict whether a baby will experience symptoms of withdrawal that require pharmacological treatment?

No. It has been well established that the maternal methadone dose is not related to the infant's need for treatment. It is anticipated that this will be the same for buprenorphine.

When are the symptoms of NAS most likely to occur?

The symptoms are most likely to occur in the first 48 to 96 hours after birth.

What is the treatment for NAS?

Newborns at risk for NAS should be kept in a quiet environment. Swaddling, kangaroo care, and minimal stimulation are helpful. In some infants, pharmacologic treatment with opioids is required.

When does a baby need pharmacologic treatment for NAS?

All infants at risk for NAS should be scored with a standardized assessment tool. The American Academy of Pediatrics recognizes scoring tools such as Finnegan, Lipsitz and Ostrea . Fletcher Allen Health Care utilizes a modified Finnegan Neonatal Abstinence Scoring System (Jansson et al, 2009). Each tool has a threshold for consideration of pharmacologic treatment.

What medications are used in the treatment of NAS?

The standard of care for the treatment of NAS includes small frequent doses of short-acting opiates (e.g. morphine sulfate, dilute tincture of opium). The dose is titrated to treat the symptoms and then gradually weaned over a period of days to weeks. Infants require hospitalization and cardio respiratory monitoring and/or pulse oximetry during this period.

What about methadone treatment for infants with NAS?

Fletcher Allen Health Care has used methadone to treat many infants who require pharmacologic treatment for neonatal abstinence syndrome. This approach allows for outpatient treatment of the infant with methadone administered by parent/guardian. Infants discharged on methadone are followed every 1-2 weeks by the Neonatal Medical Follow-Up Clinic with careful monitoring of signs of NAS and dosing of methadone (through one pharmacy). While the inpatient duration of stay may be shortened, it is not recommended that providers choose this method of treatment unless they have adequate outpatient staffing to allow for tracking and communicating with families, the capacity to see patients every 1-2 weeks in follow-up and established coordination with home health agencies and a pharmacy.

The staff at my hospital is comfortable scoring and assessing neonatal opioid withdrawal. They are not prepared to treat the infant with medication should it be indicated. What do I do?

This infant has a 50% probability of needing medication for withdrawal. Delivery should be planned in a center where the infant can receive treatment. Neonatal transports are not without risk; separation of the mother and baby is not advisable.

I am a pediatrician at a community hospital. My staff is comfortable in assessing and scoring infants at risk for NAS. I am prepared to treat NAS with medication should it become necessary. How long should I score the infant in hospital before discharging home?

The infant should remain in hospital with regular scoring for NAS for a minimum of 96 hours or 4 days.

When do I have to report to Department of Children and Families (DCF)?

A baby born to a mother continuing to use any of the following substances during pregnancy, subsequent to documented teaching on the potential dangers of that substance and documentation of resources offered for cessation:

- Alcohol
- Illegal substances
- Controlled medication NOT prescribed to the mother

- Baby born to a mother who, on admission, admits to prenatal use of an illegal substance or controlled medication NOT prescribed to her and use not previously known to prenatal providers
- Baby who tests positive for any of the substances referenced above
- Babies with evidence of adverse effects due to prenatal alcohol exposure

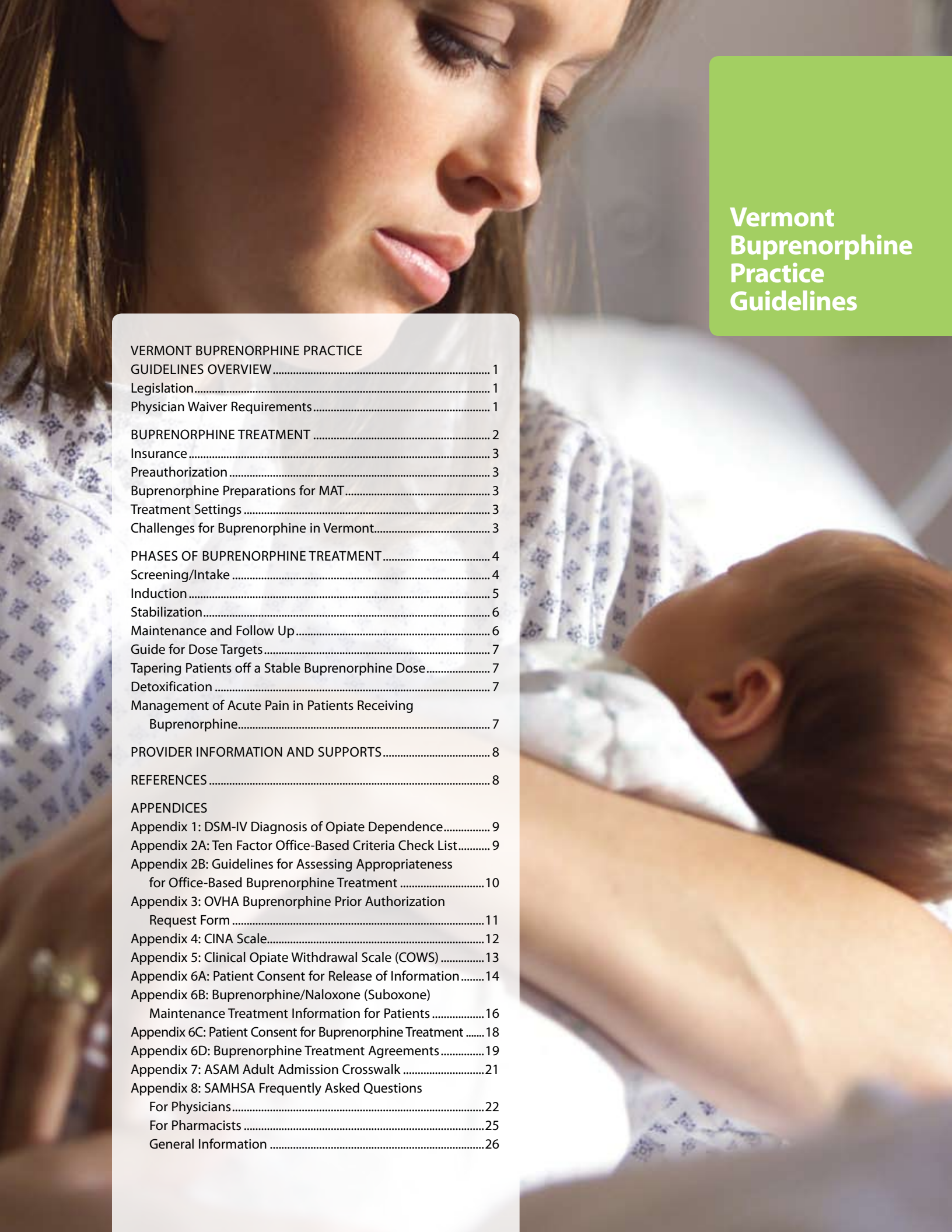
Recommendations for community hospitals planning to deliver infants exposed to methadone or buprenorphine

- The community hospital should be skilled and comfortable in the assessment, scoring, and pharmacologic treatment of infants at risk for NAS. If the staff is not prepared to assess and treat infants with NAS, delivery should be planned at a center that can provide this care.
- An opioid-exposed newborn requires a minimum of four days in hospital for NAS scoring.
- Infants on short-acting opioids for NAS should be continuously monitored with cardio respiratory monitors and/or pulse oximetry. Sufficient staffing is required for scoring and dosing of medication every 3-4 hours.
- A standardized tool such as the Finnegan Neonatal Abstinence Scoring System should be used. Symptom-based treatment guidelines for the use of short-acting opioids for NAS are available.
- The scoring of NAS can be subjective and situation-dependent. Adequate training of nursing staff is essential in ensuring consistency in scoring.

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Patricia Berry MPH, UVM
Susan Besio, PhD, DVHA
John R. Brooklyn, MD, Chittenden Center
Barbara Cimaglio, VDH/ADAP
Ron Clark, DVHA
Wendy Davis, MD, VDH
Michael Farber, MD, DVHA/UVM
Kelly Gordon, DVHA
Sarah H. Heil, PhD, UVM
Karen Lafond, DVHA
Peter Lee, VDH/ADAP
Vicki Loner, DVHA
Todd W. Mandell, MD, VDH/ADAP
Marjorie Meyer, MD, FAHC/UVM
Diane Neal, RPh, MedMetrics HP/DVHA
Tom Simpatico, MD, UVM

Vermont Buprenorphine Practice Guidelines Overview

The *Vermont Buprenorphine Practice Guidelines* were created to provide Vermont practitioners with a consolidated set of recommendations and best practices for the management of opioid dependence in an office-based setting. The content of these *Guidelines* is intended to complement information presented in online and live trainings on this subject, as well as other resources available through SAMHSA/CSAT and other national organizations. These *Guidelines* are not intended as requirements for practitioners. They should not be considered as medical advice.

LEGISLATION

Section 3502 of The Children's Health Act of 2000 (HR 4365) set forth the Drug Addiction Treatment Act of 2000 (DATA). This legislation provided significant changes in the oversight of the medical treatment of opioid addiction, allowing physicians to treat opioid addiction with opioid medications in office-based settings under certain restrictions. Whereas physicians previously were required to refer patients to specialized opioid treatment programs (OTPs), the DATA 2000 enabled physicians to treat patients in their offices for opioid addiction with Schedules III, IV and V narcotic controlled substances specifically approved by the FDA for addiction treatment.



For physicians to provide office-based treatment of opioid addiction, they must be able to recognize the condition of drug or opioid addiction and be knowledgeable about the appropriate use of opioid-agonist, antagonist, and partial agonist medications. Physicians must also demonstrate required qualifications as defined in the DATA (Public Law 106-310, Title XXXV, Sections 3501 and 3502) and obtain a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA), as authorized by the Secretary of Health and Human Services.

The Vermont Board of Medical Practice is obligated under the laws of the state of Vermont to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioids, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians must be diligent in preventing the diversion of drugs for illegitimate and non-medical uses.

PHYSICIAN WAIVER REQUIREMENTS

Training requirements for providers of office-based buprenorphine treatment are much more extensive than those needed to prescribe other medications, such as new antidepressants, other psychotropic medications, or antihypertensives.

To apply for a *DATA 2000* waiver to provide office-based treatment to patients with opioid addiction in Vermont, physicians must be licensed in the state of Vermont and must meet at least one of the following requirements:

- ABPN Added Qualification in Addiction Psychiatry
- Certified in Addiction Medicine by the American Society of Addiction Medicine (ASAM)
- Certified in Addiction Medicine by the American Osteopathic Association (AOA)
- Investigator in buprenorphine clinical trials
- Completed eight (8) hours of training provided by one of the following organizations or other designated organizations:

1. American Society of Addiction Medicine (ASAM), www.asam.org/CMEOnline.html (click on Buprenorphine and Office-Based Treatment of Opioid Dependence)
 2. American Academy of Addiction Psychiatry (AAAP), www.aaap.org (click on Buprenorphine, then Web-Based Training)
- Training/experience as determined by state medical licensing board
 - Other criteria established through regulation by the Secretary of Health and Human Services
- Physicians seeing patients under the DEA number of an Opiate Treatment Program (OTP) do not have to apply individually for the waiver and are not required to take the eight hour training course.

Following training, the physician registers at SAMHSA (<http://buprenorphine.samhsa.gov/howto.html>) to obtain a waiver. The physician will then receive an amended DEA number which must be used on all prescriptions for buprenorphine in the treatment of opioid dependence. Failure to use this amended number is a legal violation.

To qualify for a waiver, the physician must have the capacity to refer patients for appropriate counseling and other services that might be needed in conjunction with buprenorphine treatment. These services include, but are not limited to, the following:

- Different levels of chemical dependency treatment services¹
- Psychiatric consultation
- Consultation for medical co-morbidities²
- 12 Step program

Physicians should expect that clinicians to whom they refer their buprenorphine treated patients will have been trained in evidence-based therapies such as Cognitive Behavioral Therapy, Motivation Enhancement Therapy, Dialectical Behavioral Therapy, etc. Patients unfamiliar with these therapeutic approaches may not accept them without

the clinician providing some education about their benefits. Please contact the Alcohol and Drug Abuse Programs (ADAP) office at 802-651-1550 or vtadap@vdh.state.vt.us, as well as the SAMHSA website, for additional assistance for this training.

In addition, a waived physician must be able to provide the following:

- Random urine screening for buprenorphine patients, either on site or in conjunction with a certified laboratory
- Staff and patient education/training program³
- Office policies, procedures and coverage with knowledge and experience using buprenorphine
- Medication security and storage

DATA 2000, as amended in 2006, places limits on the number of patients a physician may treat with buprenorphine. During a waived physician's first year, a maximum of 30 patients may be treated at any one time. One year from the date on which the physician submitted the initial notification to apply for a waiver, the physician may submit a second notification of the need and intent to treat up to 100 patients (<http://buprenorphine.samhsa.gov/howto.html>).

BUPRENORPHINE TREATMENT

The use of agonist treatment, either methadone or buprenorphine, offers physicians an opportunity to move away from abstinence-based treatments and into the use of research grounded therapies. Abstinence-based treatments for opiate dependence are in many ways not compatible with agonist treatment.

Buprenorphine is used for both long-term maintenance and for medically supervised withdrawal/detoxification from opiates. It has been found safe and effective in minimizing withdrawal symptoms, as well as blocking the effects of illicit opiates. It is a partial opioid-agonist: at low doses, it acts as an agonist and at high doses as either an agonist or antagonist depending on the circumstance.

¹ Levels of care range from ambulatory 1:1 substance abuse counseling in conjunction with 12 Step or other community-based recovery support (least restrictive), to inpatient, medically managed acute treatment (most restrictive). (See ASAM level of care placement guidelines and Appendix 7.)

² Medical co-morbidities that may affect use of buprenorphine:

HEPATITIS B, C

- Buprenorphine inhibits hepatic mitochondrial function at high concentrations
- May cause elevation of transaminases, but no documentation of fulminant liver failure due solely to buprenorphine
- Monitor liver enzymes levels in patients with Hepatitis, especially those on Buprenorphine/NALOXONE
- Warn patients not to use Buprenorphine IV
- Renal Failure
- Few studies available
- No significant difference in kinetics of buprenorphine in patients with renal failure vs. controls
- No significant side effects in patients with renal failure

MEDICATION INTERACTIONS

- Cytochrome P450 3A4 Interactions:
 - (1) 3A4 Inhibitors may raise Buprenorphine levels [e.g., Fluoxetine (Prozac), Fluvoxamine (Luvox), nefazodone (Serzone), cimetidine (Tagamet), and possibly antiretrovirals (e.g., ritonavir)]
 - (2) 3A4 Substrates may raise Buprenorphine levels [e.g., trazodone

(Desyrel), alprazolam (Xanax), diazepam (Valium), buspirone (Buspar), zolpidem (Ambien), caffeine, haloperidol (Haldol), pimozone (Orap), erythromycin, nifedipine, oral contraceptives] (3) 3A4 Inducers may lower buprenorphine levels [e.g., carbamazepine, phenobarbital, phenytoin, barbiturates, primidone, St. John's Wort, rifampin protease inhibitors (nelfinavir, lopinavir) non-nucleoside Rtiis (nevirapine, efavirenz)]

- For a complete list of substrates, inhibitors and inducers: www.drugs.com

³ Staff and patient education/training programs (see section of Guidelines on Provider Information and Supports, Resources for Staff and Patient Education)

STAFF EDUCATION

- Treating patient with substance abuse disorders
- The disorder of opiate dependence
- Role and importance of medication in treatment of opioid dependence
- Maintenance of confidentiality
- Treatment philosophy
- Providing medication
- Role of non-pharmacological treatments
- Universal precautions

PATIENT INFORMATION

- Informed consent (see Appendix 6C)
- Treatment agreements (see Appendix 6D)

Unlike morphine or other full agonists, buprenorphine's effects are not linear with increasing doses; it exhibits a "ceiling effect" with respect to the respiratory system, making a lethal overdose unlikely. This property also means that buprenorphine is not right for everyone. Individuals with high opiate needs are better suited for methadone.

Note: The ceiling effect and its potential safety margin are eliminated when buprenorphine is combined with alcohol or a variety of other drugs, such as benzodiazepines, especially if injected. There have been reports of disastrous consequences when small children are exposed even briefly to buprenorphine as the "ceiling effect" does not appear to hold for this population. Providers should educate all patients on the importance of safe medication storage and what to do if a child comes in contact with any of the buprenorphine preparations. (Boyer EW, McCance-Katz E, Marcus, S., Methadone and Buprenorphine Toxicity in Children The American Journal on Addictions, 19: 89–95, 2009)

Insurance

Please consult your patient's health insurance carrier for preauthorization information.

Preauthorization

A medication preauthorization is required prior to starting a patient on buprenorphine. See *Appendix 3* for the Preauthorization Form for the Department of Vermont Health Access (DVHA), available at <http://dvha.vermont.gov/for-providers/buprenorphine-prior-auth-form-2009-11.pdf>.

Buprenorphine Preparations for MAT

Two sublingually dissolved buprenorphine preparations are currently available.

1. SUBUTEX is a mono-therapy containing only buprenorphine. It is available from a pharmaceutical house in small supply to be kept in physicians' offices. This preparation is more easily diverted and should be judiciously used.
2. SUBOXONE is a combination therapy, containing both buprenorphine and naloxone. Naloxone has been added to avoid diversion and intravenous abuse. Suboxone is the recommended preparation for induction, maintenance, and, if necessary, supervised withdrawal (detoxification).

To minimize diversion of buprenorphine, especially the mono-therapy product, it is recommended that Subutex only be used during the management of pregnant, opioid dependent women or in the extremely rare occurrence of allergy or intolerance to Suboxone (not just because the patient does not like the taste of Suboxone). Allergy or intolerance to Suboxone should be fully documented, including but not limited to witnessing by the treating provider.

BUPRENORPHINE DURING PREGNANCY. Although neither preparation has been approved for use during pregnancy, Subutex has been used for medically assisted treatment (MAT) during pregnancy. In addition, although the mono-product is preferred, women have conceived and delivered on the

combination-therapy product. For more information about treatment of opioid dependence during pregnancy, please contact Marjorie Meyer, MD, at Fletcher Allen Health Care/ University of Vermont at Marjorie.meyer@uvm.edu. To refer a patient directly for treatment, contact the Comprehensive Obstetrics and Gynecology Service at Fletcher Allen Health Care at 802-847-1400. You may also contact John Brooklyn, MD, at the Howard Center Chittenden Clinic, c/o University Health Care, 1 South Prospect Street, Burlington, VT 05401, 802-656-3700 or 800-413-2272.

Treatment Settings

OFFICE-BASED PRACTICE CARE may be provided by a solo practitioner or a group practice with the required training and ability to provide clinical evaluation, buprenorphine induction, maintenance and follow up. The practitioner or group also must be able to provide consultation and referrals as needed with primary care providers, medical specialists and counseling services. Some practitioners may be able to provide all services on their own (e.g., an addictions psychiatrist with buprenorphine training).

OPIATE TREATMENT PROGRAMS (OTPs) may provide Subutex or Suboxone following the same regulations that exist for methadone treatment (42 CFR Part 8: Code of Federal Regulations, Title 42: Public Health, Part 8—Certification of Opioid Treatment Programs, <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=d5f2d13f11085410f289dd08209805f4;rgn=div5;view=text;node=42%3A1.0.1.1.9;idno=42;cc=ecfr>), including a take-home schedule in which buprenorphine is dispensed from the window without giving a prescription. Due to the long-acting nature of buprenorphine, multiple day dosing can occur two to three times per week. Buprenorphine is part of the OTP's DEA registration, not an individual physician's; consequently, physicians working in OTPs do not have to seek a waiver or complete the eight hour training. In addition, these programs are exempt from the 30 patient limit.

Practices planning to provide buprenorphine in an office-based setting for more than 30 patients should review the Federal Guidelines for methadone clinics and consider issues such as "no drive" and "impairment" assessments.

Challenges with Buprenorphine Treatment in Vermont

BROADER POPULATION THAN ANTICIPATED. Office-based treatment of opioid dependence with buprenorphine was originally intended for a rather circumscribed population with existing community supports and relatively shorter addiction histories. However, demand for opioid replacement therapy in Vermont, along with insufficient availability of methadone programs, has resulted in a broader use of buprenorphine services than originally anticipated. Examples of some unexpected difficulties include:

- Patients are more time consuming than expected
- Counseling resources are not readily available
- Reports of diversion and injection have increased

Nevertheless, many physicians treat patients with excellent results and successful integration into their practices. Patient selection criteria are important.

DIVERSION of both the mono and combination buprenorphine preparations present additional challenges; most reports suggest these primarily are “lateral” or “addict to addict” diversions to help bridge the gap while awaiting treatment or when street drug supplies are limited. However, the Department of Corrections has reported that buprenorphine is one of their most frequently found contraband items among inmates, and many inmates who are not recorded as being prescribed buprenorphine are testing positive for it on random toxicology screens.

Physicians must inform patients that diversion is a reportable criminal offense, and indicate how suspicions or evidence of diversion will be handled clinically by the practice. Practices should have clinical procedures in place for minimizing diversion risk to ensure appropriate addiction treatment, such as the following:

- Routine toxicology screens
- Pill call backs (for counting)
- Bubble packing of prescriptions

Physicians also should make use of the Vermont Prescription Drug Monitoring System (VPMS), established by the Vermont Department of Health to provide health care professionals with as much information as possible to guide their prescribing practices. The VPMS may be accessed online by registered prescribers and pharmacists at <http://healthvermont.gov/adap/VPMS.aspx>. Additional information is available through the Alcohol and Drug Abuse Programs (ADAP) office at 802-652-4147.

All these concerns underscore the need for integrated and coordinated services for buprenorphine patients, with associated challenges regarding confidentiality and sharing necessary information to ensure all treatment providers are aware of the proposed treatment plan and specific patient issues. All information sharing must conform to current 42 CFR Part 2 (Code of Federal Regulations, Title 42: Public Health, Part 2 – Confidentiality of Alcohol & Drug Abuse Patient Records, <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=d5f2d13f11085410f289dd08209805f4&rgn=div5&view=text&node=42:1.0.1.1.2&idno=42>) and HIPAA standards for release of information forms (see *Appendix 6A* for sample Consent for Release of Information forms).

PHASES OF BUPRENORPHINE TREATMENT

Screening/Intake

Initial screening for opioid addiction should consist of a combination of interviews, objective screening instruments and laboratory evaluations (see *Appendices B I* and *B II* for examples of screening and assessment tools that may help determine how appropriate a patient is for office-based treatment), and include the following:

1. Medical history with attention paid to liver and cardiac

status and medications.

2. Psychiatric history with attention to treatment adherence including medications and counseling.
3. Substance abuse history and treatment history to identify whether patient was ever on buprenorphine and to insure patient is not currently on methadone but meets criteria for Opiate Dependence (see *Appendix 1*, DSM-IV Diagnosis of Opiate Dependence). If a patient reports they have been using buprenorphine obtained on the street, and even provides the dose they have been taking, they still should go through the induction process to determine the appropriate clinical dose.
4. Social, work, and family circumstances history.
5. Physical exam, mental status exam.
6. Lab screening for ALT, AST, Hep B and C, HIV, Gonorrhea, Chlamydia, Syphilis, TB test.
7. Urine screen (witnessed) with attention to opiates, including methadone and buprenorphine, and benzodiazepines.
8. If urine is negative for opiates (which may occur with synthetic opiates), evidence of IV puncture marks on the skin and evidence of withdrawal symptoms, such as runny eyes, sniffing, yawning, tremor, sweating, gooseflesh, vomiting, abdominal cramps, muscle aches, pupil dilation. The *CINA Scale* (*Clinical Institute for Narcotic Assessment Scale for Withdrawal Symptoms*) can be very useful (see *Appendix 4*).
9. In some cases, dependence may be diagnosed through the use of 1 cc of naloxone (Narcan) (0.4 mg/ml) injected subcutaneously followed by observing the patient for up to 30 minutes for evidence of precipitated withdrawal. Naltrexone (ReVia) would not be used due to the protracted withdrawal syndrome it causes. (Narcan Challenge)
10. Patients who have recently been released from prison or other restrictive, drug-free environments, may not demonstrate evidence of withdrawal. They may still be appropriate for treatment with buprenorphine to avoid relapse.
11. Women using illicit opioids may experience menstrual cycle irregularity and infertility. Unplanned pregnancy can occur as women recover and improve their health status. As opioid-agonist therapy is initiated, the potential for pregnancy should be addressed and a plan for contraception developed. If pregnancy is desired, women should receive a prescription for prenatal vitamins (for additional folic acid).

POSSIBLE INDICATIONS OF LESS APPROPRIATE CANDIDACY.

Certain factors may suggest a patient is LESS likely to be an appropriate candidate for office-based buprenorphine treatment (see *Appendices B I* and *B II* for criteria and guidelines for assessing candidacy). Some factors to consider include the following:

- Dependence on high doses of benzodiazepines, alcohol, or other CNS depressants
- Significant psychiatric co-morbidity
- Active or chronic suicidal or homicidal ideation or attempts
- Multiple previous treatments and relapses
- Non-response to buprenorphine in the past

- High level of physical dependence (risk for severe withdrawal)
- High relapse risk
- Pregnancy
- Current medical conditions that could complicate treatment
- Poor support systems
- Patient needs cannot be addressed with existing office-based resources

PATIENT CONSENT, TREATMENT AGREEMENTS, AND RELEASE OF INFORMATION FORMS. Once all screening information has been evaluated, both physician and patient review and sign a Consent for Treatment form and a Treatment Agreement (see *Appendices 6B, 6C and 6D* for sample Patient Information, Consent for Treatment and Buprenorphine Treatment Agreement forms). One copy is kept in the medical record and one goes to the patient. A copy of the agreement also should be sent to the pharmacy.

Release of Information forms should be completed for the substance abuse counselor and the pharmacy that will be dispensing the medication. Any other individuals or agencies, such as the psychiatrist, VNA, Family Services Division of the Department for Children and Families, referring treatment center, etc., should also have releases signed and placed in the patient chart (see *Appendix 6A* for sample Release of Information forms).

Induction

Induction onto buprenorphine is considered to be an ambulatory procedure not requiring an inpatient admission unless there are medical complications or other extenuating circumstances. The induction steps listed below are guidelines intended to ensure close monitoring during the initial phases of treatment. Dosing guidelines based on reported drug use can be helpful in targeting eventual final buprenorphine doses. (See Guide for Dose Targets, end of this section.)

General Guidelines for patients physically dependent on opioids:

1. Begin induction early in the week.
2. Plan on 3-5 days for stable dosing.
3. Patient's last reported use should have been at least 6 hours prior to induction.
4. **MAKE SURE THE PATIENT IS NOT ON METHADONE** as buprenorphine may cause an acute withdrawal syndrome; if patient is on methadone, see below protocol for long acting opiates.
5. Day 1: Give the patient a prescription for #2 2mg Suboxone tablets.
6. Patient takes the prescription to the pharmacy and returns to the office with the medication.
7. Patient takes the tablet and lets it dissolve under the tongue for 5 minutes with no talking, drinking, or swallowing.

8. Target buprenorphine dose range should be 12mg to 16mg per day, with a recommended maximum of 16mg daily.
9. If more than 8mg are needed, gradually increase the dose in 2mg increments over the next several days.
10. The patient's condition before dosing time is one of the best ways to assess adequacy of the dose. (Refer to *Appendix 5, Clinical Opiate Withdrawal Scale (COWS)*, for assessing withdrawal symptoms before the first dose is given and throughout the Induction period.

Guidelines for patients NOT physically dependent on opioids (e.g., coming out of incarceration or otherwise high-risk for relapse):

First dose: 2mg sublingual buprenorphine.

Monitor for 2+ hours and consider 2mg incremental dosage increases over the next several days.

Specific recommendations for patients dependent on Short-acting opioids:

1. Instruct patient to abstain from any opioid use for a minimum of 6-12 hours so they are in mild withdrawal at time of first buprenorphine dose. Note: If patient is not in withdrawal, have them wait and reassess their use or abstinence over past 12-24 hours or return another day.
2. Week 1, Day 1: First dose: 2mg sublingual Suboxone (combination therapy) with direct observation after 5 minutes that the medication is dissolved.
3. Monitor in office for up to 2 hours to insure no vomiting and tolerance of the dose.
4. Send patient home with the additional 2 mg dose and redose in 2-4 hours if withdrawal subsides, then reappears. Maximum dose for first day: 4 mg.
5. Day 2: Patient returns to office. If looks well, renew same dose of 4 mg for the next 2 days. If shows signs of withdrawal based on CINA Scale and/or Clinical Opiate Withdrawal Scale, prescribe #4 2 mg tabs, have patient go to pharmacy, return to office with medication and take 3 pills in front of nurse; wait 5 minutes and then send home and redose later in the day if needed. Maximum dose for second day: 8 mg.
6. Day 3: If patient needed the dose adjustment on Day 2, have them return for direct observation pre-dose and if looks well, give prescription for 8 mg tabs for 3 days and send them home. Have patient return for follow-up in 2 days. If showing signs of withdrawal on CINA score, give a prescription for 10 mg to take for the next 3 days.
7. Day 4: If patient stable on 4 mg on Day 2, make sure they are well and give one week's supply to take at home. If dose needs adjustment, increase to 6 mg and give one week's supply to take at home.
8. Day 5: If patient from Day 3 shows any signs of withdrawal, give an additional 2 mg dose per day and give a week's supply. Maximum dose: 12 mg.
9. Week 2: Before renewing the week's supply, have patient come in pre-dose to assess whether any adjustment in dose is needed; if needed, adjust by 2-4 mg. Maximum dose: 16 mg.

*NOTE: If a patient has insurance co-pay, consider writing prescription for #16 pills of 2 mg for a minimum of 4 days of induction. The patient can bring the pills in each day for directly observed dosing to make sure they are taking them. **The most critical thing is making sure the patient is taking the correct dose. Doing this early will reduce diversion later on.***

Specific recommendations for patients dependent on LONG ACTING opioids:

1. Doses of methadone should be decreased to a stable state of 30mg of methadone or equivalent.
2. The following dose equivalents are target doses, not starting doses:
Methadone 40 mg = Buprenorphine 8 mg
Methadone 60 mg = Buprenorphine 12 mg
Methadone 80 mg = Buprenorphine 16 mg
3. Begin Induction 24 hours after last methadone. No additional methadone given after Induction begins.
4. Follow same protocol for short-acting opioids, but faster dose adjustments may be needed daily for the first week.

Stabilization

Patient should receive daily dose until stabilized.

An option is to shift to alternate day dosing, by increasing the amount on the dosing day by the amount not received on the intervening days (see #5 below).

1. Urine screens should be done once a week.
2. Non-attendance for counseling for more than two

consecutive sessions should trigger an automatic call from the counselor. The physician should schedule an office visit with the patient to make sure the patient understands that failure to follow through with counseling jeopardizes treatment and puts them outside of "good standing."

3. Write 7 days' worth of medication at a time for 2 months and appropriateness of treatment in an office-based setting will be re-evaluated.

Maintenance and Follow Up

4. Once patient has remained compliant with counseling and physician visits, has not had any mishaps with the Suboxone, and feels ready to do so, extend the prescriptions to 14 days for the next 2 months.
5. A patient may choose to take Suboxone every 2 or 3 days. The dose is doubled or tripled, depending on the time frame, and taken all at once. This is very effective in controlled settings, such as dispensing by a family member or clinic, but may be done for patient preference only.
6. After an agreed upon period of treatment adherence, prescriptions for 30 days may be written. Random pill counts may be useful at this point.
7. Urine drug testing is now available for determining the presence of the buprenorphine metabolite and this may be used as a clinical tool to encourage success in treatment, as well as a precautionary measure for avoiding diversion.

SUBOXONE TAPER REGIMEN FOR TWO STUDY TAPER GROUPS

Stabilization*Dose		7-Day Taper Period			28-Day Taper Period		
		8 mg	16 mg	24 mg	8 mg	16 mg	24 mg
Study Day	1	8	16	24	8	16	24
	2	6	12	20	8	16	24
	3	6	10	17	6	12	20
	4	4	8	12	6	12	20
	5	4	4	8	6	12	20
	6	2	2	4	6	10	16
	7	2	2	2	6	10	16
	8				6	10	16
	9-11				6	8	12
	12-14				4	8	10
	15-16				4	6	8
	17-19				4	4	6
	20-22				2	4	4
	23-25				2	2	2
	26-28				2	2	2

*dose noted is the dose of buprenorphine

Ling, W., et al., Buprenorphine Tapering Schedule and Illicit Opioid Use, *Addiction*, 104, 2009.

GUIDE FOR DOSE TARGETS

Buprenorphine Doses	Oxycodone	Morphine	Heroin	Methadone
2 mg	30 mg	60 mg	1-2 bags	10 mg
4 mg	60 mg	120 mg	3 bags	20 mg
6 mg	90 mg	180 mg	4 bags	30 mg
8 mg	120 mg	240 mg	6 bags	40 mg
12 mg	180 mg	360 mg	8 bags	60 mg
16 mg	240 mg	480 mg	10 bags	80 mg

Tapering Patients Off a Stable Buprenorphine Dose

There may be well-stabilized patients who desire to be withdrawn from buprenorphine medication. There is evidence a relatively quick taper from buprenorphine may be advantageous and will not result in relapse at greater rates than for patients weaned more slowly. Research comparing relatively shorter taper periods (7-days) with relatively longer ones (28-days) found a higher percentage of patients in the 7-day taper group were opioid free at the end of the taper, and both self-reports and physician observation of withdrawal symptoms and craving were no different between the two groups. In addition, no differences between the two groups were found in the rate of relapse to illicit opioid use three months after the taper period ended. The following table provides taper schedules for both taper periods.

Detoxification

Rapid detox: Three days or less

- Low doses of buprenorphine given 2-3 times daily
- More effective in suppressing withdrawal than clonidine
- Long term efficacy not well documented
- Not recommended due to poor outcomes and should only be done when there is a compelling reason for patient to be detoxed quickly (e.g., out of country travel, imminent incarceration)

Moderate detox: 30 days or less

- Raise dose daily over 4 days to equal opiates taken, then decrease by 2 mg every 1-2 days until weaned
- Better tolerated than clonidine
- Few studies of buprenorphine for this time period

Long detox: more than 30 days

- Raise dose daily over 4 days to equal opiates taken, then reduce by 2 mg weekly until weaned
- Not well studied but some evidence suggests this approach is more efficacious than briefer ones, especially if naltrexone is started after an appropriate wash out period

Management of Acute Pain in Patients Receiving Buprenorphine

Management of acute pain in patients receiving buprenorphine products (either mono therapy or combination buprenorphine/naloxone) is a common clinical challenge. While no approach to this has been rigorously tested, commonly accepted principles have developed over the years. The following article also may be of interest: www.pcssmentor.org/pcss/documents2/PCSS_AcutePain_052307.pdf

Buprenorphine blocks opiate receptors, making them unavailable for further opiate analgesic effects. The dose of buprenorphine predicts how many of the receptors are blocked; generally, any buprenorphine dose above 10 mg will block opiate analgesics for pain.

As a general rule, a patient who will experience acute pain from surgery or a recent injury should have the dose of buprenorphine reduced to 8 mg; to make up the opiate debt, the remaining amount of buprenorphine is converted to short-acting opiates. (Refer to the chart on page 18 of these Guidelines for reasonable equal-analgesic doses of oxycodone and morphine.)

For example, carpal tunnel release surgery is planned for a patient taking 16 mg of buprenorphine. The typical post operative treatment for this surgery is 10 mg of oxycodone every 4 hours for 3 days. Therefore, the patient would stop taking one of the 8 mg buprenorphine tablets the day of surgery. A prescription for 30 mg of oxycodone to be taken 4 times a day for 3 days would be provided to MAKE UP THE OPIATE DEBT FROM THE 8 MG OF BUPRENORPHINE that has been stopped. In addition, post operatively the patient would take 10 mg of oxycodone every 4 hours for the 3 post operative days.

After the end of the 3 day post operative period, the patient resumes taking the 8 mg of buprenorphine that had been stopped, discontinues the replacement oxycodone, and begins using non-opiate analgesics. Of course, in cases with persistent pain the above regimen could be continued for a longer period of time, and for some procedures several weeks might be needed. Seeing the patient every 3-5 days to manage their pain is most effective as it provides the patient with stability and prevents relapse and misuse of opiates.

PROVIDER INFORMATION AND SUPPORTS

Vermont Opioid Treatment Provider List Serve

This is a provider-only list serve hosted by the Vermont Medical Society that serves as a venue for buprenorphine providers to obtain support from other Vermont providers. The email address is: opiatetreatment@Vtmd.org. To register with the list serve and receive information, please contact Stephanie Winters at swinters@vtmd.org.

Physician Clinical Support System (PCSS)

The SAMHSA-funded PCSS is designed to assist practicing physicians, in accordance with the Drug Addiction Treatment Act of 2000 (DATA 2000), with incorporating buprenorphine treatment of prescription opioid and heroin dependent patients into their practices. Physicians may use this resource for assistance with obtaining a mentor for beginning an office-based practice. The PCSS service is available, at no cost, to interested physicians and staff. <http://pcssmentor.org>. Phone: 877-630-8812

SAMHSA Websites

Substance Abuse and Mental Health Services Administration (SAMHSA): www.samhsa.gov and www.buprenorphine.samhsa.gov. Provides information on the *DATA 2000*, physician waiver qualifications, how to request a waiver form, buprenorphine trainings, and other information.

Center for Substance Abuse Treatment (CSAT): csat.samhsa.gov. Phone: 866-BUP-CSAT

National Clearinghouse for Alcohol and Drug Information (NCADI) – a Department of Health and Human Services and SAMHSA website: www.health.org

Resources for Staff and Patient Education

Medication-Assisted Treatment For Opioid Addiction in Opioid Treatment Programs Inservice Training, based on Treatment Improvement Protocol 43. http://buprenorphine.samhsa.gov/bwns/tip43_curriculum.pdf

Buprenorphine: A Guide for Nurses http://buprenorphine.samhsa.gov/bwns/TAP_30_Certified.pdf

Note: Guides for Counselors and Pharmacists will be made available in the near future through SAMHSA. For questions: info@buprenorphine.samhsa.gov

Responsible Opioid Prescribing: A Physician's Guide. Scott Fishman, MD. Waterford Life Sciences, Washington, DC, 2007.

Universal Precautions: A Matter of Mutual Trust and Responsibility. Pain Medicine. Goulay, D., and Heit, H. March-April 2006, 7(2):210-211, author reply, 212.

Other Substance Abuse-Related Web Sites

American Academy of Addiction Psychiatry (AAAP). Web-based training, information on live training, news, governmental agency links: www.aaap.org/buprenorphine/buprenorphine.html. Phone: 401-524-3076

Food and Drug Administration. Provides talk paper, drug label, patient leaflet, physician information, pharmacist information, Q&A about Subutex and Suboxone: www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm

Addiction Treatment Watchdog (ATW): www.atwatchdog.org

AL-ANON and ALATEEN: www.al-anon.alateen.org

American Association for the Treatment of Opioid Dependence (AATOD) – formerly the American Methadone Treatment Association, Inc: www.aatod.org

Join Together Online – Take Action Against Substance Abuse and Gun Violence: www.jointogether.org

Narcotics Anonymous: www.na.org

National Alliance of Methadone Advocates (NAMA): www.methadone.org

Project Cork, Authoritative Information on Substance Abuse, Dartmouth Medical School: www.projectcork.org

REFERENCES

Buprenorphine Clinical Practice Guidelines Field Review Draft, November 17, 2000.

Buprenorphine in the Treatment of Opioid Dependence. American Academy of Addiction Psychiatry. Eric Strain, MD and Jeff Novey, MPH.

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. SAMHSA/CSAT Treatment Improvement Protocols, TIP 40. Laura McNicholas, MD, PhD, Consensus Panel Chair.

Confidentiality of Patient Records for Alcohol and Other Drug Treatment. Center for Substance Abuse Treatment, Technical Assistance Publication (TAP) Series, Number 13. Rockville, MD: Center for Substance Abuse Treatment, 1994.

Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV).

Drug Addiction Treatment Act of 2000 (DATA 2000).

Patient Placement Criteria. American Society of Addiction Medicine.

PCSS Guidance – Treatment of Acute Pain in Patients Receiving Buprenorphine/Naloxone. David Fiellin, MD. Physician Clinical Support System, November 10, 2005.

Use of Buprenorphine in Pharmacologic Management of Opioid Dependence. Elinore F. McCance-Katz, MD, PhD, course director. Medical College of Virginia.

Appendix 1: DSM-IV Diagnosis of Opiate Dependence

Maladaptive pattern of use, leading to significant impairment or distress, as manifested by 3 or more of the following, occurring at any time in the same 12-month period:

1. Tolerance, as defined by decreased effect with same amount or increased amount needed to achieve same effect.
2. Withdrawal, as defined by characteristic syndrome for the substance when withdrawn or closely related substance taken to relieve the syndrome.
3. An increase in the amount or the duration from what was intended.
4. Persistent desire or unsuccessful attempts to cut down or control use.
5. Spending a great deal of time in activities needed to obtain or use the substance or recover from the effects of it.
6. Giving up social, occupational, or recreational activities because of use.
7. Continuing the use despite knowing that it is causing or worsening a persistent or recurrent psychological or physical problem.

Appendix 2A: Ten Factor Office-Based Criteria Check List

In general, 10 factors help determine whether a patient is appropriate for office-based buprenorphine treatment. This checklist may be useful during the screening process. Check “yes” or “no” next to each factor.

FACTOR

- | | |
|---|--|
| 1. Does the patient have a diagnosis of opioid dependence? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Is the patient interested in office-based buprenorphine treatment? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. Is the patient aware of the other treatment options? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4. Does the patient understand the risks and benefits of buprenorphine treatment and that it will address some aspects of the substance abuse, but not all aspects? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. Is the patient expected to be reasonably compliant? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6. Is the patient expected to follow safety procedures? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 7. Is the patient psychiatrically stable? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 8. Are the psychosocial circumstances of the patient stable and supportive? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 9. Are resources available in the office to provide appropriate treatment?
Are there other physicians in the group practice?
Are treatment programs available that will accept referral for more intensive levels of service? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 10. Is the patient taking other medications that may interact with buprenorphine, such as naltrexone, benzodiazepines, or other sedative-hypnotics? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

Source: Based on the CSAT-funded curriculum *Use of Buprenorphine in the Pharmacologic Management of Opioid Dependence*. American Academy of Addiction Psychiatry on line training. Eric Strain, MD and Jeff Novey, MPH. Course revised by Elinore F. McCance-Katz, MD, Ph.D., 2004.

Appendix 2B: Guidelines for Assessing Appropriateness for Office-Based Buprenorphine Treatment*

The following guidelines will help in deciding whether to treat with buprenorphine in the office. They assume the person is opioid dependent.

SCORING KEY

- 0-5: Excellent candidate for office-based treatment.
- 6-10: Good candidate for office-based treatment.
- 11-15: Good candidate, but only with tightly structured program providing supervised dosing and on site counseling.
- 16-20: Candidate for office-based treatment by board certified addiction physician in a tightly structured program or hub induction with follow-up by office-based provider or methadone clinic referral.
- 21-25: Candidate for methadone program only.

For each answer check YES or NO and add points for YES and NO below.

Questions	Points:	Yes	No	Possible
Is the person employed?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Is the family intact?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have a partner who uses drugs or alcohol?		<input type="checkbox"/> 1	<input type="checkbox"/>	<input type="checkbox"/> 1
Is the person's housing stable?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have legal issues?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have any convictions for drug dealing?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Is the person on probation?		<input type="checkbox"/> 1	<input type="checkbox"/>	<input type="checkbox"/> 1
Does the person have psychiatric problems, e.g., major depression, bipolar, severe anxiety, PTSD, schizophrenia, personality subtype of antisocial, borderline, or sociopathy?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Does the person have a chronic pain syndrome that needs treatment?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Does the person have reliable transportation?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have a reliable phone number?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Has the person been on medicated assisted treatment before?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Was the medicated assisted treatment successful?		<input type="checkbox"/>	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Does the person have a problem with alcohol?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Does the person have a problem with cocaine?		<input type="checkbox"/> 1	<input type="checkbox"/>	<input type="checkbox"/> 1
Does the person have a problem with benzodiazepines?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Is the person motivated for treatment in the office?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Is the person currently going to counseling, AA, or NA?		<input type="checkbox"/>	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Total points possible: 25	Total each column:			
	Total both columns:			

Provided by John R. Brooklyn, MD, May 21, 2009

Appendix 3: DVHA Buprenorphine Prior Authorization Request Form



Office of Vermont Health Access Agency of Human Services, 312 Hurricane Lane, Suite 201, Williston, VT 05495

BUPRENORPHINE PRIOR AUTHORIZATION REQUEST FORM

Vermont Medicaid has established criteria for prior authorization of buprenorphine (Suboxone®, Subutex®). These criteria are based on concerns about safety and the potential for abuse and diversion. For beneficiaries to receive coverage for Suboxone® or Subutex®, it will be necessary for the prescriber to telephone or complete and fax this form to MedMetrics Health Partners. Please complete this form in its entirety and sign and date below. Incomplete requests will be returned for additional information.

Submit request via: Fax: 1-866-767-2649 or Phone: 1-800-918-7549

Prescribing physician:

NAME

PHONE

FAX

ADDRESS

CONTACT PERSON AT OFFICE

PHARMACY

PHONE

FAX

Beneficiary:

NAME

MEDICAID ID NO.

DATE OF BIRTH

DIAGNOSIS

Qualifications:

MD/DO	Prescribers must have a DATA 2000 waiver ID (X-DEA license) in order to prescribe.
Patients	Patients must have a diagnosis of opiate dependence confirmed.

Process: Answer the following questions.

Is buprenorphine being prescribed for opiate dependency?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the prescriber signing this form have a DATA 2000 waiver ID number (X-DEA license)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Request is for the following medication: <input type="checkbox"/> Suboxone® (buprenorphine/naloxone) <input type="checkbox"/> Subutex® (buprenorphine)	
Anticipated maintenance dose/frequency: Dose _____ Frequency: _____	
If this request is for Subutex®, please answer the following questions: Is the member pregnant? If yes, anticipated date of delivery: _____ Does the member have a documented allergic reaction to naloxone that has been witnessed by a health care professional? If yes, please provide medical records documenting the allergic reaction.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
Additional clinical information to support PA request: 	

PRESCRIBER SIGNATURE

DATE

Appendix 4: Clinical Institute Narcotic Assessment (CINA) Scale for Withdrawal Symptoms

The Clinical Institute Narcotic Assessment (CINA) Scale measures 11 signs and symptoms commonly seen in patients during narcotic withdrawal. This can help to gauge the severity of the symptoms and to monitor changes in the clinical status over time.

Parameters Based on Questions and Observation	Findings	Points
1 Abdominal changes: Do you have any pains in your abdomen? Crampy abdominal pain, diarrhea, active bowel sounds.	No abdominal complaints, normal bowel sound. Reports waves of crampy abdominal pain.	0 1 2
2 Changes in temperature: Do you feel hot or cold? clammy to touch. Uncontrolled shivering.	None reported. Reports feeling cold, hands cold and	0 1 2
3 Nausea and vomiting: Do you feel sick in your stomach? Have you vomited?	No nausea or vomiting. Mild nausea; no retching or vomiting. Intermittent nausea with dry heaves. Constant nausea; frequent dry heaves and/or vomiting.	0 2 4 6
4 Muscle aches: Do you have any muscle cramps?	No muscle aching reported, arm and neck muscles soft at rest. Mild muscle pains. Reports severe muscle pains, muscles in legs, arms or neck in constant state of contraction.	0 1 3
Parameters based on Observation Alone	Findings	Points
5 Goose flesh	None visible. Occasional goose flesh but not elicited by touch; not permanent. Prominent goose flesh in waves and elicited by touch. Constant goose flesh over face and arms.	0 1 2 3
6 Nasal congestion	No nasal congestion or sniffing. Frequent sniffing. Constant sniffing, watery discharge.	0 1 2
7 Restlessness	Normal activity. Somewhat more than normal activity; moves legs up and down; shifts position occasionally. Moderately fidgety and restless; shifting position frequently. Gross movement most of the time or constantly thrashes about.	0 1 2 3
8 Tremor	None. Not visible but can be felt fingertip to fingertip. Moderate with patient's arm extended. Severe even if arms not extended.	0 1 2 3
9 Lacrimation	None. Eyes watering; tears at corners of eyes. Profuse tearing from eyes over face.	0 1 2
10 Sweating	No sweat visible. Barely perceptible sweating; palms moist. Beads of sweat obvious on forehead. Drenching sweats over face and chest.	0 1 2 3
11 Yawning	None. Frequent yawning. Constant uncontrolled yawning.	0 1 2
TOTAL SCORE	Sum of points for all 11 parameters	

Minimum score = 0, Maximum score = 31. The higher the score, the more severe the withdrawal syndrome.
Percent of maximal withdrawal symptoms = total score/31 x 100%.

Source: Adapted from Peachey, J.E., and Lei, H. Assessment of opioid dependence with naloxone. *British Journal of Addiction* 83(2):193–201, 1988.
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Appendix 5: Clinical Opiate Withdrawal Scale (COWS)

For Suboxone (Buprenorphine/naloxone) induction: Enter scores at time zero, 1-2 hours after first dose, and at additional times Suboxone is given over the induction period.

	Date/Time	Date/Time	Date/Time
Resting Pulse Rate: (record beats per minute) <i>Measured after patient is sitting/lying for one minute.</i> 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120			
Sweating: <i>Over past ½ hour not accounted for by room temperature or patient activity.</i> 0 no report of chills or flushing 1 one subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face			
Restlessness: <i>Observation during assessment.</i> 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 2 unable to sit still for more than a few seconds			
Pupil Size: 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 2 pupils so dilated that only rim of the iris is visible			
Bone or Joint Aches: <i>If patient was having pains previously, only the additional component attributed to opiate withdrawal is scored.</i> 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort			
Runny Nose or Tearing: <i>Not accounted for by cold symptoms or allergies.</i> 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks			
GI Upset: <i>Over last ½ hour.</i> 0 no GI symptoms 1 stomach cramps 2 nausea or loose stools 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting			
Tremor: <i>Observation of outstretched hands.</i> 0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching			
Yawning: <i>Observation during assessment.</i> 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute			
Anxiety or Irritability 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable, anxious 4 patient so irritable or anxious that participation in the assessment is difficult			
Gooseflesh Skin 0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection			
Total Score			
Observer's Initials			
Blood Pressure/Pulse			
Dose of Suboxone Given			

SCORE Mild: 5-12 Moderate: 13-24 Moderately Severe: 25-36 Severe Withdrawal: More than 36

Appendix 6A: Patient Consent for Release of Information

SAMPLE 1

I, _____, born on _____
PATIENT NAME PATIENT BIRTH DATE

SSN _____, authorize _____ to _____
PATIENT SOCIAL SECURITY NO. CLINIC /DOCTOR'S NAME

disclose to _____
NAME AND LOCATION OF PERSON/ORGANIZATION TO RECEIVE INFORMATION

the following information: _____

The purpose of this disclosure is: _____

This authorization expires on: _____, or

whenever _____ is no longer providing me with services.

Appendix 6A: Release of Information Form

SAMPLE 2

Required elements:

A written consent to a disclosure under these regulations must include:

1. The specific name or general designation of the program or person permitted to make the disclosure.
2. The name or title of the individual or the name of the organization to which disclosure is to be made.
3. The name of the patient.
4. The purpose of the disclosure.
5. How much and what kind of information is to be disclosed.
6. The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under §2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under §2.15 in lieu of the patient.
7. The date on which the consent is signed.
8. A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.
9. The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

Sample consent form:

The following form complies with the required elements above, but other elements may be added.

1. I (patient name) ☐ Request ☐ Authorize: _____
2. Name or general designation of program which is to make the disclosure: _____
3. To disclose (kind and amount of information to be disclosed): _____
4. To: (name or title of the person or organization to which disclosure is to be made): _____
5. For (purpose of the disclosure): _____
6. Date (on which this consent is signed): _____
7. Signature of patient: _____
8. Signature of parent or guardian (where required): _____
9. Signature of person authorized to sign in lieu of the patient (where required): _____

Appendix 6B: Buprenorphine/Naloxone (Suboxone) Maintenance Treatment Information for Patients

BUPRENORPHINE/NALOXONE (SUBOXONE) TREATMENT FOR OPIOID ADDICTION

Buprenorphine is an opioid medication which has been used as an injection for treatment of pain while patients are hospitalized, for example for surgical patients. It is a long acting medication, and binds for a long time to the “mu” opioid receptor.

Buprenorphine/naloxone or Suboxone is a combination medication that can be used to treat opioid dependence (addiction). Patients only need to take medication once daily and some will be able to take this medication less frequently (every other day or every third day). Buprenorphine is not absorbed very well orally (by swallowing) – so a sublingual (dissolve under the tongue) tablet has been developed for treatment of addiction. Buprenorphine/naloxone (Suboxone) tablets also contain a small amount of naloxone (Narcan) which is an opioid antagonist. Naloxone is poorly absorbed from under the tongue, but if Suboxone is injected, the naloxone will cause withdrawal symptoms. The reason that naloxone is combined with the buprenorphine in Suboxone is to help discourage abuse of this drug by injection.

Aside from being mixed with naloxone to discourage needle use, buprenorphine itself has a “ceiling” for narcotic effects (it is termed a “partial agonist”) which makes it safer in case of overdose. This means that by itself, even in large doses, it doesn’t suppress breathing to the point of death in the same way that heroin, methadone and other opioids could do in huge doses. These are some of the unusual qualities of this medication which make it safer to use outside of the usual strict methadone regulations at a clinic and, after stabilization, most patients would be able to take home up to two-four weeks worth of buprenorphine/naloxone (Suboxone) at a time.

Will Buprenorphine/Naloxone (Suboxone) be Useful for Patients on Methadone?

Methadone maintenance patients may be interested in whether this medication might help them. Unfortunately, because of the partial agonist nature of the medication, it is not equivalent in maintenance strength to methadone. In order to even try buprenorphine/naloxone (Suboxone) without going into major withdrawal, a methadone-maintained patient would have to taper down to 30 mg of methadone

daily or lower. In some cases, buprenorphine may not be strong enough for patients used to high doses of methadone and may lead to increased cravings and the risk of a relapse to opiate use. If you are methadone-maintained and decide to try buprenorphine, please be aware of this risk, and keep the door open for resuming methadone immediately if necessary.

There are also some studies which show that detoxification from buprenorphine/naloxone (Suboxone) is effective. Some patients may decide to use buprenorphine/naloxone (Suboxone) to detoxify from heroin or prescription narcotics, instead of other detoxification treatments (methadone, clonidine, etc). Despite the effectiveness of buprenorphine detoxification, all narcotic addicts are at high-risk for relapse and should consider the benefits of maintenance treatment. One issue with buprenorphine/naloxone treatment is that not all insurers will pay for treatment with this medication. Many doctors are requiring patients to pay for treatment and get reimbursed by their insurance company if possible.

Remember the Following Tips:

- If you are offered Suboxone by a “friend” and you are taking methadone or are addicted to prescription opioids, the buprenorphine in Suboxone will push the other opioids off the receptor site, and you may be in withdrawal and very uncomfortable.
- If you dissolve and inject the buprenorphine-naloxone (Suboxone) sublingual tablet it may induce severe withdrawal because of the naloxone, which is an antagonist.
- If you are on methadone treatment and wish to transfer to buprenorphine/naloxone (Suboxone), your dose has to be at or below 30 mg daily.
- There have been deaths reported when buprenorphine is injected in combination with high doses of benzodiazepines. (This family of drugs includes Klonopin, Ativan, Halcion, Valium, Xanax, Librium, etc.) There is a risk of overdose when any narcotic drug is taken in combination with alcohol and/or other sedative drugs. If you drink excessively, or take any of these drugs, either by prescription or on your own, buprenorphine may not be a good treatment for you.

Appendix 6C: Patient Consent for Buprenorphine Treatment

SAMPLE 1

Consent for Treatment with Suboxone (Buprenorphine/Naloxone)

Buprenorphine is a medication approved by the Food and Drug Administration (FDA) for treatment of people with opioid dependence. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary.

Buprenorphine itself is an opioid, but it is not as strong an opioid as heroin or morphine. Buprenorphine treatment can result in physical dependence of the opiate type. Buprenorphine withdrawal is generally less intense than with heroin or methadone. If buprenorphine is suddenly discontinued, some patients have no withdrawal symptoms; others have symptoms such as muscle aches, stomach cramps, or diarrhea lasting several days. To minimize the possibility of opiate withdrawal, buprenorphine should be discontinued gradually, usually over several weeks or more.

If you are dependent on opiates (heroin or prescription opioids such as Lortab or Lorcet, Percodan or Percocet, Oxycontin, Dilaudid, methadone, morphine, MS Contin), you should be in as much withdrawal as possible when you take the first dose of buprenorphine. If you are not in withdrawal, buprenorphine may cause significant opioid withdrawal. For that reason, you should take the first dose in the office and remain in the office for observation. Within a few days, you will have a prescription for buprenorphine that will be filled in a pharmacy.

Some patients find that it takes several days to get used to the transition from the opioid they had been using to buprenorphine. During that time, any use of other opioids may cause an increase in symptoms. After you become stabilized on buprenorphine, it is expected that other opioids will have less effect. Attempts to override the buprenorphine by taking more opioids could result in an

opioid overdose. You should not take any other medication without discussing it with your doctor first.

Combining buprenorphine with alcohol or some other medications may also be hazardous. The combination of buprenorphine with medication such as Valium, Librium, Ativan has resulted in deaths.

The form of buprenorphine (Suboxone) you will be taking is a combination of buprenorphine with a short-acting opiate blocker (Naloxone). If the Suboxone tablet were dissolved and injected by someone taking heroin or another strong opioid, it could cause severe opiate withdrawal.

Buprenorphine tablets must be held under the tongue until they dissolve completely. Buprenorphine is then absorbed over the next 30 to 120 minutes from the tissue under the tongue. Buprenorphine will not be absorbed from the stomach if it is swallowed.

Buprenorphine will cost \$10+/day just for the medication. If you have medical insurance, you should find out whether or not buprenorphine is a benefit. In any case, office fees must be kept current or you will not be able to continue receiving this treatment from this program.

Alternatives to Buprenorphine

Some hospitals that have specialized drug abuse treatment units can provide detoxification and intensive counseling for drug abuse. Some outpatient drug abuse treatment services also provide individual and group therapy, which may emphasize treatment that does not include maintenance on buprenorphine or other opiate-like medications. Other forms of opioid maintenance therapy include methadone maintenance. Some opioid treatment programs use naltrexone, a medication that blocks the effects of opioids, but has no opioid effects of its own.

SIGNATURE

DATE

PRINT NAME

WITNESS

Appendix 6C: Patient Consent for Buprenorphine Treatment

SAMPLE 2

Consent for Treatment with Suboxone (Buprenorphine/Naloxone)

Suboxone® (a tablet with buprenorphine and naloxone) is an FDA approved medication for treatment of people with heroin or other opioid addiction. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary. There are other treatments for opiate addiction, including methadone, naltrexone, and some treatments without medications that include counseling, groups and meetings.

If you are dependent on opiates – any opiates – **you should be in as much withdrawal as possible when you take the first dose of buprenorphine. If you are not in withdrawal, buprenorphine can cause severe opiate withdrawal.** For that reason, you should take the first dose in the office and remain in the office for at least 2 hours. We recommend that you arrange not to drive after your first dose, because some patients get drowsy until the correct dose is determined for them.

Some patients find that it takes several days to get used to the transition from the opiate they had been using to buprenorphine. During that time, any use of other opiates may cause an increase in symptoms. After you become stabilized on buprenorphine, it is expected that other opiates will have less effect. Attempts to override the buprenorphine by taking more opiates could result in an opiate overdose. You should not take any other medication without discussing it with the physician first.

Combining buprenorphine with alcohol or other sedating medications is dangerous. The combination of buprenorphine with benzodiazepines (such as Valium®, Librium®, Ativan®, Xanax®, Klonopin®, etc.) has resulted in deaths.

Although sublingual buprenorphine has not been shown to be liver-damaging, your doctor will monitor your liver tests while you are taking buprenorphine. (This is a blood test.)

The form of buprenorphine (Suboxone®) you will be

taking is a combination of buprenorphine with a short-acting opiate blocker (naloxone) in a 4 to 1 ratio (4 mg of buprenorphine to 1 mg naloxone). **It will maintain physical dependence**, and if you discontinue it suddenly, you will likely experience withdrawal. If you are not already dependent, you should not take buprenorphine; it could eventually cause physical dependence.

Buprenorphine/naloxone tablets must be held under the tongue until they dissolve completely. You will be given your first dose at the clinic, and you will have to wait as it dissolves, and for two hours after it dissolves, to see how you react. **It is important not to talk or swallow until the tablet dissolves.** This takes up to ten minutes. Buprenorphine is then absorbed over the next 30 to 120 minutes from the tissue under the tongue. Buprenorphine is poorly absorbed from the stomach. **If you swallow the tablet, you will not have the important benefits of the medication, and it may not relieve your withdrawal.**

Most patients end up at a daily dose of 12/3-16/4 mg of buprenorphine. (This is roughly equivalent to 60mg of methadone maintenance). Beyond that dose, the effects of buprenorphine plateau, so there may not be any more benefit to increase in dose. It may take several weeks to determine just the right dose for you. The first dose is usually 2/0.5-4/1 mg.

If you are transferring to Suboxone® from methadone maintenance, your dose has to be tapered until you have been **below 30mg for at least a week.** There must be **at least 24 hours** (preferably longer) between the time you take your last methadone dose and the time you are given your first dose of buprenorphine. Your doctor will examine you for clear signs of withdrawal, and you will not be given buprenorphine until you are in withdrawal.

I have read and understand these details about buprenorphine treatment. I wish to be treated with buprenorphine.

SIGNATURE

DATE

WITNESS

Appendix 6D: Buprenorphine Treatment Agreement

SAMPLE 2: AGREEMENT FOR TREATMENT WITH SUBOXONE®

I understand that Suboxone is a medication to treat opiate addiction (for example: heroin, prescription opiates such as oxycodone, hydrocodone, methadone). Suboxone contains the opiate narcotic analgesic medication buprenorphine, and the opiate antagonist drug naloxone, in a 4 to 1 (buprenorphine to naloxone) ratio. The naloxone is present in the tablet to prevent diversion to injected abuse of this medication. Injection of Suboxone by a person who is addicted to opiates will produce severe opiate withdrawal.

<input type="checkbox"/> Yes <input type="checkbox"/> No	1. I agree to keep appointments and let appropriate staff know if I will be unable to show up as scheduled.
<input type="checkbox"/> Yes <input type="checkbox"/> No	2. I agree to report my history and my symptoms honestly to my physician, nurses, and counselors involved in my care. I also agree to inform staff of all other physicians and dentists I am seeing, of all prescription and non-prescription drugs I am taking, of any alcohol or street drugs I have recently been using, and whether I have become pregnant or have developed hepatitis.
<input type="checkbox"/> Yes <input type="checkbox"/> No	3. I agree to cooperate with witnessed urine drug testing whenever requested by medical staff, to confirm if I have been using any alcohol, prescription drugs, or street drugs.
<input type="checkbox"/> Yes <input type="checkbox"/> No	4. I have been informed that buprenorphine, as found in Suboxone, is a narcotic analgesic, and thus it can produce a 'high'; I know that taking Suboxone regularly can lead to physical dependence and addiction and that if I were to abruptly stop taking Suboxone after a period of regular use, I could experience symptoms of opiate withdrawal. I also understand that combining Suboxone with benzodiazepine medications (including but not limited to Valium, Klonopin, Ativan, Xanax, Librium, Serax) has been associated with severe adverse events and even death. I also understand that I should not drink alcohol with Suboxone since it could possibly interact with Suboxone to produce medical adverse events such as reduced breathing or impaired thinking. I agree not to use benzodiazepine medications or to drink alcohol while taking Suboxone.
<input type="checkbox"/> Yes <input type="checkbox"/> No	5. I have been informed that Suboxone is to be placed under the tongue for it to dissolve and be absorbed, and that it should never be injected. I have been informed that injecting Suboxone after taking Suboxone or any other opiate regularly could lead to sudden and severe opiate withdrawal.
<input type="checkbox"/> Yes <input type="checkbox"/> No	6. I have been informed that Suboxone is a powerful drug and that supplies of it must be protected from theft or unauthorized use, since persons who want to get high by using it or who want to sell it for profit may be motivated to steal my take-home prescription supplies of Suboxone.
<input type="checkbox"/> Yes <input type="checkbox"/> No	7. I have a means to store take-home prescription supplies of Suboxone safely, where it cannot be taken accidentally by children or pets, or stolen by unauthorized users. I agree that if my Suboxone pills are swallowed by anyone besides me, I will call 911 or Poison Control at 1-800-222-1222 immediately.
<input type="checkbox"/> Yes <input type="checkbox"/> No	8. I agree that if my doctor recommends that my home supplies of Suboxone should be kept in the care of a responsible member of my family or another third party, I will abide by such recommendations.
<input type="checkbox"/> Yes <input type="checkbox"/> No	9. I will be careful with my take-home prescription supplies of Suboxone, and agree that I have been informed that if I report that my supplies have been lost or stolen, my doctors will not be requested or expected to provide me with make-up supplies. This means that if I run out of my medication supplies it could result in my experiencing symptoms of opiate withdrawal. Also, I agree that if there has been a theft of my medications, I will report this to the police and will bring a copy of the police report to my next visit.
<input type="checkbox"/> Yes <input type="checkbox"/> No	10. I agree to bring my bottle of Suboxone in with me for every appointment with my doctor so that remaining supplies can be counted.
<input type="checkbox"/> Yes <input type="checkbox"/> No	11. I agree to take my Suboxone as prescribed, to not skip doses, and that I will not adjust the dose without talking with my doctor about this so that changes in orders can be properly communicated to my pharmacy.

- ☐ Yes ☐ No 12. I agree that I will not drive a motor vehicle or use power tools or other dangerous machinery during my first days of taking Suboxone, to make sure that I can tolerate taking it without becoming sleepy or clumsy as a side-effect of taking it.
- ☐ Yes ☐ No 13. I agree that I will arrange transportation to and from the treatment facility during my first days of taking Suboxone so that I do not have to drive myself to and from the clinic or hospital
- ☐ Yes ☐ No 14. I have been informed that it can be dangerous to mix Suboxone with alcohol or another sedative drug such as Valium, Ativan, Xanax, Klonopin or any other benzodiazepine drug--so dangerous that it could result in accidental overdose, over-sedation, coma, or death. I agree to use no alcoholic beverages and to take no sedative drugs at any time while being treated with Suboxone. I have been informed that my doctor will almost certainly discontinue my buprenorphine treatment with Suboxone if I violate this agreement.
- ☐ Yes ☐ No 15. If a female, I am not pregnant, and will not attempt to become pregnant. I will not have unprotected sex while I am taking Suboxone, because of the unknown safety of buprenorphine during pregnancy. I will tell my doctor if I become pregnant so that other treatment options can be discussed with me.
- ☐ Yes ☐ No 16. I want to be in recovery from addiction to all drugs, and I have been informed that any active addiction to other drugs besides heroin and other opiates must be treated by counseling and other methods. I have been informed that buprenorphine, as found in Suboxone, is a treatment designed to treat opiate dependence, not addiction to other classes of drugs.
- ☐ Yes ☐ No 17. I agree that medication management of addiction with buprenorphine, as found in Suboxone, is only one part of the treatment of my addiction, and I agree to participate in a regular program of professional counseling while being treated with Suboxone.
- ☐ Yes ☐ No 18. I agree that professional counseling for addiction has the best results when patients also are open to support from peers who are also pursuing recovery.
- ☐ Yes ☐ No 19. I agree to participate in a regular program of peer/self-help while being treated with Suboxone.
- ☐ Yes ☐ No 20. I agree that the support of loved ones is an important part of recovery, and I agree to invite significant persons in my life to participate in my treatment.
- ☐ Yes ☐ No 21. I agree that a network of support, and communication among persons in that network, is an important part of my recovery. I will be asked for my authorization, if required (which it almost always is) to allow telephone, email, or face-to-face contact, as appropriate, between my treatment team and outside parties, including physicians, therapists, probation and parole officers, and other parties, when the staff has decided that open communication about my case, on my behalf, is necessary.
- ☐ Yes ☐ No 22. I agree that I will be open and honest with my counselors and inform staff about cravings, potential for relapse to the extent that I am aware of such, and specifically about any relapse which has occurred --before a drug test result shows it.
- ☐ Yes ☐ No 23. I have been given a copy of clinic procedures, including hours of operation, the clinic phone number, and responsibilities to me as a recipient of addiction treatment services, including buprenorphine treatment with Suboxone.

PATIENT SIGNATURE

DATE

STAFF SIGNATURE

TITLE

DATE

Appendix 7: ASAM Adult Admission Crosswalk

Dimensions	Level I Outpatient	Level II.I Intensive Outpatient	Level II.5 Partial	III.1 Clinically Managed Low Intensity Residential	III.3 Clinically Managed High-Intensity Residential Treatment	III.5 Clinically Managed Medium Intensity Residential	III.7 Medically Monitored High Intensity Residential/ Inpatient	IV. Medically Managed Intensive Inpatient
Dimension 1 Alcohol Intoxication and/or Withdrawal Potential	No significant withdrawal or at minimal risk for severe withdrawal.	Minimal risk of severe withdrawal.	Moderate risk of severe withdrawal.	Not at risk of withdrawal or experiencing minimal or stable withdrawal.	Not at risk of severe withdrawal.	Minimal risk of severe withdrawal at III.3 or III.5 If withdrawal is present, it meets Level III.2-D.	High risk of withdrawal, but manageable at Level III.7-D and not requiring full licensed hospital resources.	High risk of withdrawal requiring full licensed hospital services.
Dimension 2 Biomedical Conditions and Complications	None or very stable, or patient is receiving concurrent medical monitoring.	None or not a distraction from treatment, i.e. manageable at Level II.I.	None or not sufficient to distract from treatment, i.e. manageable at II.5.	None or stable, or patient is receiving concurrent medical monitoring.	None or stable, or patient is receiving concurrent medical monitoring.	None or stable, or patient is receiving concurrent medical monitoring.	Needs 24-hour medical monitoring but not intensive treatment.	Requires 24-hour medical and RN care.
Dimension 3 Emotional, Behavioral or Cognitive Conditions and Complications	None or very stable, or patient is receiving concurrent mental health monitoring.	Mild severity, with potential to distract from recovery; patient needs monitoring.	Mild to moderate severity, with potential to distract from recovery. Patient needs stabilization.	None or minimal; not distracting to recovery.	Mild to moderate severity; patient needs structure to focus on recovery.	Patient demonstrates repeated inability to control impulses or personality disorder requires structure to shape behavior.	Moderate severity; patient needs 24-hour structured setting.	Severe and unstable problems; requires 24-hour psychiatric care with concomitant addictions treatment.
Dimension 4 Readiness to Change	Patient is ready for recovery but needs motivating and monitoring strategies to strengthen readiness. Or, high severity in this but not other dimensions.	Variable engagement in treatment, ambivalence or lack of awareness of the substance use or mental health problem. Requires structured program several times a week to promote progress.	Poor engagement in treatment, ambivalence or lack of awareness of CD or mental health problems; requires near-daily structured program or intensive engagement.	Patient open to recovery, but needs structured environment to maintain therapeutic gains.	Little awareness and needs interventions only available at Level III.3 to engage and stay in treatment or High severity in this dimension but not in others.	Marked difficulty with or opposition to treatment with dangerous consequences, or high severity in this dimension but not in others.	High resistance and poor impulse control, despite negative consequences. Needs motivating strategies only available in a 24-hour structured setting.	Problems in this dimension do not qualify for Level IV services.
Dimension 5 Relapse, Continued Use or Continued Problem Potential	Able to maintain abstinence or control use and pursue recovery or motivational goals with minimal support.	Intensification of addiction or mental health symptoms indicate high likelihood of continued problems/use without close monitoring and support several times weekly.	Intensification of addiction or mental health symptoms despite active participation in Level I or II.I; high likelihood of relapse, continued use or problems without near-daily monitoring and support.	Patient understands relapse but needs structure to maintain therapeutic gains.	Little awareness and needs interventions available only at Level III.3 to prevent continued use, with imminent dangerous consequences due to cognitive deficits or comparable dysfunction.	No recognition of the skills needed to prevent continued use with imminent dangerous consequences.	Unable to control use, with imminently dangerous consequences despite active participation at less intensive levels of care.	Problems in this dimension do not qualify for Level IV services.

ASAM Patient Placement Criteria, Second Edition-Revised (adapted by T. W. Mandell, MD, 2002. NOT approved by ASAM)

Appendix 8: SAMHSA Frequently Asked Questions

FOR PHYSICIANS

Can Buprenex®, or any other medications besides Subutex® and Suboxone®, be prescribed/dispensed for opioid addiction treatment in practice settings other than Opioid Treatment Programs (OTPs) (e.g., methadone clinics)?

No. At the present time Subutex® and Suboxone® are the only Schedule III, IV, or V substances to have received Food and Drug Administration approval for opioid addiction treatment. Thus, they are the only opioid medications that may be prescribed or dispensed for this indication outside the OTP setting. The approval of Subutex® and Suboxone® does not affect the status of any other medications. Buprenex® is not approved for treatment of opioid addiction. The status of methadone and LAAM are also unchanged. They still can be only dispensed, not prescribed, for opioid addiction, and only at Federally regulated OTPs.

I submitted my waiver notification to SAMHSA a few weeks ago and received an acknowledgment letter, but I haven't heard anything since. How can I check on the status of my waiver?

If you have submitted a notification and received an acknowledgment letter (or e-mail) from us, then your notification is under active review. It is SAMHSA's intent to complete the review of notifications within 45 days of receipt. When processing of your notification is complete, we will mail you a letter confirming your waiver and containing your prescribing identification number.

If you have submitted a notification and received an acknowledgment from us, and it has been more than two months since you submitted your notification, OR if you submitted a notification and you did not receive an acknowledgment from us that it had been received, please call 1-866-BUP-CSAT (1-866-287-2728) or e-mail info@buprenorphine.samhsa.gov. Please be prepared to provide the date when you submitted your original notification and other identifying information.

I am a waived physician and would like to add, change, or remove my listing on the SAMHSA Buprenorphine Physician Locator Web site. How do I do this?

Waived physicians may call 1-866-BUP-CSAT (1-866-287-2728) or e-mail info@buprenorphine.samhsa.gov with requests to change Locator listings. There is also a new online form for physicians to request changes to their contact information. Click on Update Physician Contact

Information and use the State Medical License Number and DEA Registration Number that we currently have on file to locate and change your information.

I am a waived physician, and I've moved my practice location since receiving my waiver. Do I need to notify SAMHSA or DEA of my new practice address?

Waived physicians who change the primary practice address at which they intend to treat opioid addiction under the authority of their DATA 2000 waiver must notify SAMHSA by calling 1-866-BUP-CSAT (1-866-287-2728) or via e-mail at info@buprenorphine.samhsa.gov. Or you may use our new online form to submit changes to your contact information. Click on Update Physician Contact Information and use the State Medical License Number and DEA Registration Number that we currently have on file to locate and change your information. The Drug Enforcement Administration must also be notified. Call the DEA Office of Diversion Control at 1-800-882-9539. Phone numbers for local DEA offices can be found on the DEA Web site at www.dea.gov.

With a DATA 2000 waiver, can I prescribe Subutex® or Suboxone® for opioid addiction in more than one practice location? Can I dispense Subutex® or Suboxone® from more than one location?

Physicians with DATA 2000 waivers may prescribe Subutex® or Suboxone® for opioid addiction in any appropriate practice setting in which they are otherwise credentialed to practice (e.g., office, hospital). However, they may store and dispense Subutex® or Suboxone® (or any other controlled substances) only at the practice address(es) that they have registered with the DEA. Only one DATA-waiver unique identification number will be issued for each DATA-waived physician, no matter how many practice locations or DEA registrations a physician may have.

I've heard this new model for the treatment of opioid addiction referred to as "office-based opioid therapy." Does that mean that physicians with DATA 2000 waivers can use Subutex® and Suboxone® to treat opioid addiction only in the office-based setting?

No. Treatment of opioid addiction under the authority of a DATA 2000 waiver is not confined to the office-based setting. Physicians with DATA 2000 waivers may treat opioid addiction with Subutex® and Suboxone® in any practice settings in which they are otherwise credentialed to practice and in which such treatment would be medically appropriate (e.g., office, community hospital, health department).

Are there specific Federal record keeping requirements for office-based opioid therapy?

DEA record keeping requirements for office-based opioid therapy go beyond the Schedule III record keeping requirements. According to DEA:

- Practitioners must keep records (including an inventory that accounts for amounts received and amounts dispensed) for all controlled substances dispensed, including Subutex and Suboxone (21 PART 1304.03[b]). In some cases, patients return to the prescribing physician with their filled Subutex or Suboxone prescriptions so that the practitioner can monitor the induction process. While it is acceptable for the patient to return to the practitioner with their filled prescription supplies, practitioners shall not store and dispense controlled substances that are the result of filled patient prescriptions.
- Practitioners must keep records for controlled substances prescribed and dispensed to patients for maintenance or detoxification treatment (21 CFR Section 1304.03[c]). Many practitioners comply with this requirement by creating a log that identifies the patient (an ID number may be used instead of name), the name of the drug prescribed or dispensed, as well as the strength and quantity and date of issuance or dispensing. Some physicians comply with this requirement by keeping a copy of the prescription in the patient record.
- Alternatively, DEA suggests that practitioners could keep separate records for controlled substances prescribed and dispensed for maintenance or detoxification treatment to facilitate the record reviews during physician inspections for DATA compliance. This way, DEA will only review those records related to controlled substances prescribed and dispensed for maintenance or detoxification treatment for physicians maintaining separate records.

Does DATA 2000 limit the number of patients who may be treated for opioid addiction at any one time by a physician group practice?

The physician group practice limit was eliminated by Public Law 109-56, which became effective August 2, 2005.

Is there a limit on the number of patients a practitioner may treat with buprenorphine at any one time?

Yes. DATA 2000, as amended in December 2006, specifies that an individual physician may have a maximum of 30 patients on opioid therapy at any one time for the first year. One year after the date on which a physician submitted the initial notification, the physician may submit a second notification of the need and intent to treat up to 100 patients.

Can an Opioid Treatment Program (i.e., methadone clinic or OTP) dispense Subutex® and Suboxone® to patients admitted to the program? If so, is there a limit on the number of patients who can be treated with Subutex® and Suboxone® for opioid addiction treatment in an OTP? Is a DATA 2000 waiver required?

New SAMHSA regulations permit OTPs serving persons addicted to prescription opioids or heroin to offer buprenorphine treatment along with methadone and ORLAAM®. These regulations enable OTPs that are certified by SAMHSA to use Subutex® and Suboxone® for opioid maintenance or detoxification treatment. Follow this link to read the text of the Federal regulation (PDF, 43 kb).

The provision of opioid addiction treatment with Subutex® and Suboxone® in OTPs certified by SAMHSA/CSAT does not require a DATA 2000 waiver. Additionally, such treatment is not subject to the patient limits that apply to individual physicians providing opioid addiction treatment outside the OTP system under the authority of a DATA 2000 waiver. The provision of opioid addiction treatment with Subutex® or Suboxone® in treatment settings other than OTPs, even by physicians who are licensed to practice in OTPs, does require a DATA 2000 waiver and is subject to the patient limits for individual physicians.

OTPs providing Subutex® and Suboxone® for opioid maintenance or detoxification treatment must conform to the Federal opioid treatment standards set forth under 42 C.F.R. § 8.12. These regulations require that OTPs provide medical, counseling, drug abuse testing, and other services to patients admitted to treatment. To offer Subutex® and Suboxone®, OTPs will need to review their State licensing laws and regulations and to modify their registration with the DEA to add Schedule III narcotics to their registration certificates. Opioid treatment programs can initiate this streamlined process by fax or letter. The letter should include the OTP's DEA registration number and request that the registration be amended to list Schedule III narcotic drugs. The letter must be signed by the Program Sponsor (Program Director) or Medical Director. The completed letter can be either faxed to Ms. Ghana Giles at 202-353-1125 or mailed to Ms. Giles at: DEA, Registration Unit – OPRR, Washington, DC, 20537. In addition, OTPs can access the DEA registration Web site for more information.

Once the registration has been modified, OTPs can order Subutex® and Suboxone® directly from Reckitt Benckiser, the product manufacturer, by calling 1-877-782-6966.

Can the medical personnel in correctional facilities dispense (or administer) buprenorphine to incarcerated individuals?

Qualified physicians who have obtained a DATA 2000 waiver can dispense or prescribe Subutex® or Suboxone® for addiction treatment in any practice setting, including in correctional facilities. Currently, State laws and policies vary considerably regarding opioid-assisted (methadone) treatment within correctional facilities. It is assumed that this same variation will occur with the use of buprenorphine in this setting. The patient limits per waived physician as stated in the DATA 2000 legislation also apply to the prescribing or dispensing of this treatment in correctional facilities.

Can physicians and other authorized hospital staff administer buprenorphine to a patient who is addicted to opioids but who is admitted to a hospital for a condition other than opioid addiction?

Neither the Controlled Substances Act (as amended by the Drug Addiction Treatment Act of 2000) nor DEA implementing regulations (21 CFR 1306.07(c)) impose any limitations on a physician or other authorized hospital staff to maintain or detoxify a person with an opioid treatment drug like buprenorphine as an incidental adjunct to medical or surgical conditions other than opioid addiction.

Thus, a patient with opioid addiction who is admitted to a hospital for a primary medical problem other than opioid addiction, e.g., myocardial infarction, may be administered opioid-agonist medications (e.g., methadone, buprenorphine) to prevent opioid withdrawal that would complicate the primary medical problem. A DATA 2000 waiver is not required for practitioners in order to administer or dispense buprenorphine (or methadone) in this circumstance. It is good practice for the admitting physician to consult with the patient's addiction treatment provider, when possible, to obtain treatment history.

May physicians in residency training programs obtain DATA waivers?

The DATA legislation does not specify that a physician in a residency training program who otherwise meets the qualifications for a DATA waiver is ineligible to apply for and obtain a waiver. Therefore, SAMHSA has granted DATA waivers to physicians in residency training who have unrestricted licenses and the appropriate DEA registration. Individual States may have laws with more restrictive rules regarding who may prescribe or dispense Schedule III narcotic drugs for detoxification or maintenance treatment.

As a physician employed by the Federal Government (Veterans Administration, Indian Health Service, Federal Department of Corrections, etc.) practicing in a Federal Government installation, am I eligible for a DATA 2000 waiver?

Yes. Physicians employed by an agency of the Federal Government are eligible for DATA 2000 waivers. In order to be eligible for a waiver under DATA 2000, a physician must have a valid, individually assigned DEA registration number (in addition to a license to practice medicine and the credentialing/training discussed elsewhere). A physician who is directly employed by the Federal Government may obtain a DEA number, free of charge, without being licensed in the state where the Federal facility is located (the physician must have a valid state license in one of the 50 states, the District of Columbia, Virgin Islands or Puerto Rico). In order to receive a DEA number under this program, each physician must complete a DEA registration application that includes the physician's official business address and the name and phone number of the certifying official who can verify the physicians' eligibility for this program. This DEA registration number may only be used for practice within the Federal Government installation and may not be used for practice outside this setting.

Can physicians begin immediately treating patients if they have checked "Immediate" on the waiver notification form?

A place to check "Immediate" is included on the form to address a provision in the Drug Addiction Treatment Act to permit treatment while a notification is under review. Checking "Immediate" is only one of three requirements that a physician must meet in order to start a patient on treatment, and treatment is limited to ONE patient per form submitted. (Each form must have a different submission date.) The three requirements are that, first, the physician must "in good faith" meet the criteria for obtaining a waiver (i.e., valid medical license, valid DEA registration, credentialing, or 8 hours of qualifying training). Second, the physician must check "Immediate" on the waiver. Third, the physician must contact the Buprenorphine Information Center at 1-866-BUP-CSAT to verify that the notification form has been received and to notify CSAT of his/her intent to begin treating ONE patient.

Since the physician will not have the unique identifying number, pharmacists may question prescriptions received under this provision. Pharmacists may contact the Buprenorphine Information Center if additional information is needed.

How do I increase my patient limits?

To increase your patient limits, visit <http://buprenorphine.smdi.com/federal.html>.

FOR PHARMACISTS

Are Subutex® and Suboxone® available in pharmacies?

Subutex® and Suboxone® are available in pharmacies throughout the United States. Pharmacies and physicians can obtain the medications by contacting a pharmaceutical wholesaler directly, or by contacting the drug manufacturer, Reckitt Benckiser, at 1-877-782-6966. Consumers may also call the same toll-free number for additional information.

Do pharmacies need waivers to dispense buprenorphine?

No. Physicians are required to obtain DATA 2000 waivers to prescribe and dispense buprenorphine (Subutex® and Suboxone®) for opioid addiction, but pharmacists and pharmacies are not required to have any special credentials for dispensing these medications above and beyond those for other Schedule III medications. Certain Federal laws and regulations, however, do affect pharmacy practice with regard to opioid addiction treatment prescriptions.

How can a pharmacist verify if a physician has a waiver to prescribe buprenorphine (Subutex® or Suboxone®) for the treatment of opioid addiction?

Effective July 25, 2005, physicians must include their DATA 2000 waiver ID number on prescriptions for opioid addiction treatment medications. The practitioner's DEA registration number and the unique identification number (DATA 2000 waiver ID number or "X" number) must be on the prescription 21 CFR 1306.05(a). The identification number is not in lieu of the DEA registration number, it is an addition. If the prescription is telephoned to the pharmacy, the pharmacist must have both of these numbers on the prescription record so the physician can provide the numbers or the pharmacist may have them on file.

The SAMHSA Buprenorphine Physician Locator Web site lists the physicians in each state who have DATA 2000 waivers. A physician listed on the site can be considered to have a valid DATA 2000 waiver. Note, however, that the site does not list every physician with a valid waiver, only those who have agreed to be listed on the site. Physicians with valid waivers may choose not to be listed on the site.

A pharmacist desiring to verify that a physician who is not listed on the site has a valid DATA 2000 waiver can contact SAMHSA by phone at 1-866-BUP-CSAT (1-866-287-2728) or by e-mail at info@buprenorphine.samhsa.gov. Pharmacists should convey their DEA registration number with these requests.

Can Subutex® or Suboxone® be prescribed for conditions other than opioid addiction, e.g., pain control?

Subutex® and Suboxone® have received FDA approval only for the treatment of opioid addiction. However, once approved, a drug product may be prescribed by a licensed physician for any use that, based on the physician's professional opinion, is deemed to be appropriate. Neither the FDA nor the Federal government regulates the practice of medicine. Any approved product may be used by a licensed practitioner for uses other than those stated in the product label. Off-label use is not illegal, but it means that the data to support that use has not been independently reviewed by the FDA. Information on FDA policy regarding off-label use of pharmaceuticals is available on the FDA Web site, www.fda.gov/cder/cancer/tour.htm, or www.fda.gov/cder/present/diamontreal/regappr/index.htm

Physicians and other practitioners who are authorized to prescribe Schedule III controlled narcotic medications under Federal and State laws are eligible and the unique identifier under the Drug Addiction Treatment Act is not required

GENERAL INFORMATION

Can Physician Assistants or Nurse Practitioners prescribe buprenorphine for opioid addiction treatment in States that permit them to prescribe Schedule III, IV, or V medications?

No. Under DATA 2000, waivers to permit the prescription of Schedule III, IV, or V medications for opioid addiction treatment are available only to “qualifying physicians.” The term “qualifying physician” is specifically defined in DATA 2000 as a “physician who is licensed under State law,” has DEA registration to dispense controlled substances, has the capacity to refer patients for counseling and ancillary services, will treat no more than 30 such patients at any one time, and is qualified by certification, training, and/or experience to treat opioid addiction.

As a physician employed by the Federal Government (Veterans Administration, Indian Health Service, Federal Department of Corrections, etc.) practicing in a Federal Government installation, am I eligible for a DATA 2000 waiver?

Yes. Physicians employed by an agency of the Federal Government are eligible for DATA 2000 waivers. In order to be eligible for a waiver under DATA 2000, a physician must have a valid, individually assigned DEA registration number (in addition to a license to practice medicine and the credentialing/training discussed elsewhere). A physician who is directly employed by the Federal Government may obtain a DEA number, free of charge, without being licensed in the state where the Federal facility is located (the physician must have a valid state license in one of the 50 states, the District of Columbia, Virgin Islands or Puerto Rico). In order to receive a DEA number under this program, each physician must complete a DEA registration application that includes the physician's official business address and the name and phone number of the certifying official who can verify the physicians' eligibility for this program. This DEA registration number may only be used for practice within the Federal Government installation and may not be used for practice outside this setting.

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that a physician must meet in order to start a patient on treatment, and treatment is limited to ONE patient per form submitted. (Each form must have a different submission date.) The three requirements are that, first, the physician must “in good faith” meet the criteria for obtaining a waiver (i.e., valid medical license, valid DEA registration, credentialing, or 8 hours of qualifying training). Second, the physician must check “Immediate” on the waiver. Third, the physician must contact the Buprenorphine Information Center at 1-866-BUP-CSAT to verify that the notification form has been received and to notify CSAT of his/her intent to begin treating ONE patient.

Since the physician will not have the unique identifying number, pharmacists may question prescriptions received under this provision. Pharmacists may contact the Buprenorphine Information Center if additional information is needed.

Where can I get a copy of the Buprenorphine Clinical Practice Guidelines?

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, Treatment Improvement Protocol (TIP) 40, is available via SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI), or by calling 1-800-729-6686. It will also be available in the near future from the National Library of Medicine (NLM), or by calling 1-888-346-3656.

Are there exceptions when Subutex and Suboxone may be administered by a practitioner without the DATA 2000 waiver?

Under the Narcotic Addiction Treatment Act of 1974, all practitioners who use narcotic drugs for treating opiate addiction must obtain a separate registration under 21 U.S.C. Section 823(g)(1) or a DATA 2000 Waiver under 21 U.S.C. Section 823(g)(2). However, according to the Drug Enforcement Administration (DEA), an exception to the registration requirement, known as the “three-day rule” (Title 21, Code of Federal Regulations, Part 1306.07(b)), allows a practitioner who is not separately registered as a narcotic treatment program or certified as a “waivered DATA 2000 physician,” to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient's referral for treatment, under the following conditions: 1) not more than one day's medication may be administered or given to a patient at one time; 2) this treatment may not be carried out for more than 72 hours; and 3) this 72-hour period cannot be renewed or extended.

The intent of 21 CFR 1306.07(b) is to provide practitioner flexibility in emergency situations where he or she may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration. The 72-hour exception offers an opioid dependent individual relief from experiencing acute withdrawal symptoms, while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent, the separate registration requirement. The three-day (72-hour) emergency exception cannot be renewed or extended. Because this is a Drug Enforcement Administration (DEA) rule, for further details consult DEA. This information may be found at www.deadiversion.usdoj.gov/drugreg/faq.htm.

What is buprenorphine's safety profile? Some sources indicate that the medications Suboxone® and Subutex® are safer and less abusable than methadone. Other information indicates that these medications have been associated with diversion, abuse, and overdose deaths, including over 100 associated deaths tied to Subutex® in France.

The Food and Drug Administration (FDA) approved the buprenorphine products Subutex® and Suboxone® in October 2002. At the same time, the Drug Enforcement Administration (DEA) placed buprenorphine in Schedule III of the Controlled Substances Act. Schedule III substances have a potential for abuse that is less than substances in Schedule II (methadone, morphine, oxycodone, hydrocodone, cocaine, etc.); however, the abuse of Schedule III substances may still lead to moderate or low physical dependence or high psychological dependence.

The use of Suboxone® and Subutex® has increased steadily since their introduction in early 2003. In 2007 alone, over 2 million prescriptions were issued to 300,000 patients.

Almost 14,000 physicians have been authorized to prescribe buprenorphine for addiction treatment. When patients and physicians were surveyed by SAMHSA about the effectiveness of buprenorphine, they reported over 80% reductions in illicit opioid use, along with significant increases in employment, and other indices of recovery.

Suboxone® and Subutex® are also diverted and abused. A recent series of articles in the Baltimore Sun in late 2007 and early 2008 describe increasing levels of diversion and abuse in Baltimore itself, Maryland, Massachusetts, and other parts of the United States. Information from SAMHSA's Drug Abuse Warning Network (DAWN) indicates an increase in buprenorphine reports from hospital emergency departments over the last 3 years. Recent publications^{1,2} indicate a period of experimentation and increased reports of abuse to substance abuse treatment centers in the United States. Buprenorphine products are diverted, misused, and injected. In some cases, this misuse has been associated with overdose deaths.

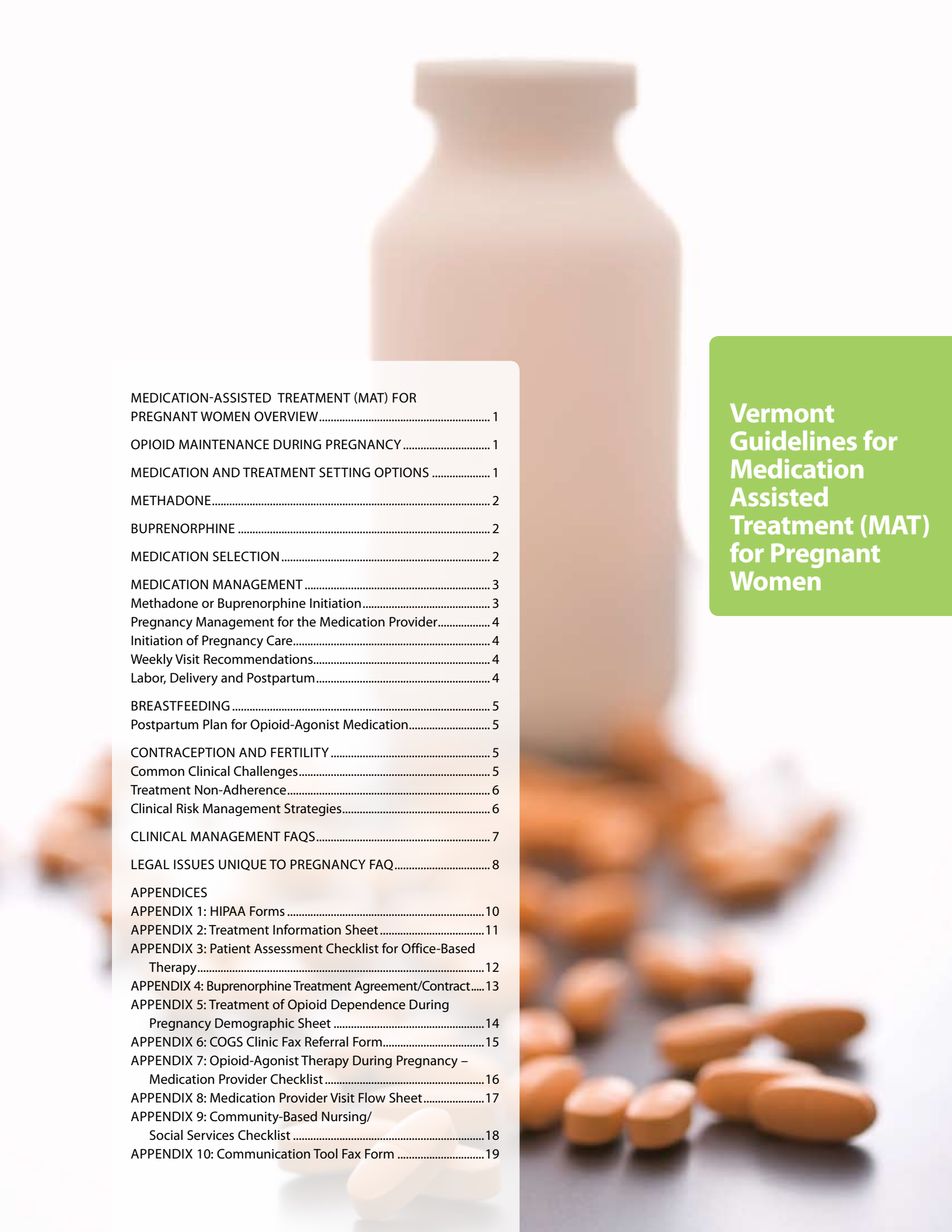
There have been many references to the French buprenorphine experience. Subutex®, the only product marketed initially in that country, was subject to misuse and many overdose deaths when co-injected with benzodiazepines. In France, however, buprenorphine remains widely available. Physicians are not subject to mandatory training/qualifications as they are in the United States, nor are French physicians subject to patient limits, as in the United States. Pharmacies in France, however, do have additional responsibilities to limit dispensing and report misuse and diversion back to prescribing physicians.

In February 2008, SAMHSA convened a special summit on buprenorphine. The meeting examined the state of buprenorphine treatment and what steps could be considered to improve office-based opioid treatment with buprenorphine and to reduce the risk of diversion and abuse. Buprenorphine is an extremely valuable treatment medication with recognized potential for abuse and diversion.

1 Cicero, T. J., Surratt, H. L., & Inciardi, J. (2007). Use and misuse of buprenorphine in the management of opioid addiction. *Journal of Opioid Management*, 3(6), 302–308.

2 Cicero, T. J., Surratt, H., Inciardi, J. A., & Munoz, A. (2007). Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States. *Pharmacoepidemiology and Drug Safety*, 16, 827–840.

In addition to this Web site, you can visit the Food and Drug Administration's buprenorphine pages at www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm, and the manufacturer's Web site at www.suboxone.com. Additionally, you can contact the SAMHSA Buprenorphine Information Center toll-free at 1-866-BUP-CSAT (1-866-287-2728), or by e-mail at info@buprenorphine.samhsa.gov.



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Vermont Guidelines for Medication Assisted Treatment (MAT) for Pregnant Women

PURPOSE/DISCLAIMER

The Vermont Guidelines for Medication-Assisted Treatment (MAT) for Pregnant Women were created to provide Vermont practitioners with a consolidated set of recommendations for the management of opioid dependence during pregnancy. The content of these guidelines is intended to complement standard medical care, the *Vermont Buprenorphine Practice Guidelines*, and other resources available through the American College of Obstetrics and Gynecology and Substance Abuse and Mental Health Services Administration (www.samhsa.gov) and Community-based Substance Abuse Treatment (www.csat.samhsa.gov).

These guidelines are not intended as requirements for practitioners. They should not be considered as medical advice.

ACKNOWLEDGEMENTS

The Vermont Guidelines for the Treatment of Opioid Dependence in Pregnancy are a collaborative effort of the Vermont Department of Health, Division of Alcohol and Substance Abuse Programs (VDH/ADAP) and the Department of Vermont Health Access (DVHA), with the guidance of local treatment providers. Many people contributed to developing these guidelines. Special thanks go to the following individuals:

John R. Brooklyn, MD
Barbara Cimaglio
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Wendy Davis, MD
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Jerilyn Metayer, RN
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Miriam Sheehey, RN
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Marjorie Meyer, MD
Eleanor Capeless, MD

Medication-Assisted Treatment (MAT) for Pregnant Women Overview

OPIOID MAINTENANCE DURING PREGNANCY

Opioid addiction is a chronic, relapsing disease. Acute opioid withdrawal is physiologically stressful, characterized by profound activation of the sympathetic nervous system with hypertension, tachycardia, and gastrointestinal symptoms. In the 1970s, a series of case reports and animal studies reported stillbirth and meconium aspiration when patients presented late in gestation in acute opioid withdrawal. Coincident with these reports, randomized trials in the general opioid dependent population demonstrated that methadone maintenance decreased opioid craving and allowed rehabilitation more effectively than acute withdrawal. As methadone maintenance for the treatment of opioid dependence became accepted as appropriate medical therapy, the use of methadone during pregnancy to prevent maternal (and fetal) withdrawal was examined. Methadone maintenance during pregnancy improved prenatal care, reduced illicit drug use, and minimized the risk of fetal *in utero* withdrawal. These demonstrated benefits led to the current recommendation for opioid agonist maintenance for opioid dependent women during pregnancy.

MEDICATION AND TREATMENT SETTING OPTIONS

Treatment with an opioid-agonist improves pregnancy outcomes for opioid-dependent women. The best outcomes are observed when women are enrolled in a comprehensive treatment program. The overarching goals of therapy for opioid dependence during pregnancy is to provide medical support to prevent withdrawal during pregnancy, minimize fetal exposure to illicit substances, and engage the mother as a leader in her recovery. Such engagement provides her the opportunity to receive both medical and ancillary services which will allow her to successfully parent her child. Recognizing that engagement into a comprehensive treatment program can be a gradual process, medication providers may face the difficult task of distinguishing the patient that needs a bit more time to become engaged in a treatment plan from the patient that is not ready for treatment. Assessment of treatment progression over some

weeks may be needed.

Office-based therapy during pregnancy favors the patient that is highly motivated to recovery and parenting. Such women usually agree to substance abuse counseling and the assistance of community-based nursing to assist in recovery. Patients unwilling to engage these services may not be optimal candidates for office-based therapy and may benefit from the structure of a methadone program or residential treatment before proceeding to office-based therapy. Inclusion of substance abuse counseling and wrap around services should be strongly encouraged for all patients, as medication alone is not sufficient for optimal pregnancy and parenting outcome.

The decision regarding the most appropriate medication should be made jointly with the opioid-agonist provider, the obstetrician, and the patient. Women that are pregnant but are not a candidate for office-based therapy should

GREATEST BENEFIT

Comprehensive treatment program opioid-agonist therapy (methadone or buprenorphine)
OPTIMAL TREATMENT

Buprenorphine without counseling; no illicit use

GREATEST RISK

Methadone or buprenorphine with continued other illicit substance use

Continued illicit drug use with no treatment

be referred to a methadone treatment center (Chittenden Center or BAART); an alternative is a residential program with reassessment for office-based therapy following successful completion of the residential treatment program.

METHADONE: OPIATE PROGRAM CENTER-BASED TREATMENT

Methadone is a pure mu opioid-agonist with a long half life (24 hours) which allows for daily dosing. Methadone is the medication of choice for treatment during pregnancy, owing to the simple fact that there are more data regarding neonatal outcomes following *in utero* exposure. It is a pregnancy category C drug and is not specifically approved for treatment of opioid dependence during pregnancy by the FDA, despite widespread recommendations as the medication of choice in pregnancy. Initiating or switching treatment to methadone should be offered to all opiate dependent pregnant patients.

Methadone for the treatment of opioid dependence is available only through opioid treatment centers. In Vermont, these centers provide medical screening and substance abuse counseling, including a full social assessment. Provision of these ancillary services has been demonstrated to improve retention in treatment and treatment outcomes.

Pregnant women are a high priority for treatment with methadone and will automatically be enrolled in a treatment program, despite long waiting lists for other patients. In Vermont, the major barriers to methadone treatment are the restricted daily dosing times and the travel time that is often needed. These issues are particularly difficult for women in school, working, with small children at home, and those that live a distance from a treatment center. Access to medication and ability to realistically comply with a treatment program can be considered in the overall decision regarding medication choice.

BUPRENORPHINE: OFFICE-BASED MEDICATION-ASSISTED TREATMENT

Buprenorphine is a partial mu opioid-agonist approved for the treatment of opioid dependence. Unlike methadone, buprenorphine is prescribed in medical offices rather than at licensed clinics. The *Vermont Buprenorphine Practice Guidelines* outline the background of office-based medication-assisted therapies and guidance for prescribers on the management of opioid dependent patients. Brand names for buprenorphine include Suboxone, which is a buprenorphine/naloxone combination and Subutex, which is buprenorphine alone.

Small cohort studies have found buprenorphine to be safe and effective in the treatment of opioid dependence during pregnancy. However, because it is a relatively new medication, long term outcome data of neonates exposed to buprenorphine *in utero* are lacking and patients seeking treatment should be informed of this. Nonetheless, risk/benefit may favor buprenorphine if the patient is otherwise

a candidate for office-based therapy and there are barriers that preclude her attending a methadone program. The data suggest that treatment with buprenorphine provides better outcomes for mother and newborn compared to no treatment.

Candidates for buprenorphine are women that are stable on buprenorphine prior to pregnancy or those unable to attend a methadone treatment center AND are otherwise candidates for office-based therapy. Pregnancy does NOT make women automatically candidates for office-based therapy with buprenorphine, even if that is the only medication available in the community. Engagement in counseling and other services is vital during pregnancy and recovery for successful postpartum transition. Some women may benefit from residential treatment with office-based therapy following stabilization.

MEDICATION SELECTION

Please see the *Vermont Buprenorphine Practice Guidelines* for detailed information regarding the choice of medication and how to determine whether a patient, irrespective of pregnancy issues, is a candidate for office-based treatment.

Choosing the best medication for pregnancy is a discussion ultimately best suited to the medication provider and the patient. Recognizing many pregnant patients will look to their obstetric care provider before initiating medication, it may be helpful for the medication provider and obstetric provider to discuss the plan before presenting the final decision to the patient.

Methadone is the medication of choice due to the long term neonatal outcome data. Buprenorphine is a reasonable alternative in select patients. The discussion and decision for medication should be reviewed with the patient and documented in the chart. Please see *Appendix 2* for a sample Patient Treatment Information sheet regarding medication during pregnancy, which can be reviewed with the patient.

For patients that are not optimal candidates for buprenorphine when methadone is not available, a step wise approach of initiation with buprenorphine with close follow-up could be considered. In these instances, buprenorphine with very close and frequent follow-up could be considered with initiation of medication and counseling. Residential treatment or methadone could be considered for difficulty in buprenorphine treatment adherence.

If you are uncertain about the optimal medication for a pregnant patient, Fletcher Allen Health Care Comprehensive Obstetrics and Gynecology Clinic or Neonatology Service can assist in this decision making process and provide care to any opioid dependent patient.

The Fletcher Allen Comprehensive Obstetrics and Gynecology Clinic is available to treat any opioid dependent women during pregnancy. (See *Appendix 6* for referral forms).

Methadone or start with residential treatment if:

- ☐ Polysubstance abuse, including alcohol or benzodiazepines
- ☐ Unstable living situation
- ☐ Abused buprenorphine (snorting)
- ☐ Declines/noncompliant with counseling
- ☐ Inability to coordinate ancillary services
- ☐ In a mandatory recovery program (parole)
- ☐ Noncompliant with obstetric or pediatric care

Office-based buprenorphine if:

- ☐ Informed consent re: new medication for pregnancy
- ☐ Opioids are the only substance of abuse
- ☐ Stable living situation
- ☐ Accepts counseling
- ☐ Can coordinate ancillary services or there is a community-based program that will do so
- ☐ Compliant with obstetric and pediatric care
- ☐ There is no alternative and the patient understands treatment may be initiated on a trial basis



MEDICATION MANAGEMENT

The information in this document is additional information for medication initiation during pregnancy. For more detailed information about initiation of medication, patient selection, or other issues surrounding initiation of buprenorphine, see the *Vermont Buprenorphine Practice Guidelines* in this booklet.

Medication should not be initiated until both opioid dependence AND a viable intrauterine pregnancy (ultrasound with heartbeat) are confirmed. Pregnancy is an indication for priority treatment but is *not* an emergency.

For initiation of medication during pregnancy, there must be a diagnosis/confirmation of pregnancy. Urine home pregnancy tests are not sufficient for initiation of treatment. Obstetric providers, community health clinic or Planned Parenthood clinics can assist with diagnosis of or confirmation of a viable intrauterine pregnancy.

For a diagnosis/confirmation of opioid dependence, a positive urine test for opioids run as either an office-based point of care test or a laboratory test can be run. Opioid dependence should be documented by the presence of opioid withdrawal symptoms, such as COWS. (see *Vermont Buprenorphine Practice Guidelines, Appendix 5, page 13*)

Query of the Vermont Prescription Monitoring System to assess prescription opioid use is recommended.

Occasional use of opioids may not cause physical dependence and therefore may not require agonist therapy; substance abuse counseling and monitoring is imperative.

Methadone or Buprenorphine Initiation

The provider should decide on medication of choice (refer to the *Vermont Buprenorphine Practice Guidelines*).

Induction of medication will be the same procedure used for non-pregnant patients in your practice (see *Vermont Buprenorphine Practice Guidelines*); pregnant women should be considered a priority induction with a goal of initiation of medication within one week of the medication decision.

Mild or even moderate (CINA 10-12 range) symptoms of opioid withdrawal are not dangerous to pregnancy. It is reasonable to ask the patient to abstain from opioid use (and have withdrawal symptoms) for the purposes of induction. Patients may be referred to an induction center for buprenorphine if that is your usual approach. Buprenorphine mono-therapy is recommended during pregnancy.

Continuation of Medication During Pregnancy

(after induction or in a previously stable patient):

If buprenorphine is being used, change to buprenorphine monotherapy at the same dose.

Assess for withdrawal symptoms weekly (see Medication Provider Visit Flow Sheet, *Appendix 8*) and adjust dose as indicated; one refill (total of two weeks of medications) may be considered for the stable patient in counseling if not well.

Provide only one week of medication at a time to minimize diversion/theft/loss of medication.

- Pregnancy specific dosing notes:
 - 70% of patients stable prior to pregnancy will need a modest dose increase (3-5 mg) during pregnancy (Fletcher Allen data); prescribed gradually throughout gestation
 - The average dose at the end of pregnancy in women started during pregnancy is 16 mg (Fletcher Allen data)
 - Large increases in buprenorphine requirements have not been noted during pregnancy; if such increases are needed, consider alternative diagnoses
- If the patient has difficulty in engaging in ancillary services and counseling, consider switch to residential program or a methadone treatment program
If methadone is being used, methadone dose may need to be split if very high doses are needed due to increased excretion.

Pregnancy Management for the Medication Provider:

As the provider of methadone or buprenorphine, you will have the longest history with the patient and the best visit compliance. Referrals for ancillary services during pregnancy are best made through your medication visits.

At Initiation of Pregnancy Care:

Referral to your district Children's Integrated Services Coordinator (CIS) should occur. See the resource section in this booklet for the agency in your district that houses the CIS intake coordinator. See the patient in weekly visits and for urine drug screens.

The stresses of pregnancy and having a newborn warrant closer follow-up even if substance abuse counseling has not been needed in the past. Obtain HIPAA consents to permit communication with obstetric provider, counselor, and planned pediatric provider. This consent should be a condition of office-based treatment. (See *Appendix 1* for samples).

Contact the obstetric provider and pediatric provider directly to document medication (methadone or buprenorphine) use in pregnancy (they will know whether delivery in your local/regional hospital is appropriate). Refer to the Services for Opioid-Dependent Pregnant Women in Vermont at the beginning of this document.

There should be documentation of estimated due date (patient report is sufficient).

Weekly Visit Recommendations (can be done by a nurse):

- Urine drug screen
- Assessment of withdrawal symptoms or evidence of functional impairment.
- Confirmation of adherence with counseling recommendations
- Confirmation of adherence with community-based nursing (parenting) plans

- Confirmation of adherence to obstetric care (monthly visits until 28 weeks; every 2 week visits 28-36 weeks; weekly visits 36 weeks to due date at 40 weeks)
- Assessment and plan for difficulty with adherence to the treatment plan (i.e.: prenatal care, counseling, connection with ancillary services) should be made with each weekly prescription
- Reassess whether the patient should remain in an office-based treatment program for repeated lack of adherence
- Provide prescription

Between 24-32 weeks establish these referrals (either send the patient directly OR specifically request the obstetric provider):

- Pediatric provider consultation for evaluation and treatment of neonatal abstinence syndrome (with specific emphasis on ability to receive all care at the hospital of planned delivery)
- Anesthesia consultation for pain management plan (reasonable for all patients; most important for those planning cesarean delivery)

36-40 weeks: Delivery and Postpartum planning

- Update the obstetric provider with the appropriate dose of medication near delivery
- Remind the obstetric provider that **NALBUPHINE and BUTORPHANOL are CONTRAINDICATED** as they can precipitate withdrawal
- Children and Infant Services referral for ancillary social services
- Encourage Breastfeeding
- Community-based nursing for parenting skills
- Partner treatment if not already done

Labor, Delivery and Postpartum:

During labor and delivery, as well as the postpartum process, reassure the patient that providing her adequate pain control is important. Conversations with obstetric and anesthesia providers should reflect that in a stable patient, there is no reason to suspect drug seeking if requesting pain medication in the appropriate clinical setting. Pediatrics should be notified that an opioid exposed neonate will be delivered soon.

A referral can be made to hospital based social work to evaluate any needs of the patient postpartum. During labor and delivery, continue scheduled methadone or buprenorphine during hospitalization. The obstetric provider can order these medications in the hospital even if not a buprenorphine prescriber, but will not be able to prescribe this medication after hospital discharge. An anesthesia consult should be made when the patient arrives in labor as indicated.

Neuraxial analgesia (spinal, epidural) is effective for pain control during labor or for cesarean delivery in opioid dependent women.

Intravenous short-acting **NALBUPHINE and BUTORPHANOL** are **CONTRAINDICATED** as they may precipitate withdrawal. If inadvertent administration occurs and the patient has withdrawal symptoms, an opioid-agonist should be administered to alleviate withdrawal symptoms; monitor for respiratory depression.

After the delivery, continue medication-assisted therapy as indicated and have hospital based social work see the patient.

For pain control, acetaminophen and non-steroidal anti-inflammatory agents should be used for mild and moderate pain with short-acting opioid analgesics used as needed. In a vaginal birth, short-acting opioids can be made available on a PRN basis, just as for non-opioid dependent patients.

Opioids for pain control should not be needed following discharge for a routine delivery. In the case of a cesarean delivery, continuous short-acting analgesics for 48 hours patient controlled analgesia with intravenous morphine or hydromorphone can be used the first 24 hours. Oral opioids can also be used.

You may expect a 70% increase in short-acting opioid analgesic requirement; often a more potent oral agent (hydromorphone) is required. Patient controlled epidural analgesia is effective for severe pain if available. Expect that short-acting opioids will be needed in decreasing amounts for 5-7 days following cesarean delivery.



BREASTFEEDING

Breastfeeding is encouraged for all patients (except those with HIV).

If Breastfeeding is declined, switch the patient back to combination buprenorphine/naloxone immediately after delivery or continue methadone.

If breastfeeding *is* accepted, consult with pediatric provider to confirm that they are aware of patient's medication-assisted treatment use.

If newborn *is not* receiving methadone or morphine for neonatal abstinence syndrome, switch mother back to buprenorphine/naloxone. If the newborn is being treated with methadone or morphine for neonatal abstinence syndrome, continue buprenorphine monotherapy until neonate is off medication or weaned from breastmilk. There may be some patients in whom combination buprenorphine/naloxone is recommended; given evidence of minimal bioavailability in breastmilk, breastfeeding should be encouraged.

Postpartum Plan for Opioid-Agonist Medication:

There is currently no evidence that dose changes of methadone or buprenorphine are needed postpartum. Special attention for somnolence is warranted. Pay special attention to relapse, especially 3-6 months postpartum. There is anecdotal evidence to suggest that this is a particularly vulnerable time for a woman in recovery. Encourage continuation of community nursing for parenting support (or start initial referral at discharge if not done previously).

Ensure each patient has a follow-up appointment with BOTH her medication provider and substance abuse counselor.

CONTRACEPTION AND FERTILITY

As with many underlying diseases, as the patient's recovery proceeds, her fertility may also increase. Patients should not assume that because they have had infertility problems in the past that it will continue after treatment is initiated. If a patient is planning a pregnancy (or sexually active without contraception), prenatal vitamins (800 mcg folic acid) are recommended prior to conception to reduce birth defects. If a patient is sexually active and not using contraception, prenatal vitamins should be recommended given high risk of pregnancy.

Contraceptive counseling and treatment are available at low cost (or free) from community health clinics and Planned Parenthood. There is no evidence of medication interaction between oral contraceptives and methadone or buprenorphine. To afford the patient the best chance for a successful recovery, address her partner/family substance abuse treatment and plan, as indicated.

Common Clinical Challenges:

Women with a history of substance abuse often have chaotic lives, experience domestic violence, and have tenuous housing. The structure imposed by treatment programs can be a difficult adjustment. Relapses are

common, especially early in treatment. A combined treatment plan developed by the patient with the obstetrician and medication provider that appropriately balances maternal and fetal risk is imperative.

Treatment Non-Adherence

The inability to remain abstinent, non adherence with counseling, or demonstration of other high-risk behavior constitutes treatment non-adherence.

Options include:

- Evaluate for more intensive services to more structured program (intensive outpatient program, residential treatment, methadone) using ASAM criteria.
- Discharge the patient from office-based therapy if she declines other options. Communication with the obstetrician, pediatrician, social work team at the hospital of planned delivery and the Department of Children and Families (DCF) should occur promptly.
- Useful cross discipline strategies for treatment non-adherence include linking the ability to pick up a buprenorphine prescription or methadone dose with prenatal care by requiring a visit to the obstetric provider office first. Consider linking the ability to pick up a buprenorphine prescription or methadone dose to counseling and referral to residential treatment or consider switch to methadone if adherence to office-based care is not possible
- For recurrent positive drug screens with benzodiazepines, particular care must be taken in management of patients dependent upon benzodiazepines and opioids, due to synergistic respiratory depression, even if the benzodiazepines are prescribed. Provision for coordination of care must be made and consideration given to admission for benzodiazepine detoxification.
- Education should be given about the potential synergy between methadone, buprenorphine and benzodiazepines which includes warnings about driving or machine operation. This intervention should be documented in the medical record.
- Other strategies include an increase in counseling and consideration of alternative medication for anxiety (i.e.: sertraline). ***Patient may not be a candidate for office-based therapy if using benzodiazepines and might be better served at an opioid treatment center or residential treatment center.***
- For recurrent positive drug screens with cocaine, discuss the specific dangers of cocaine use in pregnancy including fetal loss, bleeding, preterm labor and fetal stroke. The patient may not be a candidate for office-based therapy if using cocaine and should be referred to an opioid treatment center or residential treatment for a more structured program. Education should be provided and documented regarding potential Levamisole contamination of cocaine.
- For recurrent positive drug screens with cannabis, use

of any illicit substance should be discouraged. Given the relatively little data that THC is harmful in pregnancy combined with the clear benefit of opioid maintenance therapy, consider continuation with close follow-up or residential treatment.

- Non-adherence due to transportation and other social barriers present complex problems to successful recovery. Referral to community-based nursing/social work to develop a transportation plan (i.e.; Medicaid sponsored transportation) should be made.
- Offer residential treatment for intensive counseling which can allow for less frequent (once a week) counseling after discharge. Inadequate housing, partner use of illicit substances, and domestic violence are common issues to be addressed with counseling and community-based nursing.

Clinical Risk Management Strategies:

Documentation is crucial and the following elements must be covered: referral for treatment, treatment refusal and planned use of medications not approved by the FDA, including use of methadone vs. buprenorphine. Document when Department of Children and Families notification of drug use is made. Ancillary services provided should be documented.



Clinical Management FAQs

The following scenarios may help the obstetricians and medication providers understand treatment decisions. Close communication between providers will enable the optimal medical approach (as for any other medical illness):

Do I have to offer buprenorphine to a pregnant patient because she refuses methadone?

- ☐ The patient should receive the optimal care during pregnancy
- ☐ If she is not a candidate for buprenorphine, then she should receive methadone or referral to residential treatment
- ☐ Consider offering residential treatment and transfer to buprenorphine after successful completion of the residential program

Do I have to start buprenorphine immediately because the patient is pregnant?

- ☐ *Pregnancy is not an emergency*; simply a priority
- ☐ Confirm opioid dependence
- ☐ Confirm viable pregnancy

May I stop prescribing buprenorphine to the non-compliant patient during pregnancy?

- ☐ It is unsafe for the mother and fetus to continue to engage in risky behavior
- ☐ Medication can be discontinued for any medical reason when there is lack of benefit; alternatives should be offered (residential treatment; methadone treatment center)
- ☐ Continued high-risk behaviors in the office-based setting suggest the need for residential or center-based care.
- ☐ Document non-compliance and offers of alternative, more structured care

How do I know when to decline further office-based care with buprenorphine?

- ☐ Concurrent use of benzodiazepines
- ☐ Concurrent use of cocaine
- ☐ Difficulty engaging in counseling
- ☐ Can depend on ease of switching to methadone: assessment of overall maternal/fetal risk/benefit of continued treatment if no treatment is the option; the medication provider has some latitude if it is decided that risk/benefit favors office-based care

What should I do when I decide I cannot prescribe to a patient during pregnancy?

- ☐ Document rationale in medical record
- ☐ Offer methadone even if the patient needs to travel
- ☐ If option is buprenorphine versus no treatment:
 - Consider residential treatment
 - Consider supervised pregnancy residence
- ☐ Contact local child protection services when you discontinue medication; they can often follow-up in the hospital at delivery
- ☐ Tell the patient you must do this and document the conversation

Suggested “scripted” approaches to discussing treatment options

Initial visit script:

- Good for you in seeking help with addiction
- We need to confirm that you are pregnant and clarify the level and nature of your opioid abuse
- We routinely check the Vermont Prescription Monitoring System in all patients seeking treatment at our clinic
- Methadone is the medication of choice for the treatment of opioid dependence during pregnancy because we have years of experience with neonatal exposure
- I understand you would like to be treated with buprenorphine
- Buprenorphine is not approved for use in pregnancy and we do not have many years of experience; the oldest children are only 5 or 6
- Substance abuse counseling and engagement in community-based services to help with parenting is necessary for recovery and parenting
- Will you agree to attend counseling and receive help from community-based nursing?

Follow up sessions:

- I see that you have continued to use cocaine based on your toxicology screen. How shall we address this together?
- Let us review our plan for management of your pregnancy using buprenorphine/methadone
- Have you been able to keep your appointments with counseling and other medical providers?

Legal Issues Unique to Pregnancy FAQ

Misperceptions about legal issues are an important reason that opioid-dependent and pregnant women avoid treatment. Common misconceptions regarding treatment of the pregnant patient are addressed below.

Example: A 19 year-old with heroin addiction learns she is pregnant at a community health clinic.

Misconception: She should stop heroin immediately or she will go to jail

Fact: The American College of Obstetrics and Gynecology has a series of Committee Opinions that address ethical issues in Obstetrics and Gynecology, with the use of alcohol and illicit substances specifically considered.

- Pregnant women should be allowed to make decisions on their own behalf
- Most women will choose to proceed with treatment for the health of the fetus/newborn
- Incarceration, where there are few services, results in worse outcomes (mother: less prenatal care, less treatment, higher relapse; newborn: worse outcome in foster care than with a recovering mother)

Misconception: She should not use opioid-agonist therapy because her baby will be an addict

Fact: Randomized trials have demonstrated the long-term (3 year) benefit of methadone treatment versus taper. Studies show less relapse and neonatal outcomes similar to controls (after demographic adjustment).

Misconception: She must receive opioid-agonist therapy although she requests a taper

Fact:

- Opioid-agonist therapy is clearly the treatment of choice as it improves prenatal care, reduces relapse, and reduces exposure to other illicit drugs.
- There are no data to suggest medication-assisted withdrawal early in pregnancy (before 24 weeks) is harmful
- Abrupt withdrawal from heroin late in gestation is associated with *in utero* withdrawal, increased meconium aspiration, and may be associated with fetal death
- Once informed, if the patient would like to taper, a gradual taper of 10% per week is reasonable. Many patients will become uncomfortable and stop a taper even after requesting it.



Misconception: If she has any relapses, she will lose custody of her child

Fact: Reporting laws vary by state, but most have some mandatory reporting of any maternal behavior that can impair the wellbeing of a child. However:

- Most states will work closely with a patient in recovery to allow her to maintain custody
- Many cannot intervene until after delivery (Vermont: case can be opened 30 days prior to expected delivery)
- Reinforce to the patient that treatment during pregnancy, even if has a few slips, will improve the chances of custody retention
- Reporting during pregnancy allows social work time to understand all aspects of patient care
- Reinforce to patient that the goal of all is to help her maintain custody and receive appropriate treatment for her to parent her child. The opioid-agonist treatment provider can play an important patient advocacy role here.

RISK MANAGEMENT REFERENCES:

(2005). "ACOG Committee Opinion #321: Maternal decision making, ethics, and the law." *Obstet Gynecol* 106(5 Pt 1): 1127-37.

(2007). "ACOG Committee Opinion No. 363: patient testing: ethical issues in selection and counseling." *Obstet Gynecol* 109(4): 1021-3.

(2007). "ACOG Committee Opinion No. 390, December 2007. Ethical decision making in obstetrics and gynecology." *Obstet Gynecol* 110(6): 1479-87.

(2008). "ACOG Committee Opinion No. 422: at-risk drinking and illicit drug use: ethical issues in obstetric and gynecologic practice." *Obstet Gynecol* 112(6): 1449-60.

SAMHSA Tip 40 Guidelines for the use of buprenorphine and the *Vermont Buprenorphine Practice Guidelines* are excellent resources for the office-based treatment for opioid dependence. These guidelines below contain ancillary information for those providers that choose to prescribe opioid-agonist medication for women during pregnancy.

Providers that do not choose to prescribe during pregnancy can contact Marjorie Meyer MD or Eleanor Capeless MD at Fletcher Allen Health Care for questions (firstname.lastname@vtmednet.org) or arrange for transfer of the patient through the Comprehensive Obstetrics and Gynecology Service at Fletcher Allen Health Care at 802-847-1400.

Appendix 1: HIPAA Form

MRN

PATIENT NAME

PATIENT DATE OF BIRTH

NOTICE OF PRIVACY PRACTICES

I have received the Notice of Privacy Practices at Fletcher Allen Health Care informing me of how Fletcher Allen Health Care will use my personal health information.

My understanding of this Notice will help me ensure the accuracy of my health information, better understand who, what, where and why others may access my health information.

I acknowledge receipt of the Notice and understand any questions pertaining to Fletcher Allen Health Care's privacy policies may be answered by contacting the Fletcher Allen Health Care Patient Relations Department at (802) 847-3500.

PATIENT / GUARDIAN

DATE OF RECEIPT

RELATIONSHIP TO GUARDIAN

☐ Patient unable to sign ☐ Patient refused to sign

Reason: _____

WITNESS

Appendix 2: Treatment Information Sheet

Healthy moms are certainly more likely to have a healthy baby. It is common for women to decide to take action to treat medical problems for the health of their growing baby. A decision to receive medical treatment for opioid dependence during pregnancy is an important step in your life and that of your baby. Medical treatment can reduce other drugs in your system and increase the chances of a full recovery.

Both methadone and buprenorphine are used for the treatment of opioid dependence. Below are some facts to consider as you and your physician decide which medication is best for you:

- We have the most data about how you and your baby do in the long term when treated with methadone
- Buprenorphine is a new drug and while it appears to be safe when we examine newborns, we do not know about long term effects on the baby
- The ability to receive medication close to home may be a consideration in deciding what medication to use
- Neonatal abstinence symptoms can occur following treatment with either methadone or buprenorphine
- It is important that you can be compliant with whichever treatment you are on
- Counseling is an essential part of treatment, regardless of medication
- Not all people are candidates for office-based treatment with buprenorphine; in those cases methadone is strongly advised
- If buprenorphine treatment does not seem to be effective for you, treatment with methadone may be recommended even if it would be difficult
- Some women that strongly desire buprenorphine may do best to start treatment in a residential treatment setting

Appendix 3: Patient Assessment Checklist for Office-Based Therapy

The following guidelines will help in deciding whether to treat with buprenorphine in the office. They assume the person is opioid dependent.

SCORING KEY

- 0-5: Excellent candidate for office-based treatment.
- 6-10: Good candidate for office-based treatment.
- 11-15: Good candidate, but only with tightly structured program providing supervised dosing and on site counseling.
- 16-20: Candidate for office-based treatment by board certified addiction physician in a tightly structured program or hub induction with follow-up by office-based provider or methadone clinic referral.
- 21-25: Candidate for methadone program only.

For each answer check YES or NO and add points for YES and NO below.

Questions	Points:	Yes	No	Possible
Is the person employed?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Is the family intact?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have a partner who uses drugs or alcohol?		<input type="checkbox"/> 1	<input type="checkbox"/>	<input type="checkbox"/> 1
Is the person's housing stable?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have legal issues?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have any convictions for drug dealing?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Is the person on probation?		<input type="checkbox"/> 1	<input type="checkbox"/>	<input type="checkbox"/> 1
Does the person have psychiatric problems, e.g., major depression, bipolar, severe anxiety, PTSD, schizophrenia, personality subtype of antisocial, borderline, or sociopathy?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Does the person have a chronic pain syndrome that needs treatment?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Does the person have reliable transportation?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Does the person have a reliable phone number?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Has the person been on medicated assisted treatment before?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Was the medicated assisted treatment successful?		<input type="checkbox"/>	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Does the person have a problem with alcohol?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Does the person have a problem with cocaine?		<input type="checkbox"/> 1	<input type="checkbox"/>	<input type="checkbox"/> 1
Does the person have a problem with benzodiazepines?		<input type="checkbox"/> 2	<input type="checkbox"/>	<input type="checkbox"/> 2
Is the person motivated for treatment in the office?		<input type="checkbox"/>	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Is the person currently going to counseling, AA, or NA?		<input type="checkbox"/>	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Total points possible: 25	Total each column:			
	Total both columns:			

Provided by John R. Brooklyn, MD, May 21, 2009

Appendix 4: Buprenorphine Treatment Agreement/Contract

As a participant in the buprenorphine protocol for treatment of opioid abuse and dependence, I freely and voluntarily agree to accept this treatment agreement/contract, as follows:

I agree to keep, and be on time to, all my scheduled appointments with the doctor and his/her assistant.

I agree to attend substance abuse counseling at least weekly; more often at the initiation of treatment.

I understand that urine collections will be performed to send for drug screens.

I agree to conduct myself in a courteous manner in the physician's office.

I agree not to arrive at the office intoxicated or under the influence of drugs. If I do, the doctor will not see me, and I will not be given any medication until my next scheduled appointment.

I agree not to sell, share, or give any of my medication to another individual. I understand that such mishandling of my medication is a serious violation of this agreement and would result in my treatment being terminated without recourse for appeal.

I agree not to deal, steal, or conduct any other illegal or disruptive activities in the doctor's office.

I agree that my medication (or prescriptions) can be given to me only at my regular office visits. Any missed office visits will result in my not being able to get medication until the next scheduled visit.

I agree that the medication I receive is my responsibility and that I will keep it in a safe, secure place. I agree that lost medication will not be replaced regardless of the reasons for such loss.

I agree not to obtain medications from any physicians, pharmacies, or other sources without informing my treating physician. I understand that mixing buprenorphine with other medications, especially benzodiazepines such as valium and other drugs of abuse, can be dangerous. I also understand that a number of deaths have been reported among individuals mixing buprenorphine with benzodiazepines.

I agree to take my medication as the doctor has instructed and not to alter the way I take my medication without first consulting the doctor.

I understand that medication alone is not sufficient treatment for my disease, and I agree to participate in the patient education and relapse prevention programs, as provided, to assist me in my treatment.

I understand that I will be transitioned to Suboxone (buprenorphine/naloxone) following delivery (exception: breastfeeding and baby in treatment).

PATIENT SIGNATURE

DATE

PRINTED NAME

Appendix 5: Treatment of Opioid Dependence During Pregnancy Demographic Sheet

NAME	DATE OF BIRTH
MEDICATION	
OBSTETRIC PROVIDER	FAX NO.
PEDIATRIC PROVIDER	FAX NO.
MEDICATION PROVIDER	FAX NO.
SUBSTANCE ABUSE COUNSELOR	FAX NO.
HOME HEALTH NURSE	FAX NO.
HOSPITAL FOR DELIVERY	

Appendix 6: COGS Clinic Fax Referral Form

Patient name: _____

Referring provider (with contact and fax number): _____

Reason for referral: _____

LMP (or gest age): _____ US done: ☐ YES ☐ NO (attach record)

Prior prenatal care: ☐ YES ☐ NO Provider: _____

Medications (dose and prescribing physician; note if you will continue prescribing medication or request transfer of prescribing responsibility and last day of medication): _____

Substance abuse counselor after discharge (note if we need to set this up): _____

Appointment: _____

Date and time: _____

Place: _____

Provider: _____

Social worker appointment: _____

Fax to COGS clinic: 802-847-8433

Phone: 802-847-1400

Email: (provider to provider only): marjorie.meyer@uvm.edu

Note: please do not use patient identifiable information in the email

Appendix 7: Opioid-Agonist Therapy During Pregnancy – Medication Provider Checklist

PATIENT NAME

DATE OF BIRTH

MRN

DATE

☐ **Discuss risk benefits/Patient given risk benefit fact sheet**

- ☐ Methadone
- ☐ Buprenorphine
- ☐ No Treatment/wean

☐ **Substance abuse counselor**

☐ Name: _____

Refer to counseling if not already in treatment (counseling is strongly recommended in pregnancy)

☐ **Obstetrician**

☐ Name: _____

☐ Hospital of Delivery: _____

Anesthesia consult 24-32 weeks

☐ **Pediatrician**

☐ Name: _____

Refer at 24-32 weeks

☐ **Home Visiting Nurse**

☐ Name: _____

☐ **Urine Drug Screens**

- ☐ OB
- or
- ☐ Medication Provider

Appendix 8: Medication Provider Visit Flow Sheet

Due date: _____

Medication/dose: _____

Symptoms of withdrawal (check all withdrawal symptoms/physical findings that apply):

- ☐ Craving
- ☐ Sweating
- ☐ Lacrimation
- ☐ Runny nose
- ☐ Gooseflesh
- ☐ Yawning
- ☐ Adbominal pain
- ☐ Diarrhea

Have you seen a substance abuse counselor in the last week? _____

When is the next appointment with your obstetric care provider? _____

Have you seen community-based nursing recently? _____

Appendix 9: Community-Based Nursing/Social Services Checklist

PATIENT NAME

DATE OF BIRTH

MRN

DATE

☐ OB Provider: _____

☐ Medication Provider: _____

☐ Substance Abuse Provider: _____

☐ Primary Care Provider: _____

☐ Pediatrician: _____

☐ WIC

☐ Social Services

☐ Economic services

☐ Housing

☐ Employment

☐ Child care

Appendix 10: Communication Tool Fax Form

To:		From:	
Fax:		Pages:	
Phone:		Date:	

Name: _____

Date of birth: _____

Due date: _____

Medication/dose: _____

Visit type:

- ☐ Counseling
- ☐ OB visit
- ☐ Community nurse
- ☐ Pediatric visit

Date of visit: _____



VERMONT GUIDELINES FOR OBSTETRIC PROVIDERS

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Vermont Guidelines for Obstetric Providers

PURPOSE/DISCLAIMER

The Vermont Guidelines for Obstetric Providers were created to provide Vermont practitioners with a consolidated set of recommendations for the management of opioid dependence during pregnancy. The content of these guidelines is intended to complement standard medical care, the *Vermont Buprenorphine Practice Guidelines*, and other resources available through the American College of Obstetrics and Gynecology and Substance Abuse and Mental Health Services Administration (www.samhsa.gov) and Community-based Substance Abuse Treatment (www.csat.samhsa.gov).

These guidelines are not intended as requirements for practitioners. They should not be considered as medical advice.

ACKNOWLEDGEMENTS

The Vermont Guidelines for the *Treatment of Opioid Dependence in Pregnancy* are a collaborative effort of the Vermont Department of Health, Division of Alcohol and Substance Abuse Programs (VDH/ADAP) and the Department of Vermont Health Access (DVHA), with the guidance of local treatment providers. Many people contributed to developing these guidelines. Special thanks go to the following individuals:

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Vermont Guidelines for Obstetric Providers Overview

OPIOID MAINTENANCE DURING PREGNANCY

Opioid addiction is a chronic, relapsing disease. Acute opioid withdrawal is physiologically stressful, characterized by profound activation of the sympathetic nervous system with hypertension, tachycardia, and gastrointestinal symptoms. In the 1970s, a series of case reports and animal studies reported stillbirth and meconium aspiration when patients presented late in gestation in acute opioid withdrawal. Coincident with these reports, randomized trials in the general opioid dependent population demonstrated that methadone maintenance decreased opioid craving and allowed rehabilitation more effectively than acute withdrawal. As methadone maintenance for the treatment of opioid dependence became accepted as appropriate medical therapy, the use of methadone during pregnancy to prevent maternal (and fetal) withdrawal was examined. Methadone maintenance during pregnancy improved prenatal care, reduced illicit drug use, and minimized the risk of fetal *in utero* withdrawal. These demonstrated benefits led to the current recommendation for opioid-agonist maintenance for opioid dependent women during pregnancy.

MEDICATION AND TREATMENT SETTING OPTIONS

Treatment with an opioid-agonist improves pregnancy outcomes for opioid dependent women. The best outcomes are observed when women are enrolled in a comprehensive treatment program. The overarching goals of therapy for opioid dependence during pregnancy is to provide medical support to prevent withdrawal during pregnancy, minimize fetal exposure to illicit substances, and engage the mother as a leader in her recovery. Such engagement provides her the opportunity to receive both medical and ancillary services which will allow her to successfully parent her child. Recognizing that engagement into a comprehensive treatment program can be a gradual process, medication providers may face the difficult task of distinguishing the patient that needs a bit more time to become engaged in a treatment plan from the patient that is not ready for treatment. Assessment of treatment progression over some weeks may be needed.



GREATEST BENEFIT

Comprehensive treatment program opioid-agonist therapy (methadone or buprenorphine)

OPTIMAL TREATMENT

Buprenorphine without counseling; no illicit use

GREATEST RISK

Methadone or buprenorphine with continued other illicit substance use

Continued illicit drug use with no treatment

Office-based therapy during pregnancy favors the patient that is highly motivated to recover and parent. Such women usually agree to substance abuse counseling and the assistance of community-based nursing to assist in recovery. Patients unwilling to engage these services may not be optimal candidates for office-based therapy and may benefit from the structure of a methadone program or residential treatment before proceeding to office-based therapy. Inclusion of substance abuse counseling and wrap-around services should be strongly encouraged for all patients, as medication alone is not sufficient for optimal pregnancy and parenting outcomes.

The decision regarding the most appropriate medication should be made jointly with the opioid-agonist provider, the obstetrician, and the patient. Women that are pregnant but are not candidates for office-based therapy should be referred to a methadone treatment center (Chittenden Center or BAART). An alternative is a residential program with reassessment for office-based therapy following successful completion of the residential treatment program.

Methadone: Opiate Program Center Based Treatment

Methadone is a pure mu opioid-agonist with a long half life (24 hours) which allows for daily dosing. Methadone is the medication of choice for treatment during pregnancy, owing to the simple fact that there are more data regarding neonatal outcomes following *in utero* exposure. It is a pregnancy category C drug and is not specifically approved for treatment of opioid dependence during pregnancy by the FDA, despite widespread recommendations as the medication of choice in pregnancy. Initiating or switching treatment to methadone should be offered to all opiate dependent pregnant patients.

Methadone for the treatment of opioid dependence is available only through opioid treatment centers. In Vermont, these centers provide medical screening and substance abuse counseling, including a full social assessment. Provision of these ancillary services has been demonstrated to improve retention in treatment and treatment outcomes.

Pregnant women are a high priority for treatment with methadone and will automatically be enrolled in a treatment program, despite long waiting lists for other patients. In Vermont, the major barriers to methadone treatment are the restricted daily dosing times and the travel time that is often needed. These issues are particularly difficult for women in school, working, with small children at home, and those that live a distance from a treatment center. Access to medication and ability to realistically comply with a treatment program can be considered in the overall decision regarding medication choice.

Buprenorphine: Office-Based Medication-Assisted Treatment

Buprenorphine is a partial mu opioid-agonist approved for the treatment of opioid dependence. Unlike methadone, buprenorphine is prescribed in medical offices rather

than at licensed clinics. The *Vermont Buprenorphine Practice Guidelines* outline the background of office-based medication-assisted therapies and guidance for prescribers on the management of opioid dependent patients. Brand names for buprenorphine include Suboxone, which is a buprenorphine/naloxone combination and Subutex, which is buprenorphine alone.

Small cohort studies have found buprenorphine to be safe and effective in the treatment of opioid dependence during pregnancy. However, because it is a relatively new medication, long term outcome data of neonates exposed to buprenorphine *in utero* are lacking and patients seeking treatment should be informed of this. Nonetheless, risk/benefit may favor buprenorphine if the patient is otherwise a candidate for office-based therapy and there are barriers that preclude her attending a methadone program. The data suggest that treatment with buprenorphine provides better outcomes for mother and newborn compared to no treatment.

Candidates for buprenorphine are women that are stable on buprenorphine prior to pregnancy or those unable to attend a methadone treatment center AND are otherwise candidates for office-based therapy. Pregnancy does NOT make women automatically candidates for office-based therapy with buprenorphine, even if that is the only medication available in the community. Engagement in counseling and other services is vital during pregnancy and recovery for successful postpartum transition. Some women may benefit from residential treatment with office-based therapy following stabilization.

MEDICATION SELECTION

Please see the *Vermont Buprenorphine Practice Guidelines* for detailed information regarding the choice of medication and how to determine whether a patient, irrespective of pregnancy issues, is a candidate for office-based treatment.

Choosing the best medication for pregnancy is a discussion ultimately best suited to the medication provider and the patient. Recognizing many pregnant patients will look to their obstetric care provider before initiating medication, it may be helpful for the medication provider and obstetric provider to discuss the plan before presenting the final decision to the patient.

Methadone is the medication of choice due to the long term neonatal outcome data. Buprenorphine is a reasonable alternative in select patients. The discussion and decision for medication should be reviewed with the patient and documented in the chart. Please see *Appendix 2* in the Vermont Guidelines for Medication-Assisted Treatment (MAT) for Pregnant Women for a sample Patient Treatment Information sheet regarding medication during pregnancy, which can be reviewed with the patient.

For patients that are not optimal candidates for buprenorphine when methadone is not available, a step wise approach of initiation with buprenorphine with close follow-

up could be considered. In these instances, buprenorphine with very close and frequent follow-up could be considered with initiation of medication and counseling. Residential treatment or methadone could be considered for difficulty in buprenorphine treatment adherence.

If you are uncertain about the optimal medication for a pregnant patient, Fletcher Allen Health Care Comprehensive Obstetrics and Gynecology Clinic or Neonatology Service can assist in this decision making process and provide care to any opioid dependent patient.

The Fletcher Allen Comprehensive Obstetric Clinic is available to treat any opioid dependent women during pregnancy. (See *Appendix 6* for referral forms).

Entry into Obstetric Practice:

Prior to accepting patients maintained on methadone or buprenorphine into your obstetric practice, establish within your community of providers that appropriate training and resources are available for newborn assessment and treatment. A plan with pediatrics should be established for newborns that require medication for neonatal abstinence. (Refer to the Management of Neonatal Opioid Withdrawal section.)



If local care is not available, develop a clear process by which early antenatal care can be provided in your community with planned transition late in gestation to an obstetric service in a hospital with the ability to care for the opioid-exposed neonate. Fletcher Allen Health Care Comprehensive Obstetrical and Gynecological Service (COGS) will work collaboratively with obstetric care providers to allow community-based care with transfer of care at 36 weeks for delivery at Fletcher Allen Health Care if needed. If these criteria cannot be met, strong consideration for all antenatal care and delivery at another institution should be considered.

Prenatal Care:

As long as the pregnancy has no complications and you are sure the patient is working closely with her substance abuse medication provider, global prenatal care is appropriate. Because of the high prevalence of smoking, careful assessment of dating and fetal growth is important.

At the initial visit, obtain HIPAA consent for communication that includes results of all lab tests including urine drugs screens. The communication consent should include the substance abuse treatment provider, counselor for compliance with visits and pediatrician. Discuss smoking reduction or cessation. Include HIV testing and Hepatitis C antibody screen to the standard prenatal lab tests that are ordered. The initial visit should confirm dating with ultrasound and should include a referral to community-based nursing program (Healthy Babies).

Each visit:

- Confirm patient has seen methadone/buprenorphine provider (at least monthly)
- Document buprenorphine or methadone dose (patient report)
- Confirm that patient is receiving counseling (at least weekly)
- Encourage smoking reduction
- Confirm that community-based nursing has been established

15-20 weeks:

- Ultrasound for anomalies (especially if cocaine use in pregnancy)
- Refer to pediatric provider to discuss care of the neonate

28-34 weeks:

- Ultrasound for growth 32-34 weeks
- Discuss breastfeeding: Insufficient data regarding safety, may be reasonable with close pediatric follow-up
- If cesarean delivery planned: Refer to anesthesia for plan of pain control following surgery
- If your hospital has a pre-admission process, this is a good time to remind the staff a patient receiving opioid treatment will be delivering soon
- Meet with hospital based social work, if appropriate

Labor, Delivery and Postpartum:

During labor and delivery, as well as the postpartum process, reassure the patient that providing her adequate pain control is important. Conversations with obstetric and anesthesia providers should reflect that in a stable patient, there is no reason to suspect drug seeking if requesting pain medication in the appropriate clinical setting. Pediatrics should be notified that an opioid exposed neonate will be delivered soon.

A referral can be made to hospital based social work to evaluate any needs of the patient postpartum. During labor and delivery, continue scheduled methadone or buprenorphine during hospitalization. The obstetric provider can order these medications in the hospital even if not a buprenorphine prescriber, but will not be able to prescribe this medication after hospital discharge. An anesthesia consult should be made when the patient arrives in labor as indicated.

Neuraxial analgesia (spinal, epidural) is effective for pain control during labor or for cesarean delivery in opioid dependent women.

Intravenous short-acting **NALBUPHINE and BUTORPHANOL** are **CONTRAINDICATED** as they may precipitate withdrawal. If inadvertent administration occurs and the patient has withdrawal symptoms, an opioid-agonist should be administered to alleviate withdrawal symptoms; monitor for respiratory depression.

After the delivery, continue medication-assisted therapy



as indicated and have hospital based social work see the patient.

For pain control, acetaminophen and non-steroidal anti-inflammatory agents should be used for mild and moderate pain with short-acting opioid analgesics used as needed. In a vaginal birth, short-acting opioids can be made available on a PRN basis, just as for non-opioid dependent patients.

Opioids for pain control should not be needed following discharge for a routine delivery. In the case of a cesarean delivery, continuous short-acting analgesics for 48 hours, patient controlled analgesia with intravenous morphine, or hydromorphone can be used the first 24 hours. Oral opioids can also be used.

You may expect a 70% increase in short-acting opioid analgesic requirement; often a more potent oral agent (hydromorphone) is required. Patient controlled epidural analgesia is effective for severe pain if available. Expect that short-acting opioids will be needed in decreasing amounts for 5-7 days following cesarean delivery.

BREASTFEEDING

Breastfeeding is encouraged for all patients (except those with HIV).

If breastfeeding is declined, switch the patient back to combination buprenorphine/naloxone immediately after delivery or continue methadone.

If breastfeeding is accepted, consult with pediatric provider to confirm that they are aware of patient's medication-assisted treatment use.

If newborn *is not* receiving methadone or morphine for neonatal abstinence syndrome, switch mother back to buprenorphine/naloxone. If the newborn *is* being treated with methadone or morphine for neonatal abstinence syndrome, continue buprenorphine monotherapy until neonate is off medication or weaned from breastmilk. There may be some patients in whom combination buprenorphine/naloxone is recommended; given evidence of minimal bioavailability in breastmilk, breastfeeding should be encouraged.

Postpartum Plan for Opioid-Agonist Medication:

There is currently no evidence that dose changes of methadone or buprenorphine are needed postpartum. Special attention for somnolence is warranted. Pay special attention to relapse, especially 3-6 months postpartum. There is anecdotal evidence to suggest that this is a particularly vulnerable time for a woman in recovery. Encourage continuation of community nursing for parenting support (or start initial referral at discharge if not done previously).

Ensure each patient has a follow-up appointment with BOTH her medication provider and substance abuse counselor.

CONTRACEPTION AND FERTILITY

As with many underlying diseases, as the patient's recovery proceeds, her fertility may also increase. Patients should not assume that because they have had infertility problems in the past that it will continue after treatment is initiated. If a patient is planning a pregnancy (or sexually active without contraception), prenatal vitamins (800 mcg folic acid) are recommended prior to conception to reduce birth defects. If a patient is sexually active and not using contraception, prenatal vitamins should be recommended given high-risk of pregnancy.

Contraceptive counseling and treatment are available at low cost (or free) from community health clinics and Planned Parenthood. There is no evidence of medication interaction between oral contraceptives and methadone or buprenorphine. To afford the patient the best chance for a successful recovery, address her partner/family substance abuse treatment and plan, as indicated.

Common Clinical Challenges:

Women with a history of substance abuse often have chaotic lives, experience domestic violence, and have tenuous housing. The structure imposed by treatment programs can be a difficult adjustment. Relapses are common, especially early in treatment. A combined treatment plan developed by the patient with the obstetrician and medication provider that appropriately balances maternal and fetal risk is imperative.

Treatment Non-Adherence

The inability to remain abstinent, non adherence with counseling, or demonstration of other high-risk behavior constitutes treatment non-adherence.

Options include:

- Evaluate for more intensive services to more structured program (intensive outpatient program, residential treatment, methadone) using ASAM criteria.
- Discharge the patient from office-based therapy if she declines other options. Communication with the obstetrician, pediatrician, social work team at the hospital of planned delivery and the Department of Children and Families (DCF) should occur promptly.
- Useful cross discipline strategies for treatment non-adherence include linking the ability to pick up a buprenorphine prescription or methadone dose with prenatal care by requiring a visit to the obstetric provider office first. Consider linking the ability to pick up a buprenorphine prescription or methadone dose to counseling and referral to residential treatment or consider switch to methadone if adherence to office-based care is not possible.
- For recurrent positive drug screens with benzodiazepines, particular care must be taken in management of patients dependent upon benzodiazepines and opioids, due to synergistic respiratory depression, even if the benzodiaz-

epines are prescribed. Provision for coordination of care must be made and consideration given to admission for benzodiazepine detoxification.

- Education should be given about the potential synergy between methadone, buprenorphine and benzodiazepines which includes warnings about driving or machine operation. This intervention should be documented in the medical record.
- Other strategies include an increase in counseling and consideration of alternative medication for anxiety (i.e.: sertraline). ***Patient may not be a candidate for office-based therapy if using benzodiazepines and might be better served at an opioid treatment center or residential treatment center.***
- For recurrent positive drug screens with cocaine, discuss the specific dangers of cocaine use in pregnancy including fetal loss, bleeding, preterm labor and fetal stroke. The patient may not be a candidate for office-based therapy if using cocaine and should be referred to an opioid treatment center or residential treatment for a more structured program. Education should be provided and documented regarding potential Levamisole contamination of cocaine.
- For recurrent positive drug screens with cannabis, use of any illicit substance should be discouraged. Given the relatively little data that THC is harmful in pregnancy combined with the clear benefit of opioid maintenance therapy, consider continuation with close follow-up or residential treatment.
- Non-adherence due to transportation and other social barriers present complex problems to successful recovery. Referral to community-based nursing/social work to develop a transportation plan (i.e.; Medicaid-sponsored transportation) should be made.
- Offer residential treatment for intensive counseling which can allow for less frequent (once a week) counseling after discharge. Inadequate housing, partner use of illicit substances, and domestic violence are common issues to be addressed with counseling and community-based nursing.

Clinical Risk Management Strategies:

Documentation is crucial and the following elements must be covered: referral for treatment, treatment refusal and planned use of medications not approved by the FDA, including use of methadone vs. buprenorphine. Document when Department of Children and Families notification of drug use is made. Ancillary services provided should be documented.

Clinical Management FAQs

The following scenarios may help obstetricians and medication providers understand treatment decisions. Close communication between providers will enable the optimal medical approach (as for any other medical illness):

Do I have to offer buprenorphine to a pregnant patient because she refuses methadone?

- ☐ The patient should receive the optimal care during pregnancy
- ☐ If she is not a candidate for buprenorphine, then she should receive methadone or referral to residential treatment
- ☐ Consider offering residential treatment and transfer to buprenorphine after successful completion of the residential program

Do I have to start buprenorphine immediately because the patient is pregnant?

- ☐ *Pregnancy is not an emergency; simply a priority*
- ☐ Confirm opioid dependence
- ☐ Confirm viable pregnancy

May I stop prescribing buprenorphine to the non-compliant patient during pregnancy?

- ☐ It is unsafe for the mother and fetus to continue to engage in risky behavior
- ☐ Medication can be discontinued for any medical reason when there is lack of benefit; alternatives should be offered (residential treatment; methadone treatment center)
- ☐ Continued high-risk behaviors in the office-based setting suggest the need for residential or center-based care.
- ☐ Document non-compliance and offers of alternative, more structured care

How do I know when to decline further office-based care with buprenorphine?

- ☐ Concurrent use of benzodiazepines
- ☐ Concurrent use of cocaine
- ☐ Difficulty engaging in counseling
- ☐ Can depend on ease of switching to methadone: assessment of overall maternal/fetal risk/benefit of continued treatment if no treatment is the option; the medication provider has some latitude if it is decided that risk/benefit favors office-based care

What should I do when I decide I cannot prescribe to a patient during pregnancy?

- ☐ Document rationale in medical record
- ☐ Offer methadone even if the patient needs to travel
- ☐ If option is buprenorphine versus no treatment:
 - Consider residential treatment
 - Consider supervised pregnancy residence
- ☐ Contact local child protection services when you discontinue medication; they can often follow-up in the hospital at delivery
- ☐ Tell the patient you must do this and document the conversation

Suggested “scripted” approaches to discussing treatment options

Initial visit script:

- Good for you in seeking help with addiction
- We need to confirm that you are pregnant and clarify the level and nature of your opioid abuse
- We routinely check the Vermont Prescription Monitoring System in all patients seeking treatment at our clinic
- Methadone is the medication of choice for the treatment of opioid dependence during pregnancy because we have years of experience with neonatal exposure
- I understand you would like to be treated with buprenorphine
- Buprenorphine is not approved for use in pregnancy and we do not have many years of experience; the oldest children are only 5 or 6
- Substance abuse counseling and engagement in community-based services to help with parenting is necessary for recovery and parenting
- Will you agree to attend counseling and receive help from community-based nursing?

Follow up sessions:

- I see that you have continued to use cocaine based on your toxicology screen. How shall we address this together?
- Let us review our plan for management of your pregnancy using buprenorphine/methadone
- Have you been able to keep your appointments with counseling and other medical providers?

Legal Issues Unique to Pregnancy FAQ

Misperceptions about legal issues are an important reason that opioid-dependent and pregnant women avoid treatment. Common misconceptions regarding treatment of the pregnant patient are addressed below.

Example: A 19 year-old with heroin addiction learns she is pregnant at a community health clinic.

Misconception: She should stop heroin immediately or she will go to jail

Fact: The American College of Obstetrics and Gynecology has a series of Committee Opinions that address ethical issues in Obstetrics and Gynecology, with the use of alcohol and illicit substances specifically considered.

- Pregnant women should be allowed to make decisions on their own behalf
- Most women will choose to proceed with treatment for the health of the fetus/newborn
- Incarceration, where there are few services, results in worse outcomes (mother: less prenatal care, less treatment, higher relapse; newborn: worse outcomes in foster care than with a recovering mother)

Misconception: She should not use opioid-agonist therapy because her baby will be an addict

Fact: Randomized trials have demonstrated the long-term (3 year) benefit of methadone treatment versus taper. Studies show less relapse and neonatal outcomes similar to controls (after demographic adjustment).

Misconception: She must receive opioid-agonist therapy although she requests a taper

Fact:

- Opioid-agonist therapy is clearly the treatment of choice as it improves prenatal care, reduces relapse, and reduces exposure to other illicit drugs.
- There are no data to suggest medication-assisted withdrawal early in pregnancy (before 24 weeks) is harmful
- Abrupt withdrawal from heroin late in gestation is associated with *in utero* withdrawal, increased meconium aspiration, and may be associated with fetal death
- Once informed, if the patient would like to taper, a gradual taper of 10% per week is reasonable. Many patients will become uncomfortable and stop a taper even after requesting it.

Misconception: If she has any relapses, she will lose custody of her child

Fact: Reporting laws vary by state, but most have some mandatory reporting of any maternal behavior that can impair the wellbeing of a child. However:

- Most states will work closely with a patient in recovery to allow her to maintain custody
- Many cannot intervene until after delivery (Vermont: case can be opened 30 days prior to expected delivery)
- Reinforce to the patient that treatment during pregnancy, even if has a few slips, will improve the chances of custody retention
- Reporting during pregnancy allows social work time to understand all aspects of patient care
- Reinforce to patient that the goal of all is to help her maintain custody and receive appropriate treatment for her to parent her child. The opioid-agonist treatment provider can play an important patient advocacy role here.

Appendix 1: HIPAA Form

MRN

PATIENT NAME

PATIENT DATE OF BIRTH

NOTICE OF PRIVACY PRACTICES

I have received the Notice of Privacy Practices at Fletcher Allen Health Care informing me of how Fletcher Allen Health Care will use my personal health information.

My understanding of this Notice will help me ensure the accuracy of my health information, better understand who, what, where and why others may access my health information.

I acknowledge receipt of the Notice and understand any questions pertaining to Fletcher Allen Health Care's privacy policies may be answered by contacting the Fletcher Allen Health Care Patient Relations Department at (802) 847-3500.

PATIENT / GUARDIAN

DATE OF RECEIPT

RELATIONSHIP TO GUARDIAN

☐ Patient unable to sign ☐ Patient refused to sign

Reason: _____

WITNESS

Appendix 2: Opioid-agonist Therapy During Pregnancy – OB Provider Checklist

PATIENT NAME _____

DATE OF BIRTH _____

MRN _____

DATE _____

☐ **Medication**

Medication Provider: _____

Dose: _____

☐ **Referrals**

Substance Abuse Counselor: _____

Maternal Child Health or Home Visiting Nurse: _____

☐ **0-20 Weeks**

- ☐ Additional labs: Hepatitis C antibody; HIV; liver panel
- ☐ Dating ultrasound
- ☐ Drug screen every visit
- ☐ Check here if being done by the medication provider

☐ **24-32 Weeks**

- ☐ Refer to pediatrician: prepare for NAS scoring
- ☐ Refer for delivery elsewhere if needed

Hospital of delivery: _____

- ☐ Develop a delivery plan

Pediatrician: _____

Anesthesia consult: _____

Appendix 3: Opioid Use During Pregnancy – Women Not in Treatment

PATIENT NAME	DATE OF BIRTH
MRN	DATE

☐ **Current substances used**

Frequency: _____

Dose: _____

Route: _____

If patient has symptoms of withdrawal when not using (sniffing, yawning, nausea, goosebumps, diarrhea, restlessness) then refer to a provider of opioid-agonist medication

☐ **Referrals**

See the list of Services for Opioid-Dependent Pregnant Women in Vermont

☐ Medication Provider/given a list of what is available in the community.

If there is no provider in your community, refer to closest available referral center. Fletcher Allen COGS clinic will accept and arrange treatment for any patient in their program.

☐ Substance Abuse Counselor

☐ WIC (MCH Coordinator)

☐ CIS Intake Coordinator

☐ Declines treatment

Call Social work at the hospital

Refer to DCF within 30 days of delivery

Watch fetal growth

Appendix 4: COGS Clinic Fax Transfer Form

Patient name: _____

Referring provider (with contact and fax number): _____

Reason for referral: _____

LMP (or gest age): _____ US done: ☐ YES ☐ NO (attach record)

Prior prenatal care: ☐ YES ☐ NO Provider: _____

Medications (dose and prescribing physician; note if you will continue prescribing medication or request transfer of prescribing responsibility and last day of medication): _____

Substance abuse counselor after discharge (note if we need to set this up): _____

Appointment: _____

Date and time: _____

Place: _____

Provider: _____

Social worker appointment: _____

Fax to COGS clinic: 802-847-8433

Phone: 802-847-1400

Email: (provider to provider only): marjorie.meyer@uvm.edu

Note: please do not use patient identifiable information in the email

Appendix 5: Community-Based Nursing/Social Services Checklist

PATIENT NAME

DATE OF BIRTH

MRN

DATE

☐ OB Provider: _____

☐ Medication Provider: _____

☐ Substance Abuse Provider: _____

☐ Primary Care Provider: _____

☐ Pediatrician: _____

☐ WIC

☐ Social Services

☐ Economic services

☐ Housing

☐ Employment

☐ Child care

Appendix 6: Communication Tool Fax Form

To:		From:	
Fax:		Pages:	
Phone:		Date:	

Name: _____

Date of birth: _____

Due date: _____

Medication/dose: _____

Visit type:

- ☐ Counseling
- ☐ OB visit
- ☐ Community nurse
- ☐ Pediatric visit

Date of visit: _____



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Anne Johnston, MD

Jerilyn Metayer, RN

Elizabeth Robinson, PNP

Management of Neonatal Opioid Withdrawal

PURPOSE/DISCLAIMER

The Management of Neonatal Opioid Withdrawal was created to provide Vermont practitioners with the consolidated set of recommendations for the management of the opioid exposed newborn. The content is intended to complement standard medical care, the *Vermont Buprenorphine Practice Guidelines*, and other resources available through the American Academy of Pediatrics (www.aap.org), Substance Abuse and Mental Health Services Administration (www.samhsa.gov) and the Center for Substance Abuse Treatment (www.csat.samhsa.gov). These guidelines are not intended as requirements for practitioners. They should not be considered medical advice.

Neonatal Abstinence Syndrome Overview

Neonatal abstinence syndrome (NAS) refers to a constellation of signs in the newborn due to substance or medication withdrawal. In most cases, exposure occurs during pregnancy, but it may also describe a syndrome secondary to withdrawal of opioids and sedatives administered postnatally to infants with serious illness. Opioids (naturally occurring, synthetic and semi-synthetic) are the most frequent drugs which give rise to the typical signs.

OPIOID ADDICTION

Opioid use and dependence during pregnancy continues to be a significant public health problem. Data from the National Survey on Drug Use and Health indicate that the rate of heroin use by pregnant women has increased somewhat over time and there has been a 33% increase in non-medical use of analgesics in this population in the past decade (Substance Abuse and Mental Health Services Administration, 2006). Heroin (diacetylmorphine), a semi-synthetic opioid with a rapid onset of action and a short half life, is one of the frequently used opioids during pregnancy. Although it is typically injected, an increasing number of users are inhaling or smoking heroin. The use of other opioids, including oxycodone, hydrocodone, and the controlled-release form of oxycodone (OxyContin®) has escalated in recent years.

Acute use of heroin and other opioids stimulate the opiate receptors in the brain which may result in symptoms including euphoria, respiratory depression, analgesia, and nausea. Chronic use of opioids is associated with tolerance; higher doses of the drug are required to obtain the same effect. Tolerance leads to dependence, whereby the neuro-chemical balance in the central nervous system is altered and absence of the drug leads to a withdrawal syndrome. Opioid withdrawal is characterized by a constellation of symptoms including agitation, nasal congestion, yawning, diaphoresis, muscle cramps, diarrhea, nausea, vomiting, and depression.

Several mechanisms have been proposed to explain the phenomena of tolerance, dependence and withdrawal in the setting of chronic opioid exposure. These include (1) increased metabolic breakdown of opioid compounds, (2) decreased neurotransmitter release resulting in an increased number and sensitivity of post-synaptic receptors, and (3) down-regulation of opioid receptors resulting in decreased production of endogenous endorphins. Due to these changes, some opioid dependent patients will need medication-assisted treatment for prolonged periods, possibly for the rest of their life.

The standard of care for opioid-dependent patients is medication-assisted treatment with opioid-agonists in

conjunction with counseling and supportive services. (US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 1993). Methadone and buprenorphine are the most commonly prescribed medications for these patients.

OPIOIDS AND PREGNANCY

The cycle of opioid use and withdrawal is particularly devastating for the developing fetus. The repetitive pattern of use and withdrawal leads to fetal hypoxia and utero-placental insufficiency with resultant increased risk of prematurity, fetal demise and low birth weight. Comprehensive prenatal care is essential for these patients.

Medication-assisted treatment has been the standard of care for pregnant opioid-dependent patients. At appropriate dosages, methadone, a synthetic opioid, will eliminate symptoms and signs of withdrawal, reduce cravings, and block euphoric effects should supplemental opioids be used. The long half life and predictable dosing prevents erratic opioid levels in the fetus, and is associated with a longer duration of pregnancy and improved fetal growth. As the pregnancy progresses, methadone is metabolized more rapidly and higher doses are required. Although there were early reports suggesting that the dose of methadone correlated with the incidence and severity of neonatal withdrawal signs, recent evidence does not demonstrate such a relationship. (Berghella V, 2003) (McCarthy JJ, Leamon MH, 2005). It is well accepted that lowering the dose during pregnancy may lead to increased illicit drug use, thus exposing the mother and fetus to more harm. Buprenorphine, a partial opioid-agonist, has recently been approved by the United States Food and Drug Administration for the treatment of opioid addiction in an outpatient office setting. Although not yet approved for use in pregnancy, preliminary studies suggest that buprenorphine is associated with a decreased incidence of neonatal withdrawal when compared with methadone (Kakko J, 2008).

In addition to the concern regarding withdrawal, the prevalence of hepatitis B, hepatitis C, and human immuno-deficiency virus (HIV) is elevated in pregnant

opioid-dependent patients, primarily due to needle sharing and unsafe sexual practices. Women should be screened for these infections, and in the case of HIV infection, treatment should be initiated.

The management of addiction in pregnancy is highly complex and attention must be focused not only on medication, but also to the complicated psychological and social needs of these women. A high number of these women have a history of domestic violence, are poorly educated, financially constrained, and have poor relationships with partners who may also be substance abusers. They frequently have dysfunctional families with a high prevalence of substance abuse and alcoholism. Many of these women have co-morbid psychiatric conditions, most commonly depression and bipolar disorder, and suffer from low self-esteem (Kaltenbach K, 1998).

Neonatal Abstinence Syndrome: Clinical Presentation

The newborn with opioid withdrawal presents with central nervous system excitability, vasomotor signs and gastrointestinal signs. The timing of onset of signs varies; however, infants exposed to heroin or other short-acting opiates will typically present within the first 48–72 hours. Those exposed to methadone or buprenorphine will often present later, usually within the first 4 days.

The infant is assessed using a standardized scoring system such as the system developed by Finnegan (1975, 1992) and since modified by Jansson (2009) and others which assesses signs of withdrawal. When scores are elevated, the infant may be a candidate for pharmacologic treatment.

Newborn urine and meconium toxicology screens may aid in the diagnosis when the mother has not been in a treatment program. Urine testing generally reflects drug exposure within several days, depending upon the drug. Results of urine testing are rapidly available; however, there is a high false negative rate given the rapid clearance of most drugs and the difficulty in obtaining sufficient urine from a newborn in the first day of life. Meconium testing offers the advantage of assessing drug exposure during the previous several months. However, meconium test results are frequently not available for several days, at which time the infant may have been discharged.

The differential diagnosis should include sepsis, hypoglycemia, hypocalcemia, hypomagnesemia, hyperthyroidism, perinatal asphyxia, and intracranial hemorrhage. Recent maternal serologies for hepatitis B, hepatitis C and HIV should be determined.

Treatment

Approximately 50–75 percent of infants born to women on opioids will require treatment for opioid withdrawal. At the delivery of a known opioid-dependent woman, naloxone should be avoided in resuscitation of the infant as it may precipitate seizures.

Supportive care is essential in the management of infants exhibiting signs of withdrawal. Decreased stimulation, swaddling, and frequent feedings on demand are beneficial. Infants may require intravenous fluids to maintain hydration. Caloric expenditure is frequently elevated, and therefore increasing the caloric density of feeds may be indicated.

Pharmacologic therapy is indicated for infants with increasing severity of signs and in cases of significant vomiting, diarrhea, or excessive weight loss. Infants may be treated with a variety of medications including short-acting opioids such as morphine sulfate and long-acting opioids such as methadone (AAP Committee on Drugs. Neonatal Drug Withdrawal. Pediatrics 1998;101;1079-1088). Methadone may be continued and weaned as an outpatient whereas morphine sulfate should be restricted to hospitalized infants and weaned completely prior to discharge home.

Women on methadone or buprenorphine maintenance therapy are encouraged to breastfeed their infants, providing they are HIV negative (McCarthy J, 2000) (Substance Abuse and Mental Health Services Administration, Treatment Improvement Protocols, 2004).

Discharge Considerations

The opioid-dependent new mother undergoes significant stress during the post partum period. A comprehensive discharge plan that addresses maternal substance abuse treatment, a safe environment, parenting and community support are essential.



Guidelines for Management of Opioid-Exposed Newborns at Vermont Children's Hospital at Fletcher Allen Health Care

SITE OF CARE FOR OPIOID-EXPOSED NEWBORNS

- Infants not requiring pharmacologic treatment: Newborn Nursery
- Infants at the initiation of pharmacologic treatment: Neonatal Intensive Care Unit (NICU), or Neonatal Transitions Suite (NTS), (since the Fletcher Allen nursery does not have cardiopulmonary monitors)
- Infants on a stable methadone dose may be transferred to Newborn Nursery prior to discharge
- Infants on morphine sulfate need to remain in NICU or NTS (where monitoring available)

NEONATAL ABSTINENCE SYNDROME (NAS) SCORING

- Use modified Finnegan Neonatal Abstinence Scoring Sheet.* (See Appendix 1, Adapted from L. Jansson, 2009)
- NAS score at 2 hours of age and every 3–4 hours thereafter; continue scoring for the duration of hospitalization (minimum of 96 hours). Do not wake infant for score unless the interval >6 hours
- Initial treatment consists of providing a supportive environment (decrease sensory stimulation; implement changes in positioning, skin-to-skin (kangaroo care), swaddling, pacifier)
- NAS scoring should occur in the mother's room, whenever possible
- Score infant before feeding
- NAS score <9, continue NAS scoring in Newborn Nursery
- NAS score ≥9 attempt to feed and score within 1 hour; if both scores ≥9, notify attending physician for evaluation and possible transfer to NICU/NTS

TREATMENT

- If infant has 2 consecutive scores (e.g. before and after feed) of ≥9 with no confounding variables, consider pharmacologic treatment
- Continue to provide a supportive environment (decrease sensory stimulation; implement changes in positioning, skin-to-skin (kangaroo care), swaddling, pacifier)
- If infant meets criteria for pharmacologic treatment, the infant should be treated with methadone

Treatment Choice: Short-acting Opioid or Methadone?

- Community hospitals should treat infants with short-acting agents such as morphine sulfate or dilute tincture of opium and wean the infant completely off medication prior to discharge
- Most hospitals treat NAS with short acting morphine sulfate (Sarkar & Donn, 2006)

- At this time, community hospitals do not have the infrastructure necessary for treating infants with methadone as outpatients
- The treatment of choice for infants with NAS at Fletcher Allen is methadone, which allows for a shorter hospital stay but more intensive outpatient management
- Fletcher Allen infants who are to be discharged to an area where outpatient methadone management is unavailable and cannot come to biweekly appointments at Fletcher Allen should be treated with morphine sulfate
- Infants who can be back-transferred to hospital that has a program for inpatient treatment of NAS with morphine sulfate may be treated with morphine sulfate

Morphine Sulfate

- If infant has 2 consecutive scores (e.g. before and after feed) of ≥9, start morphine treatment at a dose corresponding to the highest score
- Administer morphine sulfate orally as follows:

Score	Morphine Initial Dose
9–12	0.04 mg
13–16	0.08 mg
17–20	0.12 mg
21–24	0.16 mg
>24	0.20 mg

- If infant's symptoms are not controlled by the above protocol (i.e., requires > 0.20 mg morphine sulfate solution every 3 hours), or if infant appears somnolent or difficult to rouse, notify treating nurse practitioner or physician immediately
- Continue morphine sulfate at initial dose every 3–4 hours with feeds
- NAS score ≥ 9: increase the dose as follows:

Score	Morphine New Dose
9–12	Previous dose + 0.02 mg
13–16	Previous dose + 0.04 mg
17–20	Previous dose + 0.06 mg
21–24	Previous dose + 0.08 mg
>24	Previous dose + 0.1 mg

- When NAS score remains <9 for 48 hours, start weaning dose by 0.02 mg every 24 hours until discontinued
- Infant may be discharged when off morphine for 24 hours with score <9
- Maximum interval for NAS scoring and morphine dosing is 4 hours while on treatment
- Note: for any score between 9 and 12, consider repeating the score after a feed before acting upon it

Methadone Treatment at Fletcher Allen Health Care

- Starting dose: 0.3 mg po q12 hours (range of 0.3–0.6 mg po q12 hours depending upon severity of signs)
- If scores are ≥ 9 after first dose, consider giving an extra dose of 0.3 mg of methadone (independent of the regular doses which should continue)
- If scores are ≥ 9 after 4 scheduled doses, consider increasing dose by 0.05–0.2 mg
- Most infants will not need more than 0.5 mg po q12 hours
- When scores are < 9 for 24–48 hours on a stable methadone dose, may discharge home
- If infant is somnolent, does not rouse spontaneously for feeds, or has abnormal eye movements, discontinue methadone immediately and continue scoring. If or when scores approach 7 or greater, restart methadone at lower dose using following guide:
 - No methadone dose for 24 hours: decrease by 0.05 mg
 - No methadone dose for 36 hours: decrease dose by 0.1 mg
 - No methadone dose for 48 hours: decrease dose by 0.15 mg
 - No methadone dose for 72 hours: decrease dose by 0.2–0.25 mg
 - If methadone is not needed by 96 hours and there are no significant signs of withdrawal, discharge infant
 - Infant should remain on cardiorespiratory monitoring and/or pulse oximetry until stable dose is achieved and somnolence has resolved

SCREENING

- Infants born to mothers in stable recovery through a drug treatment program (e.g.: methadone or buprenorphine) do not necessarily require testing, particularly if the mother's urine screens have been negative. For infants born to women with a suspected history of drug abuse during pregnancy, no prenatal care or abruption, consider urine and meconium toxicology testing.
- Newborn *urine* drug screening: (if indicated)
 - Samples should be collected within the first 24–48 hours of life
 - Standard urine toxicology screen (Drug screen compensate): amphetamines, barbiturates, benzodiazepines, cocaine, cannabinoids, and selected opioids
 - Opioids which are not detected by the standard screen may include methadone, buprenorphine and oxycodone

- Newborn *meconium* drug screening:
 - Samples may be collected during the first 3–4 days of life until stools become transitional
 - Standard meconium toxicology screen (MECDG): amphetamines, opioids, and metabolites of cocaine and marijuana
 - Confirmatory testing is available

BREASTFEEDING

- Breastfeeding is recommended for all infants unless mother is HIV positive
- Maternal hepatitis C and hepatitis B are not contraindications
- Methadone
 - Very small amounts of methadone are transmitted through breast milk even at doses of 250 mg daily, therefore maternal methadone is not a contraindication to breastfeeding (McCarthy J, 2000)
- Buprenorphine
 - Safe for breastfeeding (Substance Abuse and Mental Health Services Administration, Treatment Improvement Protocols, 2004)
 - If infant is on opioid treatment for NAS, mother should remain on Subutex®



MANAGEMENT OF INFANTS BORN TO HEPATITIS C ANTIBODY POSITIVE WOMEN

General

The overall rate of mother-to-infant HCV transmission is in the range of 1.0%-5.0% (Yeung, 2001)

Recommendations for Testing

Testing for infants born to infected mothers should be done at 18 months of age (American Academy of Pediatrics 2009)

Laboratory Test:

Hepatitis C Antibody

Follow Up Plan for Hepatitis C Positive Infants:

- Notify Primary Care Provider
- Notify family
- Provide written information
- Hepatitis A vaccine recommended
- Refer to Pediatric Gastroenterology

If Diagnosis is Needed Sooner than 18 Months of Age:

- Qualitative RNA PCR testing to detect HCV RNA may be performed at or after the infant's first well-child visit at 1–2 months of age (American Academy of Pediatrics 2009)

DISCHARGE CONSIDERATIONS FOR INFANTS ON ORAL METHADONE

- Family/caregiver to receive education regarding storage and administration of methadone
- Methadone prescription is written for 3–4 weeks supply
- Neonatal Medical Follow-up appointment within 1 week of discharge
- Family/caregiver instructed to bring methadone to every neonatal medical clinic visit

OUTPATIENT MANAGEMENT OF NEONATAL OPIOID WITHDRAWAL

Neonatal Medical Follow-Up Clinic

- Q 1–2 week visits while infant on methadone
- Q 1–2 month visits for infants not on methadone
- Family to bring methadone to every clinic appointment
- Developmental screening at 8–10 months of age
- Follow-up to continue until 12–18 months of age
- If a patient does not show for appointment the nurse clinician attempts to contact family and reschedule appointment
- If unable to contact family, the Primary Care Provider is notified

Methadone Taper

- Family/caregiver, with a syringe and air demonstrates the amount of methadone they are administering to the infant at every clinic visit
- Family should demonstrate (with syringe and air) at least 2 scheduled wean amounts
- Wean by 0.02–0.05 mg per dose, either weekly on Mondays, or twice weekly on Mondays and Thursdays as indicated
- On patient instruction sheet, wean plan is clearly written with a copy in the clinic chart
- If family or health care providers are concerned about signs of withdrawal, a call is made to the Neonatal Medical Follow Clinic prior to any change in dosing
- When a dose of 0.02–0.05 mg twice a day is tolerated for 3–7 days, then that dose is administered once daily for 3–7 days, and then discontinued

MONTHLY MULTIDISCIPLINARY MEETINGS

- ChARM (Children and Recovering Mothers) Patient Care Meeting occurs monthly
- Members are impaneled; facilitated by KidSafe Collaborative
- Participants:
 - Addiction Physician
 - Obstetrician (MFM)
 - Neonatologist
 - Social Worker (OB clinic)
 - Nurse Clinician (NeoMed)
 - VNA Nurse
 - NP methadone clinic
 - NP (NeoMed)
 - DCF intake supervisor
 - Representative DOC
 - Lund Family Center
 - Nurse (OB Clinic)
 - Social Worker (inpatient)
 - Public Health Nurse
 - Representative from ADAP

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Appendix 1: Neonatal Abstinence Syndrome Scoring Form

MRN

NAME

DOB

SIGNS

Observations from past 3–4 hours.

Start new scoring sheet each calendar day.

Birth Weight: _____ grams (x 90% = _____ grams)

Daily Weight: _____ grams

DATE:	SCORE	TIME	TIME	TIME	TIME	TIME	TIME	TIME	TIME
High pitched cry: inconsolable >15 sec. OR intermittently for <5 min.	2								
High pitched cry: inconsolable >15 sec. AND intermittently for ≥5 min.	3								
Sleeps <1 hour after feeding	3								
Sleeps <2 hours after feeding	2								
Sleeps <3 hours after feeding	1								
Hyperactive Moro	1								
Markedly hyperactive Moro	2								
Mild tremors: disturbed	1								
Moderate–severe tremors: disturbed	2								
Mild tremors: undisturbed	1								
Moderate–severe tremors: undisturbed	2								
Increased muscle tone	1–2								
Excoriation (indicate specific area): _____	1–2								
Generalized seizure	8								
Fever ≥37.2°C (99°F)	1								
Frequent yawning (≥4 in an interval)	1								
Sweating	1								
Nasal stuffiness	1								
Sneezing (≥4 in an interval)	1								
Tachypnea (rate >60/min.)	2								
Poor feeding	2								
Vomiting (or regurgitation)	2								
Loose stools	2								
≤90% of birth weight	2								
Excessive irritability	1–3								
Total score									
Initials of scorer									

Printed Name	Signature/Title	Initials	Printed Name	Signature/Title	Initials

Jansson LM, Velez M, Harrow C. The opioid-exposed newborn: assessment and pharmacologic management. *J Opioid Manag* 2009;5:47–55.

Appendix 2: Neonatal Abstinence Syndrome (NAS) Scoring Explanation

Definitions were adapted from the MOTHER study (NCT00271219) and (D'Apollito 1994).

Assessment & Documentation

- The infant is scored at 2 hours of age and every 3-4 hours prior to a feeding
- The NAS score will be recorded for the 3-4 hour period immediately before the scoring activity
- Signs and symptoms are documented on the NAS form and totaled for a score

Sleeping

- For every sign except sleeping, a score of 0 = not present
- Use the longest single continuous time sleeping since last feeding
- Sleeps 3 or more hours continuously (Score = 0)
- Sleeps 2-3 hours after feeding (Score = 1)
- Sleeps 1-2 hours after feeding (Score = 2)
- Sleeps less than 1 hour after feeding (Score = 3)
- When repeating a score within 1 hour after a feeding: use the same sleep score obtained before the feeding.

Moro Reflex

- Cup infant's head in your hand and raise his/her head about 2-3 inches above the mattress, then drop your hand while holding the infant.
- The infant should be quieted if irritability or crying is present. This will insure that the jitteriness, if present, is due to withdrawal rather than agitation.
- Hyperactive Moro: arms stay up 3-4 sec with or without tremors (Score = 1)
- Markedly Hyperactive Moro: arms stay up > 4 sec with or without tremors (Score = 2)

Tremors

- Tremors = jitteriness
- Involuntary movements that are rhythmical
- If the infant is asleep, it is normal to have a few jerking movements of the extremities
- Mild tremors: hands or feet only, last up to 3 seconds (Score = 1)
- Moderate-severe tremors: arms or legs, last more than 3 seconds (Score = 2)
- Undisturbed: tremors that occur in the absence of stimulation

Increased Muscle Tone

- While the infant is lying supine, extend and release the infant's arms and legs to observe for recoil
- Infant supine, grasp arms by wrists and gently lift infant, looking for head lag
- Difficult to straighten arms but is possible, and head lag is present (Score = 1)
- No head lag noted or arms or legs won't straighten (Score = 2)

Excoriation

- Red or broken skin from excessive rubbing (eg: extremities or chin against linens)
- Skin red but intact or is healing and no longer broken (Score = 1)
- Skin breakdown present (Score = 2)

Sweating

- Wetness felt on the infant's forehead, upper lip (Score = 1)
- Sweating on the back of the neck may be from overheating such as swaddling

Nasal Stuffiness

- Any nasal noise when breathing (Score = 1)
- Runny nose may or may not be present

Sneezing

- Infant sneezes 4 or more times in the scoring interval of 3-4 hours (Score = 1)

Tachypnea

- The infant must be quieted if crying first; count respirations for full minute
- Respiratory rate > 60/min (Score = 2)

Nasal Flaring

- Outward spreading of the nostrils during breathing (Score = 1)

Poor Feeding

Poor feeding is defined as any 1 of the following (Score = 2)

- Infant demonstrates excessive sucking prior to a feeding yet sucks infrequently while feeding and takes a small amount of formula/breast milk
- Demonstrates an uncoordinated sucking reflex (difficulty sucking and swallowing)
- Infant continuously gulps while eating and stops frequently to breathe
- Inability to close mouth around bottle/breast
- Feeding takes more than 20 minutes

Regurgitation/Vomiting

- Frequent regurgitation (vomits whole feeding or vomits 2 or more times during feed) not associated with burping (Score = 2)

Loose Stools

- Infant has a stool that is at least half liquid (Score = 2)
- When repeating a score within 1 hour after a feeding: use the same stool score obtained before the feeding.

Current Weight ≤ 90% of Birth Weight

- Infant is weighed once a day and then that score is carried through the rest of the day
- Weight is ≤ 90% of birth weight (Score = 2)
- Continue to score until infant gains weight and is > 90% of birth weight
- Use workspace at top of form

Excessive Irritability

- Distinct from, but may occur in conjunction with crying
- Marked by frequent grimacing, excessive sensitivity to sound and light
- Infant becomes fussy or irritable with light, touch or handling despite attempt to console
- Consoling calms infant in 5 minutes or less (Score = 1)
- Consoling calms infant in 6-15 minutes (Score = 2)
- Consoling takes more than 15 minutes or no amount of consoling calms infant (Score = 3)

Appendix 3: Neonatal Medical Follow-up Clinic: Antenatal Consult Form

CONSULT REQUESTED BY					AGE	EDC	LMP		
<input type="checkbox"/> G	<input type="checkbox"/> T	<input type="checkbox"/> P	<input type="checkbox"/> A	<input type="checkbox"/> L	Blood type_____	Ab screen_____	Rubella_____	Vancelia_____	HepB_____
HepC Ab_____		HIV_____	VDRL_____	GC/Chl_____	Mult markers_____	Other_____			
GEST@PRESENTATION					ACCOMPANIED BY				

Past medical history: _____

Family history: _____

Previous pregnancies: _____

Current pregnancy: _____

Drug history: _____

Rehab: _____

Drug use during pregnancy (including alcohol and tobacco): _____

Current medications: _____

Living situation: _____

Father of baby: _____

Highest level of education: _____

Occupation: _____

Goals and aspirations: _____

DOC history: _____

DCF history: _____

Home health nurse: _____

Counselor: _____

Substance abuse treatment: _____

Probation / Parole Officer: _____

Name of baby: _____

Breastfeeding plans: _____

Pediatrician: _____

Recommendations: _____

Plan: _____

SIGNATURE _____

Appendix 4: Neonatal Medical Follow-up Clinic: Infant Visit

PATIENT: LAST NAME	FIRST NAME	DOB
DATE OF VISIT	TIME	AGE
REFERRING MD	DIAGNOSIS	

Child accompanied by:			
Interval History / Hospitalizations:			
Withdrawal Signs:			
Details:			
Methadone:	mg, po,	/day	<input type="checkbox"/> Parent/Guardian dose demonstration
Last wean:			Current wean plan:
Methadone dosing times (approx.):			
Amount of remaining methadone in syringe/bottle:	mls		
Respiratory:			
Feeding:			
Bowel Habits:			
Development:			
Services (Home Health, FITP, PT, OT, Nutrition, Eyes, Hearing):			
Social History:			
Maternal Medication:		Dose:	Frequency:
Past Medical History:			
Family History:			
Medications:			
Immunizations (Flu / Synagis® if applicable):			
Review of Systems:	Negative	Positive	Comments
General	<input type="checkbox"/>	<input type="checkbox"/>	
Eyes	<input type="checkbox"/>	<input type="checkbox"/>	
ENT	<input type="checkbox"/>	<input type="checkbox"/>	
Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	
GI	<input type="checkbox"/>	<input type="checkbox"/>	
GU	<input type="checkbox"/>	<input type="checkbox"/>	
Neuro	<input type="checkbox"/>	<input type="checkbox"/>	
Extremities	<input type="checkbox"/>	<input type="checkbox"/>	
Skin	<input type="checkbox"/>	<input type="checkbox"/>	
Behavior	<input type="checkbox"/>	<input type="checkbox"/>	

Physical Examination: Wt _____ kg (_____ %) L _____ cm (_____ %) HC _____ cm (_____ %)

Wt for Length _____ % HR _____ RR _____ SpO₂ _____ FiO₂ _____ BP _____

Pain: ☐ NO ☐ YES

Findings	Normal	Abnormal	Comments
General	<input type="checkbox"/>	<input type="checkbox"/>	
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	
Chest	<input type="checkbox"/>	<input type="checkbox"/>	
CVS	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	
GU	<input type="checkbox"/>	<input type="checkbox"/>	
Neuro	<input type="checkbox"/>	<input type="checkbox"/>	
Extremities	<input type="checkbox"/>	<input type="checkbox"/>	
Skin	<input type="checkbox"/>	<input type="checkbox"/>	
Other	<input type="checkbox"/>	<input type="checkbox"/>	

Labs: _____

Radiology: _____

Assessment: _____

Med: _____ Dose: _____ Route: _____ Time: _____ Signature: _____

Plans/Recommendations:

Methadone	Volume prescribed:		
Other medications:			
Feeds:			
Referrals:			
Next appoint:			
Other:			
Education:			
Method:	<input type="checkbox"/> Handout	<input type="checkbox"/> Demonstration	<input type="checkbox"/> Verbal
Taught to:	<input type="checkbox"/> Family	<input type="checkbox"/> Caregiver	<input type="checkbox"/> Other
Barriers:	<input type="checkbox"/> None		<input type="checkbox"/> Other
Outcomes:	<input type="checkbox"/> Independent		<input type="checkbox"/> Other



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