Contact Information	Phil Capp, MD, Medical Director Ambulatory Behavioral Medicine, Swedish Health Services philip.capp@swedish.org | Tel 206.601.2186 Regional Partners: Swedish Health Services (Swedish), Therapeutic Health Services (THS)
Project Title	Directly Observed Treatment with Buprenorphine in Pregnancy (DOT-Bup)

Rationale for the Project

Pregnant women struggling with opiate addiction are among the most vulnerable individuals in our community. There is a paucity of addiction treatment services in general and buprenorphine treatment in particular is difficult to find, a scarcity that is magnified for expectant mothers given the complexity of prenatal care. The cohort of women who fail unobserved buprenorphine therapy in the community and who are subsequently transitioned to directly observed treatment (DOT) present an amazing opportunity to serve our most vulnerable women and infants. DOT with buprenorphine instead of methadone for a subset of this cohort will dramatically shorten the protracted length of hospital stay for infants suffering from neonatal abstinence syndrome (NAS). Swedish believes that access to DOT buprenorphine for pregnant women will deliver significant health benefits for new mothers and their infants along with profound cost savings.

Developing a DOT buprenorphine program for pregnant women aligns well with the Medicaid objectives published April 2015 by the GAO. This resource would add breadth and depth to a critical service that is a covered Medicaid benefit but which is simply not currently available. This initiative strengthens the provider network serving Medicaid patients in our region by forging a new ACO relationship between regional partners (Swedish and THS). This initiative will deliver improved health outcomes for both women and infants and will truly transform the way our local care system delivers addiction services to this cohort. If successful, expansion of this service to other groups struggling with opiate dependence could scale rapidly across the region. The financial benefits of this program will allow Swedish to more rapidly accelerate participation in value-based Medicaid contracts.

Swedish Health Services (SHS) is the largest nonprofit health provider in Greater Seattle, with five hospitals licensed for over 1500 beds, two ambulatory care centers, an employed medical group with more than 170 primary care and specialty care clinics, 9,450 employees, and 6,000 physicians and allied health professionals on staff. Swedish is affiliated with Providence Health & Services (PH&S), a nonprofit delivery system with 34 hospitals licensed for over 7,200 beds in five states, 475 physician clinics, more than 76,000 employees, and a health plan with over 390,000 members. The Swedish Addiction Recovery Service (ARS) led by James Walsh, MD includes a hospital based rehabilitation unit where pregnant women struggling with active addiction can be emergently admitted, medically stabilized, and receive excellent prenatal care. ARS coordinates with Swedish obstetrical services to support the highest risk pregnancies. Mothers participate in both group and individual counseling during their stay at ARS. Careful transition planning supports sobriety after discharge. The inpatient unit admits over 250 pregnant women each year. The outpatient clinic typically serves 20 women each week. The vast majority of these women are addicted to opiates.

Opiate use has increased markedly in the past two decades. In 2014, 1.9% of 18 to 25 year olds in the US were opiate addicted [1]. Over the period spanning 2000 to 2009, opioid use by pregnant women quadrupled, driving an increase in the number of infants requiring special care after delivery [2]. Recent years have seen a shift from the use of opiate pills to smoked or injected heroin. Repeated cycles of opiate withdrawal create stress on the developing pregnancy leading to an increase in miscarriage, premature delivery, and stillbirth. Opiate maintenance treatment with methadone and buprenorphine has been shown to decrease the incidence of these harms to the developing baby.

Dr. Walsh and colleagues are particularly concerned about the cohort of pregnant women who fail unobserved Medication Assisted Treatment (MAT) with buprenorphine in the community due to a variety of factors, ranging from the diversion of buprenorphine to a loved one struggling with addiction recovery, the need for a more potent opiate agent to keep cravings at bay, or an unmanageable psychosocial situation, among others. This group of women requires the structure of DOT. The only agent currently available for DOT MAT is methadone [3]. Women in this group are carefully transitioned to and stabilized on methadone in an inpatient setting at ARS.

The risks associated with methadone are much greater than the risks associated with buprenorphine, particularly with regard to overdose and death [4]. In addition, the duration of the inevitable neonatal abstinence syndrome (NAS) born to mothers on MAT with methadone is much more protracted. Recent data suggest that MAT with buprenorphine shortens neonatal length of stay by 8.5 days in conservative estimates and decreases infant exposure to opiates in the hospital [5]. There are a significant number of women who need the structure of DOT to maintain sobriety but who do not need methadone in place of buprenorphine. If DOT buprenorphine were available in the community, the average length of stay (ALOS) for neonates with NAS would drop precipitously in this particular cohort of women.

Project Description

Which Medicaid Transformation Goals are supported by this project/intervention? Check box(es)
[X] Reduce avoidable use of intensive services
[X] Improve population health, focused on prevention
[X] Accelerate transition to value-based payment
[X] Ensure Medicaid per-capita growth is below national trends

Which Transformation Project Domain(s) are involved? Check box(es)
[X] Health Systems Capacity Building
[X] Care Delivery Redesign
[X] Population Health Improvement—prevention activities

Hypothesis: The availability of DOT buprenorphine will decrease the length of stay for a subset of neonates with NAS. Published data suggests that ALOS for NAS in the maternal buprenorphine cohort is 8.5 days less than the maternal methadone cohort [5].

Proposal: SMG will partner with a local chemical dependency treatment agency, Therapeutic Health Services (THS) to offer DOT buprenorphine to expectant mothers. The executive sponsor for Swedish Medical Group is Ralph Pascualy, MD, CEO of Swedish Medical Group. The executive sponsor for Swedish Medical Center is June Altaras, RN, CEO of Swedish Medical Center and COO of Swedish Health Services. The executive sponsor for THS is Norman O. Johnson, CEO of THS. The Principle Investigator and Grant Administrator for SMG is Phil Capp, MD, Medical Director of Ambulatory Behavioral Medicine for Swedish Health Services and Regional Medical Director of Primary Care. Dr. Capp assumes full responsibility grant deliverables.

Cohort: The minimum cohort will consist of twenty-five (25) expectant mothers referred from ARS.

Process: The grant period is 12 months. Patients will be assessed at ARS and when appropriate, referred to THS to begin MAT with buprenorphine DOT. If not already connected with THS, a standardized intake process with a core group of chemical dependency counselors tailored to the unique needs of this population will be conducted. The initial dose of buprenorphine for each patient will be determined by ARS. Subsequent dosage increases will the determined by ARS protocol. Access to the Swedish electronic medical record (EMR) will be granted using EPIC CareLink, which allows visibility into the Swedish EMR from THS but no visibility into the THS EMR in order to respect to US DSHS regulations around protected health care information as stipulated in 42 CFR Part 2. The clinical contact for Swedish is Dr. James Walsh, MD. The clinical contact for THS is Patricia Edmond-Quinn, M. Ed.

Core Investment Components

Current State: In 2014, Swedish cared for 117 neonates with NAS across all hospital campuses, accounting for 13.7% of all neonatal admissions lasting more than 5 days. The average length of stay for neonates with NAS was 27.7 days. The average cost per stay was estimated at 251,208 USD with a total annual cost of **29,391,336 USD** (117 x 251,208)[6].

Projected Costs: SMG believes the major cost associated with this project will be the development and maintenance of project management resources to ensure operational excellence and a rapid move to scale once the project proves successful. Continual process and outcome measurement will require the creation and maintenance of a patient registry. Significant statistical analysis is required. In addition, there is significant cost associated with stocking and dispensing the medication for THS. SMG estimates that the cost of supporting this project in the first year is approximately 150,000 USD. In subsequent years, minimal to no funding will be required.

Scalability: Once the concept has been proven in the initial cohort, the intervention can be rapidly scaled across all campuses, limited only by the availability of willing community partners with dispensing facilities. All Swedish hospital campuses are proximate to a THS dispensary. Swedish expects other health care delivery systems to rapidly adopt the same approach.

Projected Cost Savings: The savings are based on two core assumptions: women on DOT buprenorphine will have a 25% reduction in the ALOS for NAS, and that this 25% decrease in ALOS translates into a 25% reduction in the average cost for the hospitalization. A cohort of (25) women is a reasonable target for enrollment in the first 12 months of the program.

Based on these two core assumptions and a cohort of 25 women, the projected annual savings per patient will be 62,802 USD (0.25 x 251,208) for total annual savings of **1,570,050 USD** (25 x 62,802). Based on a program cost of 150,000 USD, the program pays for itself after the third patient and delivers an overall return on investment (ROI) of **9.5** or **950%** ([1,570,050 - 150,000]/150,000).

If the assumption involves a decrease of 25% across all NAS admissions at Swedish, the total annual cost savings would be **7,347,834 USD** (0.25 x 29,391,336) with an **ROI of 48.0** or **4800%** ([7,347,834 – 150,000]/150,000).

Project Metrics

Maternal Outcomes:

- Relapse and sobriety rates for patients on DOT methadone and DOT buprenorphine and unobserved buprenorphine treatment will be calculated during pregnancy, defined as the date of first OB intake to 6 weeks post partum. Relapse and sobriety rates for patients on DOT methadone and DOT buprenorphine will be compared to unobserved buprenorphine treatment for 12 months after delivery, starting 6 weeks post-partum. These periods match the standard obstetrical definition of a pregnancy episode. Relapse is defined as the presence of an illicit substance found on urine drug screen or an admission of relapse by the patient. *Swedish expects higher relapse rates in the buprenorphine cohorts at 3 and 6 months in line with published data.*
- The incidence, prevalence, and severity of post partum depression (PPD) in each cohort will be measured for 12 months after the date of delivery using the Patient Health Questionnaire 9 item scale (PHQ-9) and/or Edinburgh Depression Scale (EDS). *Swedish expects lower rates of PPD in the buprenorphine cohorts. There are no data available to guide an estimation of effect size.*
- Intra-partum morphine equivalent dosing of narcotics will be calculated for each cohort using the hospital based medication administration record. *Swedish expects a lower MED in the buprenorphine cohorts as previously reported [2].*
- The average maternal length of hospital stay for each cohort will be calculated along with the total cost of hospitalization using hospital utilization and charge data, and when available, post-adjudicated claims data. *Swedish expects no difference in maternal ALOS or a decrease in costs associated with hospitalization*
- The number of emergency room, inpatient hospitalizations, and incarcerations will be calculated for each cohort using a combination of EMR data and public records (Department of Corrections, Emergency Department Information Exchange). *Swedish expects lower rates of utilization in the buprenorphine cohorts. There are no data available to guide an estimation of effect size.*
- The 12 month all-cause mortality rate for each cohort will be calculated using public records. *Swedish expects a decrease in the mortality rate in the buprenorphine cohort. There are no data available to guide an estimation of effect size.*

Neonatal Outcomes:

- Average length of NICU along with the total cost of hospitalization stay will be calculated for neonates born to mothers on DOT methadone, DOT buprenorphine, and unobserved buprenorphine treatment using hospital utilization and charge data, and when available, post-adjudicated claims data. *Swedish expects a seven (7) day decrease in ALOS in the buprenorphine cohort as previously reported [5].*
- NICU morphine equivalent dosing of narcotics used to treat NAS will be calculated using the hospital based medication administration record. *Swedish expects a lower MED in the buprenorphine cohorts as previously reported [2].*
- Birth weight, length, and head circumference will be reported for infants born to mothers in each cohort. *There are no data available to guide an estimation of effect size. All data to date has been retrospective, not prospective [5].*
- The number of well child checks (WCC) in the first 12 months will be calculated for infants born to mothers in each cohort using the EMR and when available, outside records. *Swedish expects an increase in WCC in the buprenorphine cohorts. There are no data available to guide an estimation of effect size.*
- The percentage of infants meeting SMG immunization standards will be calculated for infants born to mothers in each cohort by querying the Washington State Immunization Database (Child Profile). *Swedish expects an increase in WCC in the buprenorphine cohorts. There are no data available to guide an estimation of effect size.*
- The number of emergency room and inpatient hospitalizations will be calculated for infants born to mothers in each cohort using a combination of EMR data and public records (Emergency Department Information Exchange). *Swedish expects lower rates of utilization in the buprenorphine cohorts. There are no data available to guide an estimation of effect size.*
- The mortality rate will be calculated for infants born to mothers in each cohort using public records. *Swedish expects a decrease in the mortality rate in the buprenorphine cohort. There are no data available to guide an estimation of effect size.*

---

[1] 2014 National Survey on Drug Use and Health. Available at http://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf

[2] Patrick SW1, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. JAMA. May 2012;307(18):1934-40.

[3] 42 CFR 8.12 – Federal Opioid Treatment Standards. Available at https://www.gpo.gov/fdsys/granule/CFR-2002-title42-vol1/CFR-2002-title42-vol1-sec8-12.

[4] Connery HS1. Medication-assisted treatment of opioid use disorder: review of the evidence and future directions. Harv Rev Psychiatry. Mar-Apr 2015;23(2):63-75.

[5] Brogly SB, Saia KA, Walley AY, Du HM, Sebastiani P. Prenatal buprenorphine versus methadone exposure and neonatal outcomes: systematic review and meta-analysis. Am J Epidemiol. Oct 2014;180(7):673-86.

[6] Ely, Rob. SMG Care Transformation Internal Report: 2014 Inpatient Discharges with NAS breakout. Jan 2015. Available on request.