Banked Human Milk Mandated Benefit Sunrise
Follow Up Questions to Applicant Report
June 19, 2015

1. **Can you provide an estimate of the population that may need this benefit? The applicant report provides data on how many babies may have a medical need for human milk because they are preterm, low birth weight, very low birth weight, or have developed NEC. However, it does not estimate what percentage of these babies would need banked milk because they are not receiving it from their mothers.**

It is difficult to quantify the prevalence of mother's who produce insufficient milk supply as well as mothers with medical contraindications to breastfeeding and associate that with the population who would be candidates for banked human milk because of medical necessity. That data does not exist in raw form. The indicators that can be assessed to estimate the population who would qualify as candidate for banked human milk are the following:

A. **Number of Preterm births** – According to the March of Dimes, Washington's preterm birth rate in 2013 was 9.7% (appendix A). There were 8,276 infants born preterm in Washington in 2014 (cited in applicant report). Of those, 5,555 were considered low birth weight (LBW) and 930 were very low birth weight (VLBW). The LBW and VLBW infants are at greater risk of NEC and are therefore more likely to benefit from banked human milk. Not all of these infants will need banked human milk; only the ones who do not have access to mother's own milk and are considered to have a medical necessity.

B. **NEC Rates** – 10% of preterm infants born at less than 1500 grams are affected by NEC (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2677063/). NEC has also been shown to occur in 1 to 3 per 1,000 live births or 1% to 7% of all neonatal intensive care unit admissions (http://www.medscape.com/viewarticle/458205_2).

C. **Other Medical Conditions** – Conditions such as failure to thrive, severe allergies, infants with formula intolerance. Forms of these conditions that would mandate donor human milk are rare (<1% of population) but not well quantified.

D. **Breastfeeding Rates** – Most mothers initiate breastfeeding or breastmilk production. According to the March of Dimes, in 2011 Washington's breastfeeding rate at 1 month post-partum was 83.7% (appendix B).

Normal breastfeeding physiology in healthy women involves a delay in milk production of up to 5 days. Full term healthy babies can often tolerate this period of low intake, but sick, premature infants cannot. Delayed breast milk feedings in high risk populations increases the risk of NEC. Thus it is frequent that a NICU infant will need donor human milk for a short period of time until his/her mother's milk "comes in." In addition, the maternal health conditions that are commonly associated with giving birth to a high risk infant (e.g., diabetes, hypertension, infection, multiple gestation) also put a mother at higher risk of delayed and/or inadequate milk production (per personal communication with Dr. Isabella Knox, July 17, 2015).

An informal query of one NICU dietician (St. Joseph Hospital NICU, Tacoma, WA) found her to estimate that 50-75% of infants who receive donor human milk in their NICU require it only to bridge the time until their mother's own milk is available in sufficient supply to meet their daily needs. For the remaining 25%, donor milk is required for the full NICU policy endorsed period to supplement mother's milk production or to substitute for mother's milk in cases where her own is contraindicated (per personal communication with Dr. Isabella Knox, July 17, 2015)..

One clinical study showed first time mothers who are older, overweight, or who give birth to an infant >3600 g are at greater risk of delayed lactation and thus should be provided with appropriate lactation

support until lactogenesis has occurred and the infant is gaining well. The study cites a previous study that reported the prevalence of delayed lactation to be 33% among first time mothers (http://ajcn.nutrition.org/content/92/3/574.full).

E. **Historical usage rates of banked human milk** – Examining the usage rates of banked human milk in other states with more developed milk banking systems or an a national level will help in understanding what to expect in Washington State in terms of use and growth rates. The tables in the applicant report on page 19 and 20 attempt to forecast distribution by ounces of banked human milk in Washington based on the trend from HMBANA (which includes 18 milk banks across the U.S. and Canada). This gives some context as to what to expect in terms of potential growth trends for usage of banked human milk.

One thing is certain; the intended population for use of banked human milk is small. It includes the portion of preterm infants who are not getting sufficient breastmilk from their mothers and only in the cases where it is considered medically necessary. There are specific and small populations of other at risk infants who are candidates for banked human milk as well. The key is that human milk is should be considered medically necessary and in most cases mothers will be breastfeeding or producing at least some milk.

2. Is it your intent for this mandate to apply only to situations where the mother's milk is unavailable (unable to produce milk or a sufficient supply of milk, or the milk is contraindicated because of a mother's illness or drug use)?

Yes

3. Is donor breast milk equal to a mother's own milk?

Mother's own milk contains hundreds of biologically active substances that provide protection and growth enhancement for baby. These are not present in artificial milk/formula. Many of these biologically active substances survive past the pasteurization process and remain active in donor milk, thus providing protection unavailable from formula. Mother's own milk is always the first choice, however when mother's own milk is unavailable than banked donor milk (donor breast milk) is second best (Ewaschuk et al, 2011 – Attachment provided with article).

4. The applicant report notes that human milk is donated on a voluntary basis. Is there data and/or information regarding how much is donated to existing banks or hospitals and if there is enough to keep up with the current demands?

Since opening in 2013, NWMMB has collected over 3600 gallons of human milk from 690 volunteers. This has allowed for pasteurization and distribution of over 248,000 ounces of milk to hospitals throughout the Pacific NW. As NWMMB has focused on outreach and education about the importance of milk banking they have seen the number of milk donors' increase. They have experienced a 22% increase in the number of milk donors from this time last year. Referrals from healthcare providers, lactation consultants and partners within the breastfeeding community are essential to ensure a robust flow of milk donation. *(Per Joanne Ransom, Clinical Director of Northwest Mothers Milk Bank in Portland, OR)*

5. If human banked milk becomes a mandated benefit in Washington, how can we ensure there will be a sufficient supply donated to meet the demand?

Northwest Mothers Milk Bank is committed to providing safe, human milk to medically fragile infants throughout the Pacific Northwest. NWMMB has partnered with hospital systems, businesses and healthcare clinics to establish Milk Drops. A Milk Drop is a community location where fully screened milk donors can bring their donations that are then shipped to the milk bank for processing. Currently, five Milk Drops exist in Washington; with 3 new sites set to open in 2015. Milk Drops increase visibility and

awareness about the importance of not-for-profit milk donation. Collectively in 2015, Washington based Milk Drops have collected over 15,000 ounces of human milk, therefore exceeding the distribution volumes. This does not take into account the volume of milk independently shipped from women throughout the state. NWMMB is experiencing an increase in donorship and interest in milk donation.

Also, as a part of a network of not-for-profit HMBANA milk banks, we can seek additional volume of milk from affiliates as needed
(Per Joanne Ransom, Clinical Director of Northwest Mothers Milk Bank in Portland, OR)

6. Can you provide any data or estimates of how many infants should be receiving human banked milk in the NICU, but do not due to lack of insurance coverage?

Many hospitals use banked human milk, including but not limited to: Seattle Children's, UWMC, Evergreen Hospital, Tacoma General, and Swedish Medical Center. These and other hospitals have taken scarce and expensive resource and paid for its use because the reimbursement system has lagged behind the science. As demand increases based on new evidence, we should have system that responds rather than depending on individual budgetary decisions.

Hospitals weigh highest priority need with cost of purchasing banked human milk, because they do not receive reimbursement for donor milk. Even though ultimately they will see cost savings by using human milk over formula, it often takes someone who feels passionately about this issue to bring it and the evidence to the attention of financial decision makers. Often policies are limited to the sickest and smallest infants. One area hospital has a policy of providing banked human milk for birth weight up to 1.8 kilograms or about 4 pounds. One provider interviewed stated the ideal would be to continue using banked human milk until the preterm reaches 40 weeks and that commonly, parents ask who have researched this request continued treatment using donor milk.

To show the gap, there would have to be a recommended standard to compare each hospital policy to. This doesn't exist currently, that I am aware of. There is clear consensus that banked human milk is the best treatment for this specific infant population (preterm and at risk infants). Providers are the experts. They know their patients and the medical research and should have the ability to use the optimal treatment for as long as it's considered medically necessary and improves the outcomes of their patients.

7. On page 18 of the applicant report, you include information on the total ounces of donor milk dispensed in Washington State from January to April of 2015. Is there additional data about the donor milk dispensed, such as:

- **For how many babies was it dispensed?**

  Most of the milk was distributed to hospitals and due to HIPAA laws, this is information we are not privileged to have. However based on model calculations by Aydelio Rivera, MD, Medical Director of Mothers Milk Bank of Austin, Texas, assuming an average NICU stay entails an infant consuming an 5280 mls of donor milk. Using this calculation, approximately 57 infants were recipients of PDM from NWMMB in 7 Washington NICUs. This does not account for any additional volume that was distributed by Mothers Milk Bank of Colorado or the Mothers Milk Bank of San Jose who have also served the need for donor milk in Washington NICUS.
  (This calculation was figured by Joanne Ransom, Clinical Director of NWMMB)

  Overlake hospital NICU has about 4000 deliveries/year, which equals about 4.5% of all births in WA. In January-June 2015 they had 27 babies who were </= 1800 grams OR 33 weeks gestation. During that same period they had 29 babies who got donor milk.
  (This data was collected by Dr. Isabella Knox - Neonatologist)

- **For what purpose?** All donor milk is dispensed per a physician order. Prematurity, failure to thrive, low milk supply and maternal cancer are some of the most common diagnoses for milk dispensed in the outpatient setting.
  (Per Joanne Ransom, Clinical Director of Northwest Mothers Milk Bank in Portland, OR).

- **Whether the parents were required to pay out of pocket or it was covered under the hospital's NICU policy?** In 2015, families living in Washington State have purchased approximately 462 ounces of donor milk from NWMMB as outpatient. This is approximately $2,080 of unreimbursed cost.
  (Per Joanne Ransom, Clinical Director of Northwest Mothers Milk Bank in Portland, OR).

  Currently, in Washington State, if a NICU infant qualifies for donor milk under the hospital's medical care policy, the cost is paid by the hospital, not the family. As recently as 3-5 years ago, several families purchased donor human milk for their NICU infants (personal communication, I.Knox, MD).

8. In Graph 3 on page 19, are you assuming the projected growth rate in annual distribution for Washington will be even higher if the proposed mandate were to pass?

Although an exact prediction can't be made as to the growth rate of banked human milk in Washington State, this graph is intended to provide a projected growth rate based off the national usage data.

NWMMB was established as the Pacific Northwest's milk bank two years ago. Because this local resource for banked human milk now exists some growth is expected to occur by way of community education and provider support through NWMMB's presence.

Much of the growth over the past 5 years has come about because of changes to NICU policies from using formula to using banked human milk. Currently, all of the Level II, III, and IV NICU's in Washington state use banked human milk for selected patients. Although every NICU has its own policy, in general they target the same population—infants at risk for NEC because of prematurity, GI surgery, congenital heart disease. Thus, most at risk babies in Washington State who have demonstrable medical necessity for donor milk currently have access, funded through hospital budgets rather than through their own insurance coverage (personal communication, I. Knox, MD).

Further growth in the population for which donor human milk is medically necessary will likely be lower because it will depend on a broadening of the evidence-based indications for donor human milk. Since well-designed studies take time, this expansion of indications will not be as steep (personal communication, I. Knox, MD).

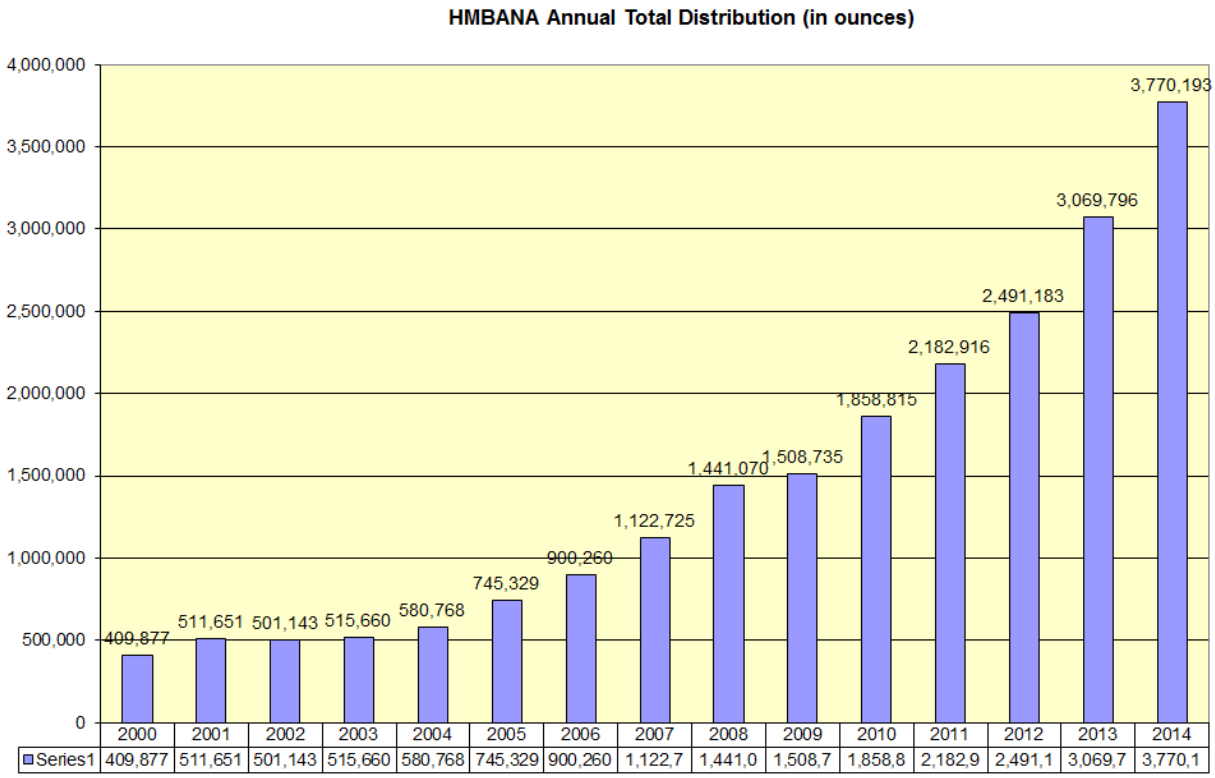
9. On page 22 under (ii), there is a statement that families report contacting their insurance companies and having obtained coverage but that is not known to be the common experience.

- **Where was this information obtained?** This information is based off of phone interviews with providers from local NICUs and several milk banking staff who hear regularly from other providers and families they work with that contacting insurers occurs, most often the claim is denied, however it is not completely unheard of that a persistent family has gotten reimbursed. I am unsure of the exact circumstances and diagnosis.

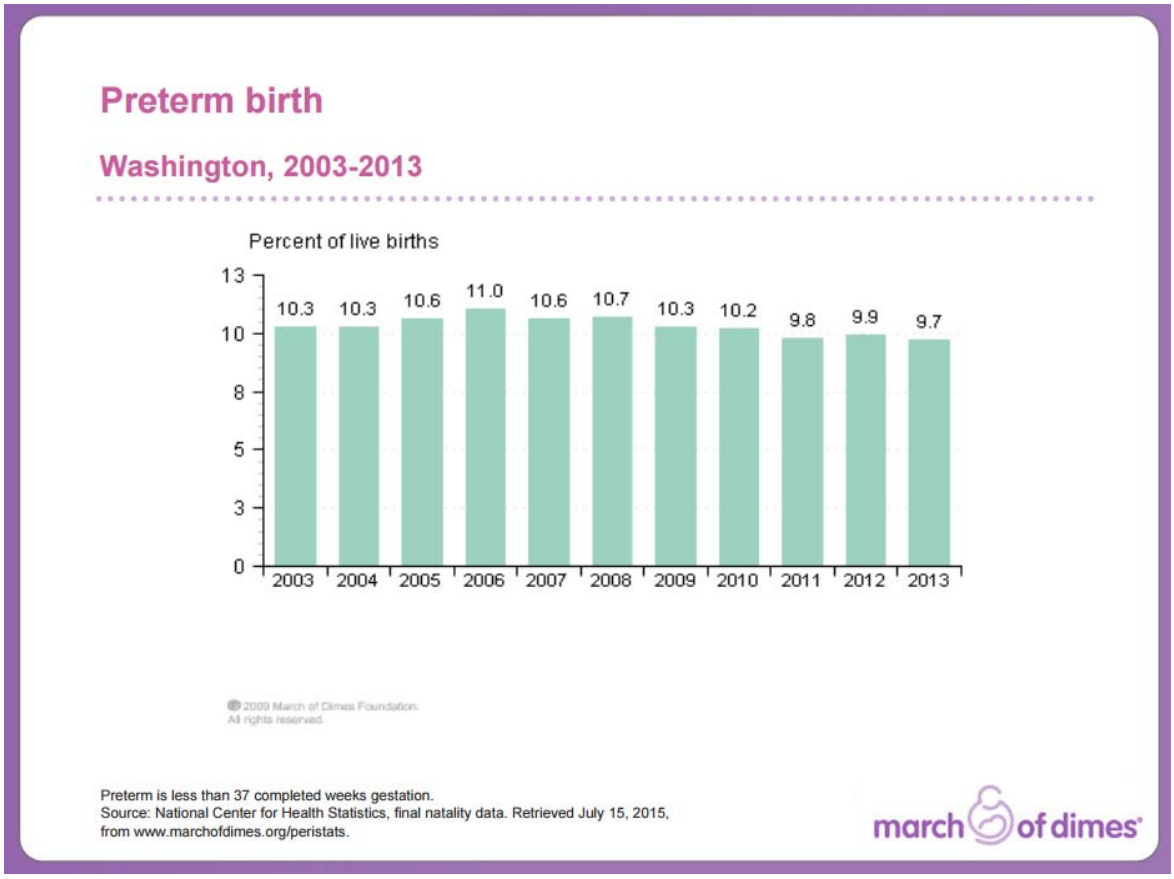
- **Is there information on how many families requested coverage and how much successfully obtained coverage?** This data does not exist in the formal sense, at least that I am aware of.

- **Were they covered because of a maternal condition or newborn condition?** I don't know the answer to this.

10. Can you please provide labels for Table 1? For instance, we are assuming the measurement on the left axis is ounces.



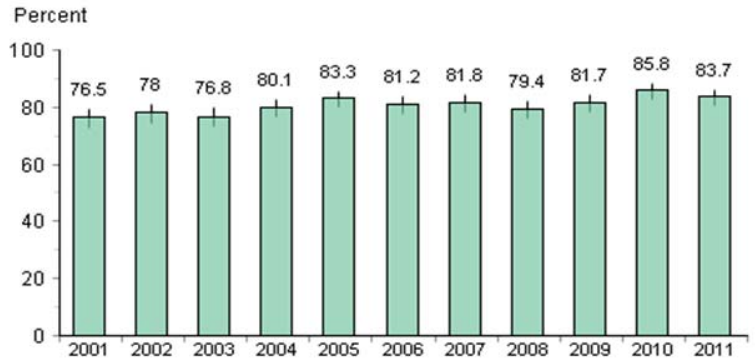
Appendix A



Appendix B

Breastfeeding one month postpartum (PRAMS)

Washington, 2001-2011



Note: Vertical lines in graph represent 95% confidence intervals.

Breastfeeding, one month: mother reported still breastfeeding four weeks after delivery.
Source: Centers for Disease Control and Prevention, Pregnancy Risk Assessment Monitoring System. Retrieved July 15, 2015, from www.marchofdimes.org/peristats.

The mark "CDC" is owned by the US Dept. of Health and Human Services and is used with permission. Use of this logo is not an endorsement by HHS or CDC of any particular product, service, or enterprise.