

**Refusal Form Subcommittee Meeting Minutes
February 1, 2018
10:00 a.m.
Conference Call**

MEMBER NAME	YES	NO	MEMBER NAME	YES	NO
Kaili Stehel, MD (Subcommittee Chair)	P		Joseph Schneider, MD	P	
Alice Gong, MD	P		Linda Zediana, RN	P	

Yes: Indicates attended the meeting **No:** Indicates did not attend the meeting **P:** Indicates participated by phone

HHS STAFF NAME	YES	NO	HHS STAFF NAME	YES	NO
Debra Freedenberg, MD, PhD, NBS Medical Director	Yes		Natalie Adelaja, HHS Assistant General Counsel	Yes	
Beth Rider, RHIA, NBS Program Specialist	Yes		Rachel Lee, PhD, Lab, Manager, Biochemistry & Genetics	Yes	
Lynette Borgfeld, Lab, NBS Group Manager	Yes				

BACKGROUND OF SUBCOMMITTEE:

Refusal Form Subcommittee Formation from February 24, 2017 Newborn Screening Advisory Committee (NBSAC) Meeting.

The Newborn Screening Advisory Committee, along with DSHS Laboratory staff, discussed continuing quality improvement regarding newborn screening. The discussion included the documentation and challenges associated with capturing better data on parental refusals for newborn screening.

Dr. Elizabeth "Kaili" Stehel made a motion to form a subcommittee to work with the Department of State Health Services (DSHS), including the legal department, to develop recommendations for better documentation/data and a more user-friendly newborn screening refusal form.

Dr. Guillory requested volunteers for the subcommittee. Members of the subcommittee are:

1. Dr. Kaili Stehel – Chair
2. Dr. Michael Speer
3. Dr. Alice Gong
4. Dr. Joseph Schneider
5. Ms. Linda Zediana

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SUBCOMMITTEE MEETING NOTES:

This was the third conference call meeting and the meeting was called to order at approximately 10:12 a.m. by Subcommittee Chair, Dr. Kaili Stehel. Dr. Stehel greeted everyone and requested attendees introduce themselves. This meeting was held via conference call and was audio recorded.

Current Texas Law:

The current statute, Texas Health and Safety Code, Sec. 33.012 states that (a) screening tests may not be done on newborns whose parents, managing conservator, or guardian objects for religious reasons or practices; and (b) the physician or person attending the newborn shall ensure the objection of the parent (etc.) is entered into the medical record and parent (etc.) shall sign the entry.

Refusal Form Summary:

The parental refusal form has been revised and with suggested language by Dr. Speer at the October Newborn Screening Advisory Committee (NBSAC) meeting, the form was approved by the Committee. This revised form is proposed to replace the current parental refusal form which is available online for providers to complete and include in the baby's medical record when the newborn screening is refused.

Refusal Form Process Summary:

Dr. Stehel summarized the goal for this meeting of the subcommittee which is to work on the current process for capturing the number of newborns who are not screened, and provide any recommendations to the overall NBSAC. Natalie Adelaja, Assistant General Counsel, was invited to give input from the legal department's perspective and to guide the subcommittee as appropriate. The perfect process would link the lab, the birth certificates, the newborn screening database and refusal records to ensure every baby is screened. Since this isn't the current process, the members and staff on the call today discussed other ways the process could be improved.

DISCUSSION: The statute is pretty silent on what can be done once a parent declines. Question to address is how can we ensure/show all babies are screened as this is part of the current statute as well. Liability is about 6,000 babies potentially not screened (1 1/2 % of all births of 400,000 births in 2014). The form would be subject to open records and we would need a consent to the parents to let them know it's sent to DSHS. Could there be a flag or a communication back to the State that the newborn screen was missed for whatever reason (refusal for religion or another

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reason)? The form is good for documentation but doesn't account for those babies not screened.

IDEAS: the blood spot card/kit could be used, without the blood samples included. The current "just the card" price is 50 cents, so \$3000 would be the cost if calculated from the 6000 missed screens.

Workable solution is to change policy to advise and educate or mandate providers to submit the (blank) card without the blood spots.

Use wording (provider would have to write) such as Not Intentionally Missed (or NIM) or even Refused (which should also have the refusal form signed and included in the medical record).

Dr. Lee asked if we would have to add consent language to the refusal form in order to ask or require providers to submit them back to DSHS to capture that information and Ms. Adelaja confirmed that because they could be subject to open records requests.

Recommendations to report to NBSAC for consideration:

- DSHS would submit the revised refusal form through internal channels for review and approval and a form number;
- Once refusal form approved, make available to providers (online or paper);
- Reiterate to providers that signed refusal form be included in medical record;
- As a quality project in a trial period of six months or 1 year: include a policy change to mandate providers send in the blank blood spot card, hopefully with wording such as Not Intentionally Missed or NIM, or Refused;
- The first choice will be providers use a Medicaid card if available, and if no Medicaid card, providers use a private insurance card and the State can implement a mechanism to give credit to the provider for that card.

Dr. Stehel will not be at the February Newborn Screening Advisory Committee, so Dr. Schneider agreed to present the above recommendations to the Committee, and Dr. Gong will be available to give additional input via the phone.

Dr. Stehel adjourned the meeting at 11:14 a.m.