Storage and Use of Newborn Screening Blood Spot Cards
New Requirements – June 1, 2012
HB 1672 and HB 411
Agenda

• History – HB 1672, HB 411
• Comparison of Requirements under Different Laws
• New Forms for HB 411 starting June 1, 2012
• New Healthcare Provider Responsibilities for HB 411
• Logistics of Transition
• HB 411 Points of Contact / Resources
History of Blood Spot Storage and Use Laws

May 2009 - HB 1672

• Outlined allowable uses of residual blood spots
• Required healthcare providers to give a form to the parents when the newborn screen was collected
  • Information about the uses of the blood spots
  • Parental request for destruction of the blood spots
History of Blood Spot Storage and Use Laws

May 2011 - HB 411

- Effective June 2011 - Strengthens the DSHS management review and approval processes of proposed post-screening uses
- Effective June 1, 2012 - Requires parental consent for:
  - Storage longer than 2 years
  - External public health research uses
- New “Decision” Form
Comparison of Timeframe Requirements

- Storage of Residual Blood Spots
- Allowed Uses
  - Internal DSHS
  - External Research
- Parent Options

May 27, 2009
HB 1672

June 1, 2012
HB 411
**Length of Storage after Completion of the Newborn Screen Test**

<table>
<thead>
<tr>
<th>Prior to May 27, 2009</th>
<th>May 27, 2009 through May 2012 (HB 1672)</th>
<th>Beginning June 1, 2012 (HB 411)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 25 years</td>
<td>To be determined</td>
<td>All blood spots are stored for up to 2 years and then destroyed unless the parent submits a completed decision form allowing for longer storage.</td>
</tr>
</tbody>
</table>
Protection of Patient Privacy

IMPORTANT:

• No information that identifies the child or parent can be released outside DSHS without specific written OK from the parent

• Specimens are stored safely and securely
Allowed DSHS Uses

- Allowed uses include:
  - Quality assurance to make sure lab tests, equipment, and supplies are working right
  - Developing new tests; and/or
  - DSHS studies of diseases that affect public health.
Public Health Research Use outside of DSHS

During all timeframes:
- DSHS IRB and management approval required
- De-identified blood spots only

<table>
<thead>
<tr>
<th>May 27, 2009 through May 2012</th>
<th>June 1, 2012 or Later</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not allowed without study specific parental consent.</td>
<td>Allowed only if parent provides written consent (decision form). Uses must follow DSHS policy for required management and IRB approvals.</td>
</tr>
</tbody>
</table>
## Parent Options

<table>
<thead>
<tr>
<th>May 27, 2009 through May 2012 HB 1672</th>
<th>June 1, 2012 or Later HB 411</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parents may direct DSHS to destroy their child’s blood spots within 60 days</td>
<td>Parents may choose to have the blood spots stored for up to 25 years and to possibly be used for de-identified public health research uses outside of DSHS.</td>
</tr>
</tbody>
</table>
New Forms for HB 411
HB 411 requires the distribution of 2 new forms to parents upon collection of each newborn screen

- Effective date: June 1, 2012
- Explains parent options
- Gives parents a means to allow or refuse long-term storage and use of specimens
- Replaces requirement to distribute current “Parent Copy” and “Disclosure / Directive to Destroy” forms
Goals of Form Development Team

- Ensure parents understand their choices
- Ensure compliance with parental choices
- Streamline healthcare provider distribution
- Ensure compliance with law
- Streamline DSHS processing
- Ensure enough information is requested on forms to match forms to specimens
- Maximize parent / patient privacy
- Improve general Newborn Screening education
New Forms – June 1, 2012

Development Summary

• 22 draft versions
• Developed with input from:
  • Professional medical organizations including TMA, TPS, and THA
  • Parents
  • Submitting facility physicians, nurses, and technologists
  • DSHS Laboratory and Clinical Care Coordination staff
  • Legal advisors
• Reviewed by
  • DSHS Executive Leadership
  • Texas Legislative Offices
  • Healthcare Provider Stakeholders
Parent Information Form

- Page 1 of 2012 Kits (Replaces Page 1 of previous kits)
- English / Spanish – Front / Back
- Distribute to parent upon collection of each specimen
- Parents should take form received at collection of first screen to their baby’s doctor when the baby is 7 to 14 days of age
- Will be OK to still distribute older version beginning June 1.
Parent instructions to take form received at 1st screen to doctor when baby is 7 to 14 days of age

Expanded and simplified general newborn screening information

Contact phone number and web address

Information about residual specimen storage / use and Parental Decision form (Page 2)

Page 17
Parental Decision for Storage and Use of NBS Blood Spot Cards

• Page 2 of 2012 Kits (Replaces Page 2 of previous kits)
• English / Spanish – Front / Back (Vietnamese online)
• By law, starting June 1, 2012, MUST be distributed to parent upon collection of each specimen
• Intent is that all parents make a decision one way or the other
• Parents may:
  • Complete form and return to healthcare provider to be shipped with any regular newborn screening specimen shipment; OR
  • Mail in at a later date
Parental Decision for Storage and Use of NBS Blood Spot Cards

Explanation of Choices

Parents only need to complete form once per child

Signature is required to process ‘OK’ selection

Forms without a signature or a selection will default to ‘No’
New Healthcare Provider Responsibilities for HB 411
Step 1: Distribute to parents upon collection of each newborn screening specimen.

“Texas Newborn Screening Parent Information” (Page 1 of 2012 Kits)

and

“Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards” (Decision form) (Page 2 of 2012 Kits)
STEP 2: Advise parents that they should:

- Read Page 1 “Texas Newborn Screening Parent Information”. Take the form given to them upon collection of the first screen to their child’s healthcare provider when the child is 7 to 14 days of age.

- Read Page 2, “Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards”, select an option, and return to DSHS.

Parents may return the form to the healthcare provider at the time of collection or mail it into DSHS at a later date.
STEP 3: Check the box on the demographic form (Page 3) that the “Use and Storage...” form was given to the parent.

STEP 4: If requested by parent, return the completed form to DSHS along with any regular newborn screening specimen shipment.
What do Healthcare Providers do with the older collection kits (2010 and 2011) starting on June 1, 2012?

Continue to use the 2010 and 2011 collection kits through the kit expiration date.

8 ½ X 11 form is available at: http://www.dshs.state.tx.us/lab/nbsBloodspots.shtm
Educational Resources

- Official notification letter
- Monthly NBS listserv updates
- Kit order inserts
- Website updates
  [http://www.dshs.state.tx.us/lab/nbsBloodspots.htm](http://www.dshs.state.tx.us/lab/nbsBloodspots.htm)
- Webinars
- CE modules
- Video
- Pamphlets / flyers
Resources

Web
http://www.dshs.state.tx.us/lab/nbsBloodspots.shtm

Phone:
1-888-963-7111, ext. 7333, or 512-776-7333

Email:
NewbornScreeningLab@dshs.state.tx.us