

## Important Newborn Screening (NBS) Program Changes

### Use and Storage of Newborn Screening Blood Spot Cards

House Bill 411 (Texas legislative 82<sup>nd</sup> Session) includes new requirements for the Department of State Health Services (DSHS) Newborn Screening (NBS) Program and newborn screening healthcare providers. These new requirements took effect on June 1, 2012 and change the actions for which Healthcare Providers are responsible.

#### What are the differences in Texas law before and after June 1, 2012?

	Date of Specimen Collection	
	On or Before May 31, 2012	June 1, 2012 or Later
<b>Blood Spot Storage after Completion of the Newborn Screening Test</b>	TO BE DETERMINED	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.
<b>De-identified Public Health Research Uses outside of DSHS</b>	Not allowed without study specific parental consent	Allowed only if parent provides written consent (decision form). Uses must follow DSHS policy for required management and IRB approvals.
<b>Parent Options</b>	Parents may direct DSHS to destroy their child's blood spots.	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.

#### What doesn't change?

- No information identifying a parent or child can be released without specific written consent from the parent.
- Stored blood spots are kept safe and secure.
- Allowed uses include:
  - Quality assurance to make sure tests, equipment, and supplies are working right
  - Developing new tests; and/or
  - DSHS studies of diseases that affect public health.

**WEB ADDRESS TO ACCESS FORMS:** All forms referenced in this document are available for download in 8½ X 11 format in English, Spanish, and Vietnamese at: <http://www.dshs.state.tx.us/lab/nbsBloodspots.shtm>

Visit the website or contact the laboratory for additional information:

- Email: [NewbornScreeningLab@dshs.state.tx.us](mailto:NewbornScreeningLab@dshs.state.tx.us)
- Phone: 1-888-963-7111 Ext. 3198

## What are the Healthcare Provider Responsibilities?

Upon collection of each newborn screening specimen:

- Distribute “**Texas Newborn Screening Parent Information**” (Page 1 of 2012 NBS collection kits)
- Distribute the form “**Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards**” (Page 2 of 2012 NBS collection kits).
- Advise parents that the parents 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 sign the form. Parents may give the form to the healthcare provider at the time of collection or mail it to DSHS at a later date.
- If requested by the parent, return the completed Parental Decision 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 specimen collection kits to collect Newborn Screening specimens until the kit expiration date (can be found on each kit).
- Remove and discard Page 2, “*Use and Storage of Newborn Screening Blood Spot Cards / Directive to Destroy Newborn Screening Blood Spot Card Following Testing*”.
- Distribute Page 1 of the 2010 and 2011 specimen collection kits to parents.
- Distribute an 8½ X 11 **Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards** form with each specimen collected.

Kit and Form Examples

2011 NBS Kit:

 TX 11-000001 3 TX 11-000001 3	Infant's Last Name _____ Infant's First Name _____ Infant's Date of Birth <u>MM/DD/YYYY</u> <b>Texas Newborn Screening – IMPORTANT – Parent Take to Doctor</b>	Serial Number <input type="checkbox"/> TX 11-000001	<b>MEDICAID / CHIP / CHARITY</b> PROVIDER: Detach this Page and Give to Parent for Review	<b>Newborn Screening</b> • This form is for the collection of a newborn screening specimen. • Collect the specimen and complete the form according to the instructions on the back of this form. • SPECIMEN REJECTED if NO Date of Collection or NO Newborn's Last Name is provided. • Do not touch the blood collection area of the form. • <b>DO NOT</b> remove fold over flap. Cover <b>DRIED</b> blood spots with the flap before mailing.
	<p>Parent, Take your baby <b>and</b> this form to your baby's doctor when your baby is 1-2 weeks of age. The State of Texas requires that every baby be screened at 1-2 days and again at 1-2 weeks of age. The screen is done on blood taken from a heel stick and tests for a number of rare disorders that can cause mental retardation or death. It is important that you take this form to the baby's doctor so that your infant's first and second screen can be linked. For more information on the Texas Newborn Screen refer to the website listed below. For information on the use and storage of newborn screening specimens see <a href="http://www.dshs.state.tx.us/lab/newbornscreening.shtm">http://www.dshs.state.tx.us/lab/newbornscreening.shtm</a></p> <p>Estimados padres: Lleve a su bebé junto con este formulario al médico de su bebé cuando el bebé tenga de 1 a 2 semanas de edad. El estado de Texas requiere que todos los bebés tengan una revisión médica al 1 ó 2 días de nacidos y otra vez a la edad de 1 a 2 semanas. Se revisa la sangre tomada con un piquete en el talón y se hacen pruebas para detectar varias enfermedades raras que podrían causar retraso mental o la muerte. Es importante que lleve este formulario al médico de su bebé para que relacionen la primera revisión de su niño con la segunda. Si desea más información sobre la Revisión de recién nacidos de Texas consulte el siguiente "website". Para informarse sobre el uso y el almacenamiento de las muestras para las pruebas de detección temprana a los recién nacidos consulte <a href="http://www.dshs.state.tx.us/lab/newbornscreening.shtm">http://www.dshs.state.tx.us/lab/newbornscreening.shtm</a> (contenido en inglés).</p> <p>Texas Department of State Health Services – Newborn Screening Program P.O. Box 149341, Austin, Texas 78714 - 9341 Expires 02/28/2014 <a href="http://www.dshs.state.tx.us/lab/newbornscreening.shtm">http://www.dshs.state.tx.us/lab/newbornscreening.shtm</a> (800) - 252-8023 <b>PARENT COPY</b></p>	<p><b>Provider/Submitter Instructions:</b> Complete Infant's Last Name, First Name and Date of Birth.</p> <p><b>For 1<sup>st</sup> screen:</b> Remove this PARENT COPY and give to the parent. Inform the parent that they MUST take this form to their infant's doctor at the baby's 1-2 week check-up.</p> <p><b>For 2<sup>nd</sup> screen:</b> Write the serial number from the 1<sup>st</sup> screen PARENT COPY (brought to you by the parent) in the box labeled "Previous Specimen Serial Number" in the Newborn Information area of the demographic form for the specimen being submitted.</p> <p>Retain the PARENT COPY from the 2<sup>nd</sup> screen in the patient chart. If an additional screen is requested, use this serial number on the additional screen form.</p> <p><b>For ALL screens:</b> Remove page 2 titled "Use and Storage of Newborn Screening Blood Spot Cards" of this kit and give to the parent. Then check the box on the Demographic Information (DHS copy) page to indicate that page 2 was distributed.</p>		

First 2 digits of serial number indicate year of kit manufacture

2012 NBS Kit:

 TX 12-000001 X TX 12-000001 X	Baby's Last Name _____ Baby's First Name _____ Baby's Date of Birth <u>MM/DD/YYYY</u> <b>Texas Newborn Screening Parent Information</b>	Serial Number <input type="checkbox"/> TX 12-000001	<b>MEDICAID / CHIP / CHARITY</b> PROVIDER: Give form to parent & Return with blood spot cards if requested.	<b>Newborn Screening</b> • This kit is for the collection of a newborn screening specimen. • Collect the specimen and complete the forms according to the instructions on the back of this kit. • SPECIMEN REJECTED if NO Date of Collection or NO Newborn's Last Name is provided. • Do not touch the blood collection area of the form. • <b>DO NOT</b> remove fold over flap. Cover <b>DRIED</b> blood spots with the flap before mailing.
	<p>Parent, Congratulations on your new baby! Take your baby to your baby's doctor when your baby is 7 to 14 days old. <b>Also, take this form!</b> This is important. This will help the doctor get the newborn screening test results.</p> <p><b>What is newborn screening?</b> It is a simple blood test to look for some diseases. These diseases can cause a baby to get really sick or die.</p> <p><b>Why should my baby be tested?</b> If we find and treat these diseases early, we can keep babies from getting sick or dying.</p> <p><b>When is my baby tested?</b> In Texas, babies have a newborn screening test when they are 1 to 2 days old. This test is done again at 7 to 14 days old. The test is done in accordance with Texas law.</p> <p><b>How is newborn screening done?</b> A little blood from your baby's foot is put on a blood spot card. The cards are sent to be tested at the Department of State Health Services (DSHS).</p> <p><b>How do I get results?</b> You can get the test results from your baby's doctor. The results are sent to the doctor from DSHS in one to two weeks.</p> <p><b>Is more testing available?</b> DSHS screens for many but not all diseases your baby may have. More tests can be done. Ask your baby's doctor and see <a href="http://www.babysfirsttest.org/find-condition">www.babysfirsttest.org/find-condition</a>.</p> <p>Texas Department of State Health Services – Newborn Screening Program P.O. Box 149341, Austin, Texas 78714 - 9341 (800) 252-8023 <b>PARENT COPY</b></p>	<p><b>PROVIDER: Fill out baby's information above. Give this form to a parent.</b> Starting June 1, 2012:</p> <ul style="list-style-type: none"> <li>DSHS keeps the blood spot cards in a secure place for up to two years. By Texas law (Health &amp; Safety Code Sec. 33.017(b)-(c)), the blood spots may be used during that time. Uses include:             <ul style="list-style-type: none"> <li>DSHS and external quality assurance to make sure tests, equipment, and supplies are working right;</li> <li>Developing new tests; and/or</li> <li>DSHS studies of diseases that affect public health.</li> </ul> </li> <li>If you give your OK, your baby's blood spot cards will be stored for up to 25 years, and they may be used for public health research outside of DSHS.</li> </ul> <p><b>Complete, sign, and return the "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form to make your choice.</b></p> <p>No matter your choice, no information that identifies you or your child can be released outside DSHS without your additional written OK. There are a few exceptions, as provided by law.</p> <p>You can change your mind at any time.</p> <p><b>For more information, call 1(888) 963-7111 ext. 7333 or visit <a href="http://www.dshs.state.tx.us/lab/newbornscreening.shtm">www.dshs.state.tx.us/lab/newbornscreening.shtm</a></b></p>		

**Use and Storage of Newborn Screening Bloodspot Cards / Directive to Destroy Newborn Screening Blood Spot Card Following Testing (Page 2 of 2010 and 2011 Kits)**

THIS FORM IS **ONLY** VALID ON SPECIMENS COLLECTED **BEFORE** JUNE 1, 2012.

**DO NOT DISTRIBUTE THIS FORM FOR SPECIMENS COLLECTED AFTER JUNE 1, 2012.**

Use and Storage of Newborn Screening Blood Spot Cards	Directive to Destroy Newborn Screening Blood Spot Card Following Testing
<p><b>PARENT / MANAGING CONSERVATOR / LEGAL GUARDIAN</b> <b>PLEASE READ CAREFULLY</b></p> <p><b>What is newborn screening (NBS)?</b> The Texas Newborn Screening Program checks Texas babies for a list of serious medical conditions. These conditions can cause death or severe disability. Finding a medical problem during newborn screening can help prevent problems and may save your baby's life.</p> <p><b>How does your baby get screened?</b> A small amount of your baby's blood is placed on a special blood spot card. The blood spot card is sent to the state laboratory and tested.</p> <p><b>What happens after the blood is tested?</b> After testing, blood spot cards are safely stored by the Texas Department of State Health Services (DSHS) because they still have important public health uses. The main uses are: 1) quality assurance/quality control, such as making sure that testing equipment continues to produce accurate newborn screening test results for Texas babies, and 2) medical research (see <i>Texas Health and Safety Code Sec. 33.017(b)-(c)</i> for a complete list of uses allowed by law). Specific information that could identify your child and connect him/her to a particular blood spot card is not allowed outside of DSHS without permission from the child's parent, managing conservator, or legal guardian unless otherwise provided by law.</p> <p>You can have your baby's blood sample destroyed if you do not want it to be used after the newborn screening tests are completed. <u>If you are okay with the sample being stored and used, as described above, then there are no further steps for you to take.</u></p> <p>If you want your baby's blood sample to be destroyed, YOU must fill out ALL of the information on this form and send it back to DSHS at the address given below (DSHS will also accept the form from your healthcare provider, once you have completed and signed the form). If the newborn screening blood spot card is destroyed, the blood sample will not be available for any future needs you may have for the sample.</p> <p><b>To request to have your child's blood spot(s) destroyed:</b></p> <ol style="list-style-type: none"> <li>1. Fill out the entire attached form. Do not leave any fields blank.</li> <li>2. Mail original to: Texas Department of State Health Services Newborn Screening Laboratory, MC 1947 PO Box 149347 Austin, Texas 78714-9347</li> <li>3. For additional information, call 1(888) 963-7111 ext. 7333 or visit web site: <a href="http://www.dshs.texas.gov/newbornscreening.shm">http://www.dshs.texas.gov/newbornscreening.shm</a></li> </ol> <p>DSHS Laboratory Services Section <b>NBS Form F 14-13230</b> - February 2010</p>	<p><b>Fill out this form ONLY if you WANT your baby's blood sample destroyed after newborn testing is complete</b></p> <p>I, _____ (please print full name) hereby certify that I am the (check one) <input type="checkbox"/> parent, <input type="checkbox"/> managing conservator, or <input type="checkbox"/> legal guardian of the child named below, and I further certify that there is no court order in effect which restricts my legal ability to make this request.</p> <p>As parent, managing conservator, or legal guardian, I am telling DSHS to destroy my child's blood spot card(s) after the newborn screen testing is finished.</p> <p>Full Name of Child: _____</p> <p>Child's Date of Birth: _____</p> <p>Full Name of Mother: _____</p> <p>Contact Information: _____ (Telephone number, e-mail address)</p> <p>_____ (Mailing address)</p> <p>_____ (City, State, Zip)</p> <p>Check here <input type="checkbox"/> to instruct DSHS to destroy NBS specimens from the child named above.</p> <p>_____ (Signature) _____ (Date)</p> <p><i>I hereby certify under penalty of law that all information I have provided here in is true and accurate. I understand that providing false information on this form constitutes a crime in Texas under Penal Code Sec. 37.09.</i></p>

Provider: Detach this Page and Give to Parent for Review

**Example**

Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards (Page 2 of 2012 Kits)



TX 12-2000001

### Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards

Effective: June 1, 2012

Please read below to decide what you would like DSHS to do with your baby's blood spot card when the Newborn Screening tests are finished.

If you check the 'OK' box AND sign this form:

- All of your baby's blood spot cards will be kept safe and secure for up to 25 years.
- The blood spot cards may be used for public health research. The research may take place outside of DSHS. This research would study public health problems like cancer, birth defects, or other diseases.
- You can change your mind at any time. Call DSHS (see number below) for details.

If you check the 'NO' box OR do not sign OR do not fill out OR do not return this form:

- The Newborn Screening tests will still be done in accordance with Texas law.
- Your baby's blood spot cards will be kept safe and secure. They will all be destroyed within two years.
- The blood spot cards will NOT be used for public health research outside DSHS.

Can information about me or my child be released without my OK?

No matter your choice on this form, no information that identifies you or your child can be released outside DSHS without your additional written OK. There are a few exceptions, as provided by law.

I've already sent this decision form. Do I need to send it again? NO.

One form applies to all of your baby's newborn screening blood spot cards.

For questions or more information:

Call 1(888) 963-7111 ext. 7333 or visit the web site: [www.dshs.state.tx.us/lab/newbornscreening.shtm](http://www.dshs.state.tx.us/lab/newbornscreening.shtm)

DSHS Laboratory Services      NBS Form EF14-13689 (June 2012)

PARENT: Please read this form. Select an option. Sign and return.

1. FILL OUT the form below.

Baby's First and Last Name: \_\_\_\_\_

Baby's Date of Birth: \_\_\_\_\_

Parent Phone Number: \_\_\_\_\_

Mother's First and Last Name: \_\_\_\_\_

2. CHECK one box only and SIGN below.

<input type="checkbox"/> <b>'OK'</b> I give my <b>OK</b> for my baby's blood spot cards to be kept by DSHS after the Newborn Screen tests are complete. The de-identified blood spots may be used for public health research outside of DSHS.	<input type="checkbox"/> <b>'NO'</b> I do <b>NOT</b> give my ok for my baby's blood spot cards to be used for any research outside of DSHS after the Newborn Screen tests are complete. I understand the blood spot cards will be destroyed by DSHS within 2 years.
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(Parent Signature)

(Date)

3. RETURN this form to hospital or doctor's office staff. They will send it in with the blood spot cards. Or, you may **MAIL** it to:

Texas Department of State Health Services (DSHS)  
Newborn Screening Laboratory, MC 1947  
PO Box 149341  
Austin, Texas 78714-9341

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para Español

PROVIDER: Give form to parent & Return with blood spot cards if requested.

Example

**Texas Newborn Screening Parent Information Form (Page 1 of 2012 Kits)**

	MM/DD/YYYY		Serial Number <input type="checkbox"/> SN TX 12-2000001
Baby's Last Name	Baby's First Name	Baby's Date of Birth	
<b>Texas Newborn Screening Parent Information</b>		<b>PROVIDER:</b> Fill out baby's information above. Give this form to a parent.	
<p><b>Parent,</b> Congratulations on your new baby!</p> <p>Take your baby to your baby's doctor when your baby is 7 to 14 days old. <b>Also, take this form!</b> This is important. This will help the doctor get the newborn screening test results.</p> <p><b>What is newborn screening?</b> It is a simple blood test to look for some diseases. These diseases can cause a baby to get really sick or die.</p> <p><b>Why should my baby be tested?</b> If we find and treat these diseases early, we can keep babies from getting sick or dying.</p> <p><b>When is my baby tested?</b> In Texas, babies have a newborn screening test when they are 1 to 2 days old. This test is done again at 7 to 14 days old. The test is done in accordance with Texas law.</p> <p><b>How is newborn screening done?</b> A little blood from your baby's foot is put on a blood spot card. The cards are sent to be tested at the Department of State Health Services (DSHS).</p> <p><b>How do I get results?</b> You can get the test results from your baby's doctor. The results are sent to the doctor from DSHS in one to two weeks.</p> <p><b>Is more testing available?</b> DSHS screens for many but not all diseases your baby may have. More tests can be done. Ask your baby's doctor and see <a href="http://www.babysfirsttest.org/find-condition">www.babysfirsttest.org/find-condition</a>.</p>	<p><b>What happens to the blood spot card after testing?</b> Starting June 1, 2012:</p> <ul style="list-style-type: none"> <li>• DSHS keeps the blood spot cards in a secure place for up to two years. By Texas law (Health &amp; Safety Code Sec. 33.017(b)-(c)), the blood spots may be used during that time. Uses include:             <ul style="list-style-type: none"> <li>○ DSHS and external quality assurance to make sure tests, equipment, and supplies are working right;</li> <li>○ Developing new tests; and/or</li> <li>○ DSHS studies of diseases that affect public health.</li> </ul> </li> <li>• If you give your OK, your baby's blood spot cards will be stored for up to 25 years, and they may be used for public health research outside of DSHS.</li> </ul> <p><b>Complete, sign, and return the "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form to make your choice.</b></p> <p>No matter your choice, no information that identifies you or your child can be released outside DSHS without your additional written OK. There are a few exceptions, as provided by law.</p> <p>You can change your mind at any time.</p> <p><b>For more information, call 1(888) 963-7111 ext. 7333 or visit:</b> <a href="http://www.dshs.state.tx.us/lab/newbornscreening.shtm">www.dshs.state.tx.us/lab/newbornscreening.shtm</a></p>		
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">SN TX 12-2000001 X</p>	<p><small>Texas Department of State Health Services Newborn Screening Program P.O. Box 149341, Austin, Texas 78714 - 9341 (800) 252-8023</small></p> <p style="color: purple; font-weight: bold;">PARENT COPY</p>		<p style="writing-mode: vertical-rl; transform: rotate(180deg);"><b>INSURANCE / SELF-PAY</b></p>
	Kit Expires 11/30/2014	<p><b>Veá el reverso para Español</b></p> 	

Example