

OPT-IN OR OPT-OUT

Texas' Experiences in Implementation of Newborn Screening Residual Specimen Storage and Use Requirements

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JUNE 2002 – MAY 2009

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All specimens stored indefinitely and allowed for external research uses
June 2002 – May, 2009

2008

2009

2010

2011

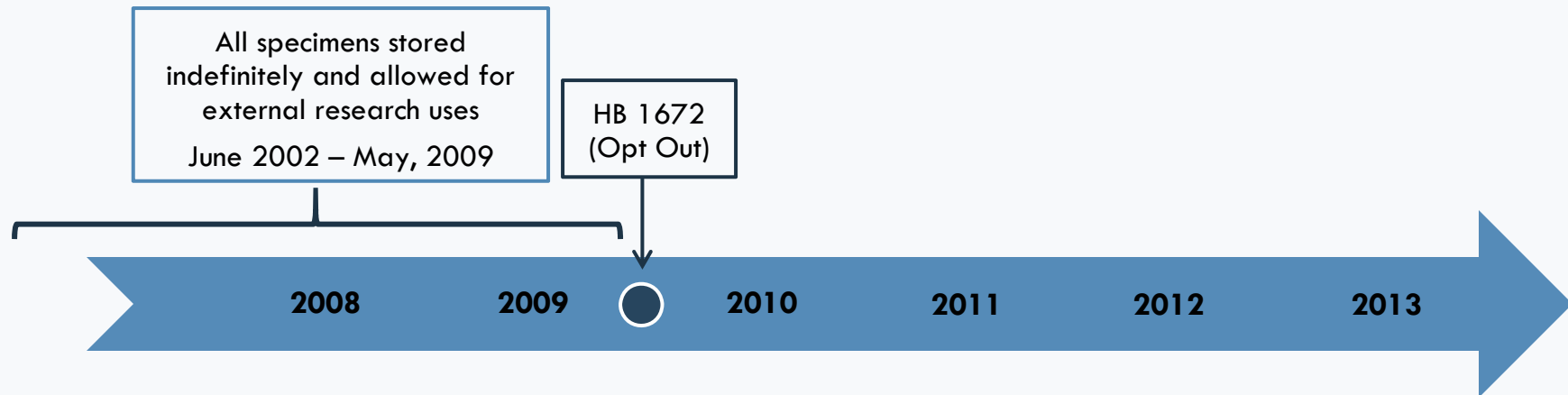
2012

2013

- ❑ All Specimens stored indefinitely
- ❑ De-identified specimens allowed for external research uses with IRB approval
- ❑ No specific policy
- ❑ Destroyed February 2010 per legal settlement

HB 1672 – OPT OUT

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- ❑ Effective immediately
- ❑ Unless parent Opt's out:
 - Specimens stored up to 25 years
 - De-identified specimens allowed for external research purposes
- ❑ Strict policy implemented outlining allowable uses and IRB / management approval requirements

HB 1672 – OPT OUT

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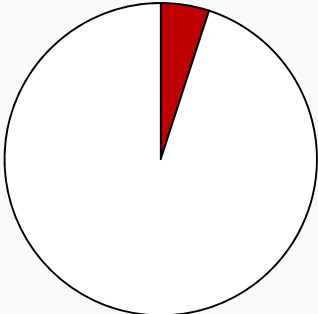
- ❑ TX DSHS developed Directive to Destroy form
- ❑ Providers required to:
 - ❑ Distribute form to parents upon each NBS collection
 - ❑ Return form to DSHS if requested by parent
- ❑ Parents direct DSHS to destroy specimens within 60 days of request receipt

Use and Storage of Newborn Screening Blood Spot Cards	Directive to Destroy Newborn Screening Blood Spot Card Following Testing
<p>PARENT / MANAGING CONSERVATOR / LEGAL GUARDIAN PLEASE READ CAREFULLY</p> <p>What is newborn screening (NBS)? 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>How does your baby get screened? 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>What happens after the blood is tested? 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 Texas Health and Safety Code Sec. 33.077(b)-(c) 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. If you are okay with the sample being stored and used, as described above, then there are no further steps for you to take.</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>To request to have your child's blood spot(s) destroyed:</p> <ol style="list-style-type: none">1. Fill out the entire attached form. Do not leave any fields blank.2. Mail original to: Texas Department of State Health Services Newborn Screening Laboratory, MC 1947 PO Box 149347 Austin, Texas 78714-93473. For additional information, call (1-888) 963-7111 ext. 7333 or visit web site: http://www.dshs.state.tx.us/nbs/newbornscreening.shtml <p>DSHS Laboratory Services Section NBS Form 14-1323b - February 2010</p>	<p>Fill out this form ONLY if you WANT your baby's blood sample destroyed after newborn testing is complete</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: _____ Child's Date of Birth: _____ Full Name of Mother: _____ Contact Information: _____ (Telephone number, e-mail address)</p> <p>(Mailing address) _____ _____ (City, State, Zip) Check here <input type="checkbox"/> to instruct DSHS to destroy NBS specimens from the child named above.</p> <p>_____ (Signature) _____ (Date) I hereby certify under penalty of law that all the information I have provided herein is true and accurate. I understand that providing false information on this form constitutes a crime in Texas under Penal Code Sec. 37.09.</p>

Provider: Detach this Page and Give to Parent for Review

HB 1672 – OPT OUT STATISTICS

Form Return Rate



- Directive to Destroy
- No Response

Process	Estimated Response Rate
TX Opt Out	5%

LESSONS LEARNED - “OPT OUT”

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□ Parents

- Often did not know they had completed form
- Did not understand form
- Completed form “DO Not Destroy”
- Did not know what newborn screening was

□ Healthcare providers

- No requirement to explain
- Often did not distribute form
- Just had parents sign

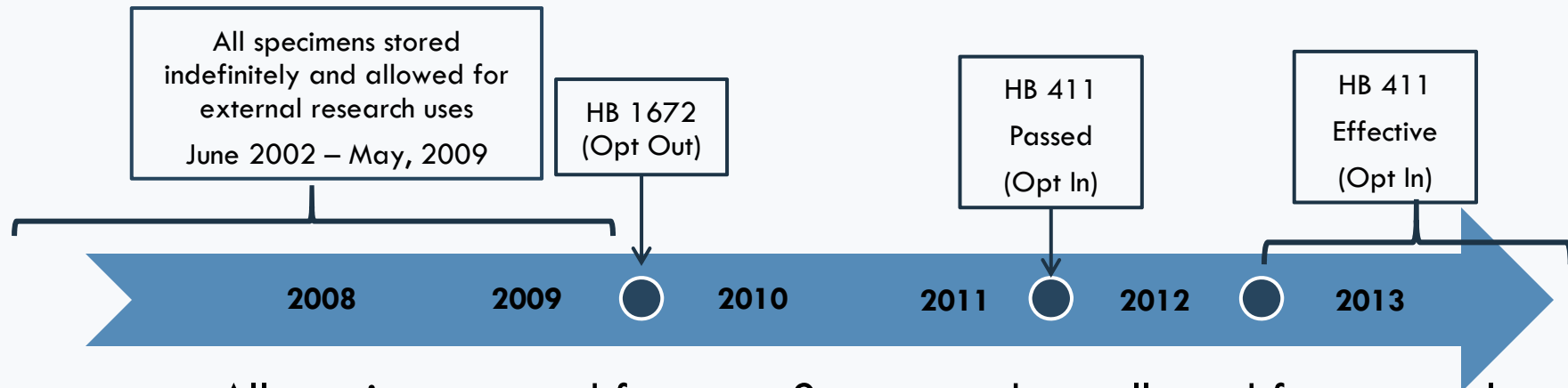


□ TX NBS Lab

- Need time to prepare
 - System and form preparation
 - Submitter education
 - Update kits
- Non – LIMS processing
 - Labor intensive and error prone
 - Difficult to identify non-compliant facilities
 - Difficult to track specimen status
- 60 day destruction timeframe
 - Impractical for 2 screen state
 - Impedes QA/QC activities
 - Does not allow parents to change their mind

HB 411 – OPT IN

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- ❑ All specimens stored for up to 2 years and not allowed for external research uses
- ❑ Parent option to store up to 25 years AND allow external research uses
- ❑ Codified policy outlining IRB and management approval requirements
- ❑ New form and process required

Challenge: What happens to specimens retained under previous law and during transition.

OPT IN – SYSTEM DESIGN GOALS

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- Parent
 - ▣ Ensure parents understand their choices
 - ▣ Be sensitive to parent / patient privacy
 - ▣ Improve general Newborn Screening education
- Healthcare Providers
 - ▣ Streamline distribution
 - ▣ Maximize return rates
- Texas DSHS
 - ▣ Streamline processing (LIMS)
 - ▣ Ensure compliance with parental choices
 - ▣ Request enough information to match forms to specimens



NOT “OPT IN” – “DECISION” – MAKE A CHOICE

HB 411 – OPT IN

Parent Information Form

- ❑ Distributed to parent upon collection of each specimen
- ❑ English / Spanish – Front / Back
- ❑ 5th grade reading level

Information about specimen storage / use and Decision form

Expanded general Newborn Screening information

MM/DD/YYYY	Serial Number [SN] TX 11- #####	
Baby's Last Name	Baby's First Name	Baby's Date of Birth
Texas Newborn Screening Parent Information		PROVIDER: Fill out baby's information above. Give this form to a parent.
<p>Parent, Congratulations on your new baby!</p> <p>Take your baby to your baby's doctor when your baby is 7 to 14 days old. Also, take this form! This is important. This will help the doctor get the newborn screening test results.</p> <p>What is newborn screening? 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>Why should my baby be tested? If we find and treat these diseases early, we can keep babies from getting sick or dying.</p> <p>When is my baby tested? 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>How is newborn screening done? 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>How do I get results? 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>Is more testing available? DSHS screens for many but not all diseases your baby may have. More tests can be done. Ask your baby's doctor and see www.babyfirsttest.org/find-condition.</p> <p><small>Texas Department of State Health Services – Newborn Screening Program P.O. Box 14 0341, Austin, Texas 78714 – 0341 (800) 252-0023</small></p>	<p>What happens to the blood spot card after testing? Starting June 1, 2012:</p> <ul style="list-style-type: none"> • DSHS keeps the blood spot cards in a safe and secure place for up to two years. The blood spot cards may be used to: <ul style="list-style-type: none"> o Make sure the newborn screening tests are working right; o Develop new newborn screening tests; and/or o Study diseases that affect public health. • 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. <p>Complete, sign, and return the "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form to make your choice. You can change your mind at any time. Call the information number below to get details.</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>For more information, call 1(888) 963-7111 ext. 7333 or visit: www.dshs.state.tx.us/lab/newbornscreening.shtml</p> <p>Kit Expires MM/DD/YYYY</p>	
07-0600002	PARENT COPY	INSURANCE / SELF-PAY
		Vea el reverso para Español

HB 411 – OPT IN

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Parental Decision for Storage Form

- ▣ Parents inform DSHS of their decision one way or the other
- ▣ Providers required to:
 - Distribute to parent upon each NBS collection
 - Return form to DSHS if requested by parent

Explanation of Choices

Barcode to streamline processing in LIMS

Effective: June 1, 2012

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

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.
- If a card is used for research, DSHS will keep at least one blood spot. This is in case it is needed for your child's medical care.
- 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 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 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

DSHS Laboratory/Genetic Section NBS Form EF14-13629 (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.

'OK' I give my **OK** for my baby's blood spot cards to be kept by DSHS after the Newborn Screen tests are complete. They may be used for public health research outside of DSHS.

'NO' I do **NOT** 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.

(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
P.O. Box 140341
Austin, Texas 78714-0341

Vea el reverso para Español

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

Parents select 1 of 2 options

Selection and Signature only required fields

Forms without a signature or a selection will default to 'No'

FORM PROCESSING

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Custom LIMS Module and Queries

- ❑ Generate barcodes
- ❑ Kit numbers scanned into system to apply “OK” or “No”
- ❑ Generate verification lists for form validation
- ❑ Uses linking to apply to all specimens for a patient
- ❑ Tracks form receipt dates and applies priority when multiple forms received.
- ❑ Create pull list of (OK or No) specimens
- ❑ Tracks Destroyed or Not

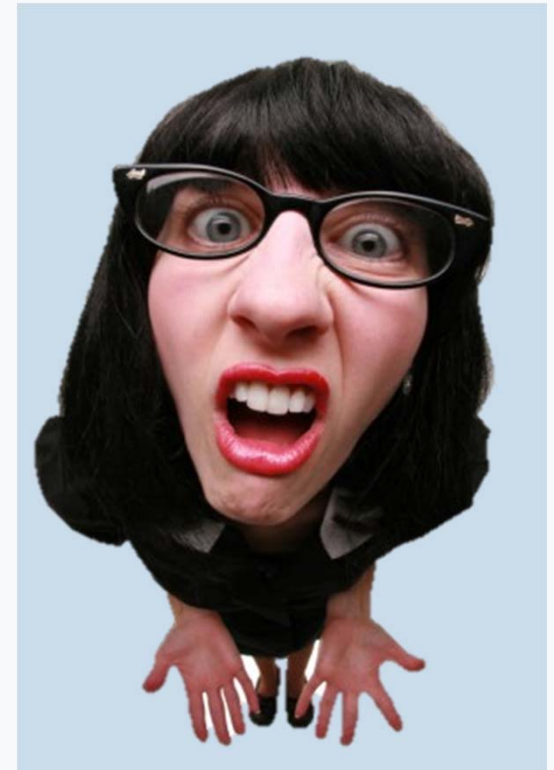
The screenshot displays the 'Specimen Logistics' software window. The title bar includes 'Print Barcodes', 'Correct Consent Details', and 'Review Batches'. The main interface is divided into two sections. The top section, 'End Consent Details', features radio buttons for 'OK' (selected) and 'NO', a 'Batch Size' field set to '100', a 'Form Date' field with a date picker, and 'Start' and 'End' time fields. Below this are 'Check Ranges' and 'Scan' buttons. The bottom section, 'Scan Accession Numbers', has a 'Kit Number #' field, a large empty list box, and buttons for 'Complete Batch', 'Cancel', 'Clear', 'Insert', 'Remove Selected', and 'Remove Last'.

LOGISTICS OF TRANSITION

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Complications

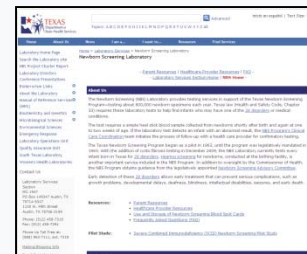
- ❑ Two laws are essentially opposite
- ❑ Providers required to “flip the switch”
- ❑ > 1800 Submitting Facilities
- ❑ No additional funding
- ❑ Minimal requirements on providers
- ❑ NBS kits valid for 3 years
 - Some providers ran out of 2010 / 2011 forms prior to June 1
 - Kits with new “Decision” form distributed prior to June 1
- ❑ 2 screen state
 - Multiple form distributions
 - Specimens collected before and after June 1
- ❑ How to handle invalid forms



EDUCATION – TRANSITION AND LONG TERM

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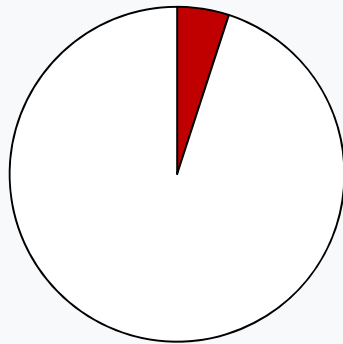
- ❑ Official notification letter
- ❑ Monthly NBS listserv updates
- ❑ Coordination with professional organizations (THA, TMA, TPS)
- ❑ Kit order inserts
- ❑ Website updates
- ❑ Webinars / Onsite Presentations
- ❑ CE modules
- ❑ Videos
- ❑ Brochures / Flyers



HB 411 – DECISION FORM STATISTICS

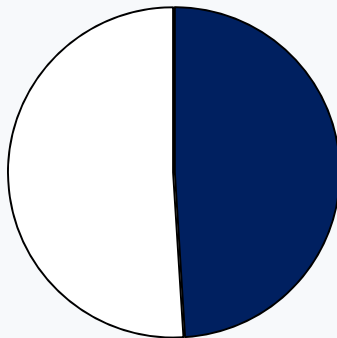
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Opt Out Form Return Rate



- Directive to Destroy
- No Response

Opt In Form Return Rate



- Decision Form
- No Response

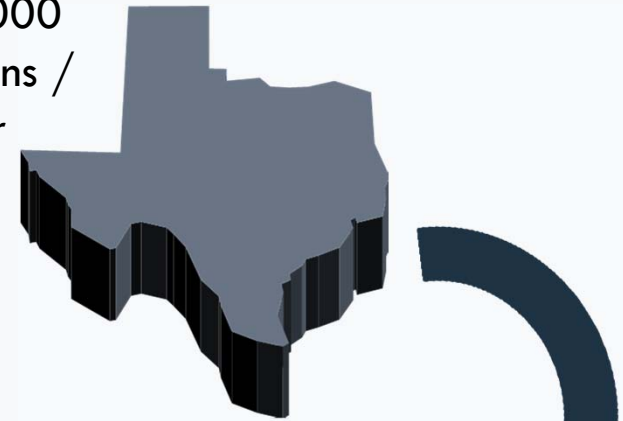
Process	Estimated Response Rate
TX Opt Out	5%
TX Opt In	49%

STATE TO STATE COMPARISON

% OK vs. No - Returned Forms

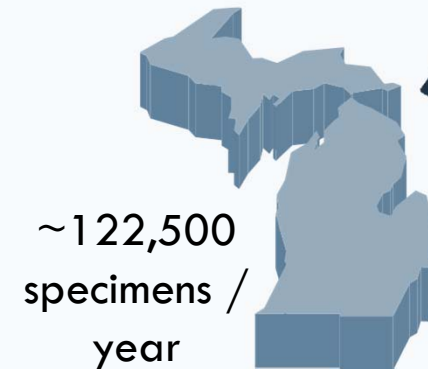
State	Estimated Response Rate	% OK	% NO
TX	49%	74	26
MI*	77%	76	24

~750,000 specimens / year



% OK vs. No - All Specimens

State	% OK	% active No	% passive No	Specimens Consented per Year
TX	36.3	12.7	51	~275,000
MI*	58	18.6	23.4	~64,000



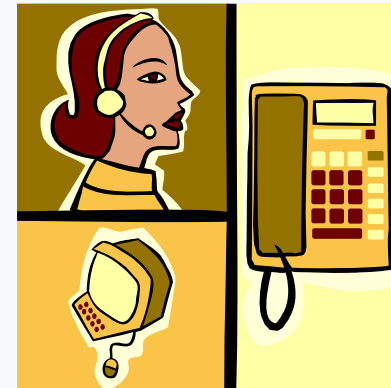
* Information provided by Michigan BioTrust for Health.

Rates are based on data for January, 2013.

EDUCATION – ONGOING

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- Direct contact with facilities with low and high return rates
- System models
- Educational Brochures
- NBS listserv updates



ISSUES / BARRIERS

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Providers:

- ❑ Minimal legal requirements.
- ❑ May not understand requirements completely.
- ❑ Minimum incentive for active collection.
- ❑ Active collection creates system inefficiencies.
 - ❑ Explanation of the form may be time consuming.
 - ❑ Parents may have questions about the form that may be difficult for providers to answer.
 - ❑ Waiting for parent to fill out the form may be time consuming.
 - ❑ Language barriers.

Parents:

- ❑ Form not received.
- ❑ Forms given as part of the “discharge packets”. No explanation.
- ❑ Not made aware of option to return completed form to provider.
- ❑ Low priority to complete and return when caring for newborn.

