2	relating to the conduct of newborn screening by the Department of		
3	State Health Services.		
4	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:		
5	SECTION 1. The heading to Chapter 33, Health and Safety		
6	Code, is amended to read as follows:		
7	CHAPTER 33. PHENYLKETONURIA, OTHER HERITABLE DISEASES, [AND]		
8	HYPOTHYROIDISM, AND CERTAIN OTHER DISORDERS		
9	SECTION 2. Subchapter A, Chapter 33, Health and Safety		
LO	Code, is amended by adding Section 33.004 to read as follows:		
L1	Sec. 33.004. STUDY ON NEWBORN SCREENING METHODOLOGY AND		
L2	EQUIPMENT. (a) Not later than March 1, 2006, the department shall:		
L3	(1) conduct a study to determine the most		
L4	cost-effective method of conducting newborn screening, including		
L5	screening for disorders listed in the core uniform panel of newborr		
L6	screening conditions recommended in the 2005 report by the America		
L7	College of Medical Genetics entitled "Newborn Screening: Toward a		
L8	Uniform Screening Panel and System" or another report determined by		
L9	the department to provide more appropriate newborn screening		
20	guidelines, to protect the health and welfare of this state's		
21	newborns and to maximize the number of newborn screenings that may		
22	be conducted with the funding available for the screening;		
23	(2) determine the disorders to be studied under		
24	Subdivision (1) and ensure the study does not examine screening and		

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- 1 services provided under Chapter 47; and
- 2 (3) obtain proposals or information regarding the
- 3 conduct of newborn screening and compare the costs of the
- 4 department performing newborn screening services to the costs of
- 5 outsourcing screening to a qualified laboratory with at least two
- 6 years' experience performing newborn screening tests.
- 7 (a-1) Not later than October 1, 2005, the department shall
- 8 review and study the National Newborn Screening and Genetics
- 9 Resources Center's assessment of the screening program in this
- 10 state. Based on the findings and recommendations in the assessment,
- 11 the executive commissioner of the Health and Human Services
- 12 Commission may adopt rules for the department to implement a
- 13 newborn screening program. In adopting rules for the newborn
- 14 screening program, the department and the executive commissioner:
- 15 <u>(1) may seek input during the rulemaking process from</u>
- 16 <u>individuals</u> and groups with an interest or expertise in newborn
- 17 screening;
- 18 (2) may use informal conferences or consultations to
- obtain opinions on the program as provided by Section 2001.031,
- 20 Government Code; and
- 21 (3) must provide an opportunity for the individuals
- 22 and groups described by Subdivision (1) to appear before the
- department before a notice of proposed rules is given as required by
- 24 Section 2001.023, Government Code.
- 25 (a-2) This subsection and Subsection (a-1) expire January
- 26 1, 2007.
- 27 (b) In accordance with rules adopted by the executive

- 1 commissioner of the Health and Human Services Commission, the
- 2 department may implement a newborn screening program.
- 3 (b-1) Not later than March 1, 2006, the department shall
- 4 file with the governor's office a written report of the results and
- 5 conclusions of the study conducted by the department under
- 6 Subsection (a). This subsection expires January 1, 2007.
- 7 (c) If the department determines under Subsection (a) that
- 8 the department's performance of newborn screening services is more
- 9 cost-effective than outsourcing newborn screening, the department
- 10 shall obtain the use of screening methodologies, including tandem
- 11 mass spectrometers, and hire the employees necessary to administer
- 12 newborn screening under this chapter.
- 13 (d) If the department determines under Subsection (a) that
- 14 outsourcing of newborn screening is more cost-effective, the
- 15 department shall contract for the resources and services necessary
- 16 to conduct newborn screening using a competitive procurement
- 17 process.
- 18 (e) The department shall periodically review the newborn
- 19 screening program as revised under this section to determine the
- 20 efficacy and cost-effectiveness of the program and determine
- 21 whether adjustments to the program are necessary to protect the
- 22 health and welfare of this state's newborns and to maximize the
- 23 number of newborn screenings that may be conducted with the funding
- 24 available for the screening.
- 25 (f) The department may adjust the amounts charged for
- 26 <u>newborn screening fees</u>, including fees assessed for follow-up
- 27 services, tracking confirmatory testing, and diagnosis.

- SECTION 3. Section 33.011, Health and Safety Code, is amended by amending Subsection (a) and adding Subsection (a-1) to read as follows:
- 4 (a) The physician attending a newborn child or the person 5 attending the delivery of a newborn child that is not attended by a 6 physician shall subject the child to screening tests approved by 7 the department for phenylketonuria, other heritable diseases, 8 [and] hypothyroidism, and other disorders for which screening is 9 required by the department.

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- (a-1) To the extent funding is available for the screening, the department shall require newborn screening tests to screen for disorders listed in the core uniform panel of newborn screening conditions recommended in the 2005 report by the American College of Medical Genetics entitled "Newborn Screening: Toward a Uniform Screening Panel and System" or another report determined by the department to provide more appropriate newborn screening guidelines to protect the health and welfare of this state's newborns.
- 19 SECTION 4. Section 33.014(a), Health and Safety Code, is 20 amended to read as follows:
 - (a) If, because of an analysis of a specimen submitted under Section 33.011, the department reasonably suspects that a newborn child may have phenylketonuria, another heritable disease, [ex] hypothyroidism, or another disorder for which the screening tests are required, the department shall notify the person who submits the specimen that the results are abnormal and provide the test results to that person. The department may notify one or more of

- 1 the following that the results of the analysis are abnormal and
- 2 recommend [that] further testing when [is] necessary:
- 3 (1) the physician attending the newborn child or the
- 4 physician's designee;
- 5 (2) the person attending the delivery of the newborn
- 6 child that was not attended by a physician;
- 7 (3) the parents of the newborn child;
- 8 (4) the health authority of the jurisdiction in which
- 9 the newborn child was born or in which the child resides, if known;
- 10 or
- 11 (5) physicians who are cooperating pediatric
- 12 specialists for the program.
- SECTION 5. Section 33.031(a), Health and Safety Code, is
- 14 amended to read as follows:
- 15 (a) All newborn children and other individuals under 21
- 16 years of age who have been screened, have been found to be
- 17 presumptively positive through the newborn screening program for
- 18 phenylketonuria, other heritable diseases, hypothyroidism, or
- 19 another disorder for which the screening tests are required, and
- 20 may be financially eligible may be referred to the department's
- 21 services program for children with special health care needs.
- SECTION 6. Section 33.032(a), Health and Safety Code, is
- 23 amended to read as follows:
- 24 (a) Within the limits of funds available for this purpose
- 25 and in cooperation with the individual's physician, the department
- 26 may provide services directly or through approved providers to
- 27 individuals of any age who meet the eligibility criteria specified

- 1 by board rules on the confirmation of a positive test for
- 2 phenylketonuria, other heritable diseases, [or] hypothyroidism, or
- 3 <u>another disorder for which the screening tests are required</u>.
- 4 SECTION 7. Not later than November 1, 2006, the Department
- 5 of State Health Services shall implement the expanded newborn
- 6 screening program using the most cost-effective methods as
- 7 determined by the department under Section 33.004, Health and
- 8 Safety Code, as added by this Act.
- 9 SECTION 8. This Act takes effect September 1, 2005.

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	H.B. No. 790			
President of the Senate	Speaker of the House			
I certify that H.B. No. 790 was passed by the House on May 5 2005, by a non-record vote; and that the House concurred in Senat amendments to H.B. No. 790 on May 27, 2005, by a non-record vote.				
	Chief Clerk of the House			
	o. 790 was passed by the Senate, with by the following vote: Yeas 31, Nays			
	Secretary of the Senate			
APPROVED:Date				
Governor				