Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	
(2) I.D. Number (Governor's Office Use) Reg. No. 10-137	IRRC Number: 2188

(3) Short Title

Screening and Follow-up for Diseases of the Newborn

(4) PA Code Cite	(5) Agency Contacts & Telephone Numbers
28 Pa. Code ch. 27 28 Pa. Code ch. 28 28 Pa. Code ch. 501	Primary Contact: Joann Adair 717-783-8143 Secondary Contact: Joan Kehler, RN 717-783-8143

(6) Type of Rulemaking (Check One)	(7) Is a 120-Day Emergency Certification Attached?
Proposed Rulemaking	X No
X Final Order Adopting Regulation	Yes: By the Attorney General
Final Order, Proposed Rulemaking Omitted	Yes: By the Governor

(8) Briefly explain the regulation in clear and non-technical language.

The Department of Health (Department), with the approval of the State Advisory Health Board (Board), is amending the regulations currently set out at 28 Pa. Code ch. 28, to incorporate changes required as a result of amendments to the Act of September 9, 1965 (P.L. 497, No. 251), known as the Newborn Child Testing Act (35 P.S. §§621-625) and to add two additional screens as permitted by 35 P.S. §623(b). The regulations amend current regulations by adding maple syrup urine disease (MSUD), hemoglobin diseases, galactosemia and congenital adrenal hyperplasia (CAH) to the list of diseases at 28 Pa. Code §28.2 (relating to newborn diseases listed) for which newborn children are routinely screened. The regulations also update existing procedures for screening and follow-up testing for those diseases, which are currently listed, as well as those, which would be added by these regulations. Finally, the regulations clarify the circumstances under which a health care provider would be responsible for collecting the initial and any repeat blood filter paper specimens for testing.

The Department is also amending its regulations at Chapter 27 (relating to reporting laboratory results indicative of certain diseases) and Chapter 501 (relating to newborn infant care policies and procedures in birth centers) of Title 28 of the Pennsylvania Code. These supplemental amendments are necessary in order to ensure conformity with the requirements of the expanded Newborn Screening Program.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Department obtains its authority to promulgate these regulations from several sources. Generally, the Disease Prevention and Control Law of 1955 (35 P.S. §521.1 et seq.) provides the Advisory Health Board with the authority to issue rules and regulations on a variety of issues relating to communicable and non-communicable diseases, including the methods of reporting diseases, the contents of those reports and the health authorities to whom diseases are to be reported. (35 P.S. §521.16(a)). §16(b) of the Disease Prevention and Control Law of 1955 (35 P.S. §521.16(b) gives the Secretary of Health (Secretary) the authority to review existing regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

The Department also finds general authority for the promulgation of its regulations in the Administrative Code of 1929 (71 P.S. §51 et seq.). Section 2102(g) of the Administrative Code (71 P.S. 532(g)) gives the Department the general authority. Section 2111(b) of the Administrative Code (71 P.S. §541(b)) provides the Advisory Health Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of the Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

The Department's specific authority for promulgating the regulations relating to newborn screening and follow-up is found in the Newborn Child Testing Act (Act) (35 P.S. §§621-625). Section 5 of the Act (35 P.S. §625) provides the Department, with the approval of the Board, with the authority to promulgate regulations for the implementation and administration of the Act. Section 3(b) of the Act (35 P.S. §623) provides the Department, with the approval of the Board, with the authority to establish by regulation those diseases for which newborn children shall be tested and the methods for testing and disseminating test results. Section 4(b) of the Act (35 P.S. §624) provides the Department with the authority to establish by regulation the methods of procurement of blood specimens of newborn children by health care providers.

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

The language in the regulations concerning the addition of MSUD and hemoglobin diseases is based upon the requirements of the Newborn Child Testing Act, 35 P.S. §§ 621-625. Galactosemia and CAH are added pursuant to 35 P.S. §§ 623(b) which permits the addition to the list by regulation of any other disease approved for such inclusion by the Department and the Board. Certain procedures, including the time frames in which to collect the specimens, are based upon the requirements for detecting MSUD, CAH and galactosemia and preventing harm to the newborn child.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Expansion of the Commonwealth's Newborn Screening Program to include hemoglobin diseases, MSUD, galactosemia and CAH and the clarification of uniform procedures governing screening, is intended to facilitate early detection and treatment of diseases and conditions in the newborn child, and will result in earlier referral for diagnosis and treatment of newborn children identified with presumptive abnormal tests for these diseases. Early detection of, treatment for, these diseases will save the lives of many newborn children, and will also significantly reduce long term health care costs for the families of affected children, as well as for public and private medical providers and insurers.

Sickle cell disease is the most common of the hemoglobin diseases and is most often found among individuals of African American origin (affecting one in every 400 black infants). Approximately 72 newborns with sickle cell disease and 28 newborns with other forms of hemoglobin diseases will be diagnosed in Pennsylvania each year. There is a high incidence of serious bacterial infections and mortality in young children with sickle cell disease. A 1986 study organized by the National Institutes of Health demonstrated that early detection of children with sickle cell disease followed by treatment with penicillin will reduce the incidence of pnuemonoccocal sepsis by 89 percent. Early identification of sickle cell disease will save the lives of many infants with disease. For others, early and improved medical care and family education will reduce time spent by the children in the hospital, and time lost from work by parents.

MSUD is a genetic disorder most prevalent in members of the Mennonite sect. One in 225,000 newborn children nationwide is identified with MSUD each year. The incidence of MSUD in Pennsylvania, however, is three times greater than the national average, and it is expected that two children will be identified with MSUD annually in the Commonwealth. MSUD is a very volatile condition that afflicts infants within days of birth, and which, if not diagnosed and treated quickly, will cause irreversible mental and physical damage, or death.

Untreated children die or are virtually incapacitated, requiring lifetime care. With early diagnosis and the institution of treatment that includes a special diet, affected children can survive with normal intelligence. As a result of screening and early treatment, costs for hospitalization of these children are greatly reduced, and long term costs for residential care are virtually eliminated.

Galactosemia is a genetic metabolic condition, which affects the body's ability to utilize certain sugars. Babies born with this condition cannot break down lactose or galactose. These are simple sugars found in breast milk, many formulas and milk products. The most common forms of galactosemia may result in death from sepsis within the first weeks of life or mental retardation in those who survive. Prompt diagnosis and intervention can prevent further damage. Treatment consists of special galactose and lactose-free milk substitutes and foods. One in 60,000 newborn is identified with classical galactosemia. When other forms of galactosemia are included, such as Duarte and Los Angeles, the rate increases to one newborn in 16,000 identified with a form of galactosemia. Forty seven other states screen for galactosemia.

CAH is a complex family of disorders arising from specific defects in the enzymes of the adrenal cortex necessary for the biosynthesis of steroids. Dehydration, shock and even death can occur, with high mortality from "adrenal crisis". Proper early intervention and medical treatment resets

the abnormal balance of hormones and permits near normal development. Incidence is one case per 12,000 births. Approximately 25 other states screen for CAH.

The Department initiated pilot screening programs for hemoglobin diseases and MSUD in several parts of the Commonwealth on June 1, 1990, and May 15, 1991, respectively. The pilot projects confirmed that addition of these diseases to the screening program was warranted. These pilot projects also provided a basis for evaluating and refining laboratory procedures and follow-up procedures for the entire screening program. Statewide screening for hemoglobin diseases began on September 28, 1992, and for MSUD on March 31, 1993. The regulations reflect these additions; they also reflect the need to obtain specimens in a shorter time period following the child's birth than the current regulations require.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

The regulations add two diseases to the current regulations as mandated by the Newborn Child Testing Act, 35 P.S. §§ 621-625, and the others pursuant to 35 P.S. §§ 623(b) which permits the addition to the list by regulations of any other disease approved for such inclusion by the Department and the Board. The regulations also change the time frames for specimen collection currently set out in the regulations. The current time frames included in regulation are too long given the extreme danger of disability and death that MSUD can pose for a newborn child. Early detection and treatment of all the disease and conditions of newborn children listed in the regulations will prevent severe mental and physical damage to newborn children, and will save long term health care costs of providing for children severely impaired by these diseases and conditions.

The regulations also provide authoritative procedures for collecting and testing newborn blood filter paper specimens, and for the follow-up of abnormal test results correctly and in a timely fashion so that disability or death of the newborn child can be averted. Due to the importance of efficient collection and testing of screening specimens for phenylketonuria (PKU), primary congenital hypothyroidism, hemoglobin diseases, MSUD, galactosemia and CAH, the regulations will designate specific responsibility for the collection and follow-up of newborn screening tests by health care providers, and will specify time of collection and mailing which will assist prompt follow-up of newborn children with one of these diseases or conditions.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The approximately 150,000 children born in the Commonwealth yearly and their families will benefit from the regulations because with early detection of PKU, MSUD, hemoglobin diseases, primary congenital hypothyroidism, galactosemia and CAH children will be referred for diagnosis and treatment within days of birth. Early medical intervention can prevent life threatening illness and permanent medical and physical disability. Approximately 90 children are diagnosed with hemoglobin diseases, 2 children with MSUD, 10 children with CAH and 10 with galactosemia in the Commonwealth each year.

The health care providers of the Commonwealth will benefit by having regulations setting out their responsibilities, including appropriate time frames for collection of specimens. Health care providers have repeatedly asked for formal guidance from the Department on this matter.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

To the extent that health care providers will be required to comply with more stringent time frames for collection of specimens, and follow more precise procedures for the collecting of specimens, these providers may be said to be adversely affected. Again, however, screening for hemoglobin diseases and MSUD began across the Commonwealth in 1992 and 1993 respectively; screening for PKU and hypothyroidism has been occurring since 1965 and 1978 respectively. Screening for galactosemia and CAH commenced on a voluntary basis in 2000-2001. Given the necessity of early detection of MSUD, common prudence and risk management would have recommended a more stringent screening time frame than that required by existing regulations in any case.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

All newborns born in Pennsylvania must be screened for PKU, sickle cell disease (hemoglobinopathies), and MSUD according to the Newborn Child Testing Act, 35 P.S. §§ 621-625. The existing regulations added screening for hypothyroidism as well.

The regulation adds MSUD, hemoglobin diseases, galactosemia and CAH to current regulations, which require screening for PKU and hypothyroidism. The statute does, however, allow parents to exercise a religious exemption to the screening requirements if they so choose. See 35 P.S. § 623(c). All health care providers (defined by the regulation to include those providing maternity and newborn services) throughout Pennsylvania are currently required by statute and regulation to collect blood filter paper specimens from newborn children and to submit them to the Department's contract laboratory for testing. The regulation reflects the 1992 amendments to the law, which added sickle cell disease (hemoglobinopathies) and MSUD to the list of diseases and conditions for which newborn children are screened. Health care providers are currently, and will continue to be required to collect and submit a blood filter paper specimen and assist with follow-up of abnormal, inconclusive, and unacceptable test results for these diseases in accordance with the regulation. Laboratories will be required by the regulations to report four additional diseases, hemoglobin diseases, MSUD, galactosemia and CAH, to the Department.

This will impact the Department's contracted laboratory, which performs all the initial testing of newborn screening specimens, and which currently does test and report findings of hemoglobin diseases and MSUD to the Department through its contract with the Department. The contract laboratory will have to expand testing to include galactosemia and CAH, although it presently screens nearly 80% of Pennsylvania's newborns for these conditions through its supplemental program. Other laboratories may be sent specimens for follow-up testing; these requirements would impact those laboratories.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

During the initial drafting of the regulation comments were solicited from the following: physicians specializing in the care of infants with metabolic, endocrine or hematologic conditions; laboratory personnel; and the state Newborn Screening Technical Advisory Committee. Strong public demand to obtain newborn screening for additional conditions was made evident through individual efforts, the public media, and service organizations.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

It is probable that since the passage of the Newborn Child Testing Act, 35 P.S. §§ 621-625, in 1992, health care providers have incurred modest costs in personnel and staff time for the provision of follow-up services for repeat specimens or abnormal test results related to MSUD and hemoglobin diseases, when necessary. Specimen collection, testing, and follow-up for MSUD and sickle cell and other abnormal hemoglobins of clinical significance have been fully integrated with existing procedures for PKU and hypothyroidism. Blood specimens for MSUD, hemoglobin diseases, galactosemia and CAH testing will be taken from the same heel stick as the specimens currently collected for hypothyroidism and PKU screening, and be placed on the same filter paper. The number of unacceptable specimens and abnormal results for which follow-up reporting and consultation services are required is expected to be low; the regulation is intended to reduce the number of unacceptable specimens and abnormal results by clarifying and standardizing procedures and timing for specimen collection.

Neither health care providers nor families of the newborn children who are tested are currently charged for laboratory screening or follow-up test costs. It should be noted that the regulation includes requirements, which were statutorily mandated in 1992, so that any increased costs associated with the additions of MSUD and hemoglobin diseases should have occurred at that time.

Without early identification, diagnosis, and treatment, newborn children affected by these diseases are at risk for early death, severe mental impairment, or at the least, medical problems. If death does not occur, the family of a child in whom these diseases go undetected may incur high costs related to hospitalization, intensive care, the need for residential care, and special education needs. The cost to institutionalize one child for one year is approximately $80,000. The number of affected newborn children who were not appropriately diagnosed and treated would multiply this cost. In the Commonwealth in 1999, there were 24 children diagnosed with PKU, four with MSUD, 45 with congenital hypothyroidism, and 99 with hemoglobin diseases (72 sickle cell disease and 27 other abnormal hemoglobinopathies). The Department expects approximately 10 newborns per year to be born with galactosemia and CAH based on recent laboratory results. Not every child diagnosed with one of these diseases is necessarily institutionalized; however, based upon $80,000 yearly cost per case, if we assume half of the newborns identified with one of these conditions is institutionalized, the cost could exceed $7 million dollars each year. These figures do not take into account anguish suffered by families whose children die or who are severely mentally impaired.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

Local governments are not affected by the regulation.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including and legal, accounting, or consulting procedures, which may be required.

Expansion of the Commonwealth's Newborn Screening Program to include MSUD and hemoglobin diseases pursuant to the requirements of the Newborn Child Testing Act, 35 P.S. §§ 621-625, has resulted in some increased program costs to the Department. The Department estimates that the additional cost for screening and follow-up for these two additional diseases is approximately $1,300,000 per year. However, state government will also realize savings through the early detection, timely referral and follow-up treatment of children afflicted with these additional conditions. Newborn screening helps to prevent various forms of developmental disabilities and their associated medical costs that are incurred for services such as in-home supports, institutionalization and other ongoing medical care. Public resources, such as state/federal Medicaid funds and state-only Mental Health/Mental Retardation program funds, often pay these costs.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government and state government for the current year and five subsequent years.

	2000/ 2001	2001/ 2002	2002/ 2003	2003/ 2004	2004/ 2005	2005/ 2006
SAVINGS:	$ * * *	$	$	$	$	$
Regulated Community	$0	0	0	0	0	0
Local Government	$ N/A	N/A	N/A	N/A	N/A	N/A
State Government	$ 0	0	0	0	0	0
Total Savings	$0	0	0	0	0	0
COSTS:	$					
Regulated Community	$0	0	0	0	0	0
Local Government	$ N/A	N/A	N/A	N/A	N/A	N/A
State Government	$1,300,000	1,300,000	1,300,000	1,300,000	1,300,000	1,300,000
Total Costs	$1,300,000	1,300,000	1,300,000	1,300,000	1,300,000	1,300,000
REVENUE LOSSES:	$ * * *					
Regulated Community	$ 0	0	0	0	0	0
Local Government	$ N/A	N/A	N/A	N/A	N/A	N/A
State Government	$0	0	0	0	0	0
Total Revenue Losses	$0	0	0	0	0	0

(20a) Explain how the cost estimates listed above were derived.

* * * The Commonwealth's Newborn Screening Program implemented statewide screening for hemoglobin diseases and MSUD in 1992 and 1993, respectively, in response to the mandates of the Newborn Child Testing Act, 35 P.S. §§621-625. Health care providers have been complying with these reporting requirements since that time. Any increased costs should have been incurred at the initiation of this screening. In addition, 80% of the providers already screen for galactosemia and CAH through a voluntary private supplemental screening program.

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(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FFY 96	FFY 97	FFY 98	FFY 99
Newborn Screening and Follow-up	$3,157,950	$3,264,480	$3,098,769	$2,571,742

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

Detecting and providing timely referral, follow up treatment on abnormal results through newborn screening helps to prevent various forms of developmental disabilities, including mental retardation and other life-long chronic, debilitating conditions and their associated medical needs. The cost-benefit of providing newborn screening, referral and follow up treatment is significant in that it saves public resources, such as state/federal Medicaid funds and state-only Mental Health/Mental Retardation program funds, due to the avoided costs later in life that are incurred for services such as in-home supports, institutionalization and ongoing and costly medical care.

(22) Describe the non-regulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

No non-regulatory approaches were considered. There are existing regulations setting out the requirements for screening and follow-up for PKU and hypothyroidism in newborn children set out at 28 Pa. Code ch. 28. These regulations were authorized by the Newborn Child Testing Act, 35 P.S. §§ 621-625; amendments to this act in 1992 mandated expansion of the Commonwealth's Newborn Screening Program to include testing for MSUD, and sickle cell disease (hemoglobinopathies). The Department is amending the existing regulations to include four additional diseases of the newborn, and to clarify screening procedures. Other abnormal hemoglobins of clinical significance, galactosemia and CAH are added pursuant to 35 P.S. §§ 623(b) which permits the addition to the list by regulation of any other disease approved for such inclusion by the Department and the Board.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No other regulatory approaches were considered. There are existing regulations setting out the requirements for screening and follow-up for PKU and hypothyroidism in newborn children set out at 28 Pa. Code ch. 28. These regulations were authorized by the Newborn Child Testing Act, 35 P.S. §§ 621-625; amendments to this act in 1992 mandated expansion of the Commonwealth's Newborn Screening Program to include testing for MSUD and sickle cell hemoglobinopathies. The Department is amending the existing regulations to include four additional diseases of the newborn, and to clarify screening procedures. Other abnormal hemoglobins of clinical significance, galactosemia and CAH are added pursuant to 35 P.S. §§ 623(b) which permits the addition to the list by regulation of any other disease approved for such inclusion by the Department and the Board.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

There are no federal requirements for the screening of the conditions and diseases of the newborn child.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This regulation does not bear upon the competitive advantage of the Commonwealth. All states are currently working together to ensure that all newborn children are screened for a minimum number of diseases and conditions. In fact, Pennsylvania screens for very few diseases and conditions compared to other states in the nation.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

As part of this rulemaking, the Department is amending 28 Pa. Code Chapters 27 (relating to Communicable and Noncommunicable Diseases) and 501, § 49 (relating to newborn infant care policies and procedures in birth centers). The minor revisions to Chapter 27, "Communicable and Noncommunicable Diseases", include adding MSUD, sickle cell disease, galactosemia and CAH to the list of reportable diseases in § 27.21a (relating to reporting of cases by health care practitioners and health care facilities), § 27.22b and e (relating to reporting of cases by clinical laboratories), and § 27.30 (relating to reporting cases of certain diseases in the newborn child).

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and locations, if available.

The Department is not planning any hearings at the present time. The Department conducted a thirty (30) day comment period after the regulations were published as proposed in the Pennsylvania Bulletin.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports, which will be required as a result of implementation, if available.

The regulations require health care providers to notify parents or guardians of newborn children when a repeat specimen is required for an abnormal or inconclusive test result or an unacceptable specimen. The regulations also place additional paperwork responsibilities on the testing laboratory and health care providers, because of the addition of four diseases to the list of disease and conditions of newborn children for which testing is required. These requirements are minimal, however. The regulations make laboratories responsible for reporting MSUD, sickle cell disease, galactosemia and CAH to the Department under revisions to the communicable disease regulations at 28 Pa. Code ch. 27. The screening test results for the four new diseases will be reported on the same report form currently being used for PKU and hypothyroidism. Further, the testing laboratory operates under a contract with the Department, and receives additional recompense for additional work. To the extent that other laboratories may do additional confirmatory or follow-up testing, they will be required to comply with these reporting requirements, as they would currently do for PKU and hypothyroidism.

Under the regulation, health care providers will be required to submit data regarding specimen collection to the Department semi-annually; the existing regulations require only that such data be maintained.

Paperwork requirements within the Department itself will remain unchanged. The addition of MSUD, hemoglobin diseases of clinical significance, galactosemia and CAH to the list of diseases tracked by the screening program has increased the number of instances in which follow-up of abnormal results is required; however, follow-up has been occurring since the implementation of the expanded screening program for hemoglobin diseases and MSUD began in 1992 and 1993, respectively.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

These regulations are intended to protect the health of all newborn children, and, therefore, no special provisions were necessary. The statute upon which the regulations are based already has a provision, which permits parents who may have religious objections to the test to request an exemption on those grounds. See 35 P.S. § 623(c).

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The Department is proposing that the regulations become effective upon their final publication in the Pennsylvania Bulletin. Adoption of the regulation is essential to ensure uniform specimen collection, testing, and follow-up procedures by health care providers throughout the Commonwealth. Compliance with the regulation requires no additional required permits, licenses, or approvals.

(31) Provide the schedule for continual review of the regulation.

The efficacy and appropriateness of the regulation will be reviewed through monitoring by Department staff in the Bureau of Family Health and the Bureau of Laboratories. The Bureau of Laboratories will continue to routinely conduct quality assurance reviews of the laboratory performing the screening tests, which is under contract with the Department. Newborn Screening Program staff in the Bureau of Family Health will routinely review reports of test results from the screening laboratory, and reports by hospitals of specimens collected and forwarded for testing. In this way, the Department will be able to determine whether modifications in the screening process are necessary, and can take steps to initiate those modifications.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

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#2188

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Copy below is hereby approved as to form and legality. Attorney General.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or independent Agencies.
BY _____ DEPUTY ATTORNEY GENERAL	DEPARTMENT OF HEALTH (AGENCY)	BY _____
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-137	2/27/02 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ (Strike inapplicable title)
	BY: Robert S. Zimmerman, Jr.	
9 Check if applicable. Copy not approved. Objections attached.	TITLE: Secretary of Health	9 Check if applicable. No Attorney General approval or objection within 30 days after submission.

FINAL RULEMAKING
DEPARTMENT OF HEALTH

TITLE 28. HEALTH AND SAFETY

[28 PA. CODE CHS 27, 28 AND 501]

NEWBORN DISEASE SCREENING AND FOLLOW-UP

The Department of Health (Department), with the approval of the State Advisory Health Board (Board), hereby adopts amendments to 28 Pa. Code Chapter 28 (relating to metabolic diseases of the newborn). The Department also adopts amendments to specific sections of 28 Pa. Code Chapters 27 (relating to communicable and noncommunicable diseases) and 501 (relating to birth centers), as made necessary by the amendments to Chapter 28. The amendments are set forth in Annex A hereto.

I. PURPOSE OF THE REGULATIONS

The regulations incorporate changes to the Newborn Screening and Follow-Up Program (Program) required as a result of amendments to the Newborn Child Testing Act (act) (35 P.S. §§ 621 – 625), made by the act of July 9, 1992 (P.L. 398, No. 86). The amendments to the act add maple syrup urine disease (MSUD) and sickle-cell hemoglobinopathies (disease and trait) to the list of diseases for which routine screening of newborns is conducted, provide for the addition to the list by regulation of any other disease approved for such inclusion by the Department and the Board, and require a screening and follow-up program to identify and treat newborn children with one of the diseases listed in the act or identified by regulation. 35 P.S. § 623. The Department is given the authority under the act to promulgate regulations, with the approval of the Board, to carry out these requirements. 35 P.S. § 625. The regulations require screening for galactosemia and congenital adrenal hyperplasia (CAH) pursuant to the Department's authority to add to the list of diseases for which routine

screening of newborns is to be conducted, by regulation, any other disease approved for such inclusion by the Department and the Board. Further, the regulations require screening for hemoglobinopathies (hemoglobin diseases) other than sickle cell hemoglobinopathies because the detection of other hemoglobin diseases, some of which may be life threatening, is unavoidable with the testing methodology currently available.

The regulations also make minor amendments to 28 Pa. Code Chapters 27 and 501. Both sets of minor revisions are necessary to ensure that no inconsistencies exist between the updated requirements of the expanded Program and other Department regulations.

The Department published proposed rulemaking in the Pennsylvania Bulletin on April 28, 2001, and provided a 30-day public comment period. (See 31 Pa.B. 2271 (April 28, 2001)). The Department received three public comments to the proposed rulemaking and additional comments from IRRC. The Department's responses to these comments appear in the summary of this final rulemaking.

II. SUMMARY

One commentator, the Pennsylvania Chapter of the American Academy of Pediatrics, stated that it was pleased to endorse the proposed regulations and offered its support in providing any necessary education to pediatricians once the regulations were final.

Another commentator believed that the Department should clarify the definition of "hemoglobin diseases." The Department had used the term "V" in that definition to indicate a variant. However, as there is no hemoglobin named "V," the commentator believed that the use of this term could be confusing. IRRC also raised this issue. The Department agrees with the commentator and the definition in § 28.1 (relating to definitions) was changed to use the word "variant" instead of the letter "V."

The final public commentator, The Hospital and Healthsystem Association of Pennsylvania (HAP), raised two concerns. The first concern was that the proposed regulations did not clearly state the process by which additions to the list of newborn disease screening are made and how public and clinical input will be sought. HAP suggested that this information be included in the final regulations. Further, HAP suggested that the Department should clearly articulate the clinical rationale and societal benefits for adding the two particular conditions (presumably CAH and galactosemia) included in these regulations.

The Department does not believe that it is necessary to include in regulations the process by which conditions are selected for screening. The process of selecting conditions for newborn screening testing is consistent with recommendations from the August 2000 National Newborn Screening Task Force Report issued by the Health Resources Services Administration (HRSA). Determinations are made based on recommendations by the Newborn Screening Technical Advisory Committee, a Department-organized committee which provides both public and clinical input. Committee members include medical

professionals in the pediatric field who specialize in endocrinology and metabolic disorders, as well as parents of affected children. The Department's Advisory Health Board must then approve the selection of conditions for screening. Criteria used in selecting conditions for screening include: reliable, valid and accurate testing methodologies must be available; there must be effective treatment that will benefit the newborn; follow-up systems must be in place to ensure access to appropriate care; properly trained professionals must be accessible; and the population demographics must support the cost effectiveness of testing.

The selection of CAH and galactosemia as conditions for which newborns are screened was the result of following the above described procedure. The clinical rationale for and societal benefit derived from screening for these two conditions were set forth in the preamble to the proposed regulations. However, for clarification, the Department will elaborate further. CAH is a complex family of disorders arising from specific defects in the enzymes of the adrenal cortex necessary for the biosynthesis of steroids. Dehydration, shock and even death can occur, with high mortality from "adrenal crisis." As severe forms of CAH can be rapidly fatal, quick diagnosis and intervention in the newborn are critical. Proper early intervention and medical treatment resets the abnormal balance of hormones and permits near normal development. Incidence is one case per 12,000 births. Approximately 25 other states screen for CAH.

Galactosemia is a genetic metabolic condition, which affects the body's ability to utilize certain sugars. Babies born with this condition cannot break down lactose or galactose. These are simple sugars found in breast milk, many formulas and milk products. The most common forms of galactosemia may result in death from sepsis within the first weeks of life or mental retardation in those who survive. Prompt diagnosis and intervention can prevent further damage. Treatment consists of special galactose and lactose-free milk substitutes and foods. One newborn in 60,000 is identified with classical galactosemia. When other forms of galactosemia are included, such as Duarte and Los Angeles, the rate increases to one newborn in 16,000 identified with a form of galactosemia. Forty-seven other states screen for galactosemia.

The second concern voiced by HAP is that the regulations have shifted the responsibility for follow-up notification and counseling to health care providers. The responsibility for follow-up has not been shifted from the Department to health care providers through these regulations. The act mandates physicians, hospitals and other institutions to test infants for PKU and other metabolic diseases.

Section 3 of the act (35 P.S. §623) specifically addresses the establishment of a Newborn Child Screening and Follow-up Program by the Department, in order to assist health care providers to determine whether treatment or other services are necessary to avert mental retardation, permanent disabilities or death. Section 4 of the act (35 P.S. §624) addresses the

procurement of specimens by health care providers and states that health care providers shall cause to be procured blood specimens of newborn children for required screening and confirmatory tests. If the initial specimen is an unacceptable specimen or as otherwise required by the Department by regulation, the act requires that the health care provider collect a repeat specimen for screening and confirmatory tests.

The law is clear in terms of assignment of responsibility. The Department's regulations follow that law and more clearly describe the responsibilities of health care providers and the Department.

IRRC also raised two concerns related to §28.21 (relating to responsibility for collecting and testing initial and repeat specimens). First, IRRC commented that the regulation does not specify what qualifications the newborn screening coordinator must have. IRRC commented that paragraph (1) of this section states that the newborn screening coordinator must "ensure that a specimen collection form contains correct and complete information" and asks, "What level of medical training does the newborn screening coordinator need to ensure the information is "correct?"

It is not the Department's intent to regulate the level of training. The Department believes that no specific level of medical training is necessary to ensure that the information is correct. However, the newborn screening coordinator must have access to the medical record to

verify that information on the specimen collection form is consistent with information on the medical record. Filling in the required information on the specimen collection form merely entails taking information from entries in the medical record and transcribing it on to the form. In some hospitals this may be performed by a nurse, medical technologist, or medical secretary with access to the medical record.

IRRC's second concern regarding §28.21, is that paragraph (7) is vague. IRRC asked what is the intent of the Department in requiring the newborn screening coordinator to assist the Department in follow-up of an abnormal or presumptive abnormal test result.

The intent of the Department is to minimize delays in notifying the parents of the test result due to inaccurate or missing demographic information on the newborn screening filter paper. A nurse who is a member of Department's Program staff receives the test result from the Department's testing laboratory. If the result is abnormal, that nurse will contact the provider's newborn screening coordinator to verify the information from the filter paper. The nurse also informs the coordinator that the Department will contact the newborn's physician. The Department then contacts the physician (by phone and fax) and discusses the need for a referral of the newborn to a treatment center or recommends a consultation with a pediatric endocrinologist depending on the condition.

It is the responsibility of the health care providers to contact the parents of the newborn to inform them of the abnormal test result. This is not a new requirement. Pursuant to the regulations prior to these amendments, §28.27 stated that "[i]f the results of any filter paper are presumptive positive, the health care provider or practitioner to whom the results were reported shall promptly notify the parents or guardian and arrange for followup and shall enter the report of the result into the patient's medical record." The Department has amended this section merely to make the language consistent with the rest of the regulations and to clarify the procedure.

The proposed regulations proposed changes to Chapter 27 (relating to communicable and noncommunicable diseases). However, that chapter was in the process of being amended at that time and the amendments to Chapter 27 have now been published as final (see 32 Pa.B. 491 (January 26, 2002)). Consequently, the language no longer exists in some of the Chapter 27 regulations to which the Department had proposed amendments to correlate with the proposed Chapter 28 newborn screening programs amendments. The revisions proposed to this Chapter in 31 Pa.B. 2271 (April 28, 2001) were re-evaluated in light of the new language of Chapter 27 and necessary changes have been incorporated into these final regulations.

In 31 Pa.B. 2271 (April 28, 2001), changes were proposed to § 27.2 (relating to reportable diseases), as that section existed on April 28, 2001. As a result of changes published on

January 26, 2002 (see 32 Pa.B. 491), the changes proposed in 31 Pa.B. 2271 (April 28, 2001) are no longer necessary.

There were no changes to § 27.4 (relating to reporting cases) proposed in 31 Pa.B. 2271 (April 28, 2001). However, organizational changes in the Department since that time have necessitated minor changes in order to reflect the correct name of the Division in which the Program is located.

The changes to Chapter 27 that were published on January 26, 2002 (see 32 Pa.B. 491) added §27.21a (relating to reporting of cases by health care practitioners and health care facilities). Now, additional changes to this section are needed to ensure that all of the conditions for which newborns are screened under Chapter 28 are reportable by health care practitioners and health care facilities.

In 31 Pa.B. 2271 (April 28, 2001), changes were proposed to § 27.22 (relating to reporting of cases by clinical laboratories) as that section existed on April 28, 2001. As a result of changes to this section that were published on January 26, 2002 (see 32 Pa.B. 491), additional changes are necessary to ensure that all of the conditions for which newborns are screened under Chapter 28 are reportable by clinical laboratories.

In 31 Pa.B. 2271 (April 28, 2001), changes were proposed to § 27.30 (relating to reporting of certain diseases in the newborn child) as that section existed on April 28, 2001. As a result of changes to this section that were published on January 26, 2002 (see 32 Pa.B. 491), additional changes are necessary to ensure that all of the conditions for which newborns are screened under Chapter 28 are reported to the Division in which the Program is located.

The proposed regulations proposed minor changes to Chapter 501 (relating to birth centers). The final regulations make only one additional change to § 501.49 (relating to newborn infant care policies and procedures) so that the terminology used is consistent with that used in Chapter 28.

III. AFFECTED PERSONS

The regulations affect all health care providers providing care to pregnant women and newborn children in Pennsylvania, as well as the treatment centers and any laboratory with which the Department contracts to provide the screening services. Health care providers are required to collect blood filter paper specimens in accordance with updated procedures, assist the Department with follow-up of certain test results, and forward data on specimen collection semiannually to the Department. Sickle cell and MSUD treatment centers are required to provide services to an increased number of children identified through the expanded Program. Treatment centers for galactosemia have been identified and are in place

for statewide screening for that condition. CAH will be dealt with in a similar fashion as primary congenital hypothyroidism, through referral to an endocrinologist. The laboratory with which the Department contracts is required to perform testing for MSUD, hemoglobin disease, galactosemia and CAH, in addition to PKU and primary congenital hypothyroidism.

These regulations also generally affect all infants born in Pennsylvania, and, in particular, children born in populations at greatest risk for certain diseases (e.g. MSUD and hemoglobin diseases).

IV. COST AND PAPERWORK ESTIMATE

A. Cost

Statutorily mandated expansion of the Program to include testing for MSUD and sickle cell hemoglobinopathies (hemoglobin disease) will result in increased cost to the Commonwealth and, on a lesser scale, to health care providers. Annual costs of the Program are expected to increase by approximately $1,300,000 to cover testing and follow-up for MSUD, hemoglobin disease, galactosemia and CAH. This amount will be funded entirely by State funds. The total annual budget for the expanded Program includes testing of 150,000 specimens for each of the six diseases (PKU, primary congenital hypothyroidism, MSUD, hemoglobin disease, galactosemia and CAH), additional personnel, new and replacement equipment for the

Bureau of Laboratories and the testing laboratory, and follow-up of children who are identified with one of the six diseases listed.

The cost to the private sector will be the cost incurred by health care providers in connection with providing the necessary follow-up to abnormal test results. The Department currently does not charge hospitals or parents for the costs of laboratory screening.

Expansion of the Program to include screening for MSUD, hemoglobin disease, galactosemia and CAH, however, will result in long-term savings as well. The total cost of screening all newborn children in Pennsylvania, including follow-up and some treatment for PKU, primary congenital hypothyroidism, MSUD, sickle cell disease, CAH and galactosemia is estimated at approximately $32 per child.

B. Additional Paperwork

The testing laboratory and health care providers will have additional reporting responsibilities resulting from the addition of diseases to the list of diseases for which screening is required. The increase in paperwork requirements will be minimal, however, because the specimens necessary for screening for MSUD, hemoglobin disease, galactosemia and CAH will be collected on the same specimen collection form currently used solely for PKU and primary congenital hypothyroidism screening. Furthermore, the testing laboratory

will report screening test results for the newly added diseases on the same report form currently used solely for PKU and primary congenital hypothyroidism. The regulations require health care providers to submit data regarding specimen collection to the Department semiannually. Paperwork requirements within the Department will not change significantly except to the extent that the addition of MSUD, hemoglobin disease, galactosemia and CAH will result in more instances in which follow-up of abnormal results will be required.

The expanded Program for screening for sickle cell hemoglobinopathies (hemoglobin disease) and MSUD was mandated by statute in 1992, and has, in fact, been operating since that time. As has been stated, screening for sickle cell hemoglobinopathies (hemoglobin disease) began in September of 1992, and for MSUD began in March of 1993. Screening for galactosemia and CAH began on a voluntary basis in State fiscal year 2000/2001. The regulations will not add to the paperwork currently being done by providers of their own volition, nor will they, for the most part, increase costs currently incurred as screening mandated by the act is carried out.

V. EFFECTIVENESS/SUNSET DATES

The regulations will become effective upon final publication in the Pennsylvania Bulletin. No sunset date has been established; the Department will continually review and monitor the effectiveness of the Program.

VI. STATUTORY AUTHORITY

The Department obtains its authority to promulgate these regulations from several sources. The Disease Prevention and Control Law of 1955 (35 P.S. §521.1 et seq.) provides the Advisory Health Board with the authority to issue rules and regulations on a variety of issues relating to communicable and non-communicable diseases, including the methods of reporting diseases, the contents of those reports and the health authorities to whom diseases are to be reported. (35 P.S. §521.16(a)). Section 16(b) of the Disease Prevention and Control Law of 1955 (35 P.S. §521.16(b)) gives the Secretary of Health (Secretary) the authority to review existing regulations and make recommendations to the Board for changes the Secretary considers to be desirable.

The Department also finds general authority for the promulgation of its regulations in the Administrative Code of 1929 (71 P.S. §51 et seq.). Section 2102(g) of the Administrative Code (71 P.S. 532(g)) gives the Department the authority to promulgate its rules and regulations. Section 2111(b) of the Administrative Code (71 P.S. §541(b)) provides the Board with additional authority to promulgate regulations deemed by the Board to be necessary for the prevention of disease, and for the protection of the lives and the health of the people of the Commonwealth. That section further provides that the regulations of the Board shall become the regulations of the Department.

The Department's specific authority for promulgating the regulations relating to newborn screening and follow-up is found in the act (35 P.S. §§621-625). Section 5 of the act (35 P.S. §625) provides the Department, with the approval of the Board, the authority to promulgate regulations for the implementation and administration of the act. Section 3(b) of the act (35 P.S. §623(b)) provides the Department, with the approval of the Board, the authority to establish by regulation those diseases for which newborn children shall be tested and the methods for testing and disseminating test results. Section 4(b) of the act (35 P.S. §624(b)) provides the Department with the authority to establish by regulation the methods of procurement of blood specimens of newborn children by health care providers.

VII. REGULATORY REVIEW

Under section 5(a) of the Regulatory Review Act, the Act of June 30, 1989 (P.L. 73, No. 19), (71 P.S. §§745.1 - 745.15), on April 18, 2001, the Department submitted copies of the Notice of Proposed Rulemaking published at 31 Pa.B. 2271 (April 28, 2001) to IRRC and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee for review and comment. In compliance with section 5(c) of the Act, the Department also provided IRRC and the Committees with copies of all comments received.

In compliance with section 5.1(a) of the Act, the Department submitted a copy of the final-form regulations to IRRC and the Committees on March 8, 2002. In addition, the Department provided IRRC and the Committees with information pertaining to commentators and a copy of the detailed regulatory analysis form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

In preparing the final-form regulations, the Department has considered all comments received from IRRC and the public.

These final-form regulations were deemed approved by the House Health and Human Services Committee on _____ and the Senate Public Health and Welfare Committee on _____. IRRC met on _____ and approved the regulations in accordance with Section 5.1(e) of the Act. The Attorney General approved the regulations on _____.

VIII. CONTACT PERSON

Questions regarding these final-form regulations may be submitted to: Joann Adair, Director, Division of Newborn Disease Prevention and Screening Services, Bureau of Family Health, Department of Health, P.O. Box 90, Harrisburg, PA 17108, (717) 783-8143. Persons

with disabilities may submit questions to Ms. Adair in alternative formats, such as by audio tape, Braille or using ITT (717) 705-5494. Persons with disabilities who would like to obtain this document in an alternative format (e.g., large print, audio tape, Braille) should contact Ms. Adair so that she may make the necessary arrangements.

IX. FINDINGS

The Department, with the approval of the Board, finds that:

(a) Public notice of the intention to adopt the regulation adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§1201 and 1202), and the regulations thereunder, 1 Pa. Code §§7.1 and 7.2.

(b) A public comment period was provided as required by law and all comments were considered.

(c) The adoption of the regulation in the manner provided by this order is necessary and appropriate for the administration of the authorizing statutes.

X. ORDER

The Department, with the approval of the Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 28 Pa. Code, Chapters 27, 28 and 501 (relating to communicable and noncommunicable diseases; screening and followup for diseases of the newborn; and birth centers), are amended by adding § 28.5; by amending §§ 27.4, 27.21a, 27.22, 27.30, 28.1—28.2, 28.11—28.12, 28.21—28.28, 28.41, 501.3 and 501.49; and by repealing §§ 28.3—28.4 and 28.29—28.31 as set forth in Annex A.

(b) The Secretary shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(c) The Secretary shall submit this order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

(d) The Secretary of Health shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect upon publication in the Pennsylvania Bulletin.

ANNEX A

TITLE 28. HEALTH AND SAFETY

* * *

PART III. PREVENTION OF DISEASE

* * *

CHAPTER 27. COMMUNICABLE AND NONCOMMUNICABLE DISEASES

* * *

~~Section 27.2. Reportable diseases.~~

~~The Board declares the following communicable diseases, unusual outbreaks of illness, noncommunicable diseases and conditions to be reportable:~~

* * *

~~Congenital adrenal hyperplasia (CAH) in children under 5 years of age.~~

* * *

~~Galactosemia in children under 5 years of age.~~

* * *

~~Maple syrup urine disease (MSUD) in children under 5 years of age.~~

* * *

~~Phenylketonuria (PKU) in children under 5 years of age.~~

* * *

~~Primary congenital hypothyroidism in children under 5 years of age.~~

* * *

~~Sickle cell disease in children under 5 years of age.~~

* * *

Section 27.4. Reporting Cases.

* * *

(d) Department offices to which this chapter requires specified case reports to be filed are as follows:

* * *

(4) Division of ~~Maternal and Child Health~~ NEWBORN DISEASE PREVENTION AND SCREENING SERVICES, Bureau of Family Health.

* * *

Section 27.21a. Reporting of cases by health care practitioners and health care facilities.

* * *

(b) The following diseases, infections and conditions in humans are reportable by health care practitioners and health care facilities within the specified time periods and as otherwise required by this chapter:

* * *

(2) The following diseases, infections and conditions are reportable within 5 work days after being identified by symptoms, appearance or diagnosis:

* * *

CONGENITAL ADRENAL HYPERPLASIA (CAH) IN CHILDREN UNDER 5 YEARS OF AGE.

* * *

GALACTOSEMIA IN CHILDREN UNDER 5 YEARS OF AGE.

* * *

sickle cell ~~hemoglobinopathies~~ DISEASE in children under 5 years of age.

* * *

~~**Section 27.22. Reporting laboratory results indicative of certain infections or conditions.**~~

* * *

~~(b) The conditions or diseases to be reported include the following:~~

~~Congenital adrenal hyperplasia (CAH) in children under 5 years of age.~~

* * *

~~Galactosemia in children under 5 years of age.~~

* * *

~~[Hypothyroidism in infants up to 24 months old.]~~

* * *

~~Maple syrup urine disease (MSUD) in children under 5 years of age.~~

* * *

~~Phenylketonuria (PKU) in children under 5 years of age~~

* * *

~~Primary congenital hypothyroidism in children under 5 years of age.~~

* * *

~~Sickle cell disease in children under 5 years of age.~~

* * *

~~(d) The report shall be submitted by the person in charge of a laboratory as follows:~~

~~(1) *Reports except for venereal diseases, [hypothyroidism in infants up to 24 months old, phenylketonuria] CAH in children under 5 years of age, galactosemia in children under 5 years of age, MSUD in children under 5 years of age, PKU in children under 5 years of age, primary congenital hypothyroidism in children under 5 years of age, sickle cell disease in children under 5 years of age, and lead poisoning or lead toxicity.* Reports shall be made to the appropriate health authority of Philadelphia or the county department of health if the patient resides in such an area. Other reports shall be sent to the Division of Epidemiology, Department of Health, Post Office Box 90, Harrisburg, Pennsylvania 17108.~~

* * *

~~(3) [*Phenylketonuria and hypothyroidism in infants up to 24 months old*] *CAH in children under 5 years of age, galactosemia in children under 5 years of age, MSUD in children under 5 years of age, PKU in children under 5 years of age, primary congenital hypothyroidism in children under 5 years of age, and sickle cell disease in children under 5 years of age.* Reports shall be made to the Division of Maternal[/] and Child Health, Department of Health, Post Office Box 90, Harrisburg, Pennsylvania 17108.~~

Section 27.22. Reporting of cases by clinical laboratories.

* * *

(b) The diseases, infections and conditions to be reported include the following:

* * *

CAH IN CHILDREN UNDER 5 YEARS OF AGE.

* * *

GALACTOSEMIA IN CHILDREN UNDER 5 YEARS OF AGE.

* * *

Sickle cell ~~hemoglobinopathies~~ DISEASE in children under 5 years of age.

* * *

(e) Reports made on paper shall be made to the LMRO where the case is diagnosed or identified. Reports made electronically shall be submitted to the Division of Infectious Disease Epidemiology, Bureau of Epidemiology. Reports of CAH, GALACTOSEMIA, maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism, sickle cell ~~hemoglobinopathies~~ DISEASE, cancer and lead poisoning shall be reported to the location specifically designated in this subchapter. See §§27.30, 27.31 and 27.34 relating to reporting cases of certain diseases in the newborn child; reporting cases of cancer; and reporting cases of lead poisoning).

* * *

~~**Section 27.30. Reporting test results [of metabolic disease testing in] which identify specific diseases of the newborn [child].**~~

~~In addition to the requirements that may be applicable under this chapter, testing conducted on newborn children shall be reported in accordance with Chapter 28 (relating to [metabolic] screening and followup for diseases of the newborn).~~

* * *

Section 27.30. Reporting cases of certain diseases in the newborn child.

Reports of CAH, GALACTOSEMIA, maple syrup urine disease, phenylketonuria, primary congenital hypothyroidism, and sickle cell ~~hemoglobinopathies~~ DISEASE shall be made to the Division of ~~Maternal and Child Health~~ NEWBORN DISEASE PREVENTION AND SCREENING SERVICES, Bureau of Family Health, as specified in Chapter 28 (relating to ~~metabolic diseases~~ SCREENING AND FOLLOW-UP FOR DISEASES of the newborn) and those provisions of § 27.4 (relating to reporting cases) consistent with the provisions of Chapter 28 and this section.

* * *

CHAPTER 28. [METABOLIC] SCREENING AND FOLLOWUP FOR DISEASES OF THE NEWBORN

GENERAL PROVISIONS

Sec.
28.1. Definitions.
28.2. [Metabolic] Newborn diseases listed.
28.3. [Tests to be performed.] (Reserved).
28.4. [Standards for collecting and testing specimens.] (Reserved).
28.5 Confidentiality.

[ADVICE TO PARENTS EXPLAINING] PURPOSE AND ADMINISTRATION OF TESTS

28.11. Informing the parent or guardian.
28.12. Religious objections.

[TIMING OF COLLECTION, HANDLING OF SPECIMENS AND REPORTS] SPECIMEN COLLECTION AND FOLLOWUP

28.21. Responsibility for collecting and testing initial and repeat specimens.
28.22. Timing of initial specimen collection [and handling in health care facilities] by birth centers or hospitals.
28.23. Timing of initial specimen collection [and handling for home births] by health care practitioners.
28.24. [Negative] Normal test results.
28.25. [Followup recall] Circumstances requiring repeat specimens.
28.26. Timing of [recall] repeat specimen collection [, handling and reporting].
28.27. [Followup of presumptive positive] Abnormal screening test results.

28.28. Followup of symptoms consistent with [metabolic] newborn diseases.
28.29. [Confirmatory test specimen required.] (Reserved).
28.30. [Phenylketonuria] (Reserved).
28.31. [Hypothyroidism] (Reserved).

RECORDS

28.41. Recordkeeping requirements.

GENERAL PROVISIONS

Section 28.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Abnormal confirmatory test result-- A test result obtained from a specimen of blood, serum, or plasma which is diagnostic of the newborn disease under investigation.

Abnormal screening test result-- A test result obtained from a specimen collected on a specimen collection form which is outside the parameters for a normal test result according to testing criteria applicable to the screening test result.

Admission-- The formal acceptance of custody or care by a [health care facility] birth center or hospital of a newborn child who is provided with bassinet or incubator, nutrition and continuous nursing service.

[*Childbearing*] *Birth center* – [A facility owned and operated by an individual, group of individuals, health agency or corporation except a hospital to provide antenatal, intrapartum and postpartum services] As defined in §802a of Chapter 8 of the Health Care Facilities Act (35 P.S. § 448.802a).

[*Bureau*-- The Bureau of Laboratories of the Department.

Confirmatory test specimen-- A specimen of blood, serum or plasma collected from the newborn child on which a confirmatory test is performed in accordance with standards established or approved by the Bureau relating to the quantitative determination of these constituents; results of the tests may be used for diagnostic purposes.]

Days of age-- The measurement of age of the newborn child in 24-hour periods so that a newborn child is one day of age 24 hours after the hour of birth.

Department-- The Department of Health of the Commonwealth.

Discharge-- The release of the newborn child from care and custody within and by the [health care facility] birth center or hospital to the care and custody of the parent or guardian.

[*Health care facility*—A hospital or institution licensed or supervised by the Commonwealth and approved to provide impatient perinatal or pediatric services or both, and childbearing center.]

Health care practitioner-- A licensed physician or a practitioner licensed [to provide maternity care and] to deliver and care for pregnant women and newborn children.

Health care provider-- A birth center, hospital or health care practitioner.

Hemoglobin diseases-- Sickle cell (SS, SC, S-V + OTHER VARIANT, S β Thalassemia, S O Arab) disease or trait or other clinically significant hemoglobin (CC, EE, F, H) disease or trait.

Hospital—As defined in §802a of Chapter 8 of the Health Care Facilities Act (35 P.S. § 448.802a).

[*Hypothyroid referral clinic laboratory*-- A clinic/laboratory sponsored and supported by the Department to provide followup serum laboratory testing, consultation, diagnosis and treatment of infants with hypothyroidism.]

Inconclusive screening test result-- A test [in which the] result obtained from a specimen collected on a specimen collection form that is equivocal [by criteria established or approved by the Bureau] according to criteria applicable to the screening test result and which indicates the need for a [recall] repeat specimen and repeat testing.

[*Initial presumptive positive test*-- A test result indicating that a metabolic disease listed in section 28.2 (relating to metabolic diseases listed) may be present; the results shall be followed by confirmatory testing for diagnostic purposes.]

Initial specimen-- The first sample of blood collected [for testing purposes] from the newborn [on a special filter paper collecting device] child and submitted for testing purposes on a specimen collection form.

[*Initial test*-- The first analysis performed on an initial specimen.]

Newborn child-- An infant less than 28 days of age.

Newborn screening program--The association of the Department, the testing laboratory, and the health care provider to ensure that every newborn child born in the Commonwealth of Pennsylvania has a blood specimen collected and screened for the newborn diseases listed in §28.2 (relating to newborn diseases listed).

[*Phenylketonuria Program Clinic*-- A clinic sponsored and supported by the Department to provide expert consultation, diagnosis and treatment for children with phenylketonuria.]

Presumptive abnormal test result-- An abnormal screening test result which is sufficiently abnormal to indicate the probable presence of a newborn disease listed in §28.2.

[*Recall*] *Repeat specimen*-- A specimen collected from [the] a newborn child on a specimen collection form after the initial specimen [; such specimens are collected for the following reasons:

(i) Early discharge of newborn child from hospital.
(ii) Unacceptable specimen.
(iii) Inconclusive test result].

[*Recall*] *Repeat test*-- The laboratory [test] testing performed on a [recall] repeat specimen.

Specimen collection form-- The official newborn screening program specimen form that includes both a multipart section for providing required information about the newborn child and a filter paper tab for application of blood.

Testing laboratory—[Licensed] The licensed clinical laboratory under contract with the Department to perform [screening tests] testing for the [metabolic] newborn diseases listed in §28.2.

Transfer-- The release of the newborn child from care and custody within and by [the health care facility for] a birth center or hospital and subsequent admission to [care and custody of] another [heath care facility or to a similar health care facility in another state] hospital.

Treatment center-- A center under contract with the Department to provide expert consultation, diagnosis and treatment for children with a presumptive abnormal test result.

Unacceptable specimen—[Blood] A blood specimen collected from a newborn child on a [special filter paper collecting device] specimen collection form which is found to be [unacceptable] unsuitable for testing in accordance with [standards established or approved] accepted laboratory testing standards as determined by the [Bureau] Department.

Section 28.2. [Metabolic] Newborn diseases listed.

[The] A newborn child born in the Commonwealth of Pennsylvania shall be screened for the following [metabolic] diseases [of the newborn child are believed to] which may cause mental retardation [or], physical defects, or death [in the newborn child] if not detected and treated soon after birth:

(1) Congenital adrenal hyperplasia (CAH).
(2) Galactosemia.

(3) Hemoglobin diseases.
(4) Maple syrup urine disease (MSUD).
[(1)] (5) Phenylketonuria (PKU).
[(2)] (6) [Hypothyroidism] Primary congenital hypothyroidism.

Section 28.3. [Tests to be performed] (Reserved).

[(a) The following tests have been approved for the screening and detection of the these diseases:

(1) *Phenylketonuria.* The following tests are approved for detection of phenylketonuria:
   (i) The Guthrie Bacterial Inhibition Assay (GBIA).
   (ii) The McCaman and Robins Fluorometric method.
   (iii) Other tests approved by the Bureau.

(2) *Hypothyroidism.* The following tests are approved for detection of hypothyroidism:
   (i) Radioimmunoassay techniques for Thyroxine (T4) and Thyroid Stimulating Hormone (TSH) according to standards established or approved by the Bureau.
   (ii) Other tests approved by the Bureau.

(b) Tests may not be administered if the parent or guardian of the newborn child objects on the grounds that the tests conflict with parent or guardian's religious beliefs or practices.]

Section 28.4. [Standards for collecting and testing specimens] (Reserved).

[A health care facility required by law or regulation to administer or cause to be administered tests for the detection of metabolic diseases in the newborn child, as specified in §28.2 (relating to metabolic diseases listed), shall collect specimens necessary to conduct the tests in accordance with standards established by the Bureau. Specimens collected shall be sent by first class mail or by other means acceptable to the Department to laboratory specified by the Department within 48 hours of collection. The Bureau will ensure the commencement of testing procedures by the testing laboratory within 48 hours of receipt of the specimen. Chapter 5 (relating to clinical laboratories), applies to the laboratory performing the tests specified in §28.3 (relating to tests to be performed).]

Section 28.5. Confidentiality.

(a) No health care provider, testing laboratory, the Department, or any other entity involved in the newborn screening program may release any identifying information relating to any newborn child screened in the newborn screening program to anyone other than a parent or guardian of the newborn child or the health care provider for the newborn child designated by a parent or the guardian except as follows:

(1) As may be necessary to provide services to the newborn child.

(2) With the consent of the newborn child's parent or guardian.

(3) With the child's consent when the child is 18 years of age or older, has graduated from high school, has married or has been pregnant.

(b) Only the Department will have the authority to release or authorize the release of nonidentifying information concerning the newborn screening program.

[ADVICE TO PARENTS EXPLAINING] PURPOSE AND ADMINISTRATION OF TESTS

Section 28.11. Informing the parent or guardian.

[The] Prior to specimen collection, the health care [facility or practitioner responsible for care of the pregnant woman or mother] provider shall provide [her] the pregnant woman, prior to the infant's birth, or the mother or guardian, after the infant's birth, with a pamphlet supplied by the Department to explain the nature of the newborn screening [neonatal] blood tests for the [metabolic] diseases listed in §28.2 (relating to [metabolic] newborn diseases listed).

Section 28.12. Religious objections.

(a) No health care provider may collect or cause to be collected, a specimen from a newborn child if the parent or guardian of the newborn child objects on the ground that the specimen collection conflicts with religious beliefs or practices held by the parent or guardian.

(b) If the parent or guardian of the newborn child objects to [a test] the collection of the specimen for screening on the ground that the [test] specimen collection conflicts with [his] religious beliefs or practices held by the parent or guardian, the health care [facility or practitioner responsible for the care of the newborn child shall be responsible to see] provider shall ensure that the recorded objection of the parent or guardian is entered into the medical record of the newborn child. The entry shall include a written statement of the objection signed by the parent or guardian.

[TIMING OF COLLECTION, HANDLING OF SPECIMENS, AND REPORTS] SPECIMEN COLLECTION AND FOLLOWUP

Section 28.21. Responsibility for collecting and testing initial and repeat specimens.

[The health care facility or practitioner to whom care of the newborn has been entrusted or who assisted the mother at delivery shall direct blood specimens to be collected and sent for testing in accordance with §§28.4, 28.11 and 28.12 (relating to standards for collecting and testing specimens; informing the parent or guardian; and religious objections)] (a) A birth center or hospital shall collect or cause to be collected from each newborn child delivered in that birth center or hospital, in accordance with instructions for newborn screening specimen collection in subsection (d), the initial and repeat specimens necessary to conduct the tests necessary for the detection of the newborn diseases specified in §28.2 (relating to newborn diseases listed).

(b) When a newborn child is delivered other than in a birth center or hospital, the health care practitioner who delivered the newborn child shall collect or cause to be collected from the newborn child, in accordance with instructions for newborn screening specimen collection in subsection (d), the initial and repeat specimens necessary to conduct the tests necessary for the detection of the newborn diseases specified in §28.2.

(c) The health care provider shall designate a newborn screening coordinator to do the following:

(1) Ensure that a specimen collection form contains correct and complete information.

(2) Ensure that the individual who collected the specimen records that act in the newborn child's medical record.

(3) Send all specimens collected by first class mail to the testing laboratory within 24 hours of collection.

(4) Record the laboratory screening results in the newborn child's medical records.

(5) Check each newborn child's record prior to discharge or release to ensure that a specimen has been collected.

(6) Ensure, in the event of transfer of the newborn child prior to 48 hours of age, that the receiving health care provider has been notified that it has the responsibility to collect the initial specimen.

(7) Assist the Department in followup of an abnormal or presumptive abnormal test result.

(8) Followup inconclusive test results.

(9) Receive notification from the testing laboratory or from the Department of the need for a repeat specimen.

(d) The health care provider shall ensure that the individual responsible for specimen collection shall collect the specimen necessary to conduct tests in accordance with consensus standards developed by the National Committee for Clinical Laboratory Standards (NCCLS) and accepted by the Department. The Department will publish these standards, and any revisions thereto, in a notice in the *Pennsylvania Bulletin*.

Section 28.22. Timing of initial specimen collection [and handling in health care facilities] by birth centers or hospitals.

(a) [An] A birth center or hospital shall collect the initial specimen [shall be collected in health care facilities] from each newborn [infants, irrespective] child regardless of [age or] feeding history [,discharged on or before the fifth day of age, as close to the time of discharge from the health care facility as is practicable] or medical condition, as close to 48 hours of age as possible but not later than 72 hours of age unless the newborn child falls into one of the following categories:

(1) *Transfer.* If the newborn child is transferred to another [health care facility] hospital for continuing care [on or before the fifth day of age, the initial,] prior to 48 hours of age, the hospital to which the newborn child has been transferred shall collect a specimen [shall be collected between the fifth and sixth day of age] from the newborn child, [irrespective] regardless of feeding history [,by the health care facility to which the newborn child has been transferred] or medical condition, as close to 48 hours of age as possible but not later than 72 hours of age.

[(2) *Late discharge.* If the newborn child is discharged from the health care facility beyond the fifth day of age, the initial blood specimen shall be collected from the newborn child between the fifth and sixth day of age, irrespective of feeding history.

(3) *Instability.* If the newborn child is transferred or detained and the child's medical condition is unstable and renders the collection of the specimen undesirable at the designated time as stated in paragraph (1) or (2), whenever practicable, the initial specimen shall be collected as soon as it is deemed appropriate, but within the first 5 to 9 days of age.]

[(4)] (2) *Exchange transfusion.* [Where] If the newborn child is to undergo an exchange transfusion, the birth center or hospital shall collect the initial specimen [shall be collected] for testing immediately prior to the exchange transfusion.

[(5)] (3) *Early discharge.* [Where] If the newborn child is discharged from the [health care facility] birth center or hospital before 24 hours of age, the birth center or hospital shall collect the initial [blood] specimen [shall be collected] from the newborn child as close to the time of discharge as is practicable, [irrespective] regardless of feeding history or medical condition. [Arrangements with the parent or guardian shall be made by the health care facility or the practitioner] The birth center or hospital shall give the parent or guardian in whose care and custody the newborn

child is discharged written notification of the need for a repeat specimen and shall also provide instructions to the parent or guardian for obtaining a [recall blood] repeat specimen from the newborn child as described in §28.26 (relating to timing of [recall] repeat specimen collection [, handling and reporting]).

(b) When a newborn child, who was delivered other than in a birth center or hospital, is admitted to a hospital within the first 27 days of age and the hospital has received no record of results of an approved screening test for the newborn diseases listed in §28.2 (relating to newborn diseases listed), the hospital to which the newborn child is admitted shall collect the initial specimen within 48 hours of admission to the hospital and shall send the specimen to the testing laboratory specified by the Department within 24 hours of collection.

Section 28.23. Timing of initial specimen collection [and handling for home births] by health care practitioners.

[(a) When a newborn child is born at home and is not admitted to a health care facility by the fifth day of age,] A health care practitioner who delivers a newborn child other than in a birth center or hospital shall collect or cause to be collected the initial specimen [shall be obtained] from the newborn child [and sent for testing between the second and sixth day of age by the practitioner to whom care of the newborn child has been entrusted or who assisted the mother at time of delivery or by the person who signed the newborn child's birth certificate], regardless of feeding history or medical condition, as close to 48 hours as possible but not later than 72 hours of age.

[(b) When a newborn child is admitted to a health care facility within the first 27 days of age who has not been born in nor admitted to a health care facility within the first 5 days of age and who has no record of results of an approved screening test for the metabolic diseases listed in §28.2 (relating to metabolic diseases listed), the initial specimen shall be collected within 48 hours of admission to the facility and sent for testing.]

Section 28.24. [Negative] Normal test results.

(a) No later than 7-calendar days following the day when the testing laboratory obtains the [negative] normal test results, the testing laboratory shall send those results to the health care [facility or practitioner under whose care the specimen was collected] provider that collected the specimen from the newborn child.

(b) The health care [facility or practitioner] provider to whom the [negative] normal test results are reported shall record the test results in the medical record of the [patient] newborn child.

Section 28.25. [Followup recall] Circumstances requiring repeat specimens.

(a) [If] The health care provider responsible for collecting the initial specimen shall collect or cause to be collected and submit for testing a repeat specimen if the initial specimen collected is either of the following:

(1) [unacceptable] Unacceptable for testing [if the results of testing are inconclusive, a recall specimen is required].

(2) Yields an inconclusive screening test result.

(b) If a birth center or hospital collects the initial specimen from a newborn child prior to 24 hours of age because the newborn child is discharged from the birth center or hospital prior to 24 hours of age, the birth center or hospital shall collect or cause to be collected a repeat specimen.

(c) If the initial specimen collected yields an abnormal screening test result, the Department may require the health care provider responsible for collecting the initial specimen to collect a repeat specimen.

Section 28.26. Timing of [recall] repeat specimen collection[, handling, and reporting].

(a) When the newborn child has been discharged from [the health care facility] a birth center or hospital before 24 hours of age, [a recall filter paper specimen shall be collected for testing between the sixth to ninth day whenever practicable by the health care facility or practitioner to whom care of the newborn child has been entrusted] the birth center or hospital shall collect or cause to be collected a repeat specimen from the newborn child, regardless of feeding history or medical condition, as close to 48 hours of age as possible but not later than 72 hours of age.

(b) When the initial specimen is unacceptable [for testing] or when [the results of] the initial specimen [are] yields an inconclusive screening test result, [a recall filter paper specimen shall be obtained promptly from the newborn child upon telephone notification from] the Department [to the] or testing laboratory will notify the health care [facility or practitioner who is providing ongoing care to the child according to procedures delineated in §§28.3(b) and 28.12 (relating to tests to be performed; and religious objections)] provider that collected the initial specimen. Within 72 hours of receipt of notice from the Department or testing laboratory, the health care provider that collected the initial specimen shall collect or cause to be collected from the newborn child a repeat specimen.

[(c) In a case where the parent or guardian has no ongoing health care provider for the newborn child, the Department will assist the parent or guardian in arranging for recall specimen collection.]

[(d)] (c) If the [appropriate] health care [facility or practitioner] provider cannot locate [the parents] a parent or guardian of the newborn child within 4 days of notification of need for a repeat [filter paper recall] specimen, the health care [facility or practitioner] provider shall [telephone] contact the Department [,which will assist in location of the parents] for consultation regarding additional means for locating a parent or guardian.

Section 28.27. [Followup of presumptive positive] Abnormal screening test results.

(a) [If the results of any filter paper test are presumptive positive, the health care facility or practitioner to whom the results were reported shall promptly notify the parents or guardian and arrange for followup and shall enter the report of the result into the patient's medical record.] When testing of the initial or repeat specimen yields an abnormal screening test result, the Department will notify the health care provider that collected the specimen. The health care provider shall promptly notify a parent or guardian of the newborn child.

(b) If the health care [facility or practitioner to whom the presumptive positive test report was made] provider cannot locate the newborn child's parent or guardian within 48 hours of receiving [the report] notice from the Department, the health care [facility or practitioner] provider shall [notify] contact the Department [, which will assist in] for consultation regarding additional means for locating [the parents] a parent or guardian.

(c) The Department will assist the health care provider with and make available confirmatory testing.

(d) If the result of the confirmatory test is abnormal, the Department will assist with referral for diagnosis, treatment, and other followup services for the newborn child through designated treatment centers or clinical specialists.

Section 28.28. Followup of symptoms consistent with [metabolic] newborn diseases.

When a sick child exhibits [signs] symptoms suggestive of a [metabolic] newborn disease listed in §28.2 (relating to [metabolic]newborn diseases listed) and has not already been determined to have one of those [metabolic] newborn diseases, [a] the health care [facility or practitioner] provider to whom care of the sick child has been entrusted by the parent or guardian shall collect and submit a blood specimen for [metabolic] newborn disease testing in accordance with standard diagnostic procedures.

Section 28.29. [Confirmatory test specimen required.] (Reserved).

[If the results of any test are presumptive positive, collection of a confirmatory test specimen is required. Within 24 hours after the test results have been obtained, the Department

will telephone the results to the appropriate health care facility or practitioner and follow up with a written report.]

Section 28.30. [Phenylketonuria.] (Reserved).

[(a) *Presumptive positive tests.* For presumptive positive tests the following shall apply:

(1) If the results of any test for phenylketonuria are presumptive positive, the Department will provide prompt confirmatory testing of the newborn child in accordance with standards established by the Bureau.

(2) The Department confirmatory laboratory testing of the newborn child will be completed within 24 hours of the receipt of the confirmatory test specimen or as soon as thereafter as practicable by the Department and will be reported and followed up under the same procedures set forth for presumptive positive tests in §§28.27 and 28.29 (relating to followup of presumptive positive test results; and confirmatory test specimen required).

(3) The Department will telephone confirmatory test results to its designated Phenylketonuria Program Clinics.

(b) *Positive confirmatory tests.* If the results of the confirmatory tests for phenylketonuria are positive, the Department will arrange for, diagnosis, and treatment, and habititative and other followup services for the child and family in accordance with standards set or approved by the Department.]

Section 28.31. [Hypothyroidism.] (Reserved).

[(a) *Presumptive positive tests.* If the results of any hypothyroidism tests are presumptive positive, the Department will make available confirmatory laboratory testing in accordance with standards established or approved by its Bureau. Testing will be initiated within 24 hours of receipt of the specimen or as soon thereafter as is practicable by the Department's designated Hypothyroid Referral Clinics/Laboratories and will be reported and followed up under the same procedures set forth for presumptive positive tests in §§28.27 and 28.29 (relating to followup of presumptive test results; and confirmatory test specimen required).

(b) *Positive confirmatory tests.* If the results of any tests for neonatal hypothyroidism are positive, the Department will provide telephone or clinic consultative services through its designated Hypothyroid Referral Clinics/Laboratories in accordance with standards set or approved by the Department.]

RECORDS

Section 28.41. Recordkeeping requirements.

A health care [facility providing] provider offering maternity and newborn services shall [be required by the Department to keep data] collect and forward data semi-annually to the Department on the number of patients for whom specimens for [metabolic] newborn disease testing have been collected and the number of patients for whom the specimens have not been collected, together with the reason in each instance for the failure to collect.

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PART IV. HEALTH FACILITIES

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CHAPTER 501. BIRTH CENTERS

Section 501.3. Reports/contact person.

(a) The facility shall report regularly to the Department, on forms issued by the Department, statistical information that the Department may request and shall comply with the requirements for recordkeeping in § 28.41 (relating to recordkeeping requirements).

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Section 501.49. Newborn infant care policies and procedures.

The newborn infant care policies, protocols[,] and procedures shall include, but not be limited to, the following:

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(4) The birth center shall explain to the mother the purpose and nature of the screening tests for ~~metabolic~~ diseases OF THE NEWBORN, required by Chapter 28 (relating to [metabolic] screening and followup for diseases of the newborn), give her an informational pamphlet provided by the Department, inform her of her right to refuse the tests because of religious beliefs or practices, and see that the recorded written objection is entered into the medical record of the newborn child and signed by the parent or guardian, if screening is refused.

(5) The birth center shall [collect an initial filter paper blood specimen, for the detection of metabolic diseases, as close to the time of discharge from the facility as is practicable, irrespective of feeding history, unless the newborn is transferred to another health care facility for continuing care. Arrangements with the parent shall be made by the birth center, for collecting an additional blood filter paper specimen between the 2nd to 9th day of age] comply with the requirements for specimen collection, testing, and followup set forth in §§28.21--28.28.

* * *

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

ROBERT S. ZIMMERMAN, JR., MPH
SECRETARY OF HEALTH

March 8, 2002

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, PA 17101

Re: Department of Health Final Regulations No. 10-137
Newborn Disease Screening and Follow-up

Dear Mr. Nyce:

Enclosed is a copy of final-form regulations for review by the Commission pursuant to the Regulatory Review Act (Act) (71 P.S. §§745.1-745.15). Section 5.1 (a) of the Act provides that, upon completion of the agency's review of the comments following proposed rulemaking, the agency is to submit to the Commission and the standing committees a copy of the agency's response to the comments received, the names and addresses of commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

The Department received 3 comments to the proposed rescission. These comments were forwarded to your Committee upon receipt by the Department. All of the commentators are being provided a copy of the final-form regulations. A list of names and addresses is enclosed.

Section 5.1 (e) of the Act provides that within 10 days following the expiration of the Standing Committee review period, or at its next regularly scheduled meeting, the Commission shall approve or disapprove the final-form regulations.

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Deborah Griffiths, Director, Office of Legislative Affairs.

Sincerely,

Robert S. Zimmerman, Jr.
Secretary of Health

Enclosures

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TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	10-137
SUBJECT:	Newborn Disease Screening & Follow-up
AGENCY:	Department of Health

TYPE OF REGULATION

Proposed Regulation

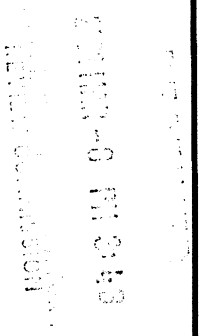
X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions



FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
3/8/02	Nancy Thompson	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
3/8/02	Karen Shaffer	
3/8/02	Kristi Kreiser	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
3/8	Lauren Clark	
3/8	E. Pagan	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

February 28, 2002