REPORT BY THE

AUDITOR GENERAL

OF CALIFORNIA

THE DEPARTMENT OF HEALTH SERVICES' NEWBORN SCREENING PROGRAM: RESPONSE TO QUESTIONS POSED BY THE LEGISLATURE

The Department of Health Services is responsible for administering the State's Newborn Screening Program. To answer specific questions posed by the Legislature, we reviewed certain aspects of this program, including the distribution of fee revenue collected for newborn screening, the timeliness of the testing program, and the contracts used to administer the program.

To date, the department has not used fee revenue to support the Newborn Screening Program. Instead, loans from the State's General Fund have been used to offset program costs. Also, laboratories under contract with the State are completing the screening for genetic diseases within two days after receiving a blood sample. Further, the department sends written notification of test results to hospitals and physicians within 10 days after a blood sample is drawn. Finally, there may be some problems related to the department's monitoring of the contracts for the area genetic centers and its method of paying for confirmation testing at one hospital.

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REPORT BY THE

OFFICE OF THE AUDITOR GENERAL

TO THE

JOINT LEGISLATIVE AUDIT COMMITTEE

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THE DEPARTMENT OF HEALTH SERVICES' NEWBORN SCREENING PROGRAM: RESPONSE TO QUESTIONS POSED BY THE LEGISLATURE

JANUARY 1982

California Legislature

Joint Legislative Audit Committee

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January 19, 1982

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The Honorable President pro Tempore of the Senate
The Honorable Speaker of the Assembly
The Honorable Members of the Senate and the
Assembly of the Legislature of California

Members of the Legislature:

Your Joint Legislative Audit Committee respectfully submits the Auditor General's report which answers specific questions posed by the Legislature concerning the Department of Health Services' Newborn Screening Program.

Respectfully submitted,

WALTER M. INGALLS
Chairman, Joint Legislative
Audit Committee

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SUMMARY

The Department of Health Services is responsible for administering the State's Newborn Screening Program. This program tests all newborns for three hereditary diseases that cause severe mental retardation--phenylketonuria, galactosemia, and hypothyroidism. To answer specific questions posed by the Legislature, we reviewed certain aspects of the Newborn Screening Program, including the distribution of fee revenue collected for newborn screening, the timeliness of the testing program, and the contracts used to administer the program.

We found that the $24 fee collected from parents whose infants are tested has been deposited into a special fund for genetic disease testing and has not been used to support the program. Instead, loans from the State's General Fund have been used to offset program costs. These loan funds are being used in accordance with Section 309 of the Health and Safety Code. Further, hospitals usually charge the newborn's parents an additional fee for other costs associated with the Newborn Screening Program. Also, we found that the department has not collected fee revenue in a timely manner.

Our review also disclosed that laboratories under contract with the State have completed the screening for all three genetic diseases within two days after receiving a blood sample. If the laboratory obtains a positive test result, the newborn's physician is immediately notified by telephone. When it has been confirmed that an infant has a genetic disease, the physician, on the average, initiates treatment in 13.7 days for phenylketonuria, in 4.8 days for galactosemia, and in 13 days for hypothyroidism. Also, we found that the department sends written notification of all test results to hospitals and physicians within an average of 10 days from the date the blood sample is drawn.

In addressing the final group of questions, we reviewed various contracts used to administer the program. We found that the department furnished equipment to the laboratories under contract with the State so that more laboratories could bid on these contracts. This action also enabled the department to relocate to a new laboratory immediately, if necessary.

Additionally, the department contracts with 13 area genetic centers to provide follow-up and other services for the Newborn Screening Program. The amount budgeted for the area genetic centers for fiscal year 1981-82 is $787,672.

Finally, when an initial test result is positive and a confirmation test is required, this test is performed either by a state laboratory or by the Children's Hospital of Los Angeles. Department officials said that a centralized state laboratory is used because it can ensure that confirmation tests are done in a timely manner. The department contracts with the Children's Hospital of Los Angeles because the staff of this hospital have the most experience with confirmation testing for galactosemia. During our review, we found that the monthly rate paid by the department for this service should be reviewed.

INTRODUCTION

In response to a request by the Joint Legislative Audit Committee, the Office of the Auditor General has reviewed specific aspects of the Newborn Screening Program administered by the Department of Health Services. This review was conducted under the authority vested in the Auditor General by Sections 10527 and 10528 of the Government Code.

We were asked to answer certain questions about the Newborn Screening Program. These questions are grouped into three general areas, the first of which concerns both the distribution of fee revenue collected for newborn screening and the other costs associated with the program. The second area focuses on the timeliness of the testing program. The final area includes questions about contracts relating to laboratory equipment, the use of area genetic centers, and confirmation testing by outside laboratories.

Background

In 1965, legislation established a newborn screening program. This program tested all newborns for a hereditary disease called phenylketonuria (PKU), which causes severe mental retardation in children. Infants with PKU appear normal

at birth, but, at about the age of six months, these infants usually begin to show signs of mental impairment. If the disease is detected at an early stage and if the child is placed on a special diet, mental retardation can be prevented.

The legislation passed in 1965 designated the Department of Health Services as the state agency responsible for establishing a genetic disease unit to coordinate the various genetic disease programs. The PKU screening program was administered by the Hereditary Defects Unit, now the Newborn Screening Unit, in Berkeley. About 105 laboratories located throughout California participated in the PKU screening program. These laboratories used different screening methods to test newborns for the disease. When a positive test result was obtained, laboratory staff notified the newborn's physician and the department of the test results. If follow-up on initial positive tests was needed, the laboratory contacted the local health officer. State staff monitored these follow-up activities to ensure that they were completed.

Legislation, effective on October 30, 1980, expanded the Newborn Screening Program to include testing for two additional heritable disorders: galactosemia and hypothyroidism. Galactosemia is a disorder of the metabolism. Most infants born with galactosemia become critically ill soon

after birth, and some affected infants die from liver failure within days. Over half of those who survive become mentally retarded or have serious physical defects such as liver damage or cataracts. Early detection and prompt treatment of the disease will prevent such complications. Hypothyroidism, a deficiency of the thyroid gland, results in mental retardation. This disorder usually remains unrecognized until the infant is over three months of age; by that time, damage to the central nervous system has become irreversible. Again, treatment must be initiated as soon as possible after birth in order to prevent mental retardation. Treatment for galactosemia is conducted by placing the infant on a special diet, while treatment for hypothyroidism involves administering a thyroid hormone to the infant.

Under this new program, the State was divided into six laboratory service areas based upon geographical location. Six private laboratories were selected on the basis of competitive bids to provide the required screening for all newborns within an area. Each of these private laboratories tests from 45,000 to 74,000 blood samples per year. In addition to these six laboratories, the State contracts with two additional laboratories that are part of a prepaid health program. The Department of Health Services also contracts with 13 area genetic centers that serve as intermediaries for the laboratories, the hospitals, and the newborns' physicians.

During the first year of the Newborn Screening Program, approximately 401,000 infants were screened. Of this total, the number of infants diagnosed as having a genetic disease is as follows:

Phenylketonuria	18 infants
Galactosemia	6 infants
Hypothyroidism	108 infants

The department reported that 15 PKU cases were missed between 1966 and 1977. Additional missed cases have not come to the department's attention since 1977, but clinical experience indicates that there can be a lag time between the time a case is missed and the time it is detected.

If a child has one of these diseases and is not diagnosed or treated, he or she may require institutionalization. Department officials emphasized that it would be costly to institutionalize children with these diseases. For example, they stated it would cost an average of $1.5 million to institutionalize an infant with PKU for the duration of the child's life.

Currently, the fee charged to the newborn's parents for the testing is $24. This fee is collected from the parents by hospitals, which are in turn billed by the State. State statutes require that this program be fully supported by fee

revenue. Costs for the Newborn Screening Program from November 1, 1980, to June 30, 1981, totaled $5.3 million. The program's budget for fiscal year 1981-82 is $7.7 million. Appendix A presents a fact summary of the old and new Newborn Screening Program.

Scope of Review

This report answers specific questions regarding the financial operations of the Newborn Screening Program; the timeliness of the testing program; and the contracts pertaining to laboratory equipment, the use of area genetic centers, and the confirmation testing conducted by outside laboratories.

To provide the information requested by the Legislature, we reviewed financial data related to the Newborn Screening Program from July 1, 1977, through October 31, 1981. We also contacted 50 hospitals to obtain data regarding the associated costs of the program. To evaluate the timeliness of the procedures used in testing newborns, we collected data at the State's Genetic Disease Section in Berkeley, at three of the eight state-contracted laboratories, and at three of the thirteen area genetic centers. Finally, we analyzed specific contracts involved in the administration of the Newborn Screening Program.

In addition to addressing these specific questions, we obtained information regarding the genetic disease testing programs in five other states whose newborn screening programs are similar to the one operating in California. Appendix B provides this information.

We limited the scope of our review to responding to the specific questions asked about the Newborn Screening Program and to certain issues associated with these questions. We did not evaluate the effectiveness of the new program as compared with the program in operation before October 30, 1980.

STUDY RESULTS

In this section, we discuss three areas that encompass the specific questions we were asked to address. The first group of questions concerns the fee revenue and associated costs of the Newborn Screening Program. The second group focuses on the timeliness of the testing program. The third group includes questions about contracts relating to laboratory equipment, the use of area genetic centers, and confirmation testing by outside laboratories.

FEE REVENUE AND ASSOCIATED COSTS OF THE NEWBORN SCREENING PROGRAM

We were asked specific questions concerning the distribution of fee revenue collected for newborn screening and the costs associated with this screening program. In addition, during our study we also found certain problem areas. The questions and the problem areas are presented below.

- How is the $24 fee being used and what entities share in the fees collected? Also, is the distribution of fee revenue in compliance with Section 309 of the Health and Safety Code?

- In addition to the $24 fee, what other associated costs are charged to the newborn's parents for the testing?

In addition to addressing the above questions, we also discuss problems relating to the accounting procedures used by the Department of Health Services for billing and collecting fee revenue.

Distribution of Fee Revenue

We found that the revenue from the $24 fee has not been used to support the Newborn Screening Program but has been deposited into a special fund for genetic disease testing. Thus, loans from the State's General Fund have been used to offset the costs of the program. Most of these costs represent state administration and contracts for laboratory testing and follow-up services. Since the revenue from the $24 fee will eventually be used to repay the loans, the funds are being distributed in compliance with Section 309 of the Health and Safety Code.

Section 309 of the Health and Safety Code requires the Department of Health Services to charge a fee for the newborn screening tests. Currently, the fee charged to a newborn's parents for these services is $24. This fee is

collected from the parents by hospitals, which are subsequently billed by the department. Program costs, such as state administration, laboratory testing and follow-up, and equipment and loan repayments, are to be fully supported by fee revenue. From October 30, 1980, to September 30, 1981, the department had collected nearly $5.3 million in fee revenue.* However, none of this revenue was used to offset program costs. Instead, the department used loans from the State's General Fund to support the program.

Since the program's inception, the department has received over $6.8 million in loans from the State's General Fund. Department officials stated that these loans have been used to support the costs of program development and program operations until sufficient fee revenue is collected to fully support the program. However, we found that although the department had collected nearly $5.3 million in fee revenue since October 30, 1980, it continued to obtain loans from the State's General Fund through September 30, 1981. For example, during the first quarter of fiscal year 1981-82, the department obtained over $2.7 million in loans, even though it had collected over $2.7 million in fee revenue during the previous

* Of the $5.3 million, $2.1 million was collected between July 1981 and September 1981.

fiscal year. The revenue collected from fees has been deposited into a special fund for genetic disease testing. The total dollar amount borrowed from the State's General Fund and the total fee revenue collected by fiscal year are presented in Table 1.

TABLE 1

SUMMARY OF
GENERAL FUND LOANS OBTAINED AND FEE REVENUE
COLLECTED BY THE DEPARTMENT OF HEALTH SERVICES

Fiscal Year	Loans Received from General Fund	Fee Revenue Collected[a]
1977-78	$ 100,000	--
1978-79	451,177	--
1979-80	819,196	--
1980-81	2,745,853	$2,749,082
1981-82[b]	2,726,664	2,536,498
Total	$6,842,890	$5,285,580

[a] Fees were not collected until fiscal year 1980-81.

[b] The data is for the first quarter of fiscal year 1981-82.

Although state law requires the department to repay these loans by June 30, 1986, a repayment schedule has not yet been established, and an interest rate has not yet been determined. The department continued to receive loans from the General Fund because it did not notify the State Controller's Office to start using the fee revenue to offset program expenditures. As a result, the program is not expeditiously repaying its loans and is therefore incurring an additional interest expense. Further, these loans to the department reduce General Fund monies available for other programs.

While we were conducting our review, the department began preparing a loan repayment schedule and notified the State Controller's Office to begin using fee revenue to offset the costs of the program.

Distribution of Program Costs

We found that the total costs of the Newborn Screening Program exceeded $9.4 million from fiscal year 1977-78 through October 1981. This total includes $2.9 million for developing the program and $6.5 million for operating the program for the first 12 months (November 1, 1980, through October 31, 1981). State administration and equipment purchases represented approximately 86 percent of the costs

incurred during the developmental stages of the program. Contracts for laboratory testing and state administration have accounted for about 76 percent of the costs incurred since October 31, 1980, when the new program began. Expenditures for state administration include the staff salaries and the operating expenses of the Newborn Screening Units within both the department's Genetic Disease Section and the Clinical Chemistry Laboratory. Table 2 provides a detailed breakdown of the distribution of program costs.

TABLE 2

NEWBORN SCREENING PROGRAM COSTS FROM FISCAL YEAR 1977-78 TO 1981-82[a]

	Program Development Costs up to October 31, 1980				Operating Costs after October 31, 1980	
Expenditures by Category	1977-78	1978-79	1979-80	1980-81 July-October 1980	1980-81 November 1980-June 1981	1981-82 July-October 1981
State administration	$158,000	$410,000	$ 706,000	$230,000	$ 861,000	$ 353,000
Laboratory contracts	0	0	0	0	3,005,000	715,000
Area genetic center contracts	0	0	245,000	0	666,000	29,000
Other contracts	1,000	9,000	14,000	0	87,000	0
Technical and scientific supplies	0	21,000	83,000	34,000	577,000	83,000
Equipment	26,000	90,000	874,000	0	144,000	0
Total expenditures by year	$185,000	$530,000	$1,922,000	$264,000	$5,340,000	$1,180,000

Total Costs up to October 31, 1980	$2,901,000
Total Costs after October 31, 1980	6,520,000
Total Program Costs	$9,421,000

[a] This table includes actual expenditures and future obligations incurred for the Newborn Screening Program.

While reviewing the total costs of the program, we also analyzed costs as they relate to the $24 fee. This fee, which is based upon estimated costs, was established by the department before the program began. The department has included these costs as components of the $24 fee: state administration, laboratory contracts, and loan repayment. For each component of the fee, we compared actual costs to estimated costs for the first 12 months of the program. The comparison of estimated and actual costs by fee component is depicted in Table 3 below.

TABLE 3

COMPARISON OF ESTIMATED AND ACTUAL COSTS INCLUDED WITHIN THE $24 FEE

Fee Component	Estimated Cost[a]	Actual Cost[b]
State administration	$ 6.13	$ 3.71
Laboratory testing	8.46	9.28
Area genetic centers	2.19	1.73
Consultation and maintenance	.74	.22
Equipment purchases	.16	.36
Equipment rental	2.52	.97
Loan repayment (principal only)	3.85	3.76
Total	$24.05	$20.03

[a] The department estimated its program costs based upon 380,000 births.

[b] Actual costs are based upon 401,000 newborn screening tests.

As shown in Table 3, we found that the actual cost of the newborn screening process is $20.03. However, this figure does not include the interest expense payable on the loans from the State's General Fund. Information about this interest expense was not available during our review.

Compliance with State Statutes Concerning the Distribution of Fee Revenue

In our review, we found that all expenditures of the Newborn Screening Program were in compliance with state statutes. Section 309 of the Health and Safety Code allows the department to use the revenue collected from newborn screening fees for activities related to genetic diseases, including services other than newborn screening. For example, the Genetic Disease Section is authorized to award grants or contracts for demonstration projects to determine the feasibility of developing additional tests for genetic disorders or to begin developing necessary services for other genetic diseases.

Although the department can use these funds in other areas involving genetic diseases, we found that, with one exception, all program expenditures were used for the Newborn Screening Program. The exception relates to the salaries of the Chief of the Genetic Disease Section and of two clerical

positions also within the Genetic Disease Section. These salaries are funded totally by the Newborn Screening Program even though these employees spend part of their time on other genetic disease programs. We found, however, that such expenditures are in compliance with state statutes.

Associated Costs of the Newborn Screening Program

In addition to the $24 fee for screening newborns, hospitals usually charge the newborn's parents a fee for associated services, such as drawing blood samples. This additional cost varied among the hospitals we surveyed. Although this cost, as well as the $24 fee, is not generally covered by major group insurance policies, both costs are covered by Medi-Cal.

We selected a sample of 50 hospitals to determine what costs in addition to the $24 screening fee are charged to the newborn's parents. We found that 49 of the 50 hospitals in our review charged the newborn's parents an additional fee for services associated with the Newborn Screening Program. These services include drawing blood, handling blood samples, and administration. The additional costs associated with the Newborn Screening Program varied from $1 to $28, while the average cost for all hospitals was $9.20. Table 4 illustrates the range of these additional costs.

TABLE 4

RANGE OF COSTS ASSOCIATED
WITH NEWBORN SCREENING

Range of Associated Costs	Number of Hospitals
$0 - $5.00	7
$5.01 - $10.00	30
$10.01 - $15.00	7
$15.01 - $20.00	5
More than $20.00	1
Total	50

We also determined whether these costs and the $24 screening fee are generally covered by group insurance policies and Medi-Cal. We contacted three major medical insurance companies and found that most of their policyholders are not covered for either the newborn screening fee or the costs associated with the screening. However, Medi-Cal does pay for both of these costs.*

Billing and Collection Procedures

During our review, we also noted some problems in the department's procedures for billing and collecting newborn screening fees. As previously noted, the $24 screening fee is collected from the newborn's parents by the hospitals, which are in turn sent an invoice by the State. Hospitals are required to pay the State upon receiving the invoice.

* For outpatient care, Medi-Cal pays the $24 screening fee but limits the reimbursement for associated costs to $4.32.

Our analysis of the department's records indicated that the department is not promptly collecting fee revenue. For the period from October 30, 1980, through September 30, 1981, the department had billed hospitals for fees totaling $8.7 million, while it had collected fee revenue totaling only $5.3 million. Based upon this data, we estimate that the department has not collected over $2.6 million in fees that have been delinquent for over 30 days. The department could have used these fees to offset current expenditures or to reduce interest costs by repaying some of the loans from the State's General Fund. In addition, the State is losing interest income from this uncollected fee revenue.

We found that the department has a large number of uncollected fees because its accounting system has not rebilled hospitals for overdue payments. Department officials stated that they are presently identifying those hospitals whose accounts are delinquent and that they will be rebilling them accordingly. Also, the department plans to rebill delinquent accounts as a regular part of its current billing procedures.

CONCLUSION

To date, the Department of Health Services has not used fee revenue to support the Newborn Screening Program. Instead, loans from the State's General

Fund have been used to offset program costs. The expenditure of these loan funds has been in compliance with state statutes. We also found that in addition to the $24 fee, hospitals usually charge the newborn's parents an additional fee for other associated costs. Finally, we found that the department is not promptly collecting fee revenue.

RECOMMENDATION

To remedy the problems we identified regarding the fee revenue collected from the Newborn Screening Program, we recommend that the Department of Health Services continue its plans to

- Use fee revenue to offset program expenditures;
- Establish a loan repayment schedule; and
- Establish a system for rebilling and collecting delinquent accounts in a timely manner. The department should also consider charging a late fee for accounts that are delinquent.

TIMELINESS OF THE NEWBORN SCREENING PROCESS

We were also asked to respond to specific questions regarding the timeliness of the procedures for screening newborns. These questions are listed below.

- As of November 1980, how long does it take laboratories to complete newborn screening tests?
- For positive notifications, what is the time interval between the date of birth and the date the physician started treatment?
- Are written reports of test results furnished to hospitals and physicians in a timely manner?

To address these issues, we examined the timeliness of newborn testing procedures for the following:

- Laboratory testing--The time interval between the date the laboratory receives the blood specimen and the date the laboratory completes the test.
- Positive test notifications--The time intervals for various stages of the newborn screening process.

- Written notification of test results--The time interval between the date the hospital draws a blood specimen and the date the department sends written notification of the test results to the hospital and the physician.

Description of the Process for Screening Newborns

As stated in the Introduction, state law requires that each newborn be tested for three genetic diseases: phenylketonuria (PKU), galactosemia, and hypothyroidism. Early identification of these diseases is critical because mental deterioration, and, as in the case of galactosemia, death can result if treatment is not started promptly. To ensure that all newborns are tested immediately, state regulations require that each hospital review newborns' medical records within 14 days from the date newborns are discharged from the hospital to determine whether the screening has been accomplished.

Departmental regulations require that hospitals take a blood sample of an infant before the infant is discharged from the hospital, except when discharged within 24 hours. This blood sample is drawn from the newborn within two to six days after birth. The hospital sends the blood sample to one of the eight laboratories under contract with the State. The laboratory then tests the sample and enters the newborn's

clinical data and test results into a computer terminal. The terminals are linked to a central computer that is monitored by the staff of the department's Newborn Screening Unit in Berkeley.

If a laboratory obtains a test result that is presumptive positive--the first indication that the infant may have a genetic disease--the laboratory immediately telephones an area genetic center. These centers are responsible for ensuring that the infant's physician is immediately notified of the test results. The physician then arranges for a second blood sample and forwards it to either the State's Clinical Chemistry Laboratory in Berkeley or the Children's Hospital of Los Angeles for confirmation testing. Physicians are notified of the confirmation test results by an area genetic center nurse and treatment is started.* Physicians and hospitals also receive written notification of all test results.

* In cases where the results of a galactosemia test are positive, treatment is started prior to confirmation testing because early treatment is necessary to prevent death or severe physical defects.

Timeliness of
Laboratory Testing

State contract provisions require laboratories to initiate all screening tests within 22 hours after receiving a blood sample.* The department's screening procedures should enable the laboratories to complete the screening for all three genetic diseases within two days after receiving a blood sample. Our review of the laboratories' processing times showed that the laboratories are, in fact, completing the tests within two days.

To determine how long it takes laboratories to process blood samples, we reviewed three of the eight laboratories under contract with the State. Two of the laboratories are privately owned; the third is part of a prepaid group health care plan. At each laboratory, we sampled 100 newborn screening cases to determine the time interval between the date the laboratory received the blood specimen and the date the laboratory completed the tests.

At the two privately owned laboratories, we found that all the newborn screening tests were completed within two days after the specimen was received. At the third laboratory,

* The two laboratories serving a prepaid group health care plan are required to initiate testing within 26 hours after receiving a blood sample.

which serves clients of the prepaid group health care plan, the tests were completed within two days after the specimen was received, except for one specific hypothyroidism test. Under special provisions of the contract, this laboratory is allowed additional time to process this test.

Time Required for
Positive Test Notification

State law requires that the department make every effort to detect, as early as possible, genetic diseases that will lead to mental retardation or other physical defects. Our analysis of presumptive positive cases for PKU and galactosemia indicated that the time intervals between the separate phases of the newborn screening process varied. We found that for confirmed cases the average time interval between the date of birth and the date the physician started treatment was 13.7 days for PKU, 4.8 days for galactosemia, and 13 days for hypothyroidism.

We analyzed the amount of time required to send positive test notification to physicians for both presumptive positive and confirmed cases for these genetic diseases. As discussed previously, a presumptive positive case is one in which the initial test result indicates that the infant may have a genetic disease. Presumptive positive cases of PKU and galactosemia are subjected to confirmation testing, which

either supports or contradicts the initial test results.* A confirmed case is one in which confirmation testing indicates that there is a strong possibility that the infant does have a genetic disease.

For presumptive positive cases, we reviewed the time interval between the various phases of the newborn screening process; that is, from the date the infant was born to the date the physician was notified of the confirmed test results. We selected a sample of presumptive positive cases. Specifically, we chose 30 PKU presumptive positive cases discovered during the last 60 days at two of the eight laboratories under contract with the State. We also selected 17 suspected cases of galactosemia sent within an eight-month period to the Children's Hospital of Los Angeles for confirmation.

Table 5 illustrates the time intervals that we found in our sample cases for the various phases of the newborn screening process.

* Confirmation testing is not required for hypothyroidism.

TABLE 5

TIME INTERVALS BETWEEN VARIOUS PHASES OF THE NEWBORN SCREENING PROCESS FOR PRESUMPTIVE POSITIVE CASES

	Average Number of Days	
	Phenylketonuria	Galactosemia
Date of birth to date first blood specimen was drawn	3.5	3.1
Date first blood specimen was drawn to date presumptive positive test result received	2.0	4.6
Date of presumptive positive test result to date second blood specimen was drawn	6.4	8.8[a]
Date second blood specimen was drawn to date physician was notified of confirmed test results	5.6	5.9[b]
Total time interval from date of birth to date of confirmed test result	17.5	22.4

[a] This figure includes two cases for which the time intervals were 34 and 39 days. If these two cases were excluded, the time interval would be 5.1 days.

[b] This figure includes one case in which the time interval was 35 days. If this case were excluded the time interval would be 3.8 days.

We also reviewed all confirmed positive cases for each disease discovered between October 30, 1980, and October 31, 1981. Table 6 shows the time interval between the date of birth and the date the physician started treatment.

TABLE 6

TIME REQUIRED FOR CONFIRMED
POSITIVE TEST NOTIFICATION
OCTOBER 30, 1980, TO OCTOBER 31, 1981

Disease	Number of Cases Identified	Average Number of Days from Date of Birth to Date Physician Started Treatment
Phenylketonuria	18	13.7
Galactosemia	6	4.8
Hypothyroidism	77[a]	13.0

[a] At the time of our review, the time interval could only be calculated for 77 of the 108 confirmed positive cases.

In addition, we examined the timeliness of PKU test notification for the Newborn Screening Program since 1966. We found that the average time interval between the date of birth and the date the physician started treatment under the previous program varied each year from 11 days to 37 days.* Appendix C illustrates the time required to identify PKU cases since 1966.

It should be noted that in both presumptive positive and confirmed positive cases, the timeliness of the newborn screening process is not entirely within the department's control. For example, the department cannot control the time

* For 1970, the average time interval was 37 days. However, during this year, one case took 167 days to complete because the patient moved to another state.

it takes the physician to arrange for another blood sample to be drawn or the time it takes to locate the infant once the child leaves the hospital.

Timeliness of Written Notification of Test Results

We found that the department is sending written notification of test results to hospitals and physicians within an average of 10 days. Thus, hospitals generally are able to comply with the state regulation requiring them to review a newborn's medical records within 14 days from the date the infant is discharged from the hospital. However, because we were unable to determine when the hospitals entered the newborn screening test results into the infant's medical records, we could not ascertain whether they were complying with the time requirements set forth in the state regulations.

To determine how long it took for hospitals and physicians to receive the department's written notification of test results, we sampled the medical records of 200 infants. Our analysis of these records indicated that hospitals and physicians are sent written notification of test results within an average of 10 days from the date the first blood sample is drawn.

In addition, we reviewed infants' medical records at six hospitals to determine whether they contained the results of the newborn screening tests. Title 17 of the California Administrative Code requires each hospital to review the newborn's medical records within 14 days from the date of the infant's discharge to ensure that the newborn screening tests are completed and that the results are properly recorded. Of the 59 medical records we reviewed, we found that 58 contained written documentation of the test results. For the one record that did not contain the test results, we found that the infant was still a patient at the hospital and had not yet been tested.

However, although personnel within the medical records section in each of the six hospitals we surveyed knew of the State's 14-day requirement, staff at only one hospital stamped the date of receipt on the test results before placing them in the infants' medical records. Therefore, we could not determine if cases we examined were reviewed in accordance with the time specified in the state regulations.

CONCLUSION

In our examination of the timeliness of the newborn testing procedures, we found the following:

- The laboratories under contract with the State completed screening for all three genetic disorders within two days after receiving the blood specimen;

- The time intervals for testing presumptive positive cases for PKU and galactosemia varied between each phase of the newborn screening process;

- When it was confirmed that an infant had a genetic disease, the physician, on the average, started treatment in 13.7 days for PKU; in 4.8 days for galactosemia; and in 13 days for hypothyroidism;

- The department sent written notification of the test results to hospitals and physicians within an average of 10 days from the date the blood sample was drawn.

Because five of the six hospitals we surveyed were not stamping the date of receipt on the test results before placing them in the infants' medical records, we could not determine if cases were being reviewed within the time limit specified by state regulations.

RECOMMENDATION

To ensure compliance with state regulations, we recommend that the Department of Health Services consider requiring all hospitals to stamp the date of receipt on all notifications of test results before placing these notifications within infants' medical records.

CONTRACTS INVOLVED IN ADMINISTERING THE NEWBORN SCREENING PROGRAM

We were asked these questions regarding the various contracts used to administer the program:

- What is the department's cost of and rationale for allowing laboratories under contract to use state-owned equipment?

- What are the functions and costs of the area genetic centers under contract?

- What is the department's rationale for additional confirmation testing at one contracted laboratory and at the state laboratory in Berkeley?

In addition to addressing these specific questions, we also discuss problems relating to the department's monitoring of the contracts for the area genetic centers and its method of paying for confirmation testing at one hospital.

Cost of and Rationale for Allowing Laboratories under Contract to Use State-owned Equipment

The department furnished equipment costing approximately $619,500 to the laboratories under contract with the State. We learned from department officals that the

department purchased the equipment to allow more laboratories to bid on contracts for the Newborn Screening Program. They stated that because the equipment is specialized, some laboratories may not have wanted to purchase it for only 22 months, as specified in the request for proposal for the contract. Additionally, we found that department officials wanted the department to own the equipment in case it was necessary to relocate a laboratory immediately.

Before October 30, 1980, laboratories were required to supply their own equipment to conduct newborn screening tests. Most of these laboratories used a manual testing method. On October 30, 1980, the department implemented a new system that used standardized testing methods and automated equipment. The department therefore provided equipment, which conducts testing procedures and prints test results by an automated process, to six of its eight laboratories under contract.* Department officials said that such a system would enable them to monitor the effectiveness of the Newborn Screening Program more efficiently. In addition, laboratory staff use state-owned computer terminals to report test results to the Genetic Disease Section in Berkeley. To eliminate the manual operation of these terminals, the department is

* The department did not provide testing equipment to the two laboratories that are part of a prepaid group health plan; for these laboratories, the department provided only computer terminals.

implementing a computer system that will report results directly to the Genetic Disease Section from the testing equipment at the laboratories. This system will become operational early in 1982.

The department purchased most of the necessary testing equipment and all of the computer equipment used by the laboratories. The testing equipment that was not purchased is being leased through an agreement that includes both the equipment and the chemicals used to conduct certain tests. Under the terms of this agreement, the total cost to the State is based upon the amount of equipment leased and the quantity of the chemicals used. The cost of the purchased equipment totaled approximately $463,000 or about $77,200 for each laboratory. The cost of the leased equipment per year, excluding chemicals, is approximately $156,600 or $26,100 per laboratory.

To determine the department's rationale for supplying equipment to the laboratories, we interviewed department officials. These officials stated that the equipment was supplied by the department to allow more laboratories to bid on contracts. For example, if laboratories were required to purchase such specialized equipment for only a 22-month contract, they may not have been willing to submit a bid

because of the cost of the equipment. We also interviewed staff at several laboratories under contract to determine if they would have submitted bids if the department had not furnished the equipment. The laboratory staff stated that they would have submitted bids but that the bid amounts would have been higher to compensate for the purchase of the required equipment.

Another reason given by the department for supplying equipment to the laboratories was the potential need for the State to relocate the laboratories immediately. Department officials stated that if a laboratory failed to comply with contract provisions and if the contract were terminated, the department could more quickly obtain the services of a new laboratory by immediately transferring the state-owned equipment to that laboratory. Thus, the regular screening process would not be delayed while a new laboratory purchased the necessary testing equipment.

Functions of the Area Genetic Centers

The State contracts with 13 area genetic centers (AGCs) to provide follow-up and other services. The purpose of these centers is to ensure that physicians are promptly notified of cases for which test results are positive and to

provide other related follow-up activities. The amount budgeted for the AGCs for fiscal year 1981-82 is $787,672. In our review of the department's contracts with the AGCs, we discovered that there were inconsistencies between the amount budgeted for an AGC's operations and the number of births in that AGC's regions. We also found instances in which the staff at some centers worked in other genetic programs and therefore worked less than the time specified in the state contract on newborn screening.

Before October 30, 1980, laboratory personnel notified physicians of any positive test results. The local county health officers also provided some follow-up services related to the program. Department officials stated that this system was incomplete and that a more comprehensive system was needed to provide these follow-up services. They also said that only a genetics program affiliated with a university could provide the entire range of services necessary for adequate follow-up.

To implement the new program, the department awarded contracts to 13 area genetic centers, which include two facilities that service prepaid health plan hospitals. A department official said that all 13 AGCs were needed to provide statewide coverage.

The AGCs serve as intermediaries between the regional laboratories and the newborns' physicians or parents. The contracts require each AGC to provide a full-time nurse, a clerk, and a part-time physician to provide the required services. The staff of these centers perform a variety of functions including the following: notifying physicians of all initial and confirmed positive test results; providing follow-up services, including referrals for diagnostic testing and treatment; counseling physicians and parents regarding the treatment of genetic diseases; and interpreting state policies and procedures for hospitals, physicians, and laboratories. Because of the time limits involved with this audit, we did not evaluate whether the current follow-up system is more effective than the system that was in operation before October 30, 1980.

For fiscal year 1981-82, the contracts for all 13 AGCs totaled $787,672. Contract amounts for individual AGCs ranged from $41,918 to $92,546. A department official stated that the contracts were awarded on a noncompetitive basis. The amount of individual contracts was the result of negotiations between the department and each AGC.

We examined the contracts with the AGCs to determine whether the funds budgeted for the centers corresponded to staff workloads. We based our analysis on the number of births

in each AGC region. Although there are other factors that could be considered in budgeting funds for these centers, the number of births should be a major consideration since it has a direct effect on the workload of the centers.

We found that there were inconsistencies between the amount budgeted for an AGC and the number of births in the regions served by that center. Some of these inconsistencies are illustrated in Table 7.

TABLE 7

ANALYSIS OF AREA GENETIC CENTERS' BUDGETS BY NUMBER OF BIRTHS AND STAFF WORKLOAD

Area Genetic Centers	1981-82 Fiscal Year Budget Amount	Number of Births in 1980	1981-82 Fiscal Year Staff under Contract Percentage of Full Time		
			Physician	Nurse	Clerk
A	$56,462	16,202	5%	100%	20%
B	$59,468	25,996	5%	100%	50%
C	$52,429	29,643	3%	100%	20%

During our survey of area genetic centers, we also found instances in which the staff at some centers worked less than the time specified in the state contract on newborn screening. However, staff at these centers worked on other genetic programs. Department officials explained that while they do monitor the services provided by the centers, they do not verify the amount of time worked by the AGC staff.

Confirmation of Test
Results by Outside Laboratories

Confirmation testing is performed by the State's Clinical Chemistry Laboratory in Berkeley and by the Children's Hospital of Los Angeles (CHLA). Department officials explained that the department can ensure that confirmation tests are promptly performed through a centralized laboratory. These officials also said that the State contracts with the CHLA because its staff has the most experience in confirming tests for galactosemia. While other states pay the CHLA a set fee for each completed test, the department pays the CHLA a monthly rate. We determined that the department should reexamine its contract with the CHLA because the department may be paying too much for that facility's services.

The initial newborn screening tests are conducted by the eight laboratories under contract with the State. When a newborn's initial test result is positive for PKU or galactosemia, a confirmation test is required. For hypothyroidism, no further screening tests are required. The department's Clinical Chemistry Laboratory in Berkeley performs the confirmation testing for PKU.* The laboratory also retests

* The two prepaid health plan laboratories conduct their own confirmation testing, except testing for galactosemia, which is performed by the CHLA.

specimens for galactosemia and hypothyroidism when a regional laboratory obtains results that are not conclusively positive or negative.

The department contracts with the Children's Hospital of Los Angeles to perform confirmation testing for galactosemia. If an initial test result is positive, a new blood sample is drawn and sent to the Children's Hospital of Los Angeles for specialized testing. The amount contracted for these services is $6,000 per month or $72,000 per year.

Department administrators stated that it is imperative that these diseases be identified as early as possible since any delay in treatment could cause mental retardation or death. These officials also indicated that the State's Clinical Chemistry Laboratory could provide maximum control in ensuring that these tests are done in a timely manner. The State contracts with the Children's Hospital of Los Angeles for galactosemia testing because its personnel are highly qualified and have had years of experience conducting tests for this disorder.

During our review of the State's contract with the Children's Hospital of Los Angeles, we found that other states send blood samples to this laboratory for galactosemia testing

but that the CHLA does not have a contract with any other state for such testing. Other states pay a fee of $73.25 for each completed test. Since the CHLA conducted only 276 tests for the department from November 1980 through September 1981, in effect, the cost per test was $239.13.* This means that California is paying about $46,000 more per year for services that are not provided to other states. These services include testing seven days a week, initiating testing within two hours after the blood sample is received, completing the test within 24 hours after initiation, and telephoning test results to the AGCs immediately. As noted earlier in the report, treatment of galactosemia is undertaken immediately after the initial test is deemed presumptive positive. Therefore, treatment is not delayed while awaiting CHLA confirmation.

CONCLUSION

The department's rationale for furnishing state-owned equipment to laboratories under contract was to allow more laboratories to bid on contracts for testing. Some laboratories may not have been willing to purchase this testing equipment for only a 22-month contract. In addition, the equipment was furnished

* The department does not pay on a per test basis; however, we calculated a per test cost based upon the monthly rate.

to the laboratories so that the department could relocate to a new laboratory immediately if necessary.

The department contracts with 13 area genetic centers to provide follow-up and other services for the Newborn Screening Program. The amount budgeted for the centers in fiscal year 1981-82 totaled $787,672. While we did not determine the cost-effectiveness of the area genetic centers, there were some inconsistencies between the amount of funds budgeted for the centers and the staff workloads at these centers. Also, the staff at some centers are working less than the time specified in the state contract on newborn screening.

Confirmation testing is performed by a state laboratory and by the Children's Hospital of Los Angeles. Department officials said that the state laboratory can provide maximum control in ensuring that these tests are done in a timely manner. Also, the department contracts with the CHLA because this hospital has the most experience with confirmation testing for galactosemia. Further,

while other states pay the CHLA a fee for each completed test, the department pays this laboratory a monthly rate.

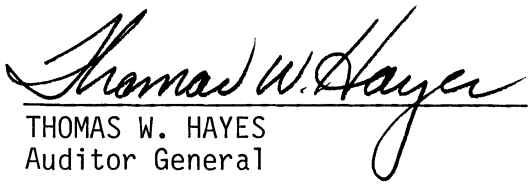
RECOMMENDATION

To improve its monitoring of the area genetic centers, we recommend that the Department of Health Services

- Consider the number of births in each center's region when computing each center's budget; and
- Require the AGCs to document the amount of time that state-contracted staff work on the Newborn Screening Program.

To determine whether the state contract with the Children's Hospital of Los Angeles should remain at the current monthly rate, we recommend that the Department of Health Services reexamine the contract with the CHLA to determine whether it should pay a fee for each completed test rather than a monthly rate. The department should also assess whether the costs for these additional services are appropriate.

Respectfully submitted,



THOMAS W. HAYES
Auditor General

Date: December 29, 1981

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Mr. Thomas W. Hayes
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Dear Mr. Hayes:

Thank you for providing this Department with an opportunity to respond to your audit entitled "Newborn Screening Program Response to Questions Posed by the Legislature".

We want to express our appreciation for the professional way this audit was conducted and commend the competence of the staff assigned.

The details of our response are as follows:

Introduction

The Auditor General's Office has conducted a limited review of certain aspects of our newborn screening program. Nevertheless, the Department is pleased to note that the Auditor's findings provide objective confirmation of the efficiency and effectiveness of our first year's operation of expanded newborn screening. Although the program is meeting its objective in terms of early detection and treatment at a reasonable cost, we do not consider the program fully implemented and welcome the recommendations for improvement. We would like to respond to the three specific areas covered in the report and recommendations in each section.

1. Fiscal Recommendations

Use of Fee Revenue

Appropriate instructions have been given to the Controller's Office so that at this time all program expenses will be paid from Genetic Disease Testing Fund.

Loan Repayment

We would first like to point out that funds deposited in the Genetic Disease Testing Fund were accumulating interest for the General Fund. The question of interest payment on the loan has not been finally determined. Should interest be ultimately charged, it will not affect the fee to the parents.

The Department initiated payment of the loans as soon as it was clear that sufficient funds were available to cover program operations. Initially collections from the hospitals were slow and it is only in the last three months that the fund has increased to the point where we can repay the General Fund.

Loan repayment instructions issued to the Controller have resulted in the transfer of $4,116,226 to the General Fund to repay the principal on the first three loans. We anticipate no problems in completely repaying the last remaining loan well in advance of the 1986 date. An evaluation of revenues will be made on an ongoing basis to determine when payments can be made on this loan. Department of Health Services will work with Department of Finance to reach a mutually agreeable schedule.

Rebilling Unpaid Invoices

We are developing the necessary computer programs to accomplish rebilling on an automatic basis. In addition we are considering the legality of other options, such as offset of payment due hospitals or late charges, to expedite payment. This will be a high priority effort.

2. Timeliness

The Auditor General reported results which are better than California's old PKU program and the Newborn Screening Programs of other states. Nevertheless, we feel confident that the time intervals can be further reduced by improvements which we are making in the system, such as use of courier rather than mail for all recall specimens.

The Auditor used the interval from birth to treatment which is one important measure of the program. However, this measure includes the results of actions on the part of hospital staff and family physicians which constitute medical practice such as additional diagnostic tests at private laboratories, and which are not controlled by State policy or regulations. A more specific measure of the actual program operation is the length of time from the point where a specimen is collected to begin the screening process until the report is made to the physician of the final test results which ends the process over which we have control. By this measure, an initial and confirmatory (recall) test was completed and the physician notified of result in an average of 8.7 days for PKU and 9.3 days for galactosemia. Hypothroid tests were completed in 4.4 days.

An important clinical measure of the program is the age that treatment is initiated. The earlier the treatment, the better the result. The Auditors obtained this data with the following results: For galactosemia, the six cases were treated (i.e., milk feedings stopped) when the infant was on the average 4.8 days of age. All cases were under treatment by seven days of age. The 18 PKU cases were under treatment when they were on the average 13.7 days of age, and the 108 cases of hypothyroidism were treated when they were on the average 13.0 days of age. Among the 108 cases there were five exceptional cases that exceeded 35 days. Excluding these cases, the average age of child at time of treatment was 11.5 days.

It is important to recognize that some of the delay is the result of failure to observe state testing regulations. All tests are to be collected by the sixth day of life, but some are not. Physicians are required to obtain recall specimens of presumptive positive PKU and galactosemia within 48 hours of notification, and this was not done in many cases. The Department is taking action to remind physicians again of their responsibilities. The Department will advise hospitals to date stamp all newborn screening results before posting in the medical records, as recommended by the Auditors.

3. Contracts

The Auditors discussed Area Genetic Center follow-up only in terms of present operations. The term "follow-up" has a broader implication than just expediting positive results. The workload of the Area Genetic Center is increasing as we implement follow-up activities designed to ensure completeness of testing. This includes checks on babies discharged without testing, babies whose first blood sample would not permit completion of tests, babies transferred from one hospital to another, home births, etc. Following the Auditor General's recommendation, the Department will include in its program audits of the area, genetic contracts documentation of time spent on newborn screening activities.

The Department will also examine the workload of each Area Genetic Center in more detail and adjust contracts accordingly as necessary. It should be pointed out that budget adjustments suggested would have negligible impact on total program costs or on the fee.

Confirmation Lab Contract

When this contract was negotiated, the number of initial positive galactosemia tests needing confirmation by the contractors was unknown and was estimated to be higher than actual experience. In order to reduce the number of false positives, the Department introduced screening modifications including use of a more objective quantitation of final results, collection of a second filter paper specimen on a selected group of false positives rather than a venous specimen, and close control over specimen handling by hospitals. These measures have been successful in maintaining a low false positive rate and, therefore, a low frequency of utilization of galactosemia confirmation.

On the other hand, it is clinically important to rapidly determine if any initial presumptive positive result represents detection of a case. The total range of services in the contract are a necessary part of this process and deserve reimbursement. The Department will, however, in accord with the Auditor General's recommendation reexamine the services, terms and conditions of this contract to assure that costs are appropriate.

Sincerely,

Beverlee A. Myers
Director

FACT SUMMARY OF THE OLD AND NEW NEWBORN SCREENING PROGRAM

	Old Program	New Program
Genetic disease tested	Phenylketonuria (PKU)	Phenylketonuria (PKU) (Galactosemia Hypothyroidism)
State-approved test	Guthrie Inhibition Assay or McCaman-Robbins Fluorometric Procedure	Automated Fluorometric Procedure (PKU) (plus four additional tests)
Number of laboratories conducting the tests	105	8
Entity responsible for follow-up services[a]	Laboratory, state, and local health officers	Area genetic centers
Fee charged for newborn testing	Varied from $3.00 to $17.00 among the laboratories[b]	$24.00[c]

[a] Follow-up services include notifying physicians of positive test results and of the need for an additional blood sample.

[b] This fee included only the costs of laboratory testing for PKU.

[c] This fee includes these costs: initial and confirmation laboratory testing for three diseases, state administration, loan repayments, and the services of the area genetic centers.

COMPARISON OF NEWBORN SCREENING PROGRAMS IN CALIFORNIA WITH THOSE IN OTHER STATES

	California	Texas	New York	Pennsylvania	Wisconsin	Oregon[a]
1. Date program initiated	1966	1965	1965	1965	1978	1961
2. Number of births (Estimated for fiscal year 1980-81)	403,000	273,000	235,000	160,000	75,000	40,000
3. Number of genetic diseases tested	3	4	8	2	4	8
4. Methods used to send blood specimens	U.S. Mail (50%) Courier Service (50%)	U.S. Mail	U.S. Mail	U.S. Mail	U.S. Mail (90%) Courier Service (10%)	U.S. Mail (99%) Courier Service (1%)
5. Number and type of laboratories conducting tests	8 Privately operated	2 1 state-operated(99%) 1 privately operated(1%)	3 1 state-operated(80%) 2 county-operated(20%)	1 Privately operated	1 State-operated	1 State-operated
6. Entity responsible for following up on positive cases	Area genetic centers	State's newborn screening section	State laboratory and private laboratories	State laboratory	State laboratory	State laboratory
7. Method used to notify physicians of test results						
- Positive - Negative	Verbal Written	Verbal Written	Verbal Written	Verbal Written	Verbal Written	Verbal Written
8. Current fee charged for testing	$24	$0	$0	$0	$8	$6.50[b]

[a] Oregon also performs newborn screening for four other states.
[b] Each infant is tested twice at $8.25 per test; therefore, the total fee is $6.50.

TIMELINESS OF TESTING FOR PHENYLKETONURIA BEFORE AND AFTER OCTOBER 30, 1980

Year	Average Number of Days between the Date of Birth and the Date Physician Started Treatment
1966	17.2
1967	18.4
1968	12.2
1969	13.1
1970	37.0[a]
1971	21.3
1972	22.7
1973	22.0
1974	22.8
1975	22.7
1976	14.8
1977	13.0
1978	12.6
1979	14.8
1980	11.1[b]
1981	13.7[c]

[a] As explained in the text, during this year one case took 167 days to complete because the patient moved to another state.

[b] This figure represents the period from January 1, 1980 to October 29, 1980.

[c] This figure represents the period from October 30, 1980 to October 31, 1981.

cc: Members of the Legislature
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