California State Auditor

BUREAU OF STATE AUDITS

Department of Health Services:

The Genetic Disease Branch's Fee Setting, Billing, and Collection Processes Need Improvement, and Its Regulations Do Not Warrant Emergency Status

September 1997
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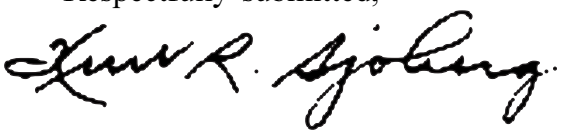
September 4, 1997 97105

The Governor of California
President pro Tempore of the Senate
Speaker of the Assembly
State Capitol
Sacramento, California 95814

Dear Governor and Legislative Leaders:

As requested by the Joint Legislative Audit Committee, the Bureau of State Audits presents its audit report concerning the Department of Health Services' Genetic Disease Branch (branch). This report concludes that the branch has weaknesses in fee setting, billing, and collection. As a result, the public may be paying more than necessary for prenatal screening services. Additionally, the branch has written off $9.7 million in prenatal testing fees since July 1993 and may not collect an additional $6.5 million. Moreover, branch staff neglected to bill Medi-Cal promptly for another $1.1 million and these fees may now be uncollectable. Finally, branch regulations no longer warrant emergency status because most of them concern administrative changes rather than true emergencies.

Respectfully submitted,



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Summary

Audit Highlights . . .

In administering its screening programs, the Genetic Disease Branch uses inadequate methods for fee setting, billing, and collection. Our review indicated that the branch:

- ☑ ***Charged the public fees that exceeded costs by 13 and 12 percent.***
- ☑ ***Wrote off $9.7 million in uncollectable patient fees since July 1993 and may not collect another $6.5 million.***
- ☑ ***Neglected to bill Medi-Cal $1.1 million.***
- ☑ ***Has kept $775,000 in overpayments of fees.***

In addition, the department does not need specific authority to adopt branch regulations as emergencies.

Results in Brief

The Department of Health Services' Genetic Disease Branch (branch), which provides a valuable public service by screening for genetic disorders, has displayed serious weaknesses in the methods it uses to establish fees for its prenatal and newborn screening programs. The branch also uses faulty procedures to bill and collect fees from patients who take prenatal tests. In fact, because fees have significantly exceeded costs for the prenatal testing program, the public may be paying more than necessary for program services. In addition, the branch has written-off $9.7 million in prenatal testing fees since 1993, and it may not be able to collect from patients an additional $6.5 million. Finally, branch regulations adopted by the Department of Health Services (DHS) no longer need emergency status because most involve administrative changes and do not address emergencies.

Under the department's direction, the branch offers to California residents various genetic services, including those furnished by its prenatal and newborn screening programs. For a single fee for each patient, the programs screen pregnant women and newborn babies to detect genetic disorders and then provides follow-up counseling and diagnostic services when necessary.

Focusing on the structure and administration of these two programs, our review revealed the following shortcomings at the branch:

- During fiscal year 1995-96, the branch charged fees that exceeded costs by 13 and 12 percent for the prenatal and newborn testing programs, respectively. Some excess fees resulted from branch assumptions that did not materialize.

- Because it has an ineffective process for billing and collecting prenatal testing fees from patients, the branch has written off $9.7 million in uncollectable fees since July 1993, and it may soon add an additional $6.5 million to this figure.

- Branch staff were unaware that they had not billed the California Medical Assistance Program (Medi-Cal) $1.1 million for prenatal tests provided between July and November 1995, and these fees may now be uncollectable. Even if Medi-Cal pays the fees, the branch has lost an estimated $65,000 in interest earnings.

- Because it returns overpayments only when requested, the branch is holding approximately $775,000 in overpaid fees for prenatal screening tests.

- The branch generally complies with state laws and regulations on contracting, but it has not always followed good business practices. From 1990-1996, the branch did not seek competitive bids for the laboratory testing contracts that it awarded.

Besides examining fees and contracting at the branch, we assessed whether the department uses its emergency regulatory powers appropriately when it adopts branch regulations. Our analysis showed that the department's emergency regulatory authority is unnecessary. Even though the Health and Safety Code designates as emergencies all branch regulations affecting the prenatal and newborn screening programs, many branch regulations that the department has adopted concern administrative issues rather than true emergencies. Also, the Administrative Procedures Act enables the department to adopt emergency regulations when emergencies arise.

Further, the department has not benefited from oversight by the Office of Administrative Law (office), which makes certain that agencies complete the regulatory process promptly and also repeals regulations when necessary. Because the Health and Safety Code exempts from repeal any regulations governing the newborn and prenatal screening programs, the department could misuse its regulatory powers.

Without supervision by the office, the department in one instance failed to complete the regulatory process on time. The department also violated the Administrative Procedures Act by increasing fees for both programs and modifying its prenatal screening tests without first adopting regulations to authorize these changes.

Recommendations

To improve its fee setting, billing, and collection processes for the prenatal and newborn screening programs, the branch needs to do the following:

- Establish procedures for monitoring and analyzing separately the revenues and costs for each program.

- Examine fees for each program at least once a year and then adjust patient fees if the difference between costs and fees is significant.

- Reduce prenatal fees so that they more closely reflect the costs of the program.

- Offer each prenatal screening patient various ways to make payments. The branch should also require the patient to select a payment option and to make a payment at the time of testing.

- Bill more health plans directly for prenatal testing fees.

- Include on patient invoices language that highlights overdue balances, and continue to bill patients who fail to pay.

- Establish a process for attaching a patient's tax refund for the amount due if the patient does not pay her bill for the prenatal screening test.

- Continue trying to obtain the $1.1 million in prenatal fees due from Medi-Cal.

- Develop procedures to refund the overpayments of prenatal testing fees that it currently holds, and promptly refund any overpayments it receives in the future.

Further, the branch needs to ensure that it receives the highest-quality services at the most reasonable prices and makes the best use of public resources. To achieve these goals, the branch should continue to use a competitive bidding process to award contracts for laboratory testing services.

Finally, to make certain that the department adopts emergency regulations only when necessary and that it complies with the Administrative Procedures Act, the following changes need to occur:

- The Legislature should remove language from the Health and Safety Code that designates as emergencies all regulations related to the prenatal and newborn screening programs.

- The Legislature should also delete language in the Health and Safety Code that requires the department to file branch regulations directly with the Secretary of State and that exempts the regulations from possible repeal by the Office of Administrative Law.

- Before implementing program changes, the department should comply with the Administrative Procedures Act by adopting regulations that cover those changes.

Agency Comments

In its response, the department provides additional information regarding the branch's fee setting and collection efforts. Although it generally concurs with our recommendations, it does not agree that the Office of Administrative Law should review branch regulations.

Introduction

Background

The mission of the Department of Health Services (department) is to protect and improve the health of all California residents. To accomplish this mission, the department administers a variety of programs to promote a preventive, coordinated, accountable, high-quality, and affordable health care system for all residents. The department's effort includes programs for testing pregnant women and newborn babies for genetic disorders.

The Genetic Disease Branch (branch) administers the department's genetic services programs. The branch's goal is to reduce for all Californians the burden of disability and death caused by inherited or genetically determined disorders and congenital malformations. To accomplish its goal, the branch provides early diagnosis, prenatal detection, education and counseling, prevention, and referral for treatment. The prenatal and newborn screening programs, which are the branch's two main programs, test pregnant women and newborn babies for certain genetic disorders. The branch also operates the Genetic Disease Laboratory, which is responsible for monitoring laboratories that contract with the branch and providing quality control over the screening programs.

The Prenatal Screening Program for Pregnant Women

Called the California Expanded Alpha-Fetoprotein Screening Program, the current prenatal screening program is voluntary, and its goal is to offer a screening test to all women in California who are between 15 to 20 weeks pregnant. The prenatal program began in 1986 when the State offered to pregnant women a test to screen for neural tube defects in their fetuses (unborn babies). Such defects include spina bifida, which is a genetic disorder that results in severe crippling, mental retardation, or death of the child after birth. Known as a single marker test, the screening procedure also detects a small percentage of certain chromosomal disorders, such as Down syndrome. In July 1995, the branch expanded the prenatal program to include tests that improve the detection of chromosomal disorders. The expanded prenatal program

employs a triple marker test that analyzes the existence of genetic disorders based on three substances contained in a pregnant woman's blood.

During fiscal year 1995-96, approximately 355,000 women chose to take tests under the branch's prenatal program. A $115 fee covers all necessary program services. (Women who have undergone certain genetic testing before their 15th week of pregnancy receive only the single marker test; the branch charges a $57 fee for this test.) The prenatal program covers the woman's initial blood test and all necessary follow-up diagnostic testing. A screening test can only assess the risk that a genetic disorder exists. Thus, if the screening test indicates a higher-than-normal risk of a genetic disorder, the woman receives from the State, at no additional cost to her, both counseling and the necessary diagnostic testing to confirm whether the unborn baby has the genetic disorder. The cost of these follow-up services is much greater than the $115 fee. In fiscal year 1995-96, more than 20,000 women (5.6 percent of women participating) chose to have follow-up services.

State regulations require prenatal care providers (clinicians) to offer every pregnant woman the prenatal screening test. If the woman accepts, she has a blood sample drawn by her clinician or any laboratory. The woman's blood sample is sent to one of eight private laboratories under contract with the branch. These laboratories analyze the blood samples using equipment and chemicals provided by the branch. The laboratories enter the test results, along with applicable demographic data, into computer terminals linked to the branch's computer system. Before the branch releases the results to the patient's clinician, its Genetic Disease Laboratory performs a quality control check and the branch's computer system interprets the test results and demographic data to assess the risk that the unborn baby may have a genetic disorder.

When test results indicate that a pregnant woman's unborn baby has a higher-than-normal risk of a genetic disorder, the branch communicates the test result to a coordinator at one of 14 area genetic centers. The coordinator then contacts the pregnant woman's clinician to arrange for follow-up services to determine if the unborn baby has the genetic disorder. These services are provided by one of 26 prenatal diagnostic centers approved by the branch and are included in the cost of the original screening test. The coordinator supplies the woman's clinician with the names of the prenatal diagnostic centers in the area; the clinician chooses where to send the woman for follow-up services.

For women who need follow-up services, the prenatal diagnostic centers initially provide genetic counseling, an ultrasound of the unborn child, and any necessary diagnostic testing. To determine whether the unborn child has the genetic disorder, the prenatal diagnostic center performs an amniocentesis (drawing of fluid from the pregnant woman's uterus) and karyotype (analysis of the chromosomes in this fluid). This procedure yields highly accurate results, which are available in about two weeks. If the results show a genetic disorder, the pregnant woman receives additional genetic counseling to explain the results and to discuss her options. At that point, the State's prenatal program services end, and the woman must decide any further steps she wishes to take.

The Screening Program for Newborn Babies

Almost all states offer newborn screening tests to their residents, and the newborn screening program is mandatory in California. Under this program, approximately 540,000 newborns in California received tests for certain genetic disorders during fiscal year 1995-96.

The newborn screening program began in 1966 when the State required that all newborns receive tests for phenylketonuria (PKU). Babies born with PKU cannot fully metabolize protein foods. If the babies go untreated, they can become mentally retarded. This disorder affects only about one in 20,000 newborns; however, before the State initiated this program, one out of every 100 residents of state mental hospitals had this disorder. In October 1980, the State expanded its newborn screening program to test for two more genetic disorders. In February 1990, the State added screening tests for sickle-cell disease and related disorders. Early detection of these genetic disorders permits treatment to prevent mental retardation or, in the case of sickle-cell disease, fatal infections.

Usually, testing of newborns begins at the hospitals where the babies were born. Before each baby goes home, the hospital collects a few drops of blood from the newborn's heel on a piece of filter paper. The hospital then sends the newborn's blood sample to one of eight private laboratories under contract with the branch. (The same eight laboratories perform both the prenatal and newborn testing.) As in the case of prenatal testing, these laboratories analyze newborns' blood samples and enter the test results, together with applicable demographic data, into computer terminals linked to the

branch's computer system. Before the branch releases the test results to physicians and their patients, its Genetic Disease Laboratory reviews the results for accuracy.

For a test result that indicates a higher-than-normal risk of a genetic disorder, the laboratory immediately telephones the results to a coordinator at one of 13 area genetic centers. The coordinator then contacts the newborn's physician to arrange for additional testing to confirm whether the infant has the genetic disorder and to offer the latest information on diagnosis and treatment. For certain disorders, a contract laboratory or the branch's Genetic Disease Laboratory performs follow-up tests.

The fee for the newborn screening test is $42 and covers the initial blood test, any follow-up tests, and counseling for parents of newborns diagnosed with sickle-cell disease.

Screening Programs at a Glance

	Prenatal Screening	***Newborn Screening***
Who receives tests?	Women between 15-20 weeks pregnant (optional)	Newborns (required)
What genetic disorders does the test detect?	In the unborn child: Neural tube defects like spina bifida, abdominal wall defects, and chromosomal disorders such as Down syndrome and Trisomy 18	Phenylketonuria, galactosemia, congenital primary hypothyroidism, and hemoglobin disorders, including sickle-cell disease
What services does the branch provide?	Initial blood test, genetic counseling, ultrasound, amniocentesis, chromosome analysis to diagnose if a genetic disorder exists	Initial blood test, follow-up tests to diagnose if a genetic disorder exists, counseling for parents of newborns with sickle-cell disease
What do the tests detect or prevent?	Detects disorders that cause mental retardation, severe crippling, or death	Detects disorders and allows treatment to prevent the development of mental retardation, slow growth, and fatal infections
What is the fee?	$115 for triple marker $57 for single marker	$42

Scope and Methodology

At the request of the Joint Legislative Audit Committee, we performed a comprehensive review of the branch and its authority to issue emergency regulations. To gain an understanding of the branch's responsibilities, we reviewed state laws and regulations relevant to the branch and the programs it administers. In addition, we interviewed branch personnel and reviewed their manuals and procedures so that we could identify and understand the branch's major functions and activities.

Because fiscal year 1995-96 was the most recent year for which the department's accounting records were complete, we took revenues and costs from that year to analyze the prenatal and newborn testing fees. Using the department's accounting records, we calculated the amount the branch spent to administer its screening programs during this period. We adjusted for any errors or other known costs. For example, the branch misallocated to fiscal year 1995-96 $2.8 million in equipment costs that were actually fiscal year 1996-97 expenditures. Further, because the branch historically has not collected a significant portion of its prenatal testing fees, we reduced the revenue figures to allow for uncollectable accounts. We examined the branch's collections of prenatal testing fees over the past three years and arrived at an estimate of 13 percent as the allowance for uncollectable fees. We then compared the revenues and costs to determine if the prenatal and newborn testing fees are reasonable.

In addition, we compared fees collected against fees billed to determine if the branch collected all fees charged. We then analyzed the adequacy of the branch's collection procedures.

To assess whether the branch complied with state laws and regulations and used cost-effective means to procure goods and services, we reviewed the sections of the Public Contract Code, Health and Safety Code, State Administrative Manual, and State Contracting Manual that apply to the branch's contracts. We also analyzed contracts, vendor agreements, purchase orders, bidding documents, and other documents supporting the branch's contracts. To determine the appropriateness of the branch's use of certain contracts, we also obtained a legal opinion from the Legislative Counsel of California (legislative counsel). Additionally, we interviewed branch and Genetic Disease Laboratory managers, reviewed their economic interest statements, and found no indications that the managers hold any economic interests in contractors doing business with the branch. Moreover, we found no indications of bias toward contractors. Finally, to determine

whether the branch's method of delivering services through contractors is appropriate and effective, we reviewed the responsibilities of these contractors and analyzed relevant workload statistics. This review showed that the branch's use of contractors is generally an appropriate and effective means to deliver services.

To determine whether the branch appropriately used its authority to issue emergency regulations, we reviewed the laws and policies governing how state agencies issue regulations. In addition, we interviewed Office of Administrative Law staff and obtained an opinion from the legislative counsel to clarify our understanding of these laws. We then identified all regulations the branch issued since 1987 and assessed the branch's compliance with these laws. To determine if the branch still needs authority to issue emergency regulations, we categorized the types of regulatory changes the branch made in the last ten years. Finally, we assessed whether losing this authority would hinder the ability of the branch to administer its genetic screening programs effectively.

Chapter 1

The Genetic Disease Branch Established Fees That Significantly Exceed Its Costs

Chapter Summary

State law requires the Genetic Disease Branch (branch) to set fees to cover the costs of the prenatal and newborn testing programs. However, our analysis of each program's fiscal year 1995-96 revenues and costs revealed that, for both programs, the branch charged the public amounts in excess of its costs. Specifically, the average fee of $111.43 for each prenatal test exceeded costs by $14.05 (13 percent), and the $42 newborn testing fee exceeded costs by $5.20 (12 percent). These fees were higher than costs because certain assumptions the branch used when computing the fees for fiscal year 1995-96 did not come true. Further, once the branch sets the fees every year, it assesses the appropriateness of the fees by reviewing the overall balance in its program fund rather than by analyzing the revenues and costs of each program. As a result, branch management does not know the extent to which each fee is adequate to cover the cost of the related program.

Background

The Health and Safety Code, Section 125000(b), gives the branch authority to charge a fee for the prenatal and newborn screening tests. Because this section also states that the branch may establish and periodically adjust the amount of any fee to meet the costs of the program, fees should be adequate to meet the branch's expenses.

The branch adjusts fees when it makes changes to the screening programs or when costs increase. Basically, the branch projects its future costs to administer the prenatal and newborn screening programs. Because the programs must be self-supporting, this estimate of costs is also the estimate of the total fee revenue needed to support the programs. The branch then estimates the number of participants in each program and computes the fees for both programs by dividing costs by the number of participants.

The branch last adjusted the prenatal testing fee in July 1995, when it began offering the triple marker test and established a fee of $115 for this screening service. Earlier, in January 1994, it had increased the fee from $55 to $57 for the single marker test. At the same time, the branch adjusted the newborn testing fee from $40 to $42 to cover increased costs for the newborn program.

The Prenatal Testing Fee Was Significantly Higher Than Related Costs

In fiscal year 1995-96, the prenatal fee was $14.05, or 13 percent more than branch costs.

According to our comparison of fees and related costs for the prenatal testing program, the fee during fiscal year 1995-96 was $14.05, or 13 percent more than branch costs. To match prenatal testing fees with costs, we identified the branch costs that correlated with each fee. For fiscal year 1995-96, these costs covered the following: personnel (branch and Genetic Disease Laboratory salaries and benefits), operating expenses (branch and Genetic Disease Laboratory overhead, supplies, and equipment), laboratory screening equipment and supplies, laboratory testing services, area genetic centers (coordinator services), prenatal diagnostic centers (counseling and diagnostic testing), and estimated uncollectable fees.

We based our analysis on the weighted average prenatal fee because the branch does not maintain separate expenditure records for the single and triple marker tests even though it charges a different fee for each test. The weighted average fee represents the average amount the branch billed for each test. Table 1 shows a breakdown of the weighted average prenatal fee charged to each patient compared to prenatal program expenditures for fiscal year 1995-96.

The branch miscalculated fees because it expected more women to test positive.

In fiscal year 1995-96, the prenatal testing fee exceeded costs primarily because certain assumptions used to calculate the $115 fee for the expanded prenatal screening test did not materialize. Specifically, the branch initially believed that 9 percent of all women taking the prenatal test would have a positive test result. Instead, only 5.6 percent of the women tested positive. In addition, the branch believed that more older women would choose to take this test than did so. Because fewer women tested positive, fewer required genetic counseling or diagnostic tests to determine whether their unborn babies had genetic disorders. These changes meant that the cost related to diagnostic centers, the most expensive component of the prenatal program's costs, were $7.4 million less than anticipated for fiscal year 1995-96. Moreover, unless

Table 1

Comparison of the Weighted Average Prenatal Testing Fee With Related Costs Fiscal Year 1995-96

*Weighted average fee per test**		$111.43
Estimated uncollectable fee		(14.49)
Net weighted average fee per test		$ 96.94
Less costs per test		
Personnel	7.75	
Operating expenses	12.62	
Laboratory equipment and supplies	14.69	
Laboratory testing services	5.40	
Area genetic centers	6.98	
Prenatal diagnostic centers	35.45	
Total cost per test		82.89
Fee per test in excess of costs		$ 14.05

*The weighted average fee is based on 317,715 triple marker tests at $115 per test and 20,856 single marker tests at $57 per test.

the percentage of women using the follow-up services increases or a major program change occurs, we expect that revenues for the prenatal testing program will continue to exceed costs in fiscal year 1996-97 and future fiscal years.

The Newborn Testing Fee Was Considerably Higher Than Corresponding Costs

We analyzed the newborn testing fee and found that the fee exceeded by $5.20 (12 percent) the branch's costs to administer the newborn screening program during fiscal year 1995-96. As with the prenatal testing fee, we determined the branch costs that corresponded to each newborn testing fee. These costs covered personnel, operating expenses, laboratory equipment and supplies, laboratory testing services, area genetic centers, and diagnostic and counseling services. Table 2 compares the newborn testing fee with these related program costs.

When the branch adjusted the newborn testing fee in 1994, it intended to use the increase to lease new laboratory testing equipment and cover increased operating costs. However, plans for leasing the new equipment were delayed, and the branch is just now finalizing the lease. Had the branch leased the new equipment in fiscal year 1995-96, the costs to administer the program would have approximated the fees. In

Table 2

Comparison of the Newborn Testing Fee With Related Costs Fiscal Year 1995-96

Fee per test		$42.00
Estimated uncollectable fee		0.00
Net collectable fee per test		42.00
Less costs per test:		
Personnel	$7.46	
Operating expenses	6.22	
Laboratory equipment and supplies	7.16	
Laboratory testing services	9.59	
Area genetic centers	4.22	
Diagnostic and counseling services	2.15	
Total cost per test		36.80
Fee per test in excess of costs		$ 5.20

addition, because the branch has not yet finalized the lease and because it experienced no major cost increases during fiscal year 1996-97, newborn testing fees will continue to exceed costs in fiscal year 1996-97.

Fees in Excess of Costs Will Create a Surplus in the Genetic Disease Testing Fund

For 1995-96 alone, the branch generated $7.6 million in excess revenue from the prenatal and newborn testing fees.

If it does not adjust its prenatal testing fee to better reflect corresponding costs, the branch could produce a large surplus in its Genetic Disease Testing Fund (fund), which the branch uses to account for all revenues and expenditures of both programs. For fiscal year 1995-96 alone, we estimate that revenue from prenatal and newborn testing fees exceeded related costs by $7.6 million. Because the branch's costs will increase when it leases the new laboratory equipment for the newborn screening program, revenues from this program will probably approximate branch costs by fiscal year 1997-98. However, because the cost for the prenatal diagnostic centers was approximately the same in fiscal year 1996-97 as it was in fiscal year 1995-96, we expect that the prenatal fee will continue to exceed costs. Further, if it continues to receive $14.05 per prenatal fee in excess of program costs, and if participation remains the same, the branch will add approximately $4.8 million to the fund balance each fiscal year.

Of course, a small reserve is necessary to cover future developments and other contingencies, but a growth of $4.8 million per fiscal year is too much.

Beginning in fiscal year 1997-98, the branch plans to purchase two new computer systems for the prenatal and newborn screening programs without increasing existing fees. One system will handle screening program functions and the other will deal with accounting and business tasks; the additional cost of these two systems is $10.1 million. However, because we expect the cost of the newborn program to approximate its fees in fiscal year 1997-98, the branch will either have to increase its newborn fees or use prenatal fees to pay for the newborn screening program's share of the computer systems' costs.

The Branch Needs To Assess Regularly the Appropriateness of Its Fees

The branch assesses the adequacy of its program fees by monitoring the balance in the fund as a whole. The branch maintains separate expenditure records for the prenatal and newborn screening programs and attempts to keep fees generally equal to program expenditures. However, the branch does not analyze separately the revenues and expenditures of each program to ensure that fees equal costs. The branch's main concern is to keep the fund solvent, and it has done so.

We agree that solvency is important and that the branch's method provides a good overview of the fund. However, because it performs only an overview of the entire fund between fee-setting dates, the branch may not notice when revenues from one test are inadequate to cover its costs so long as an adequate fund balance exists. Thus, branch staff may inadvertently use fees from one test to subsidize the costs of another. A superior approach would also involve periodic monitoring of the revenues and costs for each screening test. In addition, the method would include analyses that resemble the comparisons of fees and costs presented earlier in this chapter. Such an approach would alert the branch when the costs of one test exceed revenues and when fees require adjustment.

Recommendations

To ensure that patients' fees more closely resemble the costs required to run the prenatal and newborn programs, the branch should develop a process to allow separate monitoring and analysis of each program's revenues and costs. Further, the

branch needs to analyze separately each program's fees at least once a year, and it should adjust the fees if the difference between fees and costs is significant. The branch should also reduce the prenatal screening fee to a level that more closely reflects the costs of the program.

Chapter 2

The Genetic Disease Branch Has an Ineffective Process for Billing and Collections

Chapter Summary

The Genetic Disease Branch (branch) needs to improve its process for billing and collecting prenatal testing fees. Because its current procedures do not ensure that individual patients pay the fees they owe, the branch has written off fees of $9.7 million since July 1993, and it may be unable to collect an additional $6.5 million. Further, branch staff were unaware that they had not billed the Medi-Cal program for approximately $1.1 million in prenatal testing fees. These fees may be uncollectable because Medi-Cal usually does not pay charges more than one year old. Moreover, the branch is holding approximately $775,000 in overpaid prenatal fees because it issues fee refunds only when requested to do so.

Finally, in most instances the branch has complied with state contracting laws and regulations. However, from 1990 to 1996, it did not seek competitive bids for its laboratory testing services contracts.

Background

The Health and Safety Code requires that the prenatal and newborn screening programs be self-supporting. Thus the branch charges fees to program participants to cover its costs of providing these screening tests. For the newborn screening program, the branch bills hospitals for each test provided, and it generally collects all fees charged. Under the prenatal screening program, the branch directly bills some third parties, such as the California Medical Assistance Program (Medi-Cal) and a few health plans. (Medi-Cal is a state and federal program that provides medical care assistance for needy and low-income people.) However, the branch bills patients directly for almost half of prenatal testing fees. During each month in fiscal year 1995-96, the branch sent an average of 12,500 initial patient bills totaling $1.3 million. Patients are responsible for paying the bills or forwarding them to their insurance companies.

The billing process begins even before paperwork reaches the branch's accounting unit. When a pregnant woman visits her clinician and decides to take the prenatal screening test, she initiates the process. The clinician fills out a prenatal test form that lists patient and billing information, including the patient's name, address, social security number, and health plan subscriber number or Medi-Cal number. The woman's test form and blood sample then go to one of the eight laboratories authorized by the branch to complete the screening test. Besides analyzing the blood, the laboratory enters the information from the test form into a computer terminal linked to the branch's computer database that produces the bills. Two weeks after the test, the branch mails the initial bill to the patient. If she does not respond, the branch sends out three additional bills over the next three months. If the patient does not pay after the fourth bill, the branch makes no further attempt to collect the fee. The patient will only begin receiving additional invoices if her account shows activity, such as an address change, or if the patient makes a partial payment. The branch's policy is to write off billings more than two years old.

The branch has failed to collect an average of 34 percent of prenatal fees billed to patients.

Although the branch collects almost all of the fees charged to Medi-Cal or to health plans, it has difficulty collecting the prenatal fees billed to patients. Over the past three fiscal years, the branch has failed to collect an average of 34 percent of the prenatal fees it billed to patients. As a result, the branch did not collect an average of 13 percent of the total prenatal fees it billed during the same period. Because of these collection inefficiencies, $14.49 of each fee paid by patients and health plans has subsidized nonpaying consumers.

The Branch Has Written Off Millions of Dollars in Fees Because of Weak Billing and Collection Procedures

Since July 1993, the branch has written off $9.7 million in uncollected fees because its procedures for billing and collecting prenatal testing fees are inadequate. Current patient billings indicate that an additional $6.5 million in fees are potentially uncollectable because they are more than one year old.

For several years, branch staff have been aware of deficiencies in the billing and collection procedures, and the branch has taken some action to address these deficiencies. Specifically, in February 1997, the branch completed a feasibility study for a new computer accounting system that branch management believes will correct several problems in the billing process, such as missing patient addresses and billing for co-payments,

and also improve collections. The branch began accepting credit card payments for prenatal testing fees. Further, the branch also recently reassigned two staff to its accounting unit to assist with billing. Nonetheless, despite these accomplishments, more improvement is needed.

Several aspects contribute to the branch's difficulties in collecting prenatal fees from individual patients. For example, unlike health care providers, the branch bills patients in arrears for the test rather than collecting fees at the time of service. Health care providers usually require patients without insurance to pay for services before the services are provided. Additionally, most health plans require patients to make co-payments when they visit their doctors. The branch does not require patients to make payments or to select payment options at the time of their blood tests. These options could include paying in full, paying by credit card, or making a partial payment and having the branch bill the patients later for the balance. By not requiring that patients choose payment options, the branch is not taking advantage of additional means to reduce billings and increase collections. Further, the branch could provide postage-paid envelopes with the prenatal test forms so that patients could mail their payments to the branch when they have their blood drawn. Additionally, for those patients who choose to pay by credit card, the branch could provide space on the test form for credit card information. The branch could then bill the credit card company directly.

The branch does not require patients to make payments or select payment options at the time of service.

The branch could also improve collections of prenatal testing fees by billing health plans directly. Although the branch has agreements with some health plans, it does not have agreements with many of the large health plans in California. For example, the branch has direct billing agreements with only 5 of the 16 largest health maintenance organizations operating in the State that have more than 100,000 members. When the branch does not have a direct billing agreement, it relies upon patients to forward to their health plans the bills for prenatal testing.

If it bills health plans directly, the branch can also reduce its number of individual patient billings. For example, in May 1997, the branch sent more than 24,000 initial bills and almost 58,000 follow-up bills to individual patients. At the same time, the branch billed only 119 health plans for 5,600 patients. Historically, the branch has collected almost 100 percent of its health plan billings. By billing more health plans for patients' prenatal testing fees, the branch could reduce billing costs, streamline its billing process, and increase collections.

The branch has also failed to use invoices that indicate when a bill is overdue. Currently, each of the four bills sent to patients is identical and contains no language to emphasize that payment is past due. Moreover, because collection efforts end after the fourth bill, a patient can ignore all billing notices without penalty.

Finally, the branch does not take advantage of various offset programs, such as attaching the patient's tax refund if the patient fails to pay. In February 1994, the department's internal auditors recommended that the branch start performing tax refund offsets to improve collections, but the branch has not yet done so. Instead, the branch states that it is waiting until an anticipated new computer system is in place. Once in place, the system will implement a tax refund offset process to provide annual collections of more than $700,000.

The Branch Did Not Bill Some Prenatal Fees to Medi-Cal

The branch failed to bill Medi-Cal for 10,476 patients and thus did not collect more than $1.1 million.

The branch directly bills prenatal testing fees to Medi-Cal for eligible patients and generally collects the full amount due. However, the branch did not bill Medi-Cal for tests provided to 10,476 patients between July and November 1995. Using a weighted average fee of $111.43, the average amount billed for each test, we estimate that the fees for these tests totaled over $1.1 million. According to the branch chief, Medi-Cal did not receive invoices for the prenatal tests because of a computer programming error. Until we brought the problem to their attention, the branch staff were unaware of this error; however, they agreed that the branch needed to pursue collection from Medi-Cal. In July 1997, the branch submitted these claims for payment. Unfortunately, Medi-Cal denied the claims because they were too old. Nonetheless, the branch chief will continue to negotiate with Medi-Cal for payment. Even if Medi-Cal agrees to pay the fees, the branch has already lost an estimated $65,000 in interest earnings because of the billing delay.

The Branch Returns Overpayments of Prenatal Fees Only Upon Request

Occasionally, the branch receives overpayments on patient billings for prenatal screening tests. An overpayment can occur when a patient or a health plan pays the same bill twice. During fiscal year 1995-96, the branch issued 678 refunds totaling $43,000. However, the branch has a policy not to issue refunds unless patients or health plans request them.

The branch is holding $775,000 that belongs to health plans and patients.

Since January 1995, the branch has received but not refunded overpayments totaling more than $775,000 for about 9,500 accounts. Thus the branch is holding money that rightfully belongs to others. According to the branch chief, this policy exists because a significant amount of research is necessary to verify an overpayment and the branch's priority is to collect revenue.

The Branch Generally Meets All Contracting Requirements

In general, the branch uses proper contracting and procurement procedures in compliance with state laws and regulations. However, the branch has not always followed good business practices when awarding contracts for laboratory testing services. Specifically, the branch did not use a competitive bidding process to award some contracts and thus did not ensure that the State obtained a competitive price for laboratory testing services and that other private laboratories had an opportunity to participate. The competitive bidding process allows state agencies to choose qualified vendors that present the lowest bids for services.

The California Code of Regulations requires the branch to use a competitive process to award contracts to laboratories for newborn testing services. Further, according to the State Contracting Manual, the branch should award contracts such as those for both newborn and prenatal laboratory testing services through a competitive bidding process unless the branch demonstrates a good business reason for not doing so. Every year, the branch awards two of the six regional laboratory contracts for terms of three years each. Over a six-year period beginning in 1990, the branch did not solicit competitive bids for any of these six contracts. (The branch also has two contracts with a large prepaid health plan; these contracts are not required to be bid competitively.) The branch began seeking competitive bids in 1996, and so far it has awarded four contracts. In most cases, more than one laboratory bid for these contracts. Further, we found that the branch generally paid a lower price for these services when it resumed awarding the contracts competitively. Specifically, one of the laboratories reduced its price for newborn screening tests from $9.02 to $8.10, or $.92 per test. Additionally, all four reduced their prices for prenatal screening tests, resulting in a decrease in the average price from $4.79 to $4.34, or $.45 per test for the four laboratories.

According to branch documents, the branch skipped competitive bidding from 1990 until 1996 because it did not have the staff to direct the bidding process and maintain other program functions at the same time. For instance, branch staff felt that it could not concurrently complete the bidding process and add new screening tests, replace worn or obsolete equipment, redistribute workload, and train contract laboratories. However, these situations are fundamental to the program; the branch needs to be prepared to meet such needs on an ongoing basis. To address its staffing problem, the branch recently added a position that will oversee the laboratory contracts, among other duties. The branch now needs to ensure that it continues to solicit competitive bids for its contracts.

Recommendations

To improve its collection of prenatal testing fees charged to patients, the branch should consider the following changes:

- Requiring patients to select a payment option and make a payment when tested.

- Offering patients more payment options, such as the opportunity to pay in full, pay by credit card, or make a partial payment.

- Increasing the amount of direct billing to health plans.

- Indicating on invoices when payments are overdue and continuing to bill patients until it collects in full.

- Establishing a tax refund offset process for overdue bills.

To collect the approximately $1.1 million in fees due from Medi-Cal, the branch should continue trying to obtain payment of these fees.

To ensure that it does not hold overpayments of prenatal testing fees, the branch should develop procedures to refund the overpayments that it currently possesses. Further, the branch should develop procedures to refund promptly any overpaid fees that it receives in the future.

Finally, to make certain that it receives the best services at the most competitive prices, the branch should continue to use a competitive bidding process to award contracts for laboratory testing services.

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Chapter 3

Genetic Disease Branch Regulations Do Not Warrant Emergency Status

Chapter Summary

Because many regulations affecting the Genetic Disease Branch's prenatal and newborn screening programs (branch regulations) are not truly emergencies, the Department of Health Services (department) does not need specific authority to adopt all branch regulations as emergencies. After all, the Administrative Procedures Act (act), which governs California's rule-making process, provides a method for departments to adopt emergency regulations if an emergency arises. Nonetheless, the Health and Safety Code requires the department to adopt branch regulations as emergencies. The Health and Safety Code also exempts branch regulations from review or repeal by the Office of Administrative Law (office). However, we determined that branch regulations should not be exempt from the office's review or repeal because the office provides important controls to ensure that regulations meet the act's standards and follow the act's regulatory process, which the department abused when it recently adopted an emergency regulation. Finally, although the department has generally complied with the act's rule-making process, we noted two instances in which the department delayed the adoption of two branch regulations for 41 and 23 months after the Genetic Disease Branch (branch) implemented program changes and increased program fees.

Emergency Authority Is Unnecessary for Branch Regulations

The Health and Safety Code, sections 125000 and 125070, states that branch regulations shall be considered an emergency and necessary for the immediate preservation of the public peace, health and safety, and general welfare. According to the Legislative Counsel of California (legislative counsel), these code sections require the department to adopt and file every branch regulation as an emergency, even if no emergency exists. Ordinarily, after a lengthy public hearing process, a state agency files regulations with the Secretary of State, and they become effective. In contrast, emergency regulations are filed and become effective before the public hearing process

begins. Thus emergency regulations go into effect much more quickly than do nonemergency regulations. The authority to adopt emergency regulations can be important when the department is developing new programs or making changes to established programs that affect the public health and safety. However, this authority is not appropriate when the department makes routine administrative changes to established programs.

Not All of the Branch's Regulatory Changes Are Emergencies

We reviewed branch regulations filed by the department during the past ten years and found that the department adopted all of these regulatory changes as emergencies. Some of the regulations changed existing programs substantially, but many changes were administrative. Specifically, the department adopted ten emergency regulation packages since 1987. One consisted of a significant program change, and four involved administrative changes. The remaining five incorporated both types of changes.

An emergency regulation must address the immediate preservation of the public's peace, health and safety, or general welfare.

According to the act, for a department to adopt a regulation as an emergency, the regulation must be necessary for the immediate preservation of the public peace, health and safety, or general welfare. Using this standard, we assessed whether the branch's regulatory changes made over the last ten years constituted emergencies. The following are examples of regulations we reviewed:

In December 1990, the department adopted branch regulations to increase the newborn testing fee and to limit the amount that hospitals can charge for blood specimens. According to the branch, the fee increase was an emergency because it needed to raise funds quickly so that it could implement a new test to detect sickle-cell disease. A fee increase to implement a new program, unlike a routine fee increase, may meet the criteria for an emergency. However, limiting the amounts that hospitals can charge for collecting blood specimens does not appear necessary for the immediate preservation of the public peace, health and safety, or general welfare.

In April 1992, the department adopted branch regulations to eliminate contracts and establish a vendor reimbursement system. The branch planned to implement this system by July 1992.

According to the branch, if the department had been required to file these regulations as a nonemergency, it would not have been able to meet this self-imposed July deadline, and the filing delays may have caused a lapse in services. However, altering methods of paying for services is an administrative change that does not appear to qualify as an emergency. Instead, the branch needs to be prepared to accommodate contracting changes because they are inevitable in the administration of its programs.

In June 1996, the department adopted branch regulations to implement the prenatal triple marker test and to allow noncontract laboratories to provide prenatal testing programs in addition to that offered by the State. Because the triple marker identifies more genetic disorders than does the single marker test, implementation of the triple marker test may be necessary for the preservation of the public health. However, regulations allowing noncontract laboratories to conduct prenatal screening services do not appear to be for emergencies. The branch agrees that this last change does not constitute a public health emergency.

According to the act's standard, not all of the branch's regulatory changes were emergencies; instead, many involved routine administrative changes that did not warrant emergency status.

The Department Can Adopt Emergency Regulations Under the Act's Provisions

Currently, the department adopts all branch regulations as emergencies using authority granted to it by the Health and Safety Code. However, this authority is unnecessary because the act states that the department can adopt a regulation as an emergency if the regulation is essential for the immediate preservation of the public peace, health and safety, or general welfare.

Under existing law, branch regulations do not receive a review by the Office of Administrative Law.

If the department were to adopt branch regulations as emergencies under the act, it would be required to submit those regulations to the Office of Administrative Law (office) for review and approval before the regulations could become effective. The office's review is important because it provides an independent examination of regulations to ensure they meet

the act's standards. Currently, branch regulations are not subject to this review because the Health and Safety Code requires the department to submit its regulations directly to the Secretary of State for filing. According to the branch chief, submitting branch regulations to the office will cause unnecessary delays.

However, we determined that, contrary to the branch chief's statement, subjecting branch regulations to the office's review will not significantly delay their effective dates because the act requires the office to complete its review within ten days. Additionally, the office does not disapprove emergency regulations arbitrarily. Since January 1994, the office has received 85 proposed emergency regulations from the department and has approved 80 within its ten-day review period. After the office disapproved 5 of the 85 emergency regulations, the department resubmitted 3, and the office approved one within 24 days, one within 60 days, and one within 65 days of the initial disapproval. The department did not resubmit the other 2 proposed emergency regulations.

Subjecting branch regulations to review by the Office of Administrative Law will not significantly delay their implementation.

Branch Regulations Should Not Be Exempt From Repeal by the Office

The Health and Safety Code sections requiring the adoption of branch regulations as emergencies also exempt those regulations from repeal by the office. We believe that the office provides a valuable control over the regulatory process because its authority to repeal regulations assures that departments do not adopt regulations without proper public disclosure and comment. In 1996, the department demonstrated the need for this oversight and control function when it adopted emergency regulations but did not complete the regulatory process within the time mandated by the act.

The act directs departments to complete a rule-making process after they adopt and file emergency regulations with the Secretary of State. This process includes publishing a notice of regulatory change, providing a public comment period, and holding a public hearing within 120 days of filing emergency regulations. Further, the act requires departments to submit to the office for review documentation evidencing completion of this process. If the office determines that departments did not complete the process, the act gives the office authority to repeal the emergency regulations.

Despite these provisions of law, the department adopted and filed the branch's emergency regulations but did not complete the rule-making process. Specifically, on June 14, 1996, the

In one instance, the department did not publish changes or provide for a public comment period, and it held the public hearing more than several months late.

department filed the branch's emergency regulations to expand the prenatal screening program and allow noncontract laboratories to conduct prenatal screening programs that parallel the State's program. However, the department did not publish a notice informing the public of the changes or provide a public comment period. Additionally, even though it received requests to schedule a public hearing, the department did not hold one until May 28, 1997, more than seven months later than required.

The department does not consider its failure to publish a public notice or hold a public hearing within 120 days a violation of the act because its legal counsel believes the Health and Safety Code exempts the regulations from the act's requirements. In contrast, the legislative counsel stated that the Health and Safety Code only exempts the regulations from review, approval, and repeal by the office; the department must still complete the act's rule-making process when it adopts emergency regulations.

Normally, the office could have repealed the department's emergency regulations when, after 120 days, the department did not provide evidence that it completed the rule-making process. However, the office could not repeal the regulations because the Health and Safety Code states that it cannot do so. Without the office's oversight and authority to repeal regulations, no system ensures that the department completes the rule-making process in a timely manner.

For the other regulations adopted by the department over the last ten years, the department generally complied with the act. Specifically, the department published notices of regulatory changes, provided public comment periods, and held public hearings.

The Department Implemented Program Changes Before Adopting Regulations

According to the act, departments must adopt as regulations all rules, orders, or standards before it enforces them. Additionally, the legislative counsel stated that the department must adopt in regulations its program changes and fee increases before implementing them. However, on two recent occasions, the department put into effect significant program changes and also increased program fees before filing regulations for those changes and fee increases. According to the office, rules, standards, and orders departments implement but do not adopt in regulations are "house" or "underground regulations" that are invalid and unenforceable when challenged in court.

On one occasion, in January 1994, the department increased the fees from $55 to $57 for its prenatal screening program and raised fees from $40 to $42 for its newborn screening program; however, it did not file regulations to adopt the changes until June 1997, approximately 41 months later. On another occasion, the department modified its prenatal testing program to convert the screening test from a single marker to a triple marker and to increase the fees. Although the department began this program in July 1995, it did not adopt the emergency regulations that expanded the testing until June 1996, approximately 11 months later, nor did it adopt regulations to increase the fees until June 1997, approximately 23 months later. The branch had originally developed regulations in August 1993 to address the fee increases and program changes, but internal departmental reviews and subsequent revisions impeded completion of the filing process.

The department implemented significant program changes before establishing appropriate regulations.

According to the department's deputy director in charge of the branch, the department raised newborn and prenatal fees and modified the prenatal screening program without first adopting regulations because the department has sufficient legal authority to do so. Furthermore, the changes were necessary to cover program costs or to protect the public health. In the case of the prenatal screening program, the contract laboratories were already performing the triple marker test, and the branch had new software in place to generate the test results before the department was able to resolve all of the issues related to these regulations. Because delaying implementation of the triple marker test would have meant withholding information from a woman about her risk of carrying an unborn baby with a genetic disorder, the department began using the test before necessary regulations were in place. Although it is important to make significant program changes as soon as possible, it is also important for the department to adopt its regulations in an expeditious manner. According to the legislative counsel, program changes, including fee adjustments, must appear in regulations before departments can implement the charges. Further, according to the Office of Administrative Law, these changes must be in regulation to be enforceable.

By increasing the newborn and prenatal testing fees and modifying the prenatal screening program before adopting regulations, the department violated the act and implemented underground regulations. Had participants contested the fees or the changes to the program, the department would not have been able to compel them to pay the increased fees or comply with the program changes.

Recommendations

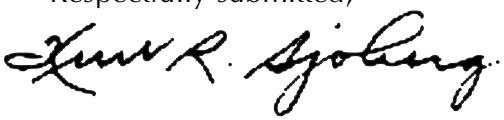
To make certain that the department adopts emergency regulations only when warranted, the Legislature needs to remove the specific language in the Health and Safety Code that considers all branch regulations emergencies.

To ensure that the department complies with the Administrative Procedures Act, the Legislature should also eliminate the specific language in the Health and Safety Code which states that the department shall file branch regulations directly with the Secretary of State, thus exempting branch regulations from review by the Office of Administrative Law. Additionally, the Legislature should delete the language which states that the Office of Administrative Law cannot repeal branch regulations.

To avoid violating the Administrative Procedures Act, the department should adopt changes to its genetic screening programs in regulations before it implements those changes.

We conducted this review under the authority vested in the California State Auditor by Section 8543 et seq. of the California Government Code and according to generally accepted governmental auditing standards. We limited our review to those areas specified in the audit scope of this report.

Respectfully submitted,



KURT R. SJOBERG
State Auditor

Date: September 4, 1997

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Response to the report provided as text only

State of California - Health and Welfare Agency Pet Wilson, Governor
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August 27, 1997

Mr. Kurt R. Sjoberg
State Auditor
Bureau of State Audits
660 J Street, Suite 300
Sacramento, CA 95814

Dear Mr. Sjoberg:

Thank you for the opportunity to review and comment on the audit of the Department's genetic disease services. Enclosed is the Department's response to the audit. We appreciate this independent review which will contribute to our effort to improve in program operations.

Sincerely,

S. Kimberly Belshe
Director

Enclosure

cc: Tameron Mitchell
Primary Care and Family Health
714 P Street, Room 450

THE DEPARTMENT OF HEALTH SERVICES RESPONSE TO:
The Genetic Disease Branch's Fee Setting, Billing And Collection Processes Need Improvement, And Its Regulations Do Not Warrant Emergency Status

Genetic Disease Branch
Primary Care and Family Health
Department of Health Services
September 1997

GENERAL COMMENTS

The Department of Health Services (DHS) welcomes the opportunity to obtain this independent evaluation of our genetic services program. The auditors assigned have conducted a thorough, professional, and comprehensive examination. The Genetic Disease Branch (GDB) management acknowledges that the consultations with the auditors and the data developed will be of great benefit in instituting improvements in operations and administration.

While the purpose of the audit is primarily to detect problems or inefficiencies and make recommendations for improvements, the overall central conclusion to be drawn from this audit is that the program is achieving its major public health objectives. The program provides universal statewide access to high quality newborn and prenatal screening services, irrespective of income, in a cost-effective manner. Over 8 million newborns and 3.3 million women have participated; 3,500 newborns with preventable heritable conditions have been detected and treated, and over 5,000 serious birth defects identified prenatally since the program was initiated.

These screening programs have enjoyed the support of the California Chapter of American Academy of Pediatrics and the American College of Obstetrics and Gynecology. A survey of prenatal care providers rated the program as excellent. The acceptance of the Department's voluntary prenatal program is illustrated by the fact that 70% of pregnant women accept the offer to participate.

The program is entirely supported by fees and uses no general fund tax revenues. The Genetic Disease Testing Fund (GDTF), a special fund established in 1975 under GDB management, has always remained solvent and has supported the operation of the existing programs and the development of new and better testing for additional conditions. Moreover, the GDTF repaid a $7 million general fund loan to cover program startup in 1979 to 1982. While the DHS can be proud of the program's accomplishments, we make no claim to have reached perfection. The Department solicits constructive criticism and suggestions for improvement from all concerned parties.

RESPONSE TO CHAPTER 1 - FEES

The cost of services provided to the public has been competitive with services in the private sector. (See Tables 1 & 2) Private laboratories charge from $70 to $186 for the triple-marker laboratory testing only, as compared to $115 for the comprehensive services provided by the state. (1)*

*The California State Auditor's comments on this reponse begin on page 41.

TABLE 1

COMPARISON OF CHARGES FOR MULTIPLE MARKER PRENATAL BLOOD TEST

	1992 ($)	1997 ($)
Alfigen Lab	71	79
Vivigen	135	Now Genzyme
Genetrix	73	Now Genzyme
Medigene	195	*
Foundation for Blood Research	70	79
Nichols	197	177
Mayo	Not offered	136.40
Collaborative Diagnostics	85	*
SmithKline	*	186
Genzyme	*	175
Womens and Infants R.I.	90	*

These charges do not include the cost of repeat tests or follow-up costs (such as genetic counseling, ultrasound, amniocentesis, chromosome studies and analysis of amniotic fluid).

*Information not available

TABLE 2

Comparison of Rate of Increase of DHS AFP fees with Mayo Clinic Laboratory

Date	DHS ($)	Mayo ($)
1986	40.00	—
1988	49.00	—
1991	53.00	44.40
1992	55.00	57.50
1993	—	62.40
1995	57.00	—
1997	57.00	70.20 (AFP only)
1997	115.00 (3 marker)	136.40 (4 marker)

The DHS fee includes all necessary follow-up services for positives (genetic counseling, ultrasound, amniocentesis, chromosome studies and analysis of amniotic fluid).

The Mayo fee is for the blood test alone.

The period from 1980 to 1990 had a 200% increase in Consumer Price Index (CPI) for medical care. The fees for newborn screening for PKU, galactosemia and hypothyroidism were unchanged for nine years and then increased 20% ($24 to $29). If the increase had kept pace with the medical CPI the fee would have been $50. In 1990 sickle cell anemia screening was added and the fee increased to $34 to cover this addition. From 1990 to 1997 the actual fee increase was 23%, as compared to a CPI increase of 133% or a CPI adjusted fee of $64. The statutory authority for fees for genetic screening have not been included in that section of the Budget Act language that requires fees be annually adjusted so as to offset at least 95% of the approved program level. This would have resulted in a gradual elevation of fees each year. It would also have resulted in a 5% shortfall in the GDTF. This is an acknowledgement that genetic testing is not a static program subject only to inflationary increases but a dynamic program with current and projected needs that can vary dramatically from year to year.

With respect to legislative intent, the Health and Safety Code 125000 (b) authorizes, "The Department shall charge a fee for any tests performed pursuant to this section. The amount of the fee shall be established and periodically adjusted by the director in order to meet the costs of this section." The legislation further provided in Section 125005 that "All moneys collected by the department under Section 125000 shall be deposited in the Genetic Disease Testing Fund that is continuously appropriated to the department to carry out the purposes of Section 125000." (emphasis added) (2)

The purposes of Section 125000 include both newborn and prenatal screening but also include "...a statewide program of information, testing and counseling services" [125000 (a)]. The purposes also include under 125000 (e) "grants or contracts for:

(1) Testing and counseling services.
(2) Demonstration projects to determine the desirability and feasibility of additional tests or new genetic services.
(3) To initiate the development of genetic services in areas of need.
(4) To purchase or provide genetic services from any sums as are appropriated for this purpose."

In addition, the Budget Acts of 1994, 1995, 1996 provided:

"The Department of Health Services shall establish a system of fees for various services and programs including any voluntary or mandatory population-based screening programs provided by the Genetic Disease Branch. The fee shall be sufficient to cover the total costs of providing all such genetic disease or population based screening services and programs provided by the Genetic Disease Branch." (emphasis added)

This language clearly indicates the intent that fees could be used to support programs in addition to population screening and an intent to use fees to offset the total GDB operating costs of a complex program.

It is the Department's view that regulations are not required for fees pursuant to Government Code Section 11343(a)(1) and the cases construing that section. Additionally, the Budget Act and the Health and Safety Code (Section 100425) distinguishes between fees set by regulations, (3)

which are subject to annual adjustment, from Branch fees that are addressed in a separate section which makes no specific reference to regulations. However, the Branch has historically set fees by regulations, and it agrees that the legal dispute on this point needs to be corrected in regulatory reform. (See response to Chapter 3)

It is the Branch's position that fees are to be set at a level that will support the entire program of genetic services. This includes some activities that do not generate fees such as public education and prevention of Rh hemolytic disease of newborns. It also includes startup costs for new tests or replacement of obsolete laboratory or computer technology.

Fees need to be set to keep the fund solvent, to generate a contingency reserve, and to provide a source of funds for development of new tests. It is not the Branch's primary goal to set fees for each individual program such that the revenues exactly equal the operating costs of that particular program.

Even if the Department were to accept this concept of exactly matching fees to costs for each program, it would be extremely difficult to achieve. Fees cannot be established in retrospect based on actual experience. Past experience is used as a guide to setting fees. However, fees must be decided on in the context of development of the State budget and, therefore, are based on estimates of activities that will occur 8 to 10 months later. The selection of a fee level is based on information and estimates developed by the program administrators using available databases. (4)

There are unique problems associated with setting a fee for a clinical service such as genetic screening. For newborn screening, a mandatory program, the following are only a few essential elements to be considered:

(a) Estimates of future births
(b) Amount of moneys encumbered and estimated rates of expenditure to support newborn screening operations (laboratory, contracts, follow-up contracts, administration, and quality assurance)
(c) Estimates of changes in operational costs, e.g., contracts renegotiated, more or less expensive technology to be added or deleted, change in number of contractors, projected addition of new tests
(d) Variations in number of newborns initially positive, and in the types and costs of follow-up activities needed
(e) Collection rate and collection costs

For prenatal screening, a voluntary program, the situation is more complicated and includes:

(a) Estimates of number of women over and under 35 who will accept an offer of testing
(b) Estimates of number of initial positives who will result in additional costs of follow-up
(c) Numbers and kinds of follow-up services needed and their costs, and acceptance rate of referral and amniocentesis
(d) Estimates of reagent costs
(e) Estimates of laboratory contract costs
(f) Follow-up vendor contracts, i.e., number of Prenatal Diagnosis Centers and reimbursement rates

(g) Administrative costs to support testing, e.g., number and costs of mailing containers, test tubes, printing instruction and forms and educational material, data collection and analysis, etc.
(h) Collection rate and costs of collection

In addition, fees can be affected by administration decisions at various levels of government. For example, requirements to maintain a specified reserve, use of surplus moneys investment accounts, absorption of general funded activities not directly related to fees collected, need to generate a surplus for future use for startup costs for addition of new tests, replacement of laboratory equipment and re-engineering the information technology component. Unanticipated costs such as a demand for licensing fees of over $1,000,000 annually for using one of the analytical assays could affect fee calculation. The Branch has not increased reimbursement to clinical geneticists and counselors for follow-up services since 1992. The Branch needs to consider adjustments to reflect the vendors increased costs of operation.

The auditors examined the process used to set Expanded Alpha-Feto Protein (XAFP) fees. In FY 95-96, Branch administration was operating a program using AFP alone that was detecting 70% of the Neural Tube Defects (NTD) and 15% of the Down syndrome (DS). XAFP would improve the DS detection but would not increase NTD detection. There was therefore no past experience which could be used to adjust fee. The incremental costs of XAFP needed to be related to benefits of improved DS detection. The existing program was fiscally sound, based on data from past experience, so the operational costs of this established program were used as a baseline. In order to determine the new fee the Branch estimated the additional cost of adding two markers. (5)

The analysis of revenues and fees in the audit was a retrospective analysis based on the first year's experience with the new expanded prenatal screening program. The Branch had no past history to use as a guide. The assumptions used were necessarily designed to support service capacity sufficient to meet any need and to avoid a disastrous shortfall. Some of the assumptions were not born out in practice. The Branch now has the benefit of the FY 95-96 experience and has adjusted estimates. In FY 96-97 a negative Budget Concept Proposal reduced the budget authority by $2 million dollars. The Branch attempts to keep fees as low as possible to encourage participation.

The Branch periodically reviews the status of the GDTF including operational costs and fees as needed for fiscal decision. Until last year the Branch provided the Department of Finance with workload changes, estimates, and a status report on the GDTF in May and November of each year. This was discontinued based on a directive from the Department of Finance.

RESPONSE TO CHAPTER 2 - COLLECTIONS

The auditors identified problems in collection of prenatal testing fees. The Branch has demonstrated creativity in addressing the problem, e.g., addition of credit card billing, using universal insurance forms for billing. The Branch has consistently struggled to improve the amount of and accountability for fees collected beginning in FY 90-91. The Branch has utilized outside consultants and its own information technology expertise to develop a major redesign

and automation of the total accounting and revenue collection system. After four years of discussion and review by Data Systems Branch, Department of Information Technology (DOIT), and the Department of Finance Technology Investment Review Unit (TIRU), GDB is expecting final approval of the Feasibility Study Report entitled, "Information Technology for Accounting and Other Business Services at the Genetic Disease Branch." A contract with a private vendor to provide a system that meets our detailed specifications, and that will address the problems identified by the auditors and the Branch will soon be executed. The Branch, therefore, acknowledges the problems that have developed in the collections and is committed to rectifying them.

The Branch has a unique problem as compared to other units responsible for fee collection in the DHS. Most programs collect fees for licenses or documents and can withhold the desired license or document if fees are not paid. Moreover, the small group of payers responsible for the fee is clearly defined. The Branch, on the other hand, collects the fee after provision of services to a large group of women where responsibility for payment is difficult to define. The effort dwarfs other departmental collections. The Branch mails 70,000 individual bills each month including 15,000 new bills and maintains 266,000 individual accounts. Since 1993, the period discussed in the audit, GDB has effectively collected over $83 million dollars in prenatal fees.

The auditors are concerned about the amount of uncollectable revenue. The Branch shares the auditors concern with respect to the number of uncollectable bills and is committed to constantly working to reduce the rate of uncollectable bills as much as possible, recognizing that no system or program collects 100% of moneys due. The dollar amount of the uncollectable is large because the total amount due is large. However, the only valid measure of effectiveness is the percent of total that are uncollectable. In the course of development of the program, the Branch informed the Department of Finance and the Legislature that collection of revenue will be incomplete. Our budget presentation has always included our estimate of 13% to 17% in uncollectable prenatal fees. Even though bills are eligible for write-off after one year, the Branch does not write-off these bills. Based on past experience the Branch believes that a significant percentage in the eligible for write-off category will ultimately be collected. The Branch estimates that the total write-offs in FY 95/96 will be less than $5 million. In that fiscal year GDB billed a total of $31,716,092 and in FY 95/96 collected $10,900,487 or 34%. However, in FY 96/97, $17,616,027 was collected or an additional 56% for FY 95/96. The total prenatal fees ultimately written off will be less than 10% of total billings. The Branch includes, in the determination of the fee, an estimate of uncollectable bills. Therefore, the write-offs do not represent deficits to the State but only loss of additional potential revenues for the Genetic Disease Testing Fund.

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While the overall collection rate is 87%, the audit does point out a specific area of concern to the Branch where improvement needs to be made, namely, collection of individual bills sent directly to women served. There are many reasons for the size of this figure, some of which are being addressed or will be addressed in the future, and some of which are beyond Branch control, e.g., approximately one-quarter of the women served have no health insurance, and among the insured there is no universal coverage of this screening in spite of the recognition it is a standard of prenatal care. As the auditors correctly point out this subsidizes women and insurance companies unable or unwilling to pay full fees. The decision to bill in arrears is based on the major

emphasis of this program as a preventative public health program. It is designed to reduce barriers to participation and prepayment would be a barrier to low income women. (7)

The Branch, however, believes the auditors have made constructive recommendations such as provision of payment envelopes at time of service. The Branch is accepting credit card payment at this time. The use of a credit card at point of service is more complex but will be aggressively explored. The auditors recommend billing health plans directly. However, this is easier said than done. The Branch has assigned health plans billing numbers, but 60% of the doctors do not put billing information on the specimen collection form and over 35% fail to enter social security numbers. The program is dependent on the physician ordering the screening test to provide complete and accurate billing information. Title 17 CCR, Section 6527 (d) provides "If the pregnant woman consents to testing the clinician shall arrange for prenatal screening by...(l) Fully and accurately completing all required specimen collection forms provided by the Department for this purpose." The Branch's policy is to contact physicians to obtain patient addresses when addresses are wrong or data entry error occurs as entered by the laboratory from the prenatal testing forms or when addresses are missing. This includes ensuring that social security numbers are complete and accurate. However, the Branch does not contact physicians to obtain patient social security numbers or the name of their health insurance and subscriber identification number when this information is missing or incorrect in its database.

Moreover, some health plans and almost all insurance companies refuse to use the billing number or to pay for their enrollees. The collection of fees from third party payers except Medi-Cal, is complicated by not having a single CPT (common procedural terminology) billing code that represents the complete combination of individual services provided. The billing codes are used universally by third parties to itemize services and they have no provisions to pay for "bundled" public health screening services.

The Branch does not have a way to use patients' social security numbers or the name of their health insurance and subscriber identification number as a means to collect unpaid prenatal fees that is acceptable to the companies. Insurance companies reject the bills as "screening services not covered" or due to need for copayment or meeting deductibles or for limitations on coverage of normal pregnancy, etc. They are reluctant to negotiate a direct billing agreement if their competitors will not do likewise since those that pay full fees subsidize those that do not. We depend on the woman who has the information on coverage policies to submit our bill to the insurance company.

The Branch agrees with the auditors that if health plans were clearly required to pay full fees directly to the Department, they would aggressively inform their physicians and enrollees about the coverage, and how to use the billing number. Billing and collections could be streamlined and reduced for both the Department and the health plans.

The Branch accepts and will implement the recommendation to print an overdue message on all billings after the first bill. The Branch already indicates partial payments are acceptable on selected bills, but will extend this statement to all subsequent bills.

The Branch has discussed setting up offset procedures with the Franchise Tax Board (FTB). Since several items and identifiers are needed to identify taxpayers, GDB needs to send FTB computer tapes to use for matching. This recommendation will be pursued in the re-engineered information technology project. In addition, the Branch has developed additional ideas that will contribute to improved collections. (8)

The Branch agrees that the refund process must be improved. Currently, if an overpayment is discovered or is requested, a refund is made. However, the Branch does not use limited staff to actively search for refunds. The automatic refund of overpayments that can be validated in accordance with State accounting procedures will be a part of the accounting computer solution. A review of the FY 95-96 indicates that GDB credited payments to 113,400 individual patient accounts and identified only 678 overpayments which are 6 per 1,000 accounts. An analysis of overpayments revealed 95% are due to insurance company errors, only 5% were situations where only the woman overpaid. Forty-percent of refunds would go to women and 60% would go to insurance companies.

Contracts

The Branch is committed to the use of competitive contracts and has redirected the necessary staff to ensure this will be accomplished. The hiatus in laboratory contracting from 1990 to 1996 was requested by the Genetic Disease Laboratory due to staff limitations and higher priority tasks of initiating sickle cell screening and Expanded AFP screening. Both were very labor intensive processes involving changing laboratory analytic equipment and procedures specified in the contracts. As the audit points out, staffing has been improved so that a fixed schedule of annual bidding of all laboratory services has been and will be maintained.

RESPONSE TO CHAPTER 3 - REGULATIONS

The Branch agrees with the auditors' analysis that not all regulations are emergencies and believes clarification of the statute is required. GDB also agree that the public interest is better served if all regulations required a public comment. The ten regulations filed prior to 1996 were filed after public input and with full compliance to the Administrative Procedure Act including public hearings. However, the differing interpretations of the regulatory authority in statute needs to be clarified by making clear that fee changes must be made by means of regulation (9)

The Branch supports the concept that the Office of Administrative Law (OAL) needs to review the regulation process, validate that the procedures in the Administrative Procedure Act (designed to ensure appropriate public participation) have been observed and repeal any regulation failing this test. However, the Branch does not support the concept that review of regulations for content, clarity, necessity, non-duplication, authority, and references by OAL is necessary given the work done by program staff and DHS legal staff who are informed and equipped to deal with the sensitive and complex genetic services issues as demonstrated in the past regulatory adoptions in this area. This extra layer of review has the potential to delay or prevent implementation of needed prevention programs until issues raised by OAL are resolved. Unless procedural requirements are not met, the Department wants to retain its statutory authority for its regulations to be filed directly with the Secretary of State and not to be repealed by the office or by operation of law after 120 days. (10)

RESPONSE TO RECOMMENDATIONS IN AUDIT SUMMARY

1. Establish procedures for monitoring and analyzing separately the revenues and costs for each program.

   Branch agrees and this will be addressed in the Accounting Information Technology project.

2. Examine fees for each program at least once a year and then adjust patient fees if the difference between costs and fees is significant.

   Branch agrees. The Branch will examine fees at least annually and adjust either the fees or the costs to maintain affordability of testing and solvency of the fund.

3. Reduce prenatal fees so that they more closely reflect the costs of the program.

   The Branch believes that current fees should not be changed until we have completed our budget review. The Branch must pay for upgraded NBS laboratory equipment and two major information technology projects essential to accurate and cost-efficient operation. The current fees will generate sufficient funds to cover these needed maintenance projects. In addition, funds are needed to examine new technologies and new tests and to increase vendor reimbursements. The Branch will review the issues related to fee adjustment in the context of the total solvency of the GDTF and present a detailed analysis as part of our budgetary proposal in FY 97-98 and FY 98-99. (2) (11)

4. Offer each prenatal screening patient various ways to make payments. The Branch should also require the patient to select a payment option and to make a payment at the time of testing.

   The Branch will explore use of credit card at point of service and include acceptance of partial payment on bills. We feel requiring payment at time of service is an unnecessary barrier to these prevention services. (7)

5. Increase the amount of direct billing to health plans.

   The Branch will pursue direct billing to third parties to the extent permitted by law.

6. Include on patient invoices language that highlights overdue balances, and continue to bill patients who fail to pay.

   The Branch will implement in the immediate future.

7. Establish a process for attaching a patient's tax refund for the amount due if the patient does not pay her bill for the prenatal screening test.

   The Branch will implement as part of Accounting I.T. project. (8)

8. Continue trying to obtain the $1.1 million in prenatal fees due from Medi-Cal.

   The Branch is continuing to explore possibilities of collection.

9. Develop procedures to refund the overpayments of prenatal testing fees that it currently holds, and promptly refund any overpayments it receives in the future.

   The Branch will implement as part of Accounting I.T. project. (8)

10. The Branch should continue to use a competitive bidding process to award contracts for laboratory testing services.

    The Branch will continue the competitive bidding process.

11. The Legislature should remove language from the Health and Safety Code that designates as emergencies all regulations related to the prenatal and newborn screening programs.

    This is a recommendation to the Legislature.

12. The Legislature should also delete language in the Health and Safety Code that directs the Department to file branch regulations directly with the Secretary of State and that exempts the regulations from possible repeal by the Office of Administrative Law.

    This is a recommendation to the Legislature.

13. Before implementing program changes, the Department should comply with the Administrative Procedures Act by adopting regulations that cover those changes.

    The Department will comply with time frames for public notice and public comments periods as set forth in the Administrative Procedure Act.

    The Department does not support the concept that review of regulations for content, clarity, necessity, non-duplication, authority, and references by OAL is necessary given the work done by program staff and DHS legal staff who are informed and equipped to deal with the sensitive and complex genetic services issues as demonstrated in the past regulatory adoptions in this area. This extra layer of review has the potential to delay or prevent implementation of needed prevention programs until issues raised by OAL are resolved. (10)

Comments

California State Auditor's Comments on the Response From the Department of Health Services

To provide clarity and perspective, we are commenting on the Department of Health Services' (department) response to our audit report. The numbers correspond to the numbers we have placed in the response.

(1) Even though the prenatal testing fee may be competitive with fees in the private sector, the fact remains that the branch is charging pregnant women more than necessary for prenatal screening tests. Because the branch does not allow private businesses outside its program to provide prenatal screening services, the branch's main concern should not be that its fees are competitive with the private sector. Rather, it should focus on providing these services at the lowest possible price.

(2) We agree that program fees must be sufficient to cover the costs of all of the branch's genetic services. Consequently, in our analysis, we not only included all of the branch's fiscal year 1995-96 expenditures, but we also considered its fiscal year 1996-97 and planned expenditures. Even after considering all these factors, we concluded that the prenatal testing fee is excessive.

(3) During his analysis of the Administrative Procedures Act's (act) requirements, the Legislative Counsel of California considered Government Code Section 11343(a)(1) and concluded that the department must adjust fees in regulations before implementing them.

(4) The branch misrepresents our position. We do not believe that fees must exactly match costs. However, we believe that each program's fees should reasonably reflect the branch's planned expenditures. Using this standard, we found that, although both the prenatal and the newborn testing fees exceeded costs in fiscal year 1995-96, only the prenatal testing fee needs to be reduced because we expect that it will continue to significantly exceed related costs in the foreseeable future.

(5) We recognize the difficulties the branch faced in calculating the fee for the expanded prenatal screening program, and we do not take issue with the assumptions the branch used to compute this fee nor with the fact that the branch had no past history to use as a guide when setting the fee. However, as we noted in Chapter 1, the branch lacks adequate procedures for monitoring its fees between fee-setting dates and it did not adequately assess the accuracy of the prenatal testing fee once it was set.

(6) Unlike the branch, we did not limit our review to the collection of fiscal year 1995-96 billings. Nonetheless, we question the accuracy of the branch's assertions that it has collected 90 percent and will write off less than 10 percent of its fiscal year 1995-96 prenatal testing fees. Our review of the branch's statistics revealed its estimate is based on the branch's receiving payments from Medi-Cal totaling 118 percent of the amount billed, an obvious error. Correcting for this error alone, we calculate that even if the branch receives 100 percent of the amount it billed Medi-Cal, its overall collection rate would be only 84 percent. Thus, we estimate that the branch will write off approximately 16 percent of its fiscal year 1995-96 prenatal testing fees.

(7) The branch asserts that requiring payment at the time of service creates an unnecessary barrier to participation in the prenatal screening program but offers no evidence to support its claim. Further, we do not suggest that the branch require women to pay the entire fee in advance of receiving prenatal screening tests. Instead, we recommend that the branch require women to select a payment option at the time of service and thus make a commitment to paying the fee. Payment options could include paying in full, paying by credit card, or making a partial payment and having the branch bill patients later for their balances. We do not believe that requiring patients to select a payment option at the time of service creates a barrier to participation.

(8) Although the branch plans to implement these recommendations as part of its new computer accounting system, the State has not yet approved this system. Therefore, if the new system is not approved or if its implementation is significantly delayed, the branch needs to design processes to perform tax offsets and refund overpayments using its current system.

(9) We agree that the department generally complied with the act when it adopted emergency regulations before 1996. However, in its response, the department fails to mention that it did not complete the public hearing process when required for regulations adopted in June 1996. Additionally, the department

fails to acknowledge that it had not yet adopted regulations when it increased both the prenatal and newborn screening fees in January 1994 and implemented changes to the prenatal screening program in July 1995.

(10) We agree that the department's program and legal staff spend a considerable amount of time and effort adopting regulations. However, the review by the Office of Administrative Law is important because it provides an objective look at the department's regulations; such objectivity cannot be obtained from internal program and legal staff. Moreover, we found that the Office of Administrative Law does not significantly delay or arbitrarily deny emergency regulations.

(11) Although the branch recognizes the need to analyze the reasonableness of the fees, it has not embraced the concept that the fees support two separate and distinct programs. Because these programs are separate, the branch should analyze regularly the revenue and cost of each program to determine the reasonableness of each fee. By doing so, the branch will ensure that revenue from each test is adequate to cover its costs and that neither fee subsidizes the costs of the other.

cc: Members of the Legislature
Office of the Lieutenant Governor
Attorney General
State Controller
Legislative Analyst
Assembly Office of Research
Senate Office of Research
Assembly Majority/Minority Consultants
Senate Majority/Minority Consultants
Capitol Press Corps