F I S C A L I M P A C T R E P O R T

SPONSOR: Komadina DATE TYPED: 3/13/03 HB

SHORT TITLE: Newborn Infant Testing SB 870

ANALYST: Dunbar

APPROPRIATION

Appropriation Contained		Estimated Additional Impact		Recurring or Non-Rec	Fund Affected
FY03	**FY04**	**FY03**	**FY04**		
	NFI				

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION

Responses Received From

Department of Health (DOH)
Health Policy Commission (HPC)
Attorney Generals Office (AGO)

SUMMARY

Synopsis of Bill

This bill enacts a new section of the Public Health Act that requires the Health Department to adopt rules to require newborns to be tested for congenital, genetic and metabolic disorders before being discharged from the health facility, and/or for those newborns brought to a licensed health facility after birth who have not yet been tested. Although the newborn screening tests is required under the section, the section allows for an exemption for parents of newborns who object due to religious beliefs.

Significant Issues

New Mexico already allows for newborn screening tests of congenital diseases, SB 870 expands the newborn screening tests to genetic and metabolic disorders. Newborn screening involves the analysis of a child's blood, or less commonly, urine or stool to look for abnormal levels of enzymes, metabolites or other chemicals. Newborn testing is designed to identify disorders that cause mental retardation and other health problems unless they are diagnosed and treated early in life.

SB 870 would, however, expand the newborn screening to test for genetic and metabolic disor-

ders as well. Genetic testing involves the analysis of chromosomes, DNA, RNA, genes, and/or gene products to determine whether an alteration is present that is causing, or is likely to cause, a specific disease or condition. A metabolic disease is a disorder caused by a problem with the accumulation of chemicals produced naturally in the body. These diseases are usually very serious, some are even life threatening. Others may slow down physical development or cause mental retardation.

The Newborn Screening Program in New Mexico currently screens approximately 97% of all newborns for six congenital, genetic and metabolic conditions. These six disorders are congenital hypothyroidism, phenylketonuria, sickle cell conditions (sickle cell disease and hemoglobinopathy), biotinidase deficiency, galactosemia, and congenital adrenal hyperplasia. The vast majority of births occur in hospitals, but approximately 1.5% (358-410) a year take place outside of a hospital. Some of alternate birth location include: freestanding birthing centers, clinics, doctor's offices, and at home. The current DOH screening program is two-tiered; infants are screened initially between 24 and 72 hours of age and the second screen is obtained between 8 – 15 days of age. The first screen is obtained prior to hospital discharge or by the birth attendant (nurse, nurse midwife, midwife or responsible person), according to current state regulations (DOH 92-02 PHD) contained in Section 9-7-6 NMSA 1978 and Section 24-1-6, 1978 as amended laws 1981, Chapter 95. Sec. 1.

The Newborn Screening Program has seen a dramatic decrease in the number of second screens done. Parental waiver (dissent to screen) activity has increased over the last 4 years. The number of Newborn Screening Program Waiver forms received in 1996 was six (6), in 2001 seventy-three (73) and in 2002 sixty-four (64).

ADMINISTRATIVE IMPLICATIONS

The DOH would have to develop some protocols and active oversight for newborn screening practices among the lay midwives or licensed independent practitioners.

TECHNICAL ISSUES

The AGO indicates:

Potential conflict between the current New Mexico Public Health Act and SB 870 provisions when providing exemptions to parents or guardians to waive the requirements for newborn testing of congenital, genetic and metabolic diseases.

- New Mexico permit parents to refuse screening for any reason at all. S*ee e.g., Fla. Stat. Ann. § 383.14(4)(providing that a parent's or guardian's unqualified objection suffices to prevent any testing required by the statute.*
- New Mexico's Public Health Act under NMSA 1978, Section 24-1-6(A), *Tests required for newborn infants* allows parents or guardians of newborns to waive the requirements for tests for detection of PKU and other congenital diseases in writing.
- SB 870 creates a new section under the Public Health Act and proposes to provide an exemption for parents of the newborns who object to tests for congenital, genetic and metabolic disorders due to religious beliefs.
- Also compare Public Health Act under NMSA 1978, Section 24-1-6.1 *Newborn hearing testing required; department of health* allows parents to object to the screening for hearing sensi-

tivity of a newborn infant on the grounds that it conflicts with their religious beliefs.

- These exemptions as provided for within the same Act under different sections conflict with each other and may lead to confusion in enforcing and complying with the Act.

The use of the terms "guardian" or "authorized representative" are not included under the SB870 provisions although they are included under other sections of the same Act dealing with similar requirements.

- SB870 does not use the terms guardian or authorized representative in the Act, although a similar provision under the Public Health Act, NMSA 1978, Section 24-1-6(A), *Tests required for newborn infants* includes guardians as well as parents; and the Genetic Information Privacy Act includes the term authorized representative under NMSA 1978, Section 24-21-3 (E) to waive the newborn screening test requirements for genetic information and analysis.

SB 870 may not ensure consistency between the Public Health Act and the Genetic Information Privacy Act that provides for the confidentiality of genetic information.

- Whether parents want or should be allowed to know about their children's genetic predisposition, other groups, such as insurers and employers may have strong economic reasons for wanting this information. Because genetic data is contained in blood samples obtained by the state at birth, it becomes critical that the state ensure the confidentiality of this information.

- New Mexico has already enacted the "Genetic Information Privacy Act", (NMSA 1978, Sections 24-21-1 et. seq.) which affords certain protections to genetic analysis performed and genetic information and gene products obtained.

- The Act requires that before genetic information or samples for genetic analysis from an individual can be obtained, there must be a written consent from that person or the person's authorized representative. *See, NMSA 1978, Section 24-21-3, Genetic analysis prohibited without informed consent; exceptions.* An exemption is provided for newborn screening. *See, Section24-21-3(C).* However, similar to other provisions like NMSA 1978, Section 24-1-6.1 *Newborn hearing testing*, the Act provides an exception for authorized representative or guardian or the parent or guardian of the minor child who object to genetic screening on the grounds that it conflicts with their religious tenets or practices.

OTHER SUBSTANTIVE ISSUES

In New Mexico, approximately 1.5% of infants are born outside hospital setting and in the comfort of the family home, attended by midwives who are either licensed or nationally certified. Currently, the home birth attendant usually obtains the first screen, but there is a decline in obtaining the second screen. Many of these home births have the screening done well outside of the nationally recommended standards (AAP, ACMG, HRSA Genetics Branch)of the first screen (between 24 – 72 hours) and the second screen (between 8 – 15 days of age). SB 870 would limit the practice of the licensed independent practitioner to do the newborn testing in a licensed health care facility. SB 870 would also bring up the second newborn screening rates or dissent activity.

Screening done well outside of the recommended intervals and/or declined could result in an increased risk of missing a congenital, genetic or metabolic disorder that could benefit from early intervention services. Early intervention has been shown to reduce the effects of mental retardation, learning and cognitive disabilities, growth impairment, etc. Many couples opting for home births may not seek out a licensed health facility to obtain the newborn screen. These couples may prefer to have the newborn screen done by the birth attendant.

In 2000, a study was undertaken by Newborn Screening Data Linkage Project (1998 and 2001) revealed only 64% of infants born were being screened twice. A further study examined the refusals by parents for a second screen; which revealed that over 90% of those declining screening were home births attended by 'lay midwives' (Newborn Screening Program Waiver/Dissent Tally Report 2000-2002). Every year, the DOH Newborn Screening Program has identified at least 4 infants with congenital conditions, that were picked up on the second screen only. In 2002, the Newborn Screening Program received 64 waivers to dissent against screening. The vast majority of these deliveries where attended by 'lay-wives', making the infant at risk for mental retardation, learning and cognitive disabilities, growth retardation, etc.

According to the New Mexico Scientific Laboratory Division's report on Newborn Screening (2003):

- Testing and screening newborns for sickle cell anemia can reduce deaths from this disease by up to 84%.
- Newborn screening coupled with rapid diagnosis and treatment prevents mental retardation, illness, and death in newborns.
- For every $1 spent on newborn screening, $9 in medical care and treatment costs are saved – resulting in a national savings of $36 million every year.

According to information on birth certificates, congenital anomalies occurred with 2.0% of the aggregate 1996-2000 New Mexico resident live births:

- The percent of live births with reported congenital anomalies was higher among American Indians (2.71%) than any other race/ethnic group, followed by Black (2.12%).
- The highest percentages of births with congenital anomalies were reported for mothers, age group 40+ and lowest for the age group <15.
- The counties reporting the highest percentage of congenital anomalies were Lincoln, (6.90%) and Los Alamos, (4.03%) counties.
  (New Mexico Selected Health Statistics Annual Report, 2000)

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