Mandated Benefits Review by the
Pennsylvania Health Care Cost Containment Council

Senate Bill 938
(97-98 session)

Universal Newborn Hearing Screening

January 1999
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EXECUTIVE SUMMARY

After reviewing the staff analysis of Senate Bill 938 (97-98 session) – the Universal Newborn Hearing Screening Act – the Pennsylvania Health Care Cost Containment Council does not find evidence to recommend passage of this legislation in its current form. This bill deals with two separate and distinct proposals – mandating that all newborns be screened for a hearing loss and mandating that insurance carriers cover the cost of the screening. While the issue of newborn hearing loss is emotionally compelling, we were unable to find that mandatory testing of all newborns and mandatory coverage of universal newborn hearing screening would be cost effective. We note the following:

- The screening of high-risk newborns may be more efficient and cost effective than universal screening. The incidence of hearing loss in the high-risk population is ten to forty times the incidence in the normal-risk population. Even though only 9 percent of newborns are considered to be at risk for hearing loss, over half of all cases of hearing loss are detected in high-risk infants. In addition, the estimated cost to screen the high-risk population is less than ten percent of the estimated cost to screen all infants. Twenty-one states have some type of legislative mandate related to newborn hearing screening; 17 of these focus only on children who exhibit one or more high-risk indicators. At the same time, it is important to point out that high-risk screening may miss up to half of all infants with a hearing loss, so educating parents and pediatricians about the risk factors and early signs of hearing loss could serve as an important component in early identification of hearing loss. For example, some hospitals have developed a pamphlet on hearing loss that is distributed to parents upon discharge.

- There is no consensus on the issue of universal newborn screening. National health agencies have issued conflicting recommendations on universal newborn hearing screening. The U.S. Preventive Services Task Force states that “there is little evidence to support the use of routine, universal screening for all neonates.” The National Institutes of Health, however, issued a consensus statement which recommends that “universal screening be implemented for all infants within the first 3 months of life.”

- While the Council received information in support of Senate Bill 938 from a number of pediatricians, we also received letters from other pediatricians opposing universal screening. Letters raised concerns about the practicality of testing all newborns before discharge, the high rate of false positive results, and the effect that false positives may have on parental bonding.

- Due to debris and fluid in newborns’ ears, screening tests are least reliable within the first 48 hours of life. One screening procedure – the otoacoustic emissions test – has a failure rate of approximately 40 percent within the first few days of life. Since Senate Bill 938 urges newborns to be tested before hospital discharge, the accuracy of tests in the first hours of life is important. Some pediatricians suggest that it is more appropriate and effective to screen infants at regular 2 and 4-month check ups.
• Some Pennsylvania hospitals already have universal screening programs. Information from these programs and from other states suggests that universal screening may be accomplished without a legislative mandate. Funding for screening programs come from a variety of sources. Some hospitals elect to operate a screening program as a marketing strategy or as a public service.

• Even if a universal newborn hearing program were to be established, the Council received strong opposition to imposing an insurance mandate. Of the four states with universal newborn hearing screening programs, only one state – Rhode Island – has mandated insurance coverage of the screening examinations.

• Finally, the Council’s enabling legislation provides for a preliminary review of submitted materials to determine if the documentation received is sufficient to proceed with the formal Mandated Benefits Review process outlined in Act 34 of 1993. We concluded that neither proponents nor opponents of the bill provided sufficient information to warrant a full review by a Mandated Benefits Panel; nor, given the documentation received, do we believe a panel of experts would come to conclusions different than the ones reached here.
The Mandated Benefits Review Process

The Pennsylvania Health Care Cost Containment Council’s enabling legislation, Act 89 of 1986 (as re-authorized by Act 34 of 1993), provides that the Council review existing or proposed mandated health benefits when requested by the executive and legislative branches of government.

On June 24, 1998, Senator F. Joseph Loeper, Majority Leader and Chairman of the Committee on Rules and Executive Nominations, requested that the Council review the provisions of Senate Bill 938 (PN 1952 – Senator Lemmond), which would establish a universal newborn hearing screening program and require health insurance companies to cover hearing screening tests and any necessary follow-up testing.

Notification was published in the Pennsylvania Bulletin on July 11, 1998, requesting that interested parties submit documentation and information pertaining to the bill to the Council. Letters were also sent to potentially interested individuals and organizations informing them of the pending review and inviting them to submit information pursuant to the notice. Following the initial comment period, an opportunity was provided for interested individuals and organizations to examine the responses received. The Pennsylvania Department of Health and the Insurance Department were notified of the review and received a copy of the submissions. Respondents were also given an opportunity to review the initial submissions and submit a second round of documentation. Final submissions were due to the Council on September 25, 1998.

A list of documentation submitted to the Council is attached.

Act 34 also provides for a preliminary Council staff review of submitted materials to determine if documentation submitted is sufficient to proceed with the formal Mandated Benefits Review process outlined in the Act. This report presents the results of the Council’s preliminary staff review and the conclusions of the Council regarding whether the material is sufficient to proceed with the formal review process.

Overview of Senate Bill 938

Senate Bill 938 (97-98 session) – the Universal Newborn Hearing Screening Act – would create the Universal Newborn Hearing Screening Program within the Department of Health and would require health insurance policies to provide coverage for newborn hearing screening tests, including initial testing and any necessary follow-up testing. The Council notes the comments of the Insurance Federation in stating, “there are two distinct issues presented by the bill, viz., the medical necessity of testing all newborns for hearing deficiencies and the advisability of requiring that health insurers subject to state mandate cover those procedures.”

The first portion of Senate Bill 938 is the creation of the Universal Newborn Hearing Screening Program within the Department of Health. The Program would consist of a screening test that every newborn child would undergo for the identification of hearing loss. According to the bill, the test may be performed by “any person properly trained to do so,” and whenever possible, the test should be completed before the newborn is discharged from the hospital. If the test is not completed before discharge, the hospital is required to notify the parents of the newborn of the need to have the newborn tested within 90 days of birth. Senate Bill 938 specifies that the screening tests will include at least one of the following: auditory brain stem response, automated auditory brain stem response, otoacoustic emissions, or other appropriate technology. Parents may refuse the newborn hearing test on religious grounds.
The second portion of Senate Bill 938 would require health insurance policies to provide coverage for newborn hearing screening tests, including the initial testing and any necessary follow-up testing. The benefits for the hearing test would be subject to copayment and co-insurance provisions of the insurance policy, except that the benefits would be exempt from any deductible provision. Senate Bill 938 would require the Medical Assistance Program to cover the cost of the testing if the child is eligible for Medical Assistance. Certain types of policies are exempt from the mandates proposed in Senate Bill 938: accident only, specified disease, hospital indemnity, Medicare supplement, long-term care, or other limited benefit health insurance policies. One type of policy which is typically exempt from insurance mandates – disability income – is not exempt from the mandates proposed in Senate Bill 938. The Council received a request that if Senate Bill 938 is enacted, disability income be added to the list of exempt policies.

**Hearing Impairment in Children**

In an effort to better understand hearing loss in children, Council staff conducted research and reviewed the information included in the submissions. This section discusses the risk factors and prevalence of childhood hearing loss, the benefits of early detection, and the methods of testing proposed in Senate Bill 938.

**Risk Factors for Childhood Hearing Loss**

High-risk criteria are present in approximately 9 percent of newborns and encompass half of the children who are subsequently found to have hearing impairment. According to the American Academy of Pediatrics, risk factors of newborn hearing loss include the following:

- Family history of hereditary childhood sensorineural hearing loss
- In utero infection, such as cytomegalovirus, rubella, syphilis, herpes, or toxoplasmosis
- Craniofacial anomalies, including infants with morphologic abnormalities of the pinnae and ear canals
- Birth weight less than 1,500 grams
- Ototoxic medications
- Bacterial meningitis
- Apgar score of 0-4 at 1 minute or 0-6 at 5 minutes after birth
- Mechanical ventilation lasting five days or longer

It is also suggested that newborns in the neonatal intensive care unit should be considered high-risk. There is consensus in the medical community that all newborns considered to be high-risk should be tested for hearing impairment.

**Hearing Loss After Birth**

It should be noted that not all hearing loss in children is present at birth. According to the National Institutes of Health, “20-30 percent of children who subsequently have hearing impairment will develop hearing loss during early childhood.” Therefore, screening of newborns cannot detect all cases of hearing loss in children.
The American Academy of Pediatrics suggests that infants (age 29 days through 2 years) be rescreened when:

- There is parent-caregiver concern regarding hearing, speech, language, and/or developmental delay.
- Bacterial meningitis and other infections associated with sensorineural hearing loss have occurred.
- Head trauma associated with loss of consciousness or skull fracture has occurred.
- Stigmata or other findings associated with a syndrome known to include a sensorineural and/or conductive hearing loss is noted.
- Ototoxic medications have been used in multiple courses or in combination with loop diuretics.
- There has been recurrent or persistent otitis media with effusion for at least three months.\(^4\)

In addition, the American Academy of Pediatrics recommends that infants with the following conditions require periodic monitoring of hearing:

- Family history of hereditary childhood hearing loss
- In utero infection, such as cytomegalovirus, rubella, syphilis, herpes, or toxoplasmosis
- Neurofibromatosis Type II and neuodegenerative disorders\(^5\)

The American Academy of Pediatrics recommend that infants with these conditions should undergo a hearing evaluation at least every six months until age three and at appropriate intervals thereafter.

**Prevalence**

In the general population, the prevalence of newborn hearing loss (depending on the degree of hearing loss) is estimated to be between 1 and 6 of every 1,000 live births. For example, according to a Consensus Statement published by the National Institutes of Health in 1993, in the general population “approximately 1 of every 1,000 children is born deaf. Many more are born with less severe degrees of hearing impairment, while others develop hearing impairment during childhood.”\(^6\)

In Pennsylvania, where approximately 150,000 births occur annually, one can estimate that 150 infants are born deaf every year and that an additional 75 to 750 infants are either born with mild to moderate hearing impairment or develop hearing loss within their first few years of life.

It is important to note that the prevalence of hearing loss among those newborns with risk factors is substantially higher than the prevalence among those without risk factors. Approximately 1-3% (10/1,000 to 30/1,000) of infants admitted to the neonatal intensive care unit have significant bilateral sensorineural hearing loss\(^7\), whereas the incidence in the well-infant population is one tenth of one percent (1/1,000).\(^8\) Another source estimated a slightly higher prevalence rate of hearing loss in an intensive-care nursery at around 2-4%, whereas the prevalence in the well-baby nursery ranges from 0.05 to 0.1%, or about 1/40 the prevalence in the intensive-care nursery.\(^9\)
Benefits of Early Detection

According to the National Institutes of Health, “The first 3 years of life are the most important for speech and language acquisition. Consequently, if a child is hard of hearing or deaf at birth ... it is likely that child will not receive adequate auditory, linguistic, and social stimulation requisite to speech and language learning, social and emotional development ... The goal of early identification and intervention is to minimize or prevent these adverse effects.” The National Institutes of Health also noted, “Significant hearing loss interferes with the development of phonological and speech perception abilities needed for later language learning ... These impairments in communication skills can lead to poor academic performance (especially reading) ...”

One of the national health objectives outlined in Healthy People 2000 is to, “Reduce the average age at which children with significant hearing impairment are identified to no more than 12 months.” The Pennsylvania Speech–Language Hearing Association noted, “The average age of identification of newborn hearing loss in the United States is 20 to 24 months.”

Although proponents of newborn hearing screening recognize that prospective, randomized trials have not been done to establish whether early intervention is effective, the results of retrospective studies coupled with anecdotal evidence suggest that children provided with early diagnosis and intervention fare better academically and linguistically than children with a late diagnosis. According to one source, “a recent NIH [National Institutes of Health] study of children from birth to age 3 concluded that children with normal cognitive ability who are identified with a hearing impairment and placed in intervention before 6 months of age demonstrate age-appropriate language skills. Children who were identified later than 6 months were significantly delayed in their language skills.” One proponent stated that, “Academic achievement ... can approach or match levels reached by children with normal hearing if they are provided with amplification and auditory management by six to eight months of age.”

According to another source, statistically significant differences in development between those with early diagnosis/intervention (prior to 3 months of age) and those with later diagnosis/intervention (after 3 months of age) occurred in the areas of expressive language and general development. In other areas of testing such as gross motor skills, fine motor skills, comprehension/conceptual, comprehension/situational, and personal/social, the differences between early and later diagnosis were not statistically significant.

Methods of Hearing Screening

Three specific methods of hearing screening are mentioned in Senate Bill 938. They are auditory brain stem response, automated auditory brain stem response, and otoacoustic emissions testing. All three of these tests are non-invasive and require that the newborn is sleeping or resting quietly (in some cases, possibly even sedated).

Auditory Brain Stem Response

In an auditory brain stem response (ABR) test, sensors are placed on the scalp and behind the ears of the newborn. A series of sounds is then presented through earphones. The sensors measure electrical energy produced by the auditory nerve and the brain in response to the sound. A computer displays the responses and produces a waveform that shows the brain’s response. In a traditional auditory brain stem response test, an audiologist is needed to interpret the results of the test.
**Automated Auditory Brain Stem Response**

An automated auditory brain stem response (AABR) is very similar to the traditional auditory brain stem response test. The difference is that an audiologist need not perform the automated test. The automated test may be performed by any person who is trained in administering the test. Instead of readings appearing on a computer screen, the machine simply flashes one of two messages – Pass or Refer. According to the National Center for Hearing Assessment and Management, both types of auditory brain stem response testing take approximately 15 to 45 minutes to complete.

**Otoacoustic Emissions**

Otoacoustic emission (OAE) tests (also known as evoked otoacoustic emissions) measure the “sounds” of the inner ear. A probe is inserted into the outer ear and the device emits a clicking sound. If the inner ear is healthy, a microphone in the probe will record an echo-like response. A computer then analyzes the response to determine if the hearing is normal. Otoacoustic emission tests can also be performed by a variety of individuals other than an audiologist. According to the National Center for Hearing Assessment and Management, otoacoustic emission tests typically take between 10 and 30 minutes to perform. Another source, however, states that the screening test can take as little as two minutes to perform.

**Accuracy of Testing**

Both auditory brain stem response tests and otoacoustic emission tests are successful in detecting the vast majority of children with a hearing loss. In other words, the likelihood that a newborn with a hearing loss would pass either test is rare. However, both tests result in a high number of false-positives (i.e. people who receive a positive test result suggesting they have a hearing loss when no hearing loss actually exists). According to the National Institutes of Health, “over-referral is a problem, since there are false-positive ABRs [auditory brain stem response tests] in babies with normal hearing. In the NICU [neo-natal intensive care unit] setting, for every child with significant hearing impairment who is detected, approximately six babies are referred for follow-up. In the well-baby nursery, where the prevalence of hearing impairment is far lower, for every child with significant hearing impairment, more than 100 babies are referred.”

The use of otoacoustic emission testing in the newborn population has come under some criticism. One source noted that, “it is within that period [the first 48 hours of life] that the specificity of EOAE [evoked otoacoustic emissions] testing is at its lowest level.” Another source noted that, “Unfortunately, this quick test [otoacoustic emissions] of cochlear function is reliable on only 60 percent of newborns in the first day or two of life…” Yet another source noted, “In infants less than 24 hours, the failure rate [of otoacoustic emissions testing] was an unacceptable 43%.” Since most newborns are discharged from the hospital within 48 hours of birth, the reliability of the otoacoustic emissions test in this time frame is very important.
Staff Analysis of the Documentation Submitted
(in response to the eight requirements of Act 34, Section 9)

Act 34 of 1993 provides that the documentation submitted to the Council by supporters and opponents of a proposed mandated benefit should address eight specific areas. Following are Council staff findings pertaining to the documentation received for Senate Bill 938 addressing each of these right points.

Summary of Responses to Senate Bill 938

In general, supporters of Senate Bill 938 contend that a universal newborn hearing screening program would assist in early identification of hearing impairment. They contend that the high incidence of newborn hearing loss alone is justification for universal screening. They suggest that children provided with intervention services early (under 12 months old) fare better developmentally and linguistically than those who do not receive intervention until later. They contend that screening only those newborns who are at-risk for hearing loss misses up to half of all cases of newborn hearing loss. They further contend that the screening tests are easy to perform, quick and inexpensive.

Opponents of Senate Bill 938 contend that universal screening of all newborns for hearing loss is not warranted. They suggest that when the risk factor guidelines for hearing impairment are followed properly, most cases of newborn hearing loss are detected. They further contend that the low incidence of hearing loss in the population without risk factors does not justify the cost of screening. They cite the high false-positive rate of the screening tests and suggest that a failed screening test may interfere with the parental bonding process and cause parental anxiety. While they agree that early identification of hearing loss is important, they believe that hearing evaluation can be more appropriately conducted at regular check-ups. Opponents further suggest that the cost of the screening equipment may be burdensome for smaller hospitals and that follow-up services in rural areas may not be sufficient. They note that many infants referred for follow-up testing do not seek such testing. They further contend that screening without having adequate access to follow-up care is without merit.

In addition, opponents suggest that even if a universal newborn hearing screening program is established, it may not be necessary to mandate insurance coverage of the screening tests. They note that while several other states have newborn hearing screening programs, only one state mandates insurance reimbursement. They further suggest that many hospitals, including some in Pennsylvania, have successfully implemented a screening program without third-party reimbursement.

(i) The extent to which the proposed benefit and the services it would provide are needed by, available to and utilized by the population of the Commonwealth.

Universal Screening vs. High Risk Screening

Figures estimate that 1 of every 1,000 infants is born deaf and an additional 1 to 5 of every 1,000 infants suffer from mild to moderate hearing loss or develop hearing loss early in childhood. In Pennsylvania, there are approximately 150,000 births annually. This would suggest that every year, 150 deaf infants will be born and 75 to 750 additional infants will experience delayed onset of hearing loss or be born with mild to moderate hearing loss.
According to one proponent, “based solely on the high incidence of hearing loss, there is a need for a universal hearing screening program.” The issue here is whether a condition which affects 0.1 percent to 0.6 percent of the newborn population is considered to be high incidence. To support their position, proponents compare the prevalence of infant hearing loss to the prevalence of other conditions for which newborns are screened. For example, they note that hemoglobinopathy affects 1 of every 1,600 newborns, hypothyroidism affects 1 of every 3,000 newborns, and phenylketonuria (PKU) affects 1 of every 7,000 newborns.

One of the major issues is whether all newborns should be screened for hearing loss as Senate Bill 938 proposes, or whether screening should be limited to those infants who have risk factors for hearing loss. While submissions from both proponents and opponents suggested there is merit in screening high-risk infants, opponents of universal newborn hearing screening argue that screening all newborns is not justified.

Some suggest that the prevalence of hearing loss in newborns without risk-factors is low. One submission stated, “Only a very small proportion of the total number of newborns with sensorineural hearing loss will fail to meet HRR [high-risk] criteria or criteria for admission to an ICN [intensive care nursery]. In other words, screening all HRR [high-risk] and ICN [intensive care nursery] infants will detect most cases of newborn sensorineural hearing loss.”

Proponents, however, suggest that the statement that only a very small proportion of the total number of newborns with a hearing loss will fail to meet high-risk criteria is “absolutely false.” Proponents suggest that screening only those newborns with risk factors misses up to 50 percent of the cases of newborn hearing impairment. Opponents agree that not all infants with hearing loss will exhibit risk factors. They suggest, however, that there may be a more appropriate way to identify hearing loss than universal newborn screening. For example, one submission suggests that by following the risk-factor criteria more closely, fewer cases of hearing loss will be missed. One pediatrician who opposes universal screening states that, “The high rate of missed cases of hearing loss is due to a number of factors. … some children do not develop hearing problems in the immediate newborn period. … screening for the high risk criteria is not always followed.”

Another study suggested that the risk factors for newborn hearing loss be expanded to include additional conditions. This study found that although length of stay in neonatal intensive care unit, respiratory distress syndrome (including asphyxia), and retrolental fibroplasia were not considered to be risk factors for newborn hearing loss, these conditions were associated with a relatively high rate of newborn hearing impairment.

Conflicting arguments were made to the Council with regard to universal screening of newborns for hearing loss. It appears clear from the documentation submitted that there is a benefit to screening high-risk newborns. The need to screen all newborns remains in question. In addition, the need to mandate insurance coverage for universal screening is unclear.
Screening Tests are Already Available - Access to Follow-Up Care Raises Concerns

Based on the information submitted to the Council, several hospitals in Pennsylvania have universal newborn hearing screening programs (defined as screening at least 90% of all newborns). Additional hospitals screen high-risk newborns for hearing loss.

While some infants may not receive screening at hospitals, hearing screening is available at regular 2, 4, and 6-month check-ups. Some argue that not only is screening available at pediatrician check-ups, but it may be more appropriate to conduct screening at such visits where the rate of false-positives may be lower.

Proponents stated that, “Pennsylvania already has services in place for children who are diagnosed with hearing loss. Children are able to receive amplification [hearing aids, etc.] through the Department of Health or through the PA Medical Assistance Program. Early Interventional Services are readily available throughout the state.”

Several concerns about the availability of tests and accessibility of follow-up care were raised in the submissions. One concern is that, “having screening services available seven days a week, 24 hours a day poses a problem for hospitals since many babies are discharged within 24 hours after birth.” As one study noted, “Staffing the hearing screening program 365 days a year is necessary to be a truly universal program.”

Others note that the cost of the screening equipment may be prohibitive for hospitals with a small number of newborns. For example, the cost for the screening equipment ranges from $5,000 to $25,000 depending on the type of machine (e.g. auditory brain stem response or otoacoustic emissions). In addition, smaller hospitals may not have an audiologist on staff (under whose supervision screening is typically conducted).

Some submissions noted concerns with the availability of follow-up testing and intervention services for those in rural areas. Proponents, however, stated that, “If some of the infants have to be taken a distance from home for the diagnostic testing, that is not unlike many other medical conditions for which rural patients travel out of their area.”

Based on the submissions, universal hearing screening for newborns is currently available at some Pennsylvania hospitals. Additional hospitals provide screening for high-risk newborns. Issues of cost and professional support may impact the availability of screening tests at smaller hospitals. In addition, the availability of further diagnostic services has been called in question. It appears, however, that once a child is identified with a hearing loss, amplification (in the form of hearing aids) is available.

Poor Compliance with Referrals for Follow-Up Testing

While universal newborn hearing screening would require all newborns to undergo initial screening, a separate issue is utilization of follow-up testing. From the submissions received, compliance with referral for further testing is a major impediment to diagnosing hearing loss.

According to one proponent, “Many universal newborn hearing screening programs are experiencing difficulty getting all or most of the babies referred from the screening program to...”
complete the diagnostic process and be enrolled in intervention. Attrition rates of as high as 60% between initial referral and a diagnostic confirmation are not unusual.”\(^{34}\) Another source stated, “...follow-up may represent one of the most problematic areas of the newborn hearing screening program. Unless systematic recruitment efforts are made, 25-80% of infants can be lost to follow-up. Establishing and maintaining a successful follow-up program is considered one of the main challenges of a newborn hearing screening program.”\(^{35}\)

From the submissions, it would appear that utilization of the necessary follow-up tests appears to be rather low. If many of those referred for further diagnostic testing do not comply with the referral, the ability to detect hearing loss in many newborns may be compromised.

(ii) \(\text{The extent to which insurance coverage for the proposed benefit already exists, or if no such coverage exists, the extent to which this lack of coverage results in inadequate health care or financial hardship for the population of the Commonwealth.}\)

Coverage for medically necessary testing (i.e. testing those who are high risk), diagnostic testing, and hearing examinations performed in a physician’s office appears to be widely available. The information submitted to the Council did suggest, however, that coverage for routine screening for normal risk newborns is limited. Nonetheless, the submissions failed to demonstrate that the current lack of coverage for universal newborn hearing screening resulted in either inadequate health care or financial hardship.

\(\text{Adequate Coverage for Those at High Risk}\)

Coverage for medically necessary testing or testing for those in the high-risk population appears to be widely available. According to the Managed Care Association, “Generally, managed care plans perform hearing screening if a newborn appears to be at risk and if the test is determined to be medically necessary. Such coverage also exists for those who receive their health insurance coverage through the State’s Medical Assistance (MA) program.” In addition, diagnostic testing (not screening) is a covered benefit. Highmark stated, “If the screening is performed for non-routine purposes, it is considered diagnostic and reimbursable consistent with a contract’s diagnostic benefit allowance. However, the diagnostic benefit does not specifically list hearing screenings as an eligible service.”

\(\text{Coverage for Routine Screening by a Pediatrician is Widespread}\)

Insurers noted that hearing screening conducted in a physician’s office as part of a regular check-up may be a covered benefit. According to the Managed Care Association, “health insurance provided through HMOs and other managed care plans typically includes regular hearing screenings as part of 2, 4, 6 and 9-month check-ups following birth.” Highmark stated that their, “... health maintenance organization contracts do provide a benefit for routine hearing screening when performed by a primary care physician. This benefit, however, would not address screening administered at the hospital, since it would not be customarily performed by the physician in a hospital setting.”

\(\text{Coverage for Routine Screening May be Limited}\)

According to the Pennsylvania Speech-Language Hearing Association, ‘‘Screenings’ are generally not covered by health insurance.’’ This statement is consistent with that of Highmark. In their submission, Highmark stated, “No defined benefit exists today for newborn hearing
screening under the standard Blue Shield, Comprehensive, Point-of-Service, or Preferred Provider Organizations. All contracts contain some rendition of an exclusion for hearing aids or examinations for the prescription or filling of hearing aids.” However, Highmark also noted, “if the cost of the screening is included in the aggregate hospital billing associated with a maternity stay and associated child care, Highmark’s contractual relationship with hospitals would likely reflect payment for the procedure or procedures, if medically necessary.”

**Does Lack of Coverage Mean Inadequate Health Care?**

Most submissions did not address the issue of whether the lack of insurance coverage for hearing screening tests for newborns is inadequate health care. The two submissions which did so were at odds. The Pennsylvania Speech-Language Hearing Association stated, “It is clear that in the face of the obvious benefits to universal newborn hearing screening, hearing impaired children continue to go undiagnosed until they are beyond the age that they can take full advantage of intervention. There can be little doubt that this amounts to inadequate health care.” The Insurance Federation, however, disagrees. They stated that, “There is no case to be made that lack of an insurance mandate causes inadequate [health] care…”

Insufficient information was received to conclude what effect the lack of coverage for hearing screening of newborns has on the quality of health care.

**Universal Screening Programs Are Operated Without Third-Party Reimbursement**

It appears that a universal newborn hearing screening program may be established without mandating insurance coverage of the screening tests. For example, one source noted that, “the cost of implementing a UNHS program [universal newborn hearing screening program] … [is such] that financing has not been the major obstacle that many feared. Many hospitals have been able to secure funding for the purchase of equipment from service organizations or other foundations.”

Many avenues of funding are available for hospitals who want to implement a universal screening program. For example, one proponent stated that she “facilitated funding for a two-year infant-hearing screening program at Temple University Hospital in Philadelphia, begun in January 1998.” Other hospitals in Pennsylvania, such as Nesbitt Hospital and Penn State Geisigner – Wyoming Valley, also operate screening programs without mandated insurance coverage.

Individual hospitals may provide universal screening programs for a variety of reasons. For example, some hospitals use “the promise of hearing screening more as a public relations or marketing strategy to attract new mothers.” In discussing a universal newborn screening program at a Maryland hospital, one article noted that “No third parties are paying for newborn hearing screening at Holy Cross [the hospital], but the hospital views the program as a service to the community.”

Other states have financed screening programs through grants and other sources of funding. The Insurance Federation noted that even though several states now mandate universal screening, only one state – Rhode Island – mandates insurance reimbursement. Therefore, hospitals and other states have used various other methods to fund such hearing screening programs without mandatory insurance coverage.
As to the issue of whether or not the lack of coverage results in financial hardship, the only comment was from the Insurance Federation. The Insurance Federation stated, “There is no case to be made that lack of an insurance mandate causes inadequate … [financial] hardship.”

(iii) The demand for the proposed benefit from the public and the source and extent of the opposition to mandating the benefit.

Support for Senate Bill 938

There are two relevant issues in this bill – the issue of universal screening and the issue of an insurance mandate. The Council received submissions both supporting and opposing a universal newborn hearing screening program in Pennsylvania. If a universal hearing screening program is established, the information received by the Council suggested strong opposition to mandating insurance coverage of the screening examinations.

In general, the Council received information in support of universal newborn hearing screening programs from audiologists, those representing hearing oriented foundations, and those hospitals who currently have screening programs.

The arguments in favor of universal newborn screening have already been discussed. To summarize the arguments put forward by proponents: (1) screening all newborns for hearing loss is justified because of the high incidence of newborn hearing loss; (2) screening only infants who are at risk misses up to half of all cases of newborn hearing loss; (3) newborn hearing loss has a higher incidence and costs less per infant to diagnose than do other conditions for which newborns are commonly screened; (4) early intervention may minimize the impact of hearing impairment on language development; (5) many hospitals have successfully instituted universal newborn hearing screening programs on their own accord; and (6) the costs of educating a hearing impaired child in a regular classroom is significantly less than the cost to educate a hearing impaired child in a residential setting (this issue is discussed in section (iv) below).

The public demand for a universal newborn hearing program is not clear. The Council received only 3 letters from Pennsylvania residents in support of universal newborn hearing screening. All 3 letters were from parents of hearing impaired children.

Opposition to Senate Bill 938

The arguments against universal screening are discussed below. They include the arguments that: (1) some pediatricians recommend against universal screening in the neonatal period; (2) screening has not been proven to be effective in a randomized, controlled clinical trial; (3) the screening tests have a high rate of false positives; (4) false positive test results may have a negative impact on the parent – child relationship; and, (5) screening infants before hospital discharge may be difficult due to time constraints.

Some Pediatricians Do Not Recommend Universal Screening

There is no consensus among pediatricians as to the issue of universal screening. To illustrate this point, the Council notes the submissions from the President of the Pennsylvania Chapter of the American Academy of Pediatrics, the President of the Pittsburgh Pediatric Society, and a professor of Pediatrics at the University of Pittsburgh School of Medicine. While all three submissions supported screening high-risk infants, they agreed that there are several inherent
problems with screening all newborns. They question the need and appropriateness to screen those newborns without risk factors. This position appears to be consistent with the medical current guidelines of the American Academy of Pediatricians which state that, “Programs should be in place to provide assessment services to neonates identified to be at risk for hearing problems.”\(^{40}\) (italics added)

There are some pediatricians, however, who do recommend universal screening. For example, one pediatrician endorsed “universal screening of all newborn children before discharge from the Nursery.”\(^{41}\) The Pennsylvania Speech Language and Hearing Association was “dismayed to find that some pediatricians still question whether Universal Newborn Screening is an effective way to identify hearing loss in infants. … Clearly not all pediatricians share this view.”\(^{42}\)

This discussion illustrates that there is no consensus about universal hearing screening in the medical community.

*Efficacy of Screening has Not Been Demonstrated by a Clinical Trial*

While there have been a handful of small studies on early intervention, there has not been a clinical trial addressing the efficacy of universal screening. Some pediatricians contend that before universal screening becomes the standard of care, randomized controlled clinical trials on screening must be completed. One opponent stated, “I believe it is important that the results of universal newborn hearing screening be actually tested in a randomized clinical trial.”\(^{43}\) Even proponents of universal screening note the lack of a clinical trial. One submission stated, “Randomized clinically controlled trials of the effects of newborn hearing screening have not been done.”\(^{44}\)

*High Rate of False Positives*

Another concern of opponents of universal screening is the high rate of false positive test results. One of the supporters of universal screening states “… there is an unacceptable number of false positives…”\(^{45}\) The National Institutes of Health recognize that a high number of referrals for follow-up testing may be a problem, stating “over-referral is a problem, since there are false-positive ABRs [auditory brain stem response tests] in babies with normal hearing. In the NICU setting, for every child with significant hearing impairment who is detected, approximately six babies are referred for follow-up. *In the well-baby nursery, where the prevalence of hearing impairment is far lower, for every child with significant hearing impairment, more than 100 babies are referred.*”\(^{46}\) (italics added)

The high number of false positives can be seen in a variety of studies on newborn hearing screening. While only 0.1 percent to 0.6 percent of the newborn population has a hearing loss, as many as 10 percent of the newborns screened are referred for follow-up testing. Therefore, the majority of infants referred for follow-up care are false positive results. Senate Bill 938 would require insurers to cover the costs of the follow-up testing.

One way to reduce the number of false positives, is to re-screen infants before discharge. Some hospitals may screen an infant first with otoacoustic emissions testing. If the infant fails the initial test, they may be re-screened with auditory brain stem response testing. One hospital in Maryland even goes as far as to screen infants twice with otoacoustic emissions and once with auditory brain stem response before referring them for follow-up care. While this does reduce the number of false positives (i.e., the number of infants referred for follow-up testing) to
approximately 2 percent\textsuperscript{47}, this also necessitates more testing in the hospital. Even in the hospital where three screening tests are performed before a referral for follow-up is given, an average of 7.7 infants are referred for every 1 infant diagnosed with hearing loss.\textsuperscript{48}

**Do False Positive Results Have an Impact of the Parent-Child Relationship?**

Opponents of universal screening contend that false positive screening results may interfere with the bonding between parent and child. For example, one pediatrician stated that, “The immediate newborn period is a very sensitive time for families to become attached to their children. … Therefore, to perform a test in the newborn period which will basically give a message to 10% of all new parents that their child may not be normal is something that should not be undertaken lightly.”\textsuperscript{49}

While supporters of universal screening agree that parental anxiety may be an issue for those who receive false-positive results, they believe that, “The concern for potential parental alarm should not preclude the implementation of screening programs.”\textsuperscript{50} According to another supporter, “It is certainly worth having to put up with a few false positive tests than to miss the one child who may have a hearing loss and could have been fitted early on with hearing-aids.”\textsuperscript{51} Another proponent stated that, “We do not withhold identification and treatment of other medical disorders for concern about bonding.”\textsuperscript{52}

Proponents suggest that parental fears can be allayed by simply explaining the screening procedures and reminding parents that it is a screening test, not a diagnostic one. Opponents argue that easing these fears during the short hospital stays surrounding births is not possible.

**Is the Hospital the Proper Place to Screen?**

Another concern raised by opponents is that newborns are in the hospital for only a limited time before they are discharged. One pediatrician noted that, “The expectation that a universal hearing screening will be done in the newborn nursery within the usual 48 hour stay is difficult at best. That time period is already filled with a multiplicity of tasks geared towards stabilizing the mother and baby for discharge.”\textsuperscript{53} Another pediatrician suggested that if a newborn hearing screening program is implemented, that he “would strongly urge that it not be done in the immediate newborn period. There are far too many other crucial issues related to the birth of a new baby that need to be addressed.”\textsuperscript{54}

Proponents contend that many hospitals, including some in Pennsylvania, already have universal screening programs which screen newborns before they are discharged (and sometimes within 24 hours of birth). According to supporters, the concern that time may not be adequate for screening tests to be performed before discharge is unfounded.

**Alternatives to Universal Screening**

Opponents suggest that rather than mandating universal newborn hearing screening, added emphasis should be placed on identifying those newborns who are high risk and screening them. In addition, one opponent suggests that, “To detect those rare deaf infants in the normal nursery, a vigorous campaign directed at educating primary-care providers and parents to be continually alerted to the possibility of hearing loss makes far more sense and would cost far less than a program of universal screening.”\textsuperscript{55} Opponents also suggest that screening examinations may be more appropriately conducted at regular infant check-ups than in the hospital.
General Opposition to Health Insurance Mandates

As previously noted, Senate Bill 938 would establish a universal newborn hearing screening program and require insurers to cover the costs of screening and follow-up testing. Both the purchaser and insurer communities express strong opposition to the general idea of legislatively imposed health care mandates. In general, opponents of mandates contend that mandates result in rising health insurance costs, which cause employers and individuals to drop coverage, and thereby contribute to the increasing number of uninsured. The following are some of the arguments made by opponents of mandates:

- Mandated benefits increase premiums, which may result in employers dropping health benefits for their employees. When employers who have cancelled health insurance benefits have been polled on why they did so, the majority claimed that it was because the price was too high. Lower-income workers were the most likely to lose coverage. Employers who provide health care coverage will be faced with additional costs through mandates, thus putting them at a competitive disadvantage. Increased costs also result in more employees declining coverage when it is offered by their employer. According to a recent study, 75% of workers purchased coverage through their employers in 1989; in 1996, this figure had dropped to 70%.

- Mandates cause an increasing number of large employers to self-insure, thus avoiding such mandates. The market covered by mandates then “becomes the province (and problem) of smaller businesses.” Small businesses and individuals lack the purchasing power of larger groups. Therefore, any increase in premiums will disproportionately affect individual purchasers and small businesses. Each new benefit mandate increases by 1.5 percent the likelihood that a small business may not be able to afford or offer coverage.

- Some benefits may not be appropriate for a particular group. Mandates limit the ability of purchasers to structure benefits packages based on the needs of specific groups.

- By increasing health care costs, mandates have the potential to increase the number of uninsured. In Pennsylvania the percentage of insured increased from 8.6% in 1987 to 11.6% in 1995, a period during which several mandates were enacted.

- State benefit mandates tend to disproportionately advantage specific provider groups.
(iv) All relevant findings bearing on the social impact of the lack of the proposed benefit.

The social impact of hearing impairment is clear. The need for early identification and intervention of cases of newborn hearing loss is discussed in the section of this report entitled “Hearing Impairment in Children.” To briefly summarize, “The first 3 years of life are the most important for speech and language acquisition. Consequently, if a child is hard of hearing or deaf at birth … it is likely that child will not receive adequate auditory, linguistic, and social stimulation requisite to speech and language learning, social and emotional development …The goal of early identification and intervention is to minimize or prevent these adverse effects.”

According to one source, “a recent NIH [National Institutes of Health] study of children from birth to age 3 concluded that children with normal cognitive ability who are identified with a hearing impairment and placed in intervention before 6 months of age demonstrate age-appropriate language skills. Children who were identified later than 6 months were significantly delayed in their language skills.”

Proponents also argue that the costs for educating a child with hearing impairment can be substantial. According to the Pennsylvania Speech-Language Hearing Association, “A 1988 cost analysis conducted for the U.S. Department of Education concluded that every child with a hearing impairment who is educated in a self-contained classroom costs $6,306 more than the cost in a regular classroom. Educating a child in a residential program costs $32,397 more than a regular classroom.” One can presume that proponents would suggest that with early detection, a child may be less likely to require expensive education in a residential program, however, that argument was not explicitly made.

Some opponents, however, argue that there may be social costs to the parent-child relationship if newborn screening is mandated. They are concerned that false positive results will generate undue parental anxiety and stress in a time which is essential for the development of a parental relationship.

(v) Where the proposed benefit would mandate coverage of a particular therapy, the results of at least one professionally accepted, controlled trial comparing the medical consequences of the proposed therapy, alternative therapies, and no therapy.

One of the major concerns of opponents is that no randomized, controlled trial concerning the effects of universal newborn hearing screening has been conducted. Supporters recognize that there has not been a prospective clinical trial, but they argue that anecdotal evidence and retrospective studies indicate that early intervention (under 6 months of age) is preferable to later intervention.

Supporters contend that a randomized, controlled clinical trial to study the impact of early intervention would be unethical since it would require withholding services from infants diagnosed with a hearing loss. Opponents argue, however, that a randomized trial of screening (not early intervention) would be appropriate since treatment would not be withheld once an infant is diagnosed. Opponents contend that it is necessary to have the results of a controlled trial before any decisions are made to implement a universal screening program.
(vi) Where the proposed benefit would mandate coverage of an additional class of practitioners, the result of at least one professionally accepted, controlled trial comparing the medical results achieved by the additional class of practitioners and those practitioners already covered by benefits.

Senate Bill 938 does not specifically cover an additional class of providers. It should be recognized, however, that hearing screening is most often conducted either by or under the supervision of an audiologist. It should also be noted that Senate Bill 938 states that anyone properly trained to conduct the screening tests may do so. Therefore, some of the screening tests may be performed by volunteers, not health care professionals, as is the case in many hospitals with screening programs. It is presumed that an audiologist or other medical professional will be available to answer questions from parents, assist with testing as necessary, etc., although such a provision is not stated in the bill.

(vii) The results of any other relevant research.

Recommendations of National Health Agencies

The recommendation of the U.S. Preventive Services Task Force – an advisory board to the U.S. Public Health Service - states, “While congenital hearing loss is a serious health problem associated with developmental delay in speech and language function, there is little evidence to support the use of routine, universal screening for all neonates. Although screening methods have reasonable sensitivity and specificity, a substantial number of infants will be misclassified because the prevalence of hearing impairment is low. Also, screening technology is evolving, and the costs and feasibility for universal application are not fully known.”

A Consensus Statement issued by the National Institutes of Health recommends that, “universal screening be implemented for all infants within the first 3 months of life.” They further recommend that, “all infants admitted to the neonatal intensive care unit be screened for hearing loss prior to discharge.” It is important to note while universal screening is recommended, the National Institutes of Health does not specifically recommend that screening be conducted before a newborn is discharged from the hospital, unless that newborn was in the neonatal intensive care unit. The National Institutes of Health states that, “Identification of all children with hearing impairment at birth is ideal.” They also note, however, that, “As a practical matter, the cost of universal screening has been prohibitive.”

The results of other relevant research have been discussed in other sections of this report.

(viii) Evidence of the financial impact of the proposed legislation, including at least:

(A) The extent to which the proposed benefit would increase or decrease cost for treatment or service.

Based on the information received by the Council, it would appear that if universal newborn hearing screening is enacted, the cost for screening tests would increase. The reasons behind this are two-fold. First, some hospitals currently roll the cost of screening into maternity services. According to the Insurance Federation, “In this respect, the insurance mandate is probably counterproductive as it offers an inducement for some institutions to break out the service, increase its price and roll into it more staff time, overhead and other charges.” The second reason is that those hospitals which are currently providing screening free of charge may begin to charge for screening services, thereby raising screening costs.
Since Senate Bill 938 states that any trained individual may perform the test, another consideration is whether the test is performed by a volunteer or by a health care professional. The difference is simple – a volunteer requires no additional staff costs, whereas the cost for a paid screener is between $25 and $65 per test. The information submitted to the Council, however, was insufficient to determine the exact impact a universal hearing screening mandate would have on the increase in cost for the screening tests.

(B) **The extent to which similar mandated benefits in other states have affected charges, costs and payments for services.**

Several states have universal newborn hearing screening programs. They differ greatly in design, however. Most states require that only high-risk infants be screened for hearing loss. For example, while some sources suggest that Ohio has a universal screening program, the first level of screening is simply a questionnaire to determine if the infant is at risk for hearing loss. Only those infants who are high risk are actually screened for hearing loss using auditory brain stem response or otoacoustic emissions testing. Senate Bill 938 would require all newborns to be screened, not just high-risk infants.

According to one source, “Although 19 different states currently have some type of legislative mandate related to newborn hearing screening, 17 of these focus only on children who exhibit one or more of the high-risk indicators. Thus, Rhode Island and Hawaii are still the only two states with legislative mandates for universal newborn hearing screening.” Council staff notes that since the publication of this article, two additional states, Colorado and Utah, have enacted universal newborn hearing screening programs. This brings the number of states with legislation addressing newborn hearing to 21 and the number of states with universal programs to 4.

The states with legislation addressing newborn hearing screening are: Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Mississippi, New Jersey, Ohio, Oklahoma, Rhode Island, Utah, Virginia, and West Virginia. Only four states – Colorado, Hawaii, Rhode Island, and Utah – require all newborns to be screened. Only one state – Rhode Island – mandates insurance reimbursement for the screening examinations.

According to one source, the universal newborn hearing screening program in Hawaii has been successful. “The percentage of newborns screened in Hawaii’s program increased from 19% in 1992 to 95% in 1997. The average age of identification was reduced from 42 months for the previous five years where complete information could be obtained to 3 months. The average age of amplification (providing hearing aids, for example) declined from 50 months to 7 months in the same time period.” The cost for the universal newborn hearing screening program in Hawaii ranges from $30 to $50 per child screened.

With regard to Rhode Island, one submission noted, “In contrast to the U.S. average of 30 months, Rhode Island’s 1996 average age of diagnosis was 3.5 months.” One source calculated the cost of the universal hearing screening mandate for one Rhode Island hospital to be $26.05 per infant screened.

Pennsylvania’s proposal is different than the ones in Hawaii and Rhode Island. In Hawaii, the Department of Health provided seed money in the form of equipment, supplies, technical support, training, and (in the early years) personnel to do the screening. In Rhode Island, there
is a central registry for tracking and referring infants for follow-up testing and intervention, the Rhode Island Hearing Assessment Project. This additional agency is supported by the coordination fee of $18.15 per live birth that is paid by each hospital to the state of Rhode Island. In addition, “Rhode Island’s screening program became operational 2 ½ years before the passage of the legislation. By the time the legislation was being considered, 70% of all live births in the state were being screened.”

Therefore, the legislation had a relatively small impact.

One submission noted that “In both cases [Rhode Island and Hawaii], the legislation is simple and concise and does not specify a specific screening methodology or protocol. Given how rapidly the technology for newborn hearing screening continues to evolve, this is certainly the best approach.” Unlike the legislation in Hawaii and Rhode Island, Pennsylvania’s proposed legislation, Senate Bill 938, refers to specific screening methods.

The demographics of Pennsylvania are very different than in Hawaii and Rhode Island. In Pennsylvania, there are approximately 150,000 births annually at over 150 birthing facilities. In Hawaii, there are only 20,000 births annually, over half of which occur in two hospitals. Rhode Island has only 14,000 births annually in 8 hospitals. Therefore, the logistics of implementing a statewide universal screening program in Pennsylvania are more difficult than in Hawaii and Rhode Island.

Another consideration is that the cost of the screening programs in Hawaii and Rhode Island appears to be limited solely to the costs of the screening examination. The average cost per infant screened does not appear to take into consideration the costly follow-up testing which may be necessitated (although costs for re-screening do appear to be included); therefore, the cost estimates for the programs in Hawaii and Rhode Island may be lower than the total cost impact, including follow-up testing.

(C) The extent to which the proposed benefit would increase the appropriate use of treatment or service.

If universal newborn hearing screening is mandated, the use of screening services will increase substantially, as is the intent of the legislation. Some question whether this increase in screening is appropriate or necessary. As previously discussed, opponents suggest that the low incidence of newborn hearing loss in the population without risk factors does not justify screening this population. They further suggest that many infants referred for follow-up testing will receive additional testing which is not medically necessary. Therefore, while the use of screening will increase, it is debatable whether or not this increase is appropriate.

(D) The impact of the proposed benefit on administrative expenses of health care insurers.

Since insurers would be required to cover the costs of screening tests, referrals, and follow-up testing, there will be administrative costs involved. Highmark estimated that administrative expenses for all commercial insurers resulting from a universal newborn hearing screening mandate will initially be $569,264. The Council did not receive additional information addressing the administrative costs of the proposal.
(E) **The impact of the proposed benefits on benefits costs of purchasers.**

Insufficient information was received to determine the exact impact universal screening would have on the benefits costs of purchasers. Although submissions agreed that costs would increase, the amount of increase was in dispute. One issue which will determine the cost of the screening is the type of screening test which is used. The cost of an auditory brain stem response test can be twice the cost of an otoacoustic emissions test. In addition, one of the major costs of screening is that of staff. If screening is conducted by volunteers or by staff who fit screening tests among other responsibilities, the cost will be significantly less than if screening is conducted by staff hired solely for the purpose of conducting screening.

One proponent attempted to estimate the cost of a universal newborn hearing screening mandate. This submission calculates that the cost increase of a mandate would be between $0.39 to $0.55 per year per insured.\(^76\) This estimation, however, is based on the assumption that there are over 9.4 million privately insured Pennsylvanians and that the cost of newborn hearing screening would be spread equally among all insureds. Since the U.S. Census Bureau estimates that Pennsylvania has approximately 7.5 million privately insured people, the increase in premiums will most likely be higher. This calculation also fails to account for administrative costs of the insurer, which will also increase premiums.

Highmark calculated the average cost of a hearing screening test to be $87, including both administration of the test and interpretation of the results. Highmark calculated that the cost of a universal hearing screening mandate would be about $5,123,374 for all commercial insurers in Pennsylvania. (This figure does not include self-insured plans.) These costs would likely be passed along to purchasers, although Highmark did not specify the amount of increase purchasers could expect.

While there will be increased cost from implementing a universal screening program, the exact amount of the increase cannot be determined from the information received by the Council.

(F) **The impact of the proposed benefits on the total cost of health care within the Commonwealth.**

The information submitted to the Council suggests that universal newborn hearing screening will increase the total cost of health care in Pennsylvania.

Highmark calculates that the increase for commercial insurers (without taking self-insured plans into consideration) may be in excess of $5 million per year. The Council notes, however, that while self-insured plans may elect not to cover the cost of hearing screening examinations, the screenings will still be mandated and the costs incurred will need to be paid by someone, even if it is not an insurance company.

Even proponents agree that health care costs will increase. One proponent stated that, “The total cost of health care within the Commonwealth will increase very slightly as a result of mandating universal newborn hearing screening.”\(^77\) Proponents suggest that the cost of screening may be offset by a reduction in other services children with a hearing loss may require. For example, one proponent stated that, “The cost savings to the state in reduced special education costs for children with hearing loss would be many times the cost of implementing a universal newborn hearing screening program.”\(^78\)
For example, the submission from Pennsylvania Speech-Language Hearing Association stated, “For the first two and one-half years, no savings would be expected from a universal screening program, because unscreened hearing-impaired children are diagnosed, on average, some 30 months later. Nevertheless, beginning in the 3rd year, true savings can be calculated in the avoidable costs of later evaluation and intensive speech-language intervention. … Furthermore, additional expenses accrue for children not diagnosed at birth who go on to require some form of special intervention once they reach school age…” They provide an example that, “If only half of hearing impaired children realize some ultimate savings in school-based costs because of newborn screening and early amplification, a universal screening program … could recover all screening costs after only 10 years through subsequent savings in avoided intervention. … Recovery of all initial costs (and subsequent cost savings) is independent of improved developmental outcomes, a worthy goal in and of itself.”

This information, however, represents estimations and are not based on actual experiences. One submission noted that a “cost-benefit analysis, in which the outcomes of a screening program are assessed and assigned a monetary value and compared to the costs of the program, has not been done. Although people frequently ask whether newborn hearing screening is cost beneficial, such studies do not exist.”

Opponents note that while the costs of a newborn hearing screening mandate may not be substantial in and of themselves, they nevertheless contribute to an increase in the cost of health care. In addition, some opponents argue that a universal hearing screening mandate will contribute to the cumulative impact mandates have on increasing the number of uninsured and raising health care costs. The Managed Care Association notes, “These impacts would seem a high cost to pay when the American Academy of Pediatrics’ medical guidelines do not recommend universal screenings.”

Other Policy Considerations

This proposal raises issues of uncompensated care. Senate Bill 938 mandates that every newborn will be screened for hearing loss and mandates that insurance policies must provide coverage for such testing. State law, however, is pre-empted by the federal Employee Retirement Income and Security Act of 1974 (ERISA). Therefore, the state only has the ability to impose mandated insurance benefits on non-ERISA exempt policies. ERISA exempt employers may choose to add the benefits mandated by Senate Bill 938, but they would be under no obligation to do so. The Department of Insurance estimates that as many as half of the privately insured people in Pennsylvania receive their health insurance from an ERISA exempt employer. People without insurance would obviously not have coverage for the screening and this would thereby impose additional uncompensated care costs on the hospital.

No specific screening protocol is outlined in Senate Bill 938. The National Institutes of Health suggest that a two stage screening strategy be implemented to limit the number of false positives. They suggest all newborns should initially be screened with an otoacoustic emissions test. Those infants who fail the test should then be re-screened with auditory brain stem response test. Only those infants who fail both screening tests should be referred for follow-up testing. Senate Bill 938 does not specify that hospitals follow this screening protocol. Some hospitals may choose only to screen a newborn once before referral for follow-up. Other hospitals may choose to use the more expensive auditory brain stem response test initially.

Even following the National Institutes of Health protocol, there are possible areas of concern. First, this would require that all hospitals have the equipment to perform both types of tests.
Secondly, even using this two-tiered protocol, the majority of infants referred for follow-up will still have false positive results. Finally, conducting two (or possibly more) tests on as many as 10 percent of the newborn population raises additional cost concerns.

There is a possibility that the Commonwealth may be held liable if newborn hearing loss is not detected. One article which the Council received stated, “Interestingly, it is important to note that in some states a missed infant is allowed to bring suit up to 3 years after the age of majority. That is, an individual with hearing loss who was missed on a neonatal hearing screening test or in follow-up could conceivably sue the screening program up to 21 years after birth.”\(^{81}\) If the screening program is conducted under the supervision of the Department of Health, the state may experience additional liabilities. On the other hand, proponents note that hospitals and physicians may be at risk if a case of hearing impairment went undetected because no screening program is in place.

Council Cost Estimate

The following cost estimate was calculated by Council staff based upon information submitted in response to Senate Bill 938. This estimate represents the total cost impact of the proposal and is not designed to determine who would pay for the screening.

Population to be Affected. Figures published by the Pennsylvania Department of Health state that there were 156,431 births in 1994, 150,848 births in 1995, and 147,723 births in 1996.\(^{82}\) Based on these figures, the average number of births per year from 1994 to 1996 was 151,723. Since screening would be mandated independent of insurance coverage, all 151,723 newborns would need to be screened for hearing loss, regardless of what insurance, if any, they have.

Percentage of the population already covered. The information submitted to the Council suggested that coverage for routine hearing screening of all newborns in a hospital setting is rare. For the purposes of this cost estimate, Council staff assumed that no reimbursement for hospital based screening is currently available. Although other screenings are already reimbursed, Senate Bill 938 would require coverage of hospital based screening for all newborns. Therefore, even though managed care contracts often cover hearing screenings conducted in a pediatrician’s office, they would also be required to cover screening in the hospital.

Projected Utilization. Since all newborns would be required to be screened for hearing loss, independent of insurance coverage, Council staff assumed utilization of screenings would be 100 percent.

Cost of Screening. The cost of screening varies greatly depending on the staff involved, the method of testing used, and the location of the screening within the hospital. For example, a screening examination conducted by an audiologist utilizing auditory brain stem response technology in a room set aside particularly for hearing screening would be much more expensive than an otoacoustic emissions test conducted by a volunteer in the nursery. Either of these two combinations, as well as a variety of other options are all possible since Senate Bill 938 does not specify who must conduct the test, exactly which test must be used, or where the test would be conducted. Therefore, the cost of screening is difficult to assess.

A range of cost estimates (from an average of $7.42 per infant to $87 per infant) was submitted to the Council. Council staff based this cost estimate on the cost of a universal newborn hearing screening program at Women & Infants Hospital in Rhode Island which was $26.05 per
infant screened in 1993. Using this 1993 figure from Rhode Island and estimating an average rate of inflation of 3% per year, Council staff estimated that the cost of a newborn hearing screening program in 1999 to be approximately $31.10 per infant screened.

Projected Cost of Universal Screening. Using the population estimate of 151,723 infants born in Pennsylvania every year and the cost of screening to be $31.10 per infant, the cost of a universal newborn screening program in Pennsylvania would be approximately $4.7 million annually.

Projected Cost of Screening High-Risk Infants. According to the National Institutes of Health, approximately 9 percent of newborns have risk factors for newborn hearing loss. Combining this estimation with the population and cost estimations provided above, the cost of screening high-risk infants for hearing loss would be approximately $425,000 per year.
Submissions for Senate Bill 938

1. **The Insurance Federation of Pennsylvania** (John R. Doubman, Secretary & Counsel)
   C. Letter dated September 14, 1998, supplementing original submission on Senate Bill 938.

2. **The Managed Care Association of Pennsylvania** (Kimberly J. Kockler, Executive Director)
   A. Letter dated August 17, 1998, addressing section 9 requirements and opposing Senate Bill 938.

3. **Highmark** (Bruce R. Hironimus, Vice President, Government Affairs)
   A. Cover letter dated August 20, 1998, opposing Senate Bill 938.

4. **American Academy of Pediatrics** (Bradley J, Bradford, MD, President of the Pennsylvania Chapter)


_B. “Statement of PSHA Regarding the Health Care Cost Containment Council’s Review of Senate Bill 938.”
_D. “Joint Committee on Infant Hearing 1994 Position Statement.”
_H. “Hospitals in USA Reported to Have Universal Newborn Hearing Screening (UNHS) Programs (i.e., screening at least 90% of births/admissions as of July 1, 1997).” From the web site http://www.usu.edu/%7Encham/programs_in_us.html.


6. **National Center for Hearing Assessment and Management at Utah State University** (Karl R White, Ph.D., Director)

   A. Letter dated August 18, 1998, addressing section 9 requirements and supporting Senate Bill 938.

   B. “Universal Newborn Hearing Screening: Issues and Evidence.”

7. **National Organization for Hearing Research** (Geraldine Dietz Fox, President)


   B. “Answers to: Question/Issues for Discussion from the Pennsylvania Department of Health Regarding a Newborn Hearing Screening Workgroup Meeting held in Harrisburg in Spring, 1998.”


8. **Robert C. Cicco, M.D.** (President of the Pittsburgh Pediatric Society)
   A. Letter dated August 19, 1998, opposing Senate Bill 938 on behalf of the Pittsburgh Pediatric Society board of directors.

9. **Jack L. Paradise, M.D.** (Professor of Pediatrics, University of Pittsburgh School of Medicine, Children’s Hospital of Pittsburgh)
   F. “Letters to the Editor.” *Pediatrics*.

10. **Christina Seaborg (Director of Audiology, Penn State Geisinger - Great Valley)**

11. **Diane L. Sabo, Ph.D.** (Clinical Director of Audiology, Children’s Hospital of Pittsburgh)
    B. National Center for Hearing Assessment and Management. “Universal Newborn Hearing Screening Fact Sheet.”

12. **Eric S. Cahill, M.S. CFY-A** (Audiologist & Program Coordinator, Universal Newborn Hearing Screening, Temple University School of Medicine)

13. **Louis R. Sieminski, Ph.D.**
14. **State Interagency Coordinating Council ad Hoc Committee on Universal Hearing Screening** (Sheila Coyne, Co-Chair, and Irene B. Merenda, Secretary)

B. “Universal Hearing Screening for Infants.”
F. “Joint Committee on Infant Hearing 1994 Position Statement.”


A. “Statement of AFLAC® Regarding the Health Care Cost Containment Council’s Review of Senate Bill 938.”

16. **Women & Infants Hospital of Rhode Island**

A. “Sound Beginnings RIHAP.”
B. “Rhode Island Hearing Assessment Program.”

17. **Independent Insurance Agents of Pennsylvania** (Vince Phillips, Vice President for Government Affairs)

A. Letter dated July 16, 1998, concerning the impact mandates have on small business and the possible correlation between additional mandates and large employers becoming self-insured.

18. **Michael S. Imbrogno, M.D., F.A.A.P.**


19. **Gilbert R. Herer, Ph.D., CCC-A/SLP** (Chair, Department of Hearing and Speech, Children’s National Medical Center)

C. Letter from Kathleen M. Hanyob addressed to Dr. Herer. (distributed with permission.)
E. “Newborns Hearing Screening Program.” Pamphlet from Holy Cross Hospital.

20. Bret S. Yarczower, M.D.


21. Pennsylvania Academy of Audiology (Christina Seaborg, MA and Louis R. Sieminski, Ph.D.)

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49 cicco
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