

# **POLICY**

## **NEWBORN SCREENING & GENETICS PROGRAM NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **NEBRASKA NEWBORN SCREENING ADVISORY COMMITTEE (NBSAC) CHARTER**

#### **PURPOSE**

The Nebraska Newborn Screening Advisory Committee shall advise the Nebraska Newborn Screening & Genetics Program of the Nebraska Department of Health and Human Services on matters related to population screening of newborns for congenital diseases/disorders or conditions, inherited diseases/disorders or conditions, and inborn errors of metabolism.

#### **SCOPE OF AUTHORITY**

The Committee is responsible for reviewing the state of the art for newborn screening practices across the United States and recommending policy for appropriate adoption of newborn screening practices for the State of Nebraska.

Quality Assurance: The NBSAC shall meet quarterly, and as needed to review quality assurance reports developed by or obtained by the Newborn Screening Program. The quality assurance reports shall reflect measures of quality on all aspects of the screening system, including but not limited to: specimen collection, handling and transport, laboratory testing, laboratory reporting, initial notification, follow-up & retrieval, confirmatory testing, and for infants with a confirmed diagnosis for each of the diseases screened: diagnosis, management and treatment outcomes. The NBSAC shall make recommendations for strategies the program may employ to improve on any quality assurance measure deemed by the Committee to need improvement.

Composition of Screening Panel(s): Any member of the Committee or Program Staff may request review of a disease or diseases for addition to or deletion from the required/mandatory newborn screening panel or as a supplementary optional disorder to be made available systematically to all newborns in Nebraska. The actual review of a disease/disorder or condition must be approved by a simple majority of the committee. The Nebraska Newborn Screening Program must make all review materials available to the committee membership 2 weeks prior to the quarterly meeting following the meeting at which review was approved.

Technology review: The Committee is responsible for thoroughly reviewing technical aspects and clinical utility of analytical test methods proposed for use by the contracted newborn screening laboratory, and in the absence of a contract, by competitively bidding

contractors. Following such review the Committee shall recommend approval, disapproval or modification of any aspect of the methodology for inclusion in the contract.

All recommendations approved by a simple majority of the Committee that would/will require significant change by the program, (e.g. addition of a new disease to the required screening panel, regulation or statutory revision, or anything requiring a new or additional expenditure of funds) shall be proposed by the Chair and/or Vice Chair with the Program Manager through the Department of Health and Human Services chain of command to the Director of the Department, and the Chief Medical Officer of the Department of Health and Human Services. Changes requiring additional funding (federal or state) or approval of additional FTE's may require approval of the Director of the Department of Health and Human Services.

## **SPONSOR**

The NBSAC is commissioned by the Newborn Screening & Genetics Program in the Lifespan Health Services Unit Division of Public Health of the Nebraska Department of Health & Human Services and members are appointed by the Director of the Division of Public Health. The NBSAC is accountable to the program for analysis of results for quality improvement and advice regarding new candidates for screening and technical changes to screening paradigms.

## **SUB-COMMITTEES**

Sub-committees may be utilized by the NBSAC as deemed appropriate by the Committee for review of special topics on an ad-hoc basis. Sub Committee membership may include members and non-members of the Committee in order to obtain appropriate professional and technical expertise relevant to the topic.

## **ROLES & RESPONSIBILITIES**

Project Staff: The Newborn Screening & Genetics Program Manager, Follow-up Coordinator , Follow-up Specialist and Administrative Assistant to the program shall provide support to the committee in the following ways:

- Locating and organizing and preparing pertinent background information
- Interpreting programmatic policies, regulations and statutes
- Drafting reports and meeting minutes
- Making meeting arrangements
- Collaborating with the Committee Chair and Vice Chair in establishing meeting agendas and approval of meeting minutes
- Writing reports for the review, revision and approval of the Chair and Vice Chair on Committee recommendations for the Department's chain of command.

NBSAC members: The Committee members are responsible for:

- Providing input of ideas and participation in discussion
- Reviewing and commenting on research, reports and other background information
- Attending quarterly meetings
- Recommending strategies for program improvement
- Voting on issues requiring a vote
- Providing recommendations to the Program Manager of candidates for membership on the NBSAC to fill vacant representative positions.

Chairperson: In addition to the same responsibilities as other NBSAC members the Chairperson is responsible for:

- Approval of meeting agenda's and meeting minutes
- Consultation with program staff in reviewing reports and background materials prepared for meetings
- Chairing quarterly meetings, and emergency meetings as needed
- Declaring emergency meetings when a public health emergency relative to newborn screening is noted.
- Consultation with the Vice Chair and program staff in developing reports for recommendations to be made through the Department's chain of command.

Vice-Chairperson: In addition to the same responsibilities as other NBSAC members the Vice-Chairperson is responsible for:

- Back-up of all Chairperson responsibilities in the absence of the Chair prior to, during and after Committee meetings
- Consultation with the Chairperson and program staff in developing reports for recommendations to be made through the Department's chain of command.

## **MEMBERSHIP**

The membership of the committee shall be representative of stakeholders with interest in and concern for screening of newborns for congenital and inherited diseases/disorders and conditions and inborn errors of metabolism. Minimum membership shall consist of at least one representative from each of the following categories: a pediatric specialist relevant to each disorder screened (e.g. pediatric hematologist, a pediatric metabolic specialist, a pediatric endocrinologist, a pediatric pulmonologist, pediatric immunologist) a pediatrician practicing in a Nebraska community, a family practitioner practicing in a Nebraska community, a neonatologist, a pathologist, a laboratory Ph.D. level or above chemist, a hospital representative, a nutritionist practicing at a Nebraska metabolic clinic, a geneticist, a nurse practitioner practicing at a Nebraska metabolic clinic, a parent or consumer representative for each disorder, or class of disorders screened, and a medical ethicist. Some members may fulfill representation of more than one role.

The Chairperson and Vice-Chairperson shall be nominated by the Committee with the majority approval of the NBSAC membership.

### **Membership/Service Terms**

Each member is requested to serve a term of 3 years, but may continue to serve at their discretion for longer periods, unless their absence at meetings exceeds attendance at meetings. Specifically any member who does not participate in more than 1 of 4 meetings per year for two years in a row will be asked to vacate their representative position. The request to vacate can be over-ridden by a majority roll-call vote of the Committee.

The terms of service for the Chair and Vice Chair shall also be 3 years.

### **OPERATING PROCEDURES**

The NBSAC must have a simple majority (greater than 50% of the membership) to constitute a quorum at any meeting including teleconferences. The committee may meet without a quorum but may not vote on any issues. Issues requiring a vote are those that will require a regulatory or statutory change, or additional expenditure or FTE in order to operationalize.

Issues requiring a vote must have clearly stated motions seconded. Votes passing in the affirmative require a simple majority of the quorum voting in favor of the motion.

The NBSAC shall meet once quarterly. At least 2 meetings per year shall be held in person with the exception of emergency meetings, held in interim periods between quarters, which may be held by teleconference, videoconference or other means. The Chairperson may call for emergency/interim meetings at his/her discretion.

The NBSAC shall review the Charter at a minimum once every 2 years.

### **GUIDING PRINCIPLES**

The NBSAC shall operate with the “Guiding Principles on Human Genetic Technologies” as the governing context and standard of reference. The guiding principles as appended here from the “Report of the Nebraska Commission on Human Genetic Technologies” Submitted to the Nebraska Legislature pursuant to law 71-8106 (LB111 1997) December 1998 are:

“... {the Commission’s} central purpose is to encourage uses of human genetic technologies that contribute to the improvement of the human condition while assuring the protection of fundamental human rights. In these principles the term “respect” acknowledges that compelling social interests may at times require abridgement of individual liberties regarding the use of genetic technologies in order to protect the well-being of society as a whole.

### Respect for Humanity

1. The inherent dignity and intrinsic value of human beings must govern all uses of human genetic technologies.
2. Human uniqueness and diversity must be respected as a cherished part of our shared humanity.

### Respect for the Individual

3. Genetic information should not be used to deny individual opportunity.
4. Confidentiality and privacy concerning genetic information should be respected.
5. Individuals should be fully informed and give their voluntary consent prior to genetic testing or genetic intervention.

### Respect for the Community

6. The social values of justice, equity, beneficence, do no harm, and veracity must be respected in the development and implementation of human genetic technology.
7. No group should become the subject of unfair discriminatory policies or practices on the basis of its genetic makeup.
8. Thoughtful on-going civic discourse about the role of human genetic technologies in furthering the common purposes and goals of our shared humanity is essential.”