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.

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.

<u>Quality Assurance</u>: 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.

<u>Composition of Screening Panel(s):</u> 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.

<u>Technology review</u>: 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 Chief Executive Officer (CEO) of the Department, and the Chief Medical Officer (CMO) 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 Chief Executive Officer (CEO) 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 CMO 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

Program Staff Responsibilities

The Newborn Screening & Genetics Program Manager, Inherited Diseases Clinical Specialists and the NBS Systems Coordinator shall provide support to the committee in the following ways:

Project staff are responsible for:

1. Information Management:
    - Locating, organizing, and preparing pertinent background information for committee use.
2. Policy and Regulation Guidance:
    - Interpreting programmatic policies, regulations, and statutes to inform committee decisions.

3. Documentation:
    - Drafting reports and meeting minutes for review and approval.
4. Meeting Logistics:
    - Making meeting arrangements and ensuring all logistical needs are met.
5. Agenda Collaboration:
    - Collaborating with the Committee Chair and Vice Chair to establish meeting agendas and approve meeting minutes.
6. Report Preparation:
    - Providing reports on committee recommendations for review, revision, and approval by the Chair and Vice Chair before submission to the Department's chain of command.

NBSAC Member Responsibilities

Committee members are responsible for:

1. Engagement and Input:
    - Providing input, ideas, and participation in committee discussions.
2. Review and Feedback:
    - Reviewing and commenting on research, reports, and other background information.
3. Meeting Attendance:
    - Attending quarterly meetings and contributing to discussions and decisions.
4. Program Improvement:
    - Recommending strategies for program improvement.
5. Voting:
    - Voting on issues requiring a formal decision.
6. Membership Recommendations:
    - Recommending candidates to the Program Manager for membership on the NBSAC to fill vacant representative positions.

Chairperson Responsibilities

In addition to the responsibilities of other NBSAC members, the Chairperson is responsible for:

1. Approval Duties:
    - Approving meeting agendas and meeting minutes.
2. Consultation:
    - Consulting with program staff to review reports and background materials prepared for meetings.
3. Meeting Leadership:
    - Chairing quarterly meetings and any emergency meetings as needed.
4. Emergency Declarations:

    - Declaring emergency meetings in response to public health emergencies related to newborn screening.
5. Report Development:
    - Consulting with the Vice Chair and program staff to develop reports for recommendations to be submitted through the Department's chain of command.
6. Membership Removal:
    - Moving to remove a committee member for cause, subject to a formal vote by the committee or approval by the Department, as applicable.

Vice-Chairperson Responsibilities

In addition to the responsibilities of other NBSAC members, the Vice-Chairperson is responsible for:

1. Chairperson Support:
    - Serving as a backup for all Chairperson responsibilities in the Chair's absence, before, during, and after committee meetings.
2. Report Development:
    - Consulting with the Chairperson and program staff to develop reports for recommendations to be submitted through the Department's chain of command.
3. Membership Removal:
    - Moving to remove a committee member for cause, subject to a formal vote by the committee or approval by the Department, as applicable.

Succession of Responsibilities

In the event that both the Chair and Vice Chair are unable to fulfill their responsibilities at a committee meeting, the following procedures will be implemented:

1. **Designation of an Acting Chair**:
   a. The Chair or Vice Chair, if aware of their absence in advance, may designate an Acting Chair from among the committee members to preside over the meeting.
   b. If no designation is made in advance, the members present at the meeting shall elect an Acting Chair by majority vote at the start of the meeting.

2. **Authority of the Acting Chair**:
   The Acting Chair shall have full authority to preside over the meeting, including managing the agenda, facilitating discussions, and ensuring the meeting adheres to the established rules and procedures.

3. **Documentation**:
   The Acting Chair's role shall be noted in the meeting minutes, including the process by which they were designated or elected.

4. Notification and Reporting:
   If the absence of the Chair and Vice Chair extends beyond a single meeting, the Acting Chair or committee staff shall notify the appropriate governing body or leadership and provide updates as necessary.

This process ensures continuity in leadership and the effective functioning of the committee in the absence of the Chair and Vice Chair.

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. **Voting members** must be actively practicing in their respective fields to ensure current expertise and relevance. Minimum membership may 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, pediatric neurologist) 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 Registered Dietician practicing at a Nebraska metabolic clinic, a nurse practitioner practicing at a Nebraska metabolic clinic, parent or consumer representatives representing any disorders on the newborn screening panel, or class of disorders screened, and a medical ethicist.

Emeritus Members: Individuals who have previously served on the committee and no longer meet the criteria for active practice may be appointed as non-voting emeritus members. Emeritus members may participate in discussions, provide historical context, and share insights but will not have voting rights.

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

1. Term Length:
   - Each member is requested to serve a term of three (3) years but may continue to serve at their discretion for longer periods unless their attendance falls below the required level.
2. Attendance Requirement:
   - Members must attend at least two (2) of the four (4) scheduled meetings per year. Any member who fails to attend more than one (1) meeting per year for two (2) consecutive years will be asked to vacate their representative position.

    - Authority to Remove Members:
    - The Chair or Vice Chair may remove a committee member for cause without consulting the wider committee. Causes for removal include, but are not limited to, failure to fulfill responsibilities, conflict of interest, or conduct detrimental to the committee's mission.
3. Chair and Vice Chair Terms:
    - The terms of service for the Chair and Vice Chair shall also be three (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 central guiding mission is to promote the ethical use of human genetic technologies to improve the human condition while safeguarding fundamental human rights. These principles recognize that, while respect for individual liberties is paramount, certain compelling social interests may occasionally necessitate restrictions to ensure the well-being of society as a whole.

Principles Governing the Ethical Use of Human Genetic Technologies

Respect for Humanity

1. All applications of human genetic technologies must uphold the inherent dignity and intrinsic value of every human being.
2. Human uniqueness and diversity are essential components of our shared humanity and must be preserved and celebrated.

Respect for the Individual

3. Genetic information must not be used to limit or deny individual opportunities.

4. Confidentiality and privacy concerning genetic information must be rigorously protected.
5. Individuals must be fully informed and provide voluntary, explicit consent prior to undergoing genetic testing or intervention.

Respect for the Community

6. The principles of justice, equity, beneficence, non-maleficence (do no harm), and truthfulness must guide the development and application of human genetic technologies.
7. No group should face discrimination or unjust treatment based on genetic characteristics.
8. Ongoing, inclusive civic dialogue is essential to ensure that human genetic technologies align with and advance the common purposes and shared goals of humanity.

Charter reviewed and approved 4.22.2025