



DAVID MAXWELL-JOLLY
Director

State of California—Health and Human Services Agency
Department of Health Care Services



ARNOLD SCHWARZENEGGER
Governor

Date: June 18, 2009

TO: GENERAL ACUTE CARE HOSPITALS WITH LICENSED PERINATAL AND/OR INTENSIVE CARE-NEWBORN NURSERY SERVICES AND TO NEWBORN HEARING SCREENING PROGRAM CERTIFIED OUTPATIENT INFANT SCREENING PROVIDERS

SUBJECT: NEWBORN HEARING SCREENING EQUIPMENT

The California Newborn Hearing Screening Program (NHSP) is issuing this letter to remind all certified inpatient and outpatient Infant Hearing Screening Providers (“providers”) that, as a condition of certification and recertification, they are required to comply with the requirements and standards contained in Health and Safety Code Sections 123975, and 124115 through 124120.5 (The Newborn and Infant Hearing Screening, Tracking and Intervention Act); the NHSP “Standards for Infant Hearing Screening Services,” contained in the CCS Manual of Procedures in Sections 3.42 et seq. (www.dhcs.ca.gov/services/nhsp/pages/standards.aspx); the NHSP “Provider Manual”(www.dhcs.ca.gov/services/nhsp/Documents/ProvManual.pdf); and all other applicable directions, instructions and standards referenced or incorporated, as set forth on the NHSP website (www.dhcs.ca.gov/services/nhsp).

With regard to newborn hearing screening equipment, among other provisions, Section C.2. Facility and Equipment, of the NHSP Inpatient and Outpatient Infant Hearing Screening Standards, mandates that providers fully comply with the following requirements:

- “Infant hearing screening services in the well-baby nursery (and for infants who refer in the well-baby nursery) shall be performed using automated FDA-approved otoacoustic emissions and/or auditory brainstem response screening equipment that detects a mild (30-40 dB) hearing loss in infants and newborns.
- “Infant hearing screening services in the Intensive Care-Newborn Nursery (ICNN) (and for infants who refer in the ICNN) shall be performed using automated

General Acute Care Hospitals With Licensed Perinatal And/Or Intensive Care-Newborn Nursery Services And To Newborn Hearing Screening Program Certified Outpatient Infant Screening Providers

Page 2

June 18, 2009

FDA-approved auditory brainstem response screening equipment that detects a mild (30-40 dB) hearing loss in infants and newborns.

- “Use of screening equipment shall be in accordance with manufacturer’s protocols and stated norms.
- “The choice of equipment shall be reviewed by a CCS-approved audiologist, or by an audiologist with equivalent training and experience, and reflect knowledge of professional peer-reviewed literature and current audiological practice. The hospital shall obtain (and the outpatient screening provider shall submit, with the application) written confirmation from the manufacturer that the equipment meets the criteria above.”

As a prerequisite to the use of any newborn hearing screening equipment, providers are required to obtain, confirm and maintain documentation demonstrating that the equipment (including its specific purpose/use and method of operation), complies with the requirements listed above, whether or not the documentation is requested. This documentation shall, at all times, be made available to the NHSP and the Hearing Coordination Centers.

Thank you for your continued participation in the NHSP. If you have questions about hearing screening equipment documentation that cannot be answered by your Hearing Coordination Center, please contact Hallie Morrow, M.D., M.P.H., Program Medical Consultant, at (916) 323-8009.

Sincerely,

ORIGINAL SIGNED BY HARVEY FRY

Luis R. Rico, Acting Chief
Children’s Medical Services Branch