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To: Hospital Administrators, Chief Medical Officers and Health Care Providers

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**Alert to NYS Birthing Facilities Regarding Universal Newborn Screening for
Critical Congenital Heart Disease**

Please distribute to all staff in Obstetrics & Gynecology, Midwives, Pediatricians, Pediatric Cardiologists and Neonatologists. Please also share with your non-hospital based colleagues.

This notice contains information about new requirements for birthing facilities regarding screening for critical congenital heart disease in newborns.

Congenital heart diseases (CHD) are the most common type of birth defects in children and occur in 8 per 1,000 live birthsⁱ. About 25% of all CHDs are considered critical congenital heart diseases (CCHDs). Children with CCHD have an increased chance of developing serious complications during the first few days or weeks of life.ⁱⁱ Each year almost 300 New York State children are born with CCHD and 17% of these children die in the first year of life.

Pulse oximetry is an effective method of screening all newborns for CCHD and can reduce the number of infants who are undiagnosed. The purpose of pulse oximetry screening is to detect CCHD **before** clinical deterioration of the infant.

Governor Andrew Cuomo signed legislation on July 31, 2013 to protect the health of newborns from potentially life-threatening CCHD. Effective January 27, 2014, all birthing facilities in New York State and those required to register a child's birth are required to perform pulse oximetry screening on every newborn in its care.

It is important that birthing facilities follow evidence-based recommendations as they implement the screening program. Attached for your use is a recommended Protocol for CCHD Screening that has been reviewed by NYS specialists, including neonatologists and pediatric cardiologists. *It is expected that each birthing facility will have a written protocol in place for uniform CCHD screening.*

Best practices for newborn screening programs include documentation of the screening results in the medical record, assuring appropriate referral for diagnostic evaluation, and collection of

appropriate follow-up data so as to ensure that all babies are screened and receive needed treatment. This data collection helps in ongoing quality improvement of the screening program. Although reporting is not required at this time, documentation and collection of the following data elements are recommended: date and time of screening; screening results (Pass/Fail); referral to medical provider after a failed screen (Yes/No); identification of an infant with CCHD by another means (prenatal ultrasound or clinical signs prior to pulse oximetry screening); diagnostic results; and, parental refusal of screening.

Infants found to have congenital heart disease are to be reported to the New York State Department of Health's Congenital Malformations Registry (CMR). Hospitals and physicians are to submit case reports electronically via the Internet using the Health Commerce System (HCS).

For more information about the Congenital Malformations Registry see: http://www.health.ny.gov/diseases/congenital_malformations/cmhome.htm or contact Deborah Fox at djf03@health.state.ny.us or (518) 402-7990.

If you have questions about how to implement CCHD screening in your facility using this protocol, *please contact your Regional Perinatal Center*. Additional provider information about implementing screening for CCHD can be found in two articles from *Pediatrics* and a toolkit. The toolkit can be ordered by clicking on the web link below:

- Strategies for Implementing Screening for Critical Congenital Heart Diseaseⁱⁱⁱ
- Implementing Recommended Screening for Critical Congenital Heart Disease^{iv}
- Children's Hospital Medical Center's Congenital Heart Disease Screening Program toolkit: <http://www.childrensnational.org/pulseox/request-tool-kit.aspx>

NYS specific educational materials and resources for parents will be available at a later time. In the meantime, you may refer parents to CCHD resources at:

- Centers for Disease Control and Prevention's National Center on Birth Defects and Developmental Disabilities: <http://www.cdc.gov/ncbddd/heartdefects/index.html>

Thank you for your ongoing efforts to provide New York State newborns with quality health care. If you have questions other than screening protocol implementation, please contact program staff at (518) 473-9883.

References

ⁱReller MD, Strickland MJ, Riehle-Colarusso T, Mahle W, Correa A. Prevalence of congenital heart defects in metropolitan Atlanta, 1998-2005. *Journal of Pediatrics*. 2009 Dec; 153(6) 807-813.

ⁱⁱ Mahle WT, Newburger JW, Matherne GP, Smith FC, Hoke TR, Koppel R, Gidding SS, Beekman RH3rd, Grosse SD, American Heart Association Congenital Heart Defects Committee of the Council on Cardiovascular Disease in the Young, Council on Cardiovascular Nursing, and Interdisciplinary Council on Quality of Care and Outcomes Research, American Academy of Pediatrics Section on Cardiology and Cardiac Surgery, and Committee on Fetus and Newborn (200). Role of pulse oximetry in examining newborns for congenital heart disease; A scientific statement from the AHA and AAP. *Pediatrics*, 123(2), 823-836. doi: 10.1542/peds.2009-1397.

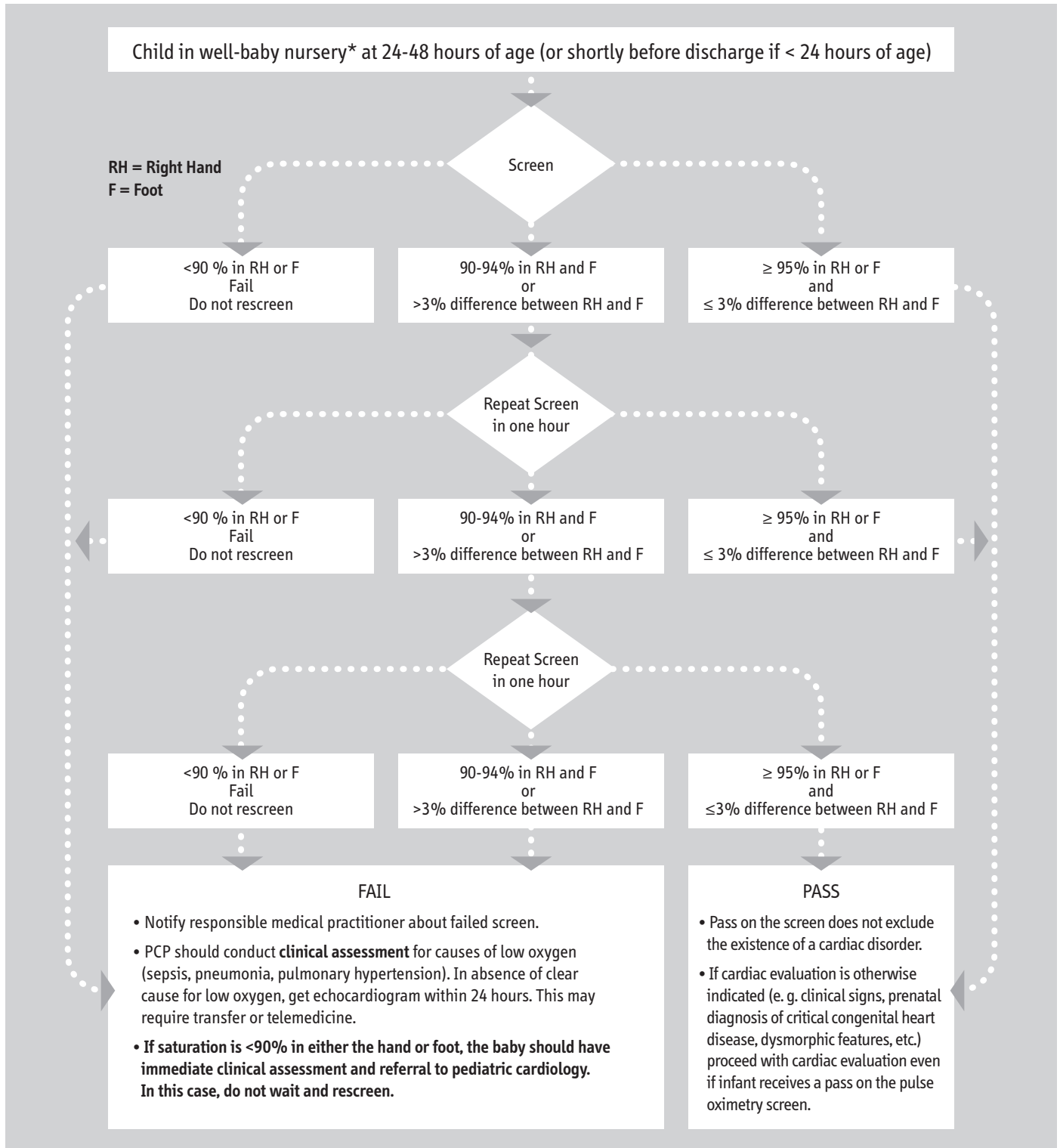
ⁱⁱⁱ Kemper AR, Mahle WT, Martin GR, et al. Strategies for implementing screening for critical congenital heart disease. *Pediatrics* 2011; 128(5). Available at: www.pediatrics.org/cgi/content/128/5/e1259

^{iv} Martin GR, Beekman RH, Mikula EB et al. Implementing recommended screening for critical congenital heart disease. *Pediatrics* 2013; 132: e185-e192.

Protocol for Critical Congenital Heart Disease Screening

Recommendations from the New York State Department of Health

Adapted from the protocol developed by the Critical Congenital Heart Disease workgroup of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.



- This screening should not take the place of clinical judgment or customary clinical practice. Symptomatic babies require clinical evaluation.
- Optimal results are obtained by using a motion-tolerant pulse oximeter that reports functional oxygen saturation, has been validated in low perfusion conditions and has been cleared by FDA for use in newborns.

*Infants in special care nurseries/NICU should be screened at 24-48 hours of age or when medically appropriate. Administration of supplemental oxygen may alter the interpretation of the screening results. For infants on oxygen, delay screening until infant is stable and off oxygen for optimally greater than 24 hours. If patient cannot be weaned from oxygen prior to discharge, obtain echocardiogram if one has not already been done.