



News Release

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Commissioner

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Department of Health and Senior Services proposes amendments to N.J.A.C. 8:45-2.1, Clinical Laboratory Services and Laboratory Charges.

The Division of Public Health Services, Public Health and Environmental Laboratories, of the Department of Health and Senior Services is proposing rulemaking to amend N.J.A.C. 8:45-2.1, which governs screening for newborn disorders.

The Department is proposing to amend N.J.A.C. 8:45-2.1 to increase the fee for the Inborn Errors of Metabolism (IEM) test from \$71 to \$90. The fee has not been increased since 2004, when a special purpose appropriation of \$3.1 million for newborn screening follow-up and treatment was eliminated. This critical program tests 111,000 newborns annually with 20,000 repeat specimens. This entails approximately 4 million tests for multiple newborn disorders.

Through the IEM test, biochemical disorders of significant importance are identified early in life. These disorders have enormous impact on the health of newborn infants and their families; without treatment, these children would have life-long health problems, including mental retardation, or premature death. The fee increase would support testing for additional disorders, for expanded follow-up and treatment, for the installation of two new tandem mass spectrometers, and to plan and initiate an upgrade of the newborn screening management information system to an integrated, web-based system that would provide faster reporting to hospitals and physicians.

In 2006, the Department's Newborn Screening Annual Review Committee recommended that the mandatory disorders that are tested for be increased to 45. The Department's tandem mass spectrometers, which are used to test samples for these disorders, have outlived their technical lifespan. The purchase of two new tandem mass spectrometers is complete and the first unit has been installed and is pending validation. The Department also partially funds specialized treatment centers that ensure access to specialized medical care for affected babies and their families.

Therefore, the fee increase is necessary to support expanded testing, an enhanced data management system, two new tandem mass spectrometer systems, and enhanced follow-up and treatment services.

The proposal appears in the May 5, 2008 issue of the New Jersey Register.

The public has until July 7, 2008 to comment on the proposal. Persons wishing to comment on the proposal must submit their comments in writing to Ruth Charbonneau, Director, Office of Legal and Regulatory Affairs, New Jersey Department of Health and Senior Services, PO Box 360, Trenton, NJ 08625. Written comments on the proposal must be postmarked on or before July 7, 2008, which is the close of the 60-day public comment period.