Original: 2188

-----Original Message-----
From: Allen Bergum [mailto:abergum@neogenscreening.com]
Sent: Wednesday, May 23, 2001 9:31 AM
To: Jack Means
Subject: proposed newborn screening regs

Hi Jack,
I was looking at the proposed rulemaking for newborn screening and found one think I thought ought to be made a bit more clear.

Under Chapter 28
28.1.1Definitions
Hemoglobin Diseases
It says --Sickle cell (SS, SC, SV, B beta.....etc.
Since there is no hemoglobin named "V" I would change SV to something like "S + other variant"
Allen

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

May 29, 2001

Jack W. Means, Jr.
Director of the Newborn Screening and
Genetic Services Section
Division of Maternal and Child Health
Bureau of Family Health
Department of Health
P.O. Box 90
Harrisburg, PA 17108

RE: Title 28, Code Chapters, 27, 28 and 501, Newborn Disease Screening and Followup

Dear Mr. Means:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of its approximately 250 member hospitals and health systems, welcomes the opportunity to comment on the proposed regulations dealing with newborn disease screening and follow-up.

Hospitals and health systems have participated in the Department of Health's newborn disease screening since the inception of the program with screening for phyenylketonuria in 1965. Hospitals and health systems are fully aware of the health benefits and societal value of early screening and disease prevention programs. However, HAP has a series of concerns with the Department of Health's proposed newborn disease screening and follow-up regulations. These concerns are of such significance that we cannot support the proposed regulations.

- HAP recognizes that amendments to the Newborn Child Testing Act provide for the addition to the list for newborn disease screening by regulation of any other disease approved for inclusion by the Department and the State Advisory Board. These regulations add two additional conditions, but provide no clear clinical rationale for why these two conditions were added versus other newborn screening tests. **The regulations should clearly state the process by which additions to the list of newborn disease screening will be made and how public and clinical input will be sought. Further, the Department of Health should clearly articulate the clinical rationale and societal benefits for adding the two particular conditions included in these regulations.**

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
haponline.org

- HAP acknowledges that follow-up for abnormal testing is important for appropriate care of the newborn as well as providing an understanding of the test results for the newborn's family. HAP believes that this responsibility is properly carried out best by public health officials, who will be able to consistently provide appropriate follow-up counseling, guidance, advice, and referrals. HAP objects to the proposed shifting of this responsibility to health care providers. Neither the act nor the amendments to the act give the Department of Health the authority to shift this responsibility. Shifting this responsibility is an abrogation of the Department of Health's public health responsibilities. Shifting the follow-up responsibility creates the potential for inconsistent and inadequate follow-up, whereas the Department of Health would be able to assure the uniform application of a follow-up protocol. HAP also believes that the shifting of this responsibility establishes an unfunded mandate on health care providers. Creating and maintaining follow-up systems will be costly and burdensome to health care providers. With the majority of hospitals and health systems losing money on patient care, few, if any, are in a position to assume this burden. **The regulations should be modified to state that the Department of Health will have primary responsibility for follow-up notification and counseling.**

Again, HAP appreciates the opportunity to comment on the Department of Health's proposed regulations addressing newborn disease screening and follow-up. HAP believes that our recommendations will improve the regulations. HAP looks forward to working with the Department of Health in the area of newborn disease screening and ensuring the vitality of the Department's public health role.

If you have any questions about our recommendations, feel free to contact Lynn Gurski-Leighton, Director, Clinical Services, HAP, at (717) 561-5308 or by email at lgleighton@haponoline.org.

Sincerely,

Paula A. Bussard

PAULA A. BUSSARD
Senior Vice President, Policy and Regulatory Services

c: John McGinley, Jr., Chairperson, Independent Regulatory Review Commission
Harold F. Mowery, Jr., Chair, Senate Public Health and Welfare Committee
Vincent J. Hughes, Minority Chair, Senate Public Health and Welfare Committee
Dennis M. O'Brien, Chair, House Health and Human Services Committee
Frank L. Oliver, Minority Chair, House Health and Human Services Committee
Lori McLauglin, Esq., Chief Counsel, Department of Health
Gary Gurian, Deputy Secretary, Public Health Programs, Department of Health

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----Original Message-----
From: Suzanne C. Yunghans [mailto:paaap@voicenet.com]
Sent: Friday, May 25, 2001 2:03 PM
To: jmeans@state.pa.us
Cc: Don McCoy (E-mail); Mark Reuben MD (E-mail)
Subject: FW: Comments needed ASAP

Mr. Means,
The PA Chapter of the American Academy of Pediatrics is pleased to endorse the proposed regulations which adds maple syrup urine disease, sickle-cell and other hemoglobinopathies, galactosemia and congenital adrenal hyperplasia to the routine screening of all newborns. We appreciate the opportunity to work with the Department in the development of these changes and can offer our support in any education of pediatricians needed once the regulations are final. Thank you.

Suzanne C. Yunghans
Executive Director
PA Chapter, American Academy of Pediatrics
919 Conestoga Rd., Bldg. 2 - Suite 307
Rosemont, PA 19010
610-520-9123
800-337-2227 (PA only)
610-520-9177 Fax
paaap@voicenet.com (e-mail)
www.paaap.org