WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION

Form #3

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: DHHR - Bureau for Public Health TITLE NUMBER: 64

CITE AUTHORITY: WV Code §§16-1-4, 16-22-3, and 16-22A-3

AMENDMENT TO AN EXISTING RULE: YES ____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: ____

TITLE OF RULE BEING AMENDED: ____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 91

TITLE OF RULE BEING PROPOSED: NEWBORN SCREENING SYSTEM

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Martha Yeager Walker
Authorized Signature

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Newborn Screening System 64CSR91

Type of Rule: X Legislative ____ Interpretive ____ Procedural

Agency: Health and Human Resources

Address: Bldg. 3 Room 206

Capitol Complex

Charleston, West Virginia 25305

Phone Number: 558-7171 Email: kathycummons@wvdhhr.org

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

The purpose of this rule is to expand the newborn metabolic screening system to include all diseases and conditions identified effective July 1, 2008. The Department of Health and Human Resources, Bureau for Public Health currently expends approximately $1.1 million of Maternal and Child Health Block Grant funds as well as maternal and child health general revenue funds to support the system. An emergency rule effective July 1, 2007 provided for an initial expansion of the screening system at an estimated cost of $481,149. The final expansion of the system that will be implemented effective July 1, 2008 will cost an estimated additional $764,697. The estimated cost to expand the system to include all diseases and conditions added as a result of changes implemented in this rule is $1,245,846. The total estimated cost of the fully implemented newborn metabolic screening system will be $2,345,846.

This rule allows the Department to charge a fee to support the newborn metabolic screening system. Effective July 1, 2007, the Department expects to bill birthing facilities a fee of $45 per live birth. The fee is based on the historical costs of the current system. Effective July 1, 2008, the Department expects to increase the fee not to exceed $125 per live birth. At an average of 21,000 live births per year, the Department could receive up to $2,625,000 in revenue.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

Effect of Proposal	Fiscal Year		
	2008 Increase/Decrease (use"-")	2009 Increase/Decrease (use"-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	1,245,846	1,245,846
Personal Services		123,846	123,846
Current Expenses		1,122,000	1,122,000
Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues		2,625,000	2,625,000

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

Personal Services: $123,846, OLS - Chemist II @ $35,000 X 19.19% (FICA, Ret., Workers Comp) = $6,717 + $6,418 (Admin Fees, Health Insurance per FTE) = $13,135; OMCFH - 1 Nurse III @ $34,116 + 1 Accounting Tech @ $18,636 = $52,752 X 19.19% (FICA, Ret, Workers Comp.) = $10,123 + $6,418 (Admin. Fees, Health Insurance per FTE) X 2 FTEs = $22,959 **Current Expense: $1,122,000**, OLS - $12,000 Supplies, $22,000 courier service, Reagent rental for Auto Delphia System $325,000, Reagent rental for Tandem Mass Spectrometer $351,000; OMCFH - Provider Education $50,000; Computers $2,000; Nutritional Supplements $50,000; Expanded WVU Pediatrics and Genetics Services Grant $310,000.

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

The costs estimated for the full expansion of the newborn screening system are in addition to the costs of the current system. Costs estimated for the emergency rule effective July 1, 2008, ($481,149) are included in the SFY 2009 estimate costs for the total expansion system. Estimated costs for the final expansion of diseases and conditions to be included in the newborn screening system are $764,697. Total system costs after that expansion would be $2,345,846. Effective July 1, 2008, the rule allows the Department to bill up to $125 per live birth which could result in total estimated revenue of up to $2,625,000. The rule allows for periodic review of the fee and adjustment to the fee to cover the actual costs of the newborn screening system.

It is expected that the birthing facilities will recover costs incurred through appropriate third party payment processes available to them.

Early screening of children with special health care needs and congenital disorders at birth is a priority across the country. For several years, West Virginia has focused on the development of a plan that will support new test technologies and the expansion of the number of newborn screening conditions. The successful implementation will require public and private healthcare to incur the cost of the service system. Cost and benefit related to the screening has been evaluated by the US Congress Office of Technology and Assessment and has been determined to be cost effective both in terms of early infant development and hospital/medical costs.

Date	Agency	Authorized Representative
7/27/07	Department of Health and Human Resources	Martha Yeager Walker

Martha Yeager Walker
Secretary

Department of Health and Human Resources
Bureau for Public Health
Legislative Rule
Title 64, Series 91

NEWBORN SCREENING STSTEM

BRIEF SUMMARY OF PROPOSED RULE

This rule expands the number of newborn disorders to be screened for all children born in this state. The expansion brings West Virginia into compliance with the U.S. Department of Health and Human Services Advisory for Heritable and Genetic Disorders recommendations. This rule also provides for the establishment of a means of payment to finance the expansion of the system.

STATEMENT OF CIRCUMSTANCES

The rules for newborn metabolic screening are being proposed as mandated by legislation passed in the 2007 session, HB 2583.

PUBLIC COMMENT PERIOD

The Office of Maternal, Child and Family Health in the Bureau for Public Health intends to notify stakeholders who are interested in the West Virginia Newborn Metabolic Screening system, including, but not limited to; physicians who care for children, county health departments, Schools of Medicine, the WV Medical Association, the WV Hospital Association, third party payors, birthing facilities, and other interested parties.

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: July 27, 2007

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) DHHR Bureau for Public Health,
Office of Maternal, Child and Family Health
350 Capitol Street, Room 427
Charleston, WV 25304-1978
(304) 558-5388

LEGISLATIVE RULE TITLE:
NEWBORN SCREENING SYSTEM - 64CSR91

1. Authorizing statute(s) citation §§16-1-4, 16-22-3 and 16-22a-3

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

   June 27, 2007

   b. What other notice, including advertising, did you give of the hearing?

   The proposed rule was discussed within the Department and also with many interested parties and stakeholders during the public comment period to further discuss the changes and elicit comments from the regulated community.

   c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

   July 27, 2007, at noon

   d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

   Attached X No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

NA

f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Ann Spaner, Director, Public Health Regulations
350 Capitol Street, Room 702
Charleston, WV 25301
(304) 558-2971
(304) 558-1035 fax
annspaner@wvdhhr.org

g. **IF DIFFERENT FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Pat Moss &/or Kathy Cummons
Office of Maternal, Child and Family Health
350 Capitol Street, Room 427
(304) 558-5388
Fax (304) 558-4984
patmoss@wvdhhr.org
kathycummons@wvdhhr.org

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

NA

b. Date of hearing or comment period:

From June 27, 2007 to July 27, 2007 at noon

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

NA

d. Attach findings and determinations and reasons:

Attached NA

COMMENTS AND RESPONSES

WVDHHR, Bureau for Public Health
64CSR91 NEWBORN SCREENING SYSTEM RULE

1. Comment from the West Virginia Hospital Association:

WEST VIRGINIA HOSPITAL ASSOCIATION

100 Association Drive
Charleston, WV 25311-1571
(304) 344-9744
FAX: (304) 344-9745
Web Page: www.wvha.org

Sent to Pat Mann.

John Law
DHHR/BPH
350 Capitol Street, Room 702
Charleston, WV 25301

July 18, 2007

Re: **64CSR91 NEWBORN SCREENING SYSTEM RULE**

Dear Mr. Law:

The West Virginia Hospital Association appreciates the opportunity to comment on the Department's rule 64CSR91, Newborn Screening System, which the Department has published as both an emergency and proposed rule. This rule is drafted as a result of the passage of HB 2583, passed during the 2007 legislative session with the Association's full support.

Association staff has participated in a number of discussions with the Office of Maternal, Child, and Family Health over the past year with regard to the costs to be incurred by both the State and providers to implement the additional tests. It was our understanding at the time this legislation was passed, that the required rule-making would allow for a process not only for the State to recoup its costs of the additional testing, but also that the rule would provide for a process to allow providers to bill third-parties for the costs associated with paying the State for these mandated tests. We believe this requirement is covered in §16-22-3(e)(2), which requires the proposed rule to include " a means for payment for the screening provided for in this section."

Unfortunately, both the emergency rule and the proposed rule only allow for a means for the State to bill providers. The only comment with regard to providers' ability to recover the cost of the State fee is in the proposed rule Memorandum, in which the Department states "It is expected that the birthing facilities will recover costs incurred through appropriate third party payment processes available to them." Unfortunately, the current third-party payment processes provide no means by which providers may recover these additional, mandated costs. Medicaid and PEIA, which currently reimburse hospitals for well over one-half of the total newborns in West Virginia each year, have historically updated their payment rates for newborns at a rate well below normal inflation, let alone allowing for these additional costs to be recouped by hospitals. As of this date, the update to the State-payor PPS system has not made any adjustment to allow providers to recover these costs through payments for newborns. In addition, the hospital rate-setting process has not allowed for an automatic pass-through of these additional costs, so that there is no assurance that non-governmental payors will be able to be billed for these additional costs as well.

Since a process to allow providers to bill for these additional screening costs has not been established, and because we believe that our concerns can be addressed in a timely fashion with little financial impact to the State, we respectfully request that the Department modify the emergency rule on Newborn Screening in consultation with providers, and re-submit the Emergency Rule only after this issue has been addressed.

We would also like to comment on the proposed increase in the State fee to providers from the proposed $45 to $125 effective July 1, 2008. Because the initial fee is based on an **estimate** of the costs to be incurred with the addition of three tests to the newborn testing panel, we believe that §64-91-7 should also include a process by which the Department is required to make a public report to all affected parties. This report should document the actual costs incurred between July 1, 2007 and July 1, 2008, compared with the budget it has established for the initial fee, so that a more reasonable determination can be made as to the need to increase the fee effective July 1, 2008, as well as for any succeeding years.

We appreciate the opportunity to comment on the Newborn Screening System proposed and emergency rules. To follow-up on the concerns that we have raised in this letter, please do not hesitate to e-mail me at mrobbins@wvha.com, or contact me 353-9721.

Sincerely,

Michael B. Robbins

Michael B. Robbins, VP/Financial Policy
West Virginia Hospital Association

Cc: Pat Moss, Office of Maternal, Child, and Family Health

Bureau for Public Health Response:

After discussion with the Hospital Association and others, the Bureau for Public Health has made the following adjustments to the rule:

7.1 Added, "There shall be no charge for second or subsequent retests".

7.6 Added, "Newborn screening system tests shall be a covered benefit reimbursed to the birthing facilities by all health insurers, including the Public Employees Insurance Agency, the Bureau for Medical Services (Medicaid), and private insurers.

7.7 Added. "The bureau shall prepare an annual report to be submitted to the legislature, and to be made available to any interested party, that will include actual expenses incurred and revenue generated by the newborn screening system each year".

2. Comment from United Hospital:

UNITED HOSPITAL CENTER
Post Office Box 1680 ■ Clarksburg, West Virginia 26302-1680 ■ Telephone 304 / 624-2121

July 23, 2007

John Law
DHHR/BPH
350 Capitol Street, Room 702
Charleston, WV 25301

RE: 64CSR91 NEWBORN SCREENING SYSTEM RULE

Dear Mr. Law:

I am writing this letter on behalf of United Hospital Center in regard to 64CSR91 Newborn Screening System Rule. As you know the Department has published an emergency and proposed rule, which is the result of the passage of HB 2583, passed during the 2007 legislative session. The hospitals in West Virginia supported the passage of this law because we believed it was in the best interest of patients and because the bill would provide for appropriate reimbursement to providers for the cost of new mandated tests.

Unfortunately, the rule provides for the state to reimburse themselves by billing hospitals like United Hospital Center initially $45 per test increasing to $125 by July 1, 2008. The proposal does not in any way provide for practical reimbursement to the providers for this new mandated testing cost. Since United Hospital Center delivers approximately 1,000 babies a year this new mandate will increase costs at United Hospital Center by approximately $125,000.00 per year.

Since most babies are covered by Medicaid and PEIA or low income individuals with no insurance, United Hospital Center has no rational method to reimburse itself for this cost simply by "billing third party payors". United Hospital Center is reimbursed on a DRG basis for inpatients, which obviously includes newborns for most major payers including Medicaid, PEIA, Blue Cross and others.

Therefore, we believe that the actions on the part of the department do not meet the spirit of each HB 2583, which was supposed to provide for a method to reimburse providers for the cost of providing the mandated testing. The only rational logical method for performing that task is to adjust the Medicaid and PEIA DRG payments for newborns to cover this additional cost.

United Hospital Center respectfully requests that the department modify the emergency rule on newborn screening in consultation with providers and resubmit the emergency rule only after this issue has been concluded. We sincerely appreciate the opportunity to comment on this proposed regulation. If you have any questions, please feel free to contact me.

Sincerely,

Bruce Carter
President

BC: kf

cc: Joe Letnaunchyn, State Hospital Association
Doug Coffman, CFO

Bureau for Public Health Response:

Please see the response for comment number one (1)

3. Comment from Joan Philips:

Women and Children's Hospital

800 Pennsylvania Ave.
PO Box 6670
Charleston, WV 25362
(304) 388-5432

July 26, 2007

Ms. Ann Spaner, Director
Public Health Regulations
Bureau for Public Health and Human Resources
350 Capitol Street, Room 702
Charleston, WV 25301

Dear Ms. Spaner:

I appreciate the opportunity to comment on the legislative rule titled "Newborn Screening System." As the Clinical Director for Children's Services at CAMC Women and Children's Hospital, I fully support the expansion of newborn screening. However, I do not support the proposed legislative rule as written. When fully implemented on July 1, 2008, the State will charge each hospital $125 per screen when there are other far less expensive alternatives available. One national firm charges $42 to screen for 60 conditions, which includes second tier DNA testing with rapid turn around time as well as follow-up guidance. As you know, a majority of births in West Virginia are paid for by Medicaid and PEIA. We have no information from Medicaid that they will reimburse CAMC an extra $45 in year one or $125 in year two. When there is national benchmarking for one third of this cost for comparable testing, it would be unrealistic to expect any healthcare plan provider to pay $125. We would be reinventing the wheel at three times the cost.

CAMC has approximately 3,200 live births per year. At $125 per screen, we calculate an expenditure of $400,000 per year. If we or the State contracted with a national firm, we would reduce our expenditure by over $260,000. According to the Health Statistics Center, there were 20,834 live births in 2005. Based on this number, the Bureau for Public Health would be overcharging West Virginia Hospitals $1,729,222 in year two.

I strongly encourage the Bureau for Public Health to withdraw this proposed rule and not to sign a lease for very expensive equipment until all alternatives are explored. A second option is to allow provider choice of lab to perform the screen, as is the process in Maryland and Louisiana. I also encourage the Department to include those of us who are providing pediatric care in future discussions and policy development. The State has an obligation to consider all alternatives and seriously evaluate each alternative based on cost, quality and access.

We have always had an excellent working relationship with the State Hygienic Laboratory and have a high respect for their work. The Laboratory would still have the very important function of follow-up and education of patients with positive screens even if the State contracted with a national firm for the test performance.

Please feel free to call if you have any questions or need additional information.

Sincerely,

Joan M. Phillips, M.D.
Clinical Director for Children's Services

c: David Ramsey, CEO, CAMC
Marsha Morris, Commissioner of Medicaid
Martha Walker, Secretary of DHHR

Q. Is there a charge for repeat newborn screens?

Bureau for Public Health Response:

No- only the initial screen will be charged.

Q. Why do the screens cost so much?

Bureau for Public Health Response:

In order to expand testing for newborn disorders, advanced technology and trained personnel are required. The cost of newborn screening not only includes additional laboratory equipment and personnel but assures follow-up and tracking of infants who have a positive screen; increases genetic medical expertise within the State; and builds capacity within WV to maintain a system of care. It is important from the moment the specimen is collected from the infant at the hospital, arrives at the laboratory, results determined, physician notified and treatment started, that it is handled expeditiously. With some newborn disorders adverse consequences can occur if not identified quickly and treatment started within days of the birth.

The $45.00 charge is based on actual cost, calculated by DHHR Finance. Because the State Legislature gave the Bureau start-up funds to expand the system, those costs are not included in the $45.00 fee. Remember, prior to the expansion the Department was spending 1.2 million per year to support screening, tracking, follow-up and medical expertise. The $125 fee is a proposed fee, and cited as "not to exceed" for the second year because we do not know how much the actual costs will be.

Other laboratories may say that they can perform newborn screening for less money. While this may be true, these charges are only for lab services, and do not include cost attributable to tracking, follow-up, courier service, medical genetics support, medically necessary prescriptions in some instances, community and public education materials, Program administration and parental support in caring for an infant with an often very rare disorder etc.

Q. Why do we have to use the State Lab?

Bureau for Public Health Response:

The WV State Laboratory has been performing newborn screening since 1965 upon initiation of Legislation. The State Laboratory has been successful in identifying infants with positive screens and notifying the Office of Maternal,

Child, and Family Health and the infant's physician within minutes of the results depending on the urgency.

West Virginia is a small state, but the system of identifying newborn disorders, follow-up and tracking, genetic services support, physician notification and beginning of treatment is a highly developed collaborative effort. Ninety-nine point seven percent (99.7%) of the infants born in WV receive a newborn screen before discharge from the hospital. Of the infants who have a positive result nearly 100% receive a repeat screen. In the last several years virtually no infant, confirmed with a disorder, was lost to follow-up and all received medical treatment immediately reducing adverse consequences and cost to insurers, education and health.

Newborn screening is a population–based core public health function that assures the early identification of infants at risk of death, or debilitating conditions. Newborn metabolic screening is an established recognized function of public health departments across the nation.

The ability to screen, track and care for children within the State is a public service. While resources around our border States will be called upon when necessary to treat rare disorders, we believe it is important for WV to provide and manage the screening program using WV resources and expertise.

Of the States performing screening for 29 disorders or more, very few use a national firm to provide the laboratory service. Most of the States are charging for system cost, and using the issuance of the screening kit to capture payment. Many states have existing in statute the expectation that insurance reimburse for this life saving service.

Q. How is the State Laboratory going to handle the enhancement?

Bureau for Public Health Response:

Even before Legislation mandated the enhancement of newborn screening to include 29 screens, the Bureau for Public Health was researching capacity needs. The State Laboratory made accommodations for equipment space two years ago and determined equipment and personnel requirements shortly thereafter.

The Department has been very planful in consideration of enhancing existing metabolic disorder screening. The Newborn Screening Advisory Committee has been involved in planning strategies and staff persons from the State Lab and OMCFH as well as medical specialists from around the State are serving on regional committees that are developing support and guidance on newborn screening efforts including identification of expert resources nationwide for consultation and/or treatment.

The Legislature provided start-up funds to obtain the required laboratory equipment and build personnel capacity. Screening for Biotinidase Deficiency began July 1, 2007 and it is expected that screening for Congenital Adrenal Hyperplasia (CAH) and Cystic Fibrosis (CF) will begin within 90 days. Screening for the remainder of the 29 mandated screens will begin July 1 2008.

The Supervisor of the Newborn Screening Section at the State Laboratory will be attending training on use of the Tandem Mass Spectometry at Mayo Medical Laboratories.

4. Comment from Dr. Hansbarger

>>> "Clark Hansbarger" <chansbarger@hsc.wvu.edu> 7/26/2007 2:47 PM >>>
It has come to my attention that tomorrow is the last day to comment of the current issue of the latest infant screening legislation. I hope this communication is acceptable for comments?
1. The WV Public Health organization is a highly respected government agent. As former Director I continue to have confidence in their mission. One of those missions is Infant Screening for congenital disease that will effect the lifetime productivity if intervention does not occur early. The result of the loss of such productivity is the increase pain for the individual and increase cost for society.In other word a public trust and responsibility.
2. The historical responsibility for such screening has been the assumed by the Public Health Department at no cost to the individual or health care provider system. The resent legislation has increased the responsibility but has become an "unfunded mandate". Because this will create hardship and delays in implementation, I suggest the DHHR seek relief in the time table for implementation in order to seek solutions to rational financing including inclusions into newborn or delivery cost as well as allocation of funds to DHHR/Public Health Labs or contract arrangements for such testing in the commercial sector.
3. There should be a "major" effort to convene the "private", public health care sectors to meet with the DHHR/Public Health to address the financing of 20,000 such test over a years time; the majority of these test would be the "clients" of the larger hospitals already under terrific financial cost pressures such that 50-100$ per test would be a budgetary "nightmare"

L. Clark Hansbarger MD
Assoc. VP Health Science Center
Dean School of Medicine, Charleston
3110 MacCorkle Ave., SE
Charleston, WV 25304
304-347-1206/ fax 347-1298
chansbarger@hsc.wvu.edu

Bureau for Public Health Response:

In response to your question regarding the recent legislation stating that the screening changes have increased responsibility for the Bureau for Public Health and the healthcare provider system, making this an "unfunded mandate," our response is as follows:

The State Legislation did provide $489,000 to facilitate the initial expansion of the metabolic screening system. Included in this commitment were monies for additional genetic support at WVU, Department of Pediatrics, and the hire of a chemist at the State Laboratory/Office of Laboratory Services, a nurse to provide tracking and medical support, and equipment rentals.

The Legislative leadership who authored the bill also referenced the expectation that the Bureau for Public Health would bill for the service system.

In response to your question that there should be a "major" effort to convene the "private" and public health care sectors to meet with the DHHR/Public Health to address the financing of 20,000 such tests over a year's time, our answer is:

Please be advised that the Bureau for Public Health, Office of Maternal, Child and Family Health does have an on-going Metabolic Advisory Committee. West Virginia University was represented by Dr. Marybeth Hummel, and CAMC personnel included Stephan Maxwell, M.D. and Sally Llewellyn, former Administrator, Women and Children's Hospital.

Further, as the national standards of practice were changing from a minimal number of tests to screening for 29 disorders among infants, we invited physicians, legislators, and insurers to participate in teleconference presentations, with question and answer periods to follow. In addition, there have been discussions with the West Virginia Hospital Association around the Bureau's plan to charge for the service system.

5. Comment from American Academy of Pediatrics

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

West Virginia Chapter

West Virginia Chapter
830 Pennsylvania Avenue
Suite 104
Charleston, WV 25302-3302
Phone: 304/388-1563
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July 26, 2007

John Law
DHHR/BPH
350 Capitol Street, Room 702
Charleston, WV 25301

Re: 64CSSR91 Newborn Screening System Rule

Dear Mr. Law:

This letter is directed as a comment to the Department's above referenced rule that has been published as both, an emergency and proposed rule. This rule proposes the implementation of HB 2583 passed during the 2007 legislative session. Numerous health organizations including the West Virginia Chapter of the American Academy of Pediatrics have supported the intent and passage of said bill. Our comments do not relate to the intent or goals of said legislation but to its proposed implementation.

If we understand correctly, the rules as written only allows for the State to bill the birthing centers for the costs of the tests, established at $45 for the first year and $125 subsequently. It is unclear how those birthing centers will recover these expenses since the majority of payors do not have a mechanism for doing that that could be easily implemented. At my local birthing facility (Grant Memorial Hospital), this will represent an extra expense of $40,000 dollars/year at a rate of 320 births /year.

The issue of cost goes beyond the issue of who absorbs this expense of the testing. Considering that in recent years, we have able to provide comprehensive quality newborn screening at commercial laboratories (my personal experience with Baylor University and Pediatrix) for 30 or so conditions for under $50 to those parents who requested it, it is hard to understand how these numbers have been reached. That cost includes follow-up and counseling.

Besides imposing what amounts to an unpaid mandate, the suggested fee appear to be disproportionate large compared to established commercial quality options. The inflationary effect that these added costs in our health care system could divert precious resources sorely needed in other areas.

It is our opinion that prior to the implementation of these rules, the reimbursement mechanism for this testing is clearly determined and that a comprehensive search for a cost efficient testing procedure or source is sought. We think that we can achieve the goals HB 2583 without imposing undue hardship on any party.

Please do not hesitate contacting us should you wish to follow-up on the concerns raised by this letter.

Sincerely yours,

Fernando J Indacochea MD, FAAP
President, WV Chapter, American Academy of Pediatrics

Bureau for Public Health Response:

Please see previous comments and in addition: Only 15 States do not use their own State Public Health Laboratories. Of those States that do not use their own State Laboratory the cost goes beyond what the contracting laboratory can provide. The contract laboratory usually provides feedback to the physician and Newborn Screening Program on the results of the screen and will have a Genetics Counselor available if needed. Most States provide way beyond that in regards to tracking and follow-up, genetic counseling services, metabolic supplements, education, courier service, treatment, specialist consultation, etc. The West Virginia charge is all inclusive.

6. Comment from Charleston Area Medical Center:

GLENN CROTTY, JR., MD, FACP
EXECUTIVE VICE PRESIDENT AND
CHIEF OPERATING OFFICER

501 Morris St.
PO Box 1547
Charleston, WV 25326
(304) 388-7438
Fax: (304) 388-7696
glenn.crotty@camc.org

July 27, 2007

Ann Spaner, Director
Public Health Regulations
Bureau for Public Health
West Virginia Department of Health
and Human Resources
350 Capitol Street, Room 702
Charleston, WV 25301

Dear Ms. Spaner:

I appreciate the opportunity to comment on the legislative rule titled "Newborn Screening System." I am a physician and Chief Operating Officer of the largest provider of newborn services in the state. The Charleston Area Medical Center ("CAMC") is a 913-bed teaching hospital located in Charleston, West Virginia. We provide highly specialized health care services to all of central and southern West Virginia. We have the only Level I trauma center in all of southern West Virginia and one of three Level III NICUs. In addition, we provide resident training to over 130 medical residents and interns, including training programs in Pediatrics and Obstetrics/Gynecology. We also have more pediatric sub specialties than any other hospital in the state. In brief, we are the true safety net hospital for southern West Virginia, providing over 22 percent of all charity care provided by acute care hospitals in the state. We are also the largest provider of health care to both Medicaid and Medicare beneficiaries in the state. We are proud of our tertiary care safety net mission, but it comes at a huge cost. Last year (FY 2006), we experienced a Medicaid loss of over $25 million. Your proposed rule will increase this loss.

While I fully support the expansion of newborn screening, I do not support the proposed legislative rule as written. When fully implemented on July 1, 2008, the State will charge each hospital $125 per screen when there are other far less expensive alternatives available. One national firm charges $42 to screen for 60 conditions. As you know, a majority of births in West Virginia are paid for by Medicaid and PEIA. We have no information from Medicaid that they will reimburse CAMC an extra $45 in year one or $125 in year two.

We at CAMC have approximately 3,200 live births per year. At $125 per screen, we are looking at an expenditure of $400,000 per year. If we, or the state, contracted with a national firm, we would reduce our expenditure by over $260,000. According to the Health Statistics Center, there were 20,834 live births in 2005. Based on this number, the Bureau for Public Health would be overcharging hospitals $1,729,222 in year two. I strongly encourage the Bureau for Public Health to withdraw this proposed rule and not to sign a lease for very expensive equipment when there are superior alternatives available. I also encourage the Department to include those of us who are providing pediatric newborn care in future discussions and policy development. The State has an obligation to consider all alternatives and seriously evaluate each alternative based on cost, quality and access.

CAMC has always had a fine relationship with the state Hygienic Laboratory and have a high respect for their work. If hospitals or the state contracted with a national firm for newborn screens, the Laboratory would still have the very important function of follow up.

Please feel free to call if you have any questions or need additional information.

Sincerely,
Glenn Crotty, Jr., M.D.
Executive Vice President and
Chief Operating Officer

Bureau for Public Health Response:

Please see previous responses and in addition: Only 15 States do not use their own state laboratories:

Alaska, Hawaii, Idaho, Nevada and Oregon use the regional laboratory at the Oregon Public Health Laboratory.

Maine, Massachusetts, New Hampshire, Rhode Island and Vermont use the New England Regional laboratory at the University of Massachusetts Medical School.

District of Columbia and Mississippi list Pediatrix Screening of Pennsylvania as their laboratory.

Indiana lists Clarian Pathology Lab for their screening.

North Dakota has Hygienic Lab of Des Moines, Iowa as their laboratory for screening.

Wyoming uses the State Laboratory of Colorado.

The bulk of the States supportthe newborn screening system, including laboratory services within their own State. The cost of newborn screening varies from state to state depending on services provided. Most states charge the hospital for the newborn screening system and the hospitals recover this expense within the DRG. The charge for the kit also varies from state to state, again depending on what services are provided, what other State monies might be available to support newborn screening, how many babies are born within the State, the number of newborn screens completed and whether there is a charge for a repeat. The Bureau has received commitment from Medicaid to support newborn screening payment to the hospitals.

The Bureau has anticipated the need to increase the number of newborn screens for several years and has explored all options mentioned in the previous comments. It was determined that the best course of action was to build upon the existing public health infrastructure. Newborn Screening has been a public health responsibility since the 1960's and West Virginia has demonstrated the ability to screen, track and secure follow-up until diagnosis of the infant. The existing system supports a relationship with the Office of Maternal, Child and Family Health, WVU Pediatrics/ Genetics, the Office of Laboratory Service, healthcare practitioners and specialists, national consortiums etc., and has been successful as evidenced by our system's performance.

7. Comment from Bureau for Medical Services (Medicaid)

The Bureau for Medical Services will comply with the mandates of HB 2583 as reflected in your proposed rule.

Shannon L. Riley, Public Information Specialist
WV Department of Health and Human Resources
Bureau for Medical Services Commissioner's Office
350 Capitol Street, Room 251
Charleston, WV 25301-3706
Phone: (304)558-6006

Bureau for Public Health Response:

Thank you

TITLE 64
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH
LEGISLATIVE RULE

SERIES 91

NEWBORN SCREENING SYSTEM

§64-91-1. General.

1.1. Scope. -- This rule directs the Bureau for Public Health, in cooperation with other state agencies and attending physicians, to provide medical, dietary and related assistance to children determined to be afflicted with any disease specified in WV Code §16-22-3, and certain other diseases specified by the Bureau for Public Health. The rule provides for a means of payment for the required screenings, and any further referral or treatment services considered necessary by the Bureau for Public Health to implement the provisions of the statute on newborn screening. This rule should be read in conjunction with WV Code §16-22-3 and §16-22A-1, et seq. and the rule on Newborn Hearing Screening, 64CSR24. The WV Code is available in public libraries and on the Legislature's webpage, www.legis.state.wv.us.

1.2. Authority. -- WV Code §§16-1-4, 16-22-3, and 16-22A-3.

1.3. Filing Date. -- June , 2007

1.4. Effective Date. --

1.5. The fee for a newborn screening system kit established in section 7 of this rule supersedes the amount in the Bureau for Public Health's Fees For Services rule, 64CSR51, Appendix A.

§64-91-2. Application and Enforcement.

2.1. Application. -- This rule applies to all infants born in West Virginia and to the hospital or birthing facility in which an infant is born, the parents or legal guardians, the physician attending a newborn child, or any person attending a newborn child not under the care of a physician and the director of the State laboratory performing mandatory newborn screening tests.

2.2. Enforcement. -- This rule is enforced by the Commissioner of the Bureau for Public Health

§64-91-3. Definitions.

3.1. Birthing Facility. -- Any licensed medical facility that offers birthing services.

3.2. Bureau. -- The Bureau for Public Health in the West Virginia Department of Health and Human Resources. The bureau is the agency responsible for administering the Newborn Screening System.

3.3. Commissioner – The Commissioner of the bureau for public health or his or her designee.

3.4. Laboratory. -- The State laboratory facility that supplies newborn screening services to all birthing facilities in the state.

3.5. Newborn Screening. -- The statutorily mandated screening of newborns by hospitals, birthing facilities, physicians or others.

3.5.a. Presently each infant born in this state is screened for:

3.5.a.1. Galactosemia, GALT;

3.5.a.2. Hearing deficiency, HEAR;

3.5.a.3. Hemoglobinopathies; which include:

3.5.a.3.A. Hemoglobin S/Beta-thalassemia, Hb S/Th;

3.5.a.3.B. Sickle cell anemia, Hb SS;

3.5.a.3.C. Sickle C disease, Hb S/C;

3.5.a.4. Hypothyroidism, CH; and

3.5.a.5. Phenylketonuria, PKU;

3.5.b. No later than July 1st, 2007, the bureau shall require screening for:

3.5.b.1. Biotinidase deficiency, BIOT;

3.5.b.2. Congenital adrenal hyperplasia, CAH; and

3.5.b.3. Cystic fibrosis, CF;

3.5.c. No later than July 1st, 2008, the bureau shall require screening for:

3.5.c.1. Argininosuccinic acidemia, ASA;

3.5.c.2. Beta-ketothiolase deficiency, BKT;

3.5.c.3. Carnitine uptake defect, CUD;

3.5.c.4. Citrullinemia, CIT;

3.5.c.5. Glutaric acidemia type I, GAI;

3.5.c.6. Homocystinuria, HCY;

3.5.c.7. 3-Hydroxy-3-methylglutaric aciduria, HMG;

3.5.c.8. Isovaleric acidemia, IVA;

3.5.c.9. Long-chain hydroxyacyl-CoA dehydrogenase deficiency, LCHAD;

3.5.c.10. Maple syrup urine disease, MSUD;

3.5.c.11. Medium-chain acyl-CoA dehydrogenase deficiency, MCAD;

3.5.c.12. 3-Methylcrotonyl-CoA carboxylase deficiency, 3MCC;

3.5.c.13. Methylmalonic acidemia - Cbl A and Cbl B forms, Cbl A,B;

3.5.c.14. Methylmalonic acidemia-mutase deficiency form, MUT;

3.5.c.15. Multiple carboxylase deficiency, MCD;

3.5.c.16. Propionic acidemia, PROP;

3.5.c.17. Trifunctional protein deficiency, TFP;

3.5.c.18. Tyrosinemia type I, TYRI;

3.5.c.19. Very long-chain acyl-CoA dehydrogenase deficiency, VLCAD; and

3.5.c.20. Any additional diseases or conditions as determined by the Commissioner.

3.6. Newborn Screening System. – The coordinated effort by the bureau and West Virginia physicians who deliver and care for children, to ensure that each newborn child is screened for metabolic disorders before discharge from birthing facilities. Infants identified with a disorder shall receive continuing care and treatment provided through a collaborative effort between the primary physician, medical specialist, the bureau and community support services.

3.7. Office of Maternal, Child and Family Health - The office in the bureau that provides coordination and leadership in working with public and private community partners and families to assure the availability and use of health care for all mothers, infants and children including children with special health care needs.

3.8. Primary Care Provider. -- The physician, physician's assistant, nurse, nurse practitioner or other licensed medical professional responsible for the infant's health services during and/or after discharge from the birthing facility.

§64-91-4. When Screening is Required.

4.1. WV Code §16-22-3 requires that all infants born in the state be screened for detection and control of diseases in newborn children as listed in section 3.5. and section 5. of this rule.

4.2. When the birth takes place in a licensed birthing facility the primary care provider shall perform or cause to be performed newborn screening as listed in section 3.5. and section 5. of this rule within forty-eight hours of birth or before hospital discharge whichever comes first.

4.3. If an infant is born in a non-hospital or non-birthing facility, including a home, the person in attendance at the birth shall perform or cause to be performed the newborn screening as listed in section 3.5 and section 5. of this rule within forty-eight hours of the birth.

4.4. If the specimen is unacceptable or a positive screen result occurs, the primary care provider shall perform or cause to be performed a second screen.

§64-91-5. Complete list of diseases and conditions to be screened after July 1st, 2008.

5.1. After July 1st, 2008, every infant born in West Virginia shall be screened for the diseases and conditions enumerated in section 3.5. of this rule. For the purpose of clarity and to make the list more readily accessible to readers, these diseases and conditions are listed below in alphabetical order:

5.2. Argininosuccinic acidemia, ASA;

5.3. Beta-ketothiolase deficiency, BKT;

5.4. Biotinidase deficiency, BIOT;

5.5. Carnitine uptake defect, CUD;

5.6. Citrullinemia, CIT;

5.7. Congenital adrenal hyperplasia, CAH;

5.8. Cystic fibrosis, CF;

5.9. Galactosemia, GALT;

5.10. Glutaric acidemia type I, GAI;

5.11. Hearing deficiency, HEAR;

5.12. Hemoglobinopathies; including:

5.12.a. Hemoglobin S/Beta-thalassemia, Hb S/Th;

5.12.b. Sickle cell anemia, Hb SS;

5.12.c. Sickle C disease, Hb S/C;

5.13. Homocystinuria, HCY;

5.14. 3-Hydroxy-3-methylglutaric aciduria, HMG;

5.15. Hypothyroidism, CH;

5.16. Isovaleric acidemia, IVA;

5.17. Long-chain hydroxyacyl-CoA dehydrogenase deficiency, LCHAD;

5.18. Maple syrup urine disease, MSUD;

5.19. Medium-chain acyl-CoA dehydrogenase deficiency, MCAD;

5.20. 3-Methylcrotonyl-CoA carboxylase deficiency, 3MCC;

5.21. Methylmalonic acidemia - Cbl A and Cbl B forms, Cbl A,B;

5.22. Methylmalonic acidemia-mutase deficiency form, MUT;

5.23. Multiple carboxylase deficiency, MCD;

5.24. Phenylketonuria, PKU;

5.25. Propionic acidemia, PROP;

5.26. Trifunctional protein deficiency, TFP;

5.27. Tyrosinemia type I, TYRI;

5.28. Very long-chain acyl-CoA dehydrogenase deficiency, VLCAD; and

5.29. Any additional diseases or conditions as determined by the Commissioner.

§64-91-6. Screening Protocol.

6.1. The primary care provider shall perform, or cause to be performed, newborn screening listed in section 3.5. and section 5 of this rule shortly after birth and before discharge from the hospital and sent to the State laboratory which performs such tests.

6.2. The screening shall be performed by trained personnel, according to the Clinical Laboratory Improvement Amendments (CLIA) standards as recommended by the American Academy of Pediatrics.

6.3. The Commissioner may update or modify the screening procedures according to screening protocol, technology and current national standards.

6.4. If the primary care provider is unable to screen or cause to have screened the infant before discharge, then the primary care provider is responsible for referring the infant for an out-patient newborn screening.

6.5. For infants born in a non-hospital or non-birthing facility, including a home, the primary care provider shall order an outpatient newborn screen.

6.6. Specimen shall be collected on collection kits obtained through the State laboratory.

6.7. Specimen shall be submitted to the State laboratory within twenty-four hours of collection through the U.S. mail or have ready for pick-up by courier service at a designated time and location.

§64-91-7. Screening Fee Schedule.

7.1. The bureau shall bill birthing facilities for each live birth in the state at the rate established in this rule. All birthing facilities shall pay the appropriate fee to the bureau for one initial newborn screening system kit per live birth. There shall be no charge for second or subsequent retests.

7.2. The fees shall be sufficient to cover the costs of the newborn screening system, kit, laboratory equipment, reagents, personnel and other associated costs.

7.3. The first fee charged shall reflect the recent historical cost of the current system. Beginning July 1, 2007, the bureau may charge birthing facilities at a rate not to exceed fifty dollars ($50.00) per newborn screening system kit.

7.4. After July 1, 2008, the fee may be increased to one hundred twenty-five ($125.00) to reflect the cost of the numerous additional newborn screening tests and associated system costs as required by law. The fee shall be charged to birthing facilities at a rate not to exceed one hundred twenty-five dollars ($125.00) per newborn screening system kit.

7.5. The fee for newborn screening system kits may be reviewed periodically by the Commissioner. As medical science evolves the number of disorders on the panel may increase to reflect national standards of care and the costs may incrementally increase to accommodate the number of disorders screened. The fee may be adjusted to cover the actual costs of the laboratory tests, reagent, materials and equipment and support for the newborn screening system. The initial amount and any increase in the fee shall be published in the State Register.

7.6. Newborn screening system tests shall be a covered benefit reimbursed to the birthing facilities

by all health insurers, including the Public Employees Insurance Agency, the Bureau for Medical Services (Medicaid) and private insurers.

7.7. The bureau shall prepare an annual report to be submitted to the legislature, and to be made available to any interested party, that will include actual expenses incurred and revenue generated by the newborn screening system each year.

§64-91-8. Screening Reporting and Assistance to Afflicted Children.

8.1. The birthing facility shall record or cause to be recorded the newborn screening results in the infant's medical record.

8.2. Positive results on any screen specified in section 3.5. or section 5. of this rule, or any other diseases specified by the bureau, shall be promptly reported to the bureau and the primary care provider by the director of the State laboratory performing such test.

8.3. The primary care provider shall report all newborn screening results to the infant's parents or legal guardian.

8.4. Assistance with referrals shall be offered by the bureau in cooperation with other state agencies to children determined to be afflicted with any disease specified in section 3.5. or section 5. of this rule for medical and dietary needs.

8.5. When an infant is born in a non-hospital or non-birthing facility, including a home, the provisions of subsection 4.3 of this rule shall apply.

§64-91-9. Confidentiality.

9.1. Any person who obtains confidential information while implementing WV Code §16-22-3 may disclose it only to reporting sources, persons demonstrating a need that is essential to health related research or care of the infant, or as required by law.

9.2. Any person who obtains confidential information while implementing WV Code §16-22-3 shall provide a written statement of confidentiality stating that he or she fully understands the privacy of the information and will maintain it.

§64-91-10. Penalties.

10.1. Any person who violates the provisions of WV Code §16-22-3, or this rule is subject to the penalties provided in WV Code §16-1-18.

10.2. For a second or subsequent failure to comply, the bureau may file a complaint against a provider with the state board of medicine.

WEST VIRGINIA
HOSPITAL ASSOCIATION

100 Association Drive
Charleston, WV 25311-1571
(304) 344-9744
FAX: (304) 344-9745
Web Page: www.wvha.org

7-20-07

Please copy for Chris + Janet R.
I had emailed John Law yesterday
trying to get this resolved/
letter to — Moss

John Law
DHHR/BPH
350 Capitol Street, Room 702
Charleston, WV 25301

July 18, 2007

Re: **64CSR91 NEWBORN SCREENING SYSTEM RULE**

Dear Mr. Law:

The West Virginia Hospital Association appreciates the opportunity to comment on the Department's rule 64CSR91, Newborn Screening System, which the Department has published as both an emergency and proposed rule. This rule is drafted as a result of the passage of HB 2583, passed during the 2007 legislative session with the Association's full support.

Association staff has participated in a number of discussions with the Office of Maternal, Child, and Family Health over the past year with regard to the costs to be incurred by both the State and providers to implement the additional tests. It was our understanding at the time this legislation was passed, that the required rule-making would allow for a process not only for the State to recoup its costs of the additional testing, but also that the rule would provide for a process to allow providers to bill third-parties for the costs associated with paying the State for these mandated tests. We believe this requirement is covered in §16-22-3(c)(2), which requires the proposed rule to include " a means for payment for the screening provided for in this section."

Unfortunately, both the emergency rule and the proposed rule only allow for a means for the State to bill providers. The only comment with regard to providers' ability to recover the cost of the State fee is in the proposed rule Memorandum, in which the Department states "It is expected that the birthing facilities will recover costs incurred through appropriate third party payment processes available to them." Unfortunately, the current third-party payment processes provide no means by which providers may recover these additional, mandated costs. Medicaid and PEIA, which currently reimburse hospitals for well over one-half of the total newborns in West Virginia each year, have historically updated their payment rates for newborns at a rate well below normal inflation, let alone allowing for these additional costs to be recouped by hospitals. As of this date, the update to the State-payor PPS system has not made any adjustment to allow providers to recover these costs through payments for newborns. In addition, the hospital rate-setting process has not allowed for an automatic pass-through of these additional costs, so that there is no assurance that non-governmental payors will be able to be billed for these additional costs as well.

1

Since a process to allow providers to bill for these additional screening costs has not been established, and because we believe that our concerns can be addressed in a timely fashion with little financial impact to the State, we respectfully request that the Department modify the emergency rule on Newborn Screening in consultation with providers, and re-submit the Emergency Rule only after this issue has been addressed.

We would also like to comment on the proposed increase in the State fee to providers from the proposed $45 to $125 effective July 1, 2008. Because the initial fee is based on an **estimate** of the costs to be incurred with the addition of three tests to the newborn testing panel, we believe that §64-91-7 should also include a process by which the Department is required to make a public report to all affected parties. This report should document the actual costs incurred between July 1, 2007 and July 1, 2008, compared with the budget it has established for the initial fee, so that a more reasonable determination can be made as to the need to increase the fee effective July 1, 2008, as well as for any succeeding years.

We appreciate the opportunity to comment on the Newborn Screening System proposed and emergency rules. To follow-up on the concerns that we have raised in this letter, please do not hesitate to e-mail me at mrobbins@wvha.com, or contact me 353-9721.

Sincerely,

Michael B. Robbins

Michael B. Robbins, VP/Financial Policy
West Virginia Hospital Association

Cc: Pat Moss, Office of Maternal, Child, and Family Health

UNITED HOSPITAL CENTER
Post Office Box 1680 ■ Clarksburg, West Virginia 26302-1680 ■ Telephone 304 / 624-2121

July 23, 2007

John Law
DHHR/BPH
350 Capitol Street, Room 702
Charleston, WV 25301

RE: 64CSR91 NEWBORN SCREENING SYSTEM RULE

Dear Mr. Law:

I am writing this letter on behalf of United Hospital Center in regard to 64CSR91 Newborn Screening System Rule. As you know the Department has published an emergency and proposed rule, which is the result of the passage of HB 2583, passed during the 2007 legislative session. The hospitals in West Virginia supported the passage of this law because we believed it was in the best interest of patients and because the bill would provide for appropriate reimbursement to providers for the cost of new mandated tests.

Unfortunately, the rule provides for the state to reimburse themselves by billing hospitals like United Hospital Center initially $45 per test increasing to $125 by July 1, 2008. The proposal does not in any way provide for practical reimbursement to the providers for this new mandated testing cost. Since United Hospital Center delivers approximately 1,000 babies a year this new mandate will increase costs at United Hospital Center by approximately $125,000.00 per year.

Since most babies are covered by Medicaid and PEIA or low income individuals with no insurance, United Hospital Center has no rational method to reimburse itself for this cost simply by "billing third party payors". United Hospital Center is reimbursed on a DRG basis for inpatients, which obviously includes newborns for most major payers including Medicaid, PEIA, Blue Cross and others.

Therefore, we believe that the actions on the part of the department do not meet the spirit of each HB 2583, which was supposed to provide for a method to reimburse providers for the cost of providing the mandated testing. The only rational logical method for performing that task is to adjust the Medicaid and PEIA DRG payments for newborns to cover this additional cost.

2

United Hospital Center respectfully requests that the department modify the emergency rule on newborn screening in consultation with providers and resubmit the emergency rule only after this issue has been concluded. We sincerely appreciate the opportunity to comment on this proposed regulation. If you have any questions, please feel free to contact me.

Sincerely,

Bruce Carter
President

BC: kf

cc: Joe Letnaunchyn, State Hospital Association
Doug Coffman, CFO

Women and Children's Hospital

800 Pennsylvania Ave.
PO Box 6670
Charleston, WV 25362
(304) 388-5432

July 26, 2007

3

Ms. Ann Spaner, Director
Public Health Regulations
Bureau for Public Health and Human Resources
350 Capitol Street, Room 702
Charleston, WV 25301

Dear Ms. Spaner:

I appreciate the opportunity to comment on the legislative rule titled "Newborn Screening System." As the Clinical Director for Children's Services at CAMC Women and Children's Hospital, I fully support the expansion of newborn screening. However, I do not support the proposed legislative rule as written. When fully implemented on July 1, 2008, the State will charge each hospital $125 per screen when there are other far less expensive alternatives available. One national firm charges $42 to screen for 60 conditions, which includes second tier DNA testing with rapid turn around time as well as follow-up guidance. As you know, a majority of births in West Virginia are paid for by Medicaid and PEIA. We have no information from Medicaid that they will reimburse CAMC an extra $45 in year one or $125 in year two. When there is national benchmarking for one third of this cost for comparable testing, it would be unrealistic to expect any healthcare plan provider to pay $125. We would be reinventing the wheel at three times the cost.

CAMC has approximately 3,200 live births per year. At $125 per screen, we calculate an expenditure of $400,000 per year. If we or the State contracted with a national firm, we would reduce our expenditure by over $260,000. According to the Health Statistics Center, there were 20,834 live births in 2005. Based on this number, the Bureau for Public Health would be overcharging West Virginia Hospitals $1,729,222 in year two.

I strongly encourage the Bureau for Public Health to withdraw this proposed rule and not to sign a lease for very expensive equipment until all alternatives are explored. A second option is to allow provider choice of lab to perform the screen, as is the process in Maryland and Louisiana. I also encourage the Department to include those of us who are providing pediatric care in future discussions and policy development. The State has an obligation to consider all alternatives and seriously evaluate each alternative based on cost, quality and access.

We have always had an excellent working relationship with the State Hygienic Laboratory and have a high respect for their work. The Laboratory would still have the very important function of follow-up and education of patients with positive screens even if the State contracted with a national firm for the test performance.

Please feel free to call if you have any questions or need additional information.

Sincerely,

Joan M. Phillips, M.D.
Clinical Director for Children's Services

c: David Ramsey, CEO, CAMC
Marsha Morris, Commissioner of Medicaid
Martha Walker, Secretary of DHHR

From: Pat Moss
To: Ann Spaner; Kathy Cummons
Date: 7/26/2007 2:58:39 PM
Subject: Fwd: Infant Screening

4

FYI

Pat

>>> "Clark Hansbarger" <chansbarger@hsc.wvu.edu> 7/26/2007 2:47 PM >>>
It has come to my attention that tomorrow is the last day to comment of the current issue of the latest infant screening legislation. I hope this communication is acceptable for comments?
1. The WV Public Health organization is a highly respected government agent. As former Director I continue to have confidence in their mission. One of those missions is Infant Screening for congenital disease that will effect the lifetime productivity if intervention does not occur early. The result of the loss of such productivity is the increase pain for the individual and increase cost for society.In other word a public trust and responsibility.
2. The historical responsibility for such screening has been the assumed by the Public Health Department at no cost to the individual or health care provider system. The resent legislation has increased the responsibility but has become an "unfunded mandate". Because this will create hardship and delays in implementation, I suggest the DHHR seek relief in the time table for implementation in order to seek solutions to rational financing including inclusions into newborn or delivery cost as well as allocation of funds to DHHR/Public Health Labs or contract arrangements for such testing in the commercial sector.
3. There should be a "major" effort to convene the "private", public health care sectors to meet with the DHHR/Public Health to address the financing of 20,000 such test over a years time; the majority of these test would be the "clients" of the larger hospitals already under terrific financial cost pressures such that 50-100$ per test would be a budgetary "nightmare"

L. Clark Hansbarger MD
Assoc. VP Health Science Center
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3110 MacCorkle Ave., SE
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CC: Chris Curtis; Janet Richards

Grant Memorial Pediatrics

#5

Fernando Indacochea, M.D., FAAP
Joan W. Lee, MD
Eleanor Feaster Berg, R.N., M.S., C-PNP

FAX COVER SHEET

DATE: 7-26-07

TO: John Law, Ann Spamer, Kathy Cumm Pat Moss

FROM: FERNANDO INDACOCHEA MD

COMMENTS: Comments 64CS5R91 Newborn Screening

NUMBER OF PAGES: 3 (inc. Cover

IF YOU DO NOT RECEIVE ALL THE PAGE(S), PLEASE CALL AS SOON AS POSSIBLE
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P.O. Box 1019, Petersburg, WV 26847
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American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

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July 26, 2007

John Law
DHHR/BPH
350 Capitol Street, Room 702
Charleston, WV 25301

Re: 64CSSR91 Newborn Screening System Rule

Dear Mr. Law:

This letter is directed as a comment to the Department's above referenced rule that has been published as both, an emergency and proposed rule. This rule proposes the implementation of HB 2583 passed during the 2007 legislative session. Numerous health organizations including the West Virginia Chapter of the American Academy of Pediatrics have supported the intent and passage of said bill. Our comments do not relate to the intent or goals of said legislation but to its proposed implementation.

If we understand correctly, the rules as written only allows for the State to bill the birthing centers for the costs of the tests, established at $45 for the first year and $125 subsequently. It is unclear how those birthing centers will recover these expenses since the majority of payors do not have a mechanism for doing that that could be easily implemented. At my local birthing facility (Grant Memorial Hospital), this will represent an extra expense of $40,000 dollars/year at a rate of 320 births /year.

The issue of cost goes beyond the issue of who absorbs this expense of the testing. Considering that in recent years, we have able to provide comprehensive quality newborn screening at commercial laboratories (my personal experience with Baylor University and Pediatrix) for 30 or so conditions for under $50 to those parents who requested it, it is hard to understand how these numbers have been reached. That cost includes follow-up and counseling.

Besides imposing what amounts to an unpaid mandate, the suggested fee appear to be disproportionate large compared to established commercial quality options. The inflationary effect that these added costs in our health care system could divert precious resources sorely needed in other areas.

It is our opinion that prior to the implementation of these rules, the reimbursement mechanism for this testing is clearly determined and that a comprehensive search for a cost efficient testing procedure or source is sought. We think that we can achieve the goals HB 2583 without imposing undue hardship on any party.

Please do not hesitate contacting us should you wish to follow-up on the concerns raised by this letter.

Sincerely yours,

Fernando J Indacochea MD, FAAP
President, WV Chapter, American Academy of Pediatrics

Charleston Area
Medical Center

GLENN CROLLY, JR., MD, FACP
Executive Vice President and
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July 27, 2007

#6

Ann Spaner, Director
Public Health Regulations
Bureau for Public Health
West Virginia Department of Health
and Human Resources
350 Capitol Street, Room 702
Charleston, WV 25301

Dear Ms. Spaner:

I appreciate the opportunity to comment on the legislative rule titled "Newborn Screening System." I am a physician and Chief Operating Officer of the largest provider of newborn services in the state. The Charleston Area Medical Center ("CAMC") is a 913-bed teaching hospital located in Charleston, West Virginia. We provide highly specialized health care services to all of central and southern West Virginia. We have the only Level I trauma center in all of southern West Virginia and one of three Level III NICUs. In addition, we provide resident training to over 130 medical residents and interns, including training programs in Pediatrics and Obstetrics/Gynecology. We also have more pediatric sub specialties than any other hospital in the state. In brief, we are the true safety net hospital for southern West Virginia, providing over 22 percent of all charity care provided by acute care hospitals in the state. We are also the largest provider of health care to both Medicaid and Medicare beneficiaries in the state. We are proud of our tertiary care safety net mission, but it comes at a huge cost. Last year (FY 2006), we experienced a Medicaid loss of over $25 million. Your proposed rule will increase this loss.

While I fully support the expansion of newborn screening, I do not support the proposed legislative rule as written. When fully implemented on July 1, 2008, the State will charge each hospital $125 per screen when there are other far less expensive alternatives available. One national firm charges $42 to screen for 60 conditions. As you know, a majority of births in West Virginia are paid for by Medicaid and PEIA. We have no information from Medicaid that they will reimburse CAMC an extra $45 in year one or $125 in year two.

We at CAMC have approximately 3,200 live births per year. At $125 per screen, we are looking at an expenditure of $400,000 per year. If we, or the state, contracted with a national firm, we would reduce our expenditure by over $260,000. According to the Health Statistics Center, there were 20,834 live births in 2005. Based on this number, the Bureau for Public Health would be overcharging hospitals $1,729,222 in year two. I strongly encourage the Bureau for Public Health to withdraw this proposed rule and not to sign a lease for very expensive equipment when there are superior alternatives available. I also encourage the Department to include those of us who are providing pediatric newborn care in future discussions and policy development. The State has an obligation to consider all alternatives and seriously evaluate each alternative based on cost, quality and access.

CAMC has always had a fine relationship with the state Hygienic Laboratory and have a high respect for their work. If hospitals or the state contracted with a national firm for newborn screens, the Laboratory would still have the very important function of follow up.

Please feel free to call if you have any questions or need additional information.

Sincerely,

Glenn Crotty, Jr., M.D.
Executive Vice President and
Chief Operating Officer

From: Shannon Riley
To: Spaner, Ann
Date: 7/27/2007 10:52:19 AM
Subject: Newborn Metabolic Screening

The Bureau for Medical Services will comply with the mandates of HB 2583 as reflected in your proposed rule.

Shannon L. Riley, Public Information Specialist
WV Department of Health and Human Resources
Bureau for Medical Services Commissioner's Office
350 Capitol Street, Room 251
Charleston, WV 25301-3706
Phone: (304)558-6006

CC: Bailes, Tina; Baston, Shelley; Curtis, Chris; Keefer, Warren; Kelley, Leonard; Law, John; Morris, Marsha; Moss, Pat; Richards, Janet