

**Newborn Screening Emergency Regulations Advisory Group Meeting
Thursday, March 30, 2005
2:00 PM – 4:30 PM**

MINUTES

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| Present: | Wanda Andrews, Lynette Bartlett, Joanne Boise, Nancy Ford, Jean Radcliffe-Shipman, Susan Tlusty, Sharon Williams |
| Absent | Nancy Bullock |
| Recorder | Nancy Ford |

| Agenda | Name | Notes / Plan |
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| 1. Welcome A. Introductions B. Membership List C. Review of Agenda D. Work Group Tasks | N. Ford | A. NA B. Jene moved from consultant to work group member. Susan Ward will be added to interested party list. C. No new items. D. Our tasks 1. Prepare Emergency Regulation Text. 2. Prepare Agency statement (Form TH-5) 3. Prepare Notice of Intended Regulatory Action (NOIRA) (same content as Form TH-5). |
| 2. Brief Overview of Regulatory Process A. Guide to Regulatory Process B. Emergency Regulatory Process C. Standard Regulatory Process. | S. Tlusty | A. Key points: 1. Statutes are enforceable by law. 2. Regulations are enforceable by law. 3. Guidance Documents: Developed by state agencies to provide general information to agency staff or the public on how to implement or interpret state law or agency regulations. Often helpful in understanding how agencies apply and enforce regulations: Not enforceable by law. Must be published on Town Hal Web site. If refer to a guidance document in reg., the guidance document must accompany reg. Bring to BOH presentations. Examples of Guidance Documents, which are published on the Town Hall Web site : a. Protocols for Hospital Newborn Hearing Screening . (FAM 102) b. Protocols for Diagnostic Audiological Assessment . (FAM 103) c. Protocols for Medical Management (hearing screening follow up) (FAM 110) d. Newborn Screening Facts: Questions Providers Frequently Ask About Newborn Screening . (FAM 403) B. Key points: 1. See ER Process Outline . 2. 3 ways to get a regulation published: a. Emergency Regulations (280 days). Our countdown begins 7/1/05. b. Standard Regulation 18 months) We will begin |

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| | | <p>the regulatory action for a permanent replacement regulation.</p> <ul style="list-style-type: none"> c. Fast-Track Regulations: for rules that are expected to be noncontroversial (e.g. additional VNSS condition). d. ER go into effect day of publication in the <i>The Virginia Register of Regulations</i>. <p>C. Standard Regulations (SR)</p> <ul style="list-style-type: none"> 1. See SR Process Basic Outline and Detailed Outline. 2. Our SR will be done concurrently with ER. 3. Board of Health Presentations, estimated timelines: <ul style="list-style-type: none"> a. Stage 1: July 2005 b. Stage 2: Jan. 2006 c. Stage 3: April 2006 |
| <p>3. Brief Overview of Legislation</p> <ul style="list-style-type: none"> A. HB 1824 (same as SB 1184) B. Expanded Panel Implementation Work Plan | <p>S. Williams</p> | <ul style="list-style-type: none"> A. Reviewed. B. Reviewed. DCLS is adding their responsibilities to timeline. |
| <p>4. Emergency Regulations</p> <ul style="list-style-type: none"> A. Proposed Timeline for VNSS Regulations B. Current Regulations C. Principles for what to include in Emerg Regs D. Outline: Draft 1 E. Text: Draft 1 F. Resources <ul style="list-style-type: none"> 1. ACMG Report 2. Other State Regs G. H. Assignments | <p>N. Ford with group discussion.</p> | <ul style="list-style-type: none"> A. Reviewed. Upcoming deadline: <ul style="list-style-type: none"> 1. July 21, 005: Presentation to Board of Health. Prior activities: that need to be completed by Work Group: <ul style="list-style-type: none"> 1. Complete Emer. Regs text draft 2. Send Emer. Regs text draft to interested parties for review. 3. Modify Emer Regs based on interested parties review. 4. Submit Emer Regs text to VDH management for review. 5. Modify Emer Regs text based on VDH Mgt review. 6. Prepare “polished presentation” for BOH presentation. 7. Develop and/or revise reference documents that will be referenced in the Emer Regs text. <p>Plan:</p> <ul style="list-style-type: none"> 1) L. Bartlett will work on revisions of <i>Newborn Screening Fact</i> booklet. 2) Work Group will what protocols need to be revised and/or developed (see Hearing protocols for examples) 3) Work Group will decide on what actions need to be taken regarding VDH-DCLS JOPs 8. Prepare Agency statement/NOIRA forms. <p>Plan:</p> <ul style="list-style-type: none"> 1) S. Tlusty will complete forms. <p>B. Decision: Repeal and Replace current regulations.</p> |

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| | | <p>Plan:</p> <ol style="list-style-type: none"> 1. S. Tlusty will notify Doug Harris. <p>C. Not finalized, however, guiding principles developed so far:</p> <ol style="list-style-type: none"> 1. Must be within our authority. 2. Include what is to be enforceable. 3. Do not include what should be in a guidance document. 4. Need to strike balance between being too general (such as current regulations) and being too specific (such as Emer Reg text draft 1) 5. Use VDH regulations as guide, and use other state regulations for working, examples, etc. <p>D. See attached.</p> <p>E. Initiated, but did not complete review.</p> <p>Plan:</p> <ol style="list-style-type: none"> 1. W. Andrews will revise Responsibilities of laboratory providing newborn bloodspot screening tests. 2. Member will complete review of text at next meeting. |
| <p>5. Future Meetings</p> | <p>N. Ford</p> | <p>All meetings will be located at VDH. Consultants are not expected to attend.</p> <ol style="list-style-type: none"> 1. Tuesday, April 5, 1:30 - 3:30 10th Floor Conf. Rm (Health Policy & Planning) 2. Tuesday, April 12, 1:30 – 3:30 5th Floor Conf. Rm.(Environmental Health) 3. Monday, April 18, 1:30 – 3:30 7th Fl. Conf. Rm. (Family Health Services) 4. Thursday, April 28, 1:30 – 3:30 8th Fl. Conf. Rm. (Child & Adolescent Health) |