

MINUTES OF THE MEETING OF THE
INDIANA STATE DEPARTMENT OF HEALTH
EXECUTIVE BOARD

July 24, 2019

(changed from original July 10, 2019 date)

The meeting of the Executive Board of the Indiana State Department of Health (ISDH) was called to order at 10:05 a.m. in the Robert O. Yoho Board Room of the ISDH building by Brenda Goff, Chair. The following Board members were present for all or part of the meeting:

Blake Dye
Brenda Goff, HFA (Chair)
Stephen Tharp, MD (Vice Chair)
Joanne Martin, DrPH, RN, FAAN
Martin Hanneman, DDS
Holly Robinson, MD
Suellyn Sorensen, PharmD, BCPS
Patricia Spence, PE
Tony Stewart, MBA, FACHE, HFA
Kristina M. Box, MD, FACOG, Secretary

Members attending via telephone:

Naveed Chowhan, MD, FACP, MBA

Members not attending:

Robin Marks, DVM

The following staff members were present for all or part of the meeting:

Judy Lovchik, Assistant Commissioner, Public Health Protection and Laboratory Services
Matthew W. Foster, Assistant Commissioner/Special Counsel, Consumer Services & Health Care Regulation
Melissa Collier, MD, MPH, Chief Medical Officer
Amy Kent, Office of Legislative & External Affairs
Kristin Schwartz, Office of Legislative & External Affairs
Kelly MacKinnon, Office of Legal Affairs
Anne McGuinness, Office of Legal Affairs
Christopher Kulik, Office of Legal Affairs
Paul Krievins, Director, Lead and Healthy Homes
Jessica Cobb, Office of Public Affairs

Guests:

Julie Halbig, Indiana Hospital Association
Carter Barrett, WFYI
Janet McCabe, IU-McKinney School of Law

Call to Order

Brenda Goff, Chair, stated that a quorum was present and called the meeting to order at 10:00 a.m. She then asked if Board members had any known conflicts of interest to declare. Hearing none she proceeded with the meeting. She stated there are two new members on the Board – Martin Hanneman, DDS (replacing Richard Martin, DDS) and Holly Robinson, MD (replacing John Gustaitis, MD). She then asked all Board members to introduce themselves.

Minutes

Ms. Goff asked for discussion and/or corrections to the minutes of the May 22, 2019 Executive Board meeting. Hearing none, she entertained a motion for approval. On a motion made by Dr. Stephen Tharp, seconded by Joanne Martin and passed by majority roll call vote, the Board approved the minutes as presented.

OFFICIAL BUSINESS OF THE STATE DEPARTMENT OF HEALTH

SECRETARY'S REPORT

Dr. Box announced that she will soon be signing a Statewide Standing Order for Tobacco Cessation Products that will be effective from August 1, 2019 to December 31, 2020 per Governor Holcomb's directive. This order will allow pharmacists to administer or dispense a tobacco cessation product. Once signed, Indiana will be the 12th state with such a standing order. This order will eliminate financial and time barriers for those considering quitting smoking. Jennifer Sullivan, MD, MPH, FSSA Secretary, is also working to direct Medicaid to reimburse health care providers offering tobacco cessation counseling for expectant mothers and is working to remove co-payments for tobacco cessation products for pregnant women up to one year postpartum. Studies show that women are more likely to quit smoking during pregnancy to give their baby the best possible start in life.

Health and Human Services Commission

Final Adoption of Perinatal Hospital Services (Levels of Care) Rule 410 IAC 39, LSA #18-416 (was finally adopted at the May 22, 2019 meeting, but must be submitted for final adoption again due to a technical correction via the Attorney General's office)

Eldon Whetstone, Assistant Commissioner, Health and Human Services Commission presented the Perinatal Hospital Services (Levels of Care) Rule 410 IAC 39 to the Board for final adoption. The proposed rule would establish a program regarding perinatal hospital and birth center services and the certification of levels of care for birth centers, obstetric units, neonatal units, and perinatal centers, including transport rules. The Notice of Intent to Adopt a Rule was published in the *Indiana Register* on October 3, 2018 starting the one-year period to adopt this rule. The Executive Board reviewed the proposed draft at the November 28, 2018 Executive Board meeting. A second draft of the rule was presented to the Executive Board at the April 3, 2019 meeting. After that presentation, the ISDH held a second public hearing on a version of the rule that was similar to what was presented to the Executive Board at the April 3, 2019 meeting. The ISDH made some changes to the rule based on public comment. The Executive Board approved the rule at the May 22, 2019 meeting for final adoption. The Office of the Attorney General (OAG) required several changes to the rule that are not substantive, but which must be made in order for the OAG to approve the rule. Staff recommends the Board approve Rule 410 IAC 39 with the suggested changes from the OAG for final adoption.

Ms. Goff asked for comments from the Board, staff and/or public. Joanne Martin asked for clarification on the OAG changes. Kelly MacKinnon explained that some documents are incorporated by reference and some are just referenced. The OAG wanted changes to the language of documents that were just referenced and not incorporated by reference. Hearing no other comments, Ms. Goff entertained a motion for final adoption. On a motion made by Joanne Martin, seconded by Patricia Spence and passed unanimously by roll call vote, the Board approved the Perinatal Hospital Services (Levels of Care) Rule 410 IAC 39 for final adoption.

Emergency Adoption of Updates to Diagnostic Testing and Hyperbaric Oxygen Treatment (HBOT) Pilot Program Rule 410 IAC 37

Amy Kent, Director of Legislative and External Affairs presented the Updates to Diagnostic Testing and Hyperbaric Oxygen Treatment (HBOT) Pilot Program Rule 410 IAC 37 for Emergency Adoption. During the 2019 legislative session, the legislature passed Senate Enrolled Act 491 which requires the ISDH to adopt emergency rules that permanently make changes to the program. The amendments to the rule will remove the requirements for a veteran to pay a 10% copay to participate in the Program and extend the period for the grants from June 30, 2020 to June 30, 2021. Staff recommends the Board approve the amendments required by SEA 491 to the Diagnostic Testing and HBOT Pilot Program Rule 410 IAC 37 for emergency adoption. Kelly MacKinnon noted that once the Board approves this emergency adoption it will be permanent and not just for 90-days.

Ms. Goff asked for comments from the Board, staff and/or public. Hearing none, she entertained a motion for emergency (and permanent) adoption. On a motion made by Dr. Tharp, seconded by Blake Dye and passed unanimously by roll call vote, the Board approved the amendments to the Diagnostic Testing and HBOT Pilot Program Rule 410 IAC 37 for emergency and final adoption.

Consumer Services and Health Care Regulation Commission

Final Adoption of Amendments to the Surgical Abortion Clinic Rule 410 IAC 26, LSA #19-164

Matt Foster, Assistant Commissioner, Consumer Services and Health Care Regulation Commission presented amendments to the Surgical Abortion Clinic Rule 410 IAC 26 for final adoption. In 2017, the Indiana General Assembly passed SEA 404 which requires the ISDH to update its abortion clinic licensure rules. ISDH was required to include provisions to:

- Separate rules for clinics offering surgical and abortion inducing drugs
- Add procedures to monitor patients after the administration of anesthesia
- Add procedures for follow-up care for patient complications
- Add a requirement for the provision of informed consent brochures
- Add a requirement for the provision of a hotline telephone number for cases of suspected coerced abortion or sex trafficking
- Require training of clinic staff by law enforcement to help identify and assist women who are coerced into abortions or victims of sex trafficking
- Require documentation of patient signature in patient medical records
- Establish procedures for clinics implementing a plan of correction and for the ISDH if the clinic fails to follow the plan of correction

In 2018, the Indiana General Assembly required the ISDH to make additional changes:

- Updating information required to be provided in an application for licensure
- For drug induced abortions, to have physicians provide manufacturers instruction sheets and patient agreement forms to patients for signature with the provider retaining a copy
- Technical corrections, i.e. update outdated regulations, etc.

The Notice of Intent to Adopt a Rule was published in the *Indiana Register* on March 20, 2019 starting the one-year period to adopt this rule. The Board approved the draft at the January 9, 2019 and April 3, 2019 meetings for 90-day emergency adoptions. The ISDH has not changed the rules from the proposed version. Staff recommends the Board approved the amendments as required by SEA 404 to the Surgical Abortion Clinic Rule 410 IAC 26 for final adoption.

Ms. Goff asked for comments from the Board, staff and/or public. Hearing none, she entertained a motion for final adoption. On a motion made by Joanne Martin, seconded by Holly Robinson and passed unanimously by roll call vote, the Board approved the amendments to the Surgical Abortion Clinic Rule 410 IAC 26 for final adoption.

Final Adoption of Rule to Regulate Abortion Clinics Performing Drug Induced Abortions Rule 410 IAC 26.5, LSA #19-163

Matt Foster, Assistant Commissioner, Consumer Services and Health Care Regulation Commission presented the rule to Regulate Abortion Clinics Performing Drug Induced Abortions Rule 410 IAC 26.5 for final adoption. In 2017, the Indiana General Assembly passed SEA 404 which requires the ISDH to update its abortion clinic licensure rules. ISDH was required to include provisions to:

- Separate rules for clinics offering surgical and abortion inducing drugs
- Add procedures to monitor patients after the administration of anesthesia
- Add procedures for follow-up care for patient complications
- Add a requirement for the provision of informed consent brochures
- Add a requirement for the provision of a hotline telephone number for cases of suspected coerced abortion or sex trafficking
- Require training of clinic staff by law enforcement to help identify and assist women who are coerced into abortions or victims of sex trafficking
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- Technical corrections, i.e. update outdated regulations, etc.

The Notice of Intent to Adopt a Rule was published in the *Indiana Register* on March 20, 2019 starting the one-year period to adopt this rule. The Board approved the draft at the January 9, 2019 and April 3, 2019 meetings for 90-day emergency adoptions. The ISDH has not changed the rules from the proposed version. Staff recommends the Board approved the amendments as required by SEA 404 to the rule to Regulate Abortion Clinics Performing Drug Induced Abortions Rule 410 IAC 26.5 for final adoption.

Ms. Goff asked for comments from the Board, staff and/or public. Hearing none, she entertained a motion for final adoption. On a motion made by Joanne Martin, seconded by Dr. Hanneman and passed unanimously by roll call vote, the Board approved the rule to Regulate Abortion Clinics Performing Drug Induced Abortions Rule 410 IAC 26.5 for final adoption.

Discussion on Petition for Rulemaking to Update Indiana State Reporting, Monitoring and Preventive Procedures for Lead Poisoning in Rule 410 IAC 29

Janet McCabe, Professor of Practice at the IU McKinney School of Law presented a Petition for Rulemaking to Update Indiana State Reporting, Monitoring, and Preventive Procedures for Lead Poisoning in Rule 410 IAC 29. This Petition was submitted to all ISDH Executive Board members. Ms. McCabe provided a brief explanation of the petition.

Dr. Box stated as someone who has brought babies into the world, it bothers her that she can do everything possible to deliver a healthy baby but that that same baby could be exposed to a substance that could have lifelong ramifications once they start crawling and putting things into their mouth. Her desire is to ensure that every Indiana child is protected from lead exposure.

The ISDH did start the process of an emergency rule that would lower the lead threshold to 5 micrograms/deciliter. However, as we were going through that process and having discussions with local health departments, we quickly discovered that the process is much more involved than just changing the level. Indiana has 93 local health departments with widely varied resources, both financial and personnel. Case management falls to local health departments under Indiana code, so understanding how a potentially higher caseload would impact local health departments has been a key part of our ongoing discussions with partners about how to increase lead testing in our children and reduce lead exposure. Some local health departments are very well resourced and already implement case management at levels of 5 ug/dL. Others are one- or two-person operations who are focused on the most emergent issues and don't have the bandwidth to take on more. When we realized that there is no one-size-fits-all approach to this issue and that the conversation about lead thresholds was much bigger than a number, we began looking at lead from a number of different angles.

We know we can't truly understand the burden of lead in our state without better data. That's why the ISDH has undertaken numerous efforts to increase lead testing, including:

- ISDH WIC lead testing pilot that launched in July to test all 1-year-olds for elevated blood lead levels.
- FSSA's Office of Medicaid, Policy & Planning this month announced it would begin reimbursing local health departments for nursing case management activities associated with children with levels at or above 5 ug/dL. (Note that all lead test results, regardless of level, are required to be reported to ISDH)
- ISDH is creating a statewide lead advisory panel consisting of stakeholders from public and private sectors who have an interest in lead issues.
- ISDH is issuing provider report cards that show missed opportunities for lead testing when a child receives immunizations.
- ISDH launched a lead abatement program in conjunction with the Indiana Housing and Community Development Agency, using federal CHIP funds. To date, 58 homes have been abated, approved for the program or are under contract.
- ISDH is also talking with all 93 local health departments to determine what case management activities are being provided to families of children with BLLs below 10 ug/dL".

Paul Krievins, Director of Health and Healthy Homes Division added that in August the ISDH will publish an updated lead risk map by census tract. The map will include data through the end of 2018 and will include updated census data, environmental data, and blood lead levels reported to determine how risk may or may not have changed in communities throughout the state.

Distribution

Ms. Goff thanked the staff for the Professional New Hire and Separation Reports, Summary of Final Orders and Consent Decrees, and Variance Waiver Approvals.

Adjournment

Hearing no additional comments from the Board, staff and/or public, Ms. Goff adjourned the meeting at 11:00 am. The next meeting is scheduled for September 11, 2019.