

Approved October 16, 2013

COLORADO BOARD OF HEALTH

MEETING MINUTES

August 21, 2013

NOTE: These minutes are a summary of the proceedings and motions of the August 21, 2013 meeting of the Colorado Board of Health. The complete and accurate record is the audio recording of the meeting. Documents referenced in the minutes are available for public inspection at the Board of Health Office, Colorado Department of Public Health and Environment, Bldg. A, 5th Floor, 4300 Cherry Creek Drive South, Denver, CO., or call 303-692-3464 to request copies.

Call to Order/Roll Call

The August 21, 2013 Colorado Board of Health meeting was called to order at approximately 10:05 a.m. at the Colorado Department of Public Health and Environment, Sabin Conference Room, 4300 Cherry Creek Drive South, Denver, Colorado, by Laura Davis, president.

Members Present

Christopher Stanley, M.D., District 1; Laura Davis, District 2; Betty McLain, District 5; Joan Sowinski, District 6; Rick Brown, District 7; Christine Nevin-Woods, D.O., At-Large; Karin McGowan, Interim Executive Director, (ex-officio).

Members Absent:

Sue Warren, At-Large, Jill Hunsaker-Ryan, County Commissioner, District 3 and Gary Teague, District 4

Staff Present:

Deborah Nelson, Board Administrator; Ann Hause, Office of Legal and Regulatory Compliance; Joni Reynolds, Health Programs Director; Jamie L. Thornton, Program Assistant; Jennifer L. Weaver, First Assistant Attorney General, legal counsel.

Approval of Minutes

BY UNANIMOUS CONSENT, the Board approved the July 17, 2013 meeting minutes as written.

Board comments regarding matters not on the agenda

Ms. Davis welcomed new Board members and thanked them for their willingness to serve on the Board.

Dr. Stanley remarked that he recently attended a stakeholder meeting pertaining to Colorado's personal belief exemption, with respect to immunizations. The meeting was coordinated by The Keystone Center. He stated that the intended outcome of these meetings is to hear various perspectives regarding the exemption and ultimately provide a recommendation to the Department. Dr. Stanley mentioned that he wanted to recognize and support the Department's efforts regarding this process.

Public comments regarding matters not on the agenda

Laura Kriho, Director, Cannabis Therapy Institute (CTI) provided an overview of the Petition for Emergency Rules to Protect Patient Privacy as described, in detail, in the original request submitted to the Board, dated August 15, 2013. Ms. Kriho stated that the primary objective of the petition is to dismantle the automated interface between the Medical Marijuana Registry (Registry) and the Colorado Bureau of Investigation (CBI) and the Colorado Crime Information Center (CCI).

Ms. Kriho remarked that an audit, released in June, by the Office of the State Auditor, validates the concerns raised in a petition brought before the Board by CTI in 2011. She commented that the purpose of the emergency rules is to protect the confidentiality of the Registry, which is protected by Article XVIII, Section 14, also known as Amendment 20. She said that based on the results of the audit Colorado medical marijuana patients will face discrimination and potential harm in all aspects of their life. Ms. Kriho remarked that the audit provides specific and numerous instances when the confidentiality of the Registry was breached; comments referenced:

- Access to the Registry by law enforcement,
- Confidentiality breaches and lack of patient notification,
- Lack of Department oversight, including the lack of confidentiality agreements
- Registry access by multiple outside entities and Department monitoring of access,
- The Department's agreement with CBI for law enforcement queries and what CBI does with information gathered, and
- The Department not following internal policies regarding security training.

Ms. Kriho stated that the Department's practices are illegal and violate the spirit of the Constitution, which states that the Department will check the Registry and provide a yes or no response. Ms. Kriho stated that confidentiality is important because marijuana use is illegal federally and individuals need to be protected from law enforcement action. Ms. Kriho stated citizens were not informed of the online database that came available in April 2013.

Ms. Kriho remarked that the Board of Health, and others, may consider the passage of Amendment 64 (concerning retail marijuana) as a solution. She went on to say that Amendment 64 does not offer the same protections as Amendment 20 and emphasized that it is not an option for patients using medical marijuana.

The Board heard public comments in support of Ms. Kriho's petition, from the following individuals: Kathleen Chippi; Mimi Friedman; J. Goberd; Audrey Hatfield; William Chengelis; Jackie Edwards; Tammy Vaughn; and Teri Robnett of Colorado NORML. Ms. Chippi discussed the court history, the impact on doctors willing to prescribe medical marijuana, CBI maintaining its own registry, and that the Registry is hooked up to the NSA database. Ms. Chippi relayed her experience calling COHELP which provided her, her doctor and card information. She stated she was not provided information for another patient. Ms. Chippi testified that the registry is voluntary. Ms. Hatfield testified that three patients visited different states and law enforcement knew they had a red card. Ms. Hatfield sought fines and punishment for these alleged breaches. Mr. Chengelis testified about the number of databases in society overall and that it constitutes an illegal search and seizure, and reiterated the testimony that the Registry violates HIPAA. Ms. Edwards testified that medical marijuana patients are treated "like we're nuts", lose housing and are in criminal databases. Ms. Robnett testified that she does not understand why the Department chose the current process rather than another one and that there is continued hostility as doctors are attacked and the Department has

resisted adding conditions. Ms. Robnett reiterated that the Department has failed to protect patients and that patients are treated like second class citizens.

Ron Hyman, State Registrar and Director, Office of Vital Statistics and Medical Marijuana Registry, responded to concerns identified in the petition and public comment period which included: a) the criteria and mechanism used by law enforcement to verify participation in the Registry; b) Registry breaches; c) law enforcement's ability to query the Registry's database; d) construction of a parallel database by law enforcement; e) use of a network system vs. a single computer to manage the Registry; f) use of an outside contractor, Colorado Help Line, to provide information about the Registry; and g) training as it relates to confidentiality. Ms. Davis acknowledged that the Department is not in control of what law enforcement keeps. Mr. Hyman discussed that the Department is reviewing the audit report and is seeking guidance from the Attorney General's Office as recommended by the State Auditor's Office. Mr. Hyman also discussed that a risk of further confidentiality breach is a consideration when determining whether a breach notification is made.

Board members discussed various aspects of the petition and the comments received during the public comment period including the purpose and tone of the audit and the next steps to be taken by the Department regarding the recommendations included in the audit. Ms. Weaver commented that the audit did not identify any issues with the Board of Health regulations. Ms. Weaver remarked that the audit pertains to the actions taken by the Department regarding confidentiality of the Registry and that the Department is seeking the Attorney General's opinion. Ms. Hause indicated that the Department did agree to pursue the advice of the Attorney General's Office on all audit recommendations that recommended that course of action.

The Board asked Ms. Weaver to review the criteria for an emergency rule-making hearing. Ms. Weaver discussed: 1) compliance with state or federal law, which has yet to be determined as the audit recommendation is to discuss compliance with the Attorney General's Office, and; 2) preservation of the public health, safety or welfare. Because the issue of compliance is under review, there is no conclusion to act on at this time.

Ms. Davis reminded the Board that they must decide to accept or reject the petition based on a Board vote. Board members discussed the petition and agreed that while the issues need to be addressed, the emergency rulemaking criteria have not been met. The Board requested that the Department follow up with the Board as to the audit findings. The Board asked the Department to include the citizen petition concerns in its analysis when crafting solutions. The Board discussed the importance of obtaining additional information prior to any Board action.

MOVED by Dr. Stanley, and seconded by Ms. McLain, to reject the petition for an emergency rule-making hearing.

MOTION CARRIED UNANIMOUSLY

Throughout this portion of the meeting, Board President Ms. Davis, repeatedly called the room back into order. Individuals were instructed to not verbally attack individuals, cease interrupting the proceeding, and proceed in a manner that allowed the Board to hear from the community. Ms. Sowinski also asked for the signs to be put down as they were distracting from the comments.

The petitioner subsequently resubmitted its petition as a request for permanent (non-

emergency) rulemaking.

Public Rulemaking Hearing: 6 CCR 1009-9, Reporting, Prevention, and Control of Aids, HIV Related Illness, and HIV Infection – CD4 Counts

Melanie Mattson, Section Chief, Sexually Transmitted Infections, Disease Control and Environmental Epidemiology Division, presented the proposed amendments which were initially discussed with the Board on June 19, 2013.

Ms. Mattson remarked that the proposed changes include revisions to the requirements for laboratory reporting of all CD4 test results, updates to the HIV counseling and testing language, and clarification and updates to language related to information sharing.

Ms. Mattson remarked that the current language in, Regulation 2 – Reporting by Laboratories, requires reporting of CD4 test results of less than 500 cells per cubic millimeter of blood or 29 percent. She stated that the proposed amendments require that all CD4 related laboratory reports, irrespective of results, be reported. She said that the proposed language adds the word “treatment” in an effort to provide clarification. She noted that treatment information is currently collected, when it is available, and that the Department would like to collect treatment information as part of the disease investigation and follow up process. She stated that access to all CD4 test results is vital to align diagnosis, treatment and support for HIV positive persons in care throughout Colorado. She stated that the proposed language does not allow increased access to medical records.

Ms. Mattson stated that the proposed language pertaining to, Regulation 3 – Information Sharing, includes the words “Laboratory Testing and Treatment”, and stipulations on appropriate exchange of information between contracted agencies, health care providers who administer direct services to persons living with HIV and CDPHE. She stated that the intent of the proposed amendments is to assist entities providing direct services to HIV infected individuals to provide proper care to patients with HIV.

Ms. Mattson remarked that the proposed amendments to, Regulation 6 – Objective Standards, include: a) increase the length of training from 16 hours to 32 hours; b) increase notification of test results from 90% of persons testing HIV positive to all persons testing HIV positive; and c) increase partner notification of newly diagnosed HIV positive individuals from 90% to all individuals newly diagnosed with HIV. She pointed out that partner notification is voluntary and will remain voluntary. She noted that the revised language regards publicly funded HIV testing and counseling projects throughout Colorado. She stated that the proposed amendments are required because the operational standards and requirements for publicly funded HIV testing and counseling have changed.

Ms. Mattson remarked that the proposed amendments to, Regulation 7 – Operational Standards, include written explanations of Colorado law regarding consent and confidentiality; as well as, written standards regarding training and referrals for various services related to treating persons with HIV. She pointed out that standards and practices regarding anonymous testing will not be affected by the proposed amendments to these regulations.

Public Comments

The following persons testified about the proposed amendments: Shannon Southhall, Executive Director, Rocky Mountain CARES; Barbara Cardel, Chair, US Women Network, National Stigma Index and Research Body; Arthur Powers, THRIVE; Penny DeNoble, The Issues of Blood Outreach; Jackie Edwards; Laura Kriho; Kathleen Chipipi; Kari Hartel,

Children's Hospital; Sharon Johnson; Diane Walker, C2EA Mountain

Individuals supported the majority of the revisions; however, comments also indicated that some proposed changes will result in barriers to testing, linkage to care, retention in care and treatment, and may result in increases of HIV in Colorado. Ms. Southhall expressed confidentiality concerns and spoke about the impact on the linkage to care and interventions. Ms. Cardel was concerned about requiring a signature for the consent. Mr. Powers testified that the Department has worked collaboratively with the community and the community supports many of the revisions; however, he believes the information sharing section of the proposed rule conflicts with statute. Mr. Powers also referenced the treatment cascade. Ms. DeNoble stated that the rule may further already existing distrust in the African American community of the medical system, information sharing and consent forms, and that it may adversely affect treatment. Ms. Edwards, Ms. Kriho and Ms. Chippi testified that the issues present in this rulemaking are similar to those raised in the Petition for Emergency Rules to Protect Patient Privacy regarding the Medical Marijuana Registry. Ms. Chippi also called for a class action lawsuit. Ms. Hartel commented that the rule needs further discussion and that she fears it is creating a barrier. She shared that she serves pregnant women and youth and that she has lost three patients because of stigma. Ms. Hartel indicated that stakeholders were not included in developing the rule. Individuals requested that the Board postpone the hearing and allow for additional outreach to stakeholders to review and develop the proposed changes.

Board Comments

Ms. Sowinski offered two amendments to the rule to improve readability and clarify the intent of the change. The first was to modify line 37 to read "HIV-related illness, HIV infection, and associated laboratory testing and treatment shall be shared." The second was to modify line 114 to insert after "signed," "(signature or anonymous code)."

Board members asked the Department to continue its outreach to the community and bring the rule back before the board after additional discussion has occurred.

MOVED by Dr. Nevin-Woods, and seconded by Ms. Sowinski, to continue the hearing to October 16, 1213.

MOTION CARRIED UNANIMOUSLY

Public Rulemaking Hearing: 6 CCR 1009-4, Ophthalmic Ointment in Newborn Infants

Melanie Mattson, Section Chief, Sexually Transmitted Infections, Disease Control and Environmental Epidemiology Division, presented the proposed amendments which were initially discussed with the Board on June 19, 2013. Ms. Mattson stated that the Department was previously required to name, approve and provide a prophylaxis to be used in treating the eyes of newly born infants. She mentioned that in March 2012, C.R.S. 25-4-301 was amended to now require health care providers to treat a newly born infant with a prophylaxis in accordance with the current medical standard of care. With this change in statute, the rule is no longer necessary.

Public Comment

None.

MOVED by Dr. Stanley, seconded by Ms. McLain, to adopt the proposed repeal of 6 CCR 1009-4, Ophthalmic Ointment in Newborn Infants,

along with the statement of basis and purpose, specific statutory authority and regulatory analysis.

MOTION CARRIED UNANIMOUSLY

Medical Marijuana Program Annual Update

Ron Hyman, State Registrar and Director, Office of Vital Statistics and Medical Marijuana Registry, presented the 2013 Medical Marijuana Registry Annual Report. Mr. Hyman's comments focused on the intent of Amendment 20, Amendment 64, medical marijuana applications, reported conditions, patient demographics and programmatic priorities.

Mr. Hyman also discussed the recommendations of the Legislative Audit Report. Audit recommendations include: a) improving oversight of physician recommendations for medical marijuana; b) improving the timeliness of processing Medical Marijuana Registry applications; c) working with the Department of Revenue and stakeholders to determine if the Department can discontinue maintaining dispensary information; d) strengthening caregiver oversight; e) ensuring the confidentiality of the Registry; f) improving the Registry's general computer controls and g) improving the management of the Medical Marijuana Cash Fund.

Ms. Nevin Woods indicated that there is no standard of care in the medical field and acknowledged the barriers to assessing the science. She also asked whether a task force would be appropriate. Ms. Davis responded that until the audit recommendations are studied, next steps for the Department are unknown.

Due to the extended public comment period, the scheduled LiveWell Colorado Annual Update did not occur.

Executive Director and Chief Medical Officer Report – Interim Executive Director Karin McGowan

Ms. McGowan mentioned that the search for a new executive director is almost over and she anticipates that an announcement will be made in the near future.

Ms. Reynolds discussed Dr. Laura Gilliam Ross' appointment as Interim Director of the Laboratory Services Division, recruiting efforts for a toxicology lab director and the press release pertaining to the results of the toxicology re-testing.

Public Health Act Update – Kathleen Matthews, Director, Office of Planning and Partnerships, Community Relations

Ms. Matthews reviewed the waiver of minimum qualifications for Shelly Warrington to serve as the Mineral County Public Health Director with the Board. She also asked the Board for a Board member volunteer to serve on the Public Health Improvement Steering Committee.

Attorney General's Report - Jennifer Weaver, First Assistant Attorney General, Health Care Unit

Ms. Weaver stated that a reconsideration petition to hear the Boyer and Todd v. Hickenlooper and Colorado Board of Health case has been submitted and a court order is anticipated next month.

Administrative Business – Ann Hause, Interim Board Administrator

Ms. Hause introduced Deborah Nelson as the new Board Administrator. She mentioned that Ms. Nelson previously worked for the Department of Human Services and that she has a great deal of experience with boards and other experiences that will be very beneficial in her new role. Ms. Hause remarked that Ms. Nelson has already been a tremendous help leading up to and including today's meeting. Ms. Hause also discussed the September 17th retreat and the September 18th regular meeting logistics.

Ms. Reynolds introduced Dana Erpelding as Interim Director for the Center for Health & Environmental Information & Statistics Division. She remarked that Ms. Erpelding has been charged with reviewing, how the Department manages data, how the various Department registries connect, and managing the Department's informatics.

Ms. Erpelding mentioned that she has been with the Department for ten years and that she is looking forward to working with the Board.

Ms. Davis recognized Amy Warner and Meredith Towle, Disease Control and Environmental Epidemiology Division, for their efforts in making Colorado a safer place to work and live.

Ms. Nelson discussed the October 17, 2013 joint meeting with the Air Quality Control Commission and asked Board members to forward her any agenda items they would like to discuss.

6 CCR 1007-1, Radiation Control Part 24, Particle Accelerators and Therapeutic Radiation Machines in the Healing Arts

James Jarvis, Hazardous Materials and Waste Management Division, presented the proposed amendments to Part 24 and asked the Board to schedule a public rulemaking hearing on November 20, 2013. Mr. Jarvis remarked that the proposed amendments apply to therapeutic radiation machines used for radiation therapy purposed in the healing arts. He commented that in 2013 there were approximately 60 radiation machines registrants in Colorado. He stated that Part 24 does not apply to diagnostic radiation (x-ray) machines, or particle accelerators or radiation machines for non-healing arts purpose, such as industrial or research purpose.

Mr. Jarvis stated that the intent of the amendments is to incorporate selected changes contained in the Conference of Radiation Control Program Directors, Inc. (CRCPD), Suggested State Radiation Control Regulations Part X (2009). He stated that the proposed changes include the addition and modification of certain definitions; clarify supervision requirements; clarify notification requirements for medical events; clarify requirements for shielding plans; and include the addition of language and requirements relating to image guided radiation therapy. He discussed the results of the stakeholder process and the feedback received the Colorado Radiation Advisory Committee.

Ms. Davis voiced her appreciation to the Division for their thorough stakeholder process and commented that the documentation was well organized and planned out.

Mr. Brown offered three comments to Mr. Jarvis: the terms in lines 256 and 261 may need to be reconciled; the term "violation" in line 326 may be better stated as "demonstration of compliance"; and a request for clarification of whether lines 341 through 347 speak to testing or operating.

Ms. Davis asked if any Board member would be interested in chairing this rulemaking meeting and Mr. Brown volunteered.

BY UNANIMOUS CONSENT, the Board scheduled a public rulemaking hearing on November 20, 2013, to consider proposed amendments to 6 CCR 1007-1, Radiation Control Part 24, Particle Accelerators and Therapeutic Radiation Machines in the Healing Arts.

This meeting was adjourned at approximately 3:10 p.m.

Copies of the rulemaking documents, reports, briefings, and presentations may be obtained by submitting a request to: cdphe.bohrequests@state.co.us