

COLORADO BOARD OF HEALTH
MINUTES
March 16, 2011

NOTE: These minutes are a summary of the proceedings and motions of the March 16, 2011 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 March 16, 2011 Colorado Board of Health meeting was called to order at approximately 9:14am 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

Philip Mehler, M.D., District 1 (arrived at 10:40 a.m.); Laura Davis, District 2; Kindra Mulch, District 4; Joan Sowinski, District 6; Jeanne McGinnis, District 7 Christine Nevin-Woods, D.O., At-Large; Martha Rudolph, Environmental Program Director; and Ann Hause, Office of Legal and Regulatory Affairs Director

Members Absent:

Glenn Schlabs, District 5; Larry Kipe, M.D., At-Large

Staff Present:

Karen Osthus, Board Administrator; Jamie L. Thornton, Program Assistant; and, Jennifer L. Weaver, First Assistant Attorney General, legal counsel.

Approval of Minutes

BY UNANIMOUS CONSENT, the February 16, 2011 minutes were approved as written.

Public comments regarding matters not on the agenda

None.

Board comments regarding matters not on the agenda

Ms. Mulch mentioned that Public Health Day is March 17 and that several events would be hosted at the Capitol.

Discussion/Requests for a Rulemaking Hearing: Proposed amendments to 6 CCR 1015-3, State Emergency Medical and Trauma Care System – pertaining to Ch.1 Education and Certification, Ch.2 Practice and Medical Director Oversight, Ch. 3 Data and Information Collection & Record Keeping, Ch. 4 Licensure of Ground Ambulance Services, and Ch. 5 Air Ambulance

Staff Comments: Randy Kuykendall, Section Chief, Emergency Medical and Trauma Services Section, Health Facilities and Emergency Medical Services Division, provided the Board with an overview of substantive and minor changes addressed in the proposed amendments. He pointed out that the primary focus of the proposed changes is to implement the National Scope of Practice Model for Colorado's emergency medical and trauma service providers. Mr. Kuykendall added that the proposed changes were developed and approved by the State Emergency Medical and Trauma Services Advisory Council. Mr. Kuykendall responded to questions from the Board and requested that a rulemaking hearing be set for May 18, 2011.

BY UNANIMOUS CONSENT, the Board scheduled a public rulemaking hearing on May 18, 2011 to consider proposed amendments to 6 CCR 1015-3, State Emergency Medical and Trauma Care

System-pertaining to Ch.1 Education and Certification, Ch. 2 Practice and Medical Director Oversight, Ch. 3 Data and Information Collection & Record Keeping, Ch. 4 Licensure of Ground Ambulance Services, and Ch. 5 Air Ambulance.

Discussion/Request for a Rulemaking Hearing: Proposed amendments to 6 CCR 1015-4, State Emergency Medical and Trauma Care System, Ch 3 – Designation of Trauma Facilities

Staff Comments: Randy Kuykendall, Section Chief, Emergency Medical & Trauma Services, Health Facilities and Emergency Medical Services Division, provided the Board with a summary of the proposed changes regarding Chapter 3, Designation of Trauma Facilities. He stated that the proposed changes include updating the fees for triennial trauma designation review process; instituting a new fee for trauma reviews based on previous deficiencies; and correcting formatting and grammatical errors. He pointed out that the fee adjustment is statutorily limited to direct activities related to the designation review process of trauma centers. He added that the designation period is on a 3-year cycle per facility and that fees have not been adjusted in fourteen years.

BY UNANIMOUS CONSENT, the Board scheduled a public rulemaking hearing on May 18, 2011 to consider proposed amendments to 6 CCR 1015-4, State Emergency Medical and Trauma Care System-pertaining to Ch.3 Designation of Trauma Facilities

Briefing/Presentation: Occupational Health Surveillance Initiatives

Staff Comments: Amy Warner, Manager, and Meredith Towle, Program Coordinator/Epidemiologist and Occupational Health Surveillance, Disease Control and Environmental Epidemiology Division provided an overview of the department's Occupational Health Surveillance Program (OHSP) as it pertains to work-related injuries, illnesses and fatalities.

Ms. Warner's comments focused on the history and importance of the OHSP, recent accomplishments, and long-term objectives of the program. She added that efforts are also focused on designing and implementing a statewide program; collecting and sharing data; and creating partnerships. She pointed out that the program was recently funded by the Centers for Disease Control (CDC) and National Institute for Occupational Safety and Health (NIOSH).

Ms. Towle provided an overview of the Occupational Health Indicators in Colorado report. She presented the Board with statistics pertaining to Colorado's workforce and reported on the financial burden associated with work related injuries and illnesses. She talked about collecting data, monitoring trends, and developing policies to improve Colorado's workplaces. Ms. Towle explained the differences between the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH).

Board members and program staff discussed various aspects of the program and report. The Board remarked on the importance of the OHSP and commended the work the division has done and requested a follow-up report as the work progresses.

Discussion/Request for a Rulemaking Hearing: Proposed amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Chapter XXIV- pertaining to Medication Administration

Staff Comments: Laurie Schoder, Policy Analyst, Health Facilities and Emergency Medical Services Division, presented the proposed amendments and asked the Board to schedule a public rulemaking hearing on May 18, 2011. Ms. Schoder mentioned that the proposed amendments correct typographical errors and add language that emphasizes the statutory requirement that only certain types of licensed health care facilities may use a Qualified Medication Administration Person (QMAPS) when providing medications.

BY UNANIMOUS CONSENT, the Board scheduled a public rulemaking hearing on May 18, 2011 to consider proposed amendments to 6 CCR 1011-1 Ch. XXIV, Standards for Hospitals and Health Facilities, pertaining to Medication Administration.

PUBLIC RULEMAKING HEARING: Proposed amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities Ch. XXVI – pertaining to Home Care Agencies

Staff Comments: Laurie Schoder, Policy Analyst, Health Facilities and Emergency Medical Services Division, presented the Board with the proposed changes to Standards for Hospitals and Health Facilities pertaining to home care agencies. Ms. Schoder reminded the Board that the 2008 General Assembly required the department to develop regulations pertaining to home care agencies. In 2010, those regulations were amended to include community center boards serving persons with developmental disabilities. She provided a summary of the issues raised during the stakeholder's process and she summarized the resolutions that were achieved.

Public Comments

Scarlet Larkin, Pediatric Speech Language Pathologist, expressed support for the proposed changes.

MOVED by Ms. McGinnis, and seconded by Dr. Nevin-Woods, to adopt the proposed amendments to Standards for Hospitals and Health Facilities, 6 CCR 1011-1 Ch. XXVI Home Care Agencies, along with the statement of basis and purpose, specific statutory authority and regulatory analysis.

MOTION CARRIED UNANIMOUSLY

PUBLIC RULEMAKING HEARING: Proposed amendments to 5 CCR 1005-4, Newborn Screening – pertaining to adding Severe Combined Immunodeficiency (SCID) to list of conditions receiving a first screen

Staff Comments: David Butcher, Director, Laboratory Services Division, requested that the proposed amendments be adopted and provided an overview of SCID. He emphasized the importance of early detection due to the life threatening nature of infections associated with this condition, the costs related to caring for children diagnosed with SCID, and the potential for favorable outcomes connected with early treatment. He added that the Colorado Newborn Screening Advisory Committee and the Health Resources and Services Administration Advisory Committee on Inheritable Disorders in Newborns and Children recommended including SCID on the list of conditions receiving first screen.

Board Comments/Discussion

The Board asked several questions regarding the costs of additional testing, the rate of testing errors, and whether SCID meets the statutory criteria to be added on the list. Mr. Butcher responded that the SCID test will add \$6.78 to the newborn screening cost for a total of \$92 and that SCID meets the statutory criteria.

Public Comments

Scott Matthews, Program Services Director, March of Dimes, thanked the Board for the work that they do regarding public health and provided testimony in support of the proposed changes.

Erwin Gelfand, M.D., Chairman, Department of Pediatrics, National Jewish Health, spoke about the importance of newborn screening in Colorado and provided his support for the proposed changes.

MOVED by Ms. Mulch, and seconded by Ms. McGinnis, to adopt the proposed amendments to 5 CCR 1005-4 Newborn Screening, adding SCID to the list of conditions receiving a first screen, along with the statement of basis and purpose, specific statutory authority and regulatory analysis.

MOTION CARRIED UNANIMOUSLY

PUBLIC RULEMAKING HEARING: Proposed amendments to 6 CCR 1007-1- pertaining to Radiation Control

Part 1 - General Provisions

Staff Comments: James Jarvis, Radiation Control Program, Hazardous Materials and Waste Management Division, presented the Board with the proposed changes to Part 1, General Provisions and he stated that the proposed changes are being made to incorporate language and requirements from the Colorado Radiation Control Act (the Act), which was amended in 2002, 2003, and 2010.

Mr. Jarvis remarked that the department conducted an extensive stakeholder process that included multiple meetings with the Radiation Advisory Committee (RAC). He stated that the department notified professional entities and other interested parties, such as the radioactive material licensees, about the proposed changes. He commented that in October 2010 and February 2011 the department sent notices to approximately 600 stakeholders. He added that comments received by the department, prior to February 20, 2011, focused on policies that are not under the Board's purview.

Mr. Jarvis remarked that the proposed changes consist of adding several definitions and clarifying the definition of “ore” from the Act. He pointed out that the Radiation Advisory Committee deliberated extensively about the definition of ore and determined that the definition provided by the Act was too broad and required additional language in order to provide clarity.

Public Comments

Jeff Parsons, representing Colorado Citizens Against ToxicWaste, (CCAT), and Sheep Mountain Alliance (SMA), stated that he is concerned with the expanded definition of ore because it causes confusion, conflicts with statutory language, and has potential for unintended consequences, such as “sham processing”. He pointed out that if the Division is concerned with laboratory analysis it would be better to include specific language addressing that issue in the regulations rather than expand the definition of ore.

Jerry Goad, Senior Assistant Attorney General, representing Colorado Department of Public Health and Environment, reminded the Board that regulatory agencies are entitled to clarify statutory definitions. He added that the department’s proposed language neither expands or contracts the definition of ore but rather clarifies the statutory definition and is within the department’s authority.

Jim Spaanstra, representing Energy Fuels Resources, provided testimony in support of the proposed amendments.

Board Comments/Discussion

The Board discussed the definition of ore, the department’s intent concerning the definition of ore, and the protections against “sham disposal” processes. The Board also considered the possible unintended consequences of expanding the definition of ore as it relates to other statutes pertaining to public health. Steve Tarlton, Radiation Program Manager, Hazardous Materials and Waste Management Division (HMWMD), testified that the rules as written provide adequate protection for human health and the environment.

Ms. Davis pointed out that the Colorado Radiation Advisory Committee supports the proposed amendments.

MOVED by Ms. Sowinski, and seconded by Ms. McGinnis, to adopt the proposed amendments to Radiation Control, 6 CCR 1007-1 Part 1, General Provisions, along with the statement of basis and purpose, specific statutory authority and regulatory analysis.

MOTION CARRIED UNANIMOUSLY

Part 3 - Licensing of Radioactive Material

Staff Comments: James Jarvis, Radiation Control Program, Hazardous Materials and Waste Management Division, presented the Board with the proposed changes to Part 3, Licensing of Radioactive Material. He pointed out that the proposed regulations apply to all facilities that are licensed for use of radioactive material. Mr. Jarvis remarked that the proposed changes are being made to incorporate language and requirements from the Act, which was amended in 2002, 2003 and 2010. He provided a summary of the proposed changes, which include; 1) a reference to Part 18; 2) language pertaining to notification and posting of financial warranty information; 3) language pertaining to license hearings specific to uranium facilities; and 4) clarifies language from the U.S. Nuclear Regulatory Commission (NRC).

Public Comments

Jeff Parsons, representing Colorado Citizens Against ToxicWaste, Inc. (CCAT), and Sheep Mountain Alliance (SMA), remarked in regard to 3.9.10.1(2), that the proposed language limits hearings specifically to a facilities’ receipt of classified material. He commented that the major concern is the department’s position that the public does not have a right to a formal hearing or the right to appear before the court and ask for a review of licensing decisions. He stated that there is a difference between a public meeting and a public hearing and argued that the public should be entitled to a public hearing. He added that his concern regarding hearings also applies to Part 18.

Jerry Goad, Senior Assistant Attorney General, representing Colorado Department of Public Health and Environment, stated that the department does not take the position that the public is not entitled to a hearing. He pointed out that during litigation related to the Pinion Ridge Mill t the department filed a motion to dismiss the case due to an incorrect assertion of jurisdiction not for the reasons claimed by Mr. Parsons.

Jim Spaanstra, representing Energy Fuels Resources, commented that the language regarding a licensee's right to a formal hearing has been in the Administrative Procedures Act (APA) for years. He also mentioned that Mr. Parsons was involved with the legislation that developed the procedure that was applied to Pinon Ridge Mill and pointed out that Mr. Parsons did not previously address the provisions being discussed today.

Board Comments/Discussion

The Board asked the department to address the concern raised regarding the circumstances when a public hearing is required. Steve Tarlton, Radiation Program Manager, HMWMD, stated that Part 18 specifically addresses requirements for public hearings and that it is not the department's intent to limit access to public hearings.

MOVED by Ms. Sowinski, and seconded by Dr. Nevin-Woods, to adopt the proposed amendments to Radiation Control, 6 CCR 1007-1 Part 3, Licensing of Radioactive Material, along with the statement of basis and purpose, specific statutory authority and regulatory analysis.

MOTION CARRIED (5-1 Ms. Mulch opposed)

Part 12 - Fees for Radiation Control Services

Staff Comments: James Jarvis, Radiation Control Program, Hazardous Materials and Waste Management Division, presented the Board with the proposed changes. Mr. Jarvis remarked that proposed language does not include changes to the fee structure. He provided a summary of the changes that include: 1) removing the fee exceptions for government entities; 2) adding clarifying language regarding fee determinations for small entities; 3) increasing the return check fee and; 4) adding clarifying language on the applicability of certain x-ray fees.

Public Comments

Prior to the public comment period Ms. Davis instructed Mr. Parson to limit his comments to the scope of the rulemaking hearing and to refrain from discussing items currently in litigation.

Jeff Parsons, representing Colorado Citizens Against ToxicWaste, Inc. (CCAT), and Sheep Mountain Alliance (SMA), commented that the NRC regularly revises their fee structure and charges substantially more than Colorado does for processing uranium milling applications. He added that he does not understand why Colorado's fees are substantially lower.

Mr. Tarlton remarked that the licensing program is fee funded and receives no general or federal funds. He added that the department is statutorily required to charge what it costs to manage the program.

Board Comments/Discussion

None.

MOVED by Ms. McGinnis, and seconded by Dr. Nevin-Woods, to adopt the proposed amendments to Radiation Control, 6 CCR 1007-1 Part 12, Fees, along with the statement of basis and purpose, specific statutory authority and regulatory analysis.

MOTION CARRIED UNANIMOUSLY

Part 13 - Penalties for Violations

Staff Comments: James Jarvis, Radiation Control Program, Hazardous Materials and Waste Management Division, presented the Board with the proposed changes and stated that the intent is to incorporate language and requirements from the Colorado Radiation Control Act (the Act), which was amended in 2002, 2003 and 2010. Mr. Jarvis remarked that the changes include: 1) changing the title of Part 13 from "Penalties for Violations" to "Compliance Enforcement"; 2) adding a definition for administrative penalty; and 3) deleting reference to example violations. He pointed out that the compliance program is not changing how business is conducted and he emphasized that the proposed changes streamline the penalty process.

Public Comments

None.

Board Comments/Discussion

None.

MOVED by Dr. Nevin-Woods, and seconded by Dr. Mehler, to adopt the proposed amendments to Radiation Control, 6 CCR 1007-1 Part 13, Penalties for Violations, along with the statement of basis and purpose, specific statutory authority and regulatory analysis, along with the amendment to strike 13.3.2 on page 13-2, line 53.

MOTION CARRIED UNANIMOUSLY

Part 18 - Licensing Requirements for Uranium and Thorium Processing

Staff Comments: James Jarvis, Radiation Control Program, Hazardous Materials and Waste Management Division, presented the Board with the proposed changes and stated that the intent is to incorporate language and requirements from the Colorado Radiation Control Act (the Act), which was amended in 2002, 2003, and 2010. Mr. Jarvis remarked that the changes include: 1) adding definitions for consistency with the Act; 2) adding exclusions for Naturally Occurring Radioactive Materials (NORM) and Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM); 3) adding language regarding coordination between state agencies; 4) adding language pertaining to environmental assessments; and 5) adding requirements for public review and hearing processes.

Public Comment

Jeff Parsons, representing Colorado Citizens Against ToxicWaste, (CCAT), and Sheep Mountain Alliance (SMA), commented that the major issue with this part is the ability of the public to have an adjudicatory hearing. He pointed out that regulations provide for adjudicatory hearings; however, in practical terms rules are not followed. He suggested that the Board compare the license requirements with the actual process the mills undergo. He pointed out that in 18.6.2.1.6 the notice requirement regarding the procedure for applying to become a party to a hearing are provided; however, in his experience the requirement is not being met during the application process. He emphasized that this practice severely limits the public's ability to participate in hearings.

Mr. Parsons remarked that it is unclear to him why there are multiple definitions for the word "facility". He stated that Part 1 and Part 18 of the regulations as well as the statute each define "facility" differently and this causes confusion.

Mr. Tarlton stated that the department met directly with members of CCAT in June, August and October of 2010 at which time they discussed the stakeholder process and specifically requested that those organizations review the regulatory changes.

Board Comments/Discussion

The Board asked Mr. Tarlton to address concerns raised regarding the multiple definitions of facilities and the department's experience as it relates to public participation. Mr. Tarlton responded by saying that the definition in the statute only applies to uranium facilities and does not address other types of licensed facilities. He added that the regulatory s definition refers to standard facilities and is not specific to uranium facilities. He pointed out that the proposed language simply applies the relevant statutory language to the corresponding regulations to provide clarity.

Mr. Tarlton stated that the department is required to comply with the Radiation Control Act and that CCAT had been involved with and the catalyst behind many of the changes in 2002, 2003 and 2010. He remarked that part of the changes included a public process for review of uranium mill licenses and he provided an overview of the review process. He added that in his opinion the process for the public to participate is not difficult.

MOVED by Ms. Sowinski, and seconded by Dr. Nevin-Woods, to adopt the proposed amendments to Radiation Control, 6 CCR 1007-1 Part 18, Licensing Requirements for Uranium and Thorium Processing, along with the amendments to section 18.1.4.4, line 42, insert "issuance of"; section 18.1.4.4, line 44, after "satisfy" insert "the requirement for a certificate of designation."; and 18.1.5, line 49, strike "he" and insert "the", along with the statement of basis and purpose, specific statutory authority and regulatory analysis.

MOTION CARRIED UNANIMOUSLY

PUBLIC RULEMAKING HEARING: Proposed amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Ch. VIII, Sub Ch. 2- pertaining to Intermediate Care Facilities for Persons with Developmental Disabilities and Sub Ch 5, Community Residential Homes for Persons with Developmental Disabilities

Staff Comments: Laurie Schoder, Policy Analyst, Health Facilities and Emergency Medical Services Division, requested that the Board adopt the proposed changes to Standards for Hospitals and Health Facilities pertaining to persons with developmental disabilities.

Ms. Schoder remarked that Chapter VIII had not been revised in more than twenty years and due to the tremendous development in treating persons with developmental disabilities the entire chapter was rewritten. She stated that a goal of the proposed changes is to create smaller facilities with a “home like” setting and she emphasized that the department wants the facilities to have the latitude to meet the individual needs of their clientele.

Ms. Schoder pointed out that the department made every effort to avoid over regulating the facilities. She commented that the proposed changes include: 1) providing updated guidelines and requirements to reflect current practices; and 2) increase the licensing fee to cover the department’s direct and indirect costs for licensing these facilities. She specifically mentioned providing facilities with the 2005 Food and Drug Administration (FDA) dietary guidelines publication and requiring facilities to conduct an annual review of dietary plans by a qualified dietitian. Ms. Schoder commented that stakeholders were involved in the process; however, consensus was not achieved on all items. She reminded the Board that Eastern Colorado Services sent a letter identifying their concerns.

Public Comments

Fran Moore, RN, Director, Eastern Colorado Services, provided a summary of the services Eastern Colorado Services provides to counties in northeastern Colorado. Her remarks focused on concerns regarding medical records retention, infectious disease prevention and control, the annual diet plan review, and medication error reporting.

Judy James-Anderson, R.N., President, Colorado Association of Nurses for the Developmentally Disabled, comments focused on concerns in Chapter VIII regarding dietary evaluations, quarterly review of medication regime, quarterly review of therapeutic and health services, and monitoring unlicensed staff. She suggested that the Board align the department’s regulations with the Department of Human Services, Developmental Disabilities Division.

Vicki Thayer, R.N., Vice President, Colorado Associations of Nurses for the Developmentally Disabled, commented that the majority of residents in these homes are not on specialized diets and the cost to conduct quarterly reviews would be burdensome to the facilities.

Sue Neberve, R.N., remarked that patients have the right to refuse medication and she asked the Board to strike the word refusal from the proposed changes.

Judy Loftis pointed out that funding for intermediate care facilities has decreased over the years and that it is getting more and more difficult to meet standards with no additional funds. She suggested that the department include interpretive guidelines to help clarify requirements and to create consistency regarding surveys.

Board Comments/Discussion

Dr. Mehler remarked that he agreed that over regulation is a real concern. He added that additional oversight regarding the medication and dietary components of these rules are important due to the impact these areas have on individuals and society.

Further Board discussion focused on 1) differing requirements for different types of homes; 2) meaning of “qualified dietitians”; 3) required annual and quarterly reviews of dietary plans, and 4) reporting of medication errors. Ms. Schoder and Judy Hughes, Section Chief, Health Facilities & Emergency Medical Service Division, responded to several questions.

After a lengthy discussion, the Board suggested the rulemaking hearing be deferred until the end of the meeting to allow all parties to continue discussing the remaining concerns. The meeting was reconvened and Ms. Schoder remarked that a consensus was achieved and she presented the Board with the recommended changes.

MOVED by Ms. Mulch, and seconded by Ms. McGinnis, to adopt the proposed amendments to Standards for Hospitals and Health Facilities, 6 CCR 1011-1Ch.VIII pertaining to Intermediate Care Facilities for Persons with Developmental Disabilities, along with the statement of basis and purpose, specific statutory authority and regulatory analysis, with the amendments noted on the errata sheet.¹

MOTION CARRIED UNANIMOUSLY

Legislative Update, Karin McGowan, Director of Policy, External Affairs and Planning

Ms. McGowan provided a brief update on the following bills: HB11-1101 - Federally Qualified Health Centers; HB11-1016 - E-Cigarettes; HB11-1043 - Medical Marijuana Clean-up; HB11-1082 – Weld County Ozone; HB11-1179 – Onsite Wastewater; HB11-1223 – Oil & Gas Commission; HB11-1261 THC blood level threshold; and SB11-063 – Local Communities/Master Plans.

She remarked that the Governor’s Office of State Planning and Budget (OSPB) and the Joint Budget Committee (JBC) would release its proposed budgets and that Legislative Council would be releasing the FY 2010-11 revenue forecast by March 21. Ms. McGowan noted that the budget would consume the majority of the General Assembly’s time for the next two weeks.

Ms. McGowan responded to several questions from Board members.

Administrative Business Karen Osthus, Board Administrator

Ms. Osthus talked about the April agenda, prospective agenda items for future meetings and the potential of the new board members. She noted that the April 20 meeting would be held via teleconference.

PUBLIC RULEMAKING HEARING: Proposed amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Chapter II, General Licensure Standards, concerning the reuse of single use disposable medical devices

Staff Comments: Lorraine Dixon-Jones, Policy Analyst, Health Facilities and Emergency Medical Services Division, stated that manufacturers currently label disposable medical devices as single use devices; however, the Food and Drug Administration (FDA) has determined that these medical devices could be used multiple times if they have been properly reprocessed. Ms. Dixon-Jones remarked that the Association of Medical Device Reprocessors (AMDR) requested that the department review the current state regulations because they were not consistent with the FDA requirements. She emphasized that the department’s regulations apply to facilities, while, the FDA regulations apply to reprocessors. Ms. Dixon-Jones provided a brief overview of the FDA’s rules and then pointed out the changes in the department’s proposed regulations. She addressed the concerns raised by the AMDR regarding the department’s requirement to track the number of times a device has been reprocessed.

Public Comments

Kathryn Balmford, Attorney, OFW Law Firm, Washington DC, Counsel to Association of Medical Device Reprocessors, reminded the Board of her written comments and provided a summary of her concerns. Ms. Balmford pointed out that with the passage of the 2002 Medical Device User Fee Amendment Act, reprocessing has been regulated at the federal level and implemented by the FDA. She noted that the federal rules include a tracking requirement and that the proposed rules create a redundancy, are open to interpretation, and place the responsibility of tracking reprocessed devices on individual hospitals. Ms. Balmford provided an overview of the reprocessing procedures and the general policies of reprocessors.

Jessie Israel, Director of Regulatory Policy, Colorado Hospital Association (CHA), stated that the department and CHA worked on the proposed amendments and that CHA supports the changes in the regulations. She stated that CHA views the tracking section of the regulations as a verification step and not a shift of responsibility regarding the number of times a device has been reprocessed.

MOVED by Ms. McGinnis, and seconded by Ms. Mulch, to adopt the proposed amendments to Standards for Hospitals and Health Facilities, 6 CCR 1011- Standards for Hospitals and Health Facilities, Ch. II General Licensure Standards concerning the reuse of single use disposable medical

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

MOTION CARRIED UNANIMOUSLY

PUBLIC RULEMAKING HEARING: Proposed amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Ch. II, General Licensure Standards - concerning the donation of unused medications, medical devices, and medical supplies

Staff Comments: Staff Comments: Lorraine Dixon-Jones, Policy Analyst, Health Facilities and Emergency Medical Services Division, commented that the existing rules are based on a law passed in 2005, which allowed certain types of facilities to donate unused medications to a pharmacist within the facility for residents residing in the same facility. She added that the statutes were expanded in 2010 to include additional facilities to the program, add medical devices and medical supplies, and allow pharmacists and facilities to donate to nonprofit relief agencies. Ms. Dixon-Jones remarked that the proposed amendments include: 1) a list of eligible items; 2) transportation procedures and; 3) policy and procedures for storage and inventory control. She pointed out that the proposed changes have been available to the public since August and that the department received numerous comments. She added that there is not any opposition to the proposed changes.

Public Comments

None.

MOVED by Ms. Mulch, and seconded by Ms. McGinnis, to adopt the proposed amendments to Standards for Hospitals and Health Facilities, 6 CCR 1011- Standards for Hospitals and Health Facilities, Ch. II General Licensure Standards concerning the donation of unused medications, medical devices, and medical supplies, along with the statement of basis and purpose, specific statutory authority and regulatory analysis.

MOTION CARRIED UNANIMOUSLY

PUBLIC RULEMAKING HEARING: Proposed amendments to 5 CCR 1006-2, Medical Use of Marijuana – pertaining to Regulation 3 and Regulation 8 – physician rules

Staff Comments: Ann Hause, Director, Office of Legal and Regulatory Affairs, reviewed the background of the proposed amendments, summarized the department’s goals to meet SB10-109 and HB10-1284 requirements; and described the stakeholder process for the proposed amendments. She remarked that the department does not have any authority over physician licenses and that the 2010 legislation only authorizes the department to regulate physicians concerning medical marijuana recommendations.

Ms. Hause pointed out that the Medical Marijuana Advisory Committee (MMAC) met on December 8, 2010, January 11, 2011 and January 27, 2011 to discuss the proposed rules. She added that these meetings were noticed as required by the Open Meetings law and open to the public. She remarked that stakeholders included in the discussions were the Colorado Medical Society, the Colorado Medical Board, physicians who recommend medical marijuana, and medical marijuana patients. She added that MMAC approved the proposed rules by a 5- 4 vote.

Ms. Hause stated that the proposed amendments include: 1) defining “physician patient relationship” and “physician in good standing”; 2) adding criteria for referring a physician to the Colorado Medical Board for investigation; and 3) adding financial prohibitions for physicians making medical marijuana recommendations. She discussed how the proposed amendments provide a structure for the department to comply with the 2010 statutes.

She summarized the issues that generated comprehensive discussion and, in some cases, resulted in the removal of language from the original proposal. Those issues included: 1) the meaning of a conditioned and/or restricted physician license; 2) the requirement that the recommending physician have responsibility for the ongoing care and treatment of a patient and; 3) the requirement that the recommending physician have a regular and permanent practice location.

Ms. Hause commented that the 2011 General Assembly is considering proposed amendments that would allow physicians to petition the Medical Board to determine if the restriction/conditions restrict their ability to make recommendations for

medical marijuana. She pointed out that the proposed amendments do not contain language that addresses restrictions/conditions and suggested adding it to the rules.

Public Comments

Betty Aldworth, representing Jill Lamoureaux, department's Medical Marijuana Advisory Committee and Department of Revenue's Medical Marijuana Advisory Committee, stated that four members of the MMAC oppose the department's proposal. She requested the Board remove the terms "unconditioned or unrestricted" from the proposed language and direct the department to approve the 1,300 applications that are currently in a pending status.

Kathleen Chippi, Patient and Caregiver Rights Litigation Project, stated that all licenses currently held at the department should be approved. She recommended that all language in the department's proposal be stricken because physicians are protected from disciplinary action by the constitutional provisions.

Corey Donahue, speaking on behalf of "Scooby", asked that the provisions of the constitutional amendment be honored by the department.

Board Comments/Discussion

Board members discussed pending applications and the criteria for a physician having a conditioned license.

Ron Hyman, State Registrar, Center for Health and Environmental Information and Statistics, stated that there are approximately 2,000 applications with recommendations by physicians that have restrictions or conditions on their license. Ms. Hause clarified that applications with recommendations from a physician with a restricted license were denied, while applications with recommendations from a physician with a conditioned license were held until this rulemaking hearing was completed. She noted that under the constitution an application is deemed approved after 35 days even if it has not been processed.

Board members agreed to add language to the proposed rules which would allow a physician with a condition or restricted license to recommend medical marijuana if they provide written confirmation from the Colorado Medical Board indicating that the restriction or condition does not preclude recommending medical marijuana.

MOVED by Ms. McGinnis, seconded by Ms. Sowinski, to adopt the proposed amendments to 5 CCR 1006-2, Medical Use of Marijuana –pertaining to the Regulation of physician along with the statement of basis and purpose, specific statutory authority and regulatory analysis, along with the following amendments: page one, line 9, after "license" insert "as defined in regulation 8"; page one, line 23: delete "unrestricted and unconditioned"; and page one, line 40, after "conditioned" insert "unless the physician has received written confirmation from the Colorado Medical Board that the physician's scope of practice does not preclude the recommending of medical marijuana."

MOTION CARRIED (4-1 Ms. Mulch opposed)

This meeting was adjourned at approximately 2:00 p.m.

Copies of the Minority Report and the Occupational Health Surveillance Initiatives are available by contacting Jamie.Thornton@state.co.us

ⁱ You may obtain a copy of the amendments by contacting Jamie Thornton, Program Assistant, at Jamie.thornton@state.co.us or 303-692-3464,