



Board:

Mark Elam, Chairman Richard (Rick) Toomey, DHA, FACHE
David W. Gillespie, MD, Vice-Chairman Seema Shrivastava-Patel
Charles M. Joye II, P.E., Secretary Jim Creel, Jr.

**Minutes of the October 12, 2018, meeting of the
South Carolina Board of Health and Environmental Control**

The South Carolina Board of Health and Environmental Control met on Friday, October 12, 2018, at 10:00 a.m. in the Board Room at the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1) The meeting was originally scheduled for Thursday, October 11, but was held on Friday, October 12, due to Hurricane Michael and the closing of Department offices in Richland County.

The following members were in attendance:

Mark Elam, Chairman, Member-at-large
Richard Toomey, DHA, FACHE, 1st District, Beaufort

In attendance via audio conference:

Seema Shrivastava-Patel, 2nd District, Lexington
Charles M. Joye, II, P.E., 3rd District, Anderson
Jim Creel, Jr., 7th District, Myrtle Beach

Not in attendance:

David W. Gillespie, MD, 6th District, Orangeburg

4th and 5th Congressional District seats are currently vacant.

Also, in attendance were David E. Wilson, Acting Director; W. Marshall Taylor, Legal Counsel; Lisa Lucas Longshore, Clerk; and Department staff.

Chairman Elam called the meeting to order and stated, "Notice of this meeting has been provided to all persons, organizations and news media, which have requested notification, as required by Section 30-4-80(e) of the South Carolina Code of Laws."

Item 1: Minutes of the July 12, 2018 and September 27, 2018 meetings (Attachment 1-1)

Mr. Toomey moved, seconded by Mr. Creel, to approve the minutes for the July 12 and September 27 meetings as presented. The Board voted, and Motion carried.

Item 2: Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation (Attachment 2-1)

Ms. Shelly Kelly, Deputy Director for Health Regulation, stated that for this reporting period one (1) Administrative Order and thirteen (13) Consent Orders had been issued with assessed penalties totaling \$72,450.

The Board accepted this item as information.

Item 3: Administrative Orders and Consent Orders issued by Environmental Affairs
(Attachment 3-1)

Ms. Robin Stephens, Assistant to Deputy Director of Environmental Affairs, stated that for this reporting period twenty-one (21) Administrative Orders and two hundred sixty-four (264) Consent Orders had been issued with total penalties totaling \$650,842.50.

The Board accepted this item as information.

Item 4: Placement of FDA-Approved Cannabidiol Drugs Containing No More than 0.1% Tetrahydrocannabinols in Schedule V for Controlled Substances (Attachment 4-1)

Ms. Heather Lukshis, Bureau of Drug Control, presented this item to the Board.

Ms. Lukshis announced the Summary Sheet had been amended to reflect the proper scheduling terminology and an amended copy had been provided to Clerk of Board for the official file. (Attachment 4-2)

Controlled substances are governed by the S.C. Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of Laws. Schedule I substances are listed in S.C. Code Ann. Section 44-53-190. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by DHEC. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate a substance as a controlled substance if the federal government has so designated.

Section 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

With the issuance of this final order, the Acting Administrator of the Drug Enforcement Administration places certain drug products that have been approved by the Food and Drug Administration (FDA) and which contain cannabidiol (CBD) in schedule V of the Controlled Substances Act (CSA). Specifically, this order places FDA-approved drugs that contain CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V. This action is required to satisfy the responsibility of the Acting Administrator under the CSA to place a drug in the schedule he deems most appropriate to carry out United States

obligations under the Single Convention on Narcotic Drugs, 1961. Also, consistent therewith, DEA is adding such drugs to the list of substances that may only be imported or exported pursuant to a permit. The federal final order became effective September 28, 2018 <https://www.gpo.gov/fdsys/pkg/FR-2018-09-28/pdf/2018-21121.pdf>

The United States is a party to the Single Convention on Narcotic Drugs, 1961 (Single Convention), and other international conventions designed to establish effective control over international and domestic traffic in controlled substances. The enactment and enforcement of the Controlled Substances Act (CSA) are the primary means by which the United States carries out its obligations under the Single Convention. On June 25, 2018, the Food and Drug Administration (FDA) announced that it approved a drug that is subject to control under the Single Convention. Specifically, the FDA announced that it approved the drug Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older.

Epidiolex is an oral solution that contains cannabidiol (CBD) extracted from the cannabis plant. This is the first FDA-approved drug made from the cannabis plant. Now that Epidiolex has been approved by the FDA, it has a currently accepted medical use in treatment in the United States for purposes of the CSA. Accordingly, Epidiolex no longer meet the criteria for placement in schedule I of the CSA. DEA must therefore take the appropriate scheduling action to remove the drug from schedule I. The Single Convention obligates parties to require a permit for the importation and exportation of drugs listed in Schedule I of the Convention. This permit requirement applies to a drug product containing CBD extracted from the cannabis plant because such a product is a Schedule I drug under the Single Convention. However, under the CSA and DEA regulations, the import/export permit requirement does not apply to all controlled substances. Rather, a permit is required to import or export any controlled substance in schedule I and II as well as certain controlled substances in schedules III, IV, and V. At present, the cannabis used to make Epidiolex is grown in the United Kingdom and the drug is imported into the United States in finished dosage form.

In response to a request from the DEA, the Department of Health and Human Services (HHS) advised DEA that it found the Epidiolex formulation to have a very low potential for abuse and, therefore, recommended that, if DEA concluded that control of the drug was required under the Single convention, Epidiolex should be placed in schedule V of the CSA. Until now, since the Epidiolex formulation had been a schedule I controlled substance, the importation of the drug from its foreign production facility has always been subject to the permit requirement. To ensure this requirement remains in place (and thus to prevent any lapse in compliance with the requirements of the Single Convention), this order will amend the DEA regulations to add the Epidiolex formulation to the list of nonnarcotic schedule III through V controlled substances that are subject to the import and export permit requirement.

By virtue of this order, Epidiolex (and any generic versions of the same formulation that might be approved by the FDA in the future) will be a schedule V controlled substance. Thus, all persons in the distribution chain who handle Epidiolex in the United States (importers, manufacturers, distributors, and practitioners) must comply with the requirements of the CSA and DEA regulations relating to schedule V controlled substances.

When determining whether a substance should be placed into Schedule V of the S.C. Controlled Substances Act, Section 44-53-260 of the S.C. Code of laws requires the Department place a substance in Schedule V if it meets the following criteria:

- (a) It has a low potential for abuse relative to the substances listed in Schedule IV;
- (b) It has a currently accepted medical use in treatment in the United States; and
- (c) Abuse of the substance may lead to limited physical dependence or psychological

dependence relative to the substances listed in Schedule IV.

As the Acting Administrator of the Drug Enforcement Administration has determined it necessary to most appropriately carry out United States Obligations under the Single Convention on Narcotic Drugs, 1961, by placing Epidiolex in Schedule V of the CSA, the Department recommended the Board adopt the scheduling of Epidiolex into Schedule V for Controlled Substances as set forth below and amend SC Code Section 44-53-270 to include:

Approved cannabidiol drugs. (1) A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R,3-methyl-6R-(1methylethenyl)-2-cyclohexen-1-yl]-S-pentyl-1,3- benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols

Mr. Toomey moved, seconded by Mr. Creel, to designate the additional substances named in the DEA Notice published in the Federal Register on September 28, 2018 and amend Section 44-53-270 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted, and Motion carried. Board Scheduling Order (Attachment 4-3)

Item 5: Notice of Proposed Regulation for Repealing Regulation 61-67.1, Requirements for State Water Pollution Control Revolving Fund Loan Assistance
(Attachment 5-1)

Mr. Chuck Gorman, Manager of State Revolving Fund Section, Bureau of Water, presented this item to the Board.

The Department proposed repeal of R.61-67.1. The regulation describes the process the Department of Health and Environmental Control ("Department") and the former South Carolina Budget and Control Board followed in administering the State Water Pollution Revolving Fund received in federal grants from the Environmental Protection Agency ("EPA"). In 1992, the General Assembly repealed S.C. Code Section 48-6-10 et seq. and replaced it with the South Carolina Water Quality Revolving Fund Authority Act (S.C. Code Section 48-5-10 et seq.). Passage of the South Carolina Water Quality Revolving Fund Authority Act ("Act") has rendered R.61-67.1 obsolete. The Act provides authority for the Department and the South Carolina Water Quality Revolving Fund Authority to administer the South Carolina clean water and drinking water revolving funds and federal grants received as supplements to the revolving funds from the EPA. The South Carolina Water Quality Revolving Fund Authority comprises the members of the State Fiscal Accountability Authority, with administrative and implementation support from the South Carolina Rural Infrastructure Authority ("RIA").

In accordance with the Act, the State Water Pollution Revolving Fund ("SRF") authorized under the former statute (Title 48, Chapter 6) remains in existence and is now referred to as the Clean Water State Revolving Fund ("CWSRF"). The CWSRF, like the former State Water Pollution Revolving Fund, provides low interest loans to public utilities and local governments for wastewater and stormwater infrastructure projects. The General Assembly amended Title 48, Chapter 5 in 1997 to include the Drinking Water State Revolving Fund ("DWSRF"), which provides low interest loans to public utilities and local governments for public drinking water infrastructure projects. The 1987 amendments to the Federal Water Pollution Act, otherwise known as the Clean Water Act, authorized federal funding for the CWSRF and the former State Water Pollution Revolving Fund. The 1996 amendments to the Safe Drinking Water Act authorized federal funding for the DWSRF. The CWSRF and DWSRF are revolving funds because they receive repayments and interest from the loans made from the funds. Additional money comes into the funds through interest on investments and annual federal grants

received from EPA. Repeal of the regulation will have no impact or implications for the current administration and implementation of the CWSRF or DWSRF.

The Department does not propose replacing this regulation with a new regulation. The Department and RIA can effectively administer and implement the SRF program using the state statute, Title 48, Chapter 5, and federal laws, regulations, and grant requirements that govern the use of the funds. Other existing state laws and regulations also are used to implement the program such as environmental permitting regulations that govern the design and construction of wastewater and drinking water infrastructure projects.

Mr. Joye moved, seconded by Mr. Toomey, to grant approval to publish the Notice of Proposed Regulation for Repealing Regulation 61-67.1, Requirements for State Water Pollution Control Revolving Fund Loan Assistance, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted, and Motion carried.

Item 6: Notice of Proposed Regulation Amending Regulation 61-79, Hazardous Waste Management Regulations (Attachment 6-1)

Mr. Joe Bowers, Program Manager, Bureau of Land and Waste Management, presented this item to the Board.

The Bureau proposes amending R.61-79 to adopt the Environmental Protection Agency's ("EPA") Hazardous Waste Generator Improvements Rule published November 28, 2016, at 81 FR 85732-85829. The Hazardous Waste Generator Improvements Rule reorganizes the hazardous waste generator regulations to improve their usability by the regulated community, provide a better understanding of how the Resource Conservation and Recovery Act ("RCRA") hazardous waste generator regulatory program works, address gaps in existing regulations to strengthen environmental protections, provide greater flexibility for hazardous waste generators to manage their hazardous waste in a cost-effective and protective manner, and make technical corrections to address inadvertent errors and remove obsolete references to programs that no longer exist.

The EPA periodically promulgates regulations that are either mandatory for authorized state programs to adopt or maintain program equivalency or are optional for states because the changes are less stringent than the current federal regulations. While the majority of the EPA's Hazardous Waste Generator Improvements Rule is equivalent to current state regulations and optional for state adoption, several provisions are more stringent and must be adopted by the Department to maintain federal program authorization. Due to the interrelated nature of the equivalent provisions and the more stringent provisions, the Department proposes adopting the rule in a single drafting that requires General Assembly review.

Mr. Creel moved, seconded by Ms. Shrivastava-Patel, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-79, Hazardous Waste Management Regulations, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted, and Motion carried.

Item 7: Notice of Proposed Regulation for Amending Regulation 61-79, Hazardous Waste Management Regulations (exempt from General Assembly Review) (Attachment 7-1)

Mr. Joe Bowers, Program Manager, Bureau of Land and Waste Management, presented this item to the Board.

The Department of Health and Environmental Control (Department) proposes amending R.61-79, Hazardous Waste Management Regulations, to adopt the Imports and Exports of Hazardous Waste Rule published November 28, 2016, at 81 FR 85696-85729 and published on November 28, 2016 at 81 FR 85696-85729 and on August 29, 2017 at 82 FR 41015-41016 in the Federal Register by the United States Environmental Protection Agency ("EPA"). The Imports and Exports of Hazardous Waste Rule amends existing requirements regarding the import and export of hazardous wastes from and into the United States.

The Department proposes adopting the rule to maintain compliance with federal law and provide greater protection to human health and the environment by making existing import- and export-related requirements more consistent with the current import-export requirements for shipments between members of the Organization for Economic Cooperation and Development, enabling electronic submittal to the EPA of all import- and export-related documents (e.g., export notices, export annual reports), and enabling electronic validation of consent in the Automated Export System for export shipments subject to Resource Conservation and Recovery Act ("RCRA") export consent requirements prior to exit.

Mr. Creel moved, seconded by Mr. Toomey, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-79, Hazardous Waste Management Regulations, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted, and Motion carried.

Item 8: Notice of Proposed Regulation for Amending Regulation 61-120, South Carolina Immunization Registry (Attachment 8-1)

Mr. Thomas Bowen, Policy Liaison for Public Health, presented this item to the Board.

Regulation 61-120, South Carolina Immunization Registry, is governed by S.C. Code Section 44-29-40, which grants the Department general direction and supervision of vaccination, screening, and immunization in the state. Section 44-29-40(B) charges the Department with establishing a statewide immunization registry and promulgating regulations for the implementation and operation of the registry.

The Bureau proposes amending Regulation 61-120 to enable the Department to provide specific Healthcare Effectiveness Data and Information Set ("HEDIS") data from the South Carolina Immunization Registry ("Registry") to health plans for public health purposes and to measure performance on important dimensions of care and service, including immunization data for clients. Proposed amendments are also intended to provide details regarding the availability and use of a patient portal, which will be a feature of a new Registry allowing patients to access their personal immunization records. The proposed amendments will also remove obsolete language and make general improvements and clarifications to the text.

Mr. Toomey moved, seconded by Mr. Joye, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-120, South Carolina Immunization Registry, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted, and Motion carried.

Item 9: Notice of Proposed Regulation Amending Regulation 61-25, Retail Food Establishments, and Repealing Regulation 61-37, Retail Food Establishment Inspection Fees (Attachment 9-1)

Ms. Sandra Craig, Director, Division of Food Protection and Rabies Prevention, presented this item.

The intent of R.61-25, Retail Food Establishments, is to safeguard public health and provide consumers safe, unadulterated food and food products at the retail level. This regulation governs restaurants, grocery stores, school cafeterias, and other establishments where food is prepared and served to the public. R.61-25, Retail Food Establishments, was last amended in 2014.

These amendments will allow the Department, through regulation, to meet the current standards of the 2017 United States Food and Drug Administration ("FDA") Food Code. The FDA Food Code is the national standard for state, local, and tribal food protection programs. The FDA Food Code offers practical, science-based guidance that addresses the risk factors known to cause foodborne illness outbreaks in retail food establishment settings. It is amended every two (2) years and published in full every four (4) years by the national Conference for Food Protection, comprised of food safety regulators, food scientists, industry representatives, and members of academia.

The amendments also include proposed revisions to selected sections of Chapter 9 of R.61-25 to reflect the current business models of the food service industry based on comments and suggestions from the regulated community.

The amendments include combining R.61-25 with revised provisions of R.61-37, Retail Food Establishment Inspection Fees, which was last amended in 2002. Specifically, the Bureau proposes revising fee schedules currently residing in R.61-37, placing the fee schedules in R.61-25, and combining the two regulations by repealing R.61-37. This would provide the retail food industry with one streamlined regulation while allowing for necessary program support through an increase in inspection fees.

The proposed amendments to R.61-25 also include other changes deemed necessary by the Department to improve the overall clarity, organization, and quality of the regulation. These proposed changes include, but are not limited to, stylistic changes, updates to definitions and exemptions, corrections for clarity, readability, grammar, punctuation, references, codification, and overall improvement of the text of the regulation.

A series of stakeholder meetings conducted across the state. The Bureau sent email invitations to more than 19,000 permitted retail food establishments as well as interested trade associations and individuals. Additionally, meeting information was posted on the Department's food industry website.

The Bureau incorporated verbal comments and suggestions from stakeholder meetings to date into the proposed regulatory text. Additional meetings were held with representatives of industry trade associations such as the S.C. Lodging and Restaurant Association and the other S.C. food safety agencies, the S.C. Department of Agriculture, Clemson Meat and Poultry Inspection Division, and the S.C. Department of Natural Resources. Suggestions from these additional meetings have been considered and incorporated where applicable.

Mr. Toomey moved, seconded by Ms. Shrivastava-Patel, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-25, Retail Food Establishments, and Repealing Regulation 61-37, Retail Food Establishment

Inspection Fees, in the State Register, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted, and Motion carried.

Item 10: Notice of Proposed Regulation Amending Regulation 61-56, Onsite Wastewater Systems, and repealing Regulation 61-55, Septic Tank Site Evaluation Fees, Regulation 61-56.1, License to Construct or Clean Onsite Sewage Treatment and Self-Contained Toilets, Regulation 61-56.2, Licensing of Onsite Wastewater Systems Master Contractors

Mr. Elam announced the Department had withdrawn this item from consideration at this meeting.

Item 11: Proposed Meeting Dates for 2019 (Attachment 11-1)

Thursday, January 3 (1st Thursday)
Thursday, February 7 (1st Thursday)
Thursday, March 7 (1st Thursday)
Thursday, April 11
Thursday, May 9
Thursday, June 13
Thursday, July 11
Thursday, August 8
Thursday, September 12
Thursday, October 10
Thursday, November 7 (1st Thursday)
Thursday, December 12

*Meetings are scheduled for 10:00 am in the Board Room of the S.C. Department of Health and Environmental Control. Dates, times or locations may change if necessary. Public notice will be given of any change in date, time or location. Meetings may be cancelled

Mr. Toomey moved, seconded by Mr. Creel, to approve the meeting dates for 2019. The Board voted, and the Motion carried.

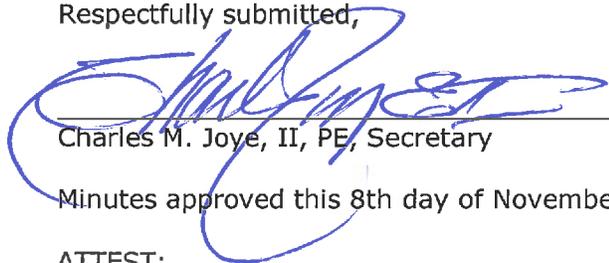
Item 12: Agency Affairs

Acting Director Wilson reported on the following: Regulation Development Annual Report and the Department Response to Hurricane Florence with a video produced by agency communications department.

Being no further business, the meeting adjourned.

All referenced attachments are made a permanent part of these minutes.

Respectfully submitted,



Charles M. Joye, II, PE, Secretary

Minutes approved this 8th day of November 2018.

ATTEST:



Mark Elam, Chairman

Attachments

- 0-1 Agenda
- 0-2 Public Attendance Record
- 1-1 July 12, 2018 and September 27, 2018 meeting minutes
- 2-1 Administrative Orders and Consent Orders issued by Health Regulation
- 3-1 Administrative Orders and Consent Orders issued by Environmental Affairs
- 4-1 Placement of FDA-Approved Cannabidiol Drugs Containing No More than 0.1% Tetrahydrocannabinols in Schedule V for Controlled Substances
- 4-2 Amended summary sheet
- 4-3 Board Scheduling Order
- 5-1 Notice of Proposed Regulation for Repealing Regulation 61-67.1, Requirements for State Water Pollution Control Revolving Fund Loan Assistance
- 6-1 Notice of Proposed Regulation Amending Regulation 61-79, Hazardous Waste Management Regulations
- 7-1 Notice of Proposed Regulation for Amending Regulation 61-79, Hazardous Waste Management Regulations (exempt from General Assembly Review)
- 8-1 Notice of Proposed Regulation for Amending Regulation 61-120, South Carolina Immunization Registry
- 9-1 Notice of Proposed Regulation Amending Regulation 61-25, Retail Food Establishments, and Repealing Regulation 61-37, Retail Food Establishment Inspection Fees
- 11-1 Proposed 2019 Meeting Dates