Minutes of the December 8, 2022, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, December 8, 2022, at 10:00 a.m. in the Boardroom (#3420) at the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance:

Robert Bolchoz, Chairman
J.B. (Sonny) Kinney, 1st District
Robert Morgan, MD, 4th District
Richard V. Lee, Jr., 5th District
Morris E. Brown, III, MD, 6th District

In attendance virtually:
Charles M. Joye, II, P.E., 3rd District
Jim P. Creel, Jr., 7th District

Not in attendance:
Seema Shrivastava-Patel, Vice-Chairwoman, 2nd District

Also, in attendance were Dr. Edward Simmer, Director; Ashley Biggers, Acting Board Counsel; M. Denise Crawford, Clerk; Department staff; and members of the public. The meeting was also available via Livestream. (Attachment 0-2)

Chairman Bolchoz called the meeting to order, and stated notice of this meeting had 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 November 10, 2022 meeting (Attachment 1-1)

Mr. Kinney moved, seconded by Mr. Lee, to approve the minutes as presented. The Board voted and Motion carried.

Item 2: Administrative Orders and Consent Orders issued by Healthcare Quality (Attachment 2-1)

Ms. Bentley White, Director of Policy and Communications, Healthcare Quality, stated that for this reporting period, two (2) Administrative Orders and three (3) Consent Orders with assessed monetary penalties totaling $11,500.00 were issued.

After discussion, ***the Board accepted this item as information.***

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

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, one hundred two (102) Consent Orders with assessed civil penalties totaling $163,350.00 and five (5) Administrative Orders with assessed civil penalties totaling $59,951.00 were issued.

After discussion, ***the Board accepted this item as information.***

Item 4: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-15, *Certification of Need for Health Facilities and Services*, Document No. 5136
(Attachment 4-1)

A Public Hearing was conducted concerning the Regulation. Mr. David Fiorini, Senior Consultant, Certificate of Need Program, Healthcare Quality, presented this item to the Board.

The Bureau of Planning and Construction ("Bureau") proposed the Notice of Final Regulation amending Regulation 61-15, *Certification of Need for Health Facilities and Services,* be filed with the Legislative Council to be forwarded to the Speaker of the House and President of Senate with a request for General Assembly review. Legal authority resides in 1976 Code Sections 44-7-110 through 44-7-340, which requires the Department of Health and Environmental Control ("Department") to establish standards to promote cost containment, prevent unnecessary duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public needs, and ensure that high quality services are provided in this state. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these amendments. The amendments will take legal effect as of the date of publication in the *State Register*.

The Bureau proposed amending Regulation 61-15 to update provisions in accordance with stakeholder input and recommendations from the Legislative Audit Council.

The Department had a Notice of Drafting published in the June 24, 2022, *State Register*. The Department received 96 public comments by July 25, 2022, the close of public comment period.

The Department held a stakeholder meeting to discuss the Notice of Drafting on July 20, 2022, with 67 participants.

Department staff conducted an internal review of the proposed amendments on August 18, 2022.

Upon receiving approval during the September 8, 2022, Board meeting, the Bureau had a Notice of Proposed Regulation published in the September 23, 2022, *State Register*. The Department received 17 public comments by October 24, 2022, the close of the public comment period.

The Department held a stakeholder meeting to discuss the Notice of Proposed Regulation on October 4, 2022, with 25 participants.

After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board in the September 8, 2022, Board meeting and published in the September 23, 2022, *State Register*.

The Bureau of Planning and Construction requested the Board to find need and reasonableness of the proposed amendments of Regulation 61-15, *Certification of Need for Health Facilities and Services*, for filing with the Legislative Council for review by the General Assembly.

Board Counsel, Ashley Biggers, opened the meeting up for public comments on this matter. One (1) member of the public spoke. (Attachment 4-2) The public comment portion of the public hearing was closed.

After discussion, **Dr. Morgan moved, seconded by Dr. Brown, that based on the public hearing and documents herein, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-15, Certificate of Need for Health Facilities and Services, Document 5136, and grant approval for submission to the General Assembly for review with the revision to section 103.1.f to increase the medical equipment threshold from two million dollars ($2,000,000) to three million dollars ($3,000,000).**

Mr. Lee made an intervening motion to amend Dr. Morgan's motion to revise section 103.1.f to increase the medical equipment threshold from two million dollars ($2,000,000) to two million, five hundred thousand dollars ($2,500,000). No one seconded the motion.

Chairman Bolchoz called for a vote on Dr. Morgan's motion. The Board voted and the motion carried by a vote of 6-1.

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 4-3)

Item 5: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-64, *X-rays (Title B)*, Document No. 5138 (Attachment 5-1)

A Public Hearing was conducted concerning the Regulation. Ms. Chrissy Chavis, Director, Division of Electronic Products, Bureau of Radiological Health, presented this item to the Board.

The Bureau of Radiological Health proposed the Notice of Final Regulation amending Regulation 61-64, *X-Rays (Title B)*. Legal authority resides in S.C. Code Section 13-7-40 et seq., which directs the Department of Health and Environmental Control ("Department") to promulgate, amend, and repeal regulations relating to the control of ionizing and nonionizing radiation, the qualifications of operators

applying ionizing or nonionizing radiation to humans, and registration of radiation sources or devices or equipment utilizing these sources. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments. The amendments will take legal effect as of the date of publication in the *State Register*.

The Bureau proposed amending Regulation 61-64 to update provision in accordance with stakeholder input and recommendations from collaborative bodies including the Conference of Radiation Control Program (CRCPD), Food and Drug Administration (FDA), National Council on Radiation Protection and Measurements (NCRP), American College of Radiology (ACR), and the American National Standards Institute (ANSI).

The Department had a Notice of Drafting published in the February 25, 2022, *State Register*. The Department received over 70 comments during the public comment period that ended March 28, 2022.

Department staff conducted regular scheduled internal reviews of the proposed amendments from February until October.

The Department held a stakeholder meeting to discuss the Notice of Drafting on March 16, 2022.

Upon receiving approval during the September 8, 2022, Board meeting, the Bureau had a Notice of Proposed Regulation published in the September 23, 2022, *State Register*. The Department received public comments from 67 comments from 17 individuals by the October 24, 2022, close of the public comment period.

The Department held a stakeholder meeting to discuss the Notice of Proposed Regulation on October 11, 2022.

After consideration of all timely received comments, staff has made substantive changes to the regulatory text of the Notice of Proposed Regulation approved by the Board during the September 8, 2022, Board meeting and published in the September 23, 2022, *State Register*.

The Bureau of Radiological Health respectfully requested the Board to find need and reasonableness of the attached proposed amendments of Regulation 61-64, *X-Rays (Title B),* for filing with the Legislative Council for review by the General Assembly.

Board Counsel, Ashley Biggers, opened the meeting up for public comments on this matter. Three (3) members of the public spoke. (Attachment 5-2) The public comment portion of the public hearing was closed.

After discussion, **Mr. Lee moved, seconded by Dr. Morgan, that based on the public hearing and documents herein, to find for the need and reasonableness of the proposed amendment of**

Regulation 61-64, *X-rays (Title B)*, Document No. 5138 and grant approval for submission to the General Assembly for review. The Board voted and the motion carried.

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 5-3)

Item 6: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-9, *Water Pollution Control Permits*, Document No. 5137 (Attachment 6-1)

A Public Hearing was conducted concerning the Regulation. Mr. Joe Koon, Director, Division of Water Monitoring Assessment and Protection, Bureau of Water, Environmental Affairs, presented this item to the Board.

The Bureau of Water (Bureau) proposed the Notice of Final Regulation amending Regulation 61-9, *Water Pollution Control Permits.* Legal authority resides in the South Carolina Pollution Control Act, S.C. Code Ann. 48-1-10 et seq., which authorizes the Department of Health and Environmental Control ("Department") to establish programs to regulate discharges from point sources, including concentrated animal feeding operations. The Administrative Procedures Act, S.C. Code Section 1-23-120, exempts these proposed amendments from General Assembly review; however, the Department is proposing to send the proposed amendments to the General Assembly for review.

Regulation 61-9.122.23, Concentrated Animal Feeding Operations (CAFOs), provides the definition of a CAFO and provides the National Discharge Pollution Elimination System (NPDES) permitting requirements for CAFOs. The Department proposes amending Regulation 61-9.122.23 for conformity with the current federal regulation in Title 40, Part 122 of the Code of Federal Regulations (40 CFR Part 122), Subpart B, Section 23, *Concentrated animal feeding operations,* and to improve regulatory clarity.

The Department had a Notice of Drafting published in the July 22, 2022, *State Register*.

Department staff conducted an internal review of the proposed amendments on August 4, 2022

Upon receiving approval during the September 8, 2022, Board meeting, the Bureau had a Notice of Proposed Regulation published in the September 23, 2022, *State Register*. The Department received public comments from a legal environmental advocacy organization on behalf of several conservation organizations by the October 24, 2022, close of the public comment period.

A stakeholder meeting was hosted by Bureau staff after publication of the Notice of Proposed Regulation, on October 17, 2022. The in-person meeting was held in the Linton Conference room in the Sims / Aycock Building. Several members of conservation organizations, Department staff, and the regulated community attended. After a brief presentation by Department staff, open discussion and questions and answers took place.

After consideration of all timely received comments, no changes are proposed to the regulatory text of the Notice of Proposed Regulation approved by the Board in the September 8, 2022, Board meeting and published in the September 23, 2022, *State Register*.

The Bureau requested the Board to find need and reasonableness of the proposed amendment of Regulation 61-9, *Water Pollution Control Permits,* for submission to the General Assembly.

Board Counsel, Ashley Biggers, opened the meeting up for public comments on this matter. One member of the public spoke. (Attachment 6-2) The public comment portion of the public hearing was closed.

After discussion, **Mr. Kinney moved, seconded by Mr. Lee, that based on the public hearing and documents herein, to find for the need and reasonableness of the proposed amendment of Regulation 61-9, *Water Pollution Control Permits*, Document No. 5137, and grant approval for submission to the General Assembly for review. The Board voted and the motion carried.**

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 6-3)

Item 7: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-62, *Air Pollution Control Regulations and Standards*, Document No. 5139 (Attachment 7-1)

A Public Hearing was conducted concerning the Regulation. Ms. Mary Peyton Wall, Section Manager, Air Regulation, Data Analysis, and SIP Management, Environmental Affairs, presented this item to the Board.

The Bureau of Air Quality (Bureau) submitted the Notice of Final Regulation amending Regulation 61-62, *Air Pollution Control Regulations and Standards,* for publication in the December 23, 2022, *South Carolina State Register* (*State Register*). Legal authority for these amendments resides in the South Carolina Pollution Control Act, S.C. Code Sections 48-1-10 *et seq*. (Pollution Control Act), which authorizes the Department of Health and Environmental Control (Department) to adopt emission control regulations, standards, and limitations, and take all actions necessary or appropriate to secure to the state the benefits of federal air pollution control laws. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department promulgates these amendments for compliance with federal air pollution control laws. The amendments will take legal effect as of the December 23, 2022, publication in the *State Register*.

Pursuant to the Pollution Control Act and the federal Clean Air Act, 42 U.S.C. Sections 7410, 7413, and 7416, the Department must ensure national primary and secondary ambient air quality standards are achieved and maintained in South Carolina. No state may adopt or enforce an emission standard or limitation less stringent than these federal standards or limitations pursuant to 42 U.S.C. Section 7416.

The United States Environmental Protection Agency (EPA) promulgates amendments to the Code of Federal Regulations (CFR) throughout each calendar year. Recent federal amendments at 40 CFR Parts 60 and 63 include revisions to New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories. The Department is amending Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*, and Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*, to incorporate by reference federal amendments promulgated from January 1, 2021, through December 31, 2021.

The Department is amending Regulation 61-62.70, *Title V Operating Permit Program*, to correct an error in an earlier amendment as required by the EPA to maintain compliance with federal law.

The Department is also making other changes to Regulation 61-62, *Air Pollution Control Regulations and Standards*, as deemed necessary to maintain compliance with federal law. These changes include corrections and other changes for internal consistency, clarification, punctuation, and overall improvement to the text of Regulation 61-62.

The Department had a Notice of Drafting published in the June 24, 2022, *State Register*.

Department staff conducted an internal review of the proposed amendments on July 12, 2022.

The Bureau published the Notice of Drafting on the Department's Regulatory Information website in the *DHEC Monthly Regulation Development Update*. The Bureau sent a copy of the Notice of Drafting to interested stakeholders via Department email list on June 27, 2022. On August 3, 2022, the Bureau contacted via email all facilities subject to Regulation 61-62.70 to inform them of the anticipated proposed amendment to the regulation.

Upon receiving approval during the September 8, 2022, Board meeting, the Bureau had a Notice of Proposed Regulation published in the September 23, 2022, *State Register*. Additionally, the Bureau sent a notice of publication of the Notice of Proposed Regulation to interested stakeholders via the Department email list on September 23, 2022. The Bureau also shared information about the Notice of Drafting and the Notice of Proposed Regulation and Public Hearing with stakeholders during the SC Chamber EAC Air Committee meeting on October 7, 2022, and the Carolinas Air Pollution Control Association (CAPCA) meeting on October 13, 2022. The Department received comments from two stakeholders during aforementioned email outreach occurring prior to the public comment period. The Department received a public comment from one other stakeholder by the October 24, 2022, close of the public comment period.

After consideration of all timely received comments, staff has made a substantive change to the regulatory text of the Notice of Proposed Regulation approved by the Board in the September 8, 2022, Board meeting and published in the September 23, 2022, *State Register*.

The Bureau of Air Quality respectfully requests the Board to find need and reasonableness of the attached amendments of Regulation 61-62, *Air Pollution Control Regulations and Standards*, for legal effect as of December 23, 2022, publication in the *State Register*.

Board Counsel, Ashley Biggers, opened the meeting up for public comments on this matter. No members of the public spoke. (Attachment 7-2) The public comment portion of the public hearing was closed.

After discussion, **Mr. Lee moved, seconded by Dr. Morgan, that based on the public hearing and documents herein, to find for the need and reasonableness of the proposed amendment of Regulation 61-62, *Air Pollution Control Regulations and Standards*, Document No. 5139, and grant approval for publication in the *State* Register. The Board voted and the motion carried.**

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 7-3)

Item 8: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-58, *State Primary Drinking Water Regulations*, Document No. 5135 (Attachment 8-1)

A Public Hearing was conducted concerning the Regulation. Mr. Richard Welch, Program Manager, Bureau of Water, , Environmental Affairs, presented this item to the Board.

The Bureau of Water proposed the Notice of Final Regulation amending Regulation 61-58, State Primary Drinking Water Regulations for publication in the December 23, 2022, South Carolina State Register ("State Register"). Legal authority resides in S.C. Code Sections 44-55-10 et seq., known as the State Safe Drinking Water Act, which directs the Department of Health and Environmental Control ("Department") to promulgate regulations governing the design, construction, operation, and maintenance of public water systems in the state. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as they are for compliance with federal law. These amendments will take legal effect as of the December 23, 2022, publication in the State Register.

Regulation 61-58 through Regulation 61-58.17 are collectively known as the State Primary Drinking Water Regulations. These regulations set design, construction, operation, maintenance, and water quality standards for public water systems in the state. The Department proposed amending Regulation 61-58 to adopt federal regulations commonly referred to as the Lead and Copper Rule Revisions, which were promulgated by the United States Environmental Protection Agency ("EPA") in a final rule published in the Federal Register on January 15, 2021 (86 FR 4198). These amendments include new and/or revised requirements for lead service line inventories, public education and outreach, and testing for lead in drinking water at schools and childcare facilities.

The Department had a Notice of Drafting published in the March 25, 2022, State Register.

On March 31, 2022, Department staff sent an email notification to all public water systems subject to these amendments outlining the requirements of the amendments and other pertinent information along with an attached copy of the Notice of Drafting.

Department staff conducted an internal review of the proposed amendments on August 17, 2022.

Upon receiving approval during the September 8, 2022 Board meeting, the Bureau had a Notice of Proposed Regulation published in the September 23, 2022, State Register. The Department received public comments from 1 person by the October 24, 2022, close of the public comment period.

The Bureau of Water requested the Board to find need and reasonableness of the proposed amendments of Regulation 61-58, State Primary Drinking Water Regulations, for legal effect as of December 23, 2022, publication in the State Register

Board Counsel, Ashley Biggers, opened the meeting up for public comments on this matter. No members of the public spoke. (Attachment 8-2) The public comment portion of the public hearing was closed.

After discussion, **Mr. Kinney moved, seconded by Mr. Joye, that based on the public hearing and documents herein, to find for the need and reasonableness of the proposed amendment of Regulation 61-58, *State Primary Drinking Water Regulations*, Document No. 5135, and grant approval for publication in the *State Register*. The Board voted and the motion carried.**

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 8-3)

Item 9: Public Hearing and Placement of Ketamine's salts, isomers, and salts of isomers; Perampanel, including its salts, isomers, and salts of isomers; and Anabolic Steroids in Schedule III for Controlled Substances in South Carolina

A Public Hearing was conducted concerning the Regulation. Mr. Ben McKever, Drug Control Upstate Agent, Bureau of Drug Control, , presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act, Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule III substances are listed in S.C. Code Section 44-53-230. South Carolina Code Section 44-53-160 provides for the manner in which changes in schedule of controlled substances are made in South Carolina. Pursuant to S.C. Code Section 44-53-160(B), the South Carolina Board of Health and Environmental Control (Board) is authorized to add, delete, or reschedule a substance as a controlled substance during the time the General Assembly is not in session after providing notice and a hearing to interested parties. The addition, deletion, or rescheduling of a substance pursuant to this subsection has the full force of law unless overturned by the General Assembly.

The Department requested the Board's approval of three substances to be added to schedule III of the South Carolina Controlled Substances Act. All three substances are schedule III controlled substances under the federal Controlled Substances Act, 21 U.S.C. 801 et seq., and are not scheduled as controlled substances under the South Carolina Controlled Substances Act.

Ketamine's Salts, Isomers, and Salts of Isomers

On July 13, 1999, the Drug Enforcement Administration (DEA) published a final rule[1] placing the substance ketamine, including its salts, isomers, and salts of isomers, into schedule III of the federal Controlled Substances Act.

On December 11, 2014, pursuant to S.C. Code Section 44-53-160(B), the Department requested, and the Board adopted[2], the scheduling of the List of Substances for Inclusion in the South Carolina Controlled Substances Act[3] (List), including the placement of ketamine into schedule III. However, the Department's request, and the Board's adoption, did not include ketamine's "salts, isomers, and salts of isomers."

Esketamine (brand name: Spravato) is the enantiomer (isomer) of ketamine, that is indicated for, in conjunction with an oral antidepressant, the treatment of treatment-resistant depression in adults. Esketamine is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risks of serious adverse outcomes from sedation, dissociation, and abuse and misuse. Even though the substance is subject to abuse and diversion, esketamine is not currently a controlled substance under the South Carolina Controlled Substances Act since it is an enantiomer (isomer) of ketamine.

Perampanel, including its Salts, Isomers, and Salts of Isomers

On December 2, 2013, the DEA published a final rule[4] placing the substance perampanel, [2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl) benzonitrile], including its salts, isomers, and salts of isomers, into schedule III of the federal Controlled Substances Act. Perampanel (brand name: Fycompa) is indicated for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older, and for the adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older.

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[1] https://www.deadiversion.usdoj.gov/fed_regs/rules/1999/fr0713.htm; https://www.govinfo.gov/content/pkg/FR-1999-07-13/pdf/99-17803.pdf.

[2] https://scdhec.gov/sites/default/files/docs/Health/docs/BoardORders/SignedBoardDesignationLettter.pdf

[3] https://scdhec.gov/sites/default/files/docs/Health/docs/BoardORders/ListOfSubstances.pdf.

[4] https://www.govinfo.gov/content/pkg/FR-2013-12-02/pdf/2013-28778.pdf.

The DEA placed perampanel into schedule III of the federal Controlled Substances Act after finding that perampanel has a potential for abuse less than the drugs or other substances in schedules I and II, perampanel has a currently accepted medical use in treatment in the United States, and abuse of perampanel may lead to moderate or low physical dependence or high psychological dependence.

Anabolic Steroids

In 1989, Act No. 115 added Article 14 to Chapter 53, Title 44, Code of Laws of South Carolina Act, thereby defining the term "anabolic steroid" in Section 44-53-1510(A).

Effective February 27, 1991, the federal Anabolic Steroids Control Act of 1990 (Title XIX of Pub. L. 101-647) first established and regulated anabolic steroids as a class of drugs under Schedule III of the federal Controlled Substances Act.

On December 11, 2014, pursuant to S.C. Code Section 44-53-160(B), the Department requested, and the Board adopted, the scheduling of the List. S.C. Code Section 44-53-1510(A), defining the term "anabolic steroid," is on the List but without a request to schedule the substance. Therefore, anabolic steroids are not a controlled substance under the South Carolina Controlled Substances Act, but anabolic steroids have been in schedule III under the federal Controlled Substances Act since 1990.

Pursuant to S.C. Code Section 44-53-160(B), the Department recommends the placement of ketamine's salts, isomers, and salts of isomers; perampanel, including its salts, isomers, and salts of isomers; and anabolic steroids in schedule III for controlled substances in South Carolina and the amendment of Section 44-53-230 of the South Carolina Code of Laws to include:

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

( ) *ketamine, including its salts, isomers, and salts of isomers*

( ) *perampanel, including its salts, isomers, and salts of isomers*

(f) Anabolic Steroids. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, esters and ethers:

(1) Anabolic steroids

The Department recommends the Board place ketamine, including its salts, isomers, and salts of isomers; perampanel, including its salts, isomers, and salts of isomers; and anabolic steroids, in schedule III of the South Carolina Controlled Substances Act.

Board Counsel, Ashley Biggers, opened the meeting up for public comments on this matter. No members of the public spoke. (Attachment 9-2) The public comment portion of the public hearing was closed.

After discussion, **Dr. Morgan moved, seconded by Mr. Lee, pursuant to Section 44-53-160 of the South Carolina Controlled Substances Act, to amend Schedule III of the South Carolina Controlled Substances for the placement of Ketamine's salts, isomers, and salts of isomers; Perampanel, including its salts, isomers, and salts of isomers; and Anabolic Steroids for consistency with the Federal scheduling. The Board voted and the motion carried.**

A verbatim transcript of these proceedings is included as part of the official record. (Attachment 9-3)

Item 10: Placement of Zipeprol in Schedule I for Controlled Substances in South Carolina

Mr. Ben McKever, Drug Control Upstate Agent, Bureau of Drug Control, , presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. 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 the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina 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, the Chairmen of the Judiciary Committee of the House of

Representatives, the Clerks of the Senate and House, and the Code Commissioner, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On November 21, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule placing zipeprol (chemical name: 1-methoxy-3-[4-(2- methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, in schedule I of the federal Controlled Substances Act ("federal CSA"). This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle zipeprol. This final rule has an effective date of December 21, 2022, *Federal Register*, Volume 87, Number 223, pages 70717-70721; *https://www.govinfo.gov/content/pkg/FR-2022-11-21/pdf/2022-25206.pdf.*

Zipeprol (chemical name: 1-methoxy3-[4-(2-methoxy-2- phenylethyl)piperazin-1-yl]-1- phenylpropan-2-ol) is pharmacologically an opioid drug with some hallucinogenic properties that has no approved medical use in the United States. In March 1995, the United Nations Commission on Narcotic Drugs, on the advice of the Director-General of the World Health Organization, placed zipeprol in Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention.

On May 20, 2013, in accordance with 21 U.S.C. 811(b), and in response to the DEA's August 3, 2009 request, the Department of Health and Human Services ("HHS") provided to DEA a scientific and medical evaluation and a scheduling recommendation for zipeprol. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data, and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I.

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA found substantial evidence of potential for abuse of zipeprol. As such, DEA permanently scheduled zipeprol as a controlled substance under the federal CSA.

The federal CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The federal CSA also outlines the findings required to place a drug or other substance in any particular schedule. After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), found that:

1) Zipeprol has a high potential for abuse. This potential is comparable to certain schedule II substances (e.g., morphine).

2) Zipeprol has no currently accepted medical use in treatment in the United States.

3) There is a lack of accepted safety for use of zipeprol under medical supervision.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing zipeprol in Schedule I in the same manner as the federal DEA. The listing includes its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. It warrants control in schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190 of the South Carolina Controlled Substances Act to include:

( ) Zipeprol (1-methoxy-3-[4- (2-methoxy-2-phenylethyl) piperazin-1-yl]-1- phenylpropan-2-ol)

After discussion, **Dr. Brown moved, seconded by Dr. Morgan, to designate Zipeprol and the additional substances named in the DEA Notice published in the Federal Register on November 21, 2022 and amend Section 44-53-190 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the motion carried.**

Item 11.Placement of Mesocarb in Schedule I for Controlled Substances in South Carolina

Mr. Ben McKever, Drug Control Upstate Agent, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. 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 the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina 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 Chairman of the Medical, Military, Public and Municipal Affairs Committee, the Chairman of the Judiciary Committee of the House of Representatives, the Clerks of the Senate and House, and the Code Commissioner, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On November 22, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule placing mesocarb (chemical name: N-phenyl-N′ -(3-(1- phenylpropan-2-yl)-1,2,3-oxadiazol-3- ium-5-yl) carbamimidate), including its salts, isomers, and salts of isomers, in schedule I of the federal Controlled Substances Act ("federal CSA"). This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle mesocarb. This final rule has an effective date of December 22, 2022, *Federal Register* 87, Number 224, pages 71247-71250; *https://www.govinfo.gov/content/pkg/FR-2022-11-22/pdf/2022-25219.pdf.*

Mesocarb (chemical name: N-phenyl-N′-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl) carbamimidate) is a central nervous system ("CNS") stimulant. At its 38th session (March 1995), the United Nations Commission on Narcotic Drugs added mesocarb to Schedule IV of the 1971 Convention, thus notifying all parties to the 1971 Convention.

On April 3, 2012, in accordance with 21 U.S.C. 811(b), and in response to the DEA's August 12, 2008 request, the Department of Health and Human Services ("HHS") provided to DEA a scientific and medical evaluation and a scheduling recommendation for mesocarb. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I.

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA found substantial evidence of potential for abuse of mesocarb. As such, DEA is permanently scheduling mesocarb as a controlled substance under the federal CSA.

The federal CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The federal CSA also outlines the findings required to place a drug or other substance in any

particular schedule. After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), found that:

1) Mesocarb has a high potential for abuse. This potential is comparable to certain schedule II substances (e.g., methamphetamine or amphetamine).

2) Mesocarb has no currently accepted medical use in treatment in the United States.

3) There is a lack of accepted safety for use of mesocarb under medical supervision.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing Mesocarb in Schedule I in the same manner as the federal DEA. The listing includes its salts, isomers, and salts of isomers in schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190 of the South Carolina Controlled Substances Act to include:

( ) Mesocarb (N-phenyl-N '-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl) carbamimidate)

After discussion, **Mr. Lee moved, seconded by Mr. Kinney, to designate Mesocarb and the additional substances named in the DEA Notice published in the Federal Register on November 22, 2022 and amend Section 44-53-190 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the motion carried.**

Item 12. Placement of Amineptine in Schedule I for Controlled Substances in South Carolina

Mr. Ben McKever, Drug Control Upstate Agent, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. 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 the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina 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 Chairman of the Medical, Military, Public and Municipal Affairs Committee, the Chairman of the Judiciary Committee of the House of Representatives, the Clerks of the Senate and House, and the Code Commissioner, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On November 17, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule placing amineptine (chemical name: 7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl) amino] heptanoic acid), including its salts, isomers, and salts of isomers, in schedule I of the federal Controlled Substances Act ("federal CSA"). This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle amineptine. This final rule was published on November 17, 2022, with an effective date of December 19, 2022, *Federal Register* 87, no. 221, pages 68895-68898; *https://www.govinfo.gov/content/pkg/FR-2022-11-17/pdf/2022-25003.pdf.*

Amineptine (chemical name: 7- [(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5- yl)amino]heptanoic acid) is a synthetic tricyclic antidepressant with central nervous system ("CNS") stimulating properties. In April 2003, the United Nations Commission on Narcotic Drugs ("CND"), on the advice of the Director-General of the World Health Organization ("WHO"), added amineptine to Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention.

On November 8, 2011, in accordance with 21 U.S.C. 811(b), and in response to the DEA's August 12, 2008 request, the Department of Health and Human Services ("HHS") provided to DEA a scientific and medical evaluation and a scheduling recommendation for amineptine. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I.

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA found substantial

evidence of potential for abuse of amineptine. As such, DEA is permanently scheduling amineptine as a controlled substance under the federal CSA.

The federal CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The federal CSA also outlines the findings required to place a drug or other substance in any particular schedule. After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1) Amineptine has a high potential for abuse. This potential is comparable to certain schedule II substances (e.g., amphetamine or cocaine).

2) Amineptine has no currently accepted medical use in treatment in the United States.

3) There is a lack of accepted safety for use of amineptine under medical supervision.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing amineptine in Schedule I in the same manner as the federal DEA. The listing includes its salts, isomers, and salts of isomers to schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190 of the South Carolina Controlled Substances Act to include:

( ) Amineptine (7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid)

After discussion, **Dr. Brown moved, seconded by Mr. Lee, to designate Amineptine and the additional substances named in the DEA Notice published in the Federal Register on November 17, 2022 and amend Section 44-53-190 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the motion carried.**

Item 13. Agency Affairs

Dr. Edward Simmer, Director, updated the Board on:

- SC Food Access Map
- Food insecurity in South Carolina
- COVID 19
- RSV
- Flu

Dr. Simmer presented Employee Appreciation Coins to Sandra Craig and Anthony Doyle.

Being no further business, Chairman Bolchoz adjourned the meeting.

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

Respectfully submitted,

Charles M. Joye, II, P.E., 3rd District, Secretary

Minutes approved this 5th day of January 2023.

ATTEST:

Robert Bolchoz, Chairman

Attachments

0-1 Agenda
0-2 Sign in Sheet
1-1 Minutes of November 10, 2022 meeting
2-1 Administrative Orders and Consent Orders issued by Healthcare Quality
3-1 Administrative Orders and Consent Orders issued by Environmental Affairs
4-1 Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-15, *Certification of Need for Health Facilities and Services*, Document No. 5136
4-2 Public Hearing Sign in Sheet
4-3 Transcript of Public Hearing
5-1 Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-64, *X-rays (Title B)*, Document No. 5138
5-2 Public Hearing Sign in Sheet
5-3 Transcript of Public Hearing
6-1 Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-9, *Water Pollution Control Permits*, Document No. 5137
6-2 Public Hearing Sign in Sheet
6-3 Transcript of Public Hearing
7-1 Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-62, *Air Pollution Control Regulations and Standards*, Document No. 5139
7-2 Public Hearing Sign in Sheet
7-3 Transcript of Public Hearing
8-1 Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-58, *State Primary Drinking Water Regulations*, Document No. 5135
8-2 Public Hearing Sign in Sheet
8-3 Transcript of Public Hearing
9-1 Public Hearing and Placement of Ketamine's salts, isomers, and salts of isomers; Perampanel, including its salts, isomers, and salts of isomers; and Anabolic Steroids in Schedule III for Controlled Substances in South Carolina
9-2 Public Hearing Sign in Sheet
9-3 Transcript of Public Hearing
10-1 Placement of Zipeprol in Schedule I for Controlled Substances in South Carolina
10-2 Board Order for Zipeprol
11-1 Placement of Mesocarb in Schedule I for Controlled Substances in South Carolina
11-2 Board Order for Mesocarb
12-1 Placement of Amineptine in Schedule I for Controlled Substances in South Carolina
12-2 Board Order for Amineptine