

**INDEPENDENT REGULATORY REVIEW COMMISSION
PUBLIC MEETING MINUTES**

10:00 A.M.

Thursday, May 16, 2019
14th Floor Conference Room
333 Market Street

I. CALL OF THE MEETING

The May 16, 2019 public meeting of the Independent Regulatory Review Commission (Commission) was called to order by Chairman Bedwick at 10:03 a.m. in the 14th Floor Conference Room, 333 Market Street, Harrisburg, PA.

Commissioners Present: George D. Bedwick, Chairman
 W. Russell Faber
 Murray Ufberg, Esq.

Telephone: John F. Mizner, Esq., Vice Chairman
 Dennis A. Watson, Esq.

II. APPROVAL OF THE APRIL 18, 2019 PUBLIC MEETING MINUTES

Chairman Bedwick asked for a motion for approval of the April 18, 2019 public meeting minutes, as submitted. Commissioner Faber made the motion and Commissioner Ufberg seconded, and the motion passed 5-0.

III. NEW BUSINESS

Chairman Bedwick said that at the March 21, 2019 public meeting, while voting on regulation No. 3164 Pennsylvania Gaming Control Board #125-204: Four Card Prime and Cajun Stud; Table Game Rules of Play, he asked the Pennsylvania Gaming Control Board to submit a letter explaining by what authority they temporarily authorized these games to be played, before the regulation was published as final. Chairman Bedwick said that the Commission received a letter of explanation from the Pennsylvania Gaming Control Board (Attachment A) and wanted it included in the minutes.

A. ACTION ITEMS

1. No. 3232 Department of Labor and Industry #12-108: Uniform Construction Code

Michelle Elliott, Regulatory Analyst, explained that the regulation updates the Uniform Construction Code by adopting Chapter 11 and Appendix E of the International Building Code of 2018, and adopts the accessibility provisions found in the International Plumbing Code of 2018, the International Existing Building Code of 2018 and the International Swimming Pool

and Spa Code. She further explained that the regulation implements the latest standards for ski lifts published by the American National Standards Institute. According to Ms. Elliott, the Commission received one comment from the Pennsylvania State Association of Township Supervisors, which stated that the organization has no concerns on the regulation. She also reported the standing committees of the General Assembly have deemed the regulation approved.

Robert Schramm, Deputy Chief Counsel, Safety & Labor-Management Relations, and Matthew Kegg, Director, Bureau of Occupational and Industrial Safety, Department of Labor & Industry (L&I), were present to answer any questions.

Mr. Schramm provided an overview of the regulation. He said that this regulatory package will adopt the most current accessibility provisions of the International Code Council codes as well as the latest standards for ski lifts and tramways. He pointed out the regulations will become effective upon publication in the *Pennsylvania Bulletin*.

Chairman Bedwick complimented L&I for meeting with industry on the regulations when they could have taken a position of not talking with anyone.

Chairman Bedwick made a motion for approval. Commissioner Faber seconded, and the motion passed 5-0.

2. No. 3163 State Board of Pharmacy #16A-5419: Compounding

Ms. Elliott told the Commissioners the regulation amends existing regulations relating to definitions and the practice of pharmacy and delegation of duties, and adds regulations relating to compounding. The objectives of the regulation are: to incorporate developments and improvements in the profession's safe, sterile practices and procedures for the compounding of pharmaceutical products for patients; to allow pharmacy technicians to assist the pharmacist in the compounding of pharmaceutical products; and to aid enforcement by adopting the federal standards for the compounding of pharmaceutical products. Ms. Elliott added that the State Board of Pharmacy (Board) currently does not have regulations governing compounding practices and developments. The Commission did not receive any comments on the final regulation and the standing committees of the General Assembly have deemed the regulation approved.

Cynthia Montgomery, Deputy Chief Counsel, Department of State, and Kerry Maloney, Board Counsel, were present to answer any questions.

Mr. Maloney said the rulemaking on compounding was "a collaborative effort from federal regulators and the experts in compounding in hospitals and compounding pharmacies." He said that they came to several meetings of the Board to discuss with the Board members the issues surrounding the regulation of compounding. Mr. Maloney explained the Board now has standards that require pharmacies to follow the federal standards, which compounding pharmacies have generally been doing already in Pennsylvania. He commented that with this regulation in place, the compounding pharmacies will not have much change in their operations.

Commissioner Ufberg wanted to know how long the process was for developing this regulation. According to Mr. Maloney, this draft started in 2015. Commissioner Ufberg then asked why it took so long. Mr. Maloney said he knew there was back and forth, and even today the United States Pharmacopeia (USP) has a new chapter that is about to go into effect. He also said there was an attempt and many discussions about getting a balance between providing some “meat” to regulations in the way of explanation and context, but not running afoul of the federal standards that are still changing today. Commissioner Ufberg wanted to know how the Board knew the pharmacies engaged in compounding were complying with federal standards and if the Board ran into any issues over the past several years where that wasn’t the case. According to Mr. Maloney, the Board had not run into issues with that in the past several years. He said it was through the Board’s discussions with the Pennsylvania Society of Health-System Pharmacists that they learned of their efforts to remain in compliance with USP and the new versions of it.

Commissioner Watson commented that he shared Commissioner Ufberg’s concern regarding the length of time it took to develop the regulations. He noted the information provided by the Board indicated this issue came to the forefront in October 2012, when the cause of a meningitis outbreak was identified as contaminated medication made by a commercial compounding pharmacy located in Massachusetts. Commissioner Watson asked if the Board could have acted with more alacrity in enacting these regulations rather than exposing the citizens of Pennsylvania to a similar health issue that was experienced in Massachusetts. Mr. Maloney stated he understood there were discussions among the Board and stakeholders since 2012 and in a number of states that were the genesis of moving compounding regulations. He explained that while these regulations were not in place, there were still inspections going on.

Commissioner Ufberg asked if the Commissioners can count on a commitment from the Department of State to ensure any modifications are acted upon with more alacrity than in the past. Mr. Maloney answered in the affirmative and added that the regulation under consideration allows for sufficient flexibility for changes in both the federal law and regulations and the USP.

Martin Farrell, a pharmacist for Rapid Equine Solutions, expressed some concern about language found in the pharmacy inspection form questions for sterile and non-sterile compounding. He said the questions on the form reference low-, middle-, and high-risk compounding. According to Mr. Farrell, this terminology on the form will be replaced with Category 1 and Category 2 in the near future. He wanted to know how this change in terminology will be affected when the regulation goes into effect and the national regulation changes.

Chairman Bedwick asked Leslie Lewis Johnson, Chief Counsel, if it is correct that the inspection form discussed by Mr. Farrell is not part of the regulation itself. Ms. Johnson responded, “That is correct.” Chairman Bedwick asked if the Board could make a change in the form without coming back to the Commission. Ms. Johnson said, “Yes.”

Chairman Bedwick made a motion for approval. Commissioner Ufberg seconded, and the motion passed 5-0.

IV. OTHER BUSINESS

Approval of Vouchers

Commissioner Faber made motions to approve vouchers and expenses for the period March 22, 2019 through April 18, 2019. Commissioner Ufberg seconded, and the motions passed 5-0.

V. DATE AND PLACE OF SUBSEQUENT MEETING

Chairman Bedwick announced the next public meeting is scheduled for Thursday, June 20, 2019, at 10:00 a.m. in the 14th Floor Conference Room, 333 Market Street, Harrisburg.

VI. EXECUTIVE SESSION ANNOUNCEMENTS

Chairman Bedwick announced that no executive session would be held.

VII. ADJOURNMENT

Chairman Bedwick announced the meeting adjourned at 10:31 a.m.

#3164



PENNSYLVANIA GAMING CONTROL BOARD
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C. DANIEL HASSFEL
RUSSELL C. REDDING
JOSEPH M. TORSSELLA

April 29, 2019

Chairman George D. Bedwick
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

RE: Table game rules approval procedures

Dear Chairman Bedwick:

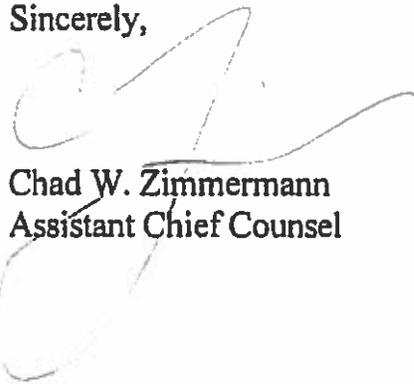
I was present at the March 21, 2019 Public Meeting of the Independent Regulatory Review Commission ("IRRC") on behalf of the Pennsylvania Gaming Control Board ("PGCB" or "Board"). After my presentation of Final Form Rulemaking #125-204, you asked me a procedural question regarding the table games rules of play for casino games in the Commonwealth. Specifically, you inquired as to whether the Board allows casinos to offer table games while the regulations adopted by the Board are in Proposed Rulemaking status, prior to being adopted as a Final Form Rulemaking.

Pursuant to the Pennsylvania Race Horse Development and Gaming Act of 2004 ("the Act"), the Board is granted authority to promulgate temporary regulations governing the rules of new table games that are not subject to the Commonwealth Documents Law, the Regulatory Review Act and the Commonwealth Attorneys Act. See 4 Pa.C.S. § 13A03 (a)(1)(2)(3). Regulations promulgated as temporary regulations expire two years after the date of publication in the Pennsylvania Bulletin. See 4 Pa.C.S. § 13A03(a).

Prior to the expiration of the temporary regulations relating to new table games, the Board begins the process of promulgating the same regulations through the traditional regulatory review process and subject to the Commonwealth Documents Law, the Regulatory Review Act and the Commonwealth Attorneys Act. To that end, because the temporary regulation is already in place allowing a gaming entity to offer table games, the entity is permitted to continue offering that game authorized by the applicable regulation during the formal promulgation of that regulation.¹

I trust this response answers the question you asked. If you have any further questions or concerns regarding this matter, please do not hesitate to contact me further.

Sincerely,



Chad W. Zimmermann
Assistant Chief Counsel

¹ By way of background, table games manufacturers (the owner of the rights to various table games) seeking approval for a new table game by submitting the game including rules and statistical analysis to the Board's Office of the Gaming Laboratory which reviews the game, reviews the statistical analysis of the game and compares it to the submitted rules of play to determine if the game is appropriate to be offered in the Commonwealth. After Gaming Laboratory review and verification, the table game will be subject to submission for Board approval and ultimately posting of the rules of the game and offering by a casino.