INDEPENDENT REGULATORY REVIEW COMMISSION

ORDER

Commissioners Voting:

George D. Bedwick, Chairman
John F. Mizner, Esq., Vice Chairman
John J. Soroko, Esq.
Murray Ufberg, Esq.
Dennis A. Watson, Esq.

Public Meeting Held September 11, 2024

28 Pa. Code Chapter 5
Department of Health
Clinical Laboratories

The House Health Committee (Committee) submitted a letter to the Independent Regulatory Review Commission (Commission) requesting review under Section 8.1 of the Regulatory Review Act (RRA) (71 P.S. §745.8a) of existing regulations of the Pennsylvania Department of Health (Department) in 28 Pa. Code (relating to Health and Safety). These regulations include:

- **Chapter 5 *Clinical Laboratories***;
- Chapter 30 *Blood Banks*;
- Chapter 51 *General Information*;
- Chapter 53 *Photo Identification Badges*;
- Part IV, Subpart B *General and Special Hospitals*, encompassing Chapters 101 to 158; and
- Part IV, Subpart F *Ambulatory Surgical Facilities*, encompassing Chapters 551 to 573.

This Order addresses Chapter 5 (*Clinical Laboratories),* which includes requirements for permits, personnel, physical facilities, procedures, records, quality control, ethical practice, and equipment to determine blood alcohol content. Chapter 5 was last amended in 1984.

Based upon this Commission's review of this regulation, the enabling statute and subsequent amendments, information provided by the Department, and concerns raised by the Committee, we find the regulation is no longer in the public interest under the RRA criteria of legislative intent, clarity, consistency with statutes, and comments by the Committee. *See* 71 P.S. § 745.5b. We recommend the Department amend Chapter 5 to address, at a minimum, the following issues:

1. Since Chapter 5 is based on and defines the Clinical Laboratory Improvement Amendments of 1967, it should be updated to reflect the Clinical Laboratory Improvement Amendments of 1988 or any subsequent legislation.

2. Section 5.1 (relating to definitions) defines "Clinical Laboratories Improvement Act of 1967 (CLIA)—Section 353 of the act of July 1, 1944, Pub. L. No. 90-174 (42 U.S.C.A. § 263), and the regulations which apply thereto." The current standard is the CLIA of 1988 (not 1967). The citation to 42 U.S.C.A. § 263 should be 42 U.S.C.A. § 263a. Additionally, since this definition is used within Chapter 5 at Sections 5.41(c)(3) and 5.83, these provisions commensurately set an outdated standard.

3. The definition of "Clinical Laboratory" in Section 5.1 lacks clarity and is outdated, as written. The list of exceptions in Subparagraph (ii) has not been amended since 1984. It does not include any innovations since this definition was implemented.

4. Section 5.2. (relating to scope and exception), states "[T]his chapter is applicable to all clinical laboratories operating within this Commonwealth...." Whereas, amendments to the statute made by Act 122 of 2013, Section 3 apply "...regardless of whether the person or clinical laboratory is located in this Commonwealth...." Therefore, the scope Section 5.2 sets for Chapter 5 is not consistent with Act 122.

5. Subsection 5.11(b) includes the statutory $25 permit fee established by Act 389 of 1951 (35 P.S. § 2154). However, Act 389 of 1951 was repealed insofar as it establishes a fee that is inconsistent with the fees set forth in Act 48 of 1981. Regardless, the $25 fee in Subsection 5.11(b) is outdated.

6. Section 5.71 (relating to restrictions on solicitation) is outdated because it does not reflect the statutory amendments made by Section 3 of Act 122 which expanded upon unlawful conduct.

George D. Bedwick, Chairman

INDEPENDENT REGULATORY REVIEW COMMISSION

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Public Meeting Held September 11, 2024

28 Pa. Code Chapter 30
Department of Health
Blood Banks

The House Health Committee (Committee) submitted a letter to the Independent Regulatory Review Commission (Commission) requesting review under Section 8.1 of the Regulatory Review Act (RRA) (71 P.S. §745.8a) of existing regulations of the Pennsylvania Department of Health (Department) in 28 Pa. Code (relating to Health and Safety). These regulations include:

- Chapter 5 *Clinical Laboratories*;
- **Chapter 30 *Blood Banks*;**
- Chapter 51 *General Information*;
- Chapter 53 *Photo Identification Badges*;
- Part IV, Subpart B *General and Special Hospitals*, encompassing Chapters 101 to 158; and
- Part IV, Subpart F *Ambulatory Surgical Facilities*, encompassing Chapters 551 to 573.

This Order addresses Chapter 30 which, as written, applies to all blood banks operating in Pennsylvania (except blood banks operated by the Federal government, or to any blood bank operated purely for research and teaching purposes, provided blood or blood products from such research or teaching are not injected into humans). The content of Chapter 30 includes requirements for licensing, fees, inspections, physical facilities, records, and compliance with federal law.

Based upon this Commission's review of this regulation, the enabling statute and subsequent amendments, information provided by the Department, and concerns raised by the Committee, we find the regulation is no longer in the public interest under the RRA criteria of clarity, consistency with statutes, and comments by the Committee. *See* 71 P.S. § 745.5b. We recommend the Department amend Chapter 30 to address, at a minimum, the following issues:

1. Subparagraph 30.30(7)(i) states: "...The possible presence of the agent or viral hepatitis in donors cannot at present be detected with certainty by any available means...." [Emphasis added.] The Hepatitis Screening Act (35 P.S. §§ 630.11 - 630.16), effective September 19, 2016, addresses testing and screening for Hepatitis C. The Hepatitis B Prevention Act (35 P.S. §§ 630.1 – 630.3), effective March 29 of 1996, requires a statewide program for Hepatitis B immunization relating to school aged children. The Centers for Disease Control and Infection website currently includes discussion of tests for Hepatitis (https://www.cdc.gov/hepatitis/abc/index.htm). Subsection 30.30 (7)(i) needs to be updated accordingly.

2. Subparagraph 30.30(7)(ii) refers to the former United States Department of Health, Education, and Welfare. The regulation should be updated to the current name of the agency, which is the United States Department of Health and Human Services.

3. Subsection 30.32(c) refers to The Clinical Laboratory Act of 1951. 35 P.S. § 2151 specifies a short title of "The Clinical Laboratory Act." The amended law is The Clinical Laboratory Act of 1988. The regulation should be updated accordingly.

George D. Bedwick, Chairman

INDEPENDENT REGULATORY REVIEW COMMISSION

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Public Meeting Held September 11, 2024

28 Pa. Code Chapter 51
Department of Health
General Information

The House Health Committee (Committee) submitted a letter to the Independent Regulatory Review Commission (Commission) requesting review under Section 8.1 of the Regulatory Review Act (RRA) (71 P.S. §745.8a) of existing regulations of the Pennsylvania Department of Health (Department) in 28 Pa. Code (relating to Health and Safety). These regulations include:

- Chapter 5 *Clinical Laboratories*;
- Chapter 30 *Blood Banks*;
- **Chapter 51 *General Information*;**
- Chapter 53 *Photo Identification Badges*;
- Part IV, Subpart B *General and Special Hospitals*, encompassing Chapters 101 to 158; and
- Part IV, Subpart F *Ambulatory Surgical Facilities*, encompassing Chapters 551 to 573.

This Order addresses Chapter 51 which contains standards which are applicable to all entities licensed as health care facilities under the Health Care Facilities Act (HCFA). It also identifies specific health care services which are restricted to specified health care facilities.

In response to the Commission's request for information, the Department explained that pursuant to Act 95 of 1998, hospices are operating under the HCFA and under Federal law and regulations. The Department further explained that while Act 13 of 2002 abrogated 28 Pa. Code § 51.3(f) and (g) for a "medical facility," Subsections (f) and (g) are still applicable to home healthcare agencies, hospices, and long-term care nursing facilities due to the broader definition in Section 802a of the HFCA. Thus, the reporting requirements in Subsections (f) and (g) are still applicable to home health care agencies, home care agencies, hospices, and long-term care nursing facilities. Finally, the Department acknowledged that Act 87 of 2022 abrogated 28 Pa. Code §§ 51.22 and 551.21 in part, to allow cardiac catheterization to be performed in outpatient settings as opposed to only in an acute care hospital.

Based upon this Commission's review of this regulation, the enabling statute and subsequent amendments, information provided by the Department, and concerns raised by the Committee, we find the regulation is no longer in the public interest under the RRA criteria of legislative intent, clarity, consistency with statutes, and comments by the Committee. *See* 71 P.S. § 745.5b. We recommend the Department amend Chapter 51 to address, at a minimum, the following issues:

1. Act 95 of 1998 amended the HCFA to include hospice services. Act 95 provided that hospice and hospice services established therein, including application fees and licensure requirements, should be directly in regulation. Accordingly, the regulation should be amended to include these services.

2. Act 13 of 2002 abrogated Subsections 51.3(f) and (g) (relating to notification) "with respect to a medical facility upon the reporting of a serious event, incident or infrastructure failure pursuant to section 313." The regulation should specify the facilities Subsections (f) and (g) continue to apply to.

3. Act 87 of 2022 abrogated Section 51.22. (relating to cardiac catheterization) and Section 551.21 (relating to criteria for ambulatory surgery) insofar as they are inconsistent with Section 822 of the HCFA. The regulation should be amended to reflect the Department's specific interpretation of Act 87.

George D. Bedwick, Chairman

INDEPENDENT REGULATORY REVIEW COMMISSION

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Public Meeting Held September 11, 2024

28 Pa. Code Chapter 53
Department of Health
Photo Identification Badges

The House Health Committee (Committee) submitted a letter to the Independent Regulatory Review Commission (Commission) requesting review under Section 8.1 of the Regulatory Review Act (RRA) (71 P.S. § 745.8a) of existing regulations of the Pennsylvania Department of Health (Department) in 28 Pa. Code (relating to Health and Safety). These regulations include:

- Chapter 5 *Clinical Laboratories*;
- Chapter 30 *Blood Banks*;
- Chapter 51 *General Information*;
- **Chapter 53 *Photo Identification Badges*;**
- Part IV, Subpart B *General and Special Hospitals*, encompassing Chapters 101 to 158; and
- Part IV, Subpart F *Ambulatory Surgical Facilities*, encompassing Chapters 551 to 573.

This Order addresses Chapter 53 which contains photo identification badge standards that apply to all entities licensed as health care facilities and the private practice of a physician. Chapter 53 was adopted as an interim regulation pursuant to Section 809.2(b) of Act 110 of 2010 (Act 110), which amended the Health Care Facilities Act (HCFA). 35 P.S. § 448.80-9b. The interim regulation was effective December 10, 2011, and expired 18 months following the effective date.

The Department explains that the requirements for photo identification badges are set forth by statute in Section 809.2 of the HCFA. However, it acknowledges that interim Chapter 53 has expired. The Department also explains that Act 79 of 2022 (Act 79), effective July 11, 2022, provides the Department with two years to implement the statutory amendments to Section 809.2(a)(1) and (e). To date, the Department has not met the timeframe specified by Act 79.

Based upon this Commission's review of this regulation, the enabling statute, information provided by the Department, and concerns raised by the Committee, we find the regulation is no longer in

the public interest under the RRA criteria of statutory authority, legislative intent, need, reasonableness, and comments by the Committee. *See* 71 P.S. § 745.5. To avoid any possibility of confusion, we recommend the Department amend or repeal Chapter 53 to comply with Act 110 and Act 79.

George D. Bedwick, Chairman

INDEPENDENT REGULATORY REVIEW COMMISSION

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Public Meeting Held September 11, 2024

28 Pa. Code Part IV, Subpart B, Chapters 101 to 158
Department of Health
General and Special Hospitals

The House Health Committee (Committee) submitted a letter to the Independent Regulatory Review Commission (Commission) requesting review under Section 8.1 of the Regulatory Review Act (RRA) (71 P.S. § 745.8a) of existing regulations of the Pennsylvania Department of Health (Department) in 28 Pa. Code (relating to Health and Safety). These regulations include:

- Chapter 5 *Clinical Laboratories*;
- Chapter 30 *Blood Banks*;
- Chapter 51 *General Information*;
- Chapter 53 *Photo Identification Badges*;
- **Part IV, Subpart B *General and Special Hospitals*, encompassing Chapters 101 to 158;** and
- Part IV, Subpart F *Ambulatory Surgical Facilities*, encompassing Chapters 551 to 573.

This Order addresses Chapters 101 to 158 of Part IV, Subpart B "which applies to all general and special hospitals within this Commonwealth except those hospitals operated by the United States. Chapters 101 through 158 include 32 chapters that address a broad range of topics, including governance and management, admission and discharge, medical staff, as well as nursing services, pharmacy services, emergency services, surgical services, neonatal services, and many other services. The majority of the chapters, 26 of them, were last amended in the 1980s, three were amended in the 1990s, and a single chapter was amended in 2008.

Based upon this Commission's review of this regulation, the enabling statute, information provided by the Department, and concerns raised by the Committee, we find the regulation is no longer in the public interest under the RRA criteria of statutory authority, legislative intent, economic impact, need, reasonableness, clarity, and comments by the Committee. *See* 71 P.S. § 745.5. We

recommend the Department amend the regulation to address, at a minimum, the following outdated provisions:

1. Section 101.4 (relating to Definitions) defines the terms "May" and "Must." These definitions are not needed because Section 6.7 of the *Pennsylvania Code and Bulletin Style Manual* already specifies how they are to be used and their meaning. Further, the regulation's definition of "must" as synonymous with "shall" is inconsistent with the *Pennsylvania Code and Bulletin Style Manual.*

2. In section 101.4 (relating to Definitions), the term "Sexual assault" is defined by reference to 18 Pa.C.S. Chapter 31, Subchapter B (relating to definition of offenses) and includes two exceptions. The definition should be updated to exclude additional offenses from the definition of "sexual assault" for purposes of the regulation. For example, §3131 (relating to unlawful dissemination of intimate image) and §3133 (relating to sexual extortion) should also be considered for exclusion.

3. Section 101.63 refers to both the current Department of Environmental Protection and "DER." This provision should be updated.

4. Section 101.151 refers to the Department of Public Welfare. This provision should be updated to the Department of Human Services.

5. Under Section 101.181, all of the fees but one fee referred to in 35 P. S. § 448.807 were established by Act 179 of 1992. The "Home care agency or home care registry" fee was established by Act 69 of 2006. The Department should approach the legislature for changes to these statutory fees to better reflect inflation and the Department's costs.

6. Subparagraph 107.12(14)(iii) refers to "the Medical Practice Act of 1974 (63 P. S. §§ 421.1—421.18) (Repealed)." This provision needs to be updated.

7. The statement of policy in Section 107.12a Specified professional personnel regarding the status of Certified Registered Nurse Practitioners, Physician Assistants, and Certified Nurse Midwife should be updated and directly integrated into the regulation.

8. Section 109.7 refers to the State Board of Nurse Examiners. This is currently the State Board of Nursing.

9. Section 115.15 cross references 7 Pa. Code by stating "...regulations of the Department of Environmental Resources, set forth in 7 Pa. Code § § 78.21—78.24, 78.31 and 78.32 (Reserved)....." However, 7 Pa. Code Chapter 78 has been deleted.

10. Section 111.25 references 7 Pa. Code § § 78.41—78.43 (Reserved), which has been deleted.

11. Section 111.26 references 7 Pa. Code § § 78.61—78.65 (Reserved), which has been deleted.

12. Section 113.30 requires that if the administration suspects mishandling of drugs, it shall contact the Bureau of Drugs of the Office of Attorney General. This should be updated, presumably to the Attorney General "Bureau of Narcotics Investigation and Drug Control."

13. Section 115.24, relating to microfilm medical records, should be updated to recognize and address newer technologies.

14. Section 125.14 states the remains of a deceased patient shall not be removed...until a physician...has pronounced death...." This provision should be updated to recognize other professions that can pronounce a death, including Certified Registered Nurse Practitioners and Professional Nurses. (Act 68 of 2012 and 35 P.S. § 450.507.)

15. In Paragraph 137.21(b)(8), the reference to 35 P.S. § 621 should be rewritten to include that the referenced law was enacted in 1965 and has since been amended in 1992 (P.L. 398, No. 86).

16. In Subsection 137.24(e), the reference to 35 P.S. §§ 351-353 should be rewritten to reflect that this law was updated in 1943 by P.L. 650, No. 286.

17. The cross reference in Section 147.1 to "Department of Environmental Protection in 25 Pa. Code Chapter 173 (Reserved)" should be updated.

18. Subsection 155.8(e) refers to the "Mental Health Procedures Act of 1976 (50 P.S. §§ 7101—7503)." Since the entire Act is referenced, it is not clear what "Bill of Rights" must be used to comply with Subsection 155.8(e).

George D. Bedwick, Chairman

INDEPENDENT REGULATORY REVIEW COMMISSION

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Public Meeting Held September 11, 2024

28 Pa. Code Part IV, Subpart F, Chapters 551 to 573
Department of Health
Ambulatory Surgical Facilities

The House Health Committee (Committee) submitted a letter to the Independent Regulatory Review Commission (Commission) requesting review under Section 8.1 of the Regulatory Review Act (RRA) (71 P.S. § 745.8a) of existing regulations of the Pennsylvania Department of Health (Department) in 28 Pa. Code (relating to Health and Safety). These regulations include:

- Chapter 5 *Clinical Laboratories*;
- Chapter 30 *Blood Banks*;
- Chapter 51 *General Information*;
- Chapter 53 *Photo Identification Badges*;
- Part IV, Subpart B *General and Special Hospitals*, encompassing Chapters 101 to 158; and
- **Part IV, Subpart F *Ambulatory Surgical Facilities*, encompassing Chapters 551 to 573.**

This Order addresses Chapters 551 to 573 of Part IV, Subpart F which applies to outpatient surgical hospitals. It includes 11 chapters covering topics that include ownership, medical staff, quality assurance, nursing services, and medical records. Subpart F was established in 1987. The 11 chapters were last amended in 1999.

Based upon this Commission's review of this regulation, the enabling statute, information provided by the Department, and concerns raised by the Committee, we find the regulation is no longer in the public interest under the RRA criteria of statutory authority, legislative intent, economic impact, need, reasonableness, clarity, and comments by the Committee. *See* 71 P.S. § 745.5. We recommend the Department amend the regulation to address, at a minimum, the following outdated provisions:

1. The definition of "Act" in Section 551.3 is outdated. The current HCFA is 35 P.S. § § 448.101 to 448.904b.

2. The definition of "Dentist" in Section 551.3 is outdated. At 49 Pa. Code § 33.1, the State Board of Dentistry defines "Act" as "The Dental Law (63 P. S. § § 120—130i)..."

3. The definition of Nurse practitioner in Section 551.3 is inconsistent with The Professional Nurse Law (63 P.S. § 212) and the State Board of Nursing (49 Pa. Code § 21.251), which both define the term "Certified registered nurse practitioner."

4. Section 551.21 in the Pa. Code includes a note that "Under section 2 of the act of July 11, 2022 (P.L. 1575, No. 87), the provisions of § 551.21 are abrogated insofar as they are inconsistent with section 822 of the HCFA (35 P.S. § 448.822))." Consequently, both Sections 551.21 and 551.22 should be updated to reflect the Department's specific interpretation of Act 87.

5. In Paragraph 553.12(b)(9), the citation to the Health Care Services Malpractice Act (40 P. S. § 1301.103) needs to be updated. The provision cited was repealed by Act 13 of 2002.

6. In Section 561.15, the cross reference to 49 Pa. Code § 27.16(b)(4) needs to be corrected to 27.16(b)(3).

7. Section 561.26 requires, upon suspicion of mishandling drugs, that the administration contact the Bureau of Drugs of the Office of Attorney General. This should be updated, presumably to the Attorney General "Bureau of Narcotics Investigation and Drug Control."

8. Section 563.7, relating to microfilm medical records, should be updated to recognize and address newer technologies.

9. Subsections 567.33(c) and 567.51(a)should be updated to refer to the Department of Environmental Protection.

George D. Bedwick, Chairman