RULES AND REGULATIONS

Title 7—AGRICULTURE

DEPARTMENT OF AGRICULTURE

[7 PA. CODE CH. 137b]

Corrective Amendment to 7 Pa. Code § 137b.24

The Department of Agriculture (Department) has discovered a discrepancy between the agency text of 7 Pa. Code § 137b.24 (relating to ineligible land) as deposited with the Legislative Reference Bureau and the official text as published at 31 Pa.B. 1701 (March 31, 2001), as currently appearing in the *Pennsylvania Code*. A reference to "ineligible land" was incorrectly published as "eligible land."

Therefore, under 45 Pa.C.S. § 901: the Department has deposited with the Legislative Reference Bureau a corrective amendment to 7 Pa. Code § 137b.24. The corrective amendment to 7 Pa. Code § 137b.24 is effective as of March 31, 2001, the effective date of adoption of this section.

The correct version of 7 Pa. Code § 137b.24 appears in Annex A.

Annex A

TITLE 7. AGRICULTURE

PART V-C. FARMLAND AND FOREST LAND

CHAPTER 137b. PREFERENTIAL ASSESSMENT OF FARMLAND AND FOREST LAND UNDER THE CLEAN AND GREEN ACT

ELIGIBLE LAND

§ 137b.24. Ineligible land.

A landowner seeking preferential assessment under the act shall include ineligible land on the application if the ineligible land is part of a larger contiguous tract of eligible land, and the use of the land which causes it to be ineligible exists at the time the application is filed. Although this ineligible land may not receive preferential assessment, the applicant shall specify the boundaries and acreage of the ineligible land, and may not expand the boundaries beyond those identified in the initial application. A landowner will not be required, as a condition of county acceptance or approval of the application, to survey or redeed the tract so as to exclude the ineligible land.

Example: A landowner owns a 100-acre tract of land, 90 acres of which is productive farmland and 10 acres of which is occupied by an auto salvage yard. If the landowner seeks preferential assessment of the 90 acres of farmland, the application shall describe the entire 100-acre tract. If preferential assessment is granted, it will apply to the 90 acres of farmland. The 10-acre tract would continue to be assigned its fair market value and assessed accordingly.

[Pa.B. Doc. No. 15-1534. Filed for public inspection August 21, 2015, 9:00 a.m.]

Title 25—ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CHS. 77, 86—90 AND 211]

Land Reclamation Financial Guarantees and Bioenergy Crop Bonding

The Environmental Quality Board (Board) adds §§ 86.162b and 86.162c (relating to Land Reclamation Financial Guarantees; and Bioenergy Crop Bonding). Sections 86.162b and 86.162c implement the act of July 5, 2012 (P. L. 918, No. 95) (Act 95) and the act of October 24, 2012 (P. L. 1276, No. 157) (Act 157). The Board also amends Chapters 77, 86—90 and 211 to correct citations to the Surface Mining Conservation and Reclamation Act (SMCRA) (52 P. S. §§ 1396.1—1396.19b) to account for the addition of section 19.2 of the SMCRA (52 P. S. § 1396.19b), which was added by Act 157, and to correct other citation errors.

This final-form rulemaking was adopted by the Board at its meeting of April 21, 2015.

A. *Effective Date*

This final-form rulemaking will go into effect upon publication in the *Pennsylvania Bulletin*.

B. *Contact Persons*

For further information, contact Thomas Callaghan, PG, Director, Bureau of Mining Programs, Rachel Carson State Office Building, 5th Floor, 400 Market Street, P. O. Box 8461, Harrisburg, PA 17105-8461, (717) 787-5015; or Joseph Iole, Assistant Counsel, Bureau of Regulatory Counsel, P. O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the Pennsylvania AT&T Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This final-form rulemaking is available on the Department of Environmental Protection's (Department) web site at www.dep.state.pa.us (select "Public Participation Center," then "The Environmental Quality Board").

C. *Statutory Authority*

This final-form rulemaking is authorized under the authority of section 5 of The Clean Streams Law (35 P. S. § 691.5); sections 4(a) and 4.2 of the SMCRA (52 P. S. §§ 1396.4(a) and 1396.4b); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

D. *Background and Purpose*

Act 95 allows for reclamation bond coverage for no cost to operators who remine and then reclaim the area with biofuel crops. The final-form rulemaking provides the framework for implementing this biofuels incentive. Act 95 added section 4.14 of the SMCRA (52 P. S. § 1396.4n).

Act 157 specifically requires that the Board promulgate regulations to implement the Land Reclamation Financial Guarantee (LRFG) program. Accordingly, this final-form rulemaking provides the framework for bonding assistance underwritten by existing Commonwealth funds and premiums paid by surface mine operators.

This final-form rulemaking establishes eligibility requirements, program limits and operational standards.

Act 157

Prior to 2001, the Department operated an alternate bonding system (ABS) for surface coal mining sites. Under the ABS, flat-rate per-acre bonds were supplemented by a nonrefundable per-acre "reclamation fee." Based upon shortfalls in funding under this program, the Department terminated the ABS and converted all surface coal mine sites to full-cost bonds. Mine sites bonded under the ABS with post-mining pollutional discharges where the permittee has failed to meet its regulatory obligations constitute a legacy of the ABS for which the Department has the responsibility to operate and maintain treatment systems.

Section 213 of the act of June 22, 2001 (P. L. 979, No. 6A) (Act 6A), known as the General Appropriation Act of 2001, provided $7 million "[f]or the conservation purpose of providing sum-certain financial guarantees needed to facilitate the implementation of full-cost bonding, for a fee, and in the event of forfeiture, to finance reclamation of the forfeited surface mining site in an amount not to exceed the sum-certain guarantee." This appropriation resulted in the creation of the Conversion Assistance program.

The Department implemented Conversion Assistance under the authority of section 4(d.2) of the SMCRA, which allows for "alternative financial assurance mechanisms which shall achieve the objectives and purposes of the bonding program." Participants in the program executed an agreement through which they agreed to pay an annual premium of 1.5% of the value of the financial guarantee. During the conversion, the Department underwrote about $63 million of bond liability for Conversion Assistance. Currently, Conversion Assistance covers about $19 million in bond liability.

From the inception of the program through Fiscal Year 2013-2014, the Department collected about $6.3 million in premium payments, while about $300,000 was spent for reclamation of a forfeited site. Act 157 authorized a one-time transfer of $500,000 from this account to the remining financial assurance account to support the Remining Financial Guarantee (RFG) program. This transfer was executed in 2013. Therefore, more than $13 million is available to support the LRFG program as it is structured in Act 157.

Act 157 requires the Board to promulgate regulations to implement the LRFG program. Act 157 includes a requirement for the LRFG program fee amount to be established by regulation. It takes the funds from the Conversion Assistance and transfers them to the LRFG program and converts existing Conversion Assistance to LRFGs.

Act 157 also describes factors for eligibility for LRFGs including:

(1) The environmental and safety hazards of the site for which a guarantee is proposed.

(2) The availability of coal reserves at the site.

(3) The operator's long-term financial stability.

(4) The operator's prior denial of coverage, if any, by surety bond companies.

(5) The operator's length of time in business and compliance history.

(6) Any other factor the Department considers indicative of an operator's ability to complete reclamation and pay required premiums under the program.

Act 157 requires the Department to determine the total amount of LRFGs that can be supported by the LRFG account based on loss reserves established by the application of the historical rate of mine operator bond forfeitures, plus a reasonable margin of safety to protect the account from the risk of forfeiture. Act 157 also requires the Board to establish, by regulation, underwriting methods adequate to insure the account against the risk of forfeiture of the guarantees.

Act 157 allows the Department to transfer interest earned on the funds in the LRFG account into the Reclamation Fee O&M Trust Account established under §§ 86.17 and 86.187 (relating to permit and reclamation fees; and use of money) to supplement the funding of the Reclamation Fee O&M Trust Account, which is used to pay for the operation and maintenance of treatment systems for the ABS Legacy Sites. It also provides that premiums collected and deposited in the LRFG account may be transferred into the Reclamation Fee O&M Trust Account consistent with the requirement to assure the financial stability of the LRFG program.

Act 157 states "[t]he land reclamation financial guarantee program established by this section may be discontinued immediately upon publication of notice in the *Pennsylvania Bulletin* if twenty-five per cent or greater of the outstanding bond obligation for the land reclamation financial guarantees program is subject to forfeiture."

Act 157 includes a provision for the annual appropriation of up to $2 million collected from the gross receipts tax by the General Assembly to the Department for transfer into the Reclamation Fee O&M Trust Account established under § 86.17. Act 157 includes the following regarding the funding of this account:

> Beginning in fiscal year 2013-2014, up to two million dollars ($2,000,000) collected from the gross receipts tax on sales of electric energy in Pennsylvania authorized by Article XI of the act of March 4, 1971 (P. L. 6, No. 2), known as the "Tax Reform Code of 1971," may be appropriated annually by the General Assembly to the department for transfer to the Reclamation Fee O&M Trust Account established pursuant to 25 Pa. Code §§ 86.17 and 86.187 to be used to supplement the funding of the Reclamation Fee O&M Trust Account.

Finally, Act 157 states "[t]he Land Reclamation Financial Guarantee Account shall be the sole source of funds underwriting the land reclamation financial guarantees program and the Commonwealth shall not be obligated to expend any funds beyond the amount in the Land Reclamation Financial Guarantee Account."

Act 157 revised the SMCRA by appending section 19.2 to the end of the act. As a result, all of the regulatory references to the SMCRA need to be updated to include the current citation. The final-form rulemaking includes about 20 updates to this reference in Chapters 77, 86—90 and 211.

The LRFG program shares many concepts with the RFG program. The experience gained from implementing the RFG program since 1996 has been useful in establishing the requirements of the LRFG program. The regulations implement the requirements of Act 157.

Bioenergy Crop Bonding

Bond release for surface coal mines is achieved in three stages. Sites are eligible for Stage 2 bond release after the area has been regraded and planted, with permanent vegetation established. The remaining bond is held for at least 5 years after the date planting of the vegetation was accomplished for the reclaimed area. This 5-year period is the Stage 3 reclamation liability period.

Act 95 requires the Department to encourage and promote the use of switchgrass, camelina, canola and other bioenergy crops for the revegetation of lands affected by surface mining activities, and the land so used shall be considered to be cropland for post-mining land use purposes.

Act 95 requires that the funds for the Bioenergy Crop Bonding program be provided, to the extent funds are available from the appropriation to the Department under section 213 of Act 6A, or to the extent funds are otherwise appropriated. Act 95 also requires the Department to make sum-certain guarantees to cover Stage 3 reclamation liability available at no cost to the surface mine permittee. To qualify, a remining site must be revegetated with switchgrass, camelina, canola or other bioenergy crops. Act 95 also provides that, in the event of forfeiture, the designated funds be used to finance reclamation of the forfeited surface mining site in an amount not to exceed the sum-certain guarantee.

The regulations implement the requirements of Act 95.

Mining and Reclamation Advisory Board collaboration

The Department consulted with the Mining and Reclamation Advisory Board (MRAB) through a series of meetings with the MRAB's Regulation, Technical and Legislative Committee to develop this final-form rulemaking. The Department presented the draft proposed rulemaking to the MRAB at its October 24, 2013, meeting. The MRAB recommended that the proposed rulemaking proceed with one recommendation. The MRAB recommended that language be added to the regulation regarding the appropriation of money from the Gross Receipts Tax as described in section 19.2(b)(7) of the SMCRA.

The MRAB recommended that the following language be included in the rulemaking:

> No later than the date of the Department's annual budget request to the Governor's Budget Office, the Department shall report to the MRAB as to when a transfer from the Gross Receipts Tax to the Reclamation Fee O&M Trust Account is necessary to supplement the funding of the Reclamation Fee O&M Trust Account in order to offset an increase in the reclamation fee in the subsequent fiscal year.

As has been the practice since the Board established the adjustable per-acre reclamation fee in 2008, and as required under § 86.17(e), the Department will continue to provide information to the MRAB about the status of the on-going operation and maintenance of treatment facilities at the ABS Legacy Sites and the funding status of the Reclamation Fee O&M Trust Account. The proposed rulemaking included a revision to § 86.17(e)(2) that explicitly addressed the MRAB recommendation. In the course of fulfilling the existing obligation under this section, the Department provides the information by the time that the Department's budget request is provided to the Governor's Budget Office.

The management of the water treatment obligations associated with the legacy of the ABS requires a long-term, stable funding source. The existing funding sources have been able to provide enough money to eliminate the need for the per-acre reclamation fee for the most recent years. Current projections suggest that this trend will not continue since it was primarily the result of an initial balance in the Reclamation Fee O&M Trust Account that has been exhausted. Also, operational costs have increased, and it is expected that they will continue to do so. In addition, the treatment facilities must be operated and maintained well into the future. The adjustable reclamation fee was established to provide an on-going source of funding for these costs. However, it is necessary to have multiple funding options to assure that the treatment costs will be covered as long as treatment is needed.

The initial evaluation of the ABS discharges in 2008 indicated that the annual operation and maintenance costs would exceed $1.3 million. Additional annual costs, for occasionally rebuilding treatment systems, were estimated at about $229,000 per year. The revenue from the dedicated funding sources for the Reclamation Fee O&M Trust Account for Fiscal Year 2013-2014 totaled about $326,800. The annual Gross Receipts Tax appropriation will close this gap.

The final-form rulemaking was reviewed with the MRAB at its January 22, 2015, meeting. The MRAB recommended that the Department pursue the finalization of this final-form rulemaking.

E. *Summary of Changes to the Proposed Rulemaking*

Section 86.17(e)(2) has been revised to delete ". . . the need to offset an increase in the reclamation fee and. . . ." In addition, to assure that the Department provides the MRAB with the necessary information under their recommendation, ". . . including an estimate of the reclamation fee for the calendar year immediately following the current fiscal year" has been added. This retains the requirement to provide information to, and collaborate with, the MRAB but eliminates the impression that the reclamation fee should remain at $0.

Section 86.162b(f)(3) has been revised to more closely track the statutory language by adding "reasonable" to modify the margin of safety and add that the purpose of the margin of safety is to protect the account for the risk of forfeiture.

Section 86.162b(k)(3) has been revised to clarify the way in which an applicant can demonstrate eligibility for LRFGs. The following statement has been added: "[a]n operator will be eligible under this subsection if it has not been cited through a notice of violation under § 86.165(a) (relating to failure to maintain proper bond) within the previous 3 years prior to the request for a land reclamation financial guarantee." In addition, the reference to reclamation obligations incurred under the RFG program has been deleted because there is no straight forward way to provide this demonstration.

Section 86.162b(m)(2) has been revised to specify that a written payment schedule will be provided.

Section 86.165 (relating to failure to maintain proper bond) has been revised to add failing to make payments for LRFG as another circumstance under which this section is applicable. This revision is responsive to the comment from IRRC about the eligibility requirements for LRFGs.

F. *Summary of Comments and Responses on the Proposed Rulemaking*

Two commentators indicated that the swift passage and implementation of these regulations are important to industry and urged the Board to move forward with these regulations as quickly as the law and the regulatory process permits.

A commentator asked the Board to consider revising § 86.162b(o) to allow the Department the discretion, on a case-by-case basis, to release the operator's bond prior to release of the LRFG as it is permitted to do for RFG bonds. This option would be limited exclusively to sites that are reclaimed, grass has been planted and risk of forfeiture is negligible.

This comment is based upon a mistaken premise. Section 86.283(e) (relating to procedures) requires that an RFG bond "will be reduced or released prior to any other bond submitted by the operator to cover the reclamation obligations of that permit." The purpose of the requirement that the financial guarantees be released prior to other bonds is to limit the liability to the financial guarantees programs and to make the funds available to provide bond coverage for other mine sites. However, the Department has another program, the Land Maintenance Financial Guarantee Program, which provides for bond coverage for the scenario where the site is reclaimed, grass has been planted and the Stage 2 liability has been released. Therefore, it is not appropriate or necessary to make the suggested revision to this section.

A commentator pointed out that there is not a legal requirement or "need" to offset any increase in the $0 reclamation fee, which would have the practical effect of eliminating the reclamation fee as a source of revenue to the Reclamation Fee O&M Trust Account.

During the development of the proposed rulemaking, the MRAB expressed interest in assuring that any increases to the reclamation fee be minimized. The proposed wording overemphasized this intention to minimize the reclamation fee. Therefore, final-form § 86.17(e)(2) has been revised to delete ". . . the need to offset an increase in the reclamation fee and. . . ." In addition, to assure that the Department provides the MRAB with the necessary information under their recommendation, ". . . including an estimate of the reclamation fee for the calendar year immediately following the current fiscal year" has been added.

A commentator asserted that the proposed amendment would subvert the intention that the Reclamation Fee O&M Trust Account be funded through the adjustable reclamation fee by implementing a premise that is not in Act 157, namely that the public coffers should always be tapped in preference to charging coal mine operators a reclamation fee.

One of the intentions of Act 157 is to provide a variety of funding sources for the Reclamation Fee O&M Trust Account. This includes interest earned on the funds in the LRFG Account, and premiums paid for LRFGs. The process for the adjustable reclamation fee is required under § 86.187 and will be in place until the funding for the ABS Legacy is actuarially sound. Section 86.187(a)(1)(iii) states that the "Department may deposit other moneys into the Reclamation Fee O&M Trust Account, including appropriations, donations, or, the fees collected for sum-certain financial guarantees needed to facilitate full-cost bonding in accordance with applicable law." The Reclamation Fee O&M Trust account is intended to have a variety of funding streams, one of which is from the reclamation fee. The reclamation fee is unique in that it serves as an enforceable regulatory mechanism that provides long-term revenue and is adjustable to account for variations in costs and availability of other revenue streams.

The Independent Regulatory Review Commission (IRRC) provided a comment regarding the language added at the request of the MRAB in § 86.17(e)(2). IRRC stated that the added language could have the practical effect of eliminating the reclamation fee as a source of revenue and asked the Board to review the added language, consider amendments and provide further explanation.

The regulations require that the adjustable reclamation fee be in place until the funding for ABS Legacy is actuarially sound. Whether revenue is needed from the reclamation fee or not will be based on a number of factors, primarily whether money is available from the other sources of revenue contributing to the account. If the General Assembly appropriates all of the money authorized under section 19.2(b)(7) of the SMCRA each year, that may have the practical effect of eliminating the reclamation fee, regardless of the language in § 86.17(e)(2). The language has been revised to remove the impression that the goal is that the adjustable reclamation fee is being eliminated.

IRRC also commented regarding the language added at the request of the MRAB in § 86.17(e)(2) stating ". . . the need to offset an increase in the reclamation fee. . . ." IRRC suggested rather than using "increase," phrasing the regulation as an "adjustment" or similar language was more suitable to the Board's intent.

Section 86.17(e)(2) has been revised to delete the reference to the increase of the reclamation fee. Instead, a requirement to provide an estimate of the reclamation fee for the subsequent calendar year has been added. This provides for the information that the MRAB requested and eliminates the impression that the reclamation fee can only be increased.

IRRC recommended that § 86.162b(f)(3) be revised to include the statutory language.

This section has been revised to incorporate the statutory language.

IRRC also commented that § 86.162b(k)(3) is not clear with respect to what a coal mine operator must demonstrate.

This section has been revised to include the description that the demonstration may be done through documentation that the operator has not been subject to any notices of violation under § 86.165 for failing to maintain a proper bond based on late payments. This revision necessitated an accompanying revision to § 86.165.

IRRC suggested that § 86.162b(m)(2) be revised to specify that the payment schedule be in writing.

This suggested revision has been included in the final-form rulemaking.

G. *Benefits, Costs and Compliance*

Benefits

The primary benefit of the programs established through this final-form rulemaking is that no-cost bond coverage for the bioenergy crop bonding and low-cost bond coverage for the LRFG program will be provided to surface coal mine operators. Bonding costs have a substantial impact on a mine operator's financial status because these costs reduce available credit and capital for

on-going operations. Another benefit of this final-form rulemaking is that it provides a discretionary funding source for the legacy of the ABS through the optional transfer of interest and premiums for the LRFG program. This final-form rulemaking also promotes and provides an incentive for the utilization of bioenergy crops for mine reclamation.

Compliance costs

Participation in the LRFG program or the Bioenergy Crop Bonding Program is optional for coal mine operators. Therefore, the compliance costs are minimal. In fact, it is likely that the programs will reduce costs for coal mine operators by providing for the low-cost or no-cost bond alternatives.

Compliance Assistance Plan

Compliance assistance for this final-form rulemaking will be provided through the routine interaction with trade groups and individual applicants. There are about 500 licensed coal surface mine operators in this Commonwealth who are subject to this final-form rulemaking. It is not anticipated that the final-form rulemaking will increase costs. Most of the operators subject to this final-form rulemaking are small businesses.

Paperwork requirements

Since participation in the LRFG program or the Bioenergy Crop Bonding Program is optional for coal mine operators, coal mine operators have a choice if the additional requirements outweigh the benefits. The additional paperwork requirements associated with this final-form rulemaking with which the industry would need to comply include somewhat increased documentation to be submitted with the permit application for both programs.

H. *Pollution Prevention*

The Pollution Prevention Act of 1990 (42 U.S.C.A. §§ 13101—13109) established a National policy that promotes pollution prevention as the preferred means for achieving state environmental protection goals. The Department encourages pollution prevention, which is the reduction or elimination of pollution at its source, through the substitution of environmentally friendly materials, more efficient use of raw materials and the incorporation of energy efficiency strategies. Pollution prevention practices can provide greater environmental protection with greater efficiency because they can result in significant cost savings to facilities that permanently achieve or move beyond compliance.

I. *Sunset Review*

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they are intended.

J. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on October 7, 2014, the Department submitted a copy of the notice of proposed rulemaking, published at 44 Pa.B. 6781 (October 25, 2014), to IRRC and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the House and Senate Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on July 8, 2015, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on July 9, 2015, and approved the final-form rulemaking.

K. *Findings*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law, and all comments were considered.

(3) These regulations do not enlarge the purpose of the proposed rulemaking published at 44 Pa.B. 6781.

(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

L. *Order*

The Board, acting under the authorizing statutes, orders that:

(1) The regulations of the Department, 25 Pa. Code Chapters 77, 86—90 and 211, are amended by:

Adding § 86.162b and amending §§ 86.17 and 86.165 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

Adding § 86.162c and amending §§ 77.1, 77.126, 77.254, 86.1, 86.6, 86.12, 86.121, 86.155, 86.159, 86.182, 86.185, 86.187, 86.232, 86.252, 86.358, 87.1, 87.205, 88.482, 88.505, 89.5, 90.305 and 211.121 to read as set forth at 44 Pa.B. 6781.

(*Editor's Note*: Section 86.165 was not included in the proposed rulemaking published at 44 Pa.B. 6781.)

(2) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form as required by law.

(3) The Chairperson of the Board shall submit this order and Annex A to IRRC and the Senate and House Committees as required by the Regulatory Review Act.

(4) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.

(5) This order shall take effect immediately.

JOHN QUIGLEY,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 45 Pa.B. 4123 (July 25, 2015).)

Fiscal Note: Fiscal Note 7-489 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart C. PROTECTION OF NATURAL RESOURCES

ARTICLE I. LAND RESOURCES

CHAPTER 86. SURFACE AND UNDERGROUND COAL MINING: GENERAL

Subchapter B. PERMITS

GENERAL REQUIREMENTS FOR PERMITS AND PERMIT APPLICATIONS

§ 86.17. Permit and reclamation fees.

* * * * *

(e) In addition to the bond established under §§ 86.143, 86.145, 86.149 and 86.150 and subject to the exception provided for in § 86.283(c) (relating to procedures), the applicant for a permit or a permit amendment shall pay a per acre reclamation fee for surface mining activities except for the surface effects of underground mining. This reclamation fee will be assessed for each acre of the approved operational area and shall be paid by the applicant prior to the Department's issuance of a surface mining permit. If a permit amendment results in an increase in the approved operational area, the reclamation fee will be assessed on the increased acreage and shall be paid by the operator prior to the Department's issuance of the permit amendment.

(1) The reclamation fee will be deposited into a separate subaccount within the Surface Mining Conservation and Reclamation Fund called the Reclamation Fee O&M Trust Account, as a supplement to bonds forfeited from ABS Legacy Sites. The reclamation fee will be used by the Department to pay the construction costs and operation and maintenance costs associated with treating postmining pollutional discharges at ABS Legacy Sites, and the moneys may not be used for any other purpose. The interest earned on the moneys in the Reclamation Fee O&M Trust Account will be deposited into the Reclamation Fee O&M Trust Account and will be used by the Department to pay the construction costs and operation and maintenance costs associated with treating postmining pollutional discharges at ABS Legacy Sites. The interest may not be used for any other purpose. For purposes of this section, operation and maintenance costs include recapitalization costs.

(2) After the end of each fiscal year, the Department will prepare a fiscal-year report containing a financial analysis of the revenue and expenditures of the Reclamation Fee O&M Trust Account for the past fiscal year and the projected revenues and expenditures for the current fiscal year. The report will include the Department's calculation of the required amount of the reclamation fee, the proposed adjustment of the reclamation fee amount and information necessary for determining the need to supplement the funding of the Reclamation Fee O&M Trust Account, including an estimate of the reclamation fee for the calendar year immediately following the current fiscal year. The need to supplement the funding of the Reclamation Fee O&M Trust Account will be based on the need to provide for long-term operations at ABS Legacy Sites. The fiscal-year report will be submitted to the members of the Mining and Reclamation Advisory Board for their review and comment and will be published on the Department's web site. Notice of the report's availability will be published in the *Pennsylvania Bulletin*. The Department will review the fiscal-year report at a meeting of the Mining and Reclamation Advisory Board.

* * * * *

Subchapter F. BONDING AND INSURANCE REQUIREMENTS

FORM, TERMS AND CONDITIONS OF BONDS AND INSURANCE

§ 86.162b. Land Reclamation Financial Guarantees.

(a) The Department will designate funds in the Land Reclamation Financial Guarantee Account to underwrite Land Reclamation Financial Guarantees.

(b) The funds in the Land Reclamation Financial Guarantee Account will be used to cover obligations for all existing sum-certain financial guarantees needed to facilitate the implementation of full-cost bonding previously issued by the Department.

(c) The Department may issue Land Reclamation Financial Guarantees to financially assure the bonding obligations of qualified surface coal mining operators engaged in surface mining activities under § 86.143 (relating to requirement to file a bond).

(d) The Department will hold in reserve in the Land Reclamation Financial Guarantee Account funds that are not designated to underwrite Land Reclamation Financial Guarantees.

(e) The Department will use funds held in reserve in the Land Reclamation Financial Guarantee Account to:

(1) Assure the availability of funds to cover reclamation liabilities when there is a mine operator bond forfeiture under § 86.181 (relating to general).

(2) Underwrite sum-certain financial guarantees available under Bioenergy Crop Bonding implemented by § 86.162c (relating to Bioenergy Crop Bonding).

(3) Transfer funds available in the Land Reclamation Financial Guarantee Account to the Reclamation Fee O&M Trust Account.

(f) In administering the Land Reclamation Financial Guarantee Account, the Department will not issue:

(1) Land Reclamation Financial Guarantees for a permit in excess of 50% of the required bond amount for that permit, which is the Permit Limit.

(2) Additional Land Reclamation Financial Guarantees to a surface mining operator in excess of the Operator Limit, which is exceeded if the aggregate amount of Land Reclamation Financial Guarantees on permits issued to the operator exceeds 30% of the designated amount in the Land Reclamation Financial Guarantee Account.

(3) Additional Land Reclamation Financial Guarantees in excess of the Program Limit, which is exceeded when the aggregate amount of outstanding Land Reclamation Financial Guarantees is greater than the current designated amount in the Land Reclamation Financial Guarantee Account divided by the historical rate of mine operator bond forfeiture under § 86.181, plus a reasonable margin of safety to protect the account from risk of forfeiture as determined by the Department.

(g) Any existing sum-certain financial guarantee needed to facilitate the implementation of full-cost bonding previously issued by the Department shall be converted into a Land Reclamation Financial Guarantee subject to the following:

(1) If the conversion results in a Land Reclamation Financial Guarantee exceeding the Permit Limit established in subsection (f)(1), the Land Reclamation Financial Guarantee amount does not need to be reduced, but the permit will not be eligible for additional Land Reclamation Financial Guarantees until the total amount of the Land Reclamation Financial Guarantees for the permit is under the Permit Limit.

(2) If the conversion results in a Land Reclamation Financial Guarantee for an operator exceeding the Operator Limit established in subsection (f)(2), the Land Reclamation Financial Guarantee does not need to be reduced, but the operator will not be eligible for additional Land Reclamation Financial Guarantees until the total amount of the Land Reclamation Financial Guarantees for the operator is under the Operator Limit.

(h) The Department will periodically, but no less frequently than every 5 years, or upon request by the Mining and Reclamation Advisory Board, prepare a report containing a financial analysis of the revenue and expenditures for the Land Reclamation Financial Guarantee Account.

(1) The report will evaluate the Permit Limit, the Operator Limit, the Program Limit and the annual payment percentage rate referenced in subsection (m)(1) for Land Reclamation Financial Guarantees.

(2) The report will be submitted to the members of the Mining and Reclamation Advisory Board for their review and advice.

(3) The report will be published on the Department's web site.

(4) Notice of availability of the report will be published in the *Pennsylvania Bulletin*.

(5) The Department will review the report at a public meeting of the Mining and Reclamation Advisory Board.

(6) If the Department's review of the report at a public meeting of the Mining and Reclamation Advisory Board results in a change to the Permit Limit, the Operator Limit, the Program Limit or the annual payment percentage rate, the Department will publish a notice of the changes in the *Pennsylvania Bulletin*.

(7) Changes to the Permit Limit, the Operator Limit, the Program Limit or the annual payment percentage rate will become effective upon publication in the *Pennsylvania Bulletin*.

(i) The Department may transfer interest earned and payments collected and deposited in the Land Reclamation Financial Guarantee Account into the Reclamation Fee O&M Trust Account established under §§ 86.17 and 86.187 (relating to permit and reclamation fees; and use of money) to supplement the funding of the Reclamation Fee O&M Trust Account consistent with section 19.2(b)(5) and (6) of the Surface Mining Conservation and Reclamation Act (52 P. S. § 1396.19b(b)(5) and (6)).

(j) The Department will provide information about any proposed transfer to the Reclamation Fee O&M Trust Account to the Mining and Reclamation Advisory Board and solicit advice from Mining and Reclamation Advisory Board before making the transfer.

(k) To be eligible for a Land Reclamation Financial Guarantee, a surface coal mining operator shall demonstrate the following:

(1) The mine operator holds a valid coal mining license issued under section 3.1 of the Surface Mining Conservation and Reclamation Act (52 P. S. § 1396.3a).

(2) The mine operator, a related party, a person who owns or controls the operator, or a person who is owned or controlled by the operator satisfies the requirements of § 86.37(a)(8)—(11) and (16) (relating to criteria for permit approval or denial).

(3) For a mine operator that has previously obtained a remining financial guarantee under section 4.12 of the Surface Mining Conservation and Reclamation Act (52 P. S. § 1396.4l) or a Land Reclamation Financial Guarantee that has made timely payments for the remining financial guarantee program or for Land Reclamation Financial Guarantees. An operator will be eligible under this subsection if it has not been cited through a notice of violation under § 86.165(a) (relating to failure to maintain proper bond) within the previous 3 years prior to the request for a land reclamation financial guarantee.

(4) For operators that have not previously obtained a remining financial guarantee under section 4.12 of the Surface Mining Conservation and Reclamation Act or a Land Reclamation Financial Guarantee, the operator shall demonstrate appropriate experience in surface coal mining and reclamation by showing that it has had a coal mining license under section 3.1 of the Surface Mining Conservation and Reclamation Act for at least 5 years and that the operator would be able to obtain a surety bond otherwise required under this chapter by submitting either of the following:

(i) A surety bond for a portion of the remaining reclamation liability for the proposed site.

(ii) A letter of acceptance from a surety company licensed to do business in this Commonwealth and which writes bonds for the reclamation of mine sites located in this Commonwealth. The acceptance letter must indicate the complete name and address of the surety company and state that the surety company would write the bond.

(l) An application for a Land Reclamation Financial Guarantee must include a description of:

(1) The environmental and safety hazards of the site for which a guarantee is proposed.

(2) The availability of coal reserves at the site.

(3) Any prior denials of surety coverage.

(m) Obtaining a Land Reclamation Financial Guarantee is subject to the following:

(1) A mine operator shall make annual payments to the Department at a rate of 1.5% of the total amount of the Land Reclamation Financial Guarantee.

(2) The first annual payment is due upon the operator's receipt of notice of the Department's approval of the operator's application to obtain a Land Reclamation Financial Guarantee. Payments shall be made annually thereafter concurrent with the permit anniversary date or in accordance with a schedule provided by the Department in writing.

(3) The operator is responsible for making the annual payment as calculated by the Department until the amount of the bond is reduced or released in accordance with §§ 86.170—86.172 (relating to scope; procedures for seeking release of bond; and criteria for release of bond).

(4) Payments are not refundable and will be deposited into the Land Reclamation Financial Guarantee Account to be used in the event of mine operator bond forfeiture. Excess payments may be transferred by the Department to the Reclamation Fee O&M Trust Account consistent with section 19.2(b)(6) of the Surface Mining Conservation and Reclamation Act.

(5) The operator may not substitute Land Reclamation Financial Guarantees for existing collateral or surety bonds.

(n) The Department may, after soliciting advice from the Mining and Reclamation Advisory Board and publication in the *Pennsylvania Bulletin*, adjust the annual payment percentage rate referred to in subsection (m)(1) to assure financial stability of the Land Reclamation Financial Guarantee Account and to cover the Department's costs to administer the guarantees.

(o) The Department will reduce or release an obligation covered by a Land Reclamation Financial Guarantee prior to any other bond submitted by the operator to cover the reclamation obligations of a permit, except that remining financial guarantees issued under section 4.12 of the Surface Mining Conservation and Reclamation Act will be released before Land Reclamation Financial Guarantees.

(p) If a post-mining pollutional discharge develops on a permit for which a Land Reclamation Financial Guarantee has been obtained, the operator shall, within 90 days of receipt of written notice by the Department, provide to the Department a separate bond or alternative financial assurance mechanism to cover the long-term treatment costs associated with the discharge or replace the Land Reclamation Financial Guarantee with other types of financial assurance mechanisms authorized for the purpose of covering the costs of treating the discharge.

(q) Upon mine operator bond forfeiture under § 86.181, the Department will declare forfeit the specified amount of the Land Reclamation Financial Guarantee for the permit in the Land Reclamation Financial Guarantee Account in addition to other bonds posted by the operator to cover the reclamation obligation on the permit.

(r) The Department's declaration of forfeiture under § 86.181 may not discharge an operator's obligation to meet the requirements of this chapter or other requirements under the Surface Mining Conservation and Reclamation Act.

(s) Upon declaration of forfeiture, the Department will use the bond money posted by the operator, the specified amount of the Land Reclamation Financial Guarantee, and any other financial assurance mechanisms to complete the reclamation of the mine site in accordance with the procedures and criteria in § 86.187 and §§ 86.188—86.190 (relating to evaluation of bond forfeiture sites; reclamation of bond forfeiture sites; and sites where reclamation is unreasonable, unnecessary or impossible; excess funds).

(t) The Department may suspend the issuance of Land Reclamation Financial Guarantees upon notice in the *Pennsylvania Bulletin* when the number of participating permits declared forfeit under this section equals the number of participating permits multiplied by the historical rate of mine operator bond forfeiture plus a margin of safety. Issuance of Land Reclamation Financial Guarantees may resume after the Department conducts an evaluation which demonstrates that adequate funding is available. The Department's evaluation will take into account advice received from the Mining and Reclamation Advisory Board.

(u) The Department will discontinue the issuance of Land Reclamation Financial Guarantees and notice will be published in the *Pennsylvania Bulletin* if 25% or more of the outstanding bond obligation for all Land Reclamation Financial Guarantees is declared forfeit under § 86.181.

(v) The Department will not approve additional Land Reclamation Financial Guarantees if Land Reclamation Financial Guarantees are discontinued. Outstanding Land Reclamation Financial Guarantees will remain in effect until released under §§ 86.170—86.172 and §§ 86.174 and 86.175 (relating to standards for release of bonds; and schedule for release of bonds).

§ 86.165. Failure to maintain proper bond.

(a) If a permittee fails to promptly post additional bond required under § 86.152 (relating to bond adjustments), or fails to make timely deposits of bond according to the schedule submitted under § 86.161 (relating to phased deposits of collateral), or fails to make payments under § 86.162a (relating to Anthracite Deep Mine Operators Emergency Bond Fund) or fails to maintain subsidence insurance provided in § 86.162 (relating to subsidence insurance in lieu of bond), or fails to make annual payments for financial guarantees as required under § 86.283(a) (relating to procedures), or fails to make annual payments for Land Reclamation Financial Guarantees as required under § 86.162b (relating to Land Reclamation Financial Guarantees), the Department will issue a notice of violation to the permittee, and if the permittee fails to correct the violation within 15 days of the notice, the Department will issue a cessation order for the permittee's permit areas and thereafter take actions that may be appropriate.

(b) The permittee shall maintain bonds in an amount and with sufficient guarantee as required by this chapter. If a surety company who had provided surety bonds, or a bank who had provided letters of credit or certificates of deposit for a permittee, enters into bankruptcy or liquidation, or has its license suspended or revoked or for another reason indicates an inability or unwillingness to provide an adequate financial guarantee of the obligations under the bond or instrument, the Department will issue a notice of violation to the permittee requiring that affected permits be rebonded according to the requirements of this subchapter and, if the permittee fails to correct the violation within 90 days of the notice, the Department will issue a cessation order for the permittee's permit areas and thereafter take appropriate action.

[Pa.B. Doc. No. 15-1535. Filed for public inspection August 21, 2015, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Collaborative Management of Drug Therapy

The State Board of Pharmacy (Board) amends §§ 27.1, 27.301 and 27.311 (relating to definitions; written protocol for the management of drug therapy in an institutional setting; and certification of professional liability insurance—written protocol) and adds §§ 27.302 and 27.312 (relating to collaborative agreement for management of drug therapy in a non-institutional setting; and certification of professional liability insurance—collaborative agreement) to read as set forth in Annex A.

Effective Date

The final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

Statutory Authority

The final-form rulemaking is authorized under sections 6(k)(9) and 9.3 of the Pharmacy Act (act) (63 P. S. §§ 390-6(k)(9) and 390-9.3).

Background and Purpose

In August 2002, section 9.1 of the act (63 P. S. § 390-9.1) was added to authorize pharmacists practicing in an institution setting to manage drug therapy by means of a written protocol. In August 2010, section 9.3 of the act was added to provide for collaborative drug therapy management in accordance with a written collaborative agreement between a physician and a pharmacist in a setting other than an institutional setting. This final-form rulemaking implements section 9.3 of the act.

Summary of Comments and Responses to Proposed Rulemaking

The Board published notice of proposed rulemaking at 43 Pa.B. 2439 (May 4, 2013), followed by a 30-day public comment period. The Board received comments from Patricia Epple, CEO of the Pennsylvania Pharmacists Association (PPA); joint comments from Jill McCormack, Regional Director, State Government Affairs, National Association of Chain Drug Stores (NACDS), and Janet Hart, RPh, President, Pennsylvania Association of Chain Drug Stores (PACDS); and comments from C. Richard Scott, MD, President, Pennsylvania Medical Society (PAMED). On June 13, 2013, the House Professional Licensure Committee (HPLC) voted to take no formal action on the proposed rulemaking until the final-form rulemaking is promulgated and to submit one comment to the Board. The Board did not receive comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC). On July 3, 2013, the Board also received comments from the Independent Regulatory Review Commission (IRRC) as part of their review of proposed rulemaking under the Regulatory Review Act (71 P. S. §§ 745.1—745.12a).

The comments were discussed at the public meeting of the Board on August 20, 2013. Present during the discussion of the comments were representatives from PPA, Target, CVS Caremark, Omnicare, Walgreens and Acme. These stakeholders did not offer additional comment during the discussion of the written comments.

The comments from PPA, NACDS and PACDS were supportive and did not offer changes to the proposed rulemaking. PAMED was supportive of the proposed rulemaking but suggested revisions.

PAMED recommended that controlled substances should be excluded from drug therapy management. The Board considered this recommendation and decided not to change this final-form rulemaking based on the fact that the parties involved, that is, the physician and the pharmacist, could limit the types of medication involved during the drug therapy management with an individual drug protocol. The Board felt it was better to leave this decision to the actual treatment providers involved with the specific drug therapy management protocol.

PAMED recommended that the agreements be placed on file with the respective physician licensing board. In response to this recommendation, the Board amended § 27.302(h) to include the requirement that the collaborative agreement shall be filed with the Bureau of Professional and Occupational Affairs (Bureau). Under section 810 of The Administrative Code of 1929 (71 P. S. § 279.1), the Commissioner of the Bureau has the power and duty "[t]o be responsible for all administrative affairs of each of the professional and occupational examining boards and to coordinate their activities." Filing the written agreement with the Bureau relieves the parties from the requirement to file multiple copies with the applicable boards. Instead, Bureau staff will distribute the agreement to the applicable boards and place an electronic copy of the written agreement on file with each licensee's licensure record maintained by the Bureau.

PAMED further recommended that physicians should have access to the pharmacist's records for review. In response to this recommendation, the Board amended § 27.302(l)(2) to include the requirement that physicians who are parties to the collaborative agreement shall have access to the pharmacy records of the drug therapy patient.

PAMED also recommended that a change in drug therapy should be reported to the physician within 48 hours. The Board considered this recommendation and decided not to change the final-form rulemaking. The Board notes that the final-form rulemaking requires it to be reported as soon as practicable, but no longer than 72 hours after the change. The Board felt that 72 hours was an appropriate time frame regarding changes regardless of the practice setting.

PAMED recommended that the Board institute workload limitations on pharmacists performing drug therapy management. The Board considered this recommendation and decided not to change the final-form rulemaking. Physicians and pharmacists are both licensed professionals and are capable of determining their own workload limitations without the need of Board guidance.

IRRC expressed concern regarding § 27.1 in that "non-institutional setting" used in § 27.302 was not specifically defined. In response to this concern, the Board defined "non-institutional setting" along with amending the definition of "institution."

IRRC and the HPLC also recommended that the written agreements be placed on file with the appropriate boards. In response to this recommendation, the Board amended § 27.302(h) to include the requirement that the collaborative agreement must be filed with the Bureau. This new provision is identical to the existing requirement in § 27.301(d) pertaining to written protocols for the management of drug therapy in institutional settings. The Bureau will ensure that the agreements are distributed to the applicable boards, and are copied and placed on file with each licensee's electronic licensure record. This process will eliminate the unnecessary filing of the same documents with multiple boards by multiple parties and is consistent with the Commissioner's authority under section 810 of The Administrative Code of 1929.

IRRC was supportive of PAMED's recommendation concerning physician access to the pharmacist's records. As previously noted, in response to this recommendation, the Board amended § 27.302(l)(2) to include the requirement that physicians who are parties to the collaborative agreement shall have access to the pharmacy records of the drug therapy patient.

Fiscal Impact and Paperwork Requirements

The final-form rulemaking will have minimal fiscal impact on the Board or the regulated community. The licensees' obligations regarding certification to the Board of professional liability insurance to practice under a

collaborative agreement would be similar to those of licensees practicing in institutional settings under a written protocol.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on April 22, 2013, the Board submitted a copy of the notice of proposed rulemaking, published at 43 Pa.B. 2439, to IRRC and the Chairpersons of the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on July 8, 2015, the final-form rulemaking was deemed approved by the HPLC and the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on July 9, 2015, and approved the final-form rulemaking.

Additional Information

Persons who require additional information about the final-form rulemaking should submit inquiries to Board Counsel, State Board of Pharmacy, P. O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-7200, st-pharmacy@state.pa.us.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The amendments to this final-form rulemaking do not enlarge the scope of proposed rulemaking published at 43 Pa.B. 2439.

(4) The final form rulemaking adopted by this order is necessary and appropriate for the administration of the act.

Order

The Board, acting under the act, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 27, are amended by adding §§ 27.302 and 27.312 and by amending §§ 27.1, 27.301 and 27.311 to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) The final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

JANET GETZEY HART, RPh,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 45 Pa.B. 4123 (July 25, 2015).)

Fiscal Note: Fiscal Note 16A-5425 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

GENERAL PROVISIONS

§ 27.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

ACPE—The Accreditation Council for Pharmacy Education.

Act—The Pharmacy Act (63 P. S. §§ 390-1—390-13).

Automated medication system—

(i) A process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing and distribution of medications, and which collects, controls and maintains all transaction information.

(ii) The term does not include an automatic counting device or unit-based dispensing cabinet.

Automatic counting device—A device used in a pharmacy to automatically count medication for dispensing.

Board—The State Board of Pharmacy.

Bureau—The Bureau of Professional and Occupational Affairs of the Department.

CEU—Continuing education units—The unit of measuring contact hours of continuing education provided by ACPE accredited providers. Ten contact hours are equivalent to 1.0 CEU.

Central fill pharmacy—A pharmacy engaging in centralized prescription processing by filling and refilling prescriptions, which includes the preparation and packaging of the medication. A central fill pharmacy may also be the originating or delivering pharmacy.

Central processing center—A pharmacy operated under the direction of a pharmacist that processes information related to the practice of pharmacy and that engages solely in centralized prescription processing but from which drugs are not dispensed.

Centralized prescription processing—The processing, under the direction of a pharmacist, of a request to fill or refill a prescription, to perform functions such as refill authorizations, interventions or other matters related to the practice of pharmacy for subsequent delivery to the delivering pharmacy.

Commissioner—The Commissioner of Professional and Occupational Affairs in the Department.

Contact hours—Continuing education units of measure equivalent to 50 to 60 minutes of participation in an approved organized learning experience, including home study with approved educational materials.

Continuing education—Professional education obtained to maintain, improve or expand current skills or knowledge, or to develop new skills or knowledge.

DEA—The Federal Drug Enforcement Administration.

Delivering pharmacy—The pharmacy that receives the processed prescription or the filled or refilled prescription for delivering to the patient or the patient's authorized representative. A delivering pharmacy may also be an originating or central fill pharmacy.

Department—The Department of State of the Commonwealth.

Drug order—

(i) An oral or written order issued by a medical practitioner which is either written on or entered by computer into the medical record of a patient in an institution for the dispensing of a drug or device for administration to the patient.

(ii) The term does not include an order for a drug for a patient in an institution which the patient will self-administer which will be considered a prescription.

FDLE—Federal Drug Law Examination.

Institution—A health care facility as defined in section 103 of the Health Care Facilities Act (35 P. S. § 448.103) which offers care and medical treatment to patients who require food, board and overnight sleeping facilities.

Licensed person—A person holding a license issued by the Board.

Long-term care facility—A nursing home, retirement care, mental care or other institution that provides extended health care to resident patients.

MJPE—Multistate Pharmacy Jurisprudence Examination.

Management of drug therapy—

(i) Any of the following processes performed under a written protocol as set forth in section 9.1 of the act (63 P. S. § 390-9.1) or under a collaborative agreement as set forth in section 9.3 of the act (63 P. S. § 390-9.3):

(A) Adjusting a drug regimen.

(B) Adjusting drug strength, frequency of administration or route.

(C) Administration of drugs.

(D) Ordering laboratory tests and ordering and performing other diagnostic tests necessary in the management of drug therapy.

(E) Monitoring the patient's vital signs.

(F) Providing education and training to the patient that is related to the management of the drug therapy.

(ii) The term excludes medication therapy management services in the practice of pharmacy provided under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173, 117 Stat. 2066).

Medical practitioner—A physician, dentist, veterinarian or other individual authorized and licensed by law to prescribe drugs.

Non-institutional setting—A setting other than an institution as defined in the act and this section.

Nonproprietary drug—A drug containing any quantity of a controlled substance or a drug which is required by an applicable Federal or state law to be dispensed only by prescription.

Order—Any directive from a medical practitioner.

Originating pharmacy—

(i) The pharmacy that receives the patient's or prescribing practitioner's request to fill or refill a prescription and performs functions such as the prospective drug review.

(ii) The term includes a central processing center or a central fill pharmacy if the prescription was transmitted by the prescriber directly to the central processing center or central fill pharmacy or if the patient requested the refill from that pharmacy.

PDR—Prospective drug review performed to assure that a drug dispensed under a prescription is not likely to have an adverse medical result by attempting to identify potential drug therapy problems that might result from therapeutic duplication, drug-drug interactions, incorrect dosage, incorrect duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse.

Pharmacist manager—The pharmacist named in the permit to operate a pharmacy who is in charge of a pharmacy and responsible for operations involving the practice of pharmacy under section 4 of the act (63 P. S. § 390-4).

Pharmacy—The place licensed by the Board where the practice of pharmacy is conducted.

Pharmacy intern—A person registered by the Board as a pharmacy intern under section 3(e) of the act (63 P. S. § 390-3(e)) and § 27.26 (relating to pharmacy internship).

Pharmacy technician—

(i) An unlicensed person working in a pharmacy to assist a pharmacist in the practice of pharmacy in accordance with § 27.12 (relating to practice of pharmacy and delegation of duties).

(ii) The term does not include a pharmacy intern, or clerical or housekeeping personnel.

Practice of pharmacy—

(i) The provision of health care services by a pharmacist, which includes:

(A) The interpretation, evaluation and implementation of medical orders for the provision of pharmacy services or prescription drug orders.

(B) The delivery, dispensing or distribution of prescription drugs.

(C) Participation in drug and device selection.

(D) Drug administration.

(E) Drug regimen review.

(F) Drug or drug-related research.

(G) Compounding.

(H) Proper and safe storage of drugs and devices.

(I) Management of drug therapy under a written collaborative agreement as set forth in section 9.3 of the act or, if in an institutional setting, consistent with the institution's assignment of clinical duties under a written protocol as set forth in section 9.1 of the act.

(J) Maintaining proper records.

(K) Patient counseling.

(L) Acts, services, operations or transactions necessary or incident to the provision of these health care services.

(M) Drug therapy management, including services provided under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(ii) The term does not include the operations of a manufacturer or distributor as defined in The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780.144).

Prescription—A written, electronic or oral order issued by a licensed medical practitioner in the course of professional practice for a controlled substance, other drug or device, or medication which is dispensed for use by a consumer.

Prescription area—

(i) That area of the pharmacy used for compounding, legend drug storage and other activities necessary to the practice of pharmacy.

(ii) The term does not include waiting counters or display space attached to the waiting counters.

Proprietary drug—A nonprescription, nonnarcotic medicine or drug which may be sold without a prescription and which is prepackaged for use by the consumer and labeled in accordance with the requirements of Federal and State statutes and regulations.

Satellite pharmacy—

(i) A pharmacy in an institution which provides specialized services for the patients of the institution and which is dependent upon the centrally located pharmacy for administrative control, staffing and drug procurement.

(ii) The term does not include a pharmacy serving the public on the premises of the institution nor does it include a pharmacy located off premises from the centrally located pharmacy of the institution regardless of whether the pharmacy is owned by the same person or entity which owns the institution.

MANAGEMENT OF DRUG THERAPY

§ 27.301. Written protocol for the management of drug therapy in an institutional setting.

(a) The management of drug therapy under section 9.1 of the act (63 P. S. § 390-9.1) shall be performed under a written protocol consistent with the institution's assignment of clinical duties. Ordering of laboratory tests and ordering or performing other diagnostic tests necessary in the management of drug therapy shall be consistent with the testing standards of the institution.

(b) The written protocol for management of drug therapy between physicians and pharmacists must contain:

(1) A statement identifying the physician responsible for authorizing management of drug therapy.

(2) A statement identifying the pharmacist authorized to perform management of drug therapy.

(3) A statement requiring that regimens for the management of drug therapy be initiated by a physician for patients referred to a pharmacist for management of drug therapy.

(4) A statement identifying the types of decisions regarding the management of drug therapy that the pharmacist is authorized to make, including a statement of the ailments or diseases involved within the physician's scope of practice, and types of management of drug therapy authorized.

(5) A statement of the functions and tasks the pharmacist shall follow in the course of exercising management of drug therapy, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation of each intervention shall occur as soon as practicable, but no later than 72 hours after the intervention in the patient's medical record and shall also be recorded in the pharmacist's records.

(6) A statement that requires notification to the authorizing physician of any changes in dose, duration or frequency of medication prescribed as soon as practicable but no longer than 72 hours after the change.

(7) A provision for implementation of the written protocol when a physician or pharmacist who is a party to the protocol is temporarily unavailable to participate in its implementation.

(8) A provision for notification of the role of the pharmacist by a physician to each referred patient the management of whose drug therapy may be affected by the written protocol and providing an opportunity for the patient to refuse management of drug therapy by a pharmacist.

(9) The signatures of the physicians and pharmacists who are entering into the written protocol, and the dates signed.

(10) A statement allowing for the termination of the written protocol at the request of any party to it at any time.

(c) The written protocol must be available as follows:

(1) At the practice site of each physician who is a party to the written protocol.

(2) At the practice site of each pharmacist who is a party to the written protocol.

(3) At the institution where a written protocol is in place.

(4) To any patient the management of whose drug therapy is affected by the written protocol, upon request of the patient.

(5) Upon request, to representatives of the Bureau and the Department of Health.

(d) The written protocol shall be filed with the Bureau.

(e) The written protocol must be effective for a period not to exceed 2 years from the date of execution. At the end of the 2-year period, or sooner, the parties shall review the written protocol and make a determination as to its renewal, necessary modifications or termination.

§ 27.302. Collaborative agreement for management of drug therapy in a non-institutional setting.

(a) Before practicing the management of drug therapy in a non-institutional setting, a pharmacist shall enter into a written collaborative agreement with a physician authorizing the management of drug therapy for diseases or for conditions or symptoms of diseases.

(b) The collaborative agreement must be between a physician and a pharmacist.

(c) A pharmacist may not provide economic or other incentives, inducements or benefits to a physician for the purpose of entering into a collaborative agreement for the management of drug therapy.

(d) A pharmacist who is employed by a physician under a collaborative agreement for the purpose of management of drug therapy may not engage in retail dispensing while in the health care practice or within the context of employment.

(e) Participation in a collaborative agreement authorizing the management of drug therapy is voluntary. A physician or pharmacist is not required to participate.

(f) The collaborative agreement must contain:

(1) A statement identifying the physician responsible for authorizing the management of drug therapy.

(2) A statement identifying the pharmacist authorized to perform the management of drug therapy.

(3) A statement requiring that regimens for the management of drug therapy be initiated by a physician for patients referred to a pharmacist for management of drug therapy.

(4) A statement identifying the types of decisions regarding the management of drug therapy that the pharmacist is authorized to make within the physician's scope of practice and types of management of drug therapy authorized.

(5) A statement identifying the terms under which a pharmacist providing the management of drug therapy is permitted to: adjust the drug regimen, the drug strength and the frequency of administration or the route of administration; administer drugs; order laboratory tests; and order and perform other diagnostic tests necessary in the management of drug therapy without prior written or oral consent by the collaborating physician. This paragraph does not provide prescriptive authority to a pharmacist.

(6) A statement of the functions and tasks the pharmacist shall follow in the course of exercising management of drug therapy, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation of each intervention shall occur as soon as practicable, but no later than 72 hours after the intervention, and be recorded in the pharmacist's records.

(7) A statement that requires notification to the authorizing physician of changes in dose, duration or frequency of medication prescribed as soon as practicable but no longer than 72 hours after the change.

(8) A provision for implementation of the collaborative agreement when a physician or pharmacist who is a party to the agreement is temporarily unavailable to participate in its implementation.

(9) A provision for notification of the role of the pharmacist by a physician to each referred patient the management of whose drug therapy may be affected by the collaborative agreement and providing an opportunity for the patient to refuse management of drug therapy by a pharmacist.

(10) The signatures of the physicians and pharmacists who are entering into the collaborative agreement and the dates signed.

(11) A statement allowing for the termination of the collaborative agreement at the request of a party to it at any time.

(g) The collaborative agreement must be available:

(1) At the practice site of each physician who is a party to the collaborative agreement.

(2) At the practice site of each pharmacist who is a party to the collaborative agreement.

(3) To any patient the management of whose drug therapy is affected by the agreement, upon request of the patient.

(4) Upon request, to representatives of the Bureau and the Department of Health.

(h) The collaborative agreement shall be filed with the Bureau.

(i) The collaborative agreement must be maintained on the premises of the pharmacy for review during inspection by or upon request of representatives of the Bureau and the Department of Health.

(j) The collaborative agreement must be effective for no more than 2 years from the date of execution. At the end of the 2-year period, or sooner, the parties shall review the collaborative agreement and make a determination as to its renewal, necessary modifications or termination.

(k) A pharmacist who is party to a collaborative agreement authorizing the management of drug therapy shall:

(1) Utilize an area for in-person, telephonic or other approved electronic consultations regarding the management of drug therapy that ensures the confidentiality of the patient information being discussed.

(2) Initiate the management of drug therapy only upon a written referral to the pharmacist from the physician. The written referral must include the minimum frequency in which the pharmacist shall conduct the management of the drug therapy in person.

(3) Confirm that the physician who is a party to the collaborative agreement holds an active and unrestricted license and that the terms of the collaborative agreement are within the scope of the physician's current practice at the time of the execution of the collaborative agreement.

(l) Patient records regarding the management of drug therapy may be maintained in a computerized recordkeeping system which meets the requirements for Federal and State-certified electronic health care records, subject to the following:

(1) The pharmacist who is a party to the collaborative agreement shall have access to the records of the patient who is the recipient of the management of drug therapy.

(2) The physician who is a party to the collaborative agreement shall have access to the pharmacy records of the patient who is the recipient of the management of drug therapy.

(3) The handling of patient records by the pharmacist providing the management of drug therapy shall comply with the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191, 110 Stat. 1936), the Health Information Technology for Economic and Clinical Health Act (Pub. L. No. 111-5, Div. A, Title XIII, Div. B, Title IV, 123 Stat. 226, 467), and associated rules and regulations.

PROFESSIONAL LIABILITY INSURANCE

§ 27.311. Certification of professional liability insurance—written protocol.

(a) A licensee who engages in management of drug therapy under a written protocol shall maintain professional liability insurance in the minimum amount of $1 million per occurrence or claims made. The Board will accept from a licensee as satisfactory evidence of insurance coverage any of the following:

(1) Personally purchased professional liability insurance.

(2) Professional liability insurance coverage provided by the individual licensee's employer.

(3) Similar insurance coverage acceptable to the Board.

(b) A licensee who engages in management of drug therapy under a written protocol shall certify compliance with subsection (a) on a form available from the Board. The licensee shall submit the completed certification form to the Board with the written protocol.

(c) A licensee who engages in management of drug therapy under a written protocol shall, upon request, make available to the Board or its agents a certificate of insurance regarding the licensee's maintenance of professional liability insurance.

(d) Failure to maintain insurance coverage as required under the act and this section will subject the licensee to disciplinary action under section 5(a)(6) of the act (63 P. S. § 390-5(a)(6)).

§ 27.312. Certification of professional liability insurance—collaborative agreement.

(a) A licensee who is a party to a collaborative agreement authorizing the management of drug therapy shall obtain and maintain a level of professional liability insurance coverage in the minimum amount of $1 million per occurrence or claims made. The Board will accept from a licensee as satisfactory evidence of insurance coverage any of the following:

(1) Personally purchased liability insurance.

(2) Professional liability insurance coverage provided by the individual licensee's employer.

(3) Similar insurance coverage acceptable to the Board.

(b) A licensee who engages in the management of drug therapy under a collaborative agreement shall provide an affidavit to the Board that the licensee has obtained professional liability insurance in accordance with subsection (a) on a form available from the Board. The licensee shall submit the completed affidavit form to the Board with the collaborative agreement.

(c) A licensee who engages in the management of drug therapy under a collaborative agreement shall, upon request, make available to the Board or its agents a certificate of insurance regarding the licensee's maintenance of professional liability insurance.

(d) Failure to maintain insurance coverage as required under the act and this section will subject the licensee to disciplinary action under section 5(a)(6) of the act (63 P. S. § 390-5(a)(6).

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