RULES AND REGULATIONS

Title 4—ADMINISTRATION

STATE EMPLOYEES' RETIREMENT BOARD

[4 PA. CODE CH. 241]

Preliminary Provisions

The State Employees' Retirement Board (Board) is deleting the definition of "class of service multiplier" in § 241.1 (relating to definitions). The definition is no longer needed, as it has been outmoded by changes in the benefit structure of the State Employees' Retirement System (System). Notice of proposed rulemaking was published at 35 Pa.B. 4923 (September 3, 2005).

A. *Effective Date*

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

B. *Contact Person*

For further information contact Robert Gentzel, Director of Communications and Policy, State Employees' Retirement System, 30 North Third Street, Harrisburg, PA 17101 (717) 787-9657 or Salvatore A. Darigo, Jr., Counsel, State Employees' Retirement System, 30 North Third Street, Harrisburg, PA 17101 (717) 787-7317.

C. *Statutory Authority*

This proposed rulemaking is being made under 71 Pa.C.S. § 5902(h) (relating to administrative duties of the board).

D. *Background and Purpose*

Prior to March 1, 1974, 71 Pa.C.S. Part XXV (relating to State Employees' Retirement Code) (Retirement Code) contained various benefit formulas which applied a benefit multiplier factor to a State employee's final average salary and total credited service to determine the amount of the employee's retirement benefit. The definition proposed to be deleted clarified the System's determination that persons who entered State service after March 1, 1974, would not be able to have their post-1974 retirement benefits calculated pursuant to earlier law. Subsequent amendments to the Retirement Code removed the various class of service multipliers and substituted a Class "A" retirement benefit formula.

The definition is unnecessary, outmoded and irrelevant. Deleting this definition will avoid confusion on the part of members of the System and its personnel, reduce paperwork and potentially reduce the number of administrative hearings for redress of grievances.

On November 2, 2005, the Independent Regulatory Review Commission (IRRC) suggested that the Board replace the definition with a cross reference to the definition of the term "class of service multiplier" found in 71 Pa.C.S. § 5102 (relating to definitions).

After thoughtful consideration of IRRC's suggestion, the Board respectfully declines to replace the definition with a cross reference to 71 Pa.C.S. § 5102. That section contains a complete list of the System's classes of service and their respective benefit multipliers. It is the Board's opinion that the cross reference to 71 Pa.C.S. § 5102 will not add anything.

E. *Benefits, Costs and Compliance*

Benefits

This final-form rulemaking benefits the System and its members. This definition is unnecessary, outmoded and irrelevant. Repealing this definition will avoid confusion on the part of members of System and the agency's personnel, reduce paperwork and potentially reduce the number of administrative hearings for redress of grievances.

Costs

There are no costs to the Commonwealth, its citizens or State employees associated with this proposal.

Compliance Costs

The final-form rulemaking will not impose any additional compliance costs on state employees.

F. *Sunset Review*

A sunset review date has not been established.

G. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 18, 2005, the Board submitted a copy of the proposed amendment to IRRC and the Chairpersons of the House State Government Committee and the Senate Finance Committee. In addition to submitting the proposed amendment, the Board provided IRRC and the Committees with a detailed Regulatory Analysis Form prepared by the Board. A copy of this material is available to the public upon request.

Under section 5.1(d) of the Regulatory Review Act (71 P. S. § 745.5a(d)), this final-form rulemaking was deemed approved by the House and Senate Committees on April 18, 2006. Under section 5.1(e) of the Regulatory Review Act (71 P. S. § 745.5a(e)), the final-form rulemaking was approved by IRRC effective April 19, 2006.

H. *Public Comments*

The Board has received no public comments.

I. *Findings*

The Board finds that:

(1) Public notice of intention to adopt the administrative amendment adopted by this order has been 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 the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) The adoption of the amendment of the Board in the manner provided in this order is necessary and appropriate for the administration and enforcement of the authorizing statute.

J. *Order*

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

(a) The regulations of the Board, 4 Pa. Code Chapter 241, are amended by amending § 241.1 to read as set forth at 35 Pa.B. 4923.

(b) The amendment shall be submitted to the Office of Attorney General for approval as to legality as required by law.

(c) The Secretary of the Board shall certify this order and 35 Pa.B. 4923 and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

ERIC HENRY,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 36 Pa.B. 2251 (May 6, 2006).)

Fiscal Note: Fiscal Note 31-3 remains valid for the final adoption of the subject regulation.

[Pa.B. Doc. No. 06-926. Filed for public inspection May 26, 2006, 9:00 a.m.]

STATE EMPLOYEES' RETIREMENT BOARD

[4 PA. CODE CH. 243]

Membership, Credited Service and Eligibility for Benefits

The State Employees' Retirement Board (Board) has deleted § 243.8. The section is no longer needed, as it has been outmoded by changes in the benefit structure of the State Employees' Retirement System (System). Notice of proposed rulemaking was published at 35 Pa.B. 4922 (September 3, 2005).

A. *Effective Date*

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

B. *Contact Person*

For further information contact Robert Gentzel, Director of Communications and Policy, State Employees' Retirement System, 30 North Third Street, P. O. Box 1147, Harrisburg, PA 17108-1147, (717) 787-9657 or Salvatore A. Darigo, Jr., Counsel, State Employees' Retirement System, 30 North Third Street, Harrisburg, PA 17101, (717) 787-7317.

C. *Statutory Authority*

This final-form rulemaking is being made under 71 Pa.C.S. § 5902(h) (relating to administrative duties of the board)

D. *Background and Purpose*

Section 234.8 listed the classes of service closed to new members as of March 1, 1974. Before that date, 71 Pa.C.S. §§ 5101—5956 (relating to State Employee's Retirement Code) (Retirement Code) contained various benefit formulas that applied a benefit multiplier factor to a State employee's final average salary and total credited service to determine the amount of the employee's retirement benefit.

By rescinding § 234.8, the System desires to remove a regulation from the *Pennsylvania Code* that has been rendered obsolete and irrelevant due to subsequent changes to the Board's enabling legislation. More than 30 years have passed since the classes of membership referenced in the regulation were closed to new members; therefore, there are few, if any, Commonwealth employees subject to the regulation.

On November 2, 2005, the Independent Regulatory Review Commission (IRRC) suggested that the Board retain both subsections of this regulation because there are still active members of System who have service credit in Classes C, D-3 and E-2. After thoughtful consideration of IRRC's comment, the Board has decided not to adopt the IRRC's suggestion.

The Board acknowledges that each of the categories contain active members of the System who are still employed and making contributions to the System. However, a full listing of classes of service together with their respective benefit multipliers is contained in 71 Pa.C.S. § 5102 (relating to definitions). Additionally, changes in both statutory and case law since the original promulgation of this regulation have rendered this regulation obsolete. As currently promulgated, the regulation presents an inaccurate description of the System's benefit structure and therefore should be rescinded.

E. *Benefits, Costs and Compliance*

Benefits

This final-form rulemaking benefits the System and its members. Section 248.8 is unnecessary, outmoded and irrelevant. Rescinding this section will avoid confusion on the part of members of the System and the Board's personnel, reduce paperwork and potentially reduce the number of administrative hearings for redress of grievances.

Costs

There are no costs to the Commonwealth, its citizens or State employees associated with this proposal.

Compliance Costs

The final-form rulemaking is not expected to impose any additional compliance costs on State employees.

F. *Sunset Review*

A sunset review date has not been established.

G. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 18, 2005, the Board submitted a copy of the proposed amendment to IRRC and the Chairpersons of the House State Government Committee and the Senate Finance Committee. In addition to submitting the proposed amendment, the Board has provided IRRC and the Committees with a detailed Regulatory Analysis Form prepared by the Board. A copy of this material is available to the public upon request.

Under section 5.1(d) of the Regulatory Review Act (71 P. S. § 745.5a(d)), this final-form rulemaking was deemed approved by the House and Senate Committees on April 18, 2006. Under section 5.1(e) of the Regulatory Review Act (71 P. S. § 745.5a(e)), the final-form rulemaking was approved by IRRC on April 19, 2006.

H. *Public Comments*

The Board has received no public comments.

I. *Findings*

The Board finds that:

(1) Public notice of intention to adopt the administrative amendment 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), known as the Commonwealth Documents Law and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) The adoption of the amendment is necessary and appropriate for the administration of the Retirement Code.

J. *Order*

The Board, acting under the Retirement Code and the Commonwealth Documents Law, including particularly those sections specified in the several authority sections specified with respect to each provision of the rules and procedures of the System modified by this order, orders:

(a) The regulations for the Board, 4 Pa. Code Chapter 243, are amended by deleting § 243.8 to read as set forth at 35 Pa.B. 4922.

(b) The amendment shall be submitted to the Office of Attorney General for approval as to legality as required by law.

(c) The Secretary of the Board shall certify this order and 35 Pa. B. 4922 and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

ERIC HENRY,
Secretary

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 36 Pa.B. 2251 (May 6, 2006).)

Fiscal Note: Fiscal Note 31-4 remains valid for the final adoption of the subject regulation.

[Pa.B. Doc. No. 06-927. Filed for public inspection May 26, 2006, 9:00 a.m.]

STATE EMPLOYEES' RETIREMENT BOARD
[4 PA. CODE CH. 249]
Administrative Duties of the Board

The State Employees' Retirement Board (Board) amended § 249.2 (relating to the administrative duties of the Board) by deleting subsection (a) dealing with the inspection of minutes of the Board's meetings. This subsection has been rendered obsolete. Notice of proposed rulemaking was published at 35 Pa.B. 5013 (September 10, 2005).

A. *Effective Date*

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

B. *Contact Person*

For further information contact Robert Gentzel, Director of Communications and Policy, State Employees' Retirement System, 30 North Third Street, Harrisburg, PA 17101 (717) 787-9657 or Salvatore A. Darigo, Jr., Counsel, State Employees' Retirement System, 30 North Third Street, Harrisburg, PA, 17101, (717) 787-7317.

C. *Statutory Authority*

This final-form rulemaking is being made under 71 Pa.C.S. § 5902(h) (relating to administrative duties of the Board).

D. *Background and Purpose*

The Board is responsible for implementing the retirement benefit program outlined in 71 Pa.C.S. Part XXV (relating to Public Employees' Retirement Code) (Retirement Code). Section 249.2(a) provides that the minutes of the Board's meetings will be available for public inspection at the Board's offices during normal working hours. Subsection (a) further provides that the minutes will be the only records made available for public inspection. This final-form rulemaking will remove a regulation that directly conflicts with the act of June 21, 1957 (P. L. 390, No. 212) (65 P. S. §§ 66.1—66.4), know as the Right-to-Know Law. The deletion of subsection (a) removes an outmoded and unenforceable regulation that directly conflicts with the Right-to-Know Law.

E. *Benefits, Costs and Compliance*

Benefits

This final-form rulemaking benefits the System and its members. This provision was unnecessary, outmoded and irrelevant. Repealing this provision will avoid confusion on the part of members of the System and its personnel, reduce paperwork and potentially reduce the number of administrative hearings for redress of grievances.

Costs

There are no additional costs to the Commonwealth, its citizens or State employees associated with this proposal.

Compliance Costs

This final-form rulemaking is not expected to impose any additional compliance costs on State employees.

F. *Sunset Review*

A sunset review date has not been established.

G. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 25, 2005, the Board submitted a copy of the proposed amendment to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House State Government Committee and the Senate Finance Committee. In addition to submitting the proposed amendment the Board has provided IRRC and the Committees with a detailed Regulatory Analysis Form prepared by the Department. A copy of this material is available to the public upon request.

On November 10, 2005, IRRC advised the Board that it had no objections, comments or recommendations to offer on the proposed regulation.

Under section 5.1(d) of the Regulatory Review Act (71 P. S. § 745.5a(d)), this final-form rulemaking was deemed approved by the House and Senate Committees on April 18. Under section 5(g) of the Regulatory Review Act, the final-form rulemaking was deemed approved by IRRC effective April 19, 2006.

H. *Public Comments*

The Board has received no public comments.

I. *Findings*

The Board finds that:

(1) Public notice of intention to adopt the administrative amendment 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), known as the Commonwealth Documents Law (CDL) and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) The adoption of the amendment is necessary and appropriate for the administration of the Retirement Code.

J. *Order*

The Board, acting under the Retirement Code and the CDL, including particularly those sections specified in the several authority sections herein specified with respect to

each provision of the rules and procedures of the System modified by this order, orders:

(a) The regulations for the Board, 4 Pa. Code Chapter 249, are amended by amending § 249.2 to read as set forth at 35 Pa.B. 5013.

(b) The amendment shall be submitted to the Office of Attorney General for approval as to legality as required by law.

(c) The Secretary of the Board shall certify this order and 35 Pa.B. 5013 and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

ERIC HENRY,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 36 Pa.B. 2251 (May 6, 2006).)

Fiscal Note: Fiscal Note 31-5 remains valid for the final adoption of the subject regulation.

[Pa.B. Doc. No. 06-928. Filed for public inspection May 26, 2006, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Technology and Automation

The State Board of Pharmacy (Board) amends §§ 27.1, 27.14 and 27.16 (relating to definitions; supplies; and construction and equipment requirements) and adds §§ 27.201—27.204 (relating to technology and automation) to read as set forth in Annex A. The final-form rulemaking adds definitions, updates §§ 27.14 and 27.16 and adds sections for electronically transmitted prescriptions, computerized recordkeeping systems, central fill pharmacies and automated medication systems.

Notice of proposed rulemaking was published at 34 Pa.B. 3146 (June 19, 2004). Publication was followed by a 30-day public comment period. The Board received comments from the Department of Health (Department), Cardinal Health, Diamond Pharmacy Services, WebMD, Rx.com, Neighbor Care and the Pennsylvania Society of Health-System Pharmacists (PSHP). The House Professional Licensure Committee (HPLC) submitted seven comments to the proposed rulemaking. The Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) made no comments. The Independent Regulatory Review Commission (IRRC) submitted seven comments to the proposed rulemaking. The Board discussed the comments at its August 17, 2004, and September 21, 2004, public meetings. The Board submitted the final rulemaking package to the SCP/PLC, the HPLC and IRRC on November 28, 2005. On December 12, 2005, the Board withdrew the final rulemaking package to address concerns raised by HPLC.

Summary of Comments and Responses to Proposed Rulemaking

§ 27.1 Definitions.

HPLC recommended revision of the definition of "automated medication system" and suggested alternate language. The Board has amended the definition accordingly. IRRC recommended adding a definition of the term "automatic counting device" to the final-form rulemaking. The Board has added a definition of "automatic counting device" as IRRC suggested. The PSHP and IRRC queried whether the definition of "automated medication system" would prohibit the use of automated compounding systems from a central location to fill or prepare intravenous medications or the batching of products for use in a centralized pharmacy. An automated compounding system is not included in the definition of "automated medication system." Therefore, the definition would not prohibit the use of automated compounding systems.

The HPLC and IRRC recommended rewriting the definition of "originating pharmacy" so that a licensee can clearly determine when a central fill pharmacy or a central processing center is an "originating pharmacy." The Board has amended the definition accordingly and has also amended the definitions of "central fill pharmacy" and "delivering pharmacy" to obviate any confusion between the terms used to describe pharmacies in the centralized prescription processing regulation.

IRRC commented that the definition of "prescription" should be amended to include electronic orders. The Board has amended the final-form rulemaking accordingly.

IRRC next questioned what a central processing center does. A central processing center is not a fully functional pharmacy in that it is not a place where drugs are dispensed. A central processing center is a facility that performs the refill authorizations, counseling, interventions, billing or other functions related to the practice of pharmacy. This facility would generally consist of an office and a computer and would only perform cognitive functions, not filling and labeling. It is important to license this facility as a pharmacy to give the Board jurisdiction over the facility itself, as the functions performed at the facility are integral to the practice of pharmacy.

After the final rulemaking was submitted, the HPLC raised additional concerns regarding the central processing center. HPLC was concerned that the Board was creating a new type of license in licensing a central processing center as a pharmacy. The Board notes that it is not creating a new type of license. A central processing center will be issued the same pharmacy permit that all pharmacies are issued. To address the HPLC's concerns, the Board has amended the final-form rulemaking to remove the confusing language. The Board has further amended the definition of "central processing center" to clarify that a central processing center does not dispense drugs. A central processing center is used solely for processing information related to the practice of pharmacy.

The PSHP asked whether the central pharmacy and a satellite pharmacy in an institution would be designated as one of the defined pharmacy terms for centralized prescription processing. The pharmacy terms ("originating pharmacy," "central fill pharmacy," "central processing center" and "delivering pharmacy") only pertain to centralized filling of prescriptions. Since institutions generally fill drug orders for patients of the institution, these

are not contemplated as coming under the central fill regulation. However, the terms would apply to an institution's outpatient pharmacy that fills prescriptions using a centralized filling process. By definition, satellite pharmacies do not fill outpatient prescriptions and would not come into play in the centralized prescription filling process.

§ 27.14. Supplies.

The HPLC recommended that § 27.14 contain language that makes it clear that an exception to the inventory requirements is in § 27.203(b) (relating to centralized prescription processing). IRRC also commented on the need to cross-reference this section with § 27.203(b). The Board has amended the final-form rulemaking accordingly. The Board also amended this section to exempt central processing centers from maintaining the minimum equipment, supplies and reference library. This exemption is appropriate because central processing centers will not dispense drugs. Therefore, it is unnecessary to require a central processing center to maintain equipment and supplies that are only used to dispense drugs. Instead, central processing centers will only be required to maintain equipment, supplies and a reference library recognized by the pharmacy community as meeting the minimum standards of practice as a central processing center.

§ 27.16. Construction and equipment requirements.

The Board amended the final-form rulemaking to add provisions that were overlooked in the proposed rulemaking. The amendments create an exception for central processing centers to the minimum size requirements of the prescription area and the requirement to have a sink used solely for pharmaceutical purposes. This amendment was made because central processing centers by definition will not have a prescription area or dispense drugs. It follows that the central processing center would not need a sink used solely for pharmaceutical purposes.

§ 27.201. Electronically transmitted prescriptions.

The HPLC commented that subsection (a) should be rewritten without parentheses. The Board has amended the final-form rulemaking accordingly. IRRC recommended that the definition of "electronically transmitted prescription" be amended to allow any method of electronic communication that can reliably provide the information required by § 27.201(b) and the Board has done so. IRRC commented that § 27.201(a) was difficult to comprehend. With the amendments to this section, the Board believes the final-form rulemaking is clear as to the Board's intent and is comprehendible to pharmacists and information technologists who are subject to the regulations. WebMD commented that § 27.201(a) excluded computer-to-facsimile machine electronic prescriptions. The Board agrees and has amended the section with language suggested by WebMD.

IRRC commented that subsection (b) does not address section 3(a) of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.3(a)), known as the Generic Equivalent Drug Law, and recommended that the Board address the requirements of this section in the final-form rulemaking. WebMD also requested that the Board include guidance as to how a prescriber's generic substitution instructions would be communicated in electronically transmitted prescriptions. The Generic Equivalent Drug Law instructs prescribers what must be imprinted on a prescription blank and what must be written to indicate that the brand medication should be dispensed. The Board cannot change the final-form rulemaking to address the Generic Equivalent Drug Law because the Board does not have the authority to impose an affirmative duty on a professional not licensed by the Board. The Board believes it does not have the statutory or regulatory authority to place requirements on prescribers.

WebMD commented that the regulations would prohibit prescribers' use of electronic data interchange (EDI) networks to deliver electronically transmitted prescriptions to the pharmacy of the patient's choice. EDI networks access electronically transmitted prescriptions to route the prescriptions between prescribers and pharmacies. An EDI network scans the prescription to ensure that information required by law has been entered into the appropriate data field. EDI networks decrypt the prescription's content and convert it to a format that can be received by means of a point-to-point transmission over telephone lines and printed at the pharmacy's facsimile machine. The EDI network does not actually read the prescription, nor substantively alter the prescription information. WebMD suggested alternate language to § 27.201(a) to allow EDI networks to deliver electronically transmitted prescriptions between prescribers and pharmacies. The Board agrees and has amended the final-form rulemaking with the language suggested by WebMD.

IRRC commented that given the importance of the Electronic Transactions Act (ETA) (73 P. S. §§ 2260.101—2260.5101) to this final-form rulemaking, it would be appropriate to address electronic prescription requirements in a separate subsection. The Board believes that references to the ETA are clear and the requirements of an electronic prescription are clearly stated in subsection (b). The Board cannot possibly cover every detail of electronic prescriptions. This technology is already in use at many pharmacies; however, until now it has not had specific regulations to govern its use. Pharmacies were left to apply this technology within the requirements of the regulations pertaining to paper prescriptions. The regulations are intended to provide minimum standards to protect the public by the use of this technology. Finally, the Board notes that developing further regulations at this time may be counter-productive. The Board suggests pharmacists working with the new regulations will provide the genesis for further rulemaking in the areas of automation and computer-based technology.

IRRC commented that subsection (b)(5) should be a separate subsection. The Board has amended the final-form rulemaking accordingly.

The PSHP asked whether the term "prescription" as used in § 27.201 included orders or drug orders as defined in the Board regulations. The terms "prescription" and "drug order" are separately defined in § 27.1 and a drug order is not included under the term "prescription."

§ 27.202. Computerized recordkeeping systems.

The HPLC commented that subsection (a) should be rewritten without parentheses. The Board has amended the final-form rulemaking accordingly. IRRC inquired why the Board is not requiring backup of computerized recordkeeping systems in this section. First, the Board notes that subsection (e) requires the computerized recordkeeping system to have adequate safeguards to prevent accidental erasure of information, which would accomplish the same goal as backing up the system. The Board is not using specific language such as "backing up the system" because newer technology negates the need to do this. New technology uses mirror drives and other means to ensure the safety of information without the need for back up of the system.

In subsection (d), IRRC and the PSHP questioned how the number of refills could be verified unless the patient brings the original prescription vial/container with them to the pharmacy, or if the patient is phoning in their refill. Upon further review of subsection (d), the Board removed that language in the final-form rulemaking. It deems the language unnecessary as pharmacists may use professional judgment in filling or refilling prescriptions regardless of the type of recordkeeping system in use.

The PSHP asked if the Board has considered requiring minimum contingency plans in case of a system failure. In the draft stage of the final-form rulemaking, similar provisions were included, but after careful thought were removed by the Board. These provisions can be too restrictive and would not apply to all systems. Furthermore, technological changes could render any minimum contingency plans obsolete and require frequent updating of the regulations.

§ 27.203. Centralized prescription processing.

The HPLC recommended that in subsection (a) the word "provided" be replaced with "if the following requirements are met." The Board has amended the final-form rulemaking accordingly.

Rx.com commented that other states have added language to their central fill rules that explicitly allow home delivery by central fill pharmacies. The Board notes that if the central fill pharmacy is delivering the filled prescription then it would also be the delivering pharmacy as defined by § 27.1. The Board amended the definitions of "central fill pharmacy," "delivering pharmacy" and "originating pharmacy" to clarify its intent. Because the Board's current regulations already allow for home delivery of medications by pharmacies, it is unnecessary to add specific language to the central fill regulations to allow home delivery.

In the final-form rulemaking, the Board added exemptions that were overlooked during the proposed rulemaking. A central processing pharmacy is exempt from the minimum size requirement for a prescription area as well as the requirement to have a sink used solely for pharmaceutical purposes. These exemptions are cross-referenced in § 27.16(b).

§ 27.204. Automated medication systems.

The HPLC noted that the regulations required pharmacies to have policies and procedures in place, to have policies of operation and to operate according to a written program, but there was no duty imposed on pharmacies to actually create these policies or programs. In response, the Board amended the appropriate sections to create a duty to write or adopt these policies or programs. IRRC asked who has the responsibility to write the policies and procedures. The responsibility is on the pharmacy to maintain these policies and procedures. Therefore, the owner of the pharmacy permit should have these as part of the supplies in the pharmacy and it would be up to each pharmacy how to create these. These policies could be created by any number of people. For example, the permit owner or pharmacist manager could write the policies and procedures or pharmacies could adopt policies and procedures prepared by the manufacturer of the automated medication systems.

IRRC next commented that subsection (b) uses the term "other identifier" and questions what the Board would consider an adequate method of electronically recording the activity of each pharmacist, technician or other authorized personnel. The Board notes that this term is already used in § 27.18(b)(1) (relating to standards of practice) in reference to prescribers and is not a new term. There are several means to identify a pharmacist other than initials, such as an employee number or name or by recording the information through biometrics, retina scans or bar code scans.

The HPLC commented that the Board should rewrite subsection (b)(4) so that the language clearly and accurately reflects the Board's policy. IRRC also commented that paragraph (4) was not clear. The regulation requires an audit trail to be established so that each pharmacist, technician or other authorized personnel who works on the automated medication system is identified. The Board has amended this subsection with language that clearly states that each pharmacist who works on the automated medication system will be held responsible for the transaction performed by that pharmacist. The pharmacist will also be responsible for transactions performed by personnel under the supervision of the pharmacist. Because the system has been validated, a final check of the filled prescription is unnecessary. That is, in a regular retail pharmacy situation, a pharmacist is required to check the filled prescription before it is dispensed. This pharmacist's initials are usually listed on the prescription label. The last sentence of paragraph (4) indicates that the Board will hold each pharmacist who worked with the automated medication system responsible for the pharmacist's actions and the actions of the technicians and other authorized personnel working under the pharmacist's supervision.

IRRC questioned whom the Board meant by "qualified support personnel" in subsection (d)(6). Cardinal Health also commented that subsection (d)(6) would limit access to an automated medication system to only pharmacists and qualified support personnel under the supervision of a licensed pharmacist and would prevent other healthcare professionals legally authorized to administer drugs from accessing the system. To clarify the issue expressed by Cardinal Health, the Board amended the definition of "automated medication system" in the final-form rulemaking to clarify that automated medication system does not refer to machines such as a unit based dispensing cabinet and amended the language of § 27.204(d)(6) to remove the term "qualified support personnel" and add the term "the pharmacist's designee" to allow the pharmacist operating the automated medication system greater latitude to designate who can access the system. The Board also notes in response to Cardinal Health's concerns that subsection (d)(7) specifically allows pharmacists to identify circumstances under which a licensed medical practitioner could remove medications from the automated medication system for distribution to a patient.

General Comments

The Department commented that the regulations might conflict with certain sections of the *Pennsylvania Code*. In particular, 28 Pa. Code § 25.53(b) (relating to prescription orders) requires prescribers to handwrite "brand necessary" or "brand medically necessary" and subsection (d) requires controlled substance prescriptions to be written in indelible ink, indelible pencil or typewriter. The Board notes that section 303 of the ETA (73 P. S. § 2260.303) would make these provisions unenforceable with regard to electronic prescriptions. The Department further commented that 28 Pa. Code § 25.56(a) and (b) (relating to prescription recordkeeping) requires prescription records of controlled substances in Schedules I and II to be maintained separately and controlled substances III—V to be marked with a red letter "C." Pharmacies still have

to comply with all applicable State and Federal regulations, so any pharmacy that stores prescription records on a computer will still have to adhere to this regulation. The Board's regulations do not supersede this requirement. The Board notes that when other laws or regulations prohibit the use of electronic prescriptions, these regulations would not apply. The Board urges the Department to update its regulations to take into consideration electronic prescriptions and computerized recordkeeping.

The PSHP asks whether the Board plans to reference the requirements of patient confidentiality contained in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. No. 104-191, 110 Stat. 1936) in these regulations. The Board does not intend to specifically reference HIPAA's confidentiality provisions. Confidentiality is already addressed in § 27.19(i) (relating to prospective drug review and patient counseling) and requires pharmacists to regard all information obtained as confidential unless State or Federal law or regulations require or authorize the disclosure.

The HPLC and IRRC requested that the Board consult the Department regarding its concerns before the final rulemaking was submitted. The Board has consulted with the Department and has addressed the Department's concerns in this preamble.

IRRC noted that several sections require compliance with "State and Federal laws and regulations" and commented that the Board should replace this language with specific citations to the applicable laws or regulations. The Board chose this language for two reasons: 1) several different State and Federal laws apply to the practice of pharmacy and it would be cumbersome to list each specific law and regulation; and 2) the specific area of law involving technology and automation is still evolving and there are regulations that have yet to be promulgated that would pertain to the Board's regulations. For example, the Federal Drug Enforcement Administration is in the process of promulgating Federal regulations pertaining to electronic prescribing of controlled substances. In other places in the Pharmacy Act (act) and regulations, there are general references to State and Federal laws. See section 8(11) of the act (63 P. S. § 390-8(11)) and §§ 27.14(b)(1) and (2), 27.18(p)(3) and 27.19(i)(2)(iii). References to adhering to State and Federal laws and regulations are common throughout the regulations of other pharmacy boards around the Nation. The Board is confident that its licensees are given appropriate guidance in the regulations as to what standards they must adhere to.

Statutory Authority

The final-form rulemaking is authorized under sections 4(j) and 6(k)(1) and (9) of the act (63 P. S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Fiscal Impact and Paperwork Requirements

The Board had identified no fiscal impact or paperwork requirements to State or local governments associated with the final rulemaking.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 8, 2004, the Board submitted a copy of the notice of proposed rulemaking, published at 34 Pa.B. 3146, 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 Department has considered all comments from IRRC, the HPLC and 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 April 4, 2006, the final-form rulemaking was approved by the HPLC. On April 18, 2006, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on April 19, 2006, and approved the final-form rulemaking.

Additional Information

Individuals who need information about the final-form rulemaking should contact Melanie Zimmerman, R.Ph., Executive Secretary, State Board of Pharmacy, P. O. Box 2649, Harrisburg, PA 17105-2649.

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) This final rulemaking is necessary and appropriate for the administration of the act.

(4) The amendments to this final-form rulemaking do not enlarge the original purpose of the proposed rulemaking published at 34 Pa.B. 3146.

Order

The Board orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 27, are amended by amending §§ 27.1, 27.14 and 27.16 and by adding §§ 27.201—27.204 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(*Editor's Note*: The amendment of § 27.16 was not included in the proposal at 35 Pa.B. 3146.)

(b) The Board shall submit this order and a copy of 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 shall deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

EDWARD J. BECHTEL, R.Ph.,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 36 Pa.B. 2251 (May 6, 2006).)

Fiscal Note: Fiscal Note 16A-5410 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:

* * * * *

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.

* * * * *

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.

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.

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.

* * * * *

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.

* * * * *

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.

* * * * *

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.

* * * * *

STANDARDS

§ 27.14. Supplies.

(a) A pharmacy shall maintain a supply of drugs and devices adequate to meet the needs of the health professions and the patients it is intended to serve. The applicant for a pharmacy permit shall show proof by affidavit that the applicant has ordered or possesses and shall continue to maintain an inventory of nonproprietary drugs, devices and equipment appropriate to the practice of that pharmacy. The inventory must include at least $5,000 worth of nonproprietary drugs and devices, at cost, from a licensed wholesaler or manufacturer. The inventory may not go below this figure at any time. A central processing center is not required to maintain $5,000 worth of nonproprietary drugs and devices under § 27.203(b) (relating to centralized prescription processing).

* * * * *

(c) Except for a pharmacy operating as a central processing center, a pharmacy shall maintain at least the following equipment and supplies:

* * * * *

(11) Prescription files for keeping prescriptions of nonproprietary drugs in accordance with the act and, for controlled substance prescriptions, State and Federal laws and regulations. The original prescription or image of the original prescription shall be retained for 2 years from the date of the most recent filling. A pharmacy may make use of a computerized recordkeeping system for keeping track of telephone prescriptions, refills, counseling, and the like in accordance with § 27.202 (relating to computerized recordkeeping systems).

* * * * *

(d) A pharmacy operating as a central processing center shall maintain equipment, supplies and access to a reference library recognized by the pharmacy community in this Commonwealth as meeting minimum standards of practice as a central processing center.

§ 27.16. Construction and equipment requirements.

* * * * *

(b) *Building standards*. The following apply to building standards:

(1) *Minimum size.*

(i) The minimum size of the prescription area must be at least 250 square feet, and shall be large enough, considering the level of activity, to carry on the practice of pharmacy in a manner that protects the health and safety of professionals, employees and the public. Within the prescription area, there must be a prescription working counter of at least 10 linear feet in length and 2 linear feet in width. If more than two pharmacists are on duty simultaneously, the minimum counter length shall be increased by 5 linear feet for an additional pharmacist. Institutions with special considerations may apply to the Board for a waiver.

(ii) A pharmacy operating as a central processing center need not conform to the minimum space requirements in subparagraph (i).

* * * * *

(5) *Sanitary facilities.* Except for pharmacies operating as central processing centers, pharmacies must be equipped with a sink within the prescription area to be used solely for pharmaceutical purposes. The sink must measure at least 200 square inches exclusive of drainboard area. The sink must be connected properly to supply hot and cold water. Restroom facilities for employees of the pharmacy shall be provided reasonably close to, but outside of the prescription area.

* * * * *

TECHNOLOGY AND AUTOMATION

§ 27.201. Electronically transmitted prescriptions.

(a) For the purposes of this section, an electronically transmitted prescription means the communication of an original prescription or refill authorization by electronic means, to include computer-to-computer, computer-to-facsimile machine or e-mail transmission which contains the same information it contained when the authorized prescriber transmitted it. The term does not include a prescription or refill authorization transmitted by telephone or facsimile machine.

(b) Except for Schedule II controlled substances which must conform to the requirements of § 27.18(b)(2) (relating to standards of practice), a pharmacist may accept an electronically transmitted prescription from an authorized licensed prescriber or an authorized designated agent which has been sent directly to a pharmacy of the patient's choice if all the following requirements are met:

(1) The prescription must contain the signature or the electronic equivalent of a signature of the prescriber made in accordance with the requirements of the Electronic Transactions Act (73 P. S. §§ 2260.101—2260.5101).

(2) The prescription must include the following information:

(i) The information that is required to be contained on a prescription under State and Federal law.

(ii) The prescriber's telephone number.

(iii) The date of the transmission.

(iv) The name of the pharmacy intended to receive the transmission.

(3) The prescription must be electronically encrypted or transmitted by other technological means designed to protect and prevent access, alteration, manipulation or use by any unauthorized person.

(4) A hard copy or a readily retrievable image of the prescription information that is transmitted shall be stored for at least 2 years from the date of the most recent filling.

(c) An electronically transmitted prescription shall be processed in accordance with the act and this chapter.

(d) The pharmacist and pharmacy may not provide electronic equipment to a prescriber for the purpose of transmitting prescriptions.

§ 27.202. Computerized recordkeeping systems.

(a) A computerized system used by a pharmacy for recording and maintaining information concerning prescriptions under State and Federal laws must be designed so that it is capable of providing immediate retrieval, by means of monitor, hard-copy printout or other transfer medium, of patient information for all prescriptions filled within the previous 12 months and retrieval within 3 working days of all prescriptions dispensed within the previous 24 months from the last activity date. This information must include the following data:

(1) The information required to be on prescriptions under § 27.18(b)(1) (relating to standards of practice).

(2) Identification of the pharmacist responsible for prescription information entered into the computer system.

(b) The system must be able to transfer all patient information to hard copy within 3 working days.

(c) Prescriptions entered into a computer system but not immediately dispensed must meet the following conditions:

(1) The complete prescription information must be entered in the computer system.

(2) The information must appear in the patient's profile.

(3) There must be positive identification, in the computer system or on the hard-copy prescription, of the pharmacist who is responsible for entry of the prescription information into the system.

(4) The original prescription shall be filed according to § 27.18(b).

(d) If the computerized recordkeeping system experiences down time, the prescription information shall be entered into the computerized recordkeeping system as soon as it is available for use.

(e) The system must have adequate safeguards to:

(1) Prevent access by any person who is not authorized to obtain information from the system.

(2) Identify any modification or manipulation of information concerning a prescription.

(3) Prevent accidental erasure of information.

§ 27.203. Centralized prescription processing.

(a) *Centralized prescription processing.* A central fill pharmacy or central processing center may fulfill a request for the processing, filling or refilling of a prescription from either the originating pharmacy or from the patient or the prescriber and may deliver the processed, filled or refilled prescription to a delivering pharmacy if the following requirements are met:

(1) The central fill pharmacy or the central processing center that is to process, fill or refill the prescription has a contract with or has the same owner as the originating pharmacy and the delivering pharmacy. Contractual provisions must include confidentiality of patient information.

(2) The prescription container:

(i) Is clearly labeled with the information required by Federal and State laws and regulations.

(ii) Clearly shows the name, address, telephone number and DEA number of the delivering pharmacy.

(3) Pharmacies that either utilize or act as central fill pharmacies or central processing centers shall create operating policies and procedures. The policies and procedures must include an audit trail that records and documents the central prescription process and the individuals accountable at each step in the process for complying with Federal and State laws and regulations including recordkeeping.

(4) Pharmacies that engage in centralized prescription processing share a common electronic file.

(5) Each pharmacy engaging in centralized prescription processing shall be jointly responsible for properly filling the prescription.

(6) The delivering pharmacy is responsible for making the offer to counsel to the patient under § 27.19(e) (relating to prospective drug review and patient counseling).

(b) *Exemptions*. The central processing center is exempt from:

(1) The requirement of maintaining an inventory of at least $5,000 worth of nonproprietary drugs and devices under § 27.14(a) (relating to supplies).

(2) The minimum size requirements of § 27.16(b)(1) (relating to construction and equipment requirements).

(3) The requirement to have a sink used solely for pharmaceutical purposes under § 27.16(b)(5).

§ 27.204. Automated medication systems.

(a) This section establishes standards applicable to licensed pharmacies that utilize automated medication systems which may be used to store, package, dispense or distribute prescriptions.

(b) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that:

(1) The pharmacist manager, or the pharmacist under contract with a long-term care facility responsible for the dispensing of medications if an automated medication system is utilized at a location which does not have a pharmacy onsite, is responsible for the supervision of the operation of the system.

(2) The automated medication system has been tested and validated by the pharmacy and found to dispense accurately prior to the implementation of the system. The pharmacy shall make the results of the testing available to the Board upon request.

(3) The pharmacy shall make the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the system.

(4) The automated medication system must electronically record the activity of each pharmacist, technician or other authorized personnel with the time, date and initials or other identifier so that a clear, readily retrievable audit trail is established. A pharmacist will be held responsible for transactions performed by that pharmacist or under the supervision of that pharmacist.

(c) The pharmacist manager or the pharmacist under contract with a long-term care facility responsible for the delivery of medications shall be responsible for the following:

(1) Reviewing and approving all policies and procedures for system operation, safety, security, accuracy, access and patient confidentiality.

(2) Ensuring that medications in the automated medication system are inspected, at least monthly, for expiration date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least monthly, for security and accountability.

(3) Assigning, discontinuing or changing personnel access to the automated medication system.

(4) Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation.

(5) Ensuring compliance with the applicable provisions of State and Federal law.

(d) When an automated medication system is used to fill prescriptions or medication orders, it shall be operated according to written policies and procedures of operation created or adopted by the pharmacy. The policies and procedures of operation must:

(1) Include a table of contents.

(2) Include a description of all procedures of operation.

(3) Set forth methods that ensure retention of each amendment, addition, deletion or other change to the policies and procedures of operation for at least 2 years after the change is made. Each change shall be signed or initialed by the registered pharmacist manager and include the date on which the registered pharmacist manager approved the change.

(4) Set forth methods that ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made.

(5) Set forth methods that ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records.

(6) Set forth methods that ensure that access to the automated medication system for stocking and removal of medications is limited to licensed pharmacists or the pharmacist's designee acting under the supervision of a licensed pharmacist. An accountability record which documents all transactions relative to stocking and removing medications from the automated medication system must be maintained.

(7) Identify the circumstances under which medications may be removed from the automated medication system by a licensed medical practitioner for distribution to a patient without prior order review by a licensed pharmacist.

(e) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall, at least annually, review its written policies and procedures of operation and revise them, if necessary.

(f) A copy of the written policies and procedures of operation adopted under this section shall be retained at the pharmacy and at the long-term care facility where the automated medication system is utilized. Upon request, the pharmacy shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

(g) The pharmacist manager shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all licensed practitioners and supportive personnel are trained in the pharmacy's standard operating procedures with regard to automated medication systems set forth in the written policies and procedures. The training shall be documented and available for inspection.

(h) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall create and operate according to a written program for quality assurance of the automated medication system which:

(1) Requires monitoring of the automated medication system.

(2) Establishes mechanisms and procedures to test the accuracy of the automated medication system at least every 6 months and whenever any upgrade or change is made to the system.

(3) Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least 2 years. Upon reasonable notice from the Board, the pharmacy shall provide information to the Board regarding the quality assurance program for automated medication systems.

(i) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster that interrupts the ability of the pharmacy to provide services. The written plan for recovery must include:

(1) Planning and preparation for a disaster.

(2) Procedures for response to a disaster.

(3) Procedures for the maintenance and testing of the written plan for recovery.

(j) A pharmacy that uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system. Documentation of completion of all maintenance shall be kept on file in the pharmacy for at least 2 years.

[Pa.B. Doc. No. 06-929. Filed for public inspection May 26, 2006, 9:00 a.m.]

Title 61—REVENUE

DEPARTMENT OF REVENUE

[61 PA. CODE CHS. 31, 46 AND 60]

Sales and Use Tax; Prebuilt Housing

The Department of Revenue (Department), under section 270 of the Tax Reform Code of 1971 (TRC) (72 P. S. § 7270), deletes §§ 31.30, 46.8 and 61.18 and adds § 31.33 (relating to prebuilt housing) to read as set forth in Annex A.

Purpose of this Final-Form Rulemaking

This final-form rulemaking codifies legislative changes regarding prebuilt housing in sections 201(g)(8) and (vv)—(zz), 202(f) and 204(60) of the TRC (72 P. S. §§ 7201(g)(8) and (vv)—(zz), 7202(f) and 7204(60)).

Explanation of Regulatory Requirements

The Department is adding § 31.33 to set forth the new rules regarding prebuilt housing. Definitions for use in the section are in subsection (a). Imposition rules for sales by a builder and trade-ins are in subsection (b).

Consistent with section 202(f) of the TRC, which provides that a manufacturer may elect to precollect the tax from the builder at the time of sale to the builder, subsection (c) describes the provisions that govern precollection. Subsection (d) explains that no exemptions apply to the sale of prebuilt housing.

Subsection (e) explains that the provisions of this regulation do not apply to the sale and installation of prefabricated buildings, components and accessories which do not qualify as prebuilt housing and are governed by § 31.12 (relating to imposition of tax). Similarly, subsection (f) explains that the regulation does not apply to the repair and maintenance of prebuilt housing and the rules of § 31.12 apply.

In addition, the Department has made editorial changes to several sentences for proper grammar usage. Upon adoption of § 31.33, provisions inconsistent with this section (§§ 31.30, 46.8 and 60.18) will be deleted.

Affected Parties

Manufacturers, builders and purchasers of prebuilt housing may be affected by this final-form rulemaking.

Comment and Response Summary

Notice of proposed rulemaking was published at 34 Pa.B. 6245 (November 20, 2004). This proposed rulemaking is being adopted with amendments to read as set forth in Annex A.

The Department received no comments from the public during the public comment period. No comments were received from either the House Finance Committee or the Senate Finance Committee. The only comments received on the proposed rulemaking were from the Independent Regulatory Review Commission (IRRC).

Explanations and amendments to the proposed rulemaking in response to IRRC's comments are as follows:

(1) *§ 31.33(a) (regarding definitions).* IRRC requested the following six definitions be amended to mirror the statutory definitions, replace the regulatory definitions with citations to the statute or explain the need to vary from the statute:

Prebuilt housing—The Department enhanced the statutory definition in section 201 of the TRC to provide taxpayers with additional information. Therefore, § 31.33(a)(iii) was added to the statutory definition for clarification and remains in the final-form rulemaking.

Prebuilt housing builder—The Department clarified the statutory definition in section 201 of the TRC by adding "including a prebuilt housing manufacturer" to the definition. The Department believes that the taxpayers will benefit from this enhanced definition. Therefore, the same definition remains in the final-form rulemaking.

Prebuilt housing purchaser—The Department agrees with IRRC's concern and has amended the definition by deleting the entire second sentence. This sentence has now been correctly relocated to the definition of "prebuilt housing sale."

Prebuilt housing sale—The Department agrees with IRRC's concern and has added the following sentence which was previously in the definition of "prebuilt housing purchaser:" "Temporary installation by a prebuilt housing builder for display purposes of a unit held for resale will not be considered occupancy for residential purposes." This definition mirrors the statutory definition in section 201 of the TRC and should appear in the final-form rulemaking for the convenience of taxpayers.

Purchase price—Section 201(g)(8) of the TRC defines the "purchase price" of prebuilt housing to be 60% of the manufacturer's selling prices. However, section 201(g)(8) of the TRC provides that a manufacturer has the option of precollecting the Sales Tax on 60% of the selling price, or 100% of the actual cost of the supplies and materials used in the manufacture of the housing. The TRC does not require a manufacturer to choose only one of those options, to the permanent exclusion of the other, as the regulation does. This restriction was added to the regulation at the request of the Department's Bureau of Audits (Bureau). The Bureau determined that if a manufacturer

was allowed to choose a different method of collecting tax for each customer, it would make auditing that manufacturer's books almost impossible. The Department firmly believes taxpayers will benefit from the definition.

Used prebuilt housing—The Department clarified the statutory definition in section 201 of the TRC by adding "prebuilt housing" to modify the word "sale," as the defined term is "prebuilt housing sale." The enhanced definition has not been changed in the final-form rulemaking because the Department believes it is necessary to provide clarity to the taxpayers.

(2) *§ 31.33(c) (regarding prebuilt housing manufacturer's election to collect tax).*

Paragraph (2)—IRRC requested an explanation of the rationale for and need to restrict the method to collect tax under this circumstance. Section 201(g)(8) of the TRC provides the option only when the manufacturer precollects tax from a builder. The TRC does not provide the same option when a manufacturer that is acting as a builder pays tax to the Department at the time of sales to purchasers.

Paragraph (3)—IRRC requested an explanation of how a manufacturer would request "prior authorization" to alternate between two methods of calculation and what criteria the manufacturer would have to satisfy. The Department agrees this needs clarification and has consulted with the director of the Bureau. At the request of the Bureau to provide efficient auditing procedures, the proposed language "prior authorization" has been replaced in the final-form rulemaking with "written notification to the director of the Department's Bureau of Audits."

(3) *Miscellaneous clarity issues*

(a) In § 31.33(a), IRRC stated the definition of "prebuilt housing manufacturer" lacks clarity because the definition uses the same words as the term being defined. The Department agrees and amended the definition in the final-form rulemaking.

(b) In § 31.33(b)(1), the Department added clarification language to the final-form rulemaking for auditing purposes.

(c) IRRC commented that the opening sentence of § 31.33(c)(1) uses the phrase "the law" twice. The Department acknowledges the concern and replaced "the law" with the appropriate citation to § 31.12 at the beginning of the sentence.

(d) IRRC commented that the opening sentence of § 31.33(e) discusses the changes in the law and is not needed. The Department agrees with IRRC's comment and has deleted the referenced sentence that discusses the changes in the law.

(e) A broader cross reference was requested by IRRC in § 31.33(e) and (f) instead of the language "governed by § 31.11" which is a reference to a definition section. The Department agrees with the concern and changed the cross reference to § 31.12.

Fiscal Impact

The Department has determined that the final-form rulemaking will have minimal fiscal impact on the Commonwealth.

Paperwork

The final-form rulemaking will not create additional paperwork for the public or the Commonwealth.

Effectiveness/Sunset Date

The final-form rulemaking will become effective upon publication in the *Pennsylvania Bulletin*. The regulation is scheduled for review within 5 years of publication. No sunset date has been assigned.

Contact Person

The contact person for an explanation of the final-form rulemaking is Mary R. Sprunk, Office of Chief Counsel, Department of Revenue, Dept. 281061, Harrisburg, PA 17128-1061.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on November 4, 2004, the Department submitted a copy of the notice of proposed rulemaking, published at 34 Pa.B. 6245, to IRRC and the Chairpersons of the House Committee on Finance and the Senate Committee on Finance for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the 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 May 3, 2006, 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 May 4, 2006, and approved the final-form rulemaking.

Findings

The Department finds that:

(1) Public notice of intention to amend the regulations has been duly 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 the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) The amendments are necessary and appropriate for the administration and enforcement of the authorizing statute.

Order

The Department, acting under the authorizing statute, orders that:

(a) The regulations of the Department, 61 Pa. Code Chapters 31, 46 and 60, are amended by adding § 31.33 and deleting §§ 31.30, 46.8 and 60.18 to read as set forth in Annex A.

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

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

(d) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

GREGORY C. FAJT,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 36 Pa.B. 2479 (May 20, 2006).)

Fiscal Note: Fiscal Note 15-426 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 61. REVENUE

PART I. DEPARTMENT OF REVENUE

Subpart B. GENERAL FUND REVENUES

ARTICLE II. SALES AND USE TAX

CHAPTER 31. IMPOSITION

SPECIALIZED TYPES OF BUSINESS OR PROPERTY

§ 31.30. (Reserved).

§ 31.33. Prebuilt housing.

(a) *Definitions*. The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

Prebuilt housing—Housing which qualifies either as:

(i) Manufactured housing, including mobile homes, which bears the label required by and referred to in the Manufactured Housing Construction and Safety Standards Authorization Act (35 P. S. §§ 1656.1—1656.9).

(ii) Industrialized housing as defined in the Industrialized Housing Act (35 P. S. §§ 1651.1—1651.12).

(iii) The term includes all components or accessories transferred at the time of the sale of the prebuilt housing.

Prebuilt housing builder—A person, including a prebuilt housing manufacturer, that makes a prebuilt housing sale to a prebuilt housing purchaser.

Prebuilt housing manufacturer—A person who manufactures prebuilt housing for sale to a prebuilt housing builder or prebuilt housing purchaser.

Prebuilt housing manufacturer's selling price—

(i) The total value of anything paid or delivered or promised to be paid or delivered, whether it be money or otherwise, by a prebuilt housing builder to a prebuilt housing manufacturer, for prebuilt housing, add-ons, insurance, seals, deposits, dues, optional equipment and similar charges whether or not the charges are separately stated on one or more purchase agreements.

(ii) The prebuilt housing manufacturer's selling price does not include amounts representing delivery charges, erection charges or set-up fees.

Prebuilt housing purchaser—A person who purchases prebuilt housing in a transaction and who intends to occupy the unit for residential purposes in this Commonwealth.

Prebuilt housing sale—A sale of prebuilt housing to a prebuilt housing purchaser, including a sale to a landlord, without regard to whether the person making the sale is responsible for installing the prebuilt housing or whether the prebuilt housing becomes real estate on installation. Temporary installation by a prebuilt housing builder for display purposes of a unit held for resale will not be considered occupancy for residential purposes.

Purchase price—The purchase price of prebuilt housing shall be 60% of the prebuilt housing manufacturer's selling price. A prebuilt housing manufacturer of prebuilt housing that elects to precollect tax from the prebuilt housing builder shall have the option to collect tax on 60% of the prebuilt housing manufacturer's selling price or on 100% of the actual cost of the supplies and materials used in the manufacture of prebuilt housing.

Used prebuilt housing—Prebuilt housing that was previously subject to a prebuilt housing sale to a prebuilt housing purchaser.

(b) *Imposition of tax.*

(1) *Prebuilt housing builder sales.* A prebuilt housing builder is required to pay tax on his purchase price of prebuilt housing sold to a prebuilt housing purchaser within this Commonwealth, if the prebuilt housing builder has not paid the applicable tax to the prebuilt housing manufacturer. The prebuilt housing builder is required to pay tax without regard to whether the prebuilt housing is sold as tangible personal property or as real estate. The prebuilt housing builder's written contract with the prebuilt housing purchaser shall clearly indicate that the prebuilt housing builder paid applicable tax.

(2) *Trade-in.* The value of a trade-in by a prebuilt housing purchaser to a prebuilt housing builder in connection with the purchase of housing may not be used to reduce the purchase price on which the prebuilt housing builder is required to pay tax.

(3) *Used prebuilt housing.* Sales Tax is not imposed on the purchase price of used prebuilt housing.

(c) *Prebuilt housing manufacturer's election to collect tax.*

(1) Although section 202(f) of the TRC (72 P. S. § 7202(f)) requires the prebuilt housing builder to pay tax directly to the Department, this statute also provides that the prebuilt housing manufacturer has the option to collect tax from the prebuilt housing builder at the time of the purchase of the prebuilt housing by the prebuilt housing builder from the prebuilt housing manufacturer. If the prebuilt housing manufacturer elects to collect tax, the prebuilt housing manufacturer is required to use either of the following to establish the purchase price:

(i) Sixty percent of the prebuilt housing manufacturer's selling price.

(ii) One hundred percent of the actual cost of the supplies and materials used in the manufacture of prebuilt housing.

(2) If a prebuilt housing manufacturer is also acting as a prebuilt housing builder, the purchase price of the prebuilt housing shall be 60% of the prebuilt housing manufacturer's selling price.

(3) A prebuilt housing manufacturer is not permitted to alternate between these two methods of calculation without prior written notification to the Director of the Department's Bureau of Audits.

(d) *Exemptions.* No exemptions apply to the sale of prebuilt housing. Prebuilt housing manufacturers are therefore not required to obtain exemption certificates from prebuilt housing builders. Unless the prebuilt housing manufacturer elects to precollect the tax, the prebuilt housing builder is obligated to remit tax to the Commonwealth on its sale of prebuilt housing to a prebuilt housing purchaser.

(e) *Prefabricated buildings and components which do not qualify as prebuilt housing.* The sale and installation of prefabricated buildings, components and accessories which do not qualify as prebuilt housing are governed by § 31.12 (relating to imposition of tax). Sales of prefabricated buildings, components and accessories, which do not include installation, qualify as sales of tangible personal property. Examples include construction site trailers, travel trailers and modular space units.

(f) *Repair and maintenance of prebuilt housing.* This section relates only to prebuilt housing sales and does not apply to the repair and maintenance of prebuilt housing. The application of tax on charges made for the repair and maintenance of prebuilt housing is governed by the provisions of § 31.12.

CHAPTER 46. CONSTRUCTION CONTRACTORS

§ 46.8. (Reserved).

CHAPTER 60. SALES AND USE TAX PRONOUNCEMENTS—STATEMENTS OF POLICY

§ 60.18. (Reserved).

[Pa.B. Doc. No. 06-930. Filed for public inspection May 26, 2006, 9:00 a.m.]