Regulatory An Form	alysi	203 OCT -8 AM 10: 33 INC REVIEW COMMISSION
(1) Agency		REVIEW COHMISSION
Department of State, Bureau of Profess Affairs, State Board of Nursing	sional and O	cupational
(2) I.D. Number (Governor's Office	Use)	
16A-5115		IRRC Number: 223/
(3) Short Title		
Oral Orders		
(4) PA Code Cite	(5) Agency Contacts & Telephone Numbers Primary Contact: Martha H. Brown, Counsel,	
49 Pa. Code, Chapter 21 Sections 21.14, 21.141 and 21.145	783-7200 Secondary Contact: Joyce McKeever, Deputy Chief Counsel, 783-7200	
(6) Type of Rulemaking (check one)		(7) Is a 120-Day Emergency Certification Attached?
Proposed Rulemakingx Final Order Adopting Regulationx NFinal Order, Proposed Rulemaking OmittedY		x No Yes: By the Attorney General Yes: By the Governor
practical nurse (LPN) to accept an oral situation. The regulation also updates administration of drugs by professional medications to RNs only and limits the	le § 21.145 order from a and clarifies nurses (RNs e ability of as	technical language. To remove the restriction on the ability of a licensed licensed practitioner in other than an urgent medical the language of 49 Pa. Code § 21.14, relating to the , which currently appears to limit the administration of RN to accept orders from a practitioner other than a is amending § 21.141 to define the term "oral order."

Section 2.1(k) of the Professional Nursing Law, Act of May 22, 1951, P.L. 317, <u>as amended</u>, 63 P.S. §212.1(k), and Section 17.6 of the Practical Nurse Law, Act of March 2, 1956, P.L. 1211, <u>as amended</u>, 63 P.S. §667.6, authorize the Board to establish rules and regulations for the practice of professional and practical nursing.

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

These regulations are not mandated by federal or state law, court order or federal regulations.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The public has an interest in expedient, safe and competent nursing care. The amendment to the regulations would remove unnecessary restrictions on LPNs accepting oral orders and require the nurse to exercise professional judgment when accepting written or oral orders and in making a proper record of the order in the patient's medical record.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

Nonregulation would affect the public health and safety in that there would be a lack of standards to which nurses should adhere when accepting an oral order for medication or a medical regimen, which may put patients at risk of receiving inappropriate medication or dosage of medication.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

These proposed amendments would benefit consumers of nursing services. With regard to oral orders, nurses are the major caregivers in executing medical regimens prescribed or ordered for patients. These regulations would affect patients in all settings where a nurse executes an order. The settings include nursing homes, hospitals and home care. Patients will benefit from the regulations allowing the LPN to accept an oral order by reducing the delay in administering medications. Because LPNs practice in a number of healthcare settings, it is not possible to quantify the number of patients. The Board expects that this regulation will have the most beneficial effect for consumers in long term care settings, where LPNs are often employed.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

The Board is not aware of any person or groups who would be adversely affected by the regulations.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

All nurse licensees of the Board, RNs and LPNs, will be required to comply with the regulations. There are approximately 196,030 RNs and 50,176 LPNs who possess current nursing licenses.

(16) Describe the communications with and input from the public in the development and drafting of he regulation. List the persons and/or groups who were involved, if applicable.

Notice of proposed rulemaking was published at 31 Pa.B. 6544-6546 (December 1, 2001). Publication was followed by a 30-day public comment period, during which the Board received comments from 76 public commentators. The House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) submitted comments. The Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) did not comment.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

It is not possible to provide a specific estimate of the costs or savings to the regulated community associated with complying with these regulations. Some savings may be expected from the removal of restrictions on LPNs to accept oral orders. Any savings would indirectly benefit the regulated community. Compliance should not involve any legal, accounting, or consulting procedures.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

Local government entities such as counties that provide health care services and employ nurses could realize an indirect savings. Because any such savings would be indirect, it is not possible to provide a specific estimate. This rulemaking will not involve any legal, accounting or consulting procedures.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

The Department and the State Board of Nursing will incur no costs to implement this regulation.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Y ea r	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$N/A	\$N/A	\$N/A	\$N/A	\$N/A	\$N/A
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:	N/A	N/A	N/A	N/A	N/A	N/A
Regulated Community						
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:	N/A	N/A	N/A	N/A	N/A	N/A
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	1					

(20a) Explain how the cost estimates listed above were derived.

See paragraphs (17)-(19) above.

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(20b) Provide the past three-year expenditure history for programs affected by the regulation. FY-3 FY-2 FY-1 Budgeted for Program current FY 1998-1999 1999-2000 2000-2001 2001-2002 State Board of \$3,922,622.16 \$4,514,839.67 \$4,182,833.18 \$4,827,000.00 Nursing

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

No costs or adverse effects are anticipated to result from the regulations.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

The Board considered adopting a statement of policy or guidelines. These alternatives would not establish a standard of practice which would be required of all LPNs. Inasmuch as the standard is designed to ensure safe nursing care, these nonregulatory alternatives were rejected as acceptable alternatives.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No other regulatory schemes were considered because the Board's statutory authority is limited to establishing standards for nursing practice.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

The Board is not aware of any federal standards that relate to the issues addressed in this rulemaking.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This rulemaking is consistent with the regulations and policies of other states and will not put Pennsylvania at a competitive disadvantage with other states. Of the six states surrounding the Commonwealth of Pennsylvania, Delaware, Maryland, New York, Ohio, and West Virginia permit LPNs to accept oral or verbal orders, with varying degrees of restrictions from the health care facilities in which LPNs may be employed. New Jersey, whose regulations do not currently address the issue, has been considering draft rulemaking which would explicitly permit LPNs to accept verbal orders.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

Yes. These regulations bring the nursing regulations into harmony with Department of Health and Department of Public Welfare regulations. See 28 Pa. Code § 107.62 (relating to oral orders at general and special hospitals); 28 Pa. Code § 211.3 (relating to oral and telephone orders at long term care facilities); 28 Pa. Code § 555.12 (relating to oral orders at ambulatory surgical facilities); and 55 Pa. Code § 1249.52 (relating to Medical Assistance reimbursement for home health agency services).

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

The Board holds monthly public meetings at which information relative to all rulemaking is discussed. Meetings are held in the Board's offices at 2601North Third Street, Harrisburg, Pennsylvania. A schedule of Board meeting dates is available from the Board Administrator at 783-7142 and on the Department of State's website at <u>www.dos.state.pa.us/bpoa</u>.

	Regulatory Analysis Form
requirements? De	lation change existing reporting, record keeping, or other paperwork scribe the changes and attach copies of forms or reports which will be required ementation, if available.
No.	
	y special provisions which have been developed to meet the particular needs of persons including, but not limited to, minorities, elderly, small businesses, and
	rsons with particular needs will be adversely affected by the proposed amendments, nor
does the Board anti these regulations.	cipate that any subset of nurses have any particular needs which must be addressed in
these regulations.	
	nticipated effective date of the regulation; the date by which compliance with be required; and the date by which any required permits, licenses or other obtained?
The regulation v	vill be effective upon publication of final rulemaking in the <u>Pennsylvania Bulletin</u> .
-	
(31) Provide the s	chedule for continual review of the regulation.
	tinuously reviews its regulations, periodically communicates with licensees through stains information and feedback from its licensees. The Board will evaluate the
effectiveness of the	proposed amendments following their adoption as final rulemaking.

PROPOSED RULEMAKING

STATE BOARD OF NURSING

[49 PA. CODE CH. 21]

Oral Orders

The State Board of Nursing (Board) proposes to amend §§ 21.14 and 21.145 (relating to administration of drugs; and functions of the LPN) to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

The Board is authorized to establish rules and regulations for the practice of professional and practical nursing under section 2.1(k) of the Professional Nursing Law (63 P. S. § 212.1(k)) and section 17.6 of the Practical Nurse Law (63 P. S. § 667.6).

C. Background and Purpose

The proposed amendments originated in the Board's review of its regulations under Executive Order 1996-1, which directs executive agencies to evaluate existing regulations and amend and repeal regulations as necessary to comply with the order, and in response to requests from the regulated community. The proposed amendments were generated by a request from the Pennsylvania Health Care Association (PHCA) which suggested that the Board consider removing language in § 21.145 which prohibits a licensed practical nurse (LPN) from accepting an oral order except in urgent circumstances. In accordance with the Executive Order, a draft of the proposed amendments was sent on December 12, 2000, to 27 agencies, associations, health care entities and individuals who have been identified as interested parties or who have expressed an interest in the proposed amendments. The Board reviewed these comments at its meeting of February 9, 2001.

The Board seeks to remove the prohibition in § 21.145(b) against an LPN accepting an oral order except in urgent circumstances, which the Board now regards as unnecessary and burdensome. The Board also seeks to update and clarify the language of § 21.14, which currently appears to limit the administration of medications to registered nurses (RN) only and limits the ability of an RN to accept orders from a practitioner other than a licensed doctor of the healing arts.

D. Description of Proposed Amendments

The proposed amendments would make changes to two sections of the existing regulations.

§ 21.14. Administration of drugs.

The current language of this section states that the administration of drugs is a function performed by an RN and may not be performed by anyone other than an RN and a nursing student or a graduate nurse supervised by an RN. The current language is unduly restrictive and appears to limit administration of drugs to RNs only, when, in fact, LPNs may also administer medications in accordance with \S 21.145(b).

The Board also recognizes that other licensed health care practitioners are permitted to administer medications under law and proposes to amend the language of § 21.14(a) accordingly. Therefore, the proposed amendments would also remove reference to "a licensed doctor of the healing arts" as the sole prescribers of drugs, to reflect the Board's desire that RNs and LPNs be permitted to accept orders from other practitioners with prescriptive authority who are not licensed doctors. These practitioners include certified registered nurse practitioners who prescribe medical, therapeutic or corrective measures in collaboration with and under the direction of a physician (see 63 P. S. §§ 212 and 422.15(b) and 49 Pa. Code §§ 18.21 and 21.251 (relating to definitions)), and physician assistants who prescribe and dispense drugs at the direction of a physician (see 63 P. S. § 422.13(f) and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs)).

§ 21.145(b). Oral orders and the LPN.

PHCA, an organization representing more than 280 Commonwealth long-term care facilities, by letter of September 22, 1994, requested the Board to reconsider § 21.145(b). The Pennsylvania Medical Directors Association (PMDA), an organization of long-term care physicians, by letter of October 11, 1994, supported the PHCA request and recommended that the Board remove any restriction that limits the authority of an LPN to receive an oral order. These organizations maintained that removing the restriction would enhance quality of care and eliminate delays in getting medication to a patient. PMDA maintained that the current practice in long-term care facilities was for LPNs to receive oral orders.

The Board concurs in the need for regulatory relief with regard to the language of § 21.145. The Board notes that in long-term care facilities with a census of 59 years of age and under, an LPN may be the only licensed nurse on the premises during night shifts. See 28 Pa. Code § 211.12(f)(1) (relating to nursing services). The prohibition against an LPN receiving an oral order when the LPN is the only nurse on the premises delays treatment. Even if an RN is on the premises, the RN may not be immediately available to receive the oral or telephone order and there will be a delay in treatment. These delays cannot benefit the patient.

Current regulations pertaining to long-term care facilities and general and special hospitals permit both RNs and LPNs to receive oral orders in varying circumstances. Regulations of the Department of Health pertaining to long-term care facilities authorize "a registered nurse, physician or other individual authorized by appropriate statutes and the State Boards in the Bureau of Professional and Occupational Affairs" (regardless of whether the circumstances are urgent) to receive a telephone or oral order for medication from a physician. See 28 Pa. Code § 211.3(a) (relating to oral and telephone orders). Regulations pertaining to general and special hos-pitals authorize both an RN and LPN to accept an oral order for medication or treatment "under urgent circumstances when it is impractical for the orders to be given in written manner by the responsible practitioner,' and the medical staff bylaws specify the RN or LPN as personnel qualified to accept the oral order. See 28 Pa. Code § 107.62 (relating to oral orders). Regulations pertaining to ambulatory surgical facilities authorize "personnel qualified by their professional license or certification issued by the Commonwealth and according to

medical staff bylaws or rules" to accept oral orders "under urgent circumstances when it is impractical for the orders to be given in written manner by the responsible practitioner." See 28 Pa. Code § 555.12 (relating to oral orders).

The Board does not encourage the use of oral orders, but wishes to remove unnecessary restrictions which may delay delivery of safe health care. To ensure that only an adequately instructed LPN will receive oral orders and make clear that the Board does not encourage any type of facility to unnecessarily broaden its use of oral orders, the Board proposes to add the requirements of § 21.145(b)(2)(ii)-(iv) so that an LPN may accept an oral order only if the LPN has been instructed in accepting oral orders in an educational program or in accordance with the policies and protocols of the facility and the policy of the facility and the regulations governing the facility permit an LPN to accept oral orders.

In October and November 1997, the Board solicited input from practical nursing education programs to determine the extent of LPN education in the area of pharmacology and the taking of oral orders. The Board found that practical nursing education programs in this Commonwealth gave instruction in pharmacology to practical nursing students which was the same as or similar to that received by professional nursing students. The instruction received by practical nursing students includes dose calculation, drug classification and usage and drug information sources; drug administration; and critical thinking. Pharmacology is taught both as a separate subject and is integrated into other academic and clinical subjects. The Board concluded that LPNs currently receive adequate instruction in pharmacology and critical thinking skills to render the prohibition against the receipt of oral orders other than in urgent circumstances outdated and a barrier to the delivery of safe, timely health care.

The proposed amendment to § 21.145(b)(3) also would require an LPN to question any order which is not clear or perceived as unsafe or contraindicated and take action in accordance with standards of practice and consistent with the protocols or policies of the facility. The purpose of this provision is to put licensees on notice that a nurse has a duty to attempt to resolve situations in which the nurse receives an apparently unclear, unsafe or contraindicated order, whether oral or written. In requiring an LPN to question unclear orders, the Board does not propose to grant the LPN a right, but rather would be codifying a professional obligation in the interest of patient safety. The obligation would not go beyond good nursing practice.

The Board declines to propose a single specific procedure for questioning an apparently unclear order. The particular situation itself may determine how an apparently unclear order might be clarified. Sometimes it might be necessary to contact the practitioner who issued the order. Sometimes an RN, director of nursing, pharmacist or other responsible health care practitioner might be able to resolve the situation. A facility may well have a protocol or policy which reflects its own structure or needs.

Nothing in this section suggests that anyone other than a physician will make the ultimate determination of whether an order is appropriate. It is the experience of the professional members of the Board that questions regarding orders can almost always be answered to the satisfaction of all parties, including the physician and nurse.

E. Fiscal Impact and Paperwork Requirements.

The proposed amendments will have no fiscal impact and will not impose additional paperwork on the private sector, the general public or the Commonwealth and its political subdivisions.

F. Sunset Date

The Board continuously monitors its regulations. Therefore, no sunset date has been assigned.

G. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on November 14, 2001, the Board submitted a copy of this proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. In addition to submitting the proposed rulemaking, the Board has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Board in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has objections to any portion of the proposed rulemaking, it will notify the Board within 10 days of the close of the Committees' review period. The notification shall specify the regulatory review criteria that have not been met by the portion of the proposed rulemaking to which an objection is made. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of objections raised.

H. Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed amendments to Martha Brown, Counsel, State Board of Nursing, P.O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication of the proposed amendments in the Pennsylvania Bulletin. Reference (16A-5115) Oral Orders when submitting comments.

> K. STEPHEN ANDERSON, CRNA Chairperson

Fiscal Note: 16A-5115. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 21. STATE BOARD OF NURSING

Subchapter A. REGISTERED NURSES

RESPONSIBILITIES OF THE REGISTERED NURSE § 21.14. Administration of drugs.

(a) Administering to a patient a drug ordered for that patient by a licensed doctor of the healing arts in the dosage prescribed is a procedure regulated by this section, and the function may not be performed by a person other than a licensed registered nurse, except that a licensed registered nurse, responsible for administering a drug, may supervise a nursing student in an approved pro-

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gram and a graduate nurse.] A licensed registered nurse or a licensed practical nurse who is acting in accordance with § 21.145(b) (relating to functions of the LPN) may administer a drug ordered for a patient in the dosage and manner prescribed.

(b) A licensed registered nurse, responsible for administering a drug, may supervise a graduate nurse or a nursing student in an approved nursing education program in the administration of the drug. In this section, ["supervision"] "supervise" means the licensed registered nurse is physically present in the area or unit where the student or unlicensed graduate is practicing. This definition [of "supervision"] is not intended to limit in any way the practice of practical nursing as defined in the Practical Nurse Law (63 P. S. §§ 651-667).

Subchapter B. PRACTICAL NURSES GENERAL PROVISIONS

§ 21.145. Functions of the LPN.

* * * *

(b) The LPN administers medication and carries out the therapeutic treatment prescribed or ordered for the patient in accordance with the following:

(1) The LPN [shall] may accept [only] a written [prescriptions] prescription or [orders] order for medication and therapeutic treatment from [the responsible] a practitioner [for medication and therapeutic treatment unless the urgency of the medical circumstances requires immediate medication or therapeutic treatment.] authorized by law and by facility policy to issue orders for medical and therapeutic measures.

(2) The LPN may [not] accept an oral prescription or order if the following conditions are met:

(i) The practitioner issuing the oral order is authorized by law and by facility policy to issue oral orders for medical and therapeutic measures.

(ii) The LPN has received instruction and training in accepting an oral prescription or order in an approved nursing education program or has received instruction and training in accepting an oral prescription or order in accordance with the established policies and protocols of the facility.

(iii) The policy of the facility permits an LPN to accept an oral prescription or order.

(iv) The regulations governing the facility permit an LPN to accept an oral prescription or order.

(3) The LPN shall question any prescription or order which is perceived as unsafe or contraindicated for the patient or which is not clear. If a prescription or order appears to be unclear, unsafe or contraindicated for the patient, the LPN shall raise the issue with the ordering practitioner or other responsible person consistent with the protocols or policies of the facility.

(4) The LPN may not accept an oral prescription or order [under this subsection] which is not within the scope of functions permitted by this [subsection] section or which the LPN does not understand.

(5) An oral prescription or order accepted by the LPN [under this subsection] shall be immediately tran-

scribed by the LPN in the proper place on the medical record of the patient. The transcription shall include the [name of the physician giving the order] prescriber's name, the date, [and] the time of acceptance of the oral prescription or order and the full signature of the LPN accepting the oral prescription or order. [The countersignature of the physician shall be obtained in accordance with applicable regulations of the Department of Health governing the licensed facility.]

[Pa.B. Doc. No. 01-2126. Filed for public inspection November 30, 2001, 9:00 a.m.]

STATE BOARD OF PSYCHOLOGY

[49 PA. CODE CH. 41] Computerized Examinations

The State Board of Psychology (Board) proposes to amend \$\$ 41.41, 41.42 and 41.52 (relating to examinations; reexamination; and persons licensed in other states) to account for examination changes necessitated by the computerization of the National portion of the licensure examination.

Background and Purpose

Effective April 1, 2001, applicants for licensure have been able to take the National portion of the examination by computer, rather than paper and pencil. Due to the number of items in the item bank, applicants for this National examination are able to take the examination four times a year but must wait 60 days between administrations. Applicants from this Commonwealth, however, are precluded from taking these National portions of the examination as frequently due to limitations in current § 41.42.

The State portion of the examination is still a paper and pencil examination, however efforts are being made to computerize the examination. It is currently being given two times a year, however, the number of administrations will also increase once the examination is computerized.

Statutory Authority

The amendments are proposed under the authority of section 3.2(1) of the Professional Psychologists Practice Act (63 P. S. § 1203.2(1)).

Proposed Amendments

Current § 41.41(a) explains that the written examination was developed by the Association of State and Provincial Psychology Boards (ASPPB). Current subsection (b) explains that a professional testing organization administers the examination and current subsection (c) addresses the Boards policy to accommodate persons with handicapping conditions. The Board proposes to amend subsection (a) to clarify that the examination is composed of both a National and a State portion. The Board proposes to delete subsections (b) and (c) since these provisions are governed by the Third Party Testing Law (71 P. S. § 279.3a(a)) and the Equal Opportunity for Individuals with Disabilities Act (42 U.S.C.A. §§ 12101-

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Agency List of Commentators on Proposed

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ManorCare Health Services – Jersey Shore Jan C. Stiger, Administrator 1008 Thompson Street Jersey Shore, PA 17740 (570) 398-4747 (570) 398-2245 fax

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ManorCare Twinbrook Medical Center Mary Schuster, RN, Director of Nursing 3805 Field Street Erie, PA 16511 (814) 898-5600 (814) 899-9829 fax HCR ManorCare Robin Phillips, RN, C 1964 Maple Grove Circle Williamsport, PA 17701

HCR ManorCare Joyce Book-Eckhart 940 Walnut Bottom Road Carlisle, PA 17013 (717) 249-0085 (717) 249-0647 fax

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(DEPUTY ATTORNEY GENERAL)	(AGENCY)	With for permit
	DOCUMENT/FISCAL NOTE NO.	Contraction in
DATE OF APPROVAL	DATE OF ADOPTION:	9/8/03
	BY. Janet Hunter Shields, MSN, CRNP, CS	
	Jánet Hunter Shields, MSN, CRNP, CS	Deputy General Counsel
		Independent Agency)
	Chairperson	(S <u>trike inapplicable title)</u>
	TITLE: (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	
[] Check if applicable Copy not approved. Objections attached.		I] Check if applicable. No Attorney General approval or objection within 30 days after submission.

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FINAL RULEMAKING COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF STATE BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS STATE BOARD OF NURSING 49 PA. CODE, CHAPTER 21 ORAL ORDERS

The State Board of Nursing (Board) amends its regulations governing the administration of medications by professional nurses (registered nurses or RNs) and licensed practical nurses (LPNs) at 49 Pa. Code §§ 21.14, 21.141 and 21.145 (relating to administration of drugs; definitions; and functions of the LPN) to read as set forth in Annex A.

A. Effective Date

The amendments will be effective upon publication of final-form rulemaking in the <u>Pennsylvania Bulletin</u>.

B. Statutory Authority

The Board is authorized to establish rules and regulations for the practice of professional and practical nursing under Section 2.1(k) of the Professional Nursing Law (63 P.S. § 212.1(k)) and Section 17.6 of the Practical Nurse Law (63 P.S. § 667.6).

C. Background and Purpose

Current regulations of the Board prohibit an LPN from accepting an oral order for medication and therapeutic treatment unless the urgency of the medical circumstances requires immediate medication and therapeutic treatment. In these revisions, the Board removes the prohibition in § 21.145 (relating to functions of the LPN) against an LPN accepting an oral order except in urgent circumstances, which the Board now regards as unnecessary and burdensome. The Board is also updating and clarifying the language of § 21.14 (relating to the administration of drugs), which currently appears to limit the administration of medications to RNs only and limits the ability of an RN to accept orders from a practitioner other than a licensed doctor of the healing arts. Finally, the Board is amending § 21.141 (relating to definitions) to define the term "oral order."

D. Summary of Comments and Responses on Proposed Rulemaking

Notice of the proposed rulemaking was published at 31 Pa.B. 6544 (December 1, 2001). Publication was followed by a 30-day public comment period, during which the Board received comments from 76 public commentators: The Hospital and Healthsystem Association of Pennsylvania (HAP); Pennsylvania Association of Non-Profit Home for the Aging (PANPHA); Pennsylvania Association of County Affiliated Homes (PACAH); Pennsylvania Heath Care Association (PHCA); Pennsylvania State Nurses Association (PSNA); Pennsylvania Medical Directors Association; Clearfield Hospital (Clearfield); Joanna K. Stuck, RN, BSN; Wilmac Corporation; Bonham Nursing Center (6); Martha Davis, RN; Lutheran Community at Telford;

Pleasant Ridge Manor; Commonwealth of Pennsylvania, Department of Military and Veterans Affairs, Pennsylvania Soldiers' and Sailors' Home (2); Oil City Presbyterian Home; Erie Presbyterian Lodge; Cambridge Springs Presbyterian Home; Ridge Crest Nursing and Rehabilitation Center (Ridge Crest); University of Pittsburgh School of Nursing; University of Pittsburgh Medical Center, Division of Geriatric Medicine; Peter Becker Community; County of Lehigh Cedarbrook Nursing Homes; Lock Haven Hospital; and numerous representatives of HCR ManorCare (47).

Following the close of the public comment period, the Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC). The Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) did not comment. Responses to these comments are organized by subject as follows:

A. §21.14 Administration of drugs and the RN

IRRC questioned why the Board is including an LPN as a person who may administer a drug in this section of subchapter A pertaining to registered nurses, as opposed to subchapter B, pertaining to practical nurses. The Board concurs and has deleted the reference to "a licensed practical nurse who is acting in accordance with §21.145(b)."

B. § 21.145(b) Oral Orders and the LPN

1. §21.145(b) — Oral prescriptions or orders

IRRC and HAP recommend that the Board define "oral prescription or order" and be consistent when using this terminology. The Board's intent was to include both a situation in which the ordering practitioner delivers the order in the presence of the LPN and in which the order is received over the telephone. The Board agrees that the terminology may be vague and confusing. To eliminate any confusion over the meaning of the words "prescription" and "order," the Board therefore removes reference to the word "prescription" and defines the term "oral order" in §21.141 (relating to definitions) as "a spoken order issued by a practitioner authorized by law and by facility policy to issue orders for medical and therapeutic measures."

2. §21.145(b) — Training and qualification of the LPN to accept oral orders

HPLC, IRRC, PSNA, Clearfield Hospital and the University of Pittsburgh School of Nursing have raised concerns about the level of training and instruction LPNs receive relating to their qualifications to accept oral orders and about the Board's conclusion that LPNs receive adequate instruction in pharmacology and critical-thinking skills to accept oral orders. HPLC and IRRC requested more specific information on which this conclusion is based, including curriculum

requirements for LPN education programs.

Pursuant to both statute and regulation, practical nursing programs must have a minimum of 1,500 hours of combined theory and clinical practice over at least a 12-month period. See § 5 of the Practical Nurse Law (63 P.S. § 655) and the regulations at 49 Pa. Code §21.203 (relating to specific curriculum requirements for practical nursing programs). The Board's regulations governing practical nursing education at 49 Pa. Code §21.203(c) and §21.203(d)(5) require that pharmacology content be included in the curriculum. Furthermore, Board criteria for approval of an intravenous (IV) therapy course, whether incorporated in the LPN curriculum or in an LPN IV therapy course, require content on "review of compatibility of drugs and solutions" as well as "drug actions, interactions, adverse reactions, preventions, and recognition of unexpected outcomes." (Criteria for an Pennsylvania Board Approved Intravenous Therapy Education Program for the Student/Graduate/Licensed Practical Nurse).

In response to a survey conducted by the Board in October 1997 of the 49 practical nursing programs in operation at that time, two of the programs indicated a distinct pharmacology course as part of the curriculum; 14 programs integrated pharmacology content; and 33 programs included a distinct course as well as integrated content. All of the LPN programs which responded to a related questionnaire in 1997 indicated pharmacotherapeutics, pharmacokinetics, and pharmacodynamics are covered in the curriculum. Two programs awarded three academic credits: all others included from 20 to 120 contact hours of pharmacology content. Practical nurses are instructed how to transcribe physician orders from a chart as part of their curriculum.

Because nursing practice changes frequently, the National Council of State Boards of Nursing conducts a nationwide Job Analysis Study of Newly Licensed Practical/Vocational Nurses at least every three years. Both the frequency of performance and the priority ratings provided by the respondents to the related activity statements become the basis for revision of the National Council Licensure Examination for Practical Nurses (NCLEX-PN) Test Plan. As of April of 1999, 5-11% of the items on the NCLEX-PN Test Plan currently relate to pharmacological therapies. Likewise, 5-11% of the items on the NCLEX-RN (registered nurse) Test Plan relate to pharmacological and parenteral therapies.

The administrators and representatives of several facilities, as well as the University of Pittsburgh Medical Center, Division of Geriatric Medicine, specifically commented on the ability of LPNs to accept oral orders, stating that LPNs are capable of receiving verbal orders and following the appropriate protocol in the clinical record and that practical nursing programs in the Commonwealth already give instruction in pharmacology to their students, including doses calculation, drug classification and usage (PANPHA; Oil City Presbyterian Home; Lutheran Community at Telford; County of Lehigh Cedarbrook Nursing Homes). Lutheran Community at Telford and County of Lehigh Cedarbrook Nursing Homes added that the facility would provide inservice training and supervision to the LPNs as needed.

The Board concludes that LPNs are adequately prepared to take and administer oral orders. LPNs are presently permitted to administer all written orders within their scope of practice and take and administer oral orders where the urgency of the medical circumstances requires immediate medication or therapeutic measures. The Board agrees with commentator Ridge Crest who stated it has "always found it an enigma that LPNs were able to administer any and all medications from over the counter to controlled substances, but were not able to take an [oral] order to administer the same medications that they are qualified to administer."

3. §21.145(b) — Limitation of proposed regulation to long term care facilities

HPLC questioned whether the acceptance of oral orders could be limited to long term care facilities, questioning whether the same staffing concerns exist in hospitals and ambulatory surgical facilities. HPLC requested the Board to evaluate a "limited authority" for LPNs to accept oral orders in long term care facilities but not in hospitals and ambulatory surgical facilities. After considering HPLC's comments and concerns, the Board must decline consideration of such an authority limited to certain types of facilities. Under the Professional Nursing Law (63 P.S. §§ 211-226) and the Practical Nurse Law (63 P.S. §§ 651-667.8), the State Board of Nursing establishes rules and regulations for the licensure and practice of professional and practical nursing in the Commonwealth of Pennsylvania. Under the Health Care Facilities Act (35 P.S. §§448.101-904b), the Pennsylvania Department of Health (DOH) is charged with licensing and regulating hospitals, nursing homes and ambulatory surgical facilities. Current DOH regulations specify the health care practitioners who may receive oral or telephone orders in varying circumstances at each type of facility. See 28 Pa. Code § 107.62 (relating to oral orders at general and special hospitals); 28 Pa. Code § 211.3 (relating to oral and telephone orders at long term care facilities); and 28 Pa. Code § 555.12 (relating to ambulatory surgical facilities). The Board may not alter DOH regulations or assert jurisdiction over health care facilities contrary to what is mandated by statute. In light of its authority to regulate only nurses and not facilities, the Board has taken what it feels is a balanced approach in its regulations, permitting LPNs to accept oral orders if other agency regulations recognize the practice, the organization in which the LPN is employed permits the practice, the LPN can demonstrate that he or she has had the appropriate education and training, and the LPN only accepts and acts on orders that are within the scope of practice for the LPN. If an organization or facility, for example, has a sufficient number of registered nurses and does not wish to permit LPNs to accept oral orders, it need not do so. The Board does not encourage the use of oral orders in all types of health care facilities, but wishes to remove unnecessary restrictions which may delay delivery of safe health care.

4. $\S21.145(b)(3)$ — Questioning the order

Paragraph § 21.145(b)(3) requires the LPN to both question any order which is perceived as unsafe or contraindicated for the patient or which is not clear, and to raise the issue with the ordering practitioner or other responsible person. Both IRRC and HPLC requested an explanation as to whom

the LPN is to question regarding an unclear or perceived unsafe or contraindicated order and the manner in which the LPN is to raise the issue. Should the LPN question an order perceived as unsafe or contraindicated, he or she must attempt to question the ordering practitioner first. If the ordering practitioner is not available, the LPN should raise the issue with a registered nurse at the facility, in a manner consistent with the protocols or policies of the facility. The Board has made this change in final rulemaking.

The Board declines to mandate a single specific procedure for questioning an order. The particular situation itself may determine how an apparently unclear, unsafe or contraindicated order might be clarified. Contact with the practitioner who issued the order may be by telephone or facsimile. If that practitioner is unavailable, a registered nurse should be consulted to assist the LPN by consulting drug manuals, textbooks or other available resources. Sometimes a pharmacist or other responsible health care practitioner might be able to resolve the situation, in conjunction with the RN and LPN. A facility may well have a protocol or policy which reflects its own structure or needs. It is the experience of the professional members of the Board that questions regarding orders can almost always be answered to the satisfaction of all parties, including the ordering practitioner and the nurse.

5. §21.145(b)(5) — Transcribing the oral order

Both IRRC and HPLC point out that subsection 21.145(b)(5) deletes existing language that the countersignature of the physician shall be obtained in accordance with applicable DOH regulations governing the licensed facility, and request an explanation "as to why this requirement has been deleted." The elimination of the countersignature language in this subsection would in no way eliminate the requirement for a countersignature contained in the applicable DOH regulations. The Board was attempting to eliminate what it felt was duplicative and unnecessary language referring to another agency's requirements. However, the Board will retain this reference to the DOH facility regulations, modified to reflect the fact that practitioners other than physicians are authorized to issue oral orders.

E. Fiscal Impact and Paperwork Requirements.

The amendments will have no fiscal impact and will not impose additional paperwork on licensees, the private sector, the general public and the Commonwealth and its political subdivisions.

F. Sunset Date

The Board continuously monitors its regulations. Therefore, no sunset date has been assigned.

G. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), the Board submitted copies of the notice of proposed rulemaking, published at 31 Pa.B. 6544, on December 1, 2001, to IRRC, SCP/PLC and HPLC for review and comment. In compliance with section 5(c) (71 P.S. § 745.5(c)), the Board also provided IRRC, SCP/PLC, and HPLC with copies of all comments received, as well as other documents.

Publication of the notice of proposed rulemaking was followed by a 30-day public comment period, during which the Board received comments from 76 public commentators. The Board also received comments from IRRC and HPLC. In preparing this final-form rulemaking, the Board has considered the comments received from IRRC, HPLC and the public.

This final-form regulation was (deemed) approved by the HPLC on ______, 2003, and (deemed) approved by SCP/PLC on ______, 2003. IRRC met on ______, 2003, and (deemed) approved the final-form regulation in accordance with section 5.1(e) of the Regulatory Review Act (71 P.S. § 745.5a(e)).

H. Contact Person

Further information may be obtained by contacting Martha H. Brown, Counsel, State Board of Nursing, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649, or at http://www.dos.state.pa.us/bpoa/site/default.asp.

I. Findings

The Board finds that:

- (1) Public notice of proposed rulemaking was given under sections 201 and 202 of the Commonwealth Documents Law (45 P.S. §§ 1201 and 1202) and the 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 amendment does not enlarge the purpose of the proposed rulemaking published at 31 Pa.B. 6544 on December 1, 2001.
- (4) These amendments are necessary and appropriate for administering and enforcing the

authorizing acts identified in this preamble.

J. Order

The State Board of Nursing, acting under its authorizing statutes, orders that:

- (a) The regulations of the Board, 49 Pa. Code Chapter 21, are amended to read as set forth in Annex A.
- (b) The Board shall submit this order and Annex A to the Office of General Counsel and the Office of the Attorney General 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) This order shall take effect on publication in the <u>Pennsylvania Bulletin</u>.

JANET HUNTER SHIELDS, MSN, CRNP, CS Chairperson

ANNEX A

PENNSYLVANIA ADMINISTRATIVE CODE TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS PART I. DEPARTMENT OF STATE SUBPART A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS CHAPTER 21. STATE BOARD OF NURSING SUBCHAPTER A. REGISTERED NURSES

* * *

RESPONSIBILITIES OF THE REGISTERED NURSE

* * *

§ 21.14. Administration of drugs.

(a) [Administering to a patient a drug ordered for that patient by a licensed doctor of the healing arts in the dosage prescribed is a procedure regulated by this section, and the function may not be performed by a person other than a licensed registered nurse, except that a licensed registered nurse, responsible for administering a drug, may supervise a nursing student in an approved program and a graduate nurse.] <u>A licensed registered nurse or a licensed practical nurse who is acting in accordance with § 21.145(b) (relating to functions of the LPN) may administer a drug ordered for a patient in the dosage and manner prescribed.</u>

(b) <u>A licensed registered nurse, responsible for administering a drug, may supervise a graduate</u> <u>nurse or a nursing student in an approved nursing education program in the administration of the</u> <u>drug.</u> In this section, ["supervision"] <u>"supervise"</u> means the <u>licensed</u> registered nurse is physically present in the area or unit where the student or unlicensed graduate is practicing. This definition [of "supervision"] is not intended to limit in any way the practice of practical nursing as defined in the Practical Nurse Law (63 P. S. §§ 651-667).

* * *

SUBCHAPTER B. PRACTICAL NURSES

GENERAL PROVISIONS

§ 21.141. Definitions.

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

* * *

ORAL ORDER—A SPOKEN ORDER ISSUED BY A PRACTITIONER AUTHORIZED BY LAW AND BY FACILITY POLICY TO ISSUE ORDERS FOR MEDICAL AND THERAPEUTIC MEASURES.

* * *

§ 21.145. Functions of the LPN.

* * *

(b) The LPN administers medication and carries out the therapeutic treatment prescribed or ordered for the patient in accordance with the following:

(1) The LPN [shall] <u>may</u> accept [only] <u>a</u> written [prescriptions] <u>prescription</u> or [orders] order for medication and therapeutic treatment from [the responsible] <u>a</u> practitioner [for medication and therapeutic treatment unless the urgency of the medical circumstances requires immediate medication or therapeutic treatment.] <u>authorized by law and by facility</u> <u>policy to issue orders for medical and therapeutic measures.</u>

(2) The LPN may [not] accept an oral prescription or order if the following conditions are met:

(i) The practitioner issuing the oral order is authorized by law and by facility policy to issue oral orders for medical and therapeutic measures.

(ii) The LPN has received instruction and training in accepting an oral prescription or order in an approved nursing education program or has received instruction and training in accepting an oral prescription or order in accordance with the established policies and protocols of the facility.

(iii) The policy of the facility permits an LPN to accept an oral prescription or order.

(iv) The regulations governing the facility permit an LPN to accept an oral prescription or order.

(3) The LPN shall question any prescription or order which is perceived as unsafe or contraindicated for the patient or which is not clear AND SHALL RAISE THE ISSUE WITH THE ORDERING PRACTITIONER. If a prescription or order appears to be unclear, unsafe or contraindicated for the patient, IF THE ORDERING PRACTITIONER IS NOT AVAILABLE, the LPN shall raise the issue with the ordering practitioner A REGISTERED NURSE or other responsible person IN A MANNER consistent with the protocols or policies of the facility.

(4) The LPN may not accept an oral prescription or order [under this subsection] which is not within the scope of functions permitted by this [subsection] section or which the LPN does not understand.

(5) An oral prescription or order accepted by the LPN [under this subsection] shall be immediately transcribed by the LPN in the proper place on the medical record of the patient.

9/11/03

The transcription shall include the [name of the physician giving the order] <u>prescriber's</u> <u>name</u>, the date, [and] <u>the</u> time of <u>acceptance of</u> the oral <u>prescription or</u> order and the full signature of the LPN accepting the oral prescription or order. {The countersignature of the physician ORDERING PRACTITIONER shall be obtained in accordance with applicable regulations of the Department of Health governing the licensed facility.}

* * *



COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF STATE BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS STATE BOARD OF NURSING

Post Office Box 2649 Harrisburg, Pennsylvania 17105-2649 (717) 783-7142

October 8, 2003

The Honorable John R. McGinley, Jr., Chairman INDEPENDENT REGULATORY REVIEW COMMISSION 14th Floor, Harristown 2, 333 Market Street Harrisburg, Pennsylvania 17101

Re:	Final Regulation
	State Board of Nursing
	16A-5115: Oral Orders

Dear Chairman McGinley:

JHS/MHB:kmh

Enclosed is a copy of a final rulemaking package of the State Board of Nursing pertaining to oral orders.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

genet Hunter Skield, MSN, CRNP, CS

Janet Hunter Shields, MSN, CRNP, CS, Chairperson State Board of Nursing

Enclosure cc: Scott J. Messing, Deputy Commissioner Bureau of Professional and Occupational Affairs Andrew Sislo, Chief Counsel Department of State Joyce McKeever, Deputy Chief Counsel Department of State Cynthia Montgomery, Regulatory Counsel Department of State Herbert Abramson, Senior Counsel in Charge Department of State Martha H. Brown, Counsel State Board of Nursing State Board of Nursing

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBE	R: 16A-5115	
SUBJECT:	Oral Orders	
AGENCY:	DEPARTMENT OF STATE	
	TYPE OF REGULATION Proposed Regulation	
Х	Final Regulation With Notice of Proposed Rulemaking Omitted	
	Final Regulation with Notice of Proposed Rulemaking Omitted	
	Final Regulation with Notice of Proposed Rulemaking Omitted	
	120-day Emergency Certification of the Attorney General 120-day Emergency Certification of the Governor	
	Delivery of Tolled Regulation a. With Revisions b. Without Revisions	
FILING OF REGULATION		
DATE	SIGNATURE DESIGNATION	
<u> 1. je je 2. č</u>	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE	
10/203 m	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE	
10/4/03	ZULA REAL INDEPENDENT REGULATORY REVIEW COMMISSION	
·	ATTORNEY GENERAL	
	LEGISLATIVE REFERENCE BUREAU	
October 8, 20	03	