Regulatory Analysis Form

(Completed by Promulgating Agency)

IRRC

Independent Regulatory Review Commission

SECTION I: PROFILE

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(1) Agency:
Department of Health

(2) Agency Number: 10-191

Identification Number:

IRRC Number: 2860

(3) Short Title:
Physician assistants and certified registered nurse practitioners

(4) PA Code Cite:
28 Pa. Code § 211.7

(5) Agency Contacts (List Telephone Number, Address, Fax Number and Email Address):

Primary Contact:
Melanie Waters, Director
Bureau of Facility Licensure and Certification
Department of Health
Room 932, Health and Welfare Building
625 Forster Street
Harrisburg, PA 17120-0701
Telephone (717) 787-8015

Secondary Contact:
Susan Williamson, Director
Division of Nursing Care Facilities
Department of Health
Room 526, Health and Welfare Building
625 Forster Street
Harrisburg, PA 17120-0701
Telephone (717) 787-1816

(6) Primary Contact for Public Comments (List Telephone Number, Address, Fax Number and Email Address) – Complete if different from #5:

(All Comments will appear on IRRC'S website)

Regulatory Analysis Form

(7) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- ☐ Final Regulation
- ☒ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(8) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The Department of Health (Department) amends existing 28 Pa. Code § 211.7 (relating to physician assistants and certified registered nurse practitioners) to make revisions to subsection (c), which requires that a certified registered nurse practitioner's documentation on a resident's record, including progress notes, physical examination reports, treatments, medications and any other notation made by the certified registered nurse practitioner (CRNP), be countersigned by the collaborating physician within seven days. The Department amends § 211.7(c) by removing references to CRNPs.

(9) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: _____

B. The date or dates on which public meetings or hearings will be held: _____

C. The expected date of promulgation of the proposed regulation as a final-form regulation: _____

D. The expected effective date of the final-form regulation: _____

E. The date by which compliance with the final-form regulation will be required: _____

F. The date by which required permits, licenses or other approvals must be obtained: _____

(10) Provide the schedule for continual review of the regulation.

The Department will review and revise the regulation as necessary.

SECTION II: STATEMENT OF NEED

(11) State the statutory authority for the regulation. Include specific statutory citation.

The Health Care Facilities Act (HCFA), 35 P.S. §§ 448.101-448.904b, authorizes the Department to promulgate, after consultation with the Health Policy Board (Board), regulations necessary to carry out the purposes and provisions of the HCFA. 35 P.S. §§ 448.601 and 448.803(2). The HCFA has the stated purpose to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities, intended to assure safe, adequate and efficient facilities and services, and promote the health, safety and adequate care of patients or residents of such facilities. 35 P.S. § 448.801a. The HCFA also has the stated purpose to assure that all citizens receive humane, courteous, and dignified treatment. 35 P.S. § 448.102. Finally, the HCFA provides the Department with explicit authority to enforce the rules and regulations promulgated under the HCFA. 35 P.S. § 448.201(12).

The Department also has the duty to protect the health of the people of the Commonwealth of Pennsylvania under section 2102(a) of the Administrative Code of 1929, 71 P.S. § 532(a). The Department has general authority to promulgate regulations under the Administrative Code for this purpose. 71 P.S. § 532(g).

Act 48 of 2007 (Act 48) also directs the Department to revise its regulations to implement the additions and amendments to the Professional Nursing Law created by Act 48. *See* Act 48, Section 3.

(12) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

No.

(13) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The regulation amends § 211.7 to address unnecessarily proscriptive procedures applicable to the provision of care by a CRNP to a resident of a long-term care nursing facility (nursing home). Specifically, the regulation amends § 211.7(c), as it applies to CRNPs, because the regulation places an unnecessary and broad restriction on how the CRNP, the collaborating physician, and the nursing home determine the specifics of their relationship, and results in a barrier to a nursing home resident's access to qualified health care practitioners and increased health care costs.

The Commonwealth, nursing homes, physicians, CRNPs, nursing home residents, and the general public will benefit from the proposed regulation.

(14) If scientific data, studies, references are used to justify this regulation, please submit material with the regulatory package. Please provide full citation and/or links to internet source.

None.

(15) Describe who and how many will be adversely affected by the regulation. How are they affected?

There will be no adverse effects from the regulation.

(16) 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 718 nursing homes in Pennsylvania would be required to comply with the regulation.

SECTION III: COST AND IMPACT ANALYSIS

(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. Explain how the dollar estimates were derived.

There will be no costs to the regulated community associated with the regulation. The Department is not able to quantify the expected reduction in cost that would be associated with the regulation.

(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. Explain how the dollar estimates were derived.

There will be no costs to local governments associated with the regulation. The Department is not able to quantify the expected reduction in cost that would be associated with the regulation.

(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. Explain how the dollar estimates were derived.

There will be no costs to state government associated with the regulation. The Department is not able to quantify the expected reduction in cost that would be associated with the 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 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0

(20a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3 2006-07	FY -2 2007-08	FY -1 2008-09	Current FY 2009-10
Quality Assurance	$15,557,000	$17,308,000	$15,500,000	$18,041,000

(21) Explain how the benefits of the regulation outweigh any cost and adverse effects.

There are no adverse effects or costs associated with the regulation. The amendment to § 211.7(c) removes unnecessarily proscriptive procedures applicable to the provision of care by CRNPs to nursing home residents which place an unnecessary and broad restriction on how CRNPs, the collaborating physicians, and the nursing homes, determine the specifics of their relationship. The revision will result in increased access by nursing home residents to qualified health care practitioners and health care cost reductions.

(22) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

The issues which the Department seeks to remedy through this regulation were first brought to the attention of the Department by the three nursing home associations (Pennsylvania Health Care Association (PHCA); Pennsylvania Association of Non-Profit Homes for the Aging (PANPHA); and, Pennsylvania Association of County Affiliated Homes (PACAH)), and the CRNP association (Pennsylvania Coalition of Nurse Practitioners (PCNP)). The Department has met with these stakeholders to discuss options for eliminating these unnecessary provisions.

Pursuant to 35 P.S. § 448.803(1), the draft Annex A and Preamble were also presented at the June 16, 2010 public meeting of the Board for consultation with the Board.

(23) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

The Department initially sought to address the concerns presented by § 211.7(c), by permitting the submission of requests for exceptions to the requirements of § 211.7(c) filed pursuant to 28 Pa. Code §§ 51.31-51.34. This process proved to be an additional and unnecessary burden and expense for the nursing homes and the Department. Furthermore, the information submitted by the nursing homes was sometime lacking in sufficient substance to allow the Department to grant the requests. Revising the regulation to remove the countersignature requirements for CRNPs accomplish the same objective as the exception requests without the need for each individual nursing home to file a request or for the Department to review the requests.

(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 regulations.

No. In fact, the amendment will bring the Department's regulations more in line with the applicable federal standard in 42 CFR § 483.40.

(25) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

The Department has not determined that the regulation would put the Commonwealth in a competitive disadvantage to other states. The amendment will bring the Department's regulations more in line with the applicable federal standard in 42 CFR § 483.40.

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

No other proposed or existing regulations of the Department or other state agencies are expected to be affected by the regulation.

(27) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

None. The regulation will result in a reduction of existing, unnecessary and burdensome recordkeeping and paperwork requirements.

(28) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

None.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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Copy below is hereby approved as to form and legality. Attorney General.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or independent Agencies.
BY _____ DEPUTY ATTORNEY GENERAL	Department of Health	BY: Andrew C. Clark
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-191	JUL 15 2010 DATE OF APPROVAL
	DATE OF ADOPTION: _____	(Deputy General Counsel) (~~Chief Counsel, Independent Agency~~) (~~Strike inapplicable~~ title)
	BY: Everette James	
	TITLE Secretary of Health	
☐ Check if applicable. Copy not approved. Objections attached.		☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

DEPARTMENT OF HEALTH

NOTICE OF FINAL RULEMAKING WITH PROPOSED RULEMAKING OMITTED

TITLE 28. HEALTH AND SAFETY
28 PA. CODE. PART IV HEALTH FACILITIES
SUBPART C. LONG-TERM CARE FACILITIES
CHAPTER 211. PROGRAM STANDARDS FOR LONG-TERM CARE NURSING FACILITIES

The Department of Health (Department), following consultation with the Health Policy Board, amends 28 Pa. Code Part IV, Subpart C (relating to health facilities; long-term care facilities), Chapter 211 (relating to program standards for long-term care nursing facilities), Section 211.7 (relating to physician assistants and certified registered nurse practitioners). The amended regulation is set forth in Annex A hereto.

A. PURPOSE OF THE REGULATION

The regulation amends 28 Pa. Code § 211.7 (§ 211.7) to address unnecessarily proscriptive procedures applicable to the provision of care by a certified registered nurse practitioner (CRNP) to a resident of a long-term care nursing facility (nursing home). Specifically, the regulation amends § 211.7(c), as it applies to CRNPs, because the regulation places an unnecessary and broad restriction on how the CRNP, the collaborating[1] physician, and the nursing home determine the specifics of their relationship, and results in a barrier to a nursing home resident's access to qualified health care practitioners and increased health care costs.

Section 211.7(a) and (b) set forth broad parameters for the use of CRNPs in nursing homes. Section 211.7(a) provides that CRNPs may be utilized in nursing homes, in accordance with their training and experience and the requirements in statutes and regulations governing their practice. Section 211.7(b) requires, among other things, that the nursing home establish written policies indicating the manner in which the CRNPs shall be used and the responsibilities of the collaborating physicians. Section 211.7(c), however, further requires that the collaborating physician countersign a CRNP's documentation on a resident's record within 7 days. This

[1] Although § 211.7(c) uses the term "supervising physician," the relationship between a CRNP and a physician is one of collaboration.

includes progress notes, physical examination reports, treatments, medications, and any other notation made by the CRNP. Subsection (c) unnecessarily restricts the CRNP's and collaborating physician's ability to specify how often and in what circumstances the physician's countersignature will be required on the CRNP's orders and other documentation.

Section 211.7(c) is amended by removing this unnecessary restriction on the CRNP/physician collaborative relationship. Given the CRNP's recently expanded scope of practice and the emphasis on the definition of a CRNP's practice through the collaborative agreement that now exists in the Professional Nursing Law (PNL), 63 P.S. §§ 211-225.5, and the regulations promulgated under the PNL by the State Board of Nursing (Board) relating to CRNPs, 49 Pa. Code §§ 21.251-21.377, it is unnecessary for the Department to define this particular element of the CRNP/physician relationship with so much specificity. Rather, as required by § 211.7(b) and recognized in section 8.2(c.2)(2) of the PNL, 63 P.S. § 218.2(c.2)(2), a nursing home should have the flexibility to determine the supervision or other oversight requirements for physicians and CRNPs practicing within its facility based on the needs of the nursing home's residents. Within these parameters, CRNPs and collaborating physicians should have the ability to establish their responsibilities to each other within the context of the collaborative agreement between them and without undue direction from the Department.

The PNL and the regulations promulgated by the Board provide that the collaboration process shall incorporate the availability of the physician for cosigning records, when appropriate. Placing specific restrictions on this aspect of the collaborative relationship inhibits the physician and the nursing home from fully recognizing the individual CRNP's training and experience,

unnecessarily restricts the physician's and nursing home's utilization of CRNPs in providing medical care to nursing home residents, and ultimately negatively interferes with a nursing home resident's medical care.

Section 211.7 was last revised in 1999, over a decade ago. Since that time, health care practice has evolved to refine and expand the scope of practice of non-physician health care practitioners, in particular CRNPs, to increase health care access and quality and contain or reduce health care costs. CRNPs continue to receive advanced education and training to provide them the knowledge necessary to deliver this expanded care. The recent amendments to the Board's regulations relating to CRNPs, published in the *Pennsylvania Bulletin* on December 12, 2009 [39 Pa.B. 6994], recognized the need to update requirements relating to the practice of CRNPs because "existing regulations prevented the effective use of CRNPs to the full extent of their education, skills and abilities, thereby depriving the citizens of this Commonwealth necessary, high quality care." It is for these same reasons that the Department amends § 211.7(c).

Amendments to the PNL and to the Board's regulations now provide the appropriate rules relating to the collaborative relationship between the CRNP and the physician and there is no reasonable basis for continuing the requirement applicable to CRNPs in § 211.7(c). Section 211.7(a) and (b) provide more than adequate requirements for nursing homes relating to the CRNP's practice and in addition allow for the appropriate flexibility in the relationship between the CRNP and the collaborating physician. Section 211.7(c) is a specific requirement that may or may not suit the circumstances set forth in the individual CRNP/physician collaborative agreement or the nursing home resident's medical needs.

The PNL permits a CRNP to perform acts of medical diagnosis in collaboration with a physician and in accordance with regulations promulgated by the Board. *See* 63 P.S. § 218.2(b). Specifically, the PNL permits a CRNP to prescribe medical or therapeutic corrective measures, including pharmaceuticals, if the CRNP is acting in accordance with the provisions of section 8.3 of the PNL (63 P.S. § 218.3). *See* 63 P.S. § 218.2(c). In addition, Act 48 of 2007 amended the PNL to further express the General Assembly's intent to broaden the scope of the CRNP's practice and authority, by specifically authorizing the CRNP to issue or conduct certain kinds of orders, referrals, assessments and certifications, traditionally reserved to physicians, if the CRNP is acting within the scope of the CRNP's specialty certification and the collaborative agreement with the physician. *See* 63 P.S. § 218.2(c.1). By its passage of the amendments to the PNL, the General Assembly expressed its confidence in the ability of CRNPs to provide medical services without excessive restrictions.

Section 218.2(b) of the PNL, 63 P.S. § 218.2(b), specifies that a CRNP may prescribe medical therapeutic or corrective measures (including pharmaceuticals) if the nurse is acting in accordance with section 8.3, relating to prescriptive authority for CRNPs. Section 8.3 details the conditions under which a CRNP may exercise prescriptive authority. This includes acting in collaboration with a physician as set forth in a written agreement. The agreement must identify the area of practice in which the CRNP is certified, the categories of drugs from which the CRNP may prescribe, and the circumstances and how often the collaborating physician will personally see the patient. *See* 63 P.S. § 218.3. Furthermore, under the PNL and the Board's new regulations applicable to CRNPs, the CRNP and the collaborating physician are to incorporate

into the collaboration process the availability of the physician for cosigning records when necessary to document accountability by both parties. *See* 49 Pa. Code § 21.251.

Thus, § 211.7(c) unnecessarily dictates the terms of the CRNP/physician collaborative relationship for assuring physician involvement in the medical care of the resident, by requiring a countersignature by the collaborating physician in all cases and within 7 days. This requirement may not best serve the needs of the individual resident and represents a direct barrier to the implementation of health care innovations that are intended to increase health care access and quality and contain or reduce costs. Section 211.7(c) rigidly applies in all circumstances and is contrary to the need to provide care to residents based on their individual needs and as governed by the protocols agreed to by the physician, CRNP, and the nursing home.

Section 211.7(c) was originally intended to regulate how a nursing home would ensure that a nursing home resident's physician would remain primarily involved in the medical care planning and delivery for the resident. Currently, however, physician involvement is not only required by the PNL and the Board's regulations but also by federal regulations applicable to nursing homes (*see, e.g.,* 42 CFR § 483.40 (relating to physician services)). The unnecessary rigidity of the Department's regulation has the unfortunate effect of discouraging CRNP/physician collaborative practice in nursing homes, which has a deleterious effect on nursing home residents by limiting their access to qualified health care practitioners. This is compounded by the fact that the number of primary care physicians who are able to provide services to nursing home residents is becoming more limited. Consequently, CRNPs, in collaboration with physicians,

perform an invaluable service to these most vulnerable of citizens, which should not be impeded by an outdated, burdensome regulation.

With the enactment in 2007 of legislation amending the PNL and with the promulgation of the Board's regulations in December 2009, the issue of the CRNP/physician relationship has been thoroughly reviewed, discussed, and commented upon by the public, specifically including the various associations and other groups that represent various entities affected by the regulation. Consistently, the conclusion has been that the collaborative agreement in conjunction with the health care facility's protocols for patient care should control the provision of medical services by CRNPs.

In particular, with respect to the Department's regulation, all three nursing home associations (Pennsylvania Health Care Association (PHCA); Pennsylvania Association of Non-Profit Homes for the Aging (PANPHA); and, Pennsylvania Association of County Affiliated Homes (PACAH)), as well as the CRNP association (Pennsylvania Coalition of Nurse Practitioners (PCNP)), have argued that the regulation undermines the ability to best utilize the expanded scope of practice for CRNPs. These stakeholders – currently directly affected by § 211.7(c) – believe that the collaborating physician needs to use his or her professional judgment regarding the level of oversight needed by the CRNP, and that an inflexible oversight requirement creates additional paperwork with no commensurate benefit to the nursing home resident. In addition to the objections of the nursing homes and CRNPs, the Department has also been presented with comments from physicians who practice in nursing homes and that similarly object to the unnecessary requirement.

Since the promulgation of the Board's regulations, the Department has received over 70 exception requests from nursing homes seeking relief from the Department's regulation. Given the consensus by those who have considered the issue, including major stakeholders directly affected by the regulation, deferring to the scope of practice defined in the collaborative agreement in conjunction with a nursing home's protocols for provision of medical care to its residents is in the public interest. Delay in allowing CRNPs to practice as contemplated by the amendments to the PNL and the Board's regulations will result in the provision of less than adequate care to nursing home residents and increases in health care costs. Physicians have limited availability for nursing home practice, and nursing homes are relying on CRNPs to provide needed care to residents, for which they are well qualified.

The collaborative agreement, existing law, and the more recent developments in the CRNP's scope of practice, more than sufficiently protect the needs of the nursing home resident. Requiring countersignatures on all orders and all within 7 days creates an unreasonable burden upon CRNPs and physicians practicing in nursing homes.

Pursuant to § 204 of the Commonwealth Documents Law, 45 P.S. § 1204, notice of proposed rulemaking may be omitted if the agency for good cause finds that the procedures specified in §§ 201 and 202, 45 P.S. §§ 1201-1202, are in the circumstances impracticable, unnecessary, or contrary to the public interest. Based on the above, the Department finds justification for omitting notice of proposed rulemaking to rescind § 211.7(c) as it relates to CRNPs, because in these circumstances it is unnecessary and contrary to the public interest. *See* 45 P.S. § 1204(3).

B. REQUIREMENTS OF THE REGULATION

Section 211.7. Physician assistants and certified registered nurse practitioners.

The Department amends existing § 211.7 to make revisions to subsection (c) which requires that a CRNP's documentation on the resident's record, including progress notes, physical examination reports, treatments, medications and any other notation made by the certified registered nurse practitioner, be countersigned by the supervising physician within 7 days. The Department amends § 211.7(c) by removing references to CRNPs.

C. AFFECTED PERSONS

The regulation amends existing regulations that govern the operation of nursing homes in the Commonwealth. However, as the amended regulation would not impose any new requirements on the nursing homes, and instead would remove an unnecessary existing requirement, nursing homes would not be negatively affected by the amendment.

D. COST AND PAPERWORK ESTIMATE

There are no additional costs or paperwork requirements for the Commonwealth, the regulated community, local governments, or the general public associated with the proposed regulation, and the Department expects a reduction in cost and paperwork to various stakeholders. The Department is not able to accurately quantify the expected reduction in cost and paperwork.

E. STATUTORY AUTHORITY

The Health Care Facilities Act (HCFA), 35 P.S. §§ 448.101-448.904b, authorizes the Department to promulgate, after consultation with the Health Policy Board, regulations

necessary to carry out the purposes and provisions of the HCFA. 35 P.S. §§ 448.601 and 448.803(2). The HCFA seeks to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities, and that the minimum standards are to assure safe, adequate, and efficient facilities and services, and promote the health, safety, and adequate care of patients or residents of such facilities. 35 P.S. § 448.801a. The General Assembly has also stated that a purpose of the HCFA is, among other things, to assure that all citizens receive humane, courteous and dignified treatment. 35 P.S. § 448.102. Finally, the HCFA provides the Department with explicit authority to enforce its rules and regulations promulgated under the HCFA. 35 P.S. § 448.201(12).

The Department also has the duty to protect the health of the people of the Commonwealth of Pennsylvania under section 2102(a) of the Administrative Code of 1929. 71 P.S. § 532(a). The Department has general authority to promulgate regulations under the Code for this purpose. 71 P.S. § 532(g).

Act 48 also directs the Department to make revisions to its regulations to implement the additions and amendments to the PNL created by Act 48. *See* Act 48, Section 3.

F. EFFECTIVENESS/SUNSET DATES

The amended regulation would become effective upon its publication in the *Pennsylvania Bulletin*. No sunset date has been established. The Department will continually review and monitor the effectiveness of this regulation.

G. REGULATORY REVIEW

Under Section 5.1(a) of the Regulatory Review Act (Act), 71 P.S. §§745.1-745.15, the Department submitted a copy of the regulation with proposed rulemaking omitted on July 27, 2010, to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. On the same date, the regulation was submitted to the Office of Attorney General for review and approval pursuant to the Commonwealth Attorneys Act. In addition to submitting the regulation, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

In accordance with Section 5.1(d) of the Act, the regulation was (deemed) approved by the House Health and Human Services Committee on _____ and (deemed) approved by the Senate Public Health and Welfare Committee on _____. IRRC met on _____ and approved the regulation.

H. CONTACT PERSON

Questions or comments regarding the final-form rulemaking may be submitted to Melanie Waters, Director, Bureau of Facility Licensure and Certification, Department of Health, Room 932, Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120-0701, Telephone (717) 787-8015. Comments will not be accepted via facsimile or electronic mail. Persons with a disability may submit questions in alternative formats such as audio tape or Braille or by using

V/TT, (717) 783-6514 for speech or hearing impaired persons or the Pennsylvania AT&T Relay Service, (800) 654-5984 (TT). Persons who require an alternative format of this document (that is, large print, audio tape or Braille) should contact Melanie Waters at the previous address or telephone numbers to make necessary arrangements.

The Department will accept comments in response to these amendments at any time following the effective date of the amendments.

I. FINDINGS

The Department finds that:

(1) These regulatory revisions satisfied the requirements of 45 P.S. § 1204 for submission of regulations in final rulemaking with proposed rulemaking omitted format. Notice is impractical, unnecessary or contrary to the public interest because the 7 day countersignature requirements for CRNP documentation in a resident's clinical record in 28 Pa. Code § 211.7(c) inhibits access to qualified health care practitioners by nursing home residents and interferes with the physician/CRNP collaborative relationship established in the PNL and the Board's regulations.

(2) The adoption of the final-form rulemaking in the manner provided by this order is necessary and appropriate for the administration of the authorizing statutes and is in the public interest.

J. ORDER

The Department, acting under the authorizing statutes (35 P.S. §§ 448.101-448.904b, 71 P.S. § 532(g), and 45 P.S. § 1204), orders that:

(a) The regulation of the Department, 28 Pa. Code § 211.7(c), be amended to read as set forth in Annex A.

(b) The Secretary 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 submit this order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

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

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

Annex A

TITLE 28: HEALTH AND SAFETY

* * *

PART IV. HEALTH FACILITIES

* * *

SUBPART C. LONG-TERM CARE FACILITIES

* * *

CHAPTER 211. PROGRAM STANDARDS FOR LONG-TERM CARE NURSING FACILITIES

* * *

§ 211.7. Physician assistants and certified registered nurse practitioners.

* * *

(c) Physician assistants' [and certified registered nurse practitioners'] documentation on the resident's record shall be countersigned by the supervising physician within 7 days with an original signature and date by the licensed physician. This includes progress notes, physical examination reports, treatments, medications and any other notation made by the physician assistant [or certified registered nurse practitioner].

* * *

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HEALTH
8TH FLOOR WEST, HEALTH & WELFARE BUILDING
625 FORSTER STREET, HARRISBURG, PA 17120

SECRETARY OF HEALTH

717-787-6436
FAX 717-787-0191

July 27, 2010

Mr. Kim Kaufman
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health – Final-Omit Regulation No. 10-191
Physician assistants and certified registered nurse practitioners
28 Pa. Code, Chapter 211, Section 211.7

Dear Mr. Kaufman:

Enclosed is a final-form regulation with proposed rulemaking omitted for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§ 745.1-745.15). This regulation amends the existing Department of Health regulation pertaining to requirements for countersignature by the supervising or collaborating physician of a physician assistant's or certified registered nurse practitioner's documentation of information on a long-term care nursing facility (nursing home) resident's clinical record.

Currently, the Department's regulation at 28 Pa. Code § 211.7(c) requires that any documentation by a physician assistant (PA) or certified registered nurse practitioner (CRNP) on the resident's clinical record be countersigned by the supervising or collaborating physician within seven days of the date of the documentation with an original signature and date by the licensed physician. Documentation in the record includes progress notes, physical examination reports, treatments, medications and any other notation made by the PA or CRNP.

Given the CRNP's recently expanded scope of practice and the emphasis on the definition of a CRNP's practice through the collaborative agreement that now exists in the Professional Nursing Law (PNL), 63 P.S. §§ 211-225.5, and the regulations promulgated under the PNL by the State Board of Nursing relating to CRNPs, 49 Pa. Code §§ 21.251-21.377, it is unnecessary for the Department to define this particular element of the CRNP/physician relationship with so much specificity. Rather, as required by 28 Pa. Code § 211.7(b) and recognized in section 8.2(c.2)(2) of the PNL, 63 P.S. § 218.2(c.2)(2), a nursing home should have the flexibility to determine the supervision or other oversight requirements for physicians and CRNPs practicing within its facility based on the needs of the nursing home's residents. Within these parameters, CRNPs and collaborating physicians should have the ability to

establish their responsibilities to each other within the context of the collaborative agreement between them and without undue direction from the Department.

As applied to documentation made by CRNPs, 28 Pa. Code § 211.7(c) unnecessarily restricts the CRNP's and collaborating physician's ability to specify how often and in what circumstances the physician's countersignature will be required on the CRNP's orders and other documentation. The enclosed regulation amends 28 Pa. Code § 211.7(c) to remove references to CRNPs from that subsection and relieve nursing homes of the requirement that they obtain the physician's countersignature within a prescribed time period.

Delay in allowing CRNPs to practice as contemplated by the PNL and the State Board of Nursing's regulations will result in the provision of less than adequate care to nursing home residents and increases in health care costs. Physicians have limited availability for nursing home practice, and nursing homes are relying on CRNPs to provide needed care to residents, for which they are well qualified. Pursuant to section 204 of the Commonwealth Documents Law, 45 P.S. § 1204, the Department is omitting proposed rulemaking, having for good cause found that the procedures specified in sections 201 and 202 of the Commonwealth Document Law, 45 P.S. §§ 1201-1202, are in these circumstances unnecessary and contrary to the public interest. *See* 45 P.S. § 1204(3).

Section 5.1(e) of the Act provides that within 10 days following the expiration of the Standing Committee review period, or at its next regularly scheduled meeting, the Commission shall approve or disapprove the final-form regulation with proposed rulemaking omitted.

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulation. If you have any questions, please contact Neil Malady, Director, Office of Legislative Affairs, at 717-214-7134.

Sincerely,

Everette James
Secretary of Health

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 10-191

SUBJECT: **Physician Assistants and Certified Registered Nurse Practitioners. 28 Pa. Code § 211.7**

AGENCY: **Department of Health**

TYPE OF REGULATION

RECEIVED
IRRC
2010 JUL 27 A 11:45

Proposed Regulation

Final Regulation

X 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
7/27/10	Honorable Frank L. Oliver	House Committee on Health & Human Services **Majority**
7/27/10	Honorable Matthew E. Baker	House Committee on Health & Human Services **Minority**
7/27/10	Honorable Patricia H. Vance	Senate Committee on Public Health & Welfare **Majority**
7/27/10	Honorable Vincent J. Hughes	Senate Committee on Public Health & Welfare **Minority**
7/27/10		Independent Regulatory Review Commission
7-27-10		Attorney General (for Final Omitted only)
		Legislative Reference Bureau (for Proposed only)