VOLUME 45, ISSUE 3

ISSUE DATE: **FEBRUARY** 4, 2013

RULE ADOPTIONS

LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS
BOARD OF PHARMACY

Jointly Adopted New Rules: N.J.A.C. 13:35-6.27 and 13:39-13

Collaborative Practice

Proposed: March 19, 2012 at 44 N.J.R. 655(a).

Adopted: September 12, 2012 by the State Board of Medical Examiners, George Scott, DPM, M.D., President and August 22, 2012 by the State Board of Pharmacy, Edward G. McGinley, R.Ph., President.

Filed: January 8, 2013 as R.2013 d.017, **with substantial and technical changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:14-47; 45:14-48a.(4); 45:14-61; and 45:14-62.

Effective Date: February 4, 2013.

Expiration Dates: May 3, 2018, N.J.A.C. 13:35;

May 17, 2017, N.J.A.C. 13:39.

Summary of Public Comments and Agency Responses:

The official comment period ended May 18, 2012. The Boards of Medical Examiners and Pharmacy (Boards) received two comments from the following individuals:

[page=215] 1. Debra L. Wentz, Ph.D, Chief Executive Officer, New Jersey Association of Mental Health and Addiction Agencies, Inc.

2. Lawrence Downs, J.D., General Counsel, Medical Society of New Jersey

1. COMMENT: Dr. Wentz, on behalf of New Jersey Association of Mental Health and Addiction Agencies, Inc. (the Association), fully supported the joint rules because they foster collaboration between physicians and pharmacists in ways that are likely to improve patients' health outcomes. The Association felt that patients can benefit from the unique expertise of both types of healthcare professionals. The Association believed that such collaboration could prevent or minimize negative outcomes, such as negative drug interactions. The Association also believed that collaboration will reduce healthcare costs by preventing the need for more physician visits and by helping to avoid complications that could result in higher-cost hospital visits.

Additionally, as antidepressant medications are being prescribed more commonly by primary physicians, the Association believed that collaboration with pharmacists can help to make physicians fully aware of the potentially harmful side effects of antidepressant medications, and thus take necessary measures to monitor and manage these effects.

The Association also felt that physician-pharmacist coordination will help to identify individuals with drug addictions and prevent them from circumventing the medical system to obtain drugs. Additionally, the Association noted that physicians and pharmacists would be well positioned to encourage treatment for drug abuse.

RESPONSE: The Boards thank Dr. Wentz and the Association for their support.

2. COMMENT: Lawrence Downs, on behalf of the Medical Society of New Jersey (the Society), thanked the Boards for specifically defining the bona fide relationship that must be present for a physician and pharmacist to enter into a collaborative practice arrangement. The Society was also pleased that the notice of reproposal (notice) included the concept that covering physicians and pharmacists must also meet the same standards as the parties to the agreements, and that the notice eliminated the "voucher of 2,000 hours of training" as a path for pharmacists to obtain approval to participate in collaborative practice agreements. The Society believed the notice is far clearer on the available pathways for approval.

RESPONSE: The Boards thank the Society for its support.

3. COMMENT: The Society was disappointed that the Boards did not change the reproposed rules to address the Society's concerns that there be no business or financial relationship between the collaborating physician and pharmacist at any point during the collaboration and for a reasonable time prior to its initiation. However, the Society's concerns were assuaged about inappropriate profit motives underlying these agreements because the reproposed rules limit the relationship to individual pharmacists rather than retail chains or other entities.

RESPONSE: When the Boards reproposed the rules to permit physician-pharmacist collaborative drug therapy management, the Boards' chief objective was to address the challenge of containing the high cost of medical care, and the Boards believe that collaborative practice agreements are a means to achieve that goal. As stated in the Response to Comment 22 in the notice at 44 N.J.R. 655(a), 660, the Board of Pharmacy did not believe that it was necessary to change the reproposed rules to address concerns regarding underlying business or financial relationships between collaborating physicians and pharmacists because existing N.J.A.C. 13:39-3.10 and 4.17 preclude pharmacists and pharmacies from entering into arrangements with health care practitioners for the purpose of steering patients to or from a specified pharmacy. However, the Boards are pleased that by limiting collaborative practice agreements to individual physicians and pharmacists, the Society's concerns about inappropriate profit motives have been alleviated.

4. COMMENT: The Society continued to have concerns about the level of training required for pharmacists to participate in collaborative practice agreements. The Society had proposed that a post-graduate clinical program be a requisite for participation in collaborative practice agreements. Additionally, while the three designated paths provide clarity, the Society believed that they do not provide the relevant clinical training that the Society suggested. The Society continued to have concerns about the approval of applicants without clinical or disease-specific training.

RESPONSE: The Board of Pharmacy considers the certificate and residency programs set forth in N.J.A.C. 13:39-13.3 to be post-graduate clinical programs, as pharmacists participate in these programs after graduation from pharmacy school and gain clinical experience while participating in them. The Board disagrees with the Society's position that these programs do not provide the relevant clinical training necessary to engage in collaborative practice agreements. The Board of Pharmacy believes that completion of any of the three pathways set forth in N.J.A.C. 13:39-13.3(a) will provide a proper foundation for pharmacists entering into collaborative drug therapy management. The Boards chose not to mandate specific disease training in N.J.A.C. 13:39-13.3(a) because they believe that the rules permit a physician to customize the specific clinical or disease-specific training that the physician believes is necessary for the collaborative treatment of his or her patients.

Additionally, when the Boards reproposed the rules, they recognized that collaborative practice may continue to evolve. Looking forward, the Boards believe that the rules should have sufficient flexibility to change with the demands of the professions. Furthermore, the Boards note that collaborations between physicians and pharmacists are purely voluntary. If a physician feels that a particular pharmacist requires more specific training, the physician can decline to collaborate with that pharmacist until the pharmacist acquires the training. The Boards believe that the rules strike a balance between mandating sufficient training to protect the public safety and allowing physicians the autonomy to determine what level of training is appropriate.

5. COMMENT: The Society pointed out that N.J.S.A. 45:14-62.a, requires a specification of the "patient's specific condition, disease or diseases." The Society believed that N.J.A.C. 13:35-6.27(c)4 and 13:39-13.4(a)4, requiring that the collaborative practice agreement include an indication "if appropriate, of any diagnosis or types of diseases that are specifically included or excluded," should be amended to remove the phrase "if appropriate," because N.J.S.A. 45:14-62.a requires that the condition and/or disease be specified in the agreement. The Society also requested that the phrase be removed from the Collaborative Practice Agreement Form in each of the appendices for the same reasons.

RESPONSE: The Board of Pharmacy agrees with the Society and will remove the phrase, "as appropriate" from the rules and the appendices. The Boards do not believe that this is a substantive change requiring republication. The Society correctly noted that N.J.S.A. 45:14-62.a requires that the condition and/or disease be specified in the agreement; therefore the phrase, "as appropriate" is superfluous, and its removal will not change the substance of the rule.

6. COMMENT: The Society appreciated the clarification in the notice that a pharmacist may not initiate drug or device therapy, and the Boards' acknowledgement that the enabling legislation only permits a pharmacist to "modify, continue or discontinue drug or device therapy." However, the Society believed that it is essential that the collaborative practice agreement and management be limited to specific diseases or conditions and to certain types and classes of drugs. Otherwise, the Society argued, the "therapeutic interchange" may be impermissibly expanded beyond the limitations of the statute and the pharmacists' scope of practice.

RESPONSE: The Boards agree that each collaborative practice agreement must state specifically which diseases or conditions are to be managed through the physician-pharmacist collaboration. However, the Boards disagree with the Society that the collaborative practice must be limited to specific conditions or diseases, or certain types and classes of drugs. The Boards believe that they need not be overly prescriptive as to what conditions or diseases can and cannot be the subject of a collaborative practice agreement;

as the practice of medicine advances, different conditions and diseases may become appropriate for collaborative care. Rather, the Boards believe it is up to the physician to decide when it is appropriate to enter into a collaborative practice agreement for the treatment of a specific disease or condition.

Additionally, the Boards do not share the Society's concerns regarding possible expansion of "therapeutic interchange." The Boards note that pharmacists do not have prescriptive authority. N.J.S.A. 45:14-62 and N.J.A.C. 13:39-13.7(e) specifically prohibit therapeutic interchange at the time of dispensing without the prior, specified informed consent of the patient and his or her physician. Therefore, the only way that a pharmacist would be able to engage in therapeutic interchange is with the [page=216] express consent of the physician and patient. The Boards also note that as a practical matter, there are a limited number of treatments available for most conditions, and therapeutic interchange may be related to which treatments are covered by a patient's insurance coverage.

7. COMMENT: The Society noted that the reproposed rule requires pharmacists to complete 10 hours of training biennially in the "area covered," but notes that "area covered" is not a defined term. The Society urged the Boards to more specifically define "area covered" to include the specific disease state or conditions covered by any collaborative practice agreement. They believe that it is essential to train pharmacists on specific disease states and conditions being addressed by the collaborating pharmacists.

RESPONSE: The Boards agree that the "area covered" refers to the specific disease state or conditions covered by the collaborative practice agreement, and will change the phrase "area covered" to "disease state(s) or condition(s) covered." The Boards agree that pharmacists should complete continuing education related to the disease states or conditions covered by the collaborative practice agreements, and wish to clarify that the rules would require a pharmacist who is a party to collaborative practice agreement(s) to take 10 continuing education credits in each condition or disease state covered by the collaborative practice agreement(s), unless the conditions are co-existing, interrelated conditions, such as diabetes and hypertension. The Boards will change the rules upon adoption to make this clear. The Boards believe requiring a total of 10 continuing education credits will be sufficient because continuing education courses offering a thorough review of a condition or diseased state that is often interrelated with other conditions or diseased states should include a discussion of these associated conditions or diseased states.

The Boards believe that these are clarifying changes, not substantive changes requiring republication. Although a pharmacist who is a party to several collaborative practice agreements covering several different conditions or diseases may be required to take more than 30 continuing education credits per biennial cycle, existing N.J.A.C. 13:39-3A.1(a) requires "a minimum" of 30 credits; there is no maximum number of continuing education credits set forth in the current rules. Therefore, this change would not constitute a substantial change to that requirement. The Response to Comment 11 in the notice did not directly address the more than 30 credits aspect of the comment; rather it just clarified that the 10 required by this section are part of the minimum number of 30 credits that must be completed.

8. COMMENT: The Society noted that the reproposed rules acknowledge the voluntary nature of collaborative practice agreements, the discretion of physicians to enter into these agreements, and the authority of the physicians to mandate specific training by pharmacists before entering into these agreements. The Society is concerned, however, that the Board of Pharmacy's approval may shift responsibility to the physician to determine each pharmacist's qualifications, and to require physicians to conduct a level of due diligence that

was not contemplated by the Legislature, and is more appropriately within the purview of the Board.

RESPONSE: Under the reproposed rules, the Board of Pharmacy does not approve individual collaborative practice agreements between physicians and pharmacists. Under reproposed N.J.A.C. 13:39-13.3, the Board of Pharmacy determines whether a pharmacist seeking to enter into collaborative practice has met the requirements of N.J.A.C. 13:39-13.3(a), and if so, issues an authorization to engage in collaborative drug therapy management. The Board does not believe that by giving physicians the authority to mandate additional training, that the Board has shifted the responsibility to physicians to determine the pharmacist's qualifications. The Board of Pharmacy believes that the training set forth in reproposed N.J.A.C. 13:39-13.3(a) is sufficient to prepare a pharmacist to engage in collaborative practice. However, collaborative practice agreements are voluntary and physician-driven; by giving individual physicians the authority to mandate that a pharmacist complete specific training before entering into a collaborative practice agreement, physicians can customize the clinical or disease-specific training that he or she would require for the treatment of his or her patients to suit the physician's comfort level.

Federal Standards Statement

A Federal standards analysis is not required because new N.J.A.C. 13:35-6.27 and 13:39-13 are governed by N.J.S.A. 45:14-47, 48a.(4), 61, and 62 of the Pharmacy Practice Act. The new rules are not subject to any Federal requirements or standards.

Full text of the adopted new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisk *[thus]*):

CHAPTER 35
BOARD OF MEDICAL EXAMINERS

SUBCHAPTER 6. GENERAL RULES OF PRACTICE

13:35-6.27 Standards for collaborative practice for drug therapy management with licensed pharmacists

(a) The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Bona fide physician-patient relationship" means a relationship in which the physician has ongoing responsibility for assessment, care, and treatment of the patient's medical condition for which collaborative drug therapy management is utilized. For purposes of this definition, "ongoing responsibility" means:

1. The physician-patient relationship has existed for at least one year;

2. The physician has seen and/or assessed the patient on at least four visits; or

3. The physician assumes responsibility for providing management and care of the patient's condition after conducting a comprehensive medical history and physical examination.

"Collaborative drug therapy management" means the cooperative management of a patient's drug, biological, and device-related health care needs, pursuant to a written protocol directed on a voluntary basis by a patient's physician with the patient's informed

consent, by the patient's physician and a pharmacist who has signed a collaborative practice agreement with the physician.

"Collaborative practice" means that practice whereby one or more physicians have jointly agreed to work in conjunction with one or more pharmacists for the purpose of collaborative drug therapy management of patients.

"Collaborative practice protocol" means a written document that identifies the collaborative drug therapy management actions that a pharmacist is authorized to perform for a patient and that is developed jointly by the pharmacist and the physician, and meets the requirements set forth at (c) below.

"Informed consent" means the written document that is signed by a patient whereby the patient agrees to collaborative drug therapy management by the patient's physician and a pharmacist who has entered into a collaborative practice agreement with the physician.

"Therapeutic interchange" means the substitution and dispensing of a drug chemically dissimilar from the prescription drug originally prescribed.

(b) A physician may enter into a collaborative practice agreement with one or more licensed pharmacists, as provided in N.J.S.A. 45:14-61 of the Pharmacy Practice Act, provided the collaboration that the physician agrees to conduct with the pharmacist is within the scope of the physician's practice and the pharmacist is authorized to engage in such activities pursuant to Board of Pharmacy requirements set forth at N.J.A.C. 13:39-13.

(c) A physician who engages in collaborative practice with one or more pharmacists shall provide the Board, upon request, with a signed copy of a collaborative practice agreement. The collaborative practice agreement shall be consistent with the example contained in N.J.A.C. 13:35-6.27 Appendix, which is incorporated herein by reference. The written agreement shall:

1. Identify, by name and title, each physician and each pharmacist who is permitted to participate in a patient's collaborative drug therapy management, including all covering physicians and/or pharmacists. Each covering physician shall meet the requirements of (b) above and each covering pharmacist shall meet the requirements of N.J.A.C. 13:39-13.3. [page=217] The agreement shall establish the means by which the physician and/or pharmacist will be notified about covering practitioners for collaborative practice purposes;

2. Specify the functions and responsibilities, including the scope of practice and authority, to be exercised by the pharmacist;

3. Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies;

4. Indicate*[, if appropriate,]* any diagnosis or types of diseases that are specifically included or excluded;

5. Include copies of all protocols to be used in the collaborative practice;

6. Contain an effective date for the agreement; and

7. Be signed and dated by the physician(s) and pharmacist(s).

(d) Any changes, additions, or deletions to the collaborative practice agreement shall be submitted to the Board upon request.

(e) The physician shall establish a method for monitoring both the compliance with the collaborative practice agreement and the clinical outcomes of the patients.

(f) Collaborative practice protocols shall be developed for each different type of collaborative drug therapy management authorized by the physician under the collaborative practice agreement and shall identify those activities that may be performed by the collaborating pharmacist. Each protocol shall:

1. Be jointly developed by the physician and the pharmacist, consistent with standards and practices that are deemed commonly accepted and recognized by national standard setting organizations, or national or State professional organizations of the same discipline as the treating physician, and signed and dated by both the physician and the pharmacist;

2. Be initiated and utilized at the sole discretion of the physician for a specific patient with whom the physician has a bona fide physician-patient relationship;

3. Be agreed to by both the physician and the pharmacist with the written informed consent of the patient consistent with (g) below;

4. Be available at the practice sites of the pharmacist and physician and made available at each site to the patient;

5. Establish the means by which the patient will be advised of the right to elect to participate in and withdraw from the collaborative drug therapy management;

6. Establish when physician notification is required, the physician chart update interval, and an appropriate time frame within which the pharmacist shall notify the physician of any change in dose, duration, or frequency of medication prescribed. Written notification, by either facsimile or electronic means, shall be provided to the physician no later than eight hours after any change in prescribed medication is made by the pharmacist;

7. Identify the method and time frame for notification of the physician if an adverse event occurs; and

8. Be reviewed at least once per year by the parties to determine whether the protocol should be renewed, modified or terminated.

(g) Written informed consent shall be obtained from each individual patient participating in collaborative drug therapy management. Both the physician and the pharmacist shall retain a copy of the patient's written informed consent. The written informed consent shall:

1. Contain the specific patient's name;

2. Identify the risks and benefits of collaborative drug therapy management, including the fact that services provided under collaborative drug therapy management may not be covered by the patient's insurance provider;

3. Identify the fact that covering physicians and/or pharmacists may be utilized in the collaborative drug therapy management of the patient's care;

4. Identify the patient's right to elect to participate in and withdraw from the collaborative drug therapy management; and

5. Be signed and dated by the patient.

(h) The collaborative practice agreement may be terminated at any time by either the physician or the pharmacist by written documentation. Upon termination of a collaborative practice agreement, the physician and the pharmacist shall provide notice of the termination to each individual patient who is undergoing collaborative drug therapy management. Upon termination of the agreement, the patient's informed consent for collaborative drug therapy management under the agreement shall be voided.

(i) Collaborative drug therapy management shall be between a single patient with whom the physician has a bona fide physician-patient relationship, the physician, and the pharmacist and shall address that patient's specific condition, disease, or diseases.

(j) Collaborative drug therapy management may include the collecting, analyzing, and monitoring of patient data; ordering or performing of laboratory tests based on the standing orders of a physician as set forth in the written collaborative practice protocols, consistent with (k) below; ordering of clinical tests based on the standing orders of a physician as set forth in the written collaborative practice protocols; modifying, continuing, or discontinuing drug or device therapy; and therapeutic drug monitoring with appropriate modification to dose, dosage regimen, dosage forms, or route of administration.

(k) A pharmacist may perform laboratory tests that are granted waived status in accordance with the provisions of the "New Jersey Clinical Laboratory Improvement Act," P.L. 1975, c. 166 (N.J.S.A. 45:9-42.26 et seq.), Department of Health and Senior Services' rules set forth at N.J.A.C. 8:44, and Department of Health and Senior Services CLIA Program requirements, available at http://www.state.nj.us/health/phel/instruct116.shtml, provided the tests are consistent with the pharmacy practice area or disease state covered by the collaborative practice agreement.

(l) The interpretation of clinical or laboratory tests under a written collaborative practice protocol shall be performed by a pharmacist only in direct consultation with a physician.

(m) Collaborative drug therapy management shall not include therapeutic interchange at the time of dispensing without the prior, specific informed consent of the patient and the consent of the patient's physician.

(n) Participation in, or withdrawal from, a collaborative practice agreement shall be voluntary on the part of a physician and a pharmacist.

(o) Participation in, or withdrawal from, collaborative drug therapy management shall be voluntary on the part of the individual patient.

(p) All records relating to a collaborative practice agreement shall be maintained in either hard copy or electronic form for a period of not less than seven years from the date of termination of the agreement and shall be supplied to the Board upon request.

(q) Any violation of the collaborative practice agreement or protocols on the part of the physician may be deemed professional misconduct and may subject the physician to discipline consistent with N.J.S.A. 45:1-21.

Appendix

Collaborative Practice Agreement

The Pharmacist(s) and Physician(s) listed below are parties to this collaborative practice agreement, through which the pharmacist(s) receives authority, under the supervision of the physician(s) (or covering physician), to perform the functions outlined in accordance with applicable New Jersey statutes and regulations.

Physician:

Name: _____ Title: _____

Address: _____

Phone Number: _____ License Number: _____

Type of Practice/Specialty: _____

Pharmacist:

Name:_____

Address: _____

Phone Number: _____ License Number: _____

Qualifications for Collaborative Practice: _____

Describe the functions and responsibilities, including scope and authority, to be exercised by the pharmacist (attach extra sheets if needed):

Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies under this agreement (attach extra sheets if needed):

[page=218] *[If appropriate, indicate]* ***Indicate*** any diagnosis, or types of diseases which are specifically included or excluded under this agreement (attach extra sheets if needed):

Attach any protocols to be used in decision making or other activities contemplated under this agreement. This must include a protocol for treating an acute allergic or other adverse reaction related to drug therapy. Each protocol must establish when physician notification is required, the time frame within which the pharmacist must notify the physician of any change in dose, duration or frequency of medication prescribed, and the type of pharmacist documentation required. Written notification, by either facsimile or electronic means, shall be provided to the physician no later than eight hours after any change in prescribed medication is made by the pharmacist.

Physician Signature: _____ Date: _____

Pharmacist Signature: _____ Date: _____

CHAPTER 39

STATE BOARD OF PHARMACY

SUBCHAPTER 13. COLLABORATIVE PRACTICE

13:39-13.1 Purpose and scope

The rules in this subchapter establish standards applicable to all pharmacists who seek to engage in collaborative practice with one or more physicians licensed by the Board of Medical Examiners. Only those activities that have been approved by the collaborating physician, consistent with his or her scope of practice, shall be permitted.

13:39-13.2 Definitions

(a) The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Collaborative drug therapy management" means the cooperative management of a patient's drug, biological, and device-related health care needs, pursuant to a collaborative practice protocol directed on a voluntary basis by a patient's physician with the patient's informed consent, by the patient's physician and a pharmacist who has signed a collaborative practice agreement with the physician.

"Collaborative practice" means that practice of pharmacy whereby one or more pharmacists have jointly agreed to work in conjunction with one or more physicians for the purpose of collaborative drug therapy management of patients, consistent with the requirements of this subchapter.

"Collaborative practice protocol" means a written document that identifies the collaborative drug therapy management actions that a pharmacist is authorized to perform for a patient and that is developed jointly by the pharmacist and the physician and meets the requirements outlined in N.J.A.C. 13:39-13.5.

"Informed consent" means the written document that is signed by a patient whereby the patient agrees to collaborative drug therapy management by the patient's physician and a pharmacist who has entered into a collaborative practice agreement with the physician.

"Therapeutic interchange" means the substitution and dispensing of a drug chemically dissimilar from the prescription drug originally prescribed.

13:39-13.3 Board approval; pharmacist qualifications; continuing education

(a) In order to enter into an agreement to engage in the collaborative drug therapy management of a patient with a physician licensed in this State, a licensed pharmacist shall be pre-approved by the Board to engage in such activity. In order to obtain Board approval, a pharmacist shall submit a collaborative practice application and documentation that establishes that he or she has successfully completed one of the following:

1. A certificate training program offered by an American Council of Pharmaceutical Education-approved provider;

2. A post-graduate residency program accredited by the American Society of Health-System Pharmacists; or

3. A certification program from the Board of Pharmacy Specialties.

(b) The Board shall issue an authorization to engage in collaborative drug therapy management to a pharmacist who, upon application to the Board, demonstrates satisfaction of the requirements of (a) above.

(c) A pharmacist granted authorization to engage in collaborative drug therapy management pursuant to this section shall complete a minimum of 10 credits of continuing education every biennial renewal period in *[the area]* ***each disease(s) or condition(s)*** covered by the collaborative practice agreement***(s)*** to which he or she is a party, consistent with the requirements of N.J.A.C. 13:39-3A. ***However, to the extent that a pharmacist may enter into collaborative practice agreements to treat patients with co-existing, interrelated conditions or diseases, a pharmacist need only complete a total of 10 credits in the interrelated conditions or diseases.***

13:39-13.4 Collaborative practice agreement

(a) A pharmacist who engages in collaborative practice with one or more physicians shall provide the Board, upon request, with a signed copy of a collaborative practice agreement. The collaborative practice agreement shall be consistent with the example contained in N.J.A.C. 13:39-13 Appendix, which is incorporated herein by reference. The written agreement shall:

1. Identify, by name and title, each physician and each pharmacist who is permitted to participate in a patient's collaborative drug therapy management, including all covering physicians and/or pharmacists. Each covering physician shall meet the requirements of N.J.A.C. 13:35-6.27(b) and each covering pharmacist shall meet the requirements of N.J.A.C. 13:39-13.3. The agreement shall establish the means by which the physician and/or pharmacist will be notified about covering practitioners for collaborative practice purposes;

2. Specify the functions and responsibilities, including the scope of practice and authority, to be exercised by the pharmacist;

3. Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies;

4. Indicate*[, if appropriate,]* any diagnosis or types of diseases that are specifically included or excluded;

5. Include copies of all protocols to be used in the collaborative practice;

6. Contain an effective date for the agreement; and

7. Be signed and dated by the physician(s) and pharmacist(s).

(b) Any changes, additions, or deletions to the collaborative practice agreement shall be submitted to the Board upon request.

(c) The pharmacist shall cooperate with the method established by the physician for monitoring compliance with the agreement and clinical outcomes of the patients.

(d) The collaborative practice agreement may be terminated at any time by either the

physician or the pharmacist by written documentation. Upon termination of a collaborative practice agreement, the physician and the pharmacist shall provide notice of the termination to each individual patient who is undergoing collaborative drug therapy management. Upon termination of the agreement, the patient's informed consent for collaborative drug therapy management under the agreement shall be voided.

(e) All records relating to a collaborative practice agreement shall be maintained in either hard copy or electronic form for a period of not less than seven years from the date of termination of the agreement and shall be supplied to the Board upon request. All records shall be made available to persons authorized to inspect them under State and Federal statutes and regulations. The oldest six years of information shall be maintained in such a manner, so as to be retrievable and readable within two weeks. The most recent one year of information shall be retrievable and readable within one business day. Records not currently in use need not be stored in the pharmacy, but the storage facilities shall be secure. Patient records shall be kept confidential.

13:39-13.5 Collaborative practice protocols

(a) A collaborative practice protocol shall be developed for each different type of collaborative drug therapy management authorized by the physician under the collaborative practice agreement and shall identify those activities that may be performed by the collaborating pharmacist.

[page=219] (b) Each protocol shall:

1. Be jointly developed by the physician and the pharmacist, consistent with standards and practices that are deemed commonly accepted and recognized by national standard setting organizations, or national or State professional organizations of the same discipline as the treating physician, and be signed and dated by both the physician and the pharmacist;

2. Be initiated and utilized at the sole discretion of the physician for a specific patient with whom the physician has a bona fide physician-patient relationship as defined in N.J.A.C. 13:35-6.27(a);

3. Be agreed to by both the physician and the pharmacist with the written informed consent of the patient, consistent with the requirements of N.J.A.C. 13:39-13.6;

4. Be available at the practice sites of the pharmacist and physician and made available at each site to the patient;

5. Establish the means by which the patient will be advised of the right to elect to participate in and withdraw from the collaborative drug therapy management;

6. Establish when physician notification is required, the physician chart update interval, and an appropriate time frame within which the pharmacist shall notify the physician of any change in dose, duration, or frequency of medication prescribed. Written notification, by either facsimile or electronic means, shall be provided to the physician no later than eight hours after any change in prescribed medication is made by the pharmacist;

7. Identify the method and time frame for notification of the physician if an adverse event occurs; and

8. Be reviewed at least once per year by the parties to determine whether the protocol

should be renewed, modified, or terminated.

13:39-13.6 Informed consent for collaborative drug therapy management

(a) Written informed consent shall be obtained from each individual patient participating in collaborative drug therapy management. Both the physician and the pharmacist shall retain a copy of the patient's written informed consent. The written informed consent shall:

1. Contain the specific patient's name;

2. Identify the risks and benefits of collaborative drug therapy management, including the fact that services provided under collaborative drug therapy management may not be covered by the patient's insurance provider;

3. Identify the fact that covering physicians and/or pharmacists may be utilized in the collaborative drug therapy management of the patient's care;

4. Identify the patient's right to elect to participate in and withdraw from the collaborative drug therapy management; and

5. Be signed and dated by the patient.

13:39-13.7 Scope of collaborative drug therapy management

(a) Collaborative drug therapy management shall be between a single patient with whom the physician has a bona fide physician-patient relationship, the physician, and the patient's collaborative practice pharmacist(s) and shall address that patient's specific condition, disease or diseases.

(b) Collaborative drug therapy management may include the collecting, analyzing, and monitoring of patient data, ordering or performing of laboratory tests based on the standing orders of a physician as set forth in the written collaborative practice protocols, consistent with (c) below; ordering of clinical tests based on the standing orders of a physician as set forth in the written collaborative practice protocols; modifying, continuing, or discontinuing drug or device therapy; and therapeutic drug monitoring with appropriate modification to dose, dosage regimen, dosage forms, or route of administration.

(c) A pharmacist may perform laboratory tests that are granted waived status in accordance with the provisions of the "New Jersey Clinical Laboratory Improvement Act," P.L. 1975, c. 166 (N.J.S.A. 45:9-42.26 et seq.), Department of Health and Senior Services' rules set forth at N.J.A.C. 8:44, and Department of Health and Senior Services CLIA Program requirements, available at http://www.state.nj.us/health/phel/instruct116.shtml, provided the tests are consistent with the pharmacy practice area or disease state covered by the collaborative practice agreement.

(d) The interpretation of clinical or laboratory tests under a written collaborative practice protocol shall be performed by a pharmacist only in direct consultation with a physician.

(e) Collaborative drug therapy management shall not include therapeutic interchange at the time of dispensing without the prior, specific informed consent of the patient and the consent of the patient's physician. Written confirmation of the consent, which may be by electronic means, shall be maintained at the pharmacy practice site of the collaborating pharmacist.

13:39-13.8 Voluntary participation

(a) Participation in, or withdrawal from, a collaborative practice agreement shall be voluntary on the part of a physician and a pharmacist.

(b) Participation in, or withdrawal from, collaborative drug therapy management shall be voluntary on the part of the individual patient.

13:39-13.9 Failure to comply

Any violation of the collaborative practice agreement or protocols on the part of the pharmacist may be deemed professional misconduct and may subject the pharmacist to discipline consistent with N.J.S.A. 45:1-21.

Appendix

Collaborative Practice Agreement

The Pharmacist(s) and Physician(s) listed below are parties to this collaborative practice agreement, through which the pharmacist(s) receives authority, under the supervision of the physician(s) (or covering physician), to perform the functions outlined in accordance with applicable New Jersey statutes and regulations.

Physician:

Name: _____ Title: _____

Address: _____

Phone Number: _____ License Number: _____

Type of Practice/Specialty: _____

Pharmacist:

Name: _____

Address: _____

Phone Number: _____ License Number: _____

Qualifications for Collaborative Practice: _____

Describe the functions and responsibilities, including scope and authority, to be exercised by the pharmacist (attach extra sheets if needed):

Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies under this agreement (attach extra sheets if needed):

[If appropriate, indicate] ***Indicate*** any diagnosis, or types of diseases which are specifically included or excluded under this agreement (attach extra sheets if needed):

Attach any protocols to be used in decision making or other activities contemplated under this agreement. This must include a protocol for treating an acute allergic or other adverse reaction related to drug therapy. Each protocol must establish when physician notification is required, the time frame within which the pharmacist must notify the physician of any change in dose, duration or frequency of medication prescribed, and the type of pharmacist documentation required. Written notification, by either facsimile or electronic means, shall be provided to the physician no later than eight hours after any change in prescribed medication is made by the pharmacist.

Physician Signature: _____ Date: _____

Pharmacist Signature: _____ Date: _____