



Collaborative Practice: The future of pharmacy practice?

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Objectives

Define key terms relating to collaborative practice

Discuss how collaborative practice between pharmacists and physicians can impact patient outcomes.

Describe the History of Board of Pharmacy Regulations regarding Collaborative Practice.

Identify Board of Pharmacy regulations governing Collaborative Practice

Describe potential issues facing pharmacists in the Collaborative Practice setting

Discuss current compensations challenges for those involved in Collaborative Practice.

Disclosures

The speakers have no disclosures to make

Where we are

NJ Regulations were adopted in February 2013

First pre-approval request submitted to the Board in May 2014

Since then several others have also applied.

More applications anticipated in coming months.

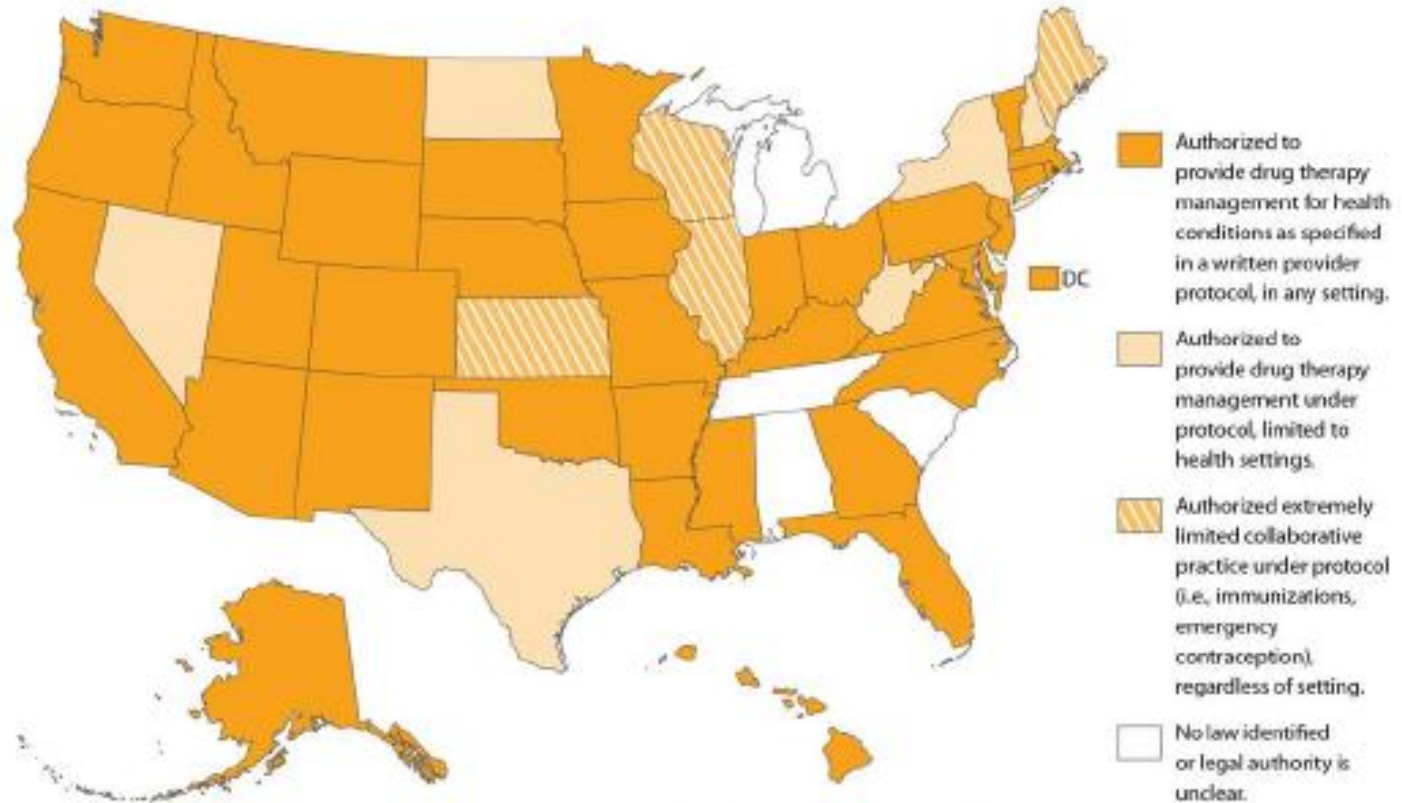
Collaborative Practice National Overview

In January 2012, the APhA Foundation convened a roundtable consortium in Washington, D.C., for the purposes of stimulating increased integration of collaborative practice agreements (CPAs) and pharmacists' patient care services into practice.

“The healthcare environment in the United States is undergoing unprecedented change, with myriad healthcare reform initiatives, mounting evidence for the positive contributions of pharmacists, and federal government interest in pharmacist-provided services from the Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention (CDC), and Surgeon General. Many individuals and groups have asserted that pharmacists are a dramatically underused resource that could help improve outcomes within our healthcare delivery system, if properly engaged as essential members of the healthcare team.”

Where we are, cont.

Figure 1. Map of States with Laws Explicitly Authorizing Pharmacist Collaborative Practice Agreements, 2012



Note: Physician delegation is considered permissive in MI and WI, allowing physicians and pharmacists to enter into CPAs.

Image by CDC

Where we are cont.

Kansas officially became one of 48 states and Washington, D.C. to adopt regulations concerning collaborative drug therapy management on July 1, 2014

The extent of these regulations varies greatly by state.

- Some simply define and authorize CDTM in broad terms
- Others limit CDTM to certain situations, medications or locations.

Collaborative Practice National Overview

McKnight AG, Thomason AR. Pharmacists' advancing roles in drug and disease management: a review of states' legislation. *J Am Pharm Assoc* (2003). 2009 Jul-Aug;49(4):554-8.

Review to determine the states which included provisions for pharmacist involvement in drug management and disease programs and collaborative practice agreements.

Also aimed to identify the certification or specialized training needed by pharmacists to engage in the above activities.

Collaborative Practice National Overview cont.

McKnight AG, Thomason AR. cont.

- 42 states (84%) – provisions for pharmacist drug and/or disease management programs
- 19 states (38%) – specific provisions for disease management
 - 33 states (66%) – provisions for medication therapy management (MTM)

37 states (74%) – provisions for collaborative practice

Collaborative Practice National Overview cont.

McKnight AG, Thomason AR. cont.

11 states (22%) – specified pharmacists receive specialized training, but differ in the type of training required

- Advanced educational requirements
 - Alaska, Arkansas, California, Colorado, Georgia, Iowa, New Mexico, North Carolina, North Dakota, Rhode Island, West Virginia

- States which require the BCPS (Board Certified Pharmacotherapy Specialist)
 - Colorado, Iowa, North Dakota, North Carolina, Rhode Island

Collaborative Practice National Overview cont.

McKnight AG, Thomason AR. cont.

16 states (32%) – required board approval, notification, or registration for collaborative practice agreements

- Alaska, Colorado, Connecticut, Iowa, Montana, Nebraska, New Mexico, North Carolina, North Dakota, Oklahoma, Pennsylvania, Texas, Utah, Virginia, Washington, Wyoming
- Iowa no longer requires registration as of July 1, 2008

States which do not require notification or registration require pharmacists to maintain records for protocols and be readily retrievable for a set number of years (usually 2 years)

Some states require pharmacists obtain liability insurance at a minimum of \$1 million

Collaborative Practice National Overview cont.

McKnight AG, Thomason AR. cont.

“Collaborative practice agreements were sometimes extensively described and governed by legislation...”

- Emergency contraception collaborative protocols only (Hawaii and Vermont)
- Vaccination collaborative protocols only (Florida, Kansas, and Wisconsin)
- All other states allowed for a broad range of collaborative practice agreements as allowed by wording

The Discussion in New Jersey

Specific provisions for which the Medical Society of NJ advocated included:

- Pharmacists may modify, continue or discontinue drug therapy, but may not initiate;
- Collaborative practice arrangements are limited to individual pharmacists (and may not be with a pharmacy or a chain);
- There must be a bona fide relationship for a physician and pharmacists to enter into a collaborative practice arrangement;
- The pathways for pharmacists to participate in collaborative agreements has been better defined; a voucher of 2,000 hours of training is not sufficient;

The Discussion in New Jersey cont.

Specific provisions for which the Medical Society of NJ advocated also included:

- Covering physicians and pharmacists must meet the same standards as the individuals entering into the arrangements;
- Specific conditions/diseases must be specified in the collaborative agreement; and
- Pharmacists must complete ten hours of continuing education on the specific disease states or conditions covered by the collaborative agreement which may require more than the minimum 30 hours, biennial, of continuing education depending on the number of conditions/disease states covered; physicians may customize the disease specific training required for the treatment of his/her patients.

The Discussion in New Jersey cont.

Can there be a financial relationship between the physician and pharmacist?

- Board Comment: When the Boards repropoed 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. [T]he Board of Pharmacy did not believe that it was necessary to change the repropoed rules to address concerns regarding underlying business or financial relationships between collaborating physicians and pharmacists because existing [regulations] 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 concerns about inappropriate profit motives have been alleviated.

The Discussion in New Jersey cont.

Is the continuing education requirements in addition to licensure requirements?

- Board Comment: 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 [CE] required by this section are part of the minimum number of 30 credits that must be completed.

The Discussion in New Jersey cont.

Are the requirements for pharmacists sufficient?

- Board Comment: The Boards chose not to mandate specific disease training 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 repropose 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.

New Jersey Collaborative Practice

Collaborative Practice – Key terms

- Collaborative drug therapy management: 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 protocol: 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 by the Board

N.J.A.C. 13:39-13.2

New Jersey Collaborative Practice cont.

Collaborative Practice – Key terms cont.

- Informed consent: 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: the substitution and dispensing of a drug chemically dissimilar from the prescription drug originally prescribed.

New Jersey Collaborative Practice cont.

Collaborative Practice – Scope

- 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.

N.J.A.C. 13:39-13.7

New Jersey Collaborative Practice cont.

Collaborative Practice – Scope

- 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.
- 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.

New Jersey Collaborative Practice cont.

Collaborative Practice – Scope

- 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.
- 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.

New Jersey Collaborative Practice cont.

Collaborative Practice – Qualifications

- Licensed pharmacist must be pre-approved by the Board to engage in such activity.
- Application process
- The Board will require:
 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.

New Jersey Collaborative Practice cont.

Collaborative Practice – Qualifications cont.

- A pharmacist granted authorization to engage in collaborative drug therapy management shall complete a minimum of 10 credits of continuing education every biennial renewal period in each disease(s) or condition(s) covered by the collaborative practice agreement(s) to which he or she is a party
- 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.

New Jersey Collaborative Practice cont.

Collaborative Practice – the Agreement

- 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.
- The collaboration that the physician agrees to conduct with the pharmacist must be within the scope of the physician's practice
- The agreement shall establish the means by which the physician and/or pharmacist will be notified about covering practitioners for collaborative practice purposes

N.J.A.C. 13:39-13.4; 13:35-6.27

New Jersey Collaborative Practice cont.

Collaborative Practice – the Agreement cont.

- Specify the functions and responsibilities, including the scope of practice and authority, to be exercised by the pharmacist;
- **Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies**
- Indicate any diagnosis or types of diseases that are specifically included or excluded
- **Include copies of all protocols to be used in the collaborative practice**
- Contain an effective date for the agreement
- Be signed and dated by the physician(s) and pharmacist(s).

New Jersey Collaborative Practice cont.

Collaborative Practice – the Agreement cont.

- The pharmacist shall cooperate with the method established by the physician for monitoring compliance with the agreement and clinical outcomes of the patients.
- The collaborative practice agreement may be terminated at any time by either the physician or the pharmacist by written documentation.
- Upon termination of the agreement, the patient's informed consent for collaborative drug therapy management under the agreement shall be voided.
 - If then restart agreement, must get new patient consent
- 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.

New Jersey Collaborative Practice cont.

Collaborative Practice – protocols

- 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
- Must be jointly developed by the physician and the pharmacist, and be signed and dated by both the physician and the pharmacist
- Be agreed to by both the physician and the pharmacist with the **written informed consent of the patient**
- Be available at the practice sites of the pharmacist and physician and made available at each site to the patient
- 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;

N.J.A.C. 13:39-13.5; 13:35-6.27

New Jersey Collaborative Practice cont.

Collaborative Practice – protocols cont.

- For a **specific patient** with whom the physician has a **bona fide physician-patient relationship**
 - 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.
 - The physician-patient relationship has existed for at least one year;
 - The physician has seen and/or assessed the patient on at least four visits; or
 - The physician assumes responsibility for providing management and care of the patient's condition after conducting a comprehensive medical history and physical examination.

New Jersey Collaborative Practice cont.

Collaborative Practice – protocols cont.

- Identify the method and time frame for notification of the physician if an adverse event occurs
- Be reviewed at least once per year by the parties to determine whether the protocol should be renewed, modified, or terminated.
- 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;

New Jersey Collaborative Practice cont.

Collaborative Practice – informed consent

- The written informed consent shall:
 - Contain the specific patient's name
 - 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;
 - Identify the fact that covering physicians and/or pharmacists may be utilized in the collaborative drug therapy management of the patient's care
 - Identify the patient's right to elect to participate in and withdraw from the collaborative drug therapy management; and
 - Be signed and dated by the patient.
- Both the physician and the pharmacist shall retain a copy of the patient's written informed consent.

N.J.A.C. 13:39-13.6

Reimbursement

In 2012, the Academy of Managed Care Pharmacy issued a Practice Advisory on Collaborative Drug Therapy Management

“Managed care organizations have three primary goals in managing the health of their enrollees: improving the quality of patient outcomes, increasing patient satisfaction and managing costs. CDTM agreements between physicians and pharmacists serving a managed care organization’s enrollees can contribute to each of those goals.”

“CDTM agreements take maximum advantage of the physician’s training and expertise in disease diagnosis and the pharmacist’s training and expertise in drug therapy and disease management.”

Reimbursement cont.

“As such, the return on investment calculated by the managed care organization is expected to be positive and may allow for the organization to take a proactive role in proposing new CDTM arrangements between willing physicians and pharmacists to be used within a managed care organization.”

Reimbursement cont.

Methods for Reimbursement: Specific method selected depends on the

- Payer
 - Medicare, Medicaid, Third Party Payers, First Party Payers
- Setting
 - Hospital based clinics, Physician clinics, Community pharmacies, Managed Health Care, Other
- Professional
 - Pharmacists
- Other methods
 - CLIA waived testing

Reimbursement cont.

CDTM arrangements exists within health plans, including:

- Emergency contraception
- Asthma therapy management
- Immunization administration
- Hypertension therapy management
- Dyslipidemia therapy management
- Warfarin/anticoagulant therapy management
- Diabetic therapy management
- Depression therapy management
- Smoking cessation therapy
- Flu/antiviral therapy

Reimbursement cont.

In a managed care environment, CDTM pharmacists can work as other advanced-trained nonphysician health care providers (eg, nurse practitioners) who are often perceived as physician extenders.

In a fee-for-service environment, pharmacists have three options: they can work as part of a physicians' group practice and file for payment under the physician's provider number, they can apply for their own provider number, or patients can pay cash for their services.

Potential Liability

Pharmacists practicing CDTM expose themselves to three different types of sanctions:

- Administrative – e.g. practicing beyond the scope of authorizing license, for which the pharmacy board can revoke or suspend the pharmacist's license.
- Civil – e.g. acting within the scope of pharmacy practice, but performing in a substandard fashion and, because of the malpractice, the patient has suffered harm.
- Criminal -- practicing medicine without a license, unlawfully prescribing controlled substances, or committing Medicare or Medicaid fraud.[39]

Potential Liability cont.

State v. Muraida, 2014-NMCA-060 (N.M. Ct. App. 2013)

- The State appeals the district court's dismissal of the criminal complaint charging Defendant Gerard Muraida, M.D., with abuse and/or neglect of a nursing home resident, who died due to blood loss from an excessively prescribed quantity of the anticoagulant drug Coumadin.

Potential Liability

cont.

Facts:

Initially, Defendant utilized a blood test called Protime to monitor the anticoagulative effects of Coumadin on D.A. This test measures the INR in comparison with the standard clotting time for the average person, for which a baseline INR value of 1.0 is assigned.

In this case, the therapeutic INR goal for D.A. was between 2.0 and 3.0.

At the admission examination conducted by Defendant on August 16, Defendant noted that D.A. had "multiple bruises[,] 'areas related to her anti[]coagulation and hospitalization.' He also noted an elevated INR of '3.4' which was higher th[an her therapeutic] 'INR' goal of '2 to 3.' [At that time, D.A.'s] Coumadin dose was 1.0 mg per day."

Potential Liability

cont.

Facts cont.

Several days later on August 19, D.A.'s "INR was 1.74, [and Defendant] increased the Coumadin dose on [August 20] to 1.5 mg per day. Inexplicably, no additional INR's were ordered for (a week) even though a new dose of Coumadin was started,

Six days following the increase in Coumadin dosage and upon discovery of blood in D.A.'s stool on August 26, Defendant "ordered [ACC] nursing to schedule a colonoscopy with a gastroenterologist . . . 'for possible hemorrhoids' ([without a] basis in [her] chart for that diagnosis). [In addition, t]he appointment was not asked for on an emergent basis." No INR test was administered at that time.

Ultimately, on September 1, D.A. was sent to the emergency room for acute rectal bleeding. The affidavit states that she was "massively over anticoagulated," possessing an INR "greater than 12.5[,] despite her anticoagulation goal being [an INR of 2.0 to 3.0]."

Potential Liability cont.

Facts cont.

D.A. died from blood loss from a tumor in her colon as a result of the anticoagulation treatment. Dr. Lipson, the State's expert, stated that "[h]ad [Defendant] on [August 26] immediately and aggressively followed up on her initial reported rectal bleeding by stopping the Coumadin and getting an emergent colon[ology]scopy [, D.A.] would not have died on [September 1, 2005]." Dr. Lipson concluded that Defendant's "grossly negligent conduct directly led to [D.A.'s] death."

Defendant contends that the complaint attempts to make Defendant " 'responsible' for the actions of other people—such that he could be held criminally liable for the[ir actions], " Defendant's team of "physician extenders" included a certified physician assistant and a certified nurse practitioner who had a collaborative practice agreement with Defendant.

Potential Liability cont.

Finding:

Ultimately the Court held that the physician could be found negligent and held liable since there was sufficient evidence that he himself failed to provide appropriate care. (“As explained above, the complaint provides several instances where Defendant personally acted or failed to act, jeopardizing D.A.’s life.”)

What if physician’s liability wasn’t as clear-cut?

Elements of a Negligence Case

- A. Duty
- B. Standard of Care
- C. Breach
- D. Cause in Fact
- E. Proximate Cause
- F. Damages
- G. Vicarious Liability
- H. Joint and Several Liability

Duty

The law normally imposes a duty to use due care on everyone.

It is generally accepted that a pharmacist owes a duty of care to a patient and their dependents.

This is based on the pharmacist-patient relationship.

Standard of Care

After finding a duty, one next must examine whether the defendant's conduct created an unreasonable risk of harm to others.

In the pharmaceutical setting that question would be framed with regard to a pharmacist.

Standard of Care (Differs Depending on the Relationship)

1. Reasonable Person Standard
2. Professionals
 - a) Basic Standard
 - b) Expert Testimony
 - c) Special Considerations

Standard of Care

1. Reasonable Person Standard

- In a non-professional setting, the reasonable person standard is utilized in this analysis.
- It asks how would a reasonable person have acted under similar circumstances.

Standard of Care

2. Professionals

- The standard of care utilized in a professional setting is that which would be exhibited by a professional under similar circumstances.
- It is important to note that this standard does not require at all times the professional to act correctly.

Standard of Care

2a) Basic Standard-

Professional conduct is measured against the minimum common skill of members in good standing in the profession.

Standard of Care

- 2b) Expert Testimony - Is generally required in determining how a professional would have acted under similar circumstances. In pharmacy matters a pharmacist would give testimony.

Standard of Care

2c) Special Considerations

- i) Locality Rule-Professionals will be held to the standards of their locality. Thus, standards may differ in a large city and a small town.

- ii) Specialists-Held to the national standard.

- iii) Civil and Criminal Statutes-If there is a specific civil liability statute on point, the pharmacist is subject to that penalty. Usually only a criminal statute applies, and it is less clear.

Breach

In performing a negligence analysis, one must simply determine whether defendant in fact breached the applicable standard of care discussed above.

To make this determination, one need look at the facts and determine if a breach occurred.

Cause in Fact

After the plaintiff has proven the above elements the next issue is whether defendant's conduct was a cause in fact or factual cause of plaintiff's harm.

Cause in Fact

1. “But For Test”
2. Substantial Factor Test
3. Action vs. Inaction
4. Summers vs. Tice

Cause in Fact

1. “But For Test”-

The but for test requires the injured party prove that his injury would not have occurred “but for” the negligent actions of defendant.

Cause in Fact

2. Substantial Factor Test-

- Can be more stringent than the “but for” test.
- Defendant’s negligent conduct must have been a “substantial factor” in causing the plaintiff’s injury.

Cause in Fact

3. Action vs. Inaction-

- Defendants can be held responsible for actions as well as inactions.
- Action-Dispensing the wrong medication.
- Inaction-Failure to warn of an adverse reaction.

Proximate Cause

If all the above elements are established, plaintiff must then demonstrate proximate cause.

This is sometimes referred to as legal cause.

Proximate Cause

Definition:

Proximate cause is concerned with policy considerations limiting the scope of liability.

For example: is it to society's benefit to hold the pharmacist liable for a certain type of conduct?

Foreseeability:

The proximate cause issue centers on whether the injury was reasonably foreseeable as resulting from the conduct in question. Palsgraph v. Long Island Railroad.

Damages

1. Mental Pain and Suffering
2. Physical Pain and Suffering
3. Medical Expenses
4. Lost Wages and Future Earnings (PA)
5. Child Care Costs
6. Loss of Consortium
7. Negligent Infliction of Emotional Distress
8. Punitive

Damages

1. Mental Pain and Suffering

- Mental anguish from an injury.

2. Physical Pain and Suffering

- Actual inflicted pain.

3. Medical Expenses

- Only those expenses not paid by insurance

4. Lost Wages and Future Earnings

- Plaintiff may be eligible for wage reimbursement for lost work days and disability.

Damages

5. Child Care Costs

- Cost of raising a child or other relevant damages.

6. Loss of Consortium

- Plaintiff may sue based on his or her loss of the right of his/her spouse to the company of, help of, affection of, and sexual relations with his or her mate.

Damages

7. Negligent Infliction of Emotional Distress

- One has a legal duty to use reasonable care to avoid causing emotional distress to another individual.
- An example is when a mother witnesses the injury of her child.

8. Punitive

- A court can award damages in amounts that exceed the economic losses and general damages of an injured party. These are intended solely to punish the defendant because of reckless or malicious acts.

QUESTIONS?