Collaborative Practice Regulations

Finally after many years of waiting – since 2010 – Collaborative Practice for pharmacists in any practice setting is permitted. The Independent Regulatory Review Commission (IRRC) voted to approve the final form of the regulation on July 9 and with its publication in the PA Bulletin, at the end of August 2015, the Act and its regulations are final and pharmacists can now expand their practice under this guidance. Here is a short summary of the Act and regulations:

- The main objectives were:
  1. To employ regulations from Act 29 of 2010, which will amend the Pharmacy Act to provide for collaborative management of drug therapy between a physician and pharmacist in a non-institutional setting, without giving prescriptive authority to the pharmacist
  2. To utilize with consistency the statutory terms
  3. To clarify and update the liability insurance obligations for pharmacists who are participating in collaborative management of drug therapy in any setting.
- Amended existing regulations 27.1, 27.301 and 27.311 and will add 27.302 and 27.312, which will discuss collaborative agreement for management of drug therapy in a non-institutional setting and certification of professional liability insurance.
- The management of drug therapy is considered:
  1. Adjusting a drug regimen
  2. Adjusting drug strength, frequency of administration or route
  3. Administration of drugs
  4. Ordering laboratory tests and ordering and performing other diagnostic tests necessary in the management of drug therapy, consistent with the testing standards of the institution
  5. Monitoring the patient’s vital signs
  6. Providing education and training to the patient that is related to the management of the drug therapy

Management in a non-institutional setting:

- Need a written collaborative agreement with a physician authorizing management of drug therapy for diseases or conditions/symptoms of a disease. Must be between physician and a pharmacists
- Pharmacist may not give economic or other incentives, inducements or benefits to physician to get them to enter into a collaborative agreement
- A pharmacists employed by a physician under a collaborative agreement for management of drug therapy may not engage in retail dispensing while in the health care practice or within the context of employment
- The collaborative agreement must contain:
1. A statement identifying the physician responsible for authorizing the management of drug therapy
2. A statement identifying the pharmacist authorized to perform the management of drug therapy
3. A statement requiring that regimens for the management of drug therapy be initiated by a physician for patients referred to a pharmacist for management of drug therapy
4. A statement identifying the types of decisions relating to the management of drug therapy that the pharmacist is authorized to make within the physician’s scope of practice and types of management of drug therapy authorized
5. A statement identifying the terms under which a pharmacist providing the management of drug therapy is permitted to: adjust the drug regimen, the drug strength and the frequency of administration or the route of administration; administer drugs; order laboratory tests and order and perform other diagnostic tests necessary in the management of drug therapy without prior written or oral consent by the collaborating physician. **This section does not provide prescriptive authority to a pharmacist.**
6. A statement of the functions and tasks the pharmacist shall follow in the course of exercising management of drug therapy, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation of each intervention shall occur as soon as practicable, but no later than 72 hours after the intervention, and be recorded in the pharmacist’s records.
7. A statement that requires notification to the authoring physician of any changes in dose, duration or frequency of medication prescribed as soon as practicable but no longer than 72 hours after the change.
8. A provision for implementation of the collaborative agreement when a physician or pharmacist who is a party to the agreement is temporarily unavailable to participate in its implementation
9. A provision for notification of the role of the pharmacist by a physician to each referred patient the management of whose drug therapy may be affected by the collaborative agreement and providing an opportunity for the patient to refuse management of drug therapy by a pharmacist
10. The signatures of the physicians and pharmacists who are entering into the collaborative agreement and the dates signed
11. A statement allowing for the termination of the collaborative agreement at the request of a party to it at any time
   - The agreement must be available: at the practice sites of each physician and pharmacist, to any patient who is affected by the protocol and upon request to representatives of the Bureau of Professional and Occupational Affairs (BPOA) and the Department of Health
   - **THE COLLABORATIVE AGREEMENT MUST BE FILED WITH THE BUREAU (BPOA).**
   - Agreement must be maintained on the premises of the pharmacy for review during inspection or by request of representatives of the BPOA and the Department of Health
• The protocol is effective for a period of no more than 2 years and at the end of the period (or sooner) the parties shall review, make any modifications, and determine renewal
• The pharmacist shall:
  1. Utilize an area for in-person, telephone or other approved electronic consultations regarding the management of drug therapy that ensures the confidentiality of the patient information being discussed
  2. Initiate the management of drug therapy only upon a written referral to the pharmacist from the physician. The written referral must include the minimum frequency in which the pharmacist shall conduct the management of the drug therapy in person
  3. Confirm that the physician who is a party to the collaborative agreement holds an active and unrestricted license and that the terms of the collaborative agreement are within the scope of the physician’s current practice at the time of the execution of the collaborative agreement
• Patient Records:
  1. The pharmacist shall have access to the records of the patient who is the recipient of the management of drug therapy
  2. The authorizing physician shall have access to the pharmacy records pertaining to the patient receiving management of drug therapy
  3. Handling of patient records must comply with HIPPA

Professional Liability Insurance (Written Protocol and Collaborative Agreement):

• Minimum amount of $1,000,000 per occurrence or claims made. Acceptable forms:
  1. Personally purchased professional liability insurance
  2. Professional liability insurance coverage provided by the individual licensee’s employer
  3. Similar insurance coverage acceptable to the Board
• Must submit certification form to the Board with the written protocol and affidavit with the collaborative agreement
• Must produce upon request to the Board or its agents a certificate of insurance regarding the licensee’s maintenance of professional liability insurance, including policies, cancelled checks, receipts or other proofs of premium payment
• Failure to maintain insurance will result in disciplinary action