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Expanding Clinical Pharmacy Services in the Independent Community Pharmacy Setting
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Objectives
At the completion of this activity, pharmacists and technicians will be able to:
1. Define Clinical Pharmacy Services
2. Describe the historical expansion and lawful procurement of clinical services in a community pharmacy setting.
3. Identify the requirements to offer clinical pharmacy services in a community setting.
4. Recognize the steps needed to establish a physician-based clinical pharmacy protocol in the community pharmacy setting.
6. Identify and document the requirements for billing for clinical pharmacy services in the community setting.

Clinical Pharmacy - defined
"Clinical Pharmacy is a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention. The practice of clinical pharmacy embraces the philosophy of pharmaceutical care; it blends a caring orientation with specialized therapeutic knowledge, experience, and judgment for the purpose of ensuring optimal patient outcomes. As a discipline, clinical pharmacy also has an obligation to contribute to the generation of new knowledge that advances health and quality of life." The Definition of Clinical Pharmacy from Pharmacotherapy 2008;28(6):816-817.

Clinical Pharmacy Services
- Clinical pharmacy services in the independent pharmacy setting are an extension of the typical daily dispensing of drugs and drug information most often associated with community pharmacies. Clinical pharmacy services are offered in a variety of specialties and meet the extended medication needs of patients to increase medication adherence, to increase patient medication safety and efficacy, and to allow pharmacists to practice at the top of their license to meet the growing demands of the health care system in regards to medication use.
- Specific examples for this presentation: Medication Therapy Management or MTM, childhood and travel immunizations and medication discharge program.
- What are other clinical pharmacy services available in the community pharmacy setting?

Historical perspectives of clinical pharmacy services
- From compounding and dispensing of drugs to dispensing drug information and providing pharmaceutical care
- Technology influences on the pharmacy profession
- Education requirements: B.S. to Pharm.D.
- Residency/Fellowships
- Hospital/clinic-based vs. Community-based
- Job Demand – shortage of pharmacists?
- Refer to Appendix A for printed timeline

CPE credit
“Expanding Clinical Pharmacy Services in the Independent Community Pharmacy Setting” is accredited by ACPE for pharmacists and technicians.
ACPE course numbers:
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- Anna H. Brozick has not disclosed any financial or conflicts of interest in relation to this program.
Laws governing clinical pharmacy

- In Texas:
  - RULE §291.33 (2)(B)(i-v) - Operational standards for community pharmacies (Class A), other pharmaceutical care services
  - RULE §295.12 - Pharmacist Certification Programs
  - RULE §295.13 - Drug Therapy Management by a Pharmacist under Written Protocol of a Physician
  - RULE §295.15 - Administration of Immunizations or Vaccinations by a Pharmacist under Written Protocol of Physician
- Disclaimer: this information is provided as a reference only. Interpretations and execution of the law, including any questions regarding specific implementation of your clinical pharmacy services should be directed to the appropriate state board.

Resources – money, time, staff, space, written protocols

Steps for developing clinical protocols

- Assess needs of your patients and practitioners
- Formalize and document your clinical pharmacy services and goals
- Develop/enhance professional relationship(s) with medical practices in your community including:
  - Primary care physicians
  - Pediatricians
  - Dentists
  - Specialists (endocrinology, cardiology, dermatology, etc.)

Developing relationships

- Utilize a marketer or other employee for marketing purposes.
- Schedule face-to-face introductions
  - Walk-ins/drop-ins are ok, but keep to a minimum: be sure you have marketing materials if you walk in or drop in
- Commit to your marketing plan: make sure you involve the practice manager in the plans even if he/she is not involved in direct patient care
- Create clinical pharmacy brochures to summarize your services – simple and succinct
- Formalize your clinical pharmacy goals to communicate with your potential clients (consider your audience – different marketing materials depending on the audience, i.e. patients vs. Prescribers)

Evaluating current pharmacy staff

- Do you have the necessary staff to implement and accomplish your clinical pharmacy services goals?
- Is your staffing structure appropriate? Consider an organizational structure or restructuring, particularly if you are expanding the number of staff members, either professional or non-professional.
  - Communicate plans and goals with existing staff
  - Solicit input and ideas from existing staff
  - Develop or modify your pharmacy’s organizational structure (this is particularly important if you own/operate more than one independent pharmacy) – refer to Appendix B for a sample organizational structure

Clinical Pharmacy Protocols

- Steps:
  - Identify needs of patients, practitioners
  - Develop relationships with prescribers
  - Write/adopt clinical protocols

Requirements for clinical pharmacy services in the independent pharmacy

- Knowledge of laws
- Assessment of community needs – what do your patients need? And what do the practitioners need?
- Evaluation of costs of clinical services
- Resources – money, time, staff, space, written protocols
General Protocol Outline

1. Service provided
   1. Definition and explanation of the service
   2. How the clinical pharmacy service benefits the patient
   3. How the clinical pharmacy service benefits the prescriber

2. Explanation of the relationship between the pharmacy:patient-prescriber

3. Costs - commitments requested from prescriber and the costs to the patient

4. Implementation procedures, including timeline for pharmacy staff and for the relationship between the pharmacy and prescriber

MTM Protocol

• MTM definition: medication therapy management is described as an individualized medication therapy review in which the pharmacist engages in a face-to-face consultation with an individual patient to discuss medication (RX, OTC and supplemental) use, safety and efficacy of medication use, cost-reduction, and medication goals while evaluating the comprehensive medication history of the patient.

MTM Protocol

• The goal of an individualized MTM consultation for the patient is to educate patients about medication drug use, thus decreasing overall drug costs, decreasing drug side effects, and increasing medication adherence.

• The benefits for the prescriber include increased adherence rates, fewer ER and hospital visits for their patients, higher scores on Medicare and HEDIS stars rating criteria, fewer “last-minute” phone calls or requests for emergency refills, among others.


Relationships

• Pharmacy:prescriber – this relationship will be enhanced and will develop more coordination between the pharmacy and all of the patient’s providers or prescribers. The pharmacy will communicate with the physicians’ offices to obtain medical records prior to the MTM consultation, compliant with HIPAA and Medicare laws. Following the individualized consultation session, every prescriber will receive the above listed patient-specific documentation to add to their EHR (CMR and MAP). If warranted, the prescriber will receive potential medication recommendations for changes to the patient’s medication therapy. Examples of recommendations could be changing from 30 day supply to 90 day supply on their maintenance medications, increasing or decreasing dose frequency/dose consolidation, changing from formulary non-preferred drugs (high cost) to formulary preferred (low-cost) drugs, and submitting prior authorization criteria to Medicare part D prescription plans (tiering/cost reduction requests, non-formulary requests, etc.)


MTM protocol: Relationships

• Patient:Pharmacy – this relationship will be enhanced and will develop more trust between the pharmacist and patient. The pharmacy staff will communicate with the patient directly to schedule the initial 30 minute individualized MTM consultation; the pharmacy staff will work with the patient to obtain necessary paperwork including Medicare insurance (for billing purposes), HIPAA forms, medical records release forms and other documentation in order to provide a comprehensive medication therapy review. Following the individualized consultation session, every patient will receive the following from the pharmacy:
  1. Comprehensive medication review (CMR) list: this list will be provided in the format compliant with Medicare Part D standards, including the list of drugs, strength, instructions for use, diagnosis/reason for taking, and any special considerations (ex. adherence, cost, dose consolidation, side effects)
  2. Medication-related Action Plan (MAP): the action plan will be Medicare-compliant formatting with patient specific goals and accountable actions the patient can take to improve medication use.

Relationships

• Prescriber:patient – this relationship will not change and the pharmacy MTM consultation does not replace or supersede the covenantal relationship between the prescriber and the patient. The patient will authorize his/her prescribers to release their medical records to the pharmacy, compliant with HIPAA and Medicare laws. Clinical research has demonstrated that patients who participate in MTM programs through their community pharmacies also higher achievement of health care goals and better quality of life.

MTM protocol: Costs

- Costs to the pharmacy: time, private consultation space, redirection of staff resources, potential hiring of new staff, documentation system, scheduling system, marketing costs, others... discuss costs with colleagues
- Costs to the patient: the pharmacy will set their own price for the MTM consultation visit. Note: it is not free. Pharmacies cannot charge non-Medicare patients less than what they charge Medicare patients.

Rupp NT. Analyzing the costs to deliver MTM services. Pharmacy Today 2011(Apr);17(4):56-64.

MTM protocol: Costs

- There is no cost to the prescriber.
- Are there ways the prescriber can assist the pharmacy by making patient referrals?
- What can the prescribers do to help the pharmacy and staff perform MTM consultations more effectively?

MTM protocol: Implementation

- Develop timeline: determine resources that need to be in place prior to starting the program.
- Set realistic goals. Example: 3 patients the first week, 10 patients in the first month
- Can you use patients to help market your MTM service?
- Creative marketing techniques: ex. offer free medication education seminars to draw patient interest to demonstrate capabilities. Discuss creative and cost-effective marketing with group.

Billing for MTM

- Apply for an NPI number as an individual – http://nppes.cms.hhs.gov/nppes then click on the hyperlink, "create a login"
- Pharmacists can bill for MTM either through a pharmacy or through a recognized provider’s office (incident to physician billing)
- Determine the clinical fees and create an itemized list of services to share with patients
- Consider creating/adapting a Superbill for patients, especially when providing multiple clinical pharmacy services

MTM (CPT) billing codes

- 99605 – for the first visit, the first 15 minutes of the consultation, new patient encounters
- 99606 – the first 15 minutes of the consultation, established patient encounters
- 99607 – each additional 15 minutes of the consultation (an add-on to either above code if needed)


MTM billing

- MTM time is billable only for live face-to-face patient interaction involving patient assessment and interventions by the pharmacist
- Examples of non-billable time: MTM preparation time, patient/technician interactions, product-specific information at the point of dispensing or other routine dispensing-related activities
- Billing for Medicare Part D beneficiaries must be done electronically using CMS 1500 claim form
**Immunization protocol**

- Immunization protocols: Immunization protocols are established between a specific pharmacist (or specific-named pharmacists) within a pharmacy and the specific prescriber or prescriber’s practice. The immunization protocol specifies which immunizations the pharmacist can administer under the supervision of the direct prescriber’s protocol. See Appendix C.
- The goal of pharmacy-based immunizations is to increase the convenience for childhood and travel immunizations for patients while decreasing the workload and burden of immunization coordination for prescriber’s offices.
- As with any new clinical service, identify whether there is a need: are you in an affluent community where travel immunizations are requested? Are you in a family-orientated community where busy parents/caregivers are juggling multiple schedules and pediatrician appointments to keep up with immunization schedules?

**Immunization protocol: Costs**

- Costs to the pharmacy: time, private immunization space, redirection of staff resources, potential hiring of new staff, documentation system, billing system, marketing costs, others... discuss costs with colleagues.
- Costs to the patient: the pharmacy will set their own price for the immunizations – could be based on drug cost alone and or incorporate an administration fee – depending on the type of immunization and the specifics described within the specific protocol.
- Costs to the prescriber: the immunization protocol will incorporate a supervising physician. The Texas State Board of Pharmacy requires the supervising physician review the immunization administration records and act as the prescriber on record. Therefore, only patients who are active within that prescriber’s practice are eligible. The prescribers would be called upon to refer their patients to the pharmacy for immunization business.

**Immunization protocol: Relationships**

- Patient:Pharmacy – this relationship will be enhanced and will develop more trust between the pharmacist and patient. The pharmacy will offer a variety of immunization services directly to the patient, adding convenience and flexibility to the patient’s schedule.
- Pharmacy:prescriber – this relationship will be enhanced and will develop more coordination between the pharmacy and all of the patient’s providers or prescribers. The pharmacy will communicate directly with the physicians’ offices to document immunizations administered, including necessary documentation required by law and the specific protocols.
- Prescriber:patient – this relationship will not change and the pharmacy immunization service does not replace or supersede the covenantal relationship between the prescriber and the patient. The patient will authorize his/her pharmacy to release their immunization records to the prescribers, compliant with HIPAA laws and the specific protocol.

**Medication Discharge Protocol**

- The benefits of the hospital medication discharge program are multi-factorial and can have positive influences on all parties involved.
- Pharmacy: increased RX script volume, increased prevalence and recognition within the greater health care community, increased patient populations served, opportunities to close the gap between in-patient and out-patient settings, provide medication reconciliation, expand opportunities for future MTM consultation visits;
- Patients: increased ease of access to medications following hospital discharge, careful follow-up with medication therapy questions following hospital discharge, decreased polypharmacy, decreased duplicate therapy, decreased side effects, lower readmission rates;
- Prescribers: increased access to medication reconciliation information during transitions of care, improved patient outcomes following hospital discharge, lower readmission rates, increased STAR scores and HEDIS measures.

**Medication discharge program protocol**

- The medication discharge program is a unique pharmacy service offered to inpatients of a partner hospital (or hospital department, ex. Cardiac transplant patients) by which the pharmacy delivers all prescription discharge medications to the hospital unit for distribution at patient bedside upon discharge from the hospital.
- The goal of the hospital medication discharge program protocol is to directly influence patient medication adherence following discharge, to decrease medication side effects from duplicate therapy and to reduce hospital 30-day readmission rates.

**Immunization protocol: Implementation**

- Develop timeline: determine resources that need to be in place prior to starting the immunization program. Write the protocol according to requirements and restrictions within the scope of pharmacy practice, according to the Texas State Board of Pharmacy. Follow DCD guidelines for pediatric immunization schedules and recommendations for travel to foreign countries.
- Set realistic goals. Example: create one new prescriber-relationship per month willing to partner for an immunization protocol.
- How will you market your immunization services?
- Creative marketing techniques: ex. Create pamphlet for the schools within your community, solicit space on a billboard within the doctor’s office or on their website. Other marketing strategies for immunization services?
Medication discharge program protocol

- Refer to the sample discharge program protocol and timeline in Appendix D.
- In your groups discuss the following:
  - Relationships between all three parties: pharmacy:patient:prescribers
  - Costs associated with a medication discharge program
  - Implementation – timeline, goal setting, marketing

Presentation wrap-up

- Take home message
- Questions
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Appendix A – Clinical Pharmacy Timeline

1928 - Pharmacists at the University of Iowa Hospital began participating in patient rounds.
1960 - First use of patient medication profiles in community pharmacy practice was done by Eugene White.
First office-based pharmacy practice opened in Berryville, VA, by Eugene White.
1962 - University of Kentucky Medical Center opened Drug Information Center.
1965 - University of Iowa Drug Information Service (IDIS) was created.
1966 - Ninth-Floor Pharmaceutical Services Project in San Francisco, CA, brought 24/7 drug distribution to the patient care area.

Timeline continued

1971 - University of Missouri- Kansas City began instructing medical students and residents in the safe, effective, and economical use of drugs.
1972 - Prescribing authority was granted to pharmacists in Indian Health Service who completed Pharmacist Practitioner Training Program.
1974 - Pharmacist-conducted drug regimen reviews were required once every 30 days for all residents of skilled nursing facilities.
1977 - Prescriptive authority was given to select pharmacists in California involved in pre-specified projects at University of Southern California and University of California via CDTM.
1979 - First clinical pharmacokinetic service was recognized by third-party payer.

Timeline concluded

1997 - The Asheville Project began using 12 community pharmacists to provide diabetes management services to city employees.
2001 - Pharmacists were represented on epilepsy treatment teams.
2004 - UNOS mandated that a pharmacist be on all transplant teams.
2007 - IDSA (Infect Dis Soc Am) recommended that pharmacists be core members of antimicrobial stewardship teams.
2008 - Pharmacists began serving as medication safety officers.

Timeline continued

1981 - California’s pharmacy practice act was amended to allow pharmacists to perform CDTM.
1985 - ASHP launched an Anticoagulation Clinic Traineeship Program.
1992 - AACP (Am Assoc Coll Pharm) House of Delegates voted to support an all-Pharm.D. program.
1994 - Pharmacists began training to administer immunizations in Washington State.
1996 - Project ImPACT was published, demonstrating the beneficial impact of pharmacists on hyperlipidemia management.
II. Reporting structure - Bottom/up or top/down approach or

- Organizational structure - Influenced by the size of staff and documentation
- Written

Medical

vaccination(s)

immunization protocol.

B. This protocol identifies TSBP registered Pharmacist as an authorized pharmacist

P:

City, ST zip

Name

Medical Practice:

P:

City, ST ZIP

Name

Pharmacy:

A. This protocol exists between the Pharmacy and the Medical Practice as follows:

II. Partners

Medical Practice (hereto referred as the Medical Practice).

two

travel-based immunizations under standing orders for established patients of XYZ

(hereto referred as the Pharmacy) in order to administer pediatric immunizations and

reporting structure consistent from location to location.

the number of pharmacies owned/operated by CEO. Keep

Executive Team including CEO/Owner, CFO, CCO, CTO

death

other

other

etc.) Do staff members function in the capacity of executive team members? For example, do you have a pharmacy technician who makes all of the outbound calls and who coordinates the marketing communications? This individual could hold a communications director title within the pharmacy organization.

II. Reporting structure - Bottom/up or top/down approach or both

a. Clinical Pharmacy Manager
b. Clinical Pharmacists
c. Pharmacy Technicians
d. Patient Care Associates

Appendix B

• Organizational structure - Influenced by the size of staff and the number of pharmacies owned/operated by CEO. Keep reporting structure consistent from location to location.

I. Executive Team including CEO/Owner, CFO, CCO, CTO etc.) Do staff members function in the capacity of executive team members? For example, do you have a pharmacy technician who makes all of the outbound calls and who coordinates the marketing communications? This individual could hold a communications director title within the pharmacy organization.

II. Reporting structure - Bottom/up or top/down approach or both

a. Clinical Pharmacy Manager
b. Clinical Pharmacists
c. Pharmacy Technicians
d. Patient Care Associates

Appendix C

I. Purpose

This protocol describes the policies and procedures for ABC Independent Pharmacy (hereto referred as the Pharmacy) in order to administer pediatric immunizations and travel-based immunizations under standing orders for established patients of XYZ Medical Practice (hereto referred as the Medical Practice).

A. This protocol exists between the Pharmacy and the Medical Practice as follows:

Pharmacy:

Name

Street Address

City, ST ZIP

P:

Medical Practice:

Name

Street Address

City, ST zip

P:

B. This protocol identifies TSBP registered Pharmacist as an authorized pharmacist immunizer for the immunization protocol.

C. The Medical Practice identifies Dr(s). Z, Y, X as the authorized prescribers for the immunization protocol.

Appendix B

Independent Pharmacy Organizational Chart (example)

CEO ≤ ---------------------------- ------ ≥ CFO

Clinical Pharmacy Manager ← ------------− ➔ Pharmacy Ops Manager ← ------------− ➔ Marketing Manager

Pharmacist in Charge ← ------------− ➔ Marketer

Staff/Float Pharmacist

Lead Technician

Technician

Cashier

Dotted line ≤ - - - - ≥ indicates information sharing, equitable responsibility/accountability

Reporting structure – this should be determined by CEO with input from staff

The direction(s) in which information or responsibility flows – as above, determined by CEO with staff input

Appendix C

Sample Immunization Protocol

III. Procedure

- The Pharmacy will obtain required documentation from each patient of the Medical Practice who reports for travel or pediatric immunizations.

- The Pharmacy will fill the standing order for the requested immunization(s) utilizing the electronic POS prescription drug software program.

- The Pharmacy will collect the standard co-pay from the patient determined by the patient’s individual prescription drug insurance company. If the immunization is not covered by the insurance company, then the Pharmacy will charge the patient $x and provide documentation for the patient to submit reimbursement claim directly with their insurance company.

- The pharmacist will evaluate the patient’s medication profile, allergies and current and past medical history; the pharmacist will perform thorough drug utilization review for every immunization prior to administration.

- Prior to the act of immunization administration by the authorized pharmacist, the Pharmacy will provide the corresponding Vaccination Immunization Sheet(s) or VIS for each immunization.

- The authorized pharmacist will administer the immunization and follow OSHA standards for disposal of contaminated sharps.

- The authorized pharmacist will monitor the patient response following each immunization to respond to syncope, mild allergy or anaphylaxis when needed.

- The authorized pharmacist will monitor the patient response following each immunization to respond to syncope, mild allergy or anaphylaxis when needed.

Sample Immunization Protocol continued

The Pharmacy will maintain the patient documentation for a period no less than two years following the administration of the vaccination(s). Such documentation will contain, but is not limited to:

- Name, phone number and address of the patient
- Patient allergies
- Age of the patient and date of birth
- Name of the patient’s primary care physician from Medical Practice
- Name, manufacturer and lot number of the administered vaccination
- Amount of vaccine administered
- Date the vaccine was administered
- Anatomic Site of the vaccination
- Route the vaccination was administered
- Name, address and title of the administering pharmacist

Within 24 hours of administering the vaccination, the Pharmacy will provide written notification (via fax or other electronic communication method) to the Medical Practice and to the Primary Care Physician to document the vaccination(s) administered for their patient.

Sample Immunization Protocol continued

IV. Authorization

1. Pediatric Immunizations – This immunization protocol authorizes the Pharmacy to provide the pediatric immunizations for established patients of the Medical Practice:

i. after a review of the patient’s existing immunization records (and)

ii. pursuant to the physician’s order (or)

iii. completing the CDC-recommended pediatric immunization guidelines (see Appendix 2)

1. Travel Immunizations – The immunization protocol authorizes the Pharmacy to provide travel immunizations for established patients of the Medical Practice; the Pharmacy will follow the CDC-recommended travel immunization guidelines to patients traveling to the following countries after a review of the patient’s existing immunization records:
Appendix D

Medication Discharge Program: proposed timeline for implementation of discharge program in partnership with hospital

Preparation
Day – 30: The hospital system should determine which departments will participate in the discharge delivery program. Policies and documentation should be reviewed and modified and concerns should be addressed. Developed a standardized process for the prescription interchange from the community pharmacy to the hospital system.

Day – 21: Determine which hospital staff from each department will interact with the community delivery staff and will have access to the in-patient nursing units.

Day – 14: The community pharmacy and the hospital should co-create a formal feedback mechanism to assess any potential benefits, failings, and overall effectiveness. All practitioners and affected units should be notified regarding the new program and provided updates on a daily basis. Additionally, in-house training should be provided for nursing/hsnt staff and community pharmacy staff involved in the program.

Day – 7: The delivering community pharmacy should train delivery staff on the procedures for prescription interchange at each nursing unit.

Day – 3: Final conformation between the community pharmacy and hospital should be conducted to establish creation of the program and to access readiness for implementation.

Day – 1: All discharge medications orders for the next day discharges should be transmitted to the community pharmacy no later than 3:00 pm.

Medication Discharge Program timeline continued

Start Of Program
Implementation Day: The nursing units will receive all discharge medications from the pharmacy no later than 11:00 am.

Day – 1 through Day + 7: Personnel from both partners will collect informal feedback about the new program from all parties. The intent of the informal feedback is to provide immediate candid and constructive feedback to improve program quality.

Day + 7 through Day + 14: Both parties work on corrections to the program as identified and suggested through informal feedback.

Day + 14: Begin formal feedback mechanism with intent to improve program (co-created by ECO Pharmacy and CHS St. Luke’s Baylor Medical Center administration).

Day + 30 through Day + 34: Identify whether the program is mutually beneficial and make decision whether to continue implementation plan, either with or without modifications, or whether to cease the program. Identify whether the program is mutually beneficial and make decision whether to continue implementation plan, either with or without modifications, or whether to cease the program.

Day + 35: Arrange an administration meeting in order to respond to decision: 1. Continue program implementation as planned including expanding units (or) 2. Continue program with modifications as needed (or) 3. Cease program until further notice.

Day + 36: Continue gathering feedback for CQI or redesign program if needed. Gather data regarding patient treatment outcomes.

Post Discharge Timeline:
0–2 Hours – Follow-up phone call after patient discharge from hospital to provide comprehensive evaluation of medication regimen.
15–20 days – Follow-up phone call to access patient compliance and adherence to medications.
Monthly – Phone call follow-up with patients for medication refills. Set-up in-home delivery for identified high-risk patients.