Practices and Processes of Care/ Organizational Agreements/ Special Issues in Pharmacy Practice

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Learning Objectives

1. Define a pharmacist's scope of practice in ambulatory care pharmacy practice.
2. Construct a collaborative practice agreement, protocol, etc., that is in accordance with legal and regulatory requirements.
3. Compare and contrast the coding and billing for immunizations under Medicare Part B and Part D.
4. Describe different types of patient care services or practice models provided by a pharmacist within an ambulatory practice.
5. Apply tools and resources to detect, classify, report, analyze, and reduce preventable and non-preventable adverse drug events.
6. Formulate a plan to ensure patient access to medications by facilitating the use of prescription drug plans and other resources.
7. Use formulary management activities to improve the prescribing of safe, effective, and affordable treatments in an organization.
8. Describe the regulatory requirements applicable to pharmacy services using point-of-care testing.

Self-Assessment Questions

Answers and explanations to these questions may be found at the end of the chapter.

1. A 77-year-old man is referred to the pharmacy for medication therapy management (MTM) under Medicare Part D. Which best describes why the patient is eligible for MTM under Medicare Part D?

    A. He pays at least $3500 per year for his Part D covered medications, has at least one chronic disease state, and takes one medication.
    B. He pays at least $3900 per year for his Part D covered medications, has at least four chronic disease states, and takes two medications.
    C. He pays at least $3919 per year for his Part D covered medications, has at least two chronic disease states, and takes three medications.
    D. He pays at least $3659 per year for his Part D covered medications, has at least three chronic disease states, and takes four medications.

2. A 64-year-old man is referred to the pharmacist by his provider for management of uncontrolled diabetes as dictated by the established collaborative drug therapy management (CDTM) agreement. Which best describes the pharmacist's general scope of practice under a CDTM agreement?

    A. Diagnose the patient with peripheral neuropathy, and initiate gabapentin.
    B. Discontinue the patient's glyburide, and initiate glargine.
    C. Order and draw the patient's chemistries and A1C.
    D. Order continuous positive airway pressure (CPAP) machine for the patient's obstructive sleep apnea.

3. A 57-year-old woman has an anticipated hospital discharge for tomorrow. She was admitted because of a mild asthma exacerbation requiring steroids and nebulizer treatments. Which best describes how a pharmacist could improve the patient's transition of care?

    A. Scheduling the patient for a comprehensive medication review (CMR) in 3 months with the pharmacist.
    B. Completing medication reconciliation for the patient on hospital admission and discharge.
    C. Providing recommendations to the inpatient team on outpatient pharmacies that will deliver the patient's medications to her home.
    D. Conducting an Asthma Control Test with the patient at a follow-up visit in the clinic.

4. Which method of medication safety analysis is best for prospectively identifying the risk of error in a process and for estimating the likelihood of a process failure?

    A. Root cause analysis
    B. Failure modes and effects analysis
    C. Safety culture assessment
    D. Analysis of medication error trends

5. Which resource would best help determine whether a pharmacist could create CDTM or collaborative practice agreements with a physician?

    A. A state's pharmacy practice act
    B. National Association of Boards of Pharmacy (NABP)
    C. Department of Public Health
    D. Patient-specific health insurance policy

6. Which best describes a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver policy?

    A. The site may perform tests of moderate complexity.
    B. The site may make minor modifications to the current manufacturer's test instructions.
    C. The site must notify the corresponding state agency when there is a change in ownership.
    D. The site must pay a certificate renewal fee every 5 years.

7. S.W. is a Medicare Part D beneficiary who is in the coverage gap of her plan. She is filling a brand-name prescription that costs $80. The pharmacy dispensing fee is $12. Which most appropriately represents patient's individual personal contribution to the true out-of-pocket (TrOOP) cost in the coverage gap?

    A. $12.00
    B. $30.60
    C. $36.00
    D. $70.00

8. Which most appropriately tiers the drug as part of formulary management to reduce cost and improve safety?

    A. Listing metoprolol tartrate as a tier 2 drug
    B. Listing rosuvastatin as a tier 1 drug
    C. Listing omeprazole as a tier 3 drug
    D. Listing epoetin alfa as a specialty-tier injectable drug

Abbreviations in This Chapter

CDTM   Collaborative drug therapy management
CLIA   Clinical Laboratory Improvement Amendments
CMM   Comprehensive medication management
ED   Emergency department
HRSA   Health Resources and Services Administration
MAC   Medicare Administrative Contractor
MTM   Medication therapy management
P&T   Pharmacy and therapeutics (committee)
TrOOP True out-of-pocket (costs)

Note: This chapter is also part of the 2017 Ambulatory Care Pharmacy Preparatory Review and Recertification Course. Although there is an Ambulatory Care focus, the core of the chapter applies to Pharmacotherapy specialists.

BPS Pharmacotherapy Specialty Examination Content Outline
This chapter covers the following sections of the Pharmacotherapy Specialty Examination Content Outline:
1. Domain I: Patient-Centered Pharmacotherapy, Task 5, Knowledge Statement 1
2. Domain III: System-Based Standards and Population-Based Pharmacotherapy
    a. Task 1, Knowledge Statements 1-3, 6, 7
    b. Task 5, Knowledge Statement 1

I. PHARMACIST SCOPE OF PRACTICE

A. Profession of Pharmacy's Mission: To improve public health through ensuring the safe, effective, and appropriate use of medications

B. Scope of Practice for Pharmacists: Ultimately regulated at the state level, creating inconsistency; www.nabp.net/

C. Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (NABP)
   1. "Practice of Pharmacy" includes but not limited to interpretation, evaluation, dispensing and/or implementation of medical orders, and the initiation and provision of Pharmacist Care Services
   2. "Pharmacist Care Services"
      a. Defined as the provision by a pharmacist of patient care activities with or without the dispensing of drugs/devices intended to achieve outcomes related to the cure or prevention of disease, elimination or reduction of a patient's symptoms, halting or slowing of a disease process
      b. Should be provided by all pharmacists to the extent of their abilities, irrespective of practice setting
   3. "Patient Counseling" is the oral communication by the pharmacist of information to the patient or caregiver to ensure proper use of drugs and devices.
   4. "Patient Intervention Program" is any structured activity that complements or supplements the existing responsibilities regarding the dispensing of prescriptions and associated patient counseling, and uses protected health information to contact the patient or caregivers by way of phone, print, electronic media, or other means to discuss, inform, and/or affect patient therapy or choice of medications.
   5. "Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement" includes duties and limitations of duties placed on one or more pharmacists by the collaborating practitioner(s), the board, and applicable law, and includes the limitations implied by the scope of practice of the collaborating practitioner(s).
   6. The Model State Pharmacy Act and the Model Rules of the NABP are updated every August to provide state boards of pharmacy with language that may be used when creating state laws or board rules for regulating the practice of pharmacy and the distribution of drugs and related devices.
   7. The NABP Survey of Pharmacy Law provides summary data on issues such as prescribing and dispensing authority, pharmacy technicians, facsimile and electronic transmission of prescriptions, and patient counseling requirements. It is revised and published annually.

D. Pharmacist's Scope of Practice in All 50 States in Any Setting
   1. Obtain medication histories.
   2. Review the patient's medications to identify medication-related problems.
   3. Intervene with the physician to resolve identified problems.
   4. Educate the patient about the proper use of medications.
   5. Encourage adherence to prescribed medications.
   6. Document and communicate information to the physician.

E. Council on Credentialing in Pharmacy's Contemporary Scope of Pharmacy Practice: The scope of practice is evolving from a model in which pharmacists primarily supervise medication distribution and counsel patients to a model in which pharmacists play an expanded, team-based clinical role of providing patient-centered MTM, health improvement, and disease prevention services.

F. The Joint Commission of Pharmacy Practitioners' (JCPP's) Vision for Pharmacy Practice: "Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare."

G. Pharmacist Recognition of Expanded Services
   1. CDTM
   2. Licensure as clinicians (i.e., New Mexico's Pharmacist Clinician)
   3. Legislation (i.e., North Carolina's Clinical Pharmacist Practitioner and California's Advanced Practice Pharmacist)

II. AMBULATORY CARE PHARMACY PRACTICE MODELS

A. Pharmaceutical Care
   1. Background: Pharmaceutical care was best defined in 1990 by Hepler and Strand, expanding the pharmacist's role from dispensing to managing drug-related effectiveness, resolving drug-related adverse events, and preventing potential drug-related problems.
   2. Definition: "Patient-centered, outcomes-oriented pharmacy practice that requires the pharmacist to work together with the patient and other health care providers to promote health, prevent disease, and assess, monitor, initiate, and modify medication use to ensure that drug therapy regimens are safe and effective"
   3. Goals
      a. Optimize the patient's health-related quality of life.
      b. Achieve positive clinical outcomes.
         i. Cure of a disease
         ii. Eliminate or reduce a patient's symptomatology.
         iii. Stop or slow disease progression.
         iv. Disease prevention or symptomatology
   4. Principles
      a. Can be accomplished by a pharmacist in any practice setting
      b. Establish and maintain a professional relationship with the patient.
      c. Patient-specific medical information is to be collected, organized, recorded, and maintained.
         i. Subjective and objective information: Health status, medical history, medication history, social history, diet and exercise, history of present illness, and economic situation
         ii. The information source can include, but is not limited to, medical records, pharmacist assessment, patient's family or caregivers, insurer, and other health care professionals.
      d. Patient-specific medical information is to be evaluated, and a drug therapy plan should be developed collaboratively with the patient.
         i. A focus should be placed on medication-related problems.
            (a) Untreated indications
            (b) Improper drug selection
            (c) Subtherapeutic dosage
            (d) Failure to receive medications
            (e) Overdosage
            (f) Adverse drug reactions
            (g) Drug interactions
            (h) Medication use without indication
         ii. The plan should improve and ensure the safety, effectiveness, and/or cost-effectiveness of current or planned drug therapy and minimize current or potential future health-related problems.
         iii. The plan and desired outcomes should be documented in the patient's medical and/or pharmacy record.

    e.   Ensure the patient has all the necessary supplies, information, and knowledge to carry out the plan.
- i.   The pharmacist assumes ultimate responsibility for the patient's ability to obtain and use any drug, products, or equipment in the drug therapy plan.
- ii.   The pharmacist should verify that the patient and/or caregivers understand the disease and the corresponding medications prescribed in the plan.
- iii.   After appropriate education has been provided, the patient is responsible for engaging in behavior that will contribute to the achievement of the positive outcomes outlined in the plan.
- iv.   Steps taken to implement the plan should be documented in the patient's medical and/or pharmacy record, including monitoring values, barriers, and follow-up.

    f.   Review, monitor, and modify the therapeutic plan, when appropriate, in collaboration with the patient and the health care team.
- i.   The pharmacist should monitor the patient's progress and coordinate modifications to the therapeutic plan with the patient and health care team to enhance the drug's safety and effectiveness, in addition to minimizing overall health care costs.
- ii.   The pharmacist should help ensure continuity of care by sharing information with other providers as the patient moves between care settings.
- iii.   Progress and modifications to the plan should be documented in the patient's medical and/or pharmacy record.

5.   Structural elements for quality pharmaceutical care
    a.   Knowledge, skill, and function of personnel
- i.   The pharmacist must have knowledge and skills in the area of patient assessment, clinical information, communication, adult teaching and learning principles, and psychosocial aspects of care.
- ii.   Personnel include pharmacists, technicians, automation, and technology.
- iii.   A process to certify and credential the implementation of pharmaceutical care should be created.

    b.   A system for data collection, documentation, and transfer of information
- i.   Pharmaceutical care is supported by data collection and documentation systems that allow patient care communication, interprofessional communications, quality assurance, and research.
- ii.   A documentation system is necessary for reimbursement considerations.

    c.   Effective workflow
    d.   References, resources, and equipment
- i.   Tools to support patient care, equipment to assess medication adherence, clinical resources, and patient educational materials are required.
- ii.   Additional tools include computer software support, drug-use evaluation programs, and disease management protocols.

    e.   Good communication skills
    f.   Commitment to quality improvement and assessment procedures

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Patient Case

1.   A patient has been referred to the pharmacist for albuterol inhaler and spacer technique education. Which best describes the pharmacist's responsibility as part of pharmaceutical care?

   A.   Inform the patient's physician that the patient came to their appointment.
   B.   Call the patient in 1 week to see if the patient still has albuterol at home.
   C.   Ensure the patient thoroughly understands the inhaler technique before leaving the visit.
   D.   Document the interaction in a personal file, should the patient return again.

B. MTM
1. Background: Medicare Modernization Act of 2003 required Medicare Part D to provide an MTM program as part of its drug benefit program offered to Medicare beneficiaries.
2. Consensus definition
    a. A distinct service or group of services that optimizes therapeutic outcomes for individual patients
    b. MTM services are independent of, but can occur in conjunction with, the provision of a medication product.
    c. Created in collaboration with 11 national pharmacy organizations
3. Goals of MTM according to the Centers for Medicare & Medicaid Services (CMS)
    a. Optimize therapeutic outcomes through improved medication use.
    b. Reduce the risk of adverse events and drug interactions.
    c. Improve medication adherence.
4. CMS requirements of MTM programs – 2017 Plan Year
    a. Enrollment
        i. Opt-out method: Plans must auto-enroll targeted beneficiaries who meet the eligibility criteria, and they are considered enrolled unless they decline enrollment.
        ii. Plans must target beneficiaries for enrollment at least quarterly during each plan year.
        iii. Plans are expected to use more than one approach, when possible, to reach eligible beneficiaries.
    b. Targeted beneficiaries
        i. Several chronic disease states, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment
            (a) Most plans require two or three chronic disease states for eligibility.
            (b) Plans that specify which chronic diseases apply must select at least five of the nine distinct core chronic diseases: Alzheimer disease, chronic heart failure, diabetes, dyslipidemia, end-stage renal disease, hypertension, respiratory disease, bone disease-arthritis, mental health disease
        ii. Multiple covered Part D medications: Eight Part D drugs is the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; most plans require two to eight medications for eligibility.
        iii. Costs of Part D medications are $3919 per year or greater.
    c. Required MTM services
        i. Interventions for both patient and prescriber on optimal medication use
        ii. MTM services can be performed by a pharmacist, pharmacy intern under direct supervision of a pharmacist, pharmacy technician, or other qualified health care provider (e.g., physician or registered nurse).
        iii. Annual CMR with written summaries in CMS's standardized format
            (a) Must be interactive, person-to-person, or telehealth consultation
            (b) Can be provided by a pharmacist, disease state management pharmacist, pharmacy intern under direct supervision of a pharmacist, or other qualified health care provider (e.g., physician or registered nurse)
            (c) If the beneficiary cannot accept participation, the CMR may be performed with the beneficiary's prescriber, caregiver, or other authorized individual.
            (d) Offered no later than 60 days after being enrolled in Medicare Part D
            (e) Adapted from the National MTM Advisory Board definition; builds on the American Pharmacists Association (APhA) medication therapy review (MTR) core element

        iv.   Quarterly targeted medication reviews (TMRs) plus follow-up reviews as needed
           (a) If the beneficiary declines the TMR, the pharmacist or other health care provider must still complete a TMR at least quarterly and communicate the interventions to the prescriber.
           (b) Communication with the prescriber can be interactive or passive (e-mail or facsimile).
    d. Plans required to have information about MTM on their website
        i.   Part D sponsor's specific MTM eligibility requirements
        ii. Whom to contact for more information
        iii. High-level summary of services offered
        iv. Statement describing benefits of MTM, including that the service is free of charge to beneficiaries
    e. Plans required to have a process in place to measure, analyze, and report outcomes of their MTM program
    f. New this year, plans must have attestation of their MTM program done by their chief executive officer, chief operating officer, or the chief financial officer.

5. APhA core elements of MTM
    a. Medication therapy review
        i.   Definition: Systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them
        ii. Comprehensive or targeted
        iii. Preferably face-to-face (in-person visit); however, person-to-person (by phone) is acceptable
        iv. Interview patient to gather data on demographics, medication history, and general health; should ideally assess the following:
           (a) Patient's overall health, including previous and current health conditions
           (b) Patient's values, preferences, goals, and quality of life
           (c) Cultural issues, education level, literacy level, and language barriers
           (d) Laboratory values and vital signs
           (e) Medication-related problems
              (1) Adverse events
              (2) Appropriateness of each medication
              (3) Adherence to therapy
              (4) Untreated conditions
              (5) Costs and access to medications and health care
              (6) Duplication of therapy
        v.   Develop a plan for each problem identified, and provide patient education.
    b. Personal medication record (PMR)
        i.   Definition: Comprehensive record of the patient's medications, including, but not limited to, herbal products, over-the-counter medications, and other dietary supplements
        ii. Intended for patients to use in medication self-management
        iii. Collaborative effort among patients, pharmacists, and other health care professionals
        iv. Preferably electronic; however, can be handwritten
        v.   An updated PMR should be created with any medication change.
        vi. May include the following:
           (a) Patient name, date of birth, and telephone number
           (b) Name and telephone number of physicians and pharmacy or pharmacies
           (c) Allergies
           (d) Date last updated
           (e) Medication information: Medication name, dose, indication, instructions for use, start and stop date, ordering prescriber, and special instructions

    c.   Medication-related action plan (MAP)

        i.   Definition: Patient-centric document containing a list of actions for the patient to use in tracking progress for self-management

        ii.   Critical component of MTM documentation

        iii.   Collaborative effort between the patient and the pharmacist

        iv.   Includes only information the patient can act on and is within the pharmacist's scope of practice or agreed on by relevant health care team members

        v.   Does not include outstanding action items that still require physician approval, such as changes in medication regimen that are pending approval

        vi.   The MAP, in conjugation with education, encourages the patient's active participation in the health care plan.

        vii.   May include the following:

           (a)   Patient name

           (b)   Name and telephone number of physician and pharmacy

           (c)   Date of MAP creation

           (d)   Action steps for the patient

           (e)   Notes for the patient

           (f)   Follow-up information

    d.   Intervention and/or referral

        i.   Definition: The pharmacist provides consultative services and intervenes to address medication-related problems; when necessary, the pharmacist refers the patient to a physician or other health care professionals.

        ii.   Pharmacist interventions within the health care team are important in improving patient outcomes; documentation of the interventions and outcomes supports the impact of pharmacists on patient outcomes.

        iii.   Any medication-related problems identified should be documented and communicated to the patient's physician.

        iv.   Suggestions to address medication problems and recommendations on follow-up are also integral to the intervention.

        v.   The intent of this core element is to optimize medication use, enhance continuity of care, and encourage patients to use health care services to prevent future adverse events.

    e.   Documentation and follow-up

        i.   Definition: MTM services are documented in a consistent manner, and follow-up MTM visits are scheduled depending on the patient's medication-related needs or if the patient is transitioning from one care setting to another.

        ii.   Ideally, electronic; alternatively, paper

        iii.   Documentation may include, but is not limited to, the following:

           (a)   Patient demographics

           (b)   Subjective and objective observations, assessment, and plan (SOAP) note format

           (c)   Education

               (1)   Disease state and medication management education

               (2)   Goal setting

           (d)   Collaboration: Communication with other health care professionals, including recommendations and referrals

           (e)   PMR and MAP

           (f)   Follow-up

               (1)   Transition plan

               (2)   Schedule follow-up visit.

      (g) Billing
        (1) Time spent on patient care
        (2) Level of complexity determined by the interventions documented
    iv. The purpose of proper documentation
      (a) Facilitate communication between the pharmacist and other health care professionals regarding recommendations to resolve medication-related problems.
      (b) Should be appropriate for evaluating patient progress and sufficient for billing purposes
      (c) Improve patient care and outcomes.
      (d) Enhance continuity of patient care.
      (e) Ensure compliance with laws and regulations.
      (f) Protect against professional liability.
      (g) Justification of reimbursement
      (h) Demonstrate the value of MTM services.

6. Barriers to and challenges of MTM
   a. Reimbursement and billing
   b. Adequate staffing and devoted time in daily workflow
   c. Lack of access to complete patient information
   d. Patients' lack of perceived benefit and interest in MTM services
   e. State variations in reimbursement and pharmacist's scope of practice
7. Billing for MTM services: See the chapter titled "Managing a Clinical Practice."
8. Benefits of MTM
   a. Improved health outcomes, including, but not limited to, a reduction in hemoglobin A1C (A1C), blood pressure, and lipid values
   b. Reduction in overall health care expenditure
   c. Improved medication adherence
   d. Decreased hospitalizations and emergency department (ED) visits
   e. Accurate and appropriate medication use
   f. Patient achievement of health-related goals

Patient Case

2. According to the CMS criteria, which best describes a targeted patient for MTM services?

   A. A patient with asthma and an upper respiratory tract infection who is taking tiotropium, albuterol, budesonide/formoterol, monetlukast, and azithromycin; his medications cost $3000 per year.
   B. A patient with diabetes, hypertension, and hyperlipidemia who is taking metformin, lisinopril, and rosuvastatin; his medications cost $3500 per year.
   C. A patient with diabetes and occasional headaches who is taking insulin glargine and insulin lispro; his medications cost $4000 per year.
   D. A patient with a kidney transplant and diabetes who is taking metformin, tacrolimus, and mycophenolate; his medications cost $5500 per year.

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9. Suggested readings
   a. Cranor CW, Bunting BA, Christensen DB. The Asheville Project: clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia. J Am Pharm Assoc 2003;43:173-84.
      i. Community pharmacists provided diabetes education on a regular basis (usually monthly) to city employees during a 6-year period.

      ii.   Significantly more patients reached an A1C goal of less than 7% compared with baseline (57% vs. 42%).

      iii. Savings of about $20,000 on overall health care expenses compared with the previous year

  b. Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in project ImPACT: hyperlipidemia. J Am Pharm Assoc 2000;40:157-65.

      i.   Community pharmacists identified patients with poorly controlled hyperlipidemia who had drug therapy problems and worked collaboratively with physicians to resolve them during a 2-year period.

      ii. Adherence to medication regimen increased from 40% to 90%.

      iii. Sixty-three percent of participants achieved National Cholesterol Education Program goals.

  c. Fera T, Bluml BM, Ellis WM. Diabetes ten city challenge: final economic and clinical results. J Am Pharm Assoc 2009;49:383-91.

      i.   Community pharmacists provided self-management care services for patients with diabetes.

      ii. Statistically significant improvements in A1C values, low-density lipoprotein cholesterol concentration, and systolic blood pressure

      iii. Total health care costs were reduced by $1079 per person per year.

  d. Isetts BJ, Schondelmeyer SW, Artz MB, et al. Clinical and economic outcomes of medication therapy management services: the Minnesota experience. J Am Pharm Assoc 2008;48:203-11.

      i.   Ambulatory care clinic pharmacists provided MTM services to patients in collaboration with physicians to compare patients' clinical outcomes and health care expenditures with those of patients who did not receive MTM services.

      ii. Improvement in achieving hypertension (71% vs. 59%) and cholesterol (52% vs. 30%) goals

      iii. Reduction in health care expenditures from $11,965 to $8197

C. Comprehensive Medication Management (CMM)

  1. Developed by Patient-Centered Primary Care Collaborative (PCPCC) Medication Management Task Force to describe the contribution of clinical pharmacists in patient-centered, team-based care (i.e., patient-centered medical homes and accountable care organizations)

  2. CMM principles

    a. Assessment of the patient's medication-related needs and identification of medication-related problems

      i.   All medications, including prescriptions, nonprescription alternatives, vitamins, nutritional supplements, sample medications, and medications from friends and family, are assessed to determine whether they are appropriate for the patient, with the primary focus being to understand how and why the patient takes his or her medications.

        (a) Each medication is assessed for appropriate indication.

          (1) Is the medication appropriate for the medical condition being treated?

          (2) Do all medical indications have appropriate medication management?

        (b) The dose, duration, and route of administration are verified.

        (c) Safety of medication is assessed.

          (1) Are there adverse drug events from the medication?

          (2) Is the patient at risk of medication toxicity?

        (d) Adherence to medication is assessed.

        (e) Changes, discrepancies, and concerns are documented in the patient's medical record.

      ii. The patient is interviewed to determine beliefs, concerns, understanding, and expectations from the medications.

b. Develop a care plan with interventions and individualized goals of therapy.
   i. Created in collaboration with the patient and primary health care providers
   ii. Care plan includes the following:
      (a) Resolution of identified medication-related problems
         (1) Initiation of necessary medications
         (2) Changing medications or medication doses
         (3) Discontinuing medications
         (4) Patient education
      (b) Goals of therapy for each medical condition dictated by the following:
         (1) National guidelines
         (2) Comorbidities
         (3) Patient preferences
         (4) Physician intentions
      (c) Established outcomes should be measurable, and progress should be easy to assess at follow-up visits.
         (1) Examples of therapeutic outcomes: A1C values, international normalized ratio (INR) levels, Asthma Control Test scores, depression scale scores
         (2) Examples of economic measures: ED visits and hospitalizations prevented, increased continuity of care, decreased sick days, improved adherence, avoidance of unnecessary referrals
      (d) Follow-up visit date for CMM should be appropriately timed for proper assessment of the intervention and goals, together with evaluation of any new safety issues.
         (1) Will vary for each patient
         (2) Has to be coordinated with the medical team to minimize interference with other care plans

3. Logistics of providing CMM
   a. Qualifying patients
      i. Have medical conditions associated with high-cost and multiple medications; examples of such conditions:
         (a) Diabetes
         (b) Cardiovascular disease
         (c) Chronic obstructive pulmonary disease
         (d) Asthma, particularly in children
         (e) Cancer chemotherapy
         (f) Depression
         (g) Pain
         (h) Hypothyroidism
      ii. Difficulty reaching goals of therapy
      iii. Experiencing adverse effects from medications
      iv. Difficulty understanding and following a medication regimen
      v. Require monitoring for a high-risk medication, such as the following:
         (a) Warfarin
         (b) Phenytoin
         (c) Methotrexate
         (d) Insulin
      vi. Have frequent hospital readmission, which is usually measured as within 30 days of original hospitalization for the same medical reason

    b. Referrals
        i. Given to a qualified medication management practitioner
           (a) Qualified pharmacist
               (1) Pharm.D. degree or equivalent clinical training/experience
               (2) Has a formal CDTM agreement with physician/medical group or has been granted authority to provide the service
               (3) Certified or eligible for certification in a pharmacy practice specialty recognized by the Board of Pharmacy Specialties
           (b) Other qualified practitioners
               (1) Physician
               (2) Nurse
        ii. Patients continue to be provided CMM until the goals of therapy are achieved or until the referring practitioner determines that the care is not necessary.
    c. Visits
        i. Communication during visits must be bidirectional.
        ii. Face-to-face
        iii. Telemedicine or virtual clinic
           (a) Ensure that both patient and provider have appropriate technology to conduct the visit and exchange all necessary information.
           (b) Practitioner must have experience with these media.
           (c) Quality of service is ensured by defining the standards of care and if or how they differ from a face-to-face visit.
    d. Documentation
        i. Electronic medical record preferred; paper charting is acceptable but less desirable
           (a) Patient's medication experience
           (b) Medication allergies
           (c) Medication history, including immunizations
           (d) Active medication list
           (e) Active drug therapy problem list, including the cause of the problem
           (f) Therapeutic treatment plan
        ii. Facilitates communication between pharmacists and other health care providers
        iii. Enhances continuity of patient care
        iv. Protects against professional liability
        v. Captures services provided for justification of billing and reimbursement
        vi. Demonstrates clinical, economic, and humanistic outcomes
4. Benefits of CMM
    a. Solves medication-related problems
        i. Current electronic systems of dispensing and e-prescribing records often have an incomplete list of the patient's home medications and omit 40%–50% of the medications taken by a patient.
        ii. These pharmacy records contain idealized prescription information (e.g., how the prescription was written but not how the medication was taken).
    b. Helps patients achieve their health-related goals
    c. Prevents ED visits, hospital admissions, and hospital readmissions; studies show a decrease in 30-day readmission rates, effective transitions of care, and medication reconciliation
5. Differences between CMM and MTM
    a. CMM includes an assessment of the patient's clinic status or therapeutic response to treatment.
    b. CMM incorporates an evaluation to assess the patient's progress toward treatment goals.
    c. CMM requires collaborations with the health care team.

6. Suggested readings
    a. Smith MA, Bates DW, Bodenheimer T, et al. Why pharmacists belong in the medical home. Health Aff 2010;29:906-13.
    b. Isetts BJ, Brummel AR, de Oliveira DW, et al. Managing drug-related morbidity and mortality in the patient-centered medical home. Med Care 2012;50:997-1001.

Patient Cases

3. A 67-year-old woman was referred to the pharmacist by her primary care physician for CMM as part of a patient-centered medical home (PCMH). Which is the best example of a patient who would qualify for CMM?

    A. A patient recently admitted for an upper respiratory tract infection and taking levofloxacin and albuterol.
    B. A patient with atrial fibrillation and taking aspirin and metoprolol. She was hospitalized 8 months ago when she was diagnosis with atrial fibrillation.
    C. A patient who was hospitalized twice in the past month; once for chest pain and once for symptomatic anemia.
    D. A patient with hypertension and taking hydrochlorothiazide and amlodipine. No hospitalizations in the past year, but hypertension is uncontrolled.

4. The pharmacist is setting up a CMM appointment for a newly referred patient. The patient asks if she has to come into the clinic to talk with the pharmacist. Which most appropriately describes how CMM can be delivered?

    A. Face-to-face only
    B. Face-to-face and telephonic visit
    C. Face-to-face, telephonic, or virtual visit
    D. Face-to-face, telephonic, virtual, or written communication

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D. CDTM
   1. Description
       a. The Alliance for Pharmaceutical Care defines CDTM as "a team approach to healthcare delivery whereby a pharmacist and prescriber establish written guidelines or protocols authorizing the pharmacist to initiate, modify or continue drug therapy for a specific patient."
       b. The partnership with the prescriber permits the pharmacist to function outside the traditional pharmacy practice laws.
       c. Can be provided in the retail, inpatient, and outpatient settings
       d. Forty-eight states have legislative provisions for CDTM; in states without specific CDTM legislation, pharmacists can collaborate with providers through CMM (www.accp.com/docs/positions/whitePapers/CDTM%20CMM%202015%20Final.pdf).
       e. Each state is required to establish its own laws regarding CDTM; defined in the state's pharmacy practice act
       f. State laws outline different requirements for pharmacists engaging in CDTM, depending on the practice setting. States may require the following:
           i. Pharmacists to have special training or certification
           ii. Protocols to be approved by the board of pharmacy
           iii. Pharmacists to carry liability insurance

2. Agreements
    a. The terms *collaborative practice agreement* and *CDTM* are often used interchangeably; however, a collaborative practice agreement is the actual written document between the physicians and the pharmacists, whereas a CDTM defines how the collaborative practice agreement will be used.
    b. Agreements can also be called protocols, standing orders, collaborative practice agreements, etc.
    c. Agreements must be kept on file in the pharmacy or place of service and made available to any appropriate health licensing board on request.
    d. According to the NABP, agreements must be reviewed, renewed, and either updated at least every year or discontinued.
    e. The NABP Model State Pharmacy Act and Model Rules outline the process and required elements for agreements but do not define the clinic activities a pharmacist should be given authority to perform. The elements include:
        i. Identification of the providers and pharmacists who are parties to the agreement
        ii. Types of decisions the pharmacist is allowed to make; may include a detailed description of:
            (a) The types of diseases, drugs, or drug categories involved, and the activities allowed in each case
            (b) The methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities
            (c) The activities the pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the provider concerning specific decisions made. In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate logbook, or in some other appropriate system.
        iii. A method for the provider to monitor adherence with the agreement and clinical outcomes and to intervene when necessary
        iv. A narrative of the continuous quality improvement program used to assess the effectiveness of patient care and ensure positive patient outcomes
        v. A provision that allows the provider to override a collaborative practice decision made by the pharmacist whenever deemed necessary or appropriate
        vi. A provision that allows either party to cancel the agreement by written notification
        vii. The effective date
        viii. Signatures of all collaborating pharmacists and providers who are party to the agreement, as well as dates of signing
    f. A medical order/referral from the provider must be placed to conduct CDTM for a patient.
    g. Activities under CDTM must be documented in the patient's medical record and available to the patient's health care providers.
3. Pharmacist responsibilities under a CDTM agreement may include all or a combination of the following items:
    a. Initiate, modify, and discontinue drug therapy for an individual patient or group of patients.
    b. Order and interpret laboratory results.
    c. Administer medications (including immunizations).
    d. Collect and review medication history.
    e. Obtain vital signs.
    f. Evaluate and provide education regarding medication regimen.
    g. Perform a physical assessment consistent with disease state and drug therapy.
    h. Communicate, provide feedback, and report to the physician about the action plan, which can occur in the prescription record, patient profile, separate logbook, or other appropriate system outlined in the written agreement.

4. Common areas of practice for CDTM
   a. Emergency contraception
   b. Asthma therapy management
   c. Immunization administration
   d. Hypertension therapy management
   e. Dyslipidemia therapy management
   f. Warfarin/anticoagulation therapy management
   g. Diabetes therapy management
   h. Depression therapy management
   i. Smoking cessation therapy management
   j. Flu/antiviral therapy management
5. Differences between CDTM, MTM, and CMM
   a. MTM and CMM do not require the development of a formal practice agreement.
   b. MTM and CMM services may be provided by physicians, registered nurses, or both.
   c. Individual state pharmacy practice laws do not establish the scope of practice for MTM and CMM.
6. Key elements to effective CDTM
   a. Access to the patient's medical records
   b. Knowledge, skills, and ability to perform authorized functions
   c. Documentation in the patient's medical records
   d. Accountability for quality measures
   e. Ability to be reimbursed for drug therapy management
   f. Committed time and resources
7. Benefits of CDTM
   a. Patient specific
      i. Extends the provision of health education, health screening, and medication management to underserved populations where physician access is limited
      ii. Improves the quality of drug therapy management by decreasing medication-related problems (e.g., adverse drug reactions, drug interactions, poor adherence) by allowing the pharmacist to make immediate therapeutic interventions when necessary
      iii. Decreases cost through optimal use of medications – Specifically, by discontinuing inappropriate medications and closely monitoring for adverse drug reactions with the aim of decreasing unnecessary physician and hospital visits
   b. Physician specific
      i. Reduces clinic visits for patients with chronic conditions, allowing more time for complex case management
      ii. Encourages continuity of care by having the pharmacist refer patients to physicians
         (a) Ensuring that patients are up to date with clinic visits with all established physicians
         (b) Providing or encouraging referrals to physicians to resolve newly identified medical issues
      iii. Increases the number of patients achieving pay-for-performance goals
   c. Pharmacist specific
      i. Reinforces relationship between pharmacist and physician
         (a) Recognized by the American College of Physicians, American Society of Internal Medicine, and Infectious Diseases Society of America
         (b) Each of the listed organizations has issued a statement of support demonstrating the value of CDTM.
      ii. For pharmacists working in the community setting, it can shift them from product-oriented service to patient-focused practice to improve outcomes
      iii. Permits pharmacists to demonstrate value as part of the health care team

  d. Health plans/managed care organizations
    i. Decrease high-cost physician visits for medication-related issues
    ii. Optimize drug therapy management through the pharmacist's ability to make therapeutic decisions at the time of service, resulting in improved outcomes
    iii. Encourage more targeted physician referrals

Patient Case

5. A pharmacist provides CDTM for a physician group. Which of the following settings is most likely to produce a successful CDTM?

  A. A pharmacist working in a community pharmacy who has access to the patient's electronic medical record

  B. A pharmacist working in the physician group's clinic who just started and came from industry working with cancer drugs

  C. A pharmacist working in the hospital who sees patients whenever she isn't busy checking prescriptions

  D. A pharmacist working for the college of pharmacy and placed in the general medicine clinic to conduct CDTM to gain pharmacy notoriety.

III. CREDENTIALING AND PRIVILEGING

 A. Definitions
  1. Credential: Documented evidence of professional qualifications (i.e., academic degree, state licensure, residency certificates, and certification)
  2. Credentialing: The process of being granted a credential or the process used by health care organizations to obtain, verify, and assess an individual's qualifications to provide patient care services
  3. Privileging: The process used by health care organizations to review a practitioner's credentials and performance, resulting in authorization of an individual practitioner to provide specific patient care services under a defined scope of practice
  4. Accreditation: The process by which an association, organization, or governmental agency grants public recognition to an organization, site, or program with certain established qualifications or standards, ascertained through initial and periodic evaluations

 B. Background
  1. Credentialing and privileging have been limited to verification by a health system's human resources or personnel department that the pharmacist is a graduate of an accredited pharmacy school and is licensed to practice pharmacy in that state.
  2. In 1989, the Joint Commission on Accreditation of Healthcare Organizations introduced credentialing to accreditation procedures.
  3. Credentialing provides an assessment of qualifications, but it does not ensure competence.
  4. For an organization to grant privileges to a practitioner, credentials must be checked; no national standards exist. This system is separate from, but linked to, establishing CDTM.
    a. CDTM agreements state what the pharmacist will do regarding patient care.
    b. Privileging authorizes the pharmacist to do those things in a certain institution. If pharmacists practice at different institutions, they may need to be given privileges at each, even if working under the same CDTM.

5. If privileging of a pharmacist does not occur, health systems usually allow pharmacists to perform all activities described in the state's pharmacy practice act.

6. Evaluation of competence is determined by the institution.

7. The Council on Credentialing in Pharmacy was founded in 1999 from a coalition of 13 national pharmacy organizations dedicated to providing leadership, guidance, public information, and coordination for credentialing programs in or relevant to pharmacy.

8. In 2012, CMS allowed hospitals and critical access hospitals to grant privileges to pharmacists.

C. Council on Credentialing in Pharmacy Guiding Principles

1. A pharmacist's licensure should ensure entry-level knowledge, skills, attitudes, and values for the provision of services and information regarding medications and their proper use. A pharmacist's post-licensure credentials should build on this groundwork.

2. Credentialing programs should be created by an efficient and effective profession-wide, consensus-building process based on the demand of patients/society.

3. Coordination and alignment between professional education, postgraduate training, and credentialing programs should be ongoing.

4. Credentialing programs should be accredited by National Commission for Certifying Agencies (NCCA), American National Standards Institute (ANSI), or other recognized national or international accreditation bodies, qualifying them as legally defensible and psychometrically sound.

5. Assessment should be performed that measures the knowledge and skills gained from postgraduate training and credentialing programs and/or provides evidence that credentialed individuals have attained the essential level of competence.

6. Credentials should permit pharmacists to gain specific patient care privileges and should not create barriers to the provision of any services that pharmacists provide to their patients.

7. Pharmacists should be expected, like other providers, to participate in credentialing and privileging to ensure the attainment and maintenance of competency to provide the scope of services and quality of care required in their practice.

8. Each practice setting, employer, and payer should be encouraged to adopt and implement its own credentialing and privileging process for pharmacists to determine and authorize the patient care responsibilities.

D. General Steps for Developing a Privileging Process

1. Gather background information from national, state, and local resources regarding The Joint Commission (TJC) regulations, a pharmacist's scope of practice, and the institution's bylaws, rules, and regulations.

2. Define the pharmacist's scope of practice and amount of supervision given by the prescriber.

3. Develop policies and procedures for the privileging process of pharmacists.
   a. Should include instructions for verifying pharmacists' credentials
   b. Can consider including mechanisms for appealing adverse decisions regarding privileging, requirements, and documentation for continuing education and requirements for professional liability insurance
   c. Obtain approval of the privileging policy from governing bodies of the institution
   d. TJC privileging process typically entails the following:
      i. Developing and approving a procedure list
      ii. Processing the application
      iii. Evaluating applicant-specific information
      iv. Making recommendations to the governing body for applicant-specific outlined privileges
      v. Notifying the applicant and relevant personnel
      vi. Monitoring the use of privileging and quality of care

E. Governing Organizations' Expectations
   1. Processes for credentialing and privileging must be clearly defined in the medical staff bylaws and the policies and procedures of each organization.
   2. TJC, formally known as the Joint Commission on Accreditation of Healthcare Organizations, requires that privileges fall within defined limits according to the licensed independent practitioner's credentials and current competence.
   3. TJC mandates that independent providers be appointed to the medical staff and granted clinical privileges if those privileges fall within the practitioner's scope of practice as defined by state law or regulations; however, once privileges are granted, the nonphysician providers are bound by the requirements of the organization's bylaws.
   4. The Health Resources and Services Administration (HRSA) developed and jointly operates a national registry (National Practitioner Data Bank [NPDB]) with TJC; NPDB is a registry of providers who lose malpractice claims or are subject to adverse actions of more than 30 days on licensure, privileges, or society membership.
   5. Health care organizations are required to query the NPDB each time a practitioner applies for a medical staff appointment or privileges and every 2 years thereafter.
   6. TJC and the National Committee for Quality Assurance (NCQA) expect health systems to perform a reappraisal of credentials and competence at least biennially for reappointment and renewal of privileges.
   7. TJC currently does not consider pharmacists independent health care providers. Health systems may choose to credential and grant privileges to pharmacists because of their complex roles in patient care, which require an assurance of competence.
   8. Credentialing and privileging are not limited to inpatient settings; the Accreditation Association for Ambulatory Health Care and NCQA also require them. Managed care organizations, large practice groups, ambulatory care organizations, and others have developed mechanisms to ensure standard qualifications and competence of autonomous care providers.
   9. TJC has created a single set of credentialing and privileging standards that apply to long-term care and subacute care programs within the organization it accredits.

F. Advantages of Privileging
   1. Minimizes the health care organization's legal liability; however, the organization can be held liable for damages if an unqualified practitioner is allowed to practice or a qualified practitioner who is not deemed competent to practice is allowed to practice
   2. Helps fulfill the mission to provide the "triple aim": improving care, improving outcomes, and reducing cost
   3. Reduces staff conflicts by establishing the criteria required to provide specific patient care services
   4. For payers, it creates a standardization and validation that pharmacists are qualified to provide the services for which they are billing.

G. Why a Pharmacist Should Participate in Privileging
   1. To gain authorization to perform specific patient care services within a health care system
   2. To gain recognition through health care regulation as providers (i.e., Medicare-recognized providers)
   3. May be needed for protocols or agreements with a medical staff member; organizations are required to assess the competency of their staff, regardless of collaborative practice agreements or department policies

H. Barriers to Pharmacist Privileging
1. Personal barriers
   a. Because it is a voluntary process, may lead to inconsistent requirements and promote misunderstanding of the process and its benefits
   b. Of the four primary elements evaluated for credentialing (academic preparation, type of licensure, postgraduate training, and other traineeship or certificate programs), postgraduate training and other traineeship or certificate programs are voluntary.
2. Institutional barriers – Institution's bylaws for privileging do not address pharmacists; however, can usually be modified
3. Regulatory barriers
   a. The focus of several regulatory organizations and professional organizations on pharmacist credentialing has led to many testing and evaluation mechanisms, resulting in confusion among pharmacists, other health care professionals, and the public.
   b. The Board of Pharmacy Specialties, the Commission for Certification in Geriatric Pharmacy, and the Council on Credentialing in Pharmacy may provide the guidance, authorization, and credentials needed.
   c. The Federal Credentialing Program was originally established to guide physicians and dentists; it may be expanded to include pharmacists and other health care professionals.

IV. PROCESSES OF CARE

A. Pharmacists' Patient Care Process
1. Created by a workgroup, under the JCPP, to provide a consistent process of care framework for delivering patient care in any practice setting
2. A cyclical model that has the patient at the core
3. For the model to succeed, it must have collaboration, communication, and documentation.
   a. Engagement and effective communication is supported by the establishment of a patient-pharmacist relationship.
   b. Pharmacists continually collaborate, document, and communicate with other members of the health care team to deliver safe, effective, and coordinated care.
   c. The process is strengthened by interoperable information technology systems that enable efficient and effective communication.
4. The process contains five main actions
   a. COLLECT subjective and objective information.
      i. Current medication list and medication history
      ii. Health data, such as medical history, biometric tests, etc.
      iii. Lifestyle preferences/beliefs, health goals, factors that could impair access to medications, etc.
   b. ASSESS the collected information.
      i. The medications' appropriateness, efficacy, safety, and adherence
      ii. Health/functional status, cultural factors, health literacy, access to medications, etc.
      iii. Need for preventive care and other services
   c. In collaboration with other health care providers and the patient, create an evidence-based, cost-effective PLAN.
      i. Address medication problems and optimize the drug regimen.
      ii. Create achievable goals to improve patient outcomes.
      iii. Empower the patient through education and self-management.
      iv. Ensure continuity of care through follow-up and transitions of care.

     d.   IMPLEMENT the care plan in conjunction with the patient and other health care providers.
        i.   Address patient issues and implement preventive care (i.e., immunizations).
        ii.   Start, change, stop, and administer appropriate medication.
        iii.   Provide education and self-management training.
        iv.   Schedule follow-up as appropriate.
     e.   FOLLOW-UP: MONITOR AND EVALUATE the effectiveness of the treatment plan, and modify it as needed.
        i.   Through health data, test results, and the patient, ensure medication appropriateness, efficacy, safety, and adherence.
        ii.   Evaluate clinical end points and outcomes of care: control of chronic conditions, patient quality of life, reduction in hospitalizations, and preventive care.

5.   JCPP is currently working on a standardized documentation format for the pharmacists' patient care process through health information technology; www.pharmacyhit.org

6.   Implementation
     a.   Outreach
     b.   Basic toolkit being developed
     c.   Accreditation Council for Pharmacy Education (ACPE) has incorporated the process into the revised Pharm.D. standards for July 2016; www.acpe-accredit.org/pdf/Guidance forStandards2016FINAL.pdf
     d.   American Society of Health-System Pharmacists incorporated into pharmacy postgraduate year 1 (PGY1) residency standards
     e.   Being incorporated into the nation's projects, grant programs, CMS innovations, some MTM services, and several different training programs

B.   Transitions of Care
   1.   Background
     a.   One in five Medicare patients discharged from a hospital is readmitted within 30 days.
     b.   Unplanned rehospitalizations cost Medicare more than $17 billion.
     c.   Half of Medicare patients do not follow up with an outpatient provider within 30 days of hospital discharge.
     d.   About 60% of medication errors arise during transitions of care.
     e.   In 2011, inadequate transitions of care were responsible for $25–$45 billion in wasteful spending.
     f.   Greater than 50% of patients have at least one medication discrepancy on hospital admission; 40% have the potential to cause harm.
     g.   Thirty percent of patients have at least one medication discrepancy with the potential to cause harm.
   2.   Definition
     a.   The movement of patients between health care locations, providers, or different levels of care within the same location as their conditions and care needs change, [and] frequently involves multiple persons, including the patient, the family member or other caregiver(s), nurse(s), social worker(s), case manager(s), pharmacist(s), physician(s), and other providers
     b.   Set of actions designed to ensure the coordination and continuity of health care as patients transfer between health care practitioners, settings, or different levels of care within the same organization during an acute or chronic illness (e.g., hospital, long-term care facilities, patient's home, primary and specialty care offices)
     c.   Comprehensive plan of care that includes logistic arrangements, education of the patient and family, and coordination among the health care professionals involved in the transition
     d.   Encompasses both the sending and receiving aspects of the transfer

3. Areas for ineffective transitions of care: Inpatient to outpatient
   a. Health care providers
      i. Poor communication between inpatient and outpatient providers; limited consequences in failing to send records to outpatient physicians on discharge
      ii. Difficulty transmitting medical records secondary to differences in documentation systems; only 12%–37% of hospital discharge summaries are sent to the outpatient physicians before the follow-up clinical visit
      iii. Lack of standardized procedures in conducting successful handoffs to providers and discharge instructions to patients
      iv. Inadequate amount of time to ensure transitions of care have been performed
      v. Lack of accountability
   b. Patients
      i. Not included in planning for transitions
      ii. Lack understanding about their medical conditions or plan of care
      iii. Confusing medication regimen
      iv. Unclear instructions about follow-up care
   c. Community pharmacies
      i. Challenges of maintaining an accurate medication list are secondary to patient use of several pharmacies.
      ii. Pharmacies often located away from medical centers and physician offices
      iii. Inadequate communication between the community pharmacist and the physician
      iv. Lack of access to patient's medical chart
4. CMS Hospital Readmissions Reduction Program (HRRP)
   a. Implemented in October 2012
   b. Provides incentives for hospitals to decrease unnecessary hospital readmissions, defined as an unplanned admission within 30 days of a hospital discharge
   c. Medical conditions include acute myocardial infarction, heart failure, pneumonia, chronic obstructive pulmonary disease, and elective hip and knee replacement
   d. Penalties
      i. Excess readmission ratio for specified medical conditions is a measure of a hospital's readmission performance compared with the national average for that condition.
      ii. About half of hospitals in the program will always face a penalty.
      iii. Overall magnitude of the penalty will remain the same even as hospitals improve.
      iv. Penalty was initially set at 1%; it was then increased to 2% in 2014 and to 3% in 2015.
   e. Providers and patients can view readmission ratios on the Medicare Hospital Compare website: www.medicare.gov/hospitalcompare/search.html.
5. Role of the pharmacist
   a. Inpatient setting
      i. Obtain admission medication history.
      ii. Complete medication reconciliation.
      iii. Assess appropriateness of medication regimen.
      iv. Resolve medication-related problems before transition.
      v. Educate patient and caregivers about discharge medications.
      vi. Conduct telephone follow-up calls 24–48 hours after discharge to review medications, identify medication discrepancies, and assist with coordination of care.
   b. Community setting (ambulatory care clinic or community pharmacy)
      i. Help patients interpret discharge paperwork.
      ii. Clarify medication discrepancies between home regimen and new regimen after transition.

      iii.   Create complete medication list.

      iv.   Provide MTM, including a CMR.

      v.   Assist with third-party formulary problems, assist with prior authorizations, and see medication assistance programs for patients without insurance.

   c.   Home

      i.   Live or virtual visit

      ii.   Provide appropriate post-discharge care, including medication reconciliation, medication adherence, monitoring of adverse events, access to medications, medication and disease state management, and communication to health care providers on patient progress and barriers.

Table 1. Established Transitions of Care Models

Model	Target Population	Intervention	Outcomes
Project RED (Re-engineered Discharge)	Adult general medicine patients	Nurse discharge advocate sets up follow-up appointments, provides patient education, completes medication reconciliation, and facilitates transmission of discharge summary to clinicians accepting care of the patient Clinical pharmacist conducts telephone follow-up 2–4 days after discharge	Reduced ED visits and hospitalizations within 30 days of discharge in the intervention group: 0.695 relative risk reduction (95% CI, 0.15–0.99)
Care Transitions	Patients with complex care needs who are discharged from the hospital to home	Transitions coach teaches self-management for 4 weeks Sets up home visit and three telephone interactions after discharge from the hospital to home Medication self-management Personal health record Follow-up with primary and/or specialty care Support for patient recognition of symptoms necessitating follow-up	Reduced readmissions at 30, 90, and 180 days Reduced mean hospital costs at 180 days
Transitional Care	Patients 65 years or older hospitalized for medical or surgical reasons and transitioning to another setting	Transitional care nurse coordinates by providing 10 essential elements, including the following: Patient-centric, multidisciplinary, collaborative, comprehensive plan of care Home care Post-acute care clinic follow-up visit support	Lower single and multiple readmission rates Greater number of days between discharge and readmission Shorter lengths of stay during readmission Fewer hospital days Longer time to first readmission or death Reduced cost of care Short-term improvements in quality of life and patient satisfaction

Table 1. Established Transitions of Care Models *(continued)*

Guided Care	Patients with many chronic conditions	Trained registered nurse in the primary care coordinates patient-centered care: Comprehensive assessment Evidence-based care planning Proactive monitoring Care coordination Transitional care Coaching for self-management Caregiver support Access to community-based services Not specific to patients undergoing transitions, but care coordination assists with transitions when they occur	Lower home health services used Higher patient-rated quality of care

CI = confidence interval.

Information from: (1) Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009;150:178-87; (2) Coleman EA, Smith JD, Frank JC, et al. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. J Am Geriatr Soc 2004;52:1817-25; (3) Naylor M, Brooten D, Jones R, et al. Comprehensive discharge planning for the hospitalized elderly: a randomized clinical trial. Ann Intern Med 1994;120:999-1006; (4) Naylor MD, Brooten D, Campbell R, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. JAMA 1999;281:613-20; (5) Naylor M, McCauley K. The effects of a discharge planning and home follow-up intervention on elders hospitalized with common medical and surgical conditions. J Cardiovasc Nurs 1999;14:44-54; (6) Naylor MD, Brooten DA, Campbell RL, et al. Transitional care of older adults hospitalized with heart failure: a randomized, controlled trial. J Am Geriatr Soc 2004;52:675-84; (7) Boult C, Reider L, Leff B, et al. The effect of guided care teams on the use of health services: results from a cluster-randomized controlled trial. Arch Intern Med 2011;171:460-6; (8) Boult C, Leff B, Boyd CM, et al. A matched-pair cluster-randomized trial of guided care for high-risk older patients. J Gen Intern Med 2013;28:612-21; (9) Boyd CM, Reider L, Frey K, et al. The effects of guided care on the perceived quality of health care for multi-morbid older persons: 18-month outcomes from a cluster-randomized controlled trial. J Gen Intern Med 2010;25:235-42.

6. Quality measures
   a. Customary metrics include readmissions, length of stay, ED visits, medication-related problems at medication reconciliation, and patient satisfaction.
   b. Cost-savings analysis to determine potential economic benefit
   c. Process indicators
      i. Percentage of patients who have a completed medication history within 24 hours of admission
      ii. Percentage of home medication lists reconciled on admission
      iii. Frequency of pharmacist-physician communication regarding medication discrepancies with respect to admission orders from the total number of home medications
      iv. The Physician Consortium for Performance Improvement approved a care transitions performance measurement set from the inpatient to the outpatient setting.
         (a) Measure 1: Reconciled medication list received by discharged patients
         (b) Measure 2: Timely transmission of transition record (transition record should be transmitted to the facility or primary physician or other health care professionals designated for follow-up care within 24 hours of discharge)

Table 2. Metrics to Evaluate Transitions of Care Performance

Measure	Description
The Joint Commission – National Patient Safety Goal 03.06.01	Obtain and document current medication information when patients are admitted to the hospital or seen in an outpatient setting Compare the patient-provided medication information with the medications ordered for the patient to identify and resolve discrepancies Provide the patient with written instructions on how to take medications when discharged from the hospital or at the end of an outpatient encounter, including name, dose, route, frequency, and purpose Explain to patients the importance of managing medication information when discharged from the hospital or at the end of an outpatient encounter
Hospital Consumer Assessment of Healthcare Providers and Systems Survey	CTM-3 Patient Questions The hospital staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left the hospital When I left the hospital, I had a good understanding of the things I was responsible for in managing my health When I left the hospital, I clearly understood the purpose for taking each of my medications
Physician Consortium for Performance Improvement Quality Measures	Care Transitions Performance Measurement Set Percentage of patients discharged from an inpatient facility to home or any other site who received a reconciled medication list and transition record Percentage of patients for whom a transition record was transmitted within 24 hours of discharge to a facility/health care professional responsible for follow-up care Percentage of patients discharged from the ED to ambulatory care or home health care who received a transition record on ED discharge
Centers for Medicare & Medicaid Services Hospital Readmission Reduction Program	Readmission rates for acute myocardial infarction, heart failure, pneumonia, chronic obstructive pulmonary disease, and elective hip or knee replacement surgery
National Committee for Quality Assurance Healthcare Effectiveness Data and Information Set – Plan All-Cause Readmissions	The percentage of discharges over one year for which medications were reconciled the date of discharge through 30 days after discharge (total of 31 days)
National Committee for Quality Assurance Healthcare Effectiveness Data and Information Set – Medication Reconciliation Measure	Percentage of hospital discharges during the measurement year for patients 66 years and older for whom medications were reconciled in the outpatient medical record within 30 days of discharge

CTM-3 = three-item care transition measure.

Information from: (1) The Joint Commission. 2017. National Patient Safety Goals Effective January 1, 2017: Hospital Accreditation Program. Available at https://www.jointcommission.org/assets/1/6/NPSG_Chapter_AHC_Jan2017.pdf. Accessed November 22, 2016 (2) National Quality Forum (NQF). Care Transitions Measure Tools: The CTM-3. Available at http://caretransitions.org/wp-content/uploads/2015/08/CTM-3.pdf. Accessed November 22, 2016 (3) Physician Consortium for Performance Improvement (PCPI). PCPI-Stewarded Measures. Available at http://www.thepcpi.org/programs-initiatives/measurement-science/measure-directory/pcpi-stewarded-measures/. Accessed November 22, 2016 (4) Centers for Medicare & Medicaid Services (CMS). Readmissions Reduction Program (HRRP). Available at https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html. Accessed November 22, 2016. (5) Agency for Healthcare Quality and Research (AHRQ). National Quality Measures Clearinghouse, October 2015. Available at https://www.qualitymeasures.ahrq.gov/summaries/summary/49833. Accessed November 22, 2016 (6) Agency for Healthcare Quality and Research (AHRQ). National Quality Measures Clearinghouse, November 2014. Available at https://www.qualitymeasures.ahrq.gov/summaries/summary/48847/medication-reconciliation-postdischarge-percentage-of-discharges-from-january-1-to-december-1-of-the-measurement-year-for-patients-66-years-of-age-and-older-for-whom-medications-were-reconciled-on-or-within-30-days-of-discharge?q=medication+reconciliation+measure. Accessed November 22, 2016.

7. Methods to improve transitions of care
   a. Multidisciplinary communication, collaboration, and coordination
      i. A care team that includes a physician, pharmacist, nurse, social worker, and others begins at admission and continues until the patient is discharged home, to ensure successful transitions.
      ii. Include patient/caregiver education.
      iii. At every point during the transition, a responsible coordinating clinician (e.g., a primary care physician or nurse practitioner) is identified by the patient to ensure thorough communication and follow-up.
   b. Patient-centered process focusing on patient safety
   c. Shared accountability by sender and receiver
   d. Comprehensive planning and risk assessment throughout the hospital stay
      i. Discharge planning begins immediately after admission.
      ii. During the hospital stay, patients are assessed for risk factors that may limit their ability to perform necessary aspects of self-care, including low literacy, several hospital admissions, and several chronic conditions or medications.
   e. Standardized transition plans, procedures, and forms
      i. The following components are included in a written transition plan or discharge summary: active issues, diagnosis, medications, required services, warning signs of a worsening condition, whom to contact in an emergency.
      ii. The transition plan should be communicated to the outpatient provider.
   f. Timely follow-up, support, and coordination after the patient leaves a care setting
   g. Standardized training of health care providers
   h. Data to justify resources
   i. Requires a process of continuous quality improvement
8. Challenges in implementing transitions of care/barriers in implementing transitional care
   a. Financial resources
   b. Staffing resources
   c. Electronic transfer of patient information and data partner groups
   d. Difficulty developing a partnership with inpatient and outpatient providers
9. Reimbursement by Medicare transitional care management codes
   a. For specifics on billing, see the chapter titled "Managing a Clinical Practice."
   b. The following health care professionals may furnish transitional care management services:
      i. Physicians (any specialty)
      ii. The following nonphysician practitioners are legally authorized and qualified to provide the services in the state in which they are furnished: certified nurse-midwives, clinical nurse specialists, nurse practitioners, and physician assistants.
      iii. Any health care provider, including pharmacists, can furnish the 2-day post-discharge communication.
10. Suggested readings
    a. Hume A, Kirwin J, Bieber H, et al. Improving care transitions: current practice and future opportunities for pharmacists. Pharmacotherapy 2012;32:e326-37.
    b. American Society of Health-System Pharmacists and APhA. Best Practices from the American Society of Health-System Pharmacists-APhA Medication Management in Care Transitions Initiative. Available at http://media.pharmacist.com/practice/ASHP_APhA_MedicationManagement inCareTransitionsBestPracticesReport2_2013.pdf.
       i. Medication REACH – Einstein Medical Center in Philadelphia
          (a) Pharmacist involvement before discharge to complete the following:
              (1) R – Medication reconciliation
              (2) E – Deliver patient-centered education.

(3)   A – Resolved medication access

(4)   C – Comprehensive counseling

(5)   H – Healthy patient at home who is adherent to medications without adverse events

(b)   Thirty-day readmission rate was 21.4% in the control group, defined as patients receiving standard of care, compared with 10.6% in the intervention group that received pharmacist care before discharge.

(c)   Twenty-five percent of interventions were caused by a gap in therapy; others included dose optimization (22%) and deletion of therapy (8%).

ii.   The Medication Management Transitions of Care Team – Johns Hopkins University School of Medicine in Baltimore, Maryland

(a)   Pharmacists

(1)   Optimize medication therapy by participating in multidisciplinary rounds.

(2)   Provide patient education.

(3)   Conduct medication reconciliation.

(4)   Ensure that patients have the opportunity to acquire the appropriate medications in hand for outpatient management on discharge.

(b)   Pharmacy technicians

(1)   Work collaboratively to process insurance claims and adjudicate prescriptions.

(2)   Discuss payment options with the patient and help assess the patient's ability to afford the medication regimen.

(3)   Refer the patient to social work or financial assistance programs as appropriate.

(c)   Patients are discharged with a follow-up primary care appointment.

(d)   Post-discharge plan and instructions are communicated to the patient's primary care physician by the pharmacist.

(e)   All patients considered at a high risk of readmission (based on their Early Screen for Discharge Planning score) are given a personal health coach, a trained nurse who provides follow-up at the patient's home to screen for complications and ensure the patient is following discharge instructions and attending follow-up appointments.

(f)   Patients may be referred to the organization's outpatient pharmacy and ambulatory pharmacists for additional outpatient pharmacy services by home health care nurses, personal coaches, and physicians.

(g)   Telephone calls after discharge are made by the inpatient pharmacist within 72 hours of discharge.

(h)   Home-based medication reconciliation is performed by a pharmacist.

c.   Centers for Medicare & Medicaid Services (CMS). Evaluation and Management Services Guide. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf Accessed November 9, 2016.

Patient Case

6.   Which would be the best quality measure for evaluating a transition of care service from the inpatient to the outpatient setting?

A.   The number of patients adherent to their medications 1 year after discharge.

B.   The number of patients who arrive at their outpatient follow-up visit after discharge.

C.   The number of patients who are knowledgeable about their medications 6 months after discharge.

D.   The number of patients who have a medication error during hospitalization out of the total number of patients admitted.

C. Medication Reconciliation
   1. Definitions
      a. According to the Agency for Healthcare Research and Quality (AHRQ): "The process of avoiding inadvertent medication discrepancies by reviewing a patient's current medication regimen and comparing it with the regimen being considered for the new setting of care"
      b. According to TJC: "Compares medications a patient should be using (and is actually using) with the new medications that are ordered"
   2. Goal: Decrease medication errors and patient harm
   3. Accreditation standards
      a. TJC National Patient Safety Goal 03.06.01
         i. Obtain and document or verify patient's medication list when admitted or seen as an outpatient. Medications to inquire about should include current prescription and over-the-counter medications.
         ii. Define the types of medication information to be collected in non–24-hour settings and different patient circumstances.
         iii. Compare medication information the patient brought to the hospital with those ordered to identify unintended discrepancies. A qualified individual conducts the comparison, according to TJC requirements. Discuss unintended discrepancies with the physician for resolution.
         iv. Provide the patient/family with written information on the medications the patient should be taking when discharged from the hospital, or at the end of an outpatient encounter.
         v. Explain the importance of managing medication information to the patient when discharged or at the end of an outpatient encounter. Instruct patients to:
            (a) Give a list to their primary care provider.
            (b) Update the list when medications are discontinued, doses are changed, or new medications (including over-the-counter medications) are added.
            (c) Carry medication information at all times in case of an emergency.
      b. NCQA Healthcare Effectiveness Data and Information Set Medication Reconciliation Post-Discharge measure
         i. Medication reconciliation is a type of review in which discharge medications are reconciled with the most recent medication list in the outpatient medical record.
         ii. Measures the percentage of discharges for members for whom medications were reconciled by a prescribing practitioner, clinical pharmacist, or registered nurse on or within 30 days of discharge
         iii. Includes only Medicare special-needs patients 66 years and older
   4. Effectiveness of medication reconciliation poorly studied
      a. Hospital-based medication reconciliation (Arch Intern Med 2012;172:1057-69)
         i. Studies have shown a reduction in medication discrepancies, potential adverse drug events, and adverse drug events.
         ii. Inconsistent reduction in post-discharge health care use (only two of eight studies showed improvement)
         iii. Successful interventions
            (a) Intensive pharmacy staff involvement
            (b) Targeting high-risk patients
            (c) Studies are needed to determine the most effective interventions.
      b. Medication reconciliation in primary care (Ann Pharmacother 2009;43:1667-75)
         i. Pharmacist medication review at hospital discharge showed no benefit.
         ii. Medication reconciliation at each ambulatory care visit revealed mixed results.

      iii. No good evidence showing the effectiveness of medication reconciliation in the primary care setting

      iv. Improving medication list accuracy alone may not improve clinical status or prevent adverse drug events; may also need to provide CMM

5. Patients are the common factor involved in medication reconciliation between settings of care.

    a. Patients need to be empowered to be more active participants.

    b. Health literacy is defined as "the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions."

      i. Inadequate or marginal health literacy has been found in 60% of hospitalized medical patients.

      ii. Within 48 hours of hospital discharge, 56% of elderly patients had a medication discrepancy between the discharge instructions medication list and the patient's actual home medication use.

      iii. Teach-back method can be used to explain information to patients and caregivers.

        (a) Used to make sure patients understand what you have just taught

        (b) Ask patients in a caring way to show or explain in their own words what they need to know or do.

        (c) Avoid simply asking patients if they understand.

        (d) Use open-ended questions instead of closed-ended questions that can be answered with "yes" or "no."

        (e) Provides opportunity to re-explain in a different way if misunderstood

    c. Even if health care providers were able to reliably access all prescription records, there would still be a need to discern how patients are actually taking their medications.

    d. Emphasize the need for patients to maintain an accurate medication list and the importance of sharing the list with all health care providers in all settings.

6. Electronic Health Information Exchange, including prescription data from community pharmacies and patient-interfacing health information technology tools, could improve the accuracy and efficiency of obtaining accurate medication histories.

    a. Pharmacy prescription records identified 41.5% more prescribed medications than medication histories obtained in the ED (J Am Med Inform Assoc 2014;21:391-8).

    b. Factors contributing to omissions from the ED medication list

      i. Patients who filled prescriptions at more than one pharmacy

      ii. Patients who took more than 12 medications

    c. Secure messaging within a patient web portal may assist with medication reconciliation after an inpatient-to-outpatient care transition and identify medication discrepancies and potential adverse drug events (J Am Med Inform Assoc 2014;21:e157-62).

    d. Creating a business case of electronic solutions (Academy of Managed Care Pharmacy 2014)

      i. Electronic efficiency

      ii. Readmission penalties

      iii. HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) incentives

      iv. Duplicative efforts by several health care providers

      v. Payer costs for readmissions

Patient Case

7. G.H. is an older adult with chronic medical conditions who takes 14 prescription medications. She has had several hospital and ED admissions this year, and she receives care from a family physician, cardiologist, nephrologist, and endocrinologist. The medication regimen for treatment of heart failure and diabetes is regularly adjusted by several providers in many settings. Which strategy is most likely to maintain the accuracy of the medication list for this patient?

   A. Provide pharmacist-led medication reconciliation in the primary care clinic after each hospital discharge.

   B. Evaluate the patient's electronic medical record for all medication changes the providers wanted to take place.

   C. Contact all pharmacies that have filled prescriptions for the patient each time she is seen in the primary care clinic.

   D. Educate her about the importance of keeping an up-to-date medication list with her at all times to share with all health care providers at every visit.

D. Immunizations
1. Background
   a. In 1996, the APhA House of Delegates adopted a policy calling on pharmacists to get involved with the nation's immunization priorities through administering vaccines, patient education, and facilitating the receipt of vaccinations by patients.
   b. In the same year, APhA established the Pharmacy-Based Immunization Delivery Program, which was endorsed by the Centers for Disease Control and Prevention (CDC).
   c. All 50 states allow pharmacists to administer vaccines; authority is governed by state laws and regulations of their individual pharmacy practice acts. Some states:
      i. Have educational and certification/licensure requirements
      ii. Allow students to administer vaccinations
      iii. Limit the types of vaccines a pharmacist can administer
      iv. Limit by age the patients whom a pharmacist can vaccinate
      v. Require a prescription from a physician
      vi. Limit the route of administration
2. Medicare vaccination coverage
   a. CMS definitions
      i. Mass immunizer: Can be a traditional Medicare provider/supplier (e.g., hospital outpatient department) or a nontraditional provider (supermarket or public health clinic) that offers influenza and/or pneumococcal vaccine to a large number of patients
      ii. Roster billing: Simplified billing process, allowing mass immunizers to submit one claim form plus the list of immunized beneficiaries
      iii. Centralized billing: Allows mass immunizers who operate in at least three different payment localities to submit all influenza and/or pneumococcal vaccination claims to one Medicare Administrative Contractor (MAC)
   b. Medicare Part B
      i. Covered vaccinations: Pneumococcal, influenza, hepatitis B for intermediate- and high-risk patients, and any vaccine necessary to treat an injury/illness
         (a) High-risk patient
            (1) Health care professionals in frequent contact with blood or blood-derived body fluids
            (2) End-stage renal disease
            (3) Individuals living with a hepatitis B virus carrier

(4) Individuals with diabetes mellitus

(5) Other situations could qualify.

(b) Treatment of illness or injury (e.g., tetanus vaccine related to an accidental puncture wound)

ii. Roster biller

(a) Must have or obtain a National Provider Identifier (NPI) for each location in which immunizations will be provided: https://nppes.cms.hhs.gov/

(b) Enroll as provider specialty type 73, Mass Immunization Roster Biller, by completing form CMS-855I for individuals or form CMS-855B for a group; as an alternative to the paper CMS-855, CMS established an Internet-based Provider Enrollment, Chain and Ownership System.

(c) Enrollment is required only before the first influenza season in which participation will occur.

(d) Bill a MAC either electronically or by paper. For paper billing, complete form 1500 or 1450 for each type of vaccination. In addition, attach a roster of patients who receive the vaccine.

(e) Neither Medicare Part B deductibles nor copayment applies to vaccines; therefore, must accept the amount Medicare pays as payment in full for both the vaccine and its administration.

iii. Centralized biller

(a) Must enroll with the MAC in writing by June 1 each year of desired influenza season participation (September 1 through August 31); enrollment process takes 8–12 weeks

(b) Need only one NPI number

(c) Use roster bills.

(d) Must submit claims electronically

(e) Neither Medicare Part B deductibles nor copayment applies to vaccines; therefore, must accept the amount Medicare pays as payment in full for both the vaccine and its administration

iv. Billing and codes

(a) Diagnosis code V06.6

(b) Administration codes: Influenza (G0008), pneumococcal (G0009)

(c) Payment linked to Current Procedural Terminology (CPT) code 90471

(d) Medicare will cover pneumococcal revaccination if a patient is uncertain of vaccination history in the past 5 years.

(e) If Medicare beneficiary is certain more than 5 years have passed since pneumococcal vaccination, revaccination is not appropriate and will not be paid for unless beneficiary is at highest risk.

c. Medicare Part D

i. Any vaccine is payable under Part D when not covered by Part B; this includes, but is not limited to, the herpes zoster vaccine.

ii. In-network retail pharmacy access

(a) The vaccine can be filled and administered through a prescription, pharmacist order, or CDTM.

(b) Billing

(1) Vaccine administration costs are a component of the negotiated price for Part D–covered vaccines; negotiated price includes the vaccine ingredient cost, a dispensing fee (if applicable), sales tax (if applicable), and a vaccine administration fee.

(2) If a copayment is charged to the patient, it will only be one copay and will be relative to the entire price of the vaccine and its administration, even if the entities are billed separately.

iii. In-network distribution approaches
(a) A network pharmacy could provide vaccines directly to physician offices.
(b) Physician sends a prescription for the vaccine to the pharmacy.
(c) The pharmacy fills the prescription and ships it to the physician's office; billing is completed under Part D.
(d) The physician does not purchase or receive reimbursement for the vaccine.
(e) Challenge for the physician is to ensure adequate freezer space to house the vaccine until it is administered.
3. Suggested readings
a. www.cdc.gov/vaccines – Schedules, recommendations, vaccine information statements
b. www.immunize.org – News, patient handouts, clinic management resources
c. http://vaers.hhs.gov/index – National vaccine safety surveillance system

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Patient Case

8. You have been appointed the manager of an independent outpatient pharmacy that just opened. It is flu season, and the pharmacists are asking whether Medicare will cover patients who get immunized with the influenza vaccine in your pharmacy. Which statement is most accurate regarding this issue?

A. No, the pharmacy cannot bill under Medicare Part B this year because mass immunizer status was not gained before flu season.
B. Yes, the pharmacy can bill for the flu vaccine under Medicare Part D.
C. Yes, the pharmacy can bill under Medicare Part D as long as the pharmacy has been certified by APhA.
D. No, the pharmacy cannot bill for the flu vaccine under Medicare Part B because this vaccine can be billed only when provided in a clinic setting.

E. Point-of-Care Testing
1. CLIA
a. CMS regulates all laboratory testing (except research) performed on humans in the United States through CLIA.
b. Implemented by the Division of Laboratory Services, within the Survey and Certification Group, under the Center for Clinical Standards and Quality
c. CLIA ensures quality laboratory testing.
d. CLIA requires all entities that perform one or more tests (includes waived tests) on "materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain federal requirements.
e. If an entity performs tests for the purposes listed, it is considered a laboratory and must be registered.
f. All clinical laboratories must be properly certified to receive Medicare or Medicaid payments.
g. CLIA application collects information to determine the type of certificate to issue and the fees to assess.
h. The U.S. Food and Drug Administration (FDA) categorizes commercially marketed in vitro diagnostic tests.

Table 3. Federal Agencies Responsible for CLIA

Agency	Responsibilities
U.S. Food and Drug Administration	Test complexity categorization Reviews requests for Waiver by Application Develops rules for CLIA complexity categorization
Centers for Medicare & Medicaid Services	Issues laboratory certificates Collects user fees Conducts inspections and enforces regulatory compliance Approves private accreditation organizations for performing inspections and approves state exemptions Monitors laboratory performance on PT and approves PT programs Publishes CLIA rules and regulations
Centers for Disease Control and Prevention	Provides analysis, research, and technical assistance Develops technical standards and laboratory practice guidelines Conducts laboratory quality improvement studies Monitors proficiency testing practices Develops/distributes professional information and educational tools Manages the Clinical Laboratory Improvement Advisory Committee

PT = proficiency testing.

Adapted from: U.S. Food and Drug Administration. April 16, 2014. Clinical Laboratory Improvement Amendments (CLIA). Available at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm. Accessed September 28, 2015.

    i.   Certificate of waiver
       i.   Laboratories must file a certificate of waiver application (CMS form 116; www.cms.gov/cmsforms/downloads/cms116.pdf).
      ii.   Applicants must obtain a separate certificate for each location.
    iii.   Applications should be sent to the local state agency; additional forms may be necessary, depending on the state.
    iv.   Waived tests: Simple laboratory examinations and procedures that meet one of the following criteria:
       (a)   Approved by the FDA for home use
       (b)   Use methods so simple and accurate that the likelihood of erroneous results is minor
       (c)   Pose no reasonable risk of patient harm if the test is performed incorrectly
      v.   The FDA's list of waived tests is continuously updated. Check the FDA website to verify that the test in question is categorized as waived (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.Cfm).
      vi.   Waivers may be granted for the following:
       (a)   Tests listed in the regulation (see Box 1)
       (b)   Test systems for which the manufacturer applies for waiver with the following criteria:
          (1)   Meet statutory criteria
          (2)   Have scientifically valid data verifying that waiver criteria have been met
       (c)   Test systems approved by the FDA for home use
     vii.   Professional-use versions of home-use tests are not automatically waived.
       (a)   Qualify for expedited waiver review.
       (b)   Review is expedited because only the differences between the home-use and professional-use versions need to be assessed.

viii. Once a waiver has been obtained:
  (a) Only waived tests can be performed.
  (b) Cannot deviate from manufacturer instructions for use
  (c) Pay the renewal fee every 2 years.
  (d) Notify the state agency of any changes to the ownership, name, address, or director within 30 days or if adding tests.
  (e) Allow announced and unannounced CMS inspections.

Box 1. Tests Specified as Waived by CLIA Regulation

Dipstick or tablet reagent urinalysis (nonautomated) for the following: • Bilirubin   • Glucose   • Hemoglobin   • Ketone   • Leukocytes   • Nitrite   • pH   • Protein   • Specific gravity   • Urobilinogen
Fecal occult blood
Ovulation tests (visual color comparison tests for luteinizing hormone)
Urine pregnancy tests (visual color comparison tests)
Erythrocyte sedimentation rate, nonautomated
Hemoglobin-copper sulfate, nonautomated
Blood glucose by glucose monitoring devices cleared by the FDA for home use
Spun microhematocrit
Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout

Adapted from: Centers for Disease Control and Prevention (CDC). Clinical Laboratory Improvement Amendments (CLIA): Standards and Certification: Laboratory Requirements (42 CFR 493). Available at www.cdc.gov/clia/Regulatory/default.aspx. Accessed November 9, 2016.

2. Safety
  a. State law must permit pharmacists to perform point-of-care testing
  b. The Occupational Safety and Health Administration (OSHA) enforces rules for workplace safety and health under the U.S. Department of Labor (Box 2).
    i. OSHA requirements can vary by state or region (www.osha.gov/dcsp/osp/index.html).
    ii. Develop a safety plan describing policies, procedures, and work practices for employee safety.
    iii. All needlestick precautions must be provided at no cost to the employee.
  c. Additional safety practices
    i. No eating, drinking, or applying makeup in areas where samples are collected and where testing is performed
    ii. Do not store food in refrigerators where testing supplies or samples are stored.
    iii. Have sinks for handwashing or antiseptic handwashing solutions available.
    iv. Post safety information for employees and patients.

Box 2. OSHA Standards for POCT

A Guide to Compliance with OSHA Standards: www.osha.gov/Publications/osha3187.pdf
Strictly enforce the use of universal precautions and compliance with the bloodborne pathogens standard: www.osha.gov/SLTC/bloodbornepathogens/index.html
Ensure the use of safer, engineered needles; sharps containers; and personal protective equipment (i.e., gloves and protective eyewear): www.osha.gov/OshDoc/data_General_Facts/ppe-factsheet.pdf
Implement a sharps injury prevention program: www.cdc.gov/sharpssafety/pdf/sharpsworkbook_2008.pdf
Offer hepatitis B vaccination at no cost for employees with possible occupational exposure
Provide safety training to employees on the safe handling of blood and other infectious materials
Provide equipment for the handling and disposing of biohazardous waste
Provide a written, easily accessible exposure control plan: www.osha.gov/SLTC/etools/hospital/hazards/tb/sampleexposurecontrolplan.html
Keep records regarding occupational injuries and illnesses

OSHA = Occupational Safety and Health Administration; POCT = point-of-care testing.

Adapted from: Centers for Disease Control and Prevention (CDC). January 2012. To Test or Not to Test: Considerations for Waived Testing. Available at www.cdc.gov/clia/resources/waivedtests/pdf/wavedtestingbookletweb.pdf. Accessed October 12, 2016.

3. Confidentiality: Health Insurance Portability and Accountability Act of 1996 (HIPAA)
   a. Requirements for confidentiality, protection, and privacy of personal health information
   b. Testing sites are required to create policies and procedures to protect the confidentiality of protected health information.
      i. Patient identification
      ii. Test results
      iii. All records of testing
   c. Personnel must receive training on maintaining the confidentiality of patient information.
   d. Additional HIPAA information: www.hhs.gov/ocr/hipaa
4. Suggested reading: Stepwise approach to developing point-of-care testing services in the community/ambulatory pharmacy setting. J Am Pharm Assoc 2006;46:594-604.

Patient Case

9. Which is the best example of a test that requires a waiver review before a pharmacy with a CLIA certificate of waiver can perform the test on patients?

   A. Dipstick urinalysis for glucose
   B. Professional-use version of a home-use test
   C. Urine pregnancy tests (visual color comparison tests)
   D. Test systems approved by the FDA for home use

F. Patient Assistance
  1. Lowering patients' prescription drug costs
      a. Switch to generic or other lower-cost drugs.
      b. Use pharmacies' $4 generic formularies.
      c. Pharmaceutical manufacturer assistance programs
          i.   Not all manufacturers offer assistance programs.
          ii.   Qualifications vary by program.
          iii. Program information and applications can be obtained by calling pharmaceutical manufacturers or searching the Internet.
          iv.   Typical application requirements
                (a) Proof of income
                (b) Valid prescription signed by prescriber
                (c) Patient information
                (d) Prescriber information
                (e) Financial information
                (f) Insurance information
                (g) Completed application with patient attestation and signature
          v.   Medicare offers a pharmaceutical assistance program website with information for Medicare beneficiaries about pharmaceutical manufacturer assistance programs (www.medicare.gov/pharmaceutical-assistance-program).
          vi.   Assistance from pharmaceutical manufacturer assistance programs will not count toward Medicare Part D TrOOP costs.
      d. State pharmaceutical assistance programs
          i.   State-administered programs that help Medicare recipients with limited income and resources afford prescription drugs
          ii.   Currently offered by 21 states and the U.S. Virgin Islands; www.medicare.gov/pharmaceutical-assistance-program/state-programs.aspx
          iii. Some programs require patients to join a specific plan or may even enroll patients.
          iv.   Most state pharmaceutical assistance programs work with Part D plans.
                (a) Pay for drugs not covered by a plan
                (b) Provide discounts on prescriptions
                (c) Offer certain medications for a low, fixed copayment
          v.   Always the payer of last resort
          vi.   Assistance provided by some of these programs may count toward Medicare Part D TrOOP costs.
      e. Medicare Part D Low-Income Subsidy (also known as *Extra Help*) for assistance with prescription drug plan costs
          i.   Estimated to be worth $4000 per year
          ii.   Qualifications
                (a) Medicare recipient
                (b) Reside in one of the 50 states or the District of Columbia
                (c) Annual income limited to $17,655 for an individual ($23,895 for a married couple living together)
                (d) Total resources must be limited to $13,640 for an individual ($27,250 for a married couple living together). Resources include the value of the things the patient owns.
                      (1) Real estate (other than your primary residence)
                      (2) Bank accounts, including checking, savings, and certificates of deposit
                      (3) Stocks

        (4) Bonds, including U.S. savings bonds

        (5) Mutual funds

        (6) Individual retirement accounts

        (7) Cash

    iii. Can be applied/reapplied any time if income status or resources change

    iv. Some patients automatically qualify for the Extra Help subsidy.

       (a) Have full Medicaid coverage

       (b) Get help from a state Medicaid program paying the patient's Part B premiums

       (c) Receive supplemental security income benefits

    v. Patients are notified each October if there is a change in their Extra Help copayments.

  f. National and local charitable groups

    i. National Patient Advocate Foundation; www.npaf.org

    ii. National Organization for Rare Disorders; www.rarediseases.org

    iii. National Council on Aging; www.benefitscheckup.org

    iv. Assistance provided by some of these programs may count toward Medicare Part D TrOOP costs.

2. 340B drug pricing program

  a. Background

    i. Created by the U.S. federal government in 1992; section 340B of the Public Health Service Act of 1992

    ii. Requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services, which limits the price manufacturers can charge certain covered entities for outpatient drugs

    iii. Administered by the Office of Pharmacy Affairs, which falls under the Healthcare Systems Bureau within HRSA

       (a) Enrollment, recertification, compliance

       (b) Must recertify annually, attesting to compliance with all requirements

  b. Purpose: Enables covered entities to stretch scarce federal resources as far as possible by expanding the services and volume of care provided to the most vulnerable patient populations

  c. Covered entities (CE) – entities must recertify their eligibility yearly and notify the Office of Pharmacy Affairs whenever there is a change in eligibility.

    i. Federally qualified health center or look-alikes

    ii. Ryan White grantees

    iii. State AIDS drug assistance programs

    iv. Medicare/Medicaid disproportionate share hospitals

    v. Children's hospitals

    vi. Critical access hospitals

    vii. Freestanding cancer hospitals

    viii. Rural referral centers

    ix. Sole community hospitals

    x. Black-lung clinics

    xi. Comprehensive hemophilia diagnostic treatment centers

    xii. Title X family planning clinics

    xiii. Sexually transmitted disease clinics

    xiv. Tuberculosis clinics

    xv. Native Hawaiian health centers

    xvi. Tribal/urban Native American health centers

    d. Pharmacies
       i. Not considered a CE
      ii. A CE can contract with a pharmacy to provide comprehensive pharmacy services to 340B-eligible patients.
     iii. Contract pharmacies dispense discounted drugs purchased under the 340B program by the CE to eligible patients.
     iv. The contracted pharmacy collects the reimbursement from the payers and shares with the CE.
    e. Patient eligibility
       i. The CE is responsible for the patient's health care (i.e., the patient has a medical record number).
      ii. Care is provided and maintained from a health care provider while working in a 340B-eligible outpatient clinic.
     iii. Prescription originated from a provider while working in a 340B-eligible outpatient clinic or is a discharge prescription from a CE hospital.
     iv. The patient does not have a Medicaid or Medicaid managed care plan; this eliminates a duplicate discount, up-front 340B discount, and back-end Medicaid rebate.
      v. Prescriptions are for outpatient medications.
    f. Eligible drugs
       i. FDA-approved prescription drugs
      ii. Over-the-counter drugs written on a prescription
     iii. Biological products dispensed only by a prescription (other than vaccines)
     iv. FDA-approved insulin
      v. Orphan drugs used for non-orphan conditions to cancer hospitals, critical access hospitals, rural referral centers, and lone community hospitals
    g. Anti-diversion
       i. Diversion occurs if 340B drugs are used for ineligible patients.
      ii. Auditing by HRSA
         (a) Began in fiscal year 2012
         (b) Risk-based audits
         (c) Targeted audits
         (d) HRSA released "Mega Guidance" for review; proposed guidance to the 340B program
     iii. Diversion can have severe penalties, including large fines and revocation of the 340B drug pricing program.

Patient Case

10. Your pharmacy is contracted to dispense 340B medications. You have a patient who presents a prescription from a physician who you know works for the covered entity your pharmacy is contracted with; however, the prescription is written on a prescription pad from a different facility. Which best describes how the prescription should be processed?

A. Using 340B medications because the physician works for the covered entity.
B. Using non-340B medications because the physician did not write the prescription while working at the covered entity.
C. Using 340B medications because the patient receives some of her care at the covered entity.
D. Using non-340B medications because the patient's insurance is a Medicare Part D plan.

V. SPECIAL ISSUES IN PHARMACY PRACTICE

A. Medication Safety
   1. Definitions
      a. Errors: Failures of planned actions to be completed as intended or the use of incorrect plans to achieve aims
      b. Medication errors: Any errors occurring in the medication use process
      c. Close calls: Errors that occurred but did not reach the patient
      d. Adverse events: An event resulting in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient
      e. Adverse drug events: Injuries caused by medications
      f. Preventable adverse drug events: Considered medication errors
      g. Non-preventable adverse drug events: Considered adverse drug reactions
   2. Medication errors
      a. Medication errors are the most common type of medical error.
      b. Error of commission
         i. Doing something wrong
         ii. Example: Ordering a medication for a patient who has a documented allergy to that medication
      c. Error of omission
         i. Failing to do the right thing
         ii. Is considered to reach the patient (i.e., not a close call)
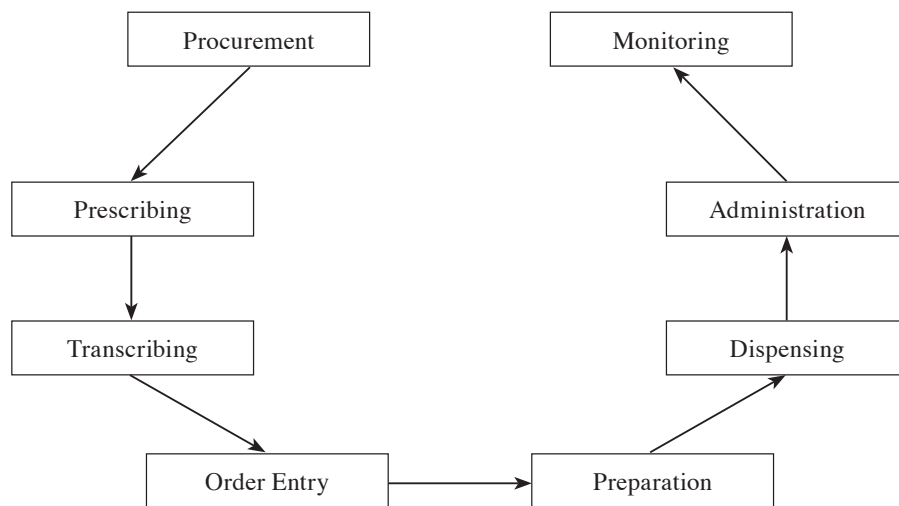   iii. Example: Failing to order venous thromboembolism prophylaxis for a patient after hip replacement surgery

Figure 1. Steps of the medication use process during which errors can occur.

   3. Adverse drug events, error reporting, and detection
      a. Safety reporting is very uncommon in ambulatory care.
      b. Reporting must be easy and efficient, yet it must provide useful data.
      c. Internal voluntary reporting
         i. Traditional efforts to detect adverse events have focused on voluntary reporting and tracking of errors.

    ii. Only 10%–20% of errors are ever reported.
- (a) Complex reporting process
- (b) Culture of fear
- (c) Culture of risk tolerance
- (d) Concern of liability
- (e) Perception reporting is not a priority

    iii. Most hospitals and large health systems have a confidential error reporting system for front-line staff.

    iv. Ideally, internal reports are conveyed externally into a larger data pool for broader analysis.

d. External voluntary reporting

    i. MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- (a) Voluntarily report product problems or unexpected adverse effects
- (b) Anyone may report – Online, mail, telephone, fax
- (c) Why to report
    - (1) Not all products have clinical data/trials before clearance to market.
    - (2) Clinical trials have limitations in identifying safety signals before marketing.
    - (3) Number of patients studied may be too small to detect rare, serious problems.
    - (4) Trials are brief.
- (d) Events to report
    - (1) Fatal
    - (2) Life threatening
    - (3) Permanent harm or disability
    - (4) Require or prolong hospitalization
    - (5) Birth defect
    - (6) Intervention required to prevent permanent damage or impairment

    ii. Vaccine Adverse Event Reporting System (VAERS); http://vaers.hhs.gov
- (a) National Vaccine Safety Surveillance Program
- (b) Report non-preventable adverse reactions to a vaccine product
- (c) Cosponsored by the CDC and the FDA
- (d) Online, fax, mail

    iii. Institute for Safe Medication Practices (ISMP)
- (a) 501(c)(3) nonprofit organization; founded in 1994
- (b) Federally certified patient safety organization (PSO) – Provides legal protection and confidentiality for data and error reports
- (c) Mission: to advance patient safety worldwide by empowering the health care community, including consumers, to prevent medication errors
- (d) ISMP Medication Errors Reporting Program (MERP); www.ismp.org/orderforms/healthcaremerp.asp
- (e) ISMP Vaccine Error Reporting Program (VERP)
    - (1) http://verp.ismp.org/
    - (2) Information confidentially forwarded to the VAERS, the manufacturer, or both
- (f) All reports sent to ISMP are sent to the FDA; however, not always the other way around.
    - (1) There is a memorandum of understanding (MOU) between the FDA and ISMP
    - (2) They develop some educational materials together

Patient Case

11. A community pharmacist overrode a serious drug-drug interaction computer alert involving warfarin; subsequently, the patient developed a stroke with permanent functional impairment because of the drug interaction. To support process improvements in the pharmacy, which would be the most appropriate reporting system to use?

    A. FDA MedWatch
    B. The pharmacy's internal voluntary reporting system
    C. ISMP reporting program
    D. FDA Vaccine Adverse Event Reporting System

    e. Methods for detecting adverse drug events
    i. International Classification of Diseases, Ninth Revision (ICD-9) and Tenth Revision (ICD-10) diagnosis codes obtained through administrative data query
        (a) Adverse drug events are not reliably or consistently coded.
        (b) Health care providers may not recognize a medical problem as being an adverse drug event.
    ii. Global Trigger Tool for Measuring Adverse Events
        (a) Developed by the Institute for Healthcare Improvement (IHI): www.ihi.org/resources/pages/ihiwhitepapers/ihiglobaltriggertoolwhitepaper.aspx
        (b) Various versions have been developed: Danish, German, Swedish, United Kingdom
        (c) Use of "triggers" or clues to identify adverse events
            (1) Orders for certain drugs
            (2) Orders for antidotes such as naloxone or vitamin K
            (3) Laboratory values such as elevated serum drug concentrations
            (4) Abrupt medication stop orders
        (d) Method for measuring the overall level of harm in a health care organization
        (e) Triggers may be identified using computer programs designed for health information systems.
        (f) Almost real-time identification of potential adverse events provides an opportunity to reduce the effect on patients.
        (g) Includes retrospective detailed chart review of patient records to determine whether an adverse event actually occurred; recommends doing a sampling of patients
        (h) Not intended to identify every single adverse event in a patient record
        (i) According to one study, the use of the Global Trigger Tool for Measuring Adverse Drug Events increased the rate of adverse drug event detection about 50 times more than traditional reporting methods (Qual Saf Health Care 2003;12:194-200).
    iii. Examples of outcome measures
        (a) Adverse events per 1000 patient-days
        (b) Adverse events per 100 admissions or office visits
        (c) Percentage of admissions or office visits with an adverse event
    iv. Other available IHI trigger tools
        (a) Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting
        (b) Trigger Tool for Measuring Adverse Drug Events in the Nursing Home
        (c) Surgical Trigger Tool for Measuring Perioperative Adverse Events
        (d) Intensive Care Unit Adverse Event Trigger Tool
        (e) Pediatric Trigger Toolkit: Measuring Adverse Drug Events in the Children's Hospital
        (f) Perinatal Trigger Tool
        (g) Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit
        (h) Outpatient Adverse Event Trigger Tool

     v.   Text searching in electronic medical record notes to find key words indicative of adverse events

     vi.   Methods involving chart review can introduce variability among reviewers.

  f. Analysis of trends

     i.   A small percentage of errors that occur are voluntarily reported.

     ii.   Need to be careful about using voluntarily reported data as measures of improvement given that reporting rates may change because of factors such as work volume, culture of safety (i.e., fear of repercussions or blame), and reporting system functionality changes.

     iii.   If voluntary reports involving a certain medication error type decrease, it may be that employees are too busy to report or they are fearful of retaliation or "looking bad" for reporting problems.

     iv.   If voluntary reports of a certain medication error type increase, there is not necessarily a new problem; reports may increase because of an augmented focus by the organization or department on a particular error type or on safety reporting in general.

4. Error prevention and management

  a. Failure modes and effects analysis

     i.   Prospectively identifies the risk of error in a process to prevent harm

     ii.   Process mapping to identify all the steps in a process

     iii.   Identifies the ways each step can go wrong (i.e., the failure modes)

     iv.   Determines the probability that each error will be detected (i.e., so that it can be corrected before causing harm)

     v.   Estimates of the likelihood of a process failure, the chance of detecting such a failure, and its impact are combined numerically to produce a criticality index.

     vi.   The criticality index assists in prioritizing targets for improvement.

  b. Systematic assessment for error prevention

     i.   Monitor actual and potential medication errors and adverse events.

     ii.   Learn from errors that have occurred, and make continual improvements.

  c. Root cause analysis

     i.   Structured retrospective method used to analyze serious adverse events

     ii.   Identifies underlying problems that increase the likelihood of errors while avoiding focusing on mistakes made by individuals

     iii.   Goal of root cause analysis is to identify the following:

        (a) Active errors – Occur at the point of interface between people and systems

        (b) Latent errors – Hidden problems within health care systems that contribute to adverse events

     iv.   Keys to success

        (a) Quality of information reported

        (b) Analysis of available information

        (c) Subsequent actions taken to improve the system and prevent future patient harm

  d. Suggested readings

     i.   AHRQ PSNet glossary; www.psnet.ahrq.gov/glossary.aspx

     ii.   Failure Modes and Effects Analysis tool; www.ihi.org/resources/Pages/Tools/FailureModes andEffectsAnalysisTool.aspx

5. Examples of strategies to reduce/prevent medication errors

  a. Avoiding error-prone abbreviations; www.Ismp.org/tools/errorproneabbreviations.pdf

  b. Tall-man lettering

     i.   Look-alike, sound-alike drug names contribute to errors.

     ii.   Drug names can be modified using mixed-case letters to draw attention to the parts of the drug names that are dissimilar.

     iii.   Highlighting sections of drug names using tall man letters can make medication mix-ups less likely.

     iv.   Promoted by ISMP, FDA, The Joint Commission, and other safety-conscious organizations

     v.   Use supported by the literature

     vi. Examples of look-alike drug pairs and recommended tall-man lettering (www.ismp.org/tools/tallmanletters.pdf):

        (a) BusPIRone and buPROPion

        (b) ChlorproMAZINE and chlorproPAMIDE

        (c) glyBURIDE and glipiZIDE

c. High-alert medications in community/ambulatory health care; www.ismp.org/communityRx/tools/ambulatoryhighalert.asp

     i.   Drugs with an increased risk of harm if an error occurs

     ii. Does not imply errors involving these drugs are more common

     iii. Special safeguards may include the following:

        (a) Mandatory patient counseling

        (b) Improve access to information concerning the drugs.

        (c) Auxiliary labels and automated alerts

        (d) Independent double-checks

        (e) Standardizing the medication use process

     iv. High-alert drug classes and specific drugs

        (a) Antiretroviral agents

        (b) Oral chemotherapeutic agents (excluding hormonal agents)

        (c) Oral hypoglycemic agents

        (d) Immunosuppressant agents

        (e) Insulin

        (f) Opioids

        (g) Pediatric liquid medications that require measurement

        (h) Pregnancy category X drugs

        (i) carBAMazepine

        (j) Chloral hydrate liquid, for sedation of children

        (k) Unfractionated heparin and low-molecular-weight heparin

        (l) metFORMIN

        (m) Methotrexate, non-oncologic use

        (n) Midazolam liquid, for sedation of children

        (o) Propylthiouracil

        (p) Warfarin

d. Clinical decision support (CDS) tools in the electronic medical record and pharmacy system may reduce medication errors.

     i.   Designed to deliver knowledge and patient-specific information

     ii. Intended to improve the quality of health care

     iii. Include patient safety alerts and reminders (e.g., drug interaction, drug allergies, dose checking)

     iv. Alert fatigue may result when alerts are too common and excessive. This may lead to alerts being indiscriminately overridden, defeating their purpose.

     v.   If override rates are high, alerts need to be refined to improve their focus and relevance and reduce alert fatigue.

     vi. Rate of medication-related CDS alert overrides in the outpatient setting at the time of prescribing is 52.6% (J Am Med Inform Assoc 2014;21:487-91).

        (a) Most common alerts: Duplicate drug (33.1%), patient allergy (16.8%), drug-drug interactions (15.8%)

        (b) Alerts most likely to be overridden: Formulary substitutions (85.0%), age-based recommendations (79.0%), renal recommendations (78.0%), and patient allergies (77.4%)

        (c) On average, 53% of overrides are classified as appropriate.

6. Safety culture
    a. Safety culture is "the set of beliefs, norms, attitudes, roles, and social and technical practices that are concerned with minimizing the exposure of employees, managers, customers and members of the public to conditions considered dangerous or injurious" (Turner 1989).
    b. Properties of safety culture
        i. Leadership
        ii. Teamwork
        iii. Communication
        iv. Patient-centeredness
        v. Evidence based
        vi. Just culture
        vii. Learning and improvement
        viii. Reporting culture
    c. *Just culture* is "a culture of trust where people are encouraged for providing essential safety-related information, but in which they are also clear about where the line must be drawn between acceptable and unacceptable behavior" (Reason 1997).
        i. Promotes a questioning attitude
        ii. Resistant to complacency
        iii. Committed to excellence
        iv. Nurtures personal accountability
        v. Promotes corporate self-regulation in safety
    d. Tools to evaluate safety culture and practices
        i. ISMP Medication Safety Self-Assessment for Community/Ambulatory Pharmacy, Hospital, Medical Office, and Nursing Home
        ii. AHRQ Surveys on Patient Safety Culture
        iii. Safety Attitudes Questionnaire (SAQ)
7. FDA
    a. The FDA is an agency within the U.S. Department of Health and Human Services concerned with protecting the public health.

Table 4. Functions of the FDA

Regulates tobacco products	
Ensures the safety, effectiveness, and quality of the following:	
Human prescription and nonprescription drugs	Veterinary drugs
Vaccines, blood products, and biologics	Medical devices
Food	Cosmetics
Dietary supplements	Products that emit radiation

    b. Recalls are actions taken to remove a product from the market.
        i. May be initiated by the manufacturer, FDA request, or FDA order under statutory authority
        ii. How the FDA gains awareness of problems
            (a) Manufacturer contacts the FDA
            (b) Manufacturing facility inspections
            (c) Reporting systems
            (d) CDC

Table 5. Classification of FDA Drug Recalls or Market Withdrawal

Type	Description
Class I recall	Reasonable probability that exposure to product will cause serious adverse health consequences or death
Class II recall	When exposure to product may cause temporary or medically reversible adverse health consequences or when the probability of serious adverse health consequences is remote
Class III recall	Exposure to product is not likely to cause adverse health consequences
Unclassified recall	A pilot program expedites notices of drug recalls that are still in the process of being classified
Market withdrawal	Product has a minor violation that would not be subject to FDA legal action (e.g., product may be removed from the market because of tampering)

       iii. Finding recall information
          (a) When the public must be alerted to serious hazards, the FDA uses press conferences, press releases, and updates to www.fda.gov.
          (b) FDA Enforcement Reports include all recalls monitored by the FDA; www.fda.gov/Safety/Recalls/EnforcementReports/ucm181313.htm
          (c) Sign up to receive e-mail alerts.
          (d) Not all recalls are announced by the media.
    c. Medication guides
       i. The FDA determines which drugs/biologics pose a serious and significant public health concern.
       ii. Requires the distribution of FDA-approved patient medication information that is necessary to patients' safe and effective use of these drugs and biologics
       iii. May be a requirement of Risk Evaluation and Mitigation Strategies (REMS)
    d. REMS
       i. The Food and Drug Amendments Act of 2007 gave the FDA the authority to require REMS from manufacturers to ensure that the benefits of a drug/biologic outweigh the risks.
       ii. REMS may include the following:
          (a) Medication guides
          (b) Communication plan
          (c) Elements to ensure safe use, which may include the following:
             (1) Patient registry
             (2) Prescriber training, experience, or special certification
             (3) Patient monitoring
             (4) Dispensing to patients only in certain health care settings
             (5) Special certification for pharmacies, practitioners, or health care settings that dispense the drug
          (d) Implementation system
             (1) May be required by the FDA
             (2) Manufacturer may be expected to take steps to monitor, evaluate, and improve implementation by parties in the health care system responsible for implementing the REMS elements.

    e.   Drug safety communications
       i.   Early communication about an ongoing safety review
          (a) Communicates early with the public when still evaluating data and a conclusion has not been reached
          (b) Informs about issues under review and anticipated completion
      ii.   Information for Healthcare Professionals
          (a) Also known as Healthcare Professional Information Sheet
          (b) The alert summarizes new safety information.
             (1) Detailed information about the safety issue
             (2) Factors to consider when making a treatment decision
             (3) Information for health care professionals to discuss with patients about reducing the risks related to the drug
             (4) Summary of the facts or data
    f.   Medical device safety alerts are issued when a medical device may present an unreasonable risk of substantial harm; recalls can occur.
    g.   Boxed warnings emphasize significant and serious safety data for prescription drugs.
    h.   Drug shortages
       i.   Primary reasons for drug shortages
          (a) Quality/manufacturing issues
          (b) Manufacturer production and raw materials supplier delays
          (c) Discontinuations
      ii.   Manufacturers are required to report information about shortages on the FDA website that includes the following:
          (a) Reasons for shortages
          (b) Expected duration of shortages
     iii.   Early notification from manufacturers of any issue that could lead to a shortage is critical to preventing or mitigating drug shortages.
     iv.   The FDA Safety and Innovation Act of 2012 enhanced the FDA's authority regarding drug shortages.
          (a) Broadened the scope of early notification requirement by demanding that all manufacturers notify the FDA of potential discontinuances (prior law applied only to sole manufacturers)
          (b) Manufacturers are required to report discontinuations, regardless of whether they are permanent or temporary.
          (c) May require mandatory reporting of shortages of biologic products (prior law excluded biologics)
          (d) Notification requirement applies to drugs that are used in emergency medical care or during surgery if intended for use in preventing a debilitating condition.
          (e) The FDA issues noncompliance letters to manufacturers who fail to comply with the drug shortage notification requirements and makes the letter and the company's response to the letter available to the public.
     v.   Current and Resolved Drug Shortages and Discontinuations Reported to FDA Database; www.accessdata.fda.gov/scripts/drugshortages/default.cfm
     vi.   Goals of Strategic Plan for Preventing and Mitigating Drug Shortages; www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf
          (a) Strengthen mitigation response
          (b) Develop long-term prevention strategies

     i. Compounding
         i. Title I of the Drug Quality and Security Act, the Compounding Quality Act, removes some provisions from section 503A of the federal Food, Drug, and Cosmetic Act (FDCA)
         ii. Under 503B, a new section of the FDCA, a compounder can become an "outsourcing facility."
         iii. Outsourcing facilities
            (a) Must comply with current good manufacturing practice requirements
            (b) Will be able to qualify for exemptions from the following:
                (1) FDA approval requirements
                (2) Requirement to label products with adequate directions for use
            (c) Will be inspected by the FDA according to a risk-based schedule
            (d) Must report adverse events
             (e) Provide FDA with information about the products they compound
                (1) List of all products compounded during the previous 6 months
                (2) Source of ingredients used to compound
         iv. State boards of pharmacy have overseen and regulated traditional pharmacy compounding.

8. Agency for Healthcare Research and Quality (AHRQ)
    a. Lead federal agency for patient safety research
    b. Offers several patient safety tools and resources; www.ahrq.gov/professionals/quality-patient-safety/index.html. Surveys on patient safety culture:
        i. Hospital
        ii. Medical office
        iii. Nursing home
        iv. Pharmacy
        v. Comparative databases exist for all surveys, except for the pharmacy survey because it is relatively new.
    c. Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS)
        i. Set of tools to train clinicians in teamwork and communication skills
        ii. Reduces patient safety risks
    d. Patient Safety Network is a web-based source for news and resources on patient safety.
    e. Pharmacy Health Literacy Center; www.ahrq.gov/professionals/quality-patient-safety/pharmhealthlit/index.html
        i. Health literacy educational resource for pharmacy personnel
        ii. Assessment tool to evaluate how prepared pharmacies are to care for patients with limited health literacy

9. Patient safety organizations
    a. Authorized by the Patient Safety and Quality Improvement Act of 2005 to improve the safety and quality of health care delivery in the United States
    b. Congress vested authority with AHRQ for implementing the Patient Safety Act.
    c. Patient safety organizations must meet the criteria established in the Patient Safety Rule.
    d. Goals
        i. Encourage health care providers and organizations to voluntarily report safety events without fear of legal discovery
        ii. Provide secure environment to identify and reduce risks
        iii. Aggregate and analyze patient safety events locally, regionally, and nationally
        iv. Gain insights into causes of patient safety events

10. The Institute for Safe Medication Practices (ISMP) is a nonprofit organization dedicated to medication error prevention and safe medication use.
    a. Educational programs on medication safety topics
    b. Safety self-assessments for organizations

    c. Tools and resources
       i. Newsletters: *ISMP Medication Safety Alert!;* https://www.ismp.org/newsletters/
          (a) Community/ambulatory care edition
          (b) Acute care edition
       ii. Guidelines and recommendations
       iii. Can submit medication error reports through ISMP
       iv. Certified as a patient safety organization

11. National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)
    a. Founded by the U.S. Pharmacopeial (USP) Convention in 1995
    b. Twenty-seven national organization members
    c. Promotes reporting, discussion, and communication about safe medication use, medication errors, error-prone processes, and error prevention strategies
    d. Strategies: Medication error reporting, understanding, and prevention
    e. Established a standard taxonomy of medication errors based on the level of harm
    f. Harm is impairment of the physical, emotional, or psychological function or structure of the body and/or pain.

Table 6. Categorizing Medication Errors

Category	Description
A	Circumstances or events that have the capacity to cause error
B	An error occurred, but the error did not reach the patient (an "error of omission" does reach the patient)
C	An error occurred that reached the patient but did not cause patient harm
D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
G	An error occurred that may have contributed to or resulted in permanent patient harm
H	An error occurred that required intervention necessary to sustain life
I	An error occurred that may have contributed to or resulted in the patient's death

Adapted from: National Coordinating Council for Medication Error Reporting and Prevention. 2001. NCC MERP Index for Categorizing Medication Errors. Available at http://www.nccmerp.org/sites/default/files/indexBW2001-06-12.pdf. Accessed November 11, 2016.

12. Other organizations that improve patient safety
    a. Centers for Medicare & Medicaid Services (CMS)
       i. Hospital Readmissions Reduction Program – Provides incentives for hospitals to decrease unnecessary hospital readmissions (within 30 days of a discharge)
       ii. Medicare Star Rating System includes quality, safety, and satisfaction measures for Medicare Part C and Part D plans.
       iii. Overutilization Monitoring System
          (a) Ensures that Part D sponsors have established reasonable and appropriate drug use management programs to prevent overuse of opioid drugs and acetaminophen-containing prescribed medications
          (b) Quarterly reports provided to Part D sponsors identifying beneficiaries with potential overuse issues identified through Medicare Part D Prescription Drug Event data

(c) Plans are expected to do the following:
  (1) Develop target criteria to identify beneficiaries who should receive case management
  (2) Investigate beneficiaries' potential overuse issues
  (3) Submit and track responses to CMS regarding overuse issues
  (4) Monitor progress in reviewing and addressing overuse issues over time

iv. Performance and quality measures are used by CMS so that Medicare beneficiaries have the information necessary to make informed enrollment decisions by comparing available health and prescription drug plans. They also provide measures of quality across Part D sponsors.
  (a) CMS calculates and publicizes eight other patient safety measures.
  (b) Monthly reports calculated using Medicare Part D Prescription Drug Event data provided to Part D plans
  (c) Measures allow prescription drug plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDs) to compare performance with overall averages and monitor progress over time.

Table 7. CMS Patient Safety Reports

Measure	Description
High-risk medication[a]	The percentage of Medicare beneficiaries 65 years and older who received two or more fills of at least one drug with a high risk of serious adverse effects in the older adult
Diabetes treatment[a]	The percentage of Medicare Part D beneficiaries 18 years and older dispensed a medication for diabetes and for hypertension whose treatment included an RAS antagonist medication (angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, or direct renin inhibitors)
Drug-drug interaction[b]	The percentage of Medicare Part D beneficiaries who received a prescription for a target medication during the measurement period and who were dispensed a prescription for a contraindicated medication with or after the initial prescription
Diabetes medication dosage[b]	The percentage of Medicare Part D beneficiaries who were dispensed a dose higher than the daily recommended dose for the following diabetes treatment therapeutic categories of oral hypoglycemic: biguanides, sulfonylureas, thiazolidinediones, and dipeptidyl peptidase–IV inhibitors
Diabetes medications[a]	The percentage of Medicare Part D beneficiaries 18 years and older who adhere to their prescribed biguanides, sulfonylureas, thiazolidinediones, dipeptidyl peptidase–IV inhibitors, incretin mimetics, meglitinides, and sodium glucose cotransporter 2 inhibitors
Hypertension[a]	The percentage of Medicare Part D beneficiaries 18 years and older who adhere to their prescribed RAS antagonist medications (angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, or direct renin inhibitors)
Cholesterol[a]	The percentage of Medicare Part D beneficiaries 18 years and older who adhere to their prescribed statin medications
HIV/AIDS	The percentage of Medicare Part D beneficiaries 18 years and older who adhere to their prescribed antiretroviral medications

[a]Measure contributes to a plan's Part D star rating; available at the Medicare Plan Finder at www.medicare.gov.

[b]Part of the Part D Display Measures. Available at www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.

IV = intravenous; RAS = renin-angiotensin system.

Adapted from: (1) Acumen, LLC. Patient Safety Analysis: High Risk Medication Measures PDP/MA-PD Contracts Report User Guide. April 2014; (2) Acumen, LLC. Patient Safety Analysis: Diabetes Treatment Measures PDP/MA-PD Contracts Report User Guide. July 2014; (3) Acumen, LLC. Patient Safety Analysis: Drug-Drug Interaction Measures PDP/MA-PD Contracts Report User Guide. April 2014; (4) Acumen, LLC. Patient Safety Analysis: Diabetes Medication Dosing Measures PDP/MA-PD Contracts Report User Guide. April 2014.

    b.   Hospital accrediting organizations
        i.   TJC National Patient Safety Goals include medication reconciliation standards for several settings (e.g., hospitals, ambulatory care, home care, long-term care).
        ii.   Healthcare Facilities Accreditation Program
        iii.   Det Norske Veritas Healthcare, Inc.
    c.   NCQA
        i.   Managed care organization accrediting body
        ii.   Healthcare Effectiveness Data and Information Set is the quality, safety, and service measurement data set used to measure performance.
    d.   National Patient Safety Foundation (NPSF) pursues improvement of the safety of care provided to patients.
    e.   National Quality Forum (NQF) reviews, endorses, and recommends use of standardized health care performance measures.
    f.   Pharmacy Quality Alliance (PQA) promotes appropriate medication use and develops strategies for measuring and reporting performance.

Patient Cases

12. You are a clinical pharmacist in the community setting. Which resource would best prevent adverse drug events from occurring in your patient population?

    A.   Monitor the FDA safety communications to identify safety concerns, and collaborate with community physicians to ensure appropriate prescribing.
    B.   Submit error reports through the ISMP website.
    C.   Sign up to receive recall notices from the FDA, and establish a standardized response to class III recalls.
    D.   Use a standard taxonomy of medication errors based on the level of harm within your pharmacy's confidential reporting system.

13. You are a clinical pharmacist who provides CMM in a primary care clinic that uses an electronic medical record. You would like to determine the most common medication errors in your practice setting and design an intervention to reduce those errors. Which would best measure the success of your intervention?

    A.   Track voluntarily reported medication errors.
    B.   Monitor the use of diagnosis codes signifying preventable adverse drug events.
    C.   Use a trigger tool to measure medication errors per 100 office visits.
    D.   Survey patients on the adverse effects they experience.

  B.   Formulary Management and Pharmacy and Therapeutics Committees
    1.   Formulary management is defined by the Academy of Managed Care Pharmacy as "an integrated patient care process which enables physicians, pharmacists and other health care professionals to work together to promote clinically sound, cost-effective medication therapy and positive therapeutic outcomes."
    2.   Pharmacy and therapeutics (P&T) committees
        a.   Usually oversee all aspects of drug therapy in an institution or organization
        b.   Pharmacists and physicians collaborate.
        c.   Influence cost-effective prescribing, and affect clinical outcomes
        d.   Adverse drug reaction and medication error monitoring
        e.   Quality assurance
        f.   Policy and procedure approval
        g.   Traditionally associated with institutional pharmacy

    h.   Other organizations have P&T committees.
- i.   Managed care organizations
- ii.   Insurance companies
- iii.   Pharmacy benefit management companies
- iv.   Unions and employers
- v.   State Medicaid boards
- vi.   State departments of public institutions
- vii.   Medicare
- viii.   Long-term care facilities
- ix.   Ambulatory clinics
- x.   Community pharmacies

3.   Drug formularies

    a.   Formulary committees deal strictly with determining which drugs are carried within an institution or organization.

    b.   A drug formulary can guide prescribing.
- i.   Safest
- ii.   Most effective agents for treating a particular medical problem
- iii.   Most reasonable cost

    c.   A drug formulary contains a list of drugs that are available under that formulary system.
- i.   Also called preferred medication lists or preferred drug lists
- ii.   A drug formulary is published as a hardcopy book, in electronic format, or both.
- iii.   Reflects the clinical judgment of the medical staff
- iv.   Listed alphabetically and/or by therapeutic class (usually American Hospital Formulary Service classification)
- v.   Contains information on the dosage forms, strengths, names (e.g., generic, trade, and chemical), and ingredients
- vi.   May include indications, adverse effects, dosing, use restrictions

    d.   Evaluating drugs for inclusion
- i.   Safety
- ii.   Efficaciousness
- iii.   Cost-effectiveness
- iv.   Other considerations
  - (a)   Variety of dosage forms available for the medication
  - (b)   Estimated volume of use
  - (c)   Convenience
  - (d)   Dosing schedule
  - (e)   Adherence
  - (f)   Abuse potential
  - (g)   Physician demand
  - (h)   Ease of preparation
  - (i)   Storage requirements

    e.   Usually, only two or three drugs from any class are added to avoid therapeutic redundancy.

    f.   Including only one agent per class is probably too restrictive to accommodate intolerances and responsiveness to medications.

    g.   Drugs or drug classes must be objectively assessed according to scientific information, preferably from clinical studies.

     h. If objective data are lacking, a committee may make a decision and schedule a product for a follow-up review.
- i. Additional prescribing and patient use data may be available.
- ii. Clinical trial data may be available.

4. Conflict of interest
   a. Decision-makers for a drug's formulary status may have a conflict of interest by receiving direct or indirect compensation from including a drug on the formulary.
      i. Stock in a company
      ii. Honoraria for speaking
      iii. Consulting fees
      iv. Gifts or grants from a company
   b. P&T committees are responsible for identifying and addressing conflict-of-interest issues in the decision-making process.
   c. Ways to avoid bias
      i. Conflict-of-interest policy, requiring regular disclosure of any possible conflicts
      ii. Regular voting P&T committee members may have to abstain from the vote if they disclose a possible conflict of interest.
      iii. Committee may vote to decide whether a conflict is significant enough to prevent voting by the individual.

5. Ambulatory drug formulary copayment structures
   a. Pharmacy benefit managers, together with their health plan clients, place formulary and nonformulary medications into tiers.
   b. Encourage the use of the most clinically appropriate, cost-effective drug while maintaining quality of care
   c. The tier copayment structure developed in response to the rising drug costs
      i. Tier 1
         (a) Usually generic drug products
         (b) Lowest copayment
      ii. Tier 2
         (a) Preferred brand-name drugs
         (b) Higher copayment because of the added cost of the brand-name drug
      iii. Tier 3
         (a) Usually reserved for nonpreferred brand-name drugs
         (b) Copayment is significantly higher.
         (c) Copayments may be calculated as a proportion of the drug cost or require paying for the entire drug cost.
      iv. Specialty tier
         (a) Highest copayment or coinsurance
         (b) Specific, very high-cost prescription drugs

6. Other formulary management activities
   a. Used to ensure that certain drugs are used correctly and only when medically necessary
   b. Prior authorizations
      i. Before the drug will be covered by a plan, the prescriber must contact the plan to show the medical necessity for that particular drug.

      ii.   Step therapy is a type of prior authorization in which patients must first try and fail less expensive drugs before a certain medication will be covered.

         (a)   Less expensive alternative was not effective.

         (b)   Less expensive alternative was not tolerated because of adverse effects.

   c.   Quantity limitations may be instituted for safety and cost reasons.

      i.   Appropriate therapy duration for an indication may be proved.

      ii.   Longer treatment courses may not be more effective or may pose more risk than benefit.

   d.   Generic substitutions can be required when a drug entity is available as an approved generic.

   e.   An exception can be requested if a prescriber believes a patient has a medical necessity to be treated with a medication that is not on the formulary.

      i.   Exceptions may be requested under several circumstances.

         (a)   Prescriber believes a patient requires a drug that is not on the formulary.

         (b)   Prescriber believes a coverage rule (such as step therapy) should be waived.

         (c)   Patient believes the copayment for a nonpreferred drug should be lower because the preferred formulary drugs are not effective or tolerated.

      ii.   Prescriber must provide a supporting statement that explains the medical reason for the request, including why a covered medication is not appropriate for the patient.

7.   Preventive medications and services covered by private health plans under the Affordable Care Act

   a.   Non-grandfathered group health plans and health insurance coverage offered in the individual or group market are required to cover preventive services without patient cost sharing (e.g., copayment, coinsurance), even if the annual deductible has not been met.

   b.   In general, these services must be delivered by a network provider to be covered.

   c.   These requirements do not apply to grandfathered health plans.

   d.   Covered preventive services are based on the following:

      i.   Evidence-based items or services that have a rating of "A" or "B" in the current recommendations of the U.S. Preventive Services Task Force (USPSTF)

      ii.   Recommendations from the Advisory Committee on Immunization Practices (ACIP) of the CDC in children, adolescents, and adults

      iii.   Evidence-informed preventive care and screenings included in the guidelines supported by HRSA for infants, children, adolescents, and women (if not already included in the current recommendations of the USPSTF)

      iv.   www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/

   e.   Immunization vaccines for adults and children can be found at www.healthcare.gov/coverage/preventive-care-benefits/.

Patient Case

14. Which scenario represents the most appropriate application of formulary management activities?

   A. A physician successfully justifies a formulary exception for oxycodone controlled release with the statement, "Patient prefers oxycodone controlled release because she has always tolerated it."

   B. A drug plan implements a quantity limit on hydrocodone 5 mg/acetaminophen 325 mg tablets in an effort to prevent patients from taking more than 4 g of acetaminophen per day.

   C. A physician submits a step therapy prior authorization for a brand-name long-acting oral narcotic to treat a patient's diabetic neuropathic pain because the physician believes it will work better than the covered options on the patient's formulary.

   D. The P&T committee includes only one drug per therapeutic class to contain costs.

C.   Medicare Part D
  1.   Medicare options
     a.   Part A – Hospital insurance
     b.   Part B – Medical insurance
     c.   Original Medicare – Fee-for-service coverage under which the government pays health care providers directly for Part A benefits, Part B benefits, or both
     d.   Part C – Medicare Advantage Plan
        i.   Medicare Advantage Plans with prescription drug coverage (MA-PDs) include Part A, B, and D coverage.
        ii.   Similar to preferred provider organization or health maintenance organization plans
        iii.   In 2016, of 57 million people receiving Medicare, most were enrolled in a traditional Medicare Part D Plan; 31% of them were enrolled in MA-PDs.
        iv.   Special Needs Plans are a type of Medicare Advantage Plan restricted to beneficiaries who meet one of the following criteria:
           (a)   Are dually eligible for Medicare and Medicaid
           (b)   Live in long-term care institutions (or would otherwise require an institutional level of care)
           (c)   Have certain chronic conditions
     e.   Part D – Medicare Prescription Drug Plan
        i.   Created by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003
        ii.   Adds drug coverage to Original Medicare
        iii.   Stand-alone prescription drug coverage (not linked to Parts A and B)
        iv.   Available to anyone enrolled in Part A or Part B
        v.   Joining a Medicare drug plan
           (a)   Enroll on the Medicare Plan Finder website (www.medicare.gov/find-a-plan/questions/home.aspx) or on the plan's website.
           (b)   Paper enrollment form
           (c)   Telephone – Call the plan.
           (d)   Telephone – Call 1-800-MEDICARE.
        vi.   If a patient is enrolled in a Medicare Advantage Plan (Part C) that includes prescription drug coverage and the patient joins a Medicare Prescription Drug Plan (Part D), the patient will be disenrolled from the Medicare Advantage Plan and returned to Original Medicare.
        vii.   Beneficiaries who do not have other creditable coverage for prescription drugs must sign up for Part D coverage within 7 months of when they are first eligible, or they are required to pay late-enrollment penalties.
        viii. Most beneficiaries have the opportunity to change plans once per year during an open enrollment period.
        ix.   2017 will have the lowest number of prescription drug plans available since Part D started in 2006.
  2.   Part D plan benefits and premiums
     a.   General concepts
        i.   A deductible is the dollar amount during the benefit period that an insured person pays before the insurer starts to make payments for covered medical services.
           (a)   For several prescriptions, the deductible will be calculated in the order the prescriptions are dispensed.
           (b)   The patient meets the deductible first.

(c) If there is a remaining balance on a prescription during the transaction in which the deductible is met, patients pay the lesser of either their copayment or the remainder of the drug's cost.

(d) For future refills, the patient pays the lesser of either the copayment or the drug's cost.

Box 3. Example Pharmacy Deductible Scenario

Pharmacy benefit: Deductible $400, $15 generic drug copayment, $30 brand-drug copayment
Patient has four prescriptions to fill:
Brand drug A costs $450
Brand drug B costs $100
Generic drug C costs $40
Generic drug D costs $35
Total drug costs for four prescriptions: $425

Patient's actual spending:
For brand drug A, the patient pays $400 toward the deductible (deductible met) plus $30 for brand copayment, which is less than the drug cost remainder
Brand drug B costs $100: Patient pays $30
Generic drug C costs $40: Patient pays $15
Generic drug D costs $35: Patient pays $15
Total paid by patient for four prescriptions: $490

Thereafter, the patient pays copayments

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ii. TrOOP costs count toward Medicare drug plan out-of-pocket expenses, and these costs determine when catastrophic coverage will begin.

iii. A coverage gap (also known as the "donut hole") exists between the initial coverage limit and the level of spending at which the TrOOP threshold is met.

(a) Under the Affordable Care Act, the standard Part D benefit now includes some level of coverage in the coverage gap.

(b) Before 2011, there was no benefit in the coverage gap.

(c) When the TrOOP threshold is met, catastrophic coverage begins.

(d) The coverage gap will gradually be phased out by 2020.

b. Standard benefits for Medicare Part D

Table 8. Standard Benefit Variables for Medicare Part D in 2017

Variable	Amount
Deductible	$400
Initial coverage limit (25% coinsurance)	$3700
TrOOP threshold	$4950
Minimum copayment under catastrophic portion of benefit	
Generic/preferred drug	$3.30
All other drugs	$8.25

TrOOP = true out-of-pocket.

Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf. Accessed October 12, 2016.

Box 4. Payments That Count Toward TrOOP Costs

Amount paid for covered prescriptions before the plan begins to pay (annual deductible)
Amount paid for covered prescriptions after the drug plan begins to pay (copayments or coinsurance during initial coverage period)
Payments made for covered prescriptions in the coverage gap if made by the patient, family/friends, qualified state pharmacy assistance programs, Medicare's Extra Help, Indian Health Service, most charities, drug manufacturers providing discounts under the Medicare coverage gap discount program, and AIDS Drug Assistance Programs

Box 5. Payments That Do Not Count Toward TrOOP Costs

Amount paid by a Medicare drug plan
Monthly plan premium
Drugs purchased outside the United States
Drugs not covered
Drugs excluded from the definition of a Part D drug (even if covered by a supplemental benefit, such as drugs for hair growth)
Over-the-counter drugs and vitamins; regardless, if required by plan as part of step therapy
Payments made or reimbursed by a third party (i.e. government-funded health programs, group health plans)

    c. Coverage gap
       i. In 2016, there will be a 42% plan benefit (58% enrollee-paid coinsurance) for generic drugs and a 5% plan benefit (45% enrollee-paid coinsurance and 50% discount provided by the manufacturer) for brand-name drugs in the coverage gap.
          (a) Manufacturers' signed agreements with Medicare to participate in the Medicare coverage gap discount program
          (b) Drug manufacturers' 50% discounts under the Medicare coverage gap discount program count toward TrOOP costs.

Box 6. Example Calculation of TrOOP Cost Contribution in Coverage Gap

Brand-name drug cost = $150 Average dispensing fee = $12 Subtract dispensing fee from the drug plan's cost = $138 The manufacturer brand discount is 50% of $138 = $69 The patient pays 45% of $138 = $62.10 The patient also pays 45% of the $12 dispensing fee = $5.40 $62.10 + $5.40 = $67.50, the patient's coverage gap brand cost sharing (also 45% of $150) The patient's coverage gap brand cost sharing ($67.50) is added to the manufacturer's brand discount ($69) for a total of $136.50, which is the value that counts toward the patient's annual TrOOP expenses The remainder of the brand-name drug costs and dispensing fee is $13.50, which is paid by the Part D plan and does not count toward TrOOP costs

   ii. Some plans offer additional coverage during the coverage gap.
    (a) Most prescription drug plans will not offer additional gap coverage beyond what is required under the standard benefit.
    (b) Plans with additional gap coverage may charge a higher monthly premium.
    (c) Additional gap coverage is usually limited to generic drugs.

3. Medicare Health Plan Quality and Performance Ratings, commonly called "star ratings"
  a. Educational tool for Medicare beneficiaries
  b. Metric that has a substantial effect on Medicare Advantage and prescription drug plan sponsor reimbursement
  c. Five-star–rated plans can enroll beneficiaries throughout the year, an advantage over non–five-star plans.

4. Formulary considerations
  a. CMS reviews and approves Part D formularies and oversees P&T committee processes.
   i. Best-practice formularies include at least one drug in each of the USP Convention Formulary Key Drug Types at a minimum.
   ii. Plans may present a reasonable clinical justification for formularies that do not contain at least one drug for each Formulary Key Drug Type.
   iii. Part D formularies must contain all or substantially all antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants, and antineoplastics.
    (a) Rationale for protected drug classes in Part D formulary requirements
     (1) To ensure that Medicare beneficiaries reliant on these drugs will not be substantially discouraged from enrolling in certain Part D plans
     (2) To mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations
    (b) CMS is considering removal of antidepressants, immunosuppressants, and antipsychotics from the list of protected classes (www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html).
    (c) Consensus panel criteria for protected class – All must be met.
     (1) Criticality: A delay in access (7 days) to a drug will likely result in hospitalization, or persistent or significant disability or incapacity, or death.
     (2) Non-interchangeability: Access to all drugs in such a category or class is necessary because differences among individual drugs in the category or class specifically determine individual drug therapy.
     (3) Access to such drugs in the class is not adequately protected by existing formulary protections (i.e., at least one drug for each USP Formulary Key Drug Type is on the formulary).
    (d) Antidepressants did not meet the criticality or non-interchangeability criteria.
    (e) Current beneficiary protections were deemed appropriate for immunosuppressants. The panel recommends using several immunosuppressive medications from specific classes.
    (f) Antipsychotics did not meet the non-interchangeability condition.
  b. CMS reviews use management tools to make sure beneficiaries have access to appropriate drugs in a timely manner.
  c. CMS reviews plans' drug use review procedures and appeals, exceptions, and grievance processes.
  d. Review of new chemical entities
   i. P&T committees should review a new chemical entity within 90 days.
   ii. Decision within 180 days of release onto the market

iii. Clinical justification should be provided if time interval is not met.

iv. Same time intervals apply to the review of products with newly approved FDA indications.

v. Plans must make access to new drugs available to enrollees when medically appropriate through exceptions processes even before these deadlines.

5. Products that are covered under Part B as a basic benefit

a. Do not apply toward the Part D TrOOP cost or total drug spending

b. Patient pays either the applicable prescription copayment or a 20% coinsurance.

c. Part B–covered drugs are usually administered in a medical clinic or hospital outpatient setting.

d. Examples of drugs covered by Part B

i. Self-administered oral chemotherapy

ii. Immunosuppressive drugs after organ transplants that are Medicare approved

iii. Medication used with durable medical equipment in the home, such as in a nebulizer

iv. Intravenous drugs that require a pump for administration

v. Antiemetic drugs for up to 48 hours after the administration of chemotherapy

(a) If being used as a full therapeutic replacement for intravenous antiemetic drugs within 48 hours of chemotherapy

(b) If a patient requires antiemetic drug therapy past the 48-hour supply, a separate prescription is processed as Part D.

vi. Blood-clotting factor for hemophilia

vii. Injectable osteoporosis drugs for homebound patients who have a bone fracture related to postmenopausal osteoporosis

viii. Intravenous immunoglobulin provided in the home for patients with a diagnosis of primary immunodeficiency disease

ix. Parenteral and enteral nutrition

x. Erythropoiesis-stimulating agents for patients with a diagnosis of end-stage renal disease and receiving home dialysis

xi. End-stage renal disease medications used to treat the following conditions (and the patient is undergoing dialysis):

(a) Fluid excess/overload secondary to dialysis

(b) Restless legs syndrome secondary to dialysis

(c) Itching secondary to dialysis

(d) Infection associated with dialysis

(e) Nausea or vomiting caused by dialysis

(f) Pain medication overdose in dialysis

xii. Select vaccines, as stated earlier in this chapter

REFERENCES

Scopes of Practice

1. Council on Credentialing in Pharmacy; Albanese NP, Rouse MJ. Scope of contemporary pharmacy practice: roles, responsibilities, and functions of pharmacists and pharmacy technicians. J Am Pharm Assoc 2010;50:e35-69.

2. Maine LL, Knapp KK, Scheckelhoff DJ. Pharmacists and technicians can enhance patient care even more once national policies, practices and priorities are aligned. Health Aff 2013;32:1956-62.

3. NABP Boards of Pharmacy. Available at www. nabp.net/boards-of-pharmacy/. Accessed October 12, 2016.

4. National Association of Boards of Pharmacy. Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. 2016;e1-206. Available at https://nabp.pharmacy/ publications-reports/resource-documents/model-pharmacy-act-rules/. Accessed October 12, 2016.

Pharmaceutical Care

1. ASHP Statement on Pharmaceutical Care. Available at www.ashp.org/doclibrary/bestpractices/orgst pharmcare.aspx. Accessed October 12, 2016.

2. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm 1990;47:533-43.

3. Principles of Practice of Pharmaceutical Care. Available at www.pharmacist.com/principles-practice-pharmaceutical-care. Accessed October 12, 2016.

Medication Therapy Management

1. American Pharmacists Association (APhA). Medication Therapy Management Digest: Perspectives on 2009: A Year of Changing Opportunities. Available at www.pharmacist.com/ sites/default/files/files/mtm_2010_digest_2.pdf. Accessed October 12, 2016.

2. American Pharmacists Association (APhA). Medication Therapy Management Digest: Tracking the Expansion of MTM in 2010: Exploring the Consumer Perspective. Available at www.pharma-cist.com/sites/default/files/files/mtm_2011_digest. pdf. Accessed October 12, 2016.

3. American Pharmacists Association and National Association of Chain Drug Stores Foundation. Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model, Version 2.0. Available at www.pharmacist. com/sites/default/files/files/core_elements_of_an_ mtm_practice.pdf. Accessed October 12, 2016.

4. Bluml BM. Definition of medication therapy management: development of professionwide consensus. J Am Pharm Assoc 2005;45:566-72.

5. Centers for Medicare & Medicaid Services (CMS). CY 2017 Medication Therapy Management Program Guidance and Submission Instructions. Available at www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/ Downloads/Memo-Contract-Year-2017-Medication-Therapy-Management-MTM-Program-Submission-v-040716.pdf. Accessed June 27, 2016.

6. Ludvigson N. Medication Therapy Management Contribution to Improved Outcomes and Cost Savings in Health Care. Available at www. drugstorenews.com/article/medication-therapy-management-contribution-improved-outcomes-and-cost-savings-health-care. Accessed October 12, 2016.

7. Pellegrino AN, Martin MT, Tilton JJ, et al. Medication therapy management services: definitions and outcomes. Drugs 2009;69:393-406.

8. Ramalho de Oliveira D, Brummel AR, Miller D, et al. Medication therapy management: 10 years of experience in a large integrated health care system. J Manag Care Pharm 2010;16:185-95.

Comprehensive Medication Management

1. Integrating Comprehensive Medication Management to Optimize Patient Outcomes. PCPCC Resource Guide, 2nd ed. June 2012. Available at www.pcpcc. org/sites/default/files/media/medmanagement.pdf. Accessed June 7, 2016.

2. McBane SE, Dopp AL, Abe A, et al. ACCP white paper: collaborative drug therapy management and comprehensive medication management— 2015. Pharmacotherapy. 2015;35:e39-50. Available at www.accp.com/docs/positions/whitePapers/ CDTM%20CMM%202015%20Final.pdf. Accessed June 7, 2016.

3. McInnis TA, Webb CE. Comprehensive Medication Management in the Patient-Centered Medical Home – Is It Critical for Success? Medical Home News. April 2010.

4. Patient-Centered Medical Home Medication Management Tool Box. Available at www.impactedu. net/pcmh/pdf/Patient-Centered%20Medical%20 Home%20Medication%20Management%20 Toolbox.pdf. Accessed October 12, 2016.

5. Rosenthal TC. The medical home: growing evidence to support a new approach to primary care. J Am Board Fam Med 2008;21:427-40.

Collaborative Drug Therapy Management

1. Collaborative Drug Therapy Management: A Coordinated Approach to Patient Care. Alliance for Pharmaceutical Care. Available at test3-www.ashp. org/DocLibrary/Affiliates/CDTM.aspx. Accessed October 18, 2016.

2. Hammond RW, Schwartz AH, Campbell MJ, et al. Collaborative drug therapy management by pharmacists—2003. Pharmacotherapy 2003;23:1210-25.

3. Kuo GM, Buckley TE, Fitzsimmons DS, et al. Collaborative drug therapy management services and reimbursement in a family medicine clinic. Am J Health Syst Pharm 2004;61:343-54.

4. McBane SE, Dopp AL, Abe A, et al. ACCP white paper: collaborative drug therapy management and comprehensive medication management— 2015. Pharmacotherapy. 2015;35:e39-50. Available at www.accp.com/docs/positions/whitePapers/ CDTM%20CMM%202015%20Final.pdf. Accessed June 7, 2016.

5. National Association of Boards of Pharmacy. Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. 2016;e1-206. Available at https://nabp.pharmacy/ publications-reports/resource-documents/model- pharmacy-act-rules/. Accessed October 12, 2016.

6. Practice Advisory on Collaborative Drug Therapy Management. Academy of Managed Care Pharmacy. February 2012. Available at http://amcp. org/WorkArea/DownloadAsset.aspx?id=14710. Accessed October 12, 2016.

Credentialing and Privileging

1. Blair MM, Carmichael J, Young E, et al. Pharmacist privileging in a health system: report of the qualified provider model ad hoc committee. Am J Health Syst Pharm 2007;64:2373-81.

2. Council on Credentialing in Pharmacy. Credentialing and Privileging of Pharmacists: A Resource Paper from the Council on Credentialing in Pharmacy. Am J Health Syst Pharm 2014;71:1891-1900.

3. Council on Credentialing in Pharmacy (CCP). Guiding Principles for Post-licensure Credentialing of Pharmacists. Available at www.pharmacycredentialing.org/Files/Guiding PrinciplesPharmacistCredentialing.pdf. Accessed October 18, 2016.

4. Galt KA. Credentialing and privileging for pharmacists. Am J Health Syst Pharm 2004;61:661-70.

Pharmacists' Patient Care Process

1. Joint Commission of Pharmacy Practitioners. The Pharmacists' Patient Care Process. Available at http://jcpp.net/patient-care-process/. Accessed October 12, 2016.

Transitions of Care

1. Agency for Healthcare Research and Quality (AHRQ). National Quality Measures Clearinghouse. October 2015. Available at www.qualitymeasures. ahrq.gov/summaries/summary/49742. Accessed October 12, 2016.

2. Physician Consortium for Performance Improvement (PCPI). PCPI-Stewarded Measures. Available at http://www.thepcpi.org/programs-initiatives/ measurement-science/measure-directory/pcpi- stewarded-measures/. Accessed November 11, 2016.

3. American Society of Health-System Pharmacists and American Pharmacists Association. ASHP- APhA Medication Management in Care Transitions Initiative Best Practices. Available at http:// media.pharmacist.com/practice/ASHP_APhA_ MedicationManagementinCareTransitionsBest PracticesReport2_2013.pdf. Accessed October 12, 2016.

4. Boult C, Leff B, Boyd CM, et al. A matched-pair cluster-randomized trial of guided care for high-risk older patients. J Gen Intern Med 2013;28:612-21.

5. Boult C, Reider L, Leff B, et al. The effect of guided care teams on the use of health services: results from a cluster-randomized controlled trial. Arch Intern Med 2011;171:460-6.

6. Boyd CM, Reider L, Frey K, et al. The effects of guided care on the perceived quality of health care for multi-morbid older persons: 18-month outcomes from a cluster-randomized controlled trial. J Gen Intern Med 2010;25:235-42.

7. Care Transitions Measure (CTM) Specifications. Available at http://caretransitions.org/wp-content/uploads/2015/08/CTM3Specs0807.pdf. Accessed October 12, 2016.

8. Centers for Medicare & Medicaid Services (CMS). Evaluation and Management Services guide. Available at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf. Accessed October 12, 2016.

9. Centers for Medicare & Medicaid Services (CMS). April 18, 2016. Readmissions Reduction Program. Available at www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html. Accessed October 12, 2016.

10. Centers for Medicare & Medicaid Services (CMS). Transitional Care Management Services. Available at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Transitional-Care-Management-Services-Fact-Sheet-ICN908628.pdf. Accessed October 12, 2016.

11. Clark K, Doyle J, Duco S, et al. Hot Topics in Health Care: Transitions of Care. Joint Commission Resources. Available at www.jointcommission.org/assets/1/18/Hot_Topics_Transitions_of_Care.pdf. Accessed October 12, 2016.

12. Coleman E, Boult C; on behalf of the American Geriatrics Society Health Care Systems Committee. Improving the quality of transitional care for persons with complex care needs. J Am Geriatr Soc 2003;51:556-7.

13. Coleman EA, Smith JD, Frank JC, et al. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. J Am Geriatr Soc 2004;52:1817-25.

14. Cornish PL et al. Arch Med 2005; 165:424-9.

15. Hume A, Kirwin J, Bieber H, et al. Improving care transitions: current practice and future opportunities for pharmacists. Pharmacotherapy 2012;32:326-37.

16. Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009;150:178-87.

17. Kirwin J, Canales A, Bentley H, et al. Process indicators of quality clinical pharmacy services during transitions of care. Pharmacotherapy 2012;3:338-47.

18. Kripalani S, LeFevre F, Phillips CO, et al. Deficits in communication and information transfer between hospital-based and primary care physicians. JAMA 2007;297:831-41.

19. Kwan Y et al. Arch Intern Med 2007;167:1034-40.

20. National Quality Forum (NQF). Safe Practices for Better Healthcare–2009 Update: A Consensus Report. Washington, DC: NQF, 2009.

21. Naylor MD, Brooten D, Campbell R, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. JAMA 1999;281:613-20.

22. Naylor M, Brooten D, Jones R, et al. Comprehensive discharge planning for the hospitalized elderly: a randomized clinical trial. Ann Intern Med 1994;120:999-1006.

23. Naylor MD, Brooten DA, Campbell RL, et al. Transitional care of older adults hospitalized with heart failure: a randomized, controlled trial. J Am Geriatr Soc 2004;52:675-84.

24. Naylor M, McCauley K. The effects of a discharge planning and home follow-up intervention on elders hospitalized with common medical and surgical conditions. J Cardiovasc Nurs 1999;14:44-54.

25. Wittkowsky AK. Impact of target-specific oral anticoagulants on transitions of care and outpatient care models. J Thromb Thrombolysis. 2013;35(3):304–311.

Medication Reconciliation

1. Academy of Managed Care Pharmacy. Report of the 2013 AMCP Partnership Forum on electronic solutions to medication reconciliation and improving transitions of care. J Manag Care Pharm 2014;20:937-47.

2. Bayoumi I, Howard M, Holbrook AM, et al. Interventions to improve medication reconciliation in primary care. Ann Pharmacother 2009;43:1667-75.

3. Heyworth L, Paquin AM, Clark J, et al. Engaging patients in medication reconciliation via a patient portal following hospital discharge. J Am Med Inform Assoc 2014;21:e157-62.

4. Lindquist LA, Go L, Fleisher J, et al. Relationship of health literacy to intentional and unintentional non-adherence of hospital discharge medications. J Gen Intern Med 2012;27:173-8.

5. Morris NS, Grant S, Repp A, et al. Prevalence of limited health literacy and compensatory strategies used by hospitalized patients. Nurs Res 2011;60:361-6.

6. Mueller SK, Sponsler KC, Kripalani S, et al. Hospital-based medication reconciliation practices: a systematic review. Arch Intern Med 2012;172:1057-69.

7. Ratzan SC, Parker RM. Introduction. In: Selden CR, Zorn M, Ratzan SC, et al., eds. National Library of Medicine current bibliographies in medicine: health literacy. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2000:v-vi.

8. Tamblyn R, Poissant L, Huang A, et al. Estimating the information gap between emergency department records of community medication compared to on-line access to the community-based pharmacy records. J Am Med Inform Assoc 2014;21:391-8.

Immunizations

1. Mass Immunizers and Roster Billing: Simplified Billing for Influenza Virus and Pneumococcal Vaccinations. Available at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Mass_Immunize_Roster_Bill_factsheet_ICN907275.pdf. Accessed October 12, 2016.

2. Pharmacy-Based Immunizations: Getting the Word Out. Available at www.pharmacist.com/pharmacy-based-immunizations-getting-word-out. Accessed October 8, 2014.

3. Vaccinations: The Expanding Role of Pharmacists. Available at www.pharmacytimes.com/publications/issue/2010/January2010/FeatureFocusVaccinations-0110. Accessed October 12, 2016.

Point-of-Care Testing

1. Amruso NA. Ability of clinical pharmacists in a community pharmacy setting to manage anticoagulation therapy. J Am Pharm Assoc 2004;44:467-71.

2. Centers for Disease Control and Prevention (CDC). Clinical Laboratory Improvement Amendments (CLIA): Standards and Certification: Laboratory Requirements (42 CFR 493). Available at www.cdc.gov/clia/Regulatory/default.aspx. Accessed July 1, 2016.

3. Centers for Disease Control and Prevention (CDC). January 2012. To Test or Not to Test: Considerations for Waived Testing. Available at www.cdc.gov/clia/Resources/WaivedTests/pdf/WavedTestingBookletWeB.pdf. Accessed July 1, 2016.

4. Stepwise approach to developing point-of-care testing services in the community/ambulatory pharmacy setting. J Am Pharm Assoc 2006;46:594-604.

Patient Assistance

1. Centers for Medicare & Medicaid Services (CMS). August 2016. 4 Ways to Help Lower Your Medicare Prescription Drug Costs. Available at www.medicare.gov/Pubs/pdf/11417-4-Ways-Lower-Prescription-Costs.pdf. Accessed October 12, 2016.

2. Health Resources and Services Administration (HRSA). 340B Drug Pricing Program. Available at www.hrsa.gov/opa/. Accessed October 12, 2016.

3. Social Security Administration. 2016. Understanding the Extra Help with Your Medicare Prescription Drug Plan. Available at www.socialsecurity.gov/pubs/EN-05-10508.pdf. Accessed October 12, 2016.

Medication Safety

1. Bates DW, Boyle DL, Vander Vliet MB, et al. Relationship between medication errors and adverse events. J Gen Intern Med 1995;10:199-205.

2. Classen DC, Resar R, Griffin F, et al. "Global trigger tool" shows that adverse events in hospitals may be ten times greater than previously measured. Health Aff 2011;30:581-9.

3. Cohen, Michael. "Medication Safety: We've Made Great Strides but We still Have A Long Way to Go." University of Illinois College of Pharmacy Preceptor Conference. Chicago, IL. 19 May 2016. Conference Presentation.

4. Institute for Safe Medication Practices (ISMP). 2011. FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters. Available at www.ismp.org/tools/tallmanletters. pdf. Accessed May 24, 2016.

5. Institute for Safe Medication Practices (ISMP). 2015. ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations. Available at www.ismp.org/tools/errorproneabbreviations.pdf. Accessed May 24, 2016.

6. Institute of Medicine (IOM). Patient Safety: Achieving a New Standard for Care. Washington, DC: National Academy Press, 2004.

7. Institute of Medicine (IOM). To Err Is Human: Building a Safer Health System. Washington, DC: National Academy Press, 2000.

8. ISMP. 2011. List of High-Alert Medications in Community/Ambulatory Healthcare. Available at www.ismp.org/communityRx/tools/ ambulatoryhighalert.asp. Accessed May 24, 2016.

9. Nanji KC, Slight SP, Seger DL, et al. Overrides of medication-related clinical decision support alerts in outpatients. J Am Med Inform Assoc 2014;21:487-91.

10. National Coordinating Council for Medication Error Reporting and Prevention. 2001. NCC MERP Index for Categorizing Medication Errors. Available at www.nccmerp.org/sites/default/files/ indexBW2001-06-12.pdf. Accessed October 12, 2016.

11. Reason J. Managing the Risks of Organizational Accidents. Hants, UK: Ashgate Publishing, 1997.

12. Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm. Qual Saf Health Care 2003;12:194-200.

13. Turner BA, Pidgeon N, Blockley D, et al. Safety Culture: Its Importance in Future Risk Management. Position Paper for the Second World Bank Workshop on Safety Control and Risk Management; 1989; Karlstad, Sweden.

14. U.S. Food and Drug Administration (FDA). Compounding Quality Act: Title I of the Drug Quality and Security Act of 2013. October 7, 2016. Available at www.fda.gov/drugs/ GuidanceComplianceRegulatoryInformation/ PharmacyCompounding/. Accessed October 12, 2016.

15. U.S. Food and Drug Administration (FDA). FDA Implementation of the Compounding Quality Act. September 14, 2016. Available at www.fda.gov/ DrugGuidanceComplianceRegulatoryInformation/ PharmacyCompounding/ucm375804.htm# Traditional. Accessed October 12, 2016.

Formulary Management and Pharmacy and Therapeutics Committees

1. ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System. Available at www.ashp.org/doclibrary/ bestpractices/formgdlptcommformsyst.pdf. Accessed October 12, 2016.

2. Centers for Medicare & Medicaid Services (CMS). October 2015. How Medicare Prescription Drug Plans and Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, and Common Coverage Rules. Available at www.medicare.gov. Accessed October 12, 2016.

3. Kaiser Family Foundation. August 4, 2015. Preventive Services Covered by Private Health Plans under the Affordable Care Act. Available at http://kff.org/health-reform/fact-sheet/preventive-services-covered-by-private-health-plans/. Accessed October 12, 2016.

Medicare Part D

1. Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at www.cms.gov/Medicare/ Health-Plans/MedicareAdvtgSpecRateStats/Down loads/Announcement2017.pdf. Accessed October 12, 2016.

2. Centers for Medicare & Medicaid Services (CMS). Medicare Modernization Act Final Guidelines — Formularies. Available at www.cms. gov/Medicare/Prescription-Drug-Coverage/ PrescriptionDrugCovContra/downloads/ FormularyGuidance.pdf. Accessed October 12, 2016.

3. Centers for Medicare & Medicaid Services (CMS). Protected Classes Review Panel Additional Documentation. Available at www.cms.gov/Medicare/ Prescription-Drug-Coverage/PrescriptionDrugCov Contra/RxContracting_FormularyGuidance.html. Accessed October 12, 2016.

4. Medicare Part D – Prescription Drug Coverage. Available at www.cms.gov/Outreach-and-Education/ Training/CMSNationalTrainingProgram/Down loads/2015-Medicare-Part-D-Prescription-Drug-Coverage-Workbook.pdf. Accessed October 12, 2016.

5. Kaiser Family Foundation. May 2016. Fact Sheet: Medicare Advantage. Available at www.kff.org/ medicare/fact-sheet/medicare-advantage-fact-sheet/. Accessed October 12, 2016.

6. Kaiser Family Foundation. October 2015. Fact Sheet: The Medicare Part D Prescription Drug Benefit. Available at http://kff.org/medicare/ fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/. Accessed October 12, 2016.

ANSWERS AND EXPLANATIONS TO PATIENT CASES

1. Answer: C

The pharmacist should involve the patient's physician and other health care providers when necessary. Alerting the referring physician of the patient to the appointment does not alter or assist in a patient's drug plan, making Answer A incorrect. Calling the patient in 1 week just to see if they still have albuterol on hand does not achieve the goals of pharmaceutical care, which are to optimize the patient's health-related quality of life and achieve positive clinical outcomes, making Answer B incorrect. Moreover, having documentation that is kept solely for your own personal use does not promote interprofessional communication to benefit the patient, making Answer D incorrect. The pharmacist's responsibility is to ensure that the patient, caregiver, or both have all the necessary supplies, information, and knowledge to carry out the plan with the patient's medication, making Answer C correct.

2. Answer: D

The CMS criteria for eligibility of MTM services are as follows: chronic disease states, multiple medications for chronic conditions, and Part D drugs costing at least $3919 per year; making Answer D correct and Answers A, B, and C incorrect.

3. Answer: D

Patients qualify for CMM if they have medical conditions associated with high-cost and multiple medications, have difficulty reaching goals of therapy, are experiencing adverse drug events, have difficulty understanding and following a medication regimen, have high-risk medications that need to be monitored, or have frequent hospital readmissions, making Answer D correct and Answers A, B, and C incorrect.

4. Answer: C

To conduct a CMM visit, communication must be bidirectional; thus, written forms of communication, such as sending a letter, are inappropriate, making Answer D incorrect. However, the visit does not have to be face-to-face only; telephonic and virtual communication are also acceptable, making Answer C correct and Answers A and B incorrect. Providers of CMM must be comfortable and well trained in all means of communication that are specific to their practice sites.

5. Answer: A

CDTM can be practiced anywhere regardless of place of service. However, the most successful practice will have access to the patient's medical records, knowledge, skills and ability to perform authorized functions, documents in the medical records, accountability for quality measures, ability to be reimbursed for drug therapy management, and committed time and resources. Answer B is incorrect because the pharmacists currently may not have the knowledge or potentially the skills because they just came from a setting that did not require clinic management of patients and their knowledge surrounded a particular disease state. Answer C is incorrect because the pharmacist does not have devoted time. Answer D is incorrect because not being considered part of the general medicine clinic may limit the pharmacist's ability to bill for services. Answer A is the best answer because they have access to the patient's medical records.

6. Answer: B

Quality measures reinforce the need for pharmacist participation during transitions of care. Assessing medication adherence and knowledge does not directly reflect the outcomes from the transitions of care service, making Answers A and C incorrect. The number of patients who actually arrived at their initial outpatient follow-up appointment after discharge is an appropriate process indicator for a transitions of care service to ensure that the patient has an appropriate follow-up to prevent readmissions, making Answer B correct. Measuring the number of patients with a medication error during hospitalization is not beneficial in assessing the quality of the transitional care service, making Answer D incorrect.

7. Answer: D

Medication reconciliation provided in the primary care clinic after hospital discharge, regardless of the provider of the service, has not shown benefit, making Answer A incorrect. Even if all of the patient's electronic medical record and prescription claims data were accessible, she would still need to explain how the medications are actually being taken, making Answers B and C incorrect. If the patient keeps an up-to-date list of medications at all times, this will probably be the most accurate medication list available, making Answer D correct.

8. Answer: A

For a pharmacy to bill for the influenza vaccine under Medicare Part B, it must become a mass immunizer before the flu season through the MAC, making Answer A correct and Answer D incorrect. Answer B is incorrect because the influenza vaccine is typically not billable under a straight Medicare Part D plan; however, some managed care Medicare plans do allow the influenza vaccine to be covered under both Part D and Part B. Answer C is incorrect because the pharmacy need not be certified by APhA to provide immunizations.

9. Answer: B

Dipstick urinalyses for both glucose and urine pregnancy tests (visual color comparison) are specifically listed as waived in the CLIA regulation, making Answers A and C incorrect. Answer D is incorrect because test systems approved by the FDA for home use are waived. Professional-use versions of a home-use test must undergo waiver review, which is usually expedited because only the differences between the home-use and the professional-use versions need to be assessed, making Answer B correct.

10. Answer B

To use a 340B medication, the covered entity should be responsible for the patient's health care, and care should be provided and maintained by a health care provider while working in a 340B-eligible outpatient clinic. Moreover, the prescription should have originated from a provider while working in a 340B-eligible outpatient clinic, or it should be a discharge prescription from a covered entity hospital. In addition, the patient should not have a Medicaid or Medicaid managed care plan. Because this prescription was not written while the physician was working at a 340B-eligible clinic and was thus written on a different prescription pad, non-340B medications must be used, making Answer B correct and Answers A, C, and D incorrect.

11. Answer: B

Answer B is correct because an internal report can be used by the pharmacy to track and trend errors, facilitating improvements in processes and systems. Answers A, C, and D are all external reports, so the pharmacy may be unaware of the error, limiting internal improvements. Answer A is also incorrect because the adverse event was the result of an error rather than an unexpected adverse effect. Answer D is also incorrect because the incident was not a non-preventable adverse reaction to a vaccine product.

12. Answer: A

Answer A is correct because the FDA safety communications will allow the pharmacist to design a specific plan to reduce adverse events for specific patients who meet certain criteria described in the communication. Submitting error reports to a national organization might raise awareness to a wider audience, but this would not necessarily facilitate a direct change within the local practice, making Answer B incorrect. Establishing a standardized response to class III recalls would not reduce adverse effects because class III recalls are unlikely to cause harm, making Answer C incorrect. Answer D is incorrect because using a standard taxonomy for medication errors might make it easier to analyze errors, but it would not reduce adverse effects without further action.

13. Answer: C

A trigger tool is 50 times more effective than voluntary reporting, making Answer C correct and Answer A incorrect. Preventable adverse drug events are considered medication errors, but diagnosis codes are not a reliable indicator of adverse drug events, making Answer B incorrect. Adverse effects are not necessarily an adverse drug event unless associated with a prescribing or dispensing error; adverse effects are usually considered adverse drug reactions, making Answer D incorrect.

14. Answer: B

Answer A is incorrect because the prescriber did not include an explanation for why a covered medication is not appropriate for the patient. Answer B is correct because the drug plan is using quantity limits in an effort to improve medication safety. Step therapy prior authorization should be initiated after the patient's covered formulary medications have failed, and not just because physicians believe the drug they have chosen will work better, making Answer C incorrect. Answer D is incorrect because including only one agent per class on a formulary is probably too restrictive to accommodate intolerances and responsiveness to medications.

ANSWERS AND EXPLANATIONS TO SELF-ASSESSMENT QUESTIONS

1.   Answer: C

According to CMS's definition in 2017, the criteria for eligibility of MTM services encompass multiple chronic disease states, multiple Part D–covered medications, and Part D drug costs of at least $3919 per year, making Answer C correct and Answers A, B, and D incorrect.

2.   Answer: B

The pharmacist's responsibilities under the CDTM agreement can include initiating, modifying, and discontinuing medications; ordering and interpreting laboratory values; and assessing and providing patient education, depending on the individual practice act covering the state of practice. Furthermore, a pharmacist can place a referral as necessary to improve patient care. The physician is responsible for determining the illness diagnosis; therefore, Answer A is incorrect. Answer C is incorrect; whereas the CDTM agreement allows for ordering labs, it does not have a provision for drawing the actual lab. Answer D is incorrect because sleep apnea is outside the scope of the CDTM agreement. Discontinuing and initiating a medication for diabetes management is in the scope of the CDTM, making Answer B correct.

3.   Answer: B

To ensure a safe and effective transition for the patient, it is important to facilitate a detailed, timely, and thorough handoff from the inpatient to the outpatient setting. Therefore, scheduling the CMR 3 months later may not be as beneficial as scheduling it within 14 days of discharge, making Answer A incorrect. To ensure a smooth transition for the patient, a thorough medication reconciliation must be completed at each transition, whether from the outpatient to inpatient setting or vice versa, and a discharge plan should be communicated to the outpatient provider verbally or in writing, making Answer B correct. Providing recommendations to the inpatient team on pharmacies located in the area may not be beneficial to patients, depending on where they live, and the pharmacy should be tailored to the patient's preference, making Answer C incorrect. Conducting an Asthma Control Test at a follow-up visit will not assist in transitioning the patient to the outpatient setting, making Answer D incorrect.

4.   Answer: B

Failure modes and effects analysis is useful for identifying potential failures to a new system or process before it is implemented, allowing safety measures to be put in place to prevent those failures or minimize their risks, making Answer B correct. Root-cause analysis is a structured retrospective method used to analyze serious adverse events, and system and process improvements are typically identified, making Answer A incorrect. Safety culture assessment facilitates the identification of problems within the culture of an organization that may not foster a safety culture, but it is not used to analyze processes, making Answer C incorrect. Analysis of medication error trends is not a prospective method, making Answer D incorrect.

5.   Answer: A

Collaborative drug therapy management or collaborative practice agreements are determined at a state level. A state's pharmacy practice act is a good resource to determine whether a CDTM is permitted and to what extent, making Answer A correct. Answers B–D are not good resources because they do not determine whether and how CDTM can be provided in each state.

6.   Answer: C

Sites with a certificate of waiver are not permitted to conduct tests of moderate complexity; they can only perform waived tests, making Answer A incorrect. Answer B is incorrect because changes to manufacturers' instructions are not allowed. The renewal fee must be paid every 2 years, not every 5 years, making Answer D incorrect. The state agency responsible for accepting CLIA applications should be notified when there is a change in ownership, name, address, or director or if the site plans to add tests that are not waived within 30 days, making Answer C correct.

7. Answer: C

Brand-name drug cost = $80

Average dispensing fee = $12

Subtracting dispensing fee from the drug plan's cost = $68

The manufacturer brand discount is 50% of $68 = $34

The patient pays 45% of $68 = $30.60

The patient also pays 45% of the $12 dispensing fee = $5.40

$30.60 + $5.40 = $36, the patient's coverage gap brand cost sharing

The patient's coverage gap brand cost sharing ($36) is added to the manufacturer's brand discount ($34) for a total of $70, which is the value that counts toward the patient's annual TrOOP expenses. The patient's individual contribution is only $36.00. Therefore, Answer C is correct and Answers A, B, and D are incorrect.

8. Answer: D

Answer D is correct because epoetin alfa is the most expensive medication listed and there are significant safety concerns with its use; thus, it is the most appropriate drug to include in a specialty tier. Answer A is incorrect because metoprolol tartrate is a generic product with a low cost; it would be better listed as a tier 1 drug. Rosuvastatin is a brand-name medication, but it is not as expensive as epoetin alfa and the safety concerns with rosuvastatin use are less significant. For these reasons, it would be better listed as a tier 2 or tier 3 drug, making Answer B incorrect. Some drug plans may decide to limit the quantities of omeprazole, thereby limiting their long-term use, but this drug is not expensive and is available as a generic product; it would be better listed as a tier 1 drug, making Answer C incorrect.