Wisconsin Act 294 – Formulary Management and Collaborative Practice Agreements in the Long-term Care Facility

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Learning Objectives

• Define Wisconsin Act 294 and describe how this legislation can improve medication management resulting in improved quality of care for Long-term Care residents.
• Describe the potential benefits and logistics of implementing formulary management and collaborative practice agreements under WI Act 294 in the Long-term Care setting.
• Review a sample collaborative practice agreement to manage antibiotic use for the treatment of urinary tract infections.

State of Wisconsin

2013 WISCONSIN ACT 294

AN ACT to amend ch. 440 (2) of the statutes; relating to therapeutic substitution drug substitutions in nursing homes, performance of patient services by pharmacists, and the practice of pharmacy.
Wisconsin Act 294

Accomplished 2 main goals
1. Established the ability of nursing homes in Wisconsin to have drug formularies
2. Allowed for a physician to delegate any patient care service to a pharmacist

Drug Formularies

• Hospitals
• Health Systems
• Insurance Companies
• State Agencies - Medicaid

Why not nursing homes?

Nursing Facility Formulary

What do you need?
• Quality Assurance and Assessment (QAA) Committee that includes a pharmacist
  OR
• A committee that consists of a physician, director of nursing, pharmacist, and at least 2 other members of nursing home staff
Nursing Home Formulary

- The QAA or other committee may establish written guidelines or procedures for making therapeutic alternate drug selections.
- The therapeutic alternate drug must be approved by
  - Patient’s personal physician
  - Patient’s physician assistant

LTC Formulary Management

Prescription Drugs
- Therapeutic Interchange Programs allow dispensing pharmacist to switch to formulary approved medications upon admission

Over the Counter Medications (OTC)
- Nursing staff can change to established therapeutic alternatives upon admission
  *Both require written procedures

Rx Formulary Interchange

- Crestor ↔ Atorvastatin
- Humalog ↔ Novolog
- Novolog ↔ Humalog
- Xopenex ↔ Albuterol
- Insulin vials ↔ Insulin Pens
- Lumigan/Zioptan/Travatan ↔ Latanoprost
OTC Formulary Examples

- Iron Preparations ➔ Ferrous Sulfate 325mg
- Calcium/Vit D Preparations ➔ Calcium carbonate 600mg with Vitamin D 400 units.
- Multivitamin Preparations
- Artificial Tears
- Probiotics
- Acetaminophen PRN orders
- Vitamin D

Benefits of Formulary Management in LTC

- Increased medication availability
- Potential to save on Medicare Part A drug spending
- Facility OTC cost reduction
  - Ingredient cost
  - Storage and ordering cost
- Safety
  - Less product variability = more familiar to nursing staff, less prone to error

Barriers to LTC Formulary

- Short Stay Residents
- MD adoption
- Pharmacy adoption
- Nursing adoption
- Large number of OTC products on the market
Wisconsin Act 294

“A pharmacist may perform any patient care service delegated to the pharmacist by a physician”

Wisconsin Act 294

2013 SENATE BILL 251

SECTION 4. 450.033 of the statutes is created to read:

• 450.033 Services delegated by physician. A pharmacist may perform any patient care service delegated to the pharmacist by a physician, as defined in s. 448.01 (5).
  o “Physician” means an individual possessing the degree of doctor of medicine or doctor of osteopathy or an equivalent degree as determined by the medical examining board, and holding a license granted by the medical examining board.
  • Note lack of Nurse Practitioner guidance
Collaborative Practice Agreements

Definition

Collaborative Practice Agreement
A voluntary agreement between one or more prescribers and pharmacists establishing cooperative practice procedures under defined conditions and/or limitations toward one common goal.

Goals

- Mutual goals and common direction
- Built upon trust and communication
- Shared responsibility for care
- Realistic and relevant to practice setting
- Improvement of patient outcomes
- Outlined procedures are broad in scope
Applications of a CPA

Activities covered may include:
- Immunizations
- Refill authorizations
- Therapeutic substitutions
- Screenings
- Disease state management
  - Selecting, initiating, adjusting, assessing, monitoring, or managing drug therapy.
  - Providing drug education
  - Formulating treatment plans
  - Performing comprehensive medication reviews

Benefits of a CPA

- Patients
  - Better access to care through a pharmacist
  - Reduced cost for care
- Physicians
  - Delegation to drug therapy experts
  - Effective use of time
  - Increased patient time with knowledgeable provider
  - Results in increased patient satisfaction
- Pharmacists
  - Autonomy in a patient focused practice
  - Improved patient relationships
  - Personal job satisfaction and professional growth
- Payers
  - Minimize total health care expenditures
  - Providing high-quality, necessary services
Key Elements of CPAs

Agreement Cover Page
- Agreement statement authorizing the CPA
- Names of individual pharmacist(s) and prescriber(s)
- Signatures of participating practitioners/directors

Purpose/Intro
- State the purpose of the CPA or background information
- Describe the qualifications of the pharmacist(s)

Policy Statement
- Conditions for following or not following the written protocol
- Description of Continuous Quality Improvement Program
- Process for reviewing, revising, and renewing CPA
- Methods for communicating clinical outcomes
- Terms of agreement for termination
- Prescriber monitoring and provision to intercede where necessary

CPA Sections

Organization of the Service/Protocol
- Patient referral procedures/methods
- Authority allowed
- Clinical activities performed by pharmacist
- Patient referral procedures/methods
- Services provided during a patient encounter
- Follow-up procedures to be used
- Documentation procedures

Appendices
- Treatment algorithms
- Educational materials
- Forms

References
CPI Information

Resources

   - Includes links to several types of CPA examples

2. Collaborative Practice Agreements and Pharmacist’s Patient Care Services: A Resource for Pharmacists.
   - https://www.cdc.gov/dhdsp/pubs/docs/Pharmacist_State_Law.PDF


4. ACCP: Collaborative Practice Agreements in Outpatient Team-Based Clinical Pharmacy Practice

5. The expanding role of pharmacists in a transformed health care system.


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National Association of Boards of Pharmacy (NABP) Model Act

10 Elements of a CPA:

1. Identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;
2. Types of decisions the Pharmacist is allowed to make;
3. A process for generating any medical/prescription orders that are required to initiate allowed activities;
4. A method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede when necessary;
NABP Model Act
(continued)

10 Elements of a CPA:

5. A description of the Continuous Quality Improvement Program used to evaluate the effectiveness of patient care and ensure positive patient outcomes;

6. A provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;

7. A provision that allows either party to cancel the Agreement by written notification.

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NABP Model Act
(continued)

10 Elements of a CPA:

8. An effective date

9. Signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing.

10. A procedure for periodic review and renewal within a time frame that is clinically appropriate.

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CPA Question 1

The National Association of Boards of Pharmacy (NABP) lists 10 elements of a CPA. Which of the following is not an example of one of the 10 elements?

A. An effective date & date of participator signatures

B. A provision that allows a third party to cancel the Agreement by verbal notification

C. A description of the Continuous Quality Improvement Program

D. Types of decisions the Pharmacist is allowed to make
CPA Question 2

Clinical pharmacist involvement in patient care can improve quality and safety measures that are increasingly tied to reimbursement. Which of the following are examples quality measures?

A. Appropriateness of treatment  
B. Timeliness of treatment  
C. Communication with patients about their medications  
D. All of the above

CPA Question 3

All of the following are potential examples of delegated pharmacist authority under a CPA except?

A. Formulating treatment plans  
B. Selecting, initiating, adjusting, assessing, monitoring or managing drug therapy  
C. Diagnosing a patient and prescribing treatment for therapy  
D. Selecting therapeutic substitutions

CPA Question 4

True or False:

Amendments to a Collaborative Practice Agreement must be documented, signed, and dated.
Urinary Tract Infection (UTI) Collaborative Practice Agreement

What's the point?

Antibiotic use in Nursing Homes

47 - 79% of nursing home residents receive antibiotics each year, and
77 - 88% of all infectious episodes are prescribed antibiotics.

This overuse of antibiotics leads to numerous complications including:
  • Drug interactions
  • Antimicrobial resistance
  • Adverse effects
  • Allergies
  • Increased rates of Clostridium difficile

Antibiotic use in Nursing Homes

Up to 80% of all antibiotic use is inappropriate in nursing homes.
What are all these antibiotics prescribed for?^{12}

Examples of clinical situations in LTC for which antibiotics are often prescribed, but rarely necessary:

- Urinary Tract Infections
- Upper Respiratory symptoms
- Viral Respiratory infections
- Skin Wounds

At least 30% of all antibiotics prescribed in LTC are for treating UTIs, the most common reason for an antibiotic order in LTCFs.

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Urinary Analysis and Antibiotic use?

- If we tested the urine of everyone in our LTC facility for a UTI what percentage would be positive for bacteria?
  
  25%?  50%?  75%?!  

- What usually happens when a physician gets a fax with a “positive urine culture?”

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Centers for Medicare & Medicaid Services (CMS):
State Operations Manual^{13}
F329: Unnecessary Medications

“Review whether the resident is receiving any medications without an indication for use, in excessive dose or duration, with inadequate monitoring, or in the presence of any adverse consequences that indicate that the dose should be reduced or discontinued.”
Wisconsin Healthcare Associated Infections in LTC Coalition

**WI 2015 F329 Violations**

134 Total 44 citations (89 examples) related to antibiotics and UTI

- 51 were related to the treatment of asymptomatic bacteriuria
- 21 instances of not collecting cultures or not waiting for culture results in the absence of warning signs before starting antibiotics
- 14 antibiotics given when sensitivities indicated the bacteria was resistant
- 3 examples of antibiotic prophylaxis for UTI

CMS “Mega Rule”

- Nursing homes will be required to have an Antibiotic Stewardship Program
- CMS encourages facilities to collaborate with their pharmacist
- “we encourage the QAA Committee to collaborate with the pharmacist to enhance the committee’s understanding and oversight of the facility’s pharmaceutical practices, especially concerning the use of psychotropic drugs and its antibiotic stewardship, as well as their QAPI activities”

§ 483.45 & “irregularities”

(d) Unnecessary drugs—General.
Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

1. In excessive dose (including duplicate drug therapy); or
2. For excessive duration; or
3. Without adequate monitoring; or
4. Without adequate indications for its use; or
5. In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
6. Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.
§ 483.45 (c)(4)¹⁴

(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum:

- the resident's name
- the relevant drug, and
- the irregularity the pharmacist identified.

§ 483.45(c)(4)(iii)¹⁴

- Requires the attending physician to document in the resident's medical record that the (pharmacist) identified irregularity has been reviewed and what, if any, action has been taken to address it.

- If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

UTI Collaborative Practice Agreement

What's the Point?

To optimize antimicrobial use for the treatment of UTIs in LTC facilities
Antibiotic Stewardship Goal

“Optimize the treatment of infections while reducing the adverse events associated with antibiotic use”
– CDC Core Elements

Implementation

“Do you have a policy for that?”

Potential Goals of a UTI CPA

- Optimize antimicrobial use, including agent selection, dose, and duration, for our residents
- Reduce unnecessary use of antimicrobials in our residents
- Facilitate appropriate monitoring and dose adjustment of antimicrobials for our residents
- Reduce the risk of adverse drug events in our residents
- To mitigate risk for development of multi-drug resistant organisms in our facility
The Wisconsin Medical Practice Act Section 448.03(2)(e) allows pharmacists to practice under a Collaborative Practice Agreement with individual physician(s) who are responsible for the patient’s care and authorized to prescribe drugs. Through such agreement, pharmacists may participate in the practice of managing and modifying drug therapy. It is the intent of this document to authorize the pharmacist(s) listed below to work in a collaborative fashion with the physician(s) listed below. The document sets forth guidelines for collaboration between the physician(s) and pharmacist(s). This agreement is voluntary and may be terminated at any time by either party.
Purpose/Background
In order to enhance collaborative patient care, optimize antimicrobial stewardship and safety for medications being used to treat lower urinary tract infections. Pharmacists will be delegated authority by participating physicians to independently manage and order antimicrobial therapy and order select labs as outlined in the agreement.

Policy
This agreement is made between _____________________________ and __________________________. This agreement applies to residents under the care of ___________________________.

Organization
Activities performed by the clinical pharmacist under the collaborative practice agreement with the physician(s) for purposes of medication therapy management may include:

• Order a basic metabolic panel (BMP) to obtain serum creatinine (SCr) if one is not available within the past 30 days.

• If not already ordered, order an International Normalized Ratio (INR) for residents on warfarin therapy to monitor for drug-drug interactions both during and at an appropriate interval post antibiotic discontinuation.

• If not already ordered, order a urinalysis with culture and sensitivity if indicated, for the purpose of targeting antibiotic therapy.

• Calculate the resident’s estimated CrCl using the Cockcroft-Gault Equation and adjust urinary tract antibiotic dose per CrCl recommendations in Table 1.

• Adjust antibiotic selection if it is contraindicated, has potential for significant drug interaction(s), adverse drug event(s), or is not recommended through reference of current clinical practice guidelines, professional judgment, or resources contained within this agreement.

The following component(s) of the CPA is/are authorized if the corresponding box is checked:

- The pharmacist may discontinue an ORAL antibiotic in an ASYMPTOMATIC patient with negative urinalysis and/or culture (<100,000 CFU/ml). Discontinuation of IV therapy requires discussion with the prescribing provider.
If a patient is on an oral antibiotic and another oral antibiotic of narrower spectrum will treat the organism, the pharmacist may de-escalate an antibiotic prescribed per culture and sensitivity data.

If the patient is on empiric oral antibiotics and sensitivity data reveals resistance to the empiric antibiotic, the pharmacist may change the antibiotic to one with a clinically available antibiotic option. If IV therapy is identified as necessary, the pharmacist is required to contact the prescribing provider to discuss the patient case and obtain a new order.

Documentation: All changes will be documented in the resident’s record and will be available for review.

Quality Improvement

• Clinical activities related to this agreement will be reviewed at least annually by the clinical pharmacist and physician providers, and revised as needed.

Clinical Pharmacist Qualifications:

• Active pharmacist licensure in good standing in the state of Wisconsin.

Goal:

Identify positive resident and facility outcomes.

Consider:

How would a physician and pharmacist CPA for UTI treatment benefit the following patients in the depicted cases?
Wisconsin Healthcare–Associated Infections in LTC Coalition

Case #1

- Resident MP is diagnosed with a UTI and starting antibiotic therapy with Bactrim DS.
- MP is currently taking warfarin, and most recent labs were taken three months ago.

**Necessary actions:**
- Ensure proper renal dosing of Bactrim.
- Acquire international normalized ratio (INR) to monitor for drug interaction.

Pharmacist actions:
- Order labs for renal dosing adjustment per CPA.
- Acquire international normalized ratio (INR) for monitoring of drug interaction.

Clinical benefit:
- Safety
  - Decreased risk for TMP/SMX toxicities
  - Decreased risk for bleeding with INR check

KM Case #2

- Resident KM is diagnosed with a UTI and starting antibiotic therapy with ciprofloxacin.

**Pharmacist actions:**
- Renal function assessment
- Review for alternative antibiotics – allergies and renal function don’t allow for a change
- Decrease dose based on renal function
KM Case #2

**Clinical benefit:**
- Safety
  - Ensuring quinolone used only if no other option (FDA advisory)
  - Decreased risk of quinolone toxicities
    - Arrhythmias
    - Muscle and tendon effects

TC Case #4

- Resident TC returned from the ER after an evaluation for a fall. ER diagnosis is UTI with orders for ciprofloxacin 250mg po BID

**Pharmacist action:**
- Discontinue Ciprofloxacin

TC Case #4

**Clinical benefits:**
- Safety
  - Prevention of antibiotic exposure (resistance)
  - Avoidance of quinolone use (FDA advisory)
  - Decreased risk of quinolone toxicities
    - Arrhythmias and drug interactions
    - Muscle and tendon effects
  - Decreased risk for *C. diff* by discontinuing broad spectrum antibiotic
**TC Case #4**

**Clinical benefits (continued):**
- **Cost**
  - Antibiotic was discontinued
  - Potential cost-avoidance for secondary infection (*C. diff*)
- **Regulatory**
  - F329 avoided

**MM Case #6**

- Resident MM diagnosed with UTI and started on nitrofurantoin, switched to TMP/SMX as symptoms unresolved. C&S results are reviewed by the pharmacist per CPA protocol

**Pharmacist action:**
- Change TMP/SMX to Ciprofloxacin 250mg PO BID x 7 days

**Clinical benefits:**
- **Safety/Cost**
  - Prevented antibiotic treatment failure and potential hospitalization
- **Regulatory**
  - F329 prevented
PK Case #7

- Resident PK diagnosed with UTI and started on Ciprofloxacin 250mg po BID. Pharmacist reviews the C&S at 48 hours per CPA protocol

Pharmacist action:

✓ De-escalate antibiotic by changing ciprofloxacin to amoxicillin 500mg Q 12H x 7 days

Clinical benefits:

- Negative outcomes prevented
  - Quinolone adverse drug reactions/use
  - Decreased risk of *C. diff* by de-escalation
  - Development of resistance

- Cost
  - What is it worth to prevent ER/hospital visit?
  - Prevention of *C. diff* requiring treatment
    - Risk for spreading infection high

What else do you need?

Procedures

- How does the pharmacist get notified?
  - Upon order for renal dose adjustments
  - Not all consultant pharmacist work for the dispensing pharmacy – you will need involvement from both

- When does the pharmacist get notified?
  - 48 hour antibiotic timeout is a good time to engage the pharmacist for antibiotic recommendations
Wisconsin Healthcare-Associated Infections in LTC Coalition

**Benefits to LTC**

Optimizing antibiotic utilization will improve resident and facility outcomes

- **Clinical outcomes**
  - Reduced *C. diff* and adverse drug event rates
  - Increase CMS star rating
    - Potential to reduce re-hospitalization rates
    - Improved quality indicators and survey results

**Benefits to LTC**

- **Decrease Regulatory Risk**
  - Required Antibiotic Stewardship Program in CMS “MegaRule”

- **Medication Cost Savings**
  - Formulary management
  - Decreased days of therapy

**Barriers to CPA**

- Physician adoption
- Pharmacist adoption
- Nurse adoption

Most issues arise from lack of communication and understanding – show them how it works.
Barriers to Pharmacist Involvement

Consultant Pharmacists usually visit monthly
- Rarely have access to electronic medical records off-site and if so they are incomplete
- Software from the hospitals doesn't communicate with the nursing home software or the pharmacy software
- Education needed

Dispensing pharmacist may need additional training and resources to provide service.

Barriers to CPA

“When you're finished changing, you're finished” --Benjamin Franklin

“It is not the strongest or the most intelligent who will survive but those who can best manage change” --Charles Darwin

Pharmacist Return on Investment (ROI)

Estimated ROI of $1.29 per $1 in MTM administrative costs.
- Of 4849 patients not at goal when they enrolled in the plan, 55% of medical conditions improved and 23% remained the same following MTM services. When surveyed, 95.3% of respondents agreed or strongly agreed that their overall health and well-being had improved because of the pharmacist involvement.
Savings were more than 2.5 times the cost of the fees for pharmacists and network administration.

- Results from a Centers for Medicare and Medicaid Services demonstration project in Connecticut where nine pharmacists worked closely with 88 Medicaid patients from July 2009 through May 2010 revealed that pharmacists identified 917 drug therapy problems and resolved nearly 80% after four encounters, resulting in an annual savings of $1,123 per patient on medication claims and $472 per patient on medical, hospital, and emergency department expenses.

Generic drug use increased 9.8% and out of pocket expenditures decreased by 68%.

- A review was conducted for the 520 patients seen during one year at a pharmacist-directed medication therapy management program in a managed care setting. Study participants were low income elderly (avg. 78 yo) with multiple chronic medical conditions, multiple medications and high drug costs. A key finding was that 41% of total patients reported that they had or would soon discontinue drugs due to cost; 87% of these patients were able to continue or resume medication therapy as a result of the pharmacist interventions.

- HR 592 (House of Representatives) and S.109 (Senate) Bills
- Pharmacy and medically underserved areas enhancement act
  - To amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of pharmacist services.
- Reach out to your representatives requesting they support these bills
## How to Start

### Embrace and encourage pharmacy involvement
- LTC facilities have access to clinical/consultant pharmacists
- Increasing trend of nurse practitioner model
  - Pharmacists and nurse practitioners can make a great team

### Raise the bar for your facility and pharmacist
- Scheduled a short meeting with your pharmacist during their next visit and share what you learned.
  - Tell them you will be implementing the When to Test Nursing Tool and you want them to help you ensure antibiotics used to treat UTIs at your facility are appropriate.

### Start with the renal dosing CPA after you and your pharmacist have trained the nursing and CNA staff on when to test urine.
- This might take awhile – don’t get discouraged.
- Or, just go for it!

## References

References