Accreditation:
It’s all about the Value

September 23, 2016
Lynnae Mahaney BSPharm, MBA, FASHP
DISCLOSURES

Lynnae Mahaney is the Executive Director of the Center for Pharmacy Practice Accreditation (CPPA®)
OBJECTIVES

- Describe the value of pharmacy practice accreditation in the healthcare system and in pharmacy.
- Describe how accreditation aligns with initiatives for quality, safety, and efficiency in pharmacy practice and for recognition of pharmacist delivered patient care services.
- Discuss the concepts in each of the standards domain areas of pharmacy practice standards.
- Describe the pharmacy practice accreditation process.
CE QUESTIONS

1. What elements contribute to the value of accreditation?
   A. National trend toward accreditation of all health care organizations and programs
   B. Changing payment structures in US Health Care System
   C. Evolution of provider and payer network requirements
   D. Align with national regulatory and organizational quality standards
   E. Harmonization with accreditation programs where possible
   F. A-D
   G. All of the above

2. The accreditation process includes:
   A. Application
   B. Letter of Agreement and BAA
   C. Document Assessment
   D. On-site Survey
   E. All of the above

3. True or False: The four Specialty Pharmacy Practice Standards domains for CPPA are:
   ▪ Organizational Infrastructure
   ▪ Access to Medications
   ▪ Clinical and Patient Management Services
   ▪ Continuous Quality Improvement
AGENDA

‘ABOUT’ CPPA®
Healthcare Value and Accreditation
Pharmacy Practice Standards and Value - ATION
CPPA Accreditation Standards and Programs
CPPA: A PROFESSIONAL PARTNERSHIP

- National Association of Boards of Pharmacy
- American Pharmacists Association
- American Society of Health-System Pharmacists
The mission is to serve the public health by raising the level of pharmacy-delivered patient care services through accreditation of the pharmacy practice.
VISION FOR PHARMACY PRACTICE ACCREDITATION

- Standards facilitate
  - High quality, safe and effective dispensing and patient care services
  - Use of patient care data to **advance patient care**, enhance medication safety, and improve care delivery.
  - Harmonization with existing accreditation programs
  - Differentiation from statutory requirements

- Accreditation process facilitates
  - Practice innovation
  - Recognition
Health outcomes achieved per dollar spent over the care cycle
ACCREDITATION VALUE

- National trend toward accreditation of all health care organizations and programs
- Payment structures in US Health Care System
  > Quality assessment and Payment linked to quality metrics
  > ACO Shared Savings
- Provider and Payer Networks
  > Network limitation trends/pay for performance-fee for service/bonus
- Align with national regulatory and organizational quality standards
- Harmonize with accreditation programs where possible
ACCREDITATION VALUE

- Payment structures
  - Moving toward quality assessment of healthcare practices
  - Payment linked to quality metrics
  - Shared savings

- Pharmacy Payment Structures - Evolving
  - Network limitation trends
    - preferred pharmacy practice network
  - Pay for performance
    - fee for service
    - bonus payments
    - shared savings
Sunflower Health Plan, a managed care organization and subsidiary of Centene Corporation, has announced an enhanced, value-based payment on each claim from network pharmacies accredited by the Center for Pharmacy Practice Accreditation (CPPA).
The pharmacy profession is under pressure to change.  
- Access  
- Affordable Care Act  
- Mergers  
- Collaborations  
- Reimbursements
There has been a dramatic increase in the past decade in the percentage of pharmacists performing health care-related services.
DEFINING EXPANDED ROLES

- Medications history
- Transition of care
- Supervisor
- State involvement
- Medication assistance
- Informatics
- Supply chain/logistics
- Specialty Pharmacy
- Educator
- Inpatient Pharmacy
- Ambulatory Pharmacy
PHARMACY PRACTICE VALUE

- Demonstrate our focus on for positive patient outcomes
- Ensure we are delivering the highest quality of care for their patients
- ‘...following best practice for safe and effective patient care’
  - gaps in our current policy and procedures-guide to best fill in those gaps
- Demonstrate our investment in providing innovative patient care services
PHARMACY PRACTICE VALUE

- ‘lead the way in advocating for reimbursement’
  - ‘for clinical services and exceptional performance provided by community practice’
  - ‘future where patients are incentivized to use providers that produce the best outcomes’
  - ‘factor in to how payers establish their networks’
- ‘...envision a time when patients and insurers will use this process to recognize quality community pharmacy practices’
- Placing “patients and their desired outcomes at the center...”
- Healthcare “that has positive results (improved patient outcomes, safety, and satisfaction) at a total cost that is reasonable and affordable.”
- A “measure of outcomes achieved per monetary expenditure” focusing on “3 critical elements...clinical benefit (efficacy), toxicity (safety), and cost (efficiency).”
A well-designed ongoing accreditation program should:

- Improve quality
- Promote innovation
- Demonstrate accountability
- Create value
ACCREDITATION STANDARDS:
PRIORITY INDICATORS FOR VALUE

- Patient care delivery and management
- Care Quality

*Practice Models which differentiate themselves through clinical capabilities and quality of care*
STANDARD: INDICATOR FOR VALUE

STANDARDS DEVELOPMENT PROCESS

- Practice area experts representing broad stakeholder input
  - Define pharmacy practice
  - Draft standards
  - Initial vetting and feedback

- Open comment period
  - Consensus based standards
  - Perspectives from pharmacists, healthcare system stakeholders, payers, specialty medication manufacturers, consumer groups, and patients
“It is no longer theoretical whether or not quality metrics are going to have an impact on their practice; it is very real.”

Lisa K. Hicks, MD, MSc
CPPA: A UNIQUE ACCREDITOR

- Our standards define, focus on, and provide direction for pharmacy ‘practice’
  - Elevates and standardizes practice
- Originates from within the pharmacy profession with the medication use experts
- Dynamic and flexible in defining the standards and advancing the services provided in pharmacy practices
CPPA: A UNIQUE ACCREDITOR

- CPPA’s mission and goals
  - Improve patient outcomes
  - Improve the delivery of pharmacy care
- The standards are comprehensive and practical
- The accreditation program/process
  - Easy to understand
  - Adaptable to different models of care
  - Can be bundled with other types of accreditation
- The accreditation program is priced competitively
ACCREDITATION PROGRAM

- Application, Letter of Agreement, BAA, invoicing, staff assignment
- Submission of Document Assessment
- Pharmacist Surveyor Document Review
- Telephonic discussion of findings with Surveyor
- On-site Survey – Unannounced unless multisite
- Survey Report
- Plan of Action
- Review by Accreditation Oversight Committee
- Accreditation Status Decision by Board of Directors
APPLICATION PROCESS

- Time to complete application is generally less than one hour
  - Business and ownership information
  - Personnel licensure
  - Facility licensure

- Organizations with multiple practice sites may take slightly longer

- Letter of Agreement with BAA

- Invoice is sent upon receipt of the application

- Accreditation Staff assignment
DOCUMENT ASSESSMENT PROCESS

- Document Assessment Tool
  - Provided after application and supplemental documentation is processed
  - Tool for self-reporting policies and procedures and compliance with standards
  - Tool will assist with organizing, collecting, and evaluating policies and procedures

©2016 CPPA. Confidential & Proprietary. Not to be reproduced or distributed without prior permission
DOCUMENT ASSESSMENT PROCESS

- Document Assessment and referenced policies and procedures are submitted via secure Box.com folder
- Documents are reviewed within 2-4 weeks and applicant receives written report of any documents missing or require clarification
- A phone call is scheduled with applicant to review report
- An unannounced visit is scheduled within 6 weeks of survey eligibility notification.
SITE SURVEY

- Unannounced visit
- Date(s) to avoid may be considered, if requested early in accreditation process
- Survey will occur during normal business hours
- Surveyor will be a pharmacist and will be sensitive to business needs
  - Typically avoiding Monday mornings, day immediately before or after a holiday

©2016 CPPA. Confidential & Proprietary. Not to be reproduced or distributed without prior permission
ON-SITE SURVEY AGENDA

- Opening Conference – attended by leaders and select staff
- Operations Observation – validation of compliance with standards
- Employee Record Review and Interviews – validation of HR policies
- Patient Record Review – validation of patient care policies and therapeutic area programs
- Quality Improvement Presentation – 15 minutes about pharmacy practice PI program
- Supplemental Document Review – complete open document issues
- Closing Conference – attended by leaders and select staff
- 1-3 days - depending on size of practice
ACCREDITATION REPORT

- A letter with report will be sent to the pharmacy practice describing best practices, consultative recommendations, and any areas of non-compliance with standards.

- Pharmacy practice responds to the survey report with a plan of action and timeline for areas of non-compliance within 30 days.

- When the plan of action is received, and all outstanding items from the site survey are complete, the accreditation report is reviewed by the Accreditation Process Oversight Committee.

©2016 CPPA. Confidential & Proprietary. Not to be reproduced or distributed without prior permission
ACCREDITATION OVERSIGHT COMMITTEE REVIEW

- Reviews Accreditation Report and Plan of Action
- Recommends pharmacy practice accreditation status to the CPPA Board of Directors
- CPPA Executive Director notifies practice of final decision.
COMMUNITY PHARMACY PRACTICE STANDARDS

Domain I   Practice Management

Domain II  Patient Care

Domain III Quality Improvement

Goal Standards
DOMAIN 1: PRACTICE MANAGEMENT

1.1 The pharmacy practice has a well-defined organizational structure that supports the safe and effective provision of services.

1.2 The pharmacy practice has appropriate professional and support staff to deliver quality services.

1.3 The pharmacy practice has an appropriate environment to deliver quality services.

1.4 The pharmacy practice uses information systems and technology to support quality service delivery.

1.5 The pharmacy practice supports the interoperability of information systems.

1.6 The pharmacy practice implements policies and procedures to maintain the integrity, security, and privacy of patient information and other data.

1.7 The pharmacy practice develops business models to support the delivery of patient care services
2.1 The pharmacy practice develops, implements, and oversees patient-centered services focused on improving patient medication use, health, and wellness.

- MTM
- At least two other patient care services

2.2 The pharmacy practice proactively provides counseling to patients regarding medications and related products.

2.3 The pharmacy practice evaluates competency and facilitates continuing professional development of staff involved in patient care service delivery based on the complexity of services and needs of patients.

2.4 The pharmacy practice has a process for evaluating the effectiveness of patient care services.
3.1 The pharmacy practice operates a CQI program.

3.2 The pharmacy practice conducts and encourages routine training and education of pharmacy staff on quality improvement initiatives.

3.3 The pharmacy practice uses consumer feedback regarding pharmacy staff and patient care services with the intent of improving patient satisfaction and outcomes of care.
GOAL STANDARDS

DOMAIN I: PRACTICE MANAGEMENT

- Promote Continuing Professional Development
- Electronic pharmacy IS to facilitate access to patient information
- Access to CDS systems for EB decision making
- Electronic interface with other health care entities for EHR
- Business model development to support delivery of value-added patient care services
Pharmacists have a relationship with prescribers caring for their patients and support collaborative practice agreements.

Explore implementation of electronic systems that generate and receive documents using SNOMED CT MTM Value Set Access to CDS systems for EB decision making.

Document patient counseling to facilitate continuity of care.

Process for evaluating effectiveness of patient care services.
GOAL STANDARDS

DOMAIN III: QUALITY IMPROVEMENT

- Pharmacy practice implements root cause analysis processes
GOAL STANDARDS

- Submission of these items is not required towards accreditation at this time; however, CPPA is collecting trend data and requests that applicant submit these items when possible.
COMMUNITY PHARMACY PRACTICE ACCREDITATION PROGRAM - STATUS

- Standards published March 2013
- Accreditation program opened April 2014
- Accredited pharmacies
  - Increasing interest-independent, chain, hospital
  - Standards applicable to hospital/clinic outpatient pharmacies
  - Standards applicable to non-dispensing pharmacies
TELEHEALTH PHARMACY PRACTICE STANDARDS

Domain I  Practice Management
Domain II  Patient Care
Domain III Quality Improvement
Goal Standards
TELEHEALTH PHARMACY PRACTICE ACCREDITATION PROGRAM - STATUS

- Standards published March 2015
- Beta site

- Growing area of interest
Domain I  Organizational Infrastructure
Domain II  Access to Medications
Domain III Clinical Management Services
Domain IV Continuous Quality Improvement
Goal Standards
CPPA SPECIALTY PHARMACY PRACTICE
ACCREDITATION STANDARDS DEVELOPMENT COMMITTEE

Bruce Scott, RPh (Chair)
President, CADENT Group LLC

Andy Pulvermacher, PharmD
Pharmacy Supervisor-Specialty Pharmacy Services University of Wisconsin Hospital and Clinics

Nick Calla, RPH, JD
VP Industry Relations
Cardinal Specialty Solutions

Gary Rice, RPh, MS, MBA, CSP
Senior Vice President, Clinical Services
Diplomat Specialty Pharmacies

Kevin Colgan, MA, FASHP
Vice-President, Chief Pharmacy Officer
University of Chicago Medical Center

Lisa Linn Siefert, RPh, FASHP, ASQ-CMQ/OE
Corporate Manager, Accreditation, Quality, and Clinical Education
Option Care Infusion and Respiratory Service

Brian K. Komoto, PharmD
President and Chief Executive Officer
Komoto Healthcare

Denise Wolff PharmD
National Account Manager
EMD Serono

Rich Palombo, RPh
Senior Director of Pharmacy Regulatory Affairs
Express Scripts

Bradley Wooldridge, RPH
RPh In Charge
Reeves Sain-EntrustRx
DEFINITION: SPECIALTY PHARMACEUTICAL

- What is a specialty pharmaceutical?
  - Typically high in cost ($600 or more per month)
  - Involve complex treatment regimens that require ongoing clinical monitoring and patient education
  - Have special handling, storage, or delivery requirements
  - Are generally biologically derived and available in injectable, infusible, or oral form
  - Are dispensed to treat individuals with chronic and/or rare diseases
  - Frequently have limited or exclusive product availability and distribution
  - Treat therapeutic categories such as oncology, autoimmune/immune, or inflammatory conditions marked by long-term or severe symptoms, side effects, or increased fatality

There is no standard definition
- The definition is likely to change over time especially due to the entrance of biosimilars and generics

What is a specialty pharmacy practice?

CPPA defines specialty pharmacy practice as a pharmacy practice created:

1. To manage the medication access and handling requirements of specialty pharmaceuticals, including dispensing and distribution, and

2. To provide clinical management services for patients with chronic, serious, life-threatening and/or rare disease or conditions receiving specialty medications, aimed towards achieving the desired patient therapeutic and economic outcomes.
PHARMACY INDUSTRY REVENUES, TRADITIONAL VS. SPECIALTY DRUGS, 2010-2020

(billions)

<table>
<thead>
<tr>
<th>Year</th>
<th>Specialty drugs</th>
<th>Traditional drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>$274</td>
<td>$233</td>
</tr>
<tr>
<td></td>
<td>$41</td>
<td>$233</td>
</tr>
<tr>
<td>2015</td>
<td>$364</td>
<td>$266</td>
</tr>
<tr>
<td></td>
<td>$98</td>
<td>$266</td>
</tr>
<tr>
<td>2020</td>
<td>$483</td>
<td>$270</td>
</tr>
<tr>
<td></td>
<td>$212</td>
<td>$270</td>
</tr>
</tbody>
</table>

Specialty as % of Pharmacy Industry Revenues

- 2010: 15%
- 2015: 27%
- 2020: 44%

Figures in billions
Source: Pembroke Consulting estimates

QUICK FACTS ON SPECIALTY PHARMACEUTICALS

- Cost per month generally ranges from $2,500 to $50,000.
- Two-thirds of new FDA approvals are for specialty drugs.
- 8 of the 10 top highest revenue drugs in 2016 will be specialty.
- Patients on these medications are complex, high-cost, and require regular follow-up.
DOMAIN 1.0 - ORGANIZATIONAL INFRASTRUCTURE

1.1 Has appropriate documents and current licensure required of the specialty pharmacy practice.

1.2 Has
   a) a clear organizational structure including a mission statement,
   b) a policy and procedure process, and
   c) delegation of organizational oversight and leadership to allow for safe and effective delivery of services.

1.3 Describes the scope of specialty pharmacy services offered.
1.4 Defines and manages internal and external delegated services.

1.5 Has appropriate professional and support staff to deliver services.

1.6 Maintains a structure to ensure appropriate fiscal management.

1.7 Has protocols for product procurement, storage, preparation, and distribution for medication safety, product integrity and timely delivery.
DOMAIN 1.0 - ORGANIZATIONAL INFRASTRUCTURE

1.8 Has an appropriate environment to maintain patient privacy and deliver patient care services.

1.9 Uses systems and technology that support safe medication distribution processes and facilitate patient safety.

1.10 Uses information systems and technology for documentation and support of the delivery of patient care services.

1.11 Information systems provide access to appropriate evidence-based references and clinical decision support programs that facilitate the delivery of patient care services.
DOMAIN 1.0 - ORGANIZATIONAL INFRASTRUCTURE

1.12 Supports the interoperability of information systems.

1.13 Ensures the integrity, security, and privacy of patient information and other data.

1.14 Maintains policies and procedures to ensure compliance with HIPAA and HITECH regulations.

1.15 Has a contingency plan in order to maintain patient care services during unplanned events.
2.1 Provides comprehensive benefits investigation, prior authorization assistance, and benefits coordination on behalf of the patients it serves.

2.2 Supports patient safety and compliance with manufacturer and payer requirements.

2.3 Facilitates patient access to care through the transparent provision of financial information to the patient and provider.
DOMAIN 3.0 - CLINICAL & PATIENT MANAGEMENT SERVICES

3.1 Facilitates patient enrollment and management through patient and provider communication and care coordination.

3.2 Communicates with healthcare providers to facilitate coordination of patient care.

3.3 Maintains internal policies and procedures for collaboration with other pharmacy providers included in the patient’s care.

3.4 Maintains a comprehensive patient profile for all patients.

3.5 Provides patient-centered consultation and education regarding expectations of therapy.
3.6 Provides and monitors pharmacy patient case management services.

- Coordination and collaboration with other pharmacy providers and other healthcare providers
- A comprehensive review of the patient’s medication history
- Use and maintenance of a patient’s personal medication list
- A care plan or action plan with action items for the patient to achieve the desired medication therapy outcomes
- Patient-specific assessments and information obtained, incorporated and documented as part of the patient case management process
- Assessment of current and prior medication therapy
- Vaccination status assessments at initiation and annually
- Assessment of all patient parameters needed to determine appropriate medication therapy
3.6 Provides and monitors pharmacy patient case management services.

- Patient reported side effects to any medications
- Drug-specific assessment and/or disease state-specific assessment including pertinent lab testing and reporting, symptom assessment
- REMS and MedGuide accommodation and documentation
- Use of medication or disease state specific protocols
- Pharmacist interventions as needed to address potential problems or issues
- Ongoing patient monitoring and follow-up
- Referrals to other health care providers and services
- Documentation of all pharmacy case management activities
- Date of previous refill and adherence assessment

9/2/2016
3.7 Modifies patient case management based on patient-specific factors when needed.

3.8 Evaluates competency and facilitates continuing professional development of staff involved in patient care service delivery based on the complexity of services and needs of patients.

3.9 Maintains consistent procedures for patient notification of interventions and delays in therapy.

3.10 Practice prohibits the use of refill protocols whereby specialty medications are filled without direct patient contact.
DOMAINE 4.0 - CONTINUOUS QUALITY IMPROVEMENT

4.1 Reports and evaluates quality outcomes to assess the effectiveness of patient care services and offer continuous quality improvement.

4.2 Implements continuous quality improvement practices based on quality metric reports.

4.3 Provides accurate data reports.
GOAL STANDARDS

DOMAIN 1  ORGANIZATIONAL INFRASTRUCTURE

▪ Annual influenza vaccination for direct care staff (1.5)

▪ Pharmacist scope of practice obtained through qualification, training, skill demonstration and allows for collaborative medication management (1.5)

▪ Electronic pharmacy information system facilitates access to clinically relevant patient information (1.10)

▪ AHRQ clinical decision support programs aid in evidence-based decision-making (1.11)

▪ Electronic interface with other healthcare entities to exchange EHR information (1.12)

©2016 CPPA. Confidential & Proprietary. Not to be reproduced or distributed without prior permission
GOAL STANDARDS

DOMAIN 2  ACCESS TO MEDICATIONS

- Internal policies provide disclosure of manufacturer-based financial agreements and financial assistance provided to patients (2.3)
- Transparency in services is provided to all patients, irrespective of financial incentives to provide differentiation (2.3)
GOAL STANDARDS

DOMAIN 3  CLINICAL MANAGEMENT SERVICES

- Collaborative practice agreements are used to facilitate patient management (3.2)

GOAL STANDARDS

DOMAIN 4  CONTINUOUS QUALITY IMPROVEMENT

- Documentation of first fill drop-off rates and continuous quality improvement measures to ensure patient continuation with therapy. (4.1)
SPECIALTY PHARMACY PRACTICE
ACCREDITATION PROGRAM - STATUS

- Standards
  - Vetted May 2014, approved by BOD June 2014
  - Open comment period September-October 2014
  - Finalized December 2014
  - Published January 2015 and accreditation program opened
  - Website documents, glossary

- Interest level HIGH!
SPECIALTY PHARMACY PRACTICE ACCREDITATION PROGRAM - STATUS

- Current sites:

- MOUs:
FUTURE CPPA

Accreditation of Pharmacy Practice Across the Entire Medication Use Process

▪ Development of other standards
  ➢ Acute Care Medication Use Processes
  ➢ Medication Safety
  ➢ Ambulatory Care (Clinic/Home Care)

▪ Collaboration with Other Accrediting Organizations
  ➢ ASHP Residency (initiated)
  ➢ Hospital or other practice site accreditors
CPPA SEAL OF ACCREDITATION
THE WAY FORWARD

The Art of the Long View

“Begin with the End in Mind”
1. What elements contribute to the Value of Accreditation
   A. National trend toward accreditation of all health care organizations and programs
   B. Changing payment structures in US Health Care System
   C. Evolution of provider and payer network requirements
   D. Align with national regulatory and organizational quality standards
   E. Harmonization with accreditation programs where possible
   F. A-D
   G. All of the above

2. The Specialty Accreditation Process includes
   A. Application
   B. Letter of Agreement and BAA
   C. Document Assessment
   D. On-site Survey
   E. All of the above

3. True or False: The four Specialty Pharmacy Practice Standards domains for CPPA are:
   - Organizational Infrastructure
   - Access to Medications
   - Clinical and Patient Management Services
   - Continuous Quality Improvement
1. What elements contribute to the Value of Accreditation
   A. National trend toward accreditation of all health care organizations and programs
   B. Changing payment structures in US Health Care System
   C. Evolution of provider and payer network requirements
   D. Align with national regulatory and organizational quality standards
   E. Harmonization with accreditation programs where possible
   F. A-D
   G. All of the above

2. The Specialty Accreditation Process includes
   A. Application
   B. Letter of Agreement and BAA
   C. Document Assessment
   D. On-site Survey
   E. All of the above

3. True or False: The four Specialty Pharmacy Practice Standards domains for CPPA are:
   - Organizational Infrastructure
   - Access to Medications
   - Clinical and Patient Management Services
   - Continuous Quality Improvement
THANK YOU

Questions?

For more information contact:

www.pharmacypracticeaccredit.org

lmahaney@pharmacypracticeaccredit.org

608.444.7847