Automation Achievements and Value of Capabilities within the Specialty Pharmacy Arena - Accreditation

May 24, 2017

Lynnae Mahaney BSPharm, MBA, FASHP
AGENDA

- Background: ‘ABOUT’ CPPA®
- Value of pharmacy practice accreditation in the healthcare system and in pharmacy
- Specialty pharmacy accreditation process/program
- Specialty pharmacy capabilities to improve and enhance patient outcomes
  - Specialty Indicators for Value
  - Specialty Pharmacy Practice Challenges – Real Time
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
A UNIQUE ACCREDITOR

- 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
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 VALUE

VALUE

Health outcomes achieved per dollar spent over the care cycle
ACCREDITATION VALUE

- Trend toward accreditation of all health care organizations and programs
  - Demand for proof of competency/value
  - Emphasizing comprehensive and continuous medical care
  - Goal of maximizing health outcomes
  - Consistent level of services and improved patient outcomes
- Align with regulatory and organizational quality standards – national/international
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
‘This focus on patient outcomes and additional services by (specialty) pharmacies mirrors the move Medicare is making toward value based care for reimbursements.’

Marc O’Connor  COO of Curant Health

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’
- Demonstrate our investment in providing innovative patient care services
- ‘Lead the way in advocating for reimbursement’
  - ‘future where patients are incentivized to use providers that produce the best outcomes’
  - ‘factor in to how payers establish their networks’
- 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 PROGRAM

- Application, Letter of Agreement, BAA, payment
- Submission of Document Assessment
- Pharmacist surveyor Document Review/Report
- 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
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
SITE SURVEY

- Unannounced visit
  - Scheduled headquarters visit for multisite practices

- 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
ACCREDITATION REPORT

- A letter with report 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.
ACCREDITATION STATUS DECISION

- Accreditation Oversight Committee (AOC) reviews Accreditation Report and Plan of Action
- AOC recommends pharmacy practice accreditation status to the CPPA Board of Directors
- Notification to practice of final decision.
SPECIALTY PHARMACY PRACTICE - MODELS OF CARE

- CPPA Current sites:

- PantheRx

- Cleveland Clinic
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>$233</td>
<td>$41</td>
</tr>
<tr>
<td>2015</td>
<td>$364</td>
<td>$266</td>
</tr>
<tr>
<td></td>
<td>$98</td>
<td>$168</td>
</tr>
<tr>
<td>2020</td>
<td>$483</td>
<td>$270</td>
</tr>
<tr>
<td></td>
<td>$212</td>
<td>$258</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.

The Growth of Specialty Pharmaceuticals

Sources: ExpressScripts Drug Trend Report, IMS Health Forecasts, and Walgreens State of the Industry Report
ACCREDITATION STANDARDS:

INDICATORS FOR VALUE
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
Domain I  Organizational Infrastructure
Domain II  Access to Medications
Domain III  Clinical Management Services
Domain IV  Continuous Quality Improvement
Goal Standards
ACCREDITATION STANDARDS:
INDICATORS FOR VALUE

- Patient care delivery and management
- Care Quality

*Practice Models which differentiate themselves through clinical capabilities and quality of care*
Facilitates patient enrollment and management through patient and provider communication and care coordination.

Communicates with healthcare providers to facilitate coordination of patient care.

Maintains a comprehensive patient profile for all patients.
STANDARD: INDICATOR FOR VALUE

CLINICAL MANAGEMENT SERVICES

- Provides and monitors pharmacy patient case management services.
  - 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
STANDARD: INDICATORS FOR VALUE

CLINICAL MANAGEMENT SERVICES CONT.

• 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
    • Focus on patient clinical outcomes activities specific to each therapeutic area
      ✓ at initiation of treatment
      ✓ with each refill
    • Best practices in each therapeutic area
STANDARD: INDICATORS FOR VALUE

CLINICAL MANAGEMENT SERVICES CONT.

- Provides and monitors pharmacy patient case management services.
  - 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
STANDARD: INDICATOR FOR VALUE

OTHER CLINICAL MANAGEMENT SERVICES

- Modifies patient case management based on patient-specific factors when needed.

- 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.

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

- Practice prohibits the use of refill protocols whereby specialty medications are filled without direct patient contact.
STANDARD: INDICATOR FOR VALUE

PATIENT CONSULTATION AND EDUCATION

- Anticipated duration of treatment
- Expected outcome and clinical goals of therapy
- Adverse event management
- Time to benefit
- Role of adherence and persistence in expected outcome
- Managing adverse events
STANDARD: INDICATOR FOR VALUE
PATIENT SAFETY AND COMPLIANCE

- Compliance with manufacturer and payer requirements
  - Financial assistance co-pay rules
  - Targeted counseling
  - REMS compliance
  - Targeted formulary interventions
  - Adherence improvement
- Integration with manufacturer HUB services
Documentation and reporting to payers and manufacturers

- Coordination of benefits investigation with prescriber including
  - alternate formulary
  - preferred therapy
  - step-therapy requirements for specific therapeutic and medication classes

Data reporting validation prior to submission
STANDARD: INDICATOR FOR VALUE
QUALITY IMPROVEMENT – OUTCOMES AND METRICS

FOCUS

How does the pharmacy improve their performance?
“If you can’t measure it, you can’t manage it.”

W. Edwards Deming
STANDARD: INDICATOR FOR VALUE
QUALITY IMPROVEMENT – OUTCOMES AND METRICS

- Quality-related events
- Cost avoidance
- MPR, PDC, MPR/PDC by therapeutic class
- Annual persistence reporting by therapeutic class
- Pharmacist interventions and impact
- Call center performance
- Patient and provider satisfaction
- Complaint outcomes
- Prescription error rates
- Serious medication-related injury
- Patient volume by disease state protocol
- Quality improvement projects and their outcomes
- Data report accuracy
“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
SPECIALTY PHARMACY PRACTICE
MEETING THE ACCREDITATION STANDARDS

‘REAL TIME’ CHALLENGES
SPECIALTY PHARMACY PRACTICE CHALLENGES

REPORTING REQUIREMENTS

- Benefits Investigation
  - Medical and pharmacy benefit
    - Prior authorization
  - Formulary status
  - Specialty pharmacy practice selection
  - Route of medication delivery
SPECIALTY PHARMACY PRACTICE CHALLENGES
REPORTING REQUIREMENTS

- Benefits Investigation cont.
  - Financial assistance enrollment
  - Payment(s) clearance
  - Integration with manufacturer HUB services
  - BI Documentation and communication with patient and physician
Targeted counseling and communication

- Initiation of therapy
- Timing delivery of medications
- Timing of refills coordinate with key treatment intervals
  - e.g. provider teaching appointments, chemotherapy cycling, patient follow-up appointments

- Adherence improvement
SPECIALTY PHARMACY PRACTICE CHALLENGES

DEMONSTRATION OF PATIENT OUTCOMES

- Quality-related events
- Cost avoidance
- MPR, PDC, MPR/PDC by therapeutic class
- Annual persistence reporting by therapeutic class
- Pharmacist interventions and impact

- Prescription error rates
- Serious medication-related injury
- Quality improvement projects and their outcomes
- Data report accuracy
Payer Requirements

- Targeted formulary interventions
- Data reporting pursuant to inclusion in third-party payer contracts/networks
  - quality metrics
  - cost avoidance
SPECIALTY PHARMACY PRACTICE CHALLENGES
REPORTING REQUIREMENTS

- Manufacturer Requirements
  - REMS compliance and documentation
  - Automation of adherence and outcomes data into reimbursement process (outcomes-base contracts)
CPPA SEAL OF ACCREDITATION
Accreditation of Pharmacy Practice Across the Entire Medication Use Process
THANK YOU
Questions?
For more information contact:
www.pharmacypracticeaccredit.org
XXRSolutions@gmail.com
608.444.7847