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Introduction
Clinical Pharmacists play an important role in the provision of comprehensive medication management to Tennesseans. Clinical Pharmacists have a unique role and skill set to identify medication management issues thereby promoting the safe and effective use of medications. This document has been created by the Tennessee Pharmacists Association in an effort to facilitate the initiation of collaborative practice agreements between clinical pharmacists and prescribing clinicians with a focus on caring for patients receiving complex medication regimens.

1. Definition of Clinical Pharmacy Practice within a CPA
The American College of Clinical Pharmacy (ACCP) defines clinical pharmacy as the area of pharmacy concerned with the science and practice of rational medication use. Clinical pharmacists have obtained advanced training so that they possess the qualifications necessary to provide team-based, direct patient care. With the creation of the collaborative practice agreement (CPA), clinical pharmacists may advance to providers with expertise in comprehensive medication management (CMM). This advancement should focus on improved clinical patient outcomes associated with various chronic disease states in the ambulatory care setting.

A. Definition of Clinical Pharmacy Services
Clinical pharmacists in a CPA work with a defined scope of practice (SOP) to independently perform CMM for patients. The clinical pharmacist with a defined SOP within a CPA provides direct patient care and functions at the highest level of clinical practice. They work with a high level of autonomy and independent decision-making within the parameters of their SOP as defined by the individual facility or provider with whom the CPA is established. Pharmacists working in this capacity can initiate, modify or discontinue medications, order and review laboratory tests, make referrals to other medical providers and serve as a conduit to increased specialized pharmacotherapy care between patients’ normal primary care provider (PCP) appointments.

Clinical pharmacists should focus on providing CMM within a CPA and address the totality of the patient’s pharmacotherapy needs. Common clinical pharmacy comprehensive medication services include but are not limited to:

1. Anticoagulation
2. Diabetes
3. Hypertension
4. Hyperlipidemia
5. Pain Management
6. Heart Failure
7. Asthma/COPD
8. Smoking Cessation
B. **Initiation of a Scope of Practice for the Clinical Pharmacist practicing within a CPA**

The initiation of scope, credentialing, and professional practice requirements for the clinical pharmacist practicing within a CPA should be established and individualized based on the health care site and/or the provider establishing the CPA. This process should follow site and area-specific credentialing practices. The SOP should allow for initiation, modification, discontinuation of medications and necessary monitoring authorities for the provision of CMM. (Attachment A-Scope of Practice/CPA Examples)

C. **Establishment of Competencies**

All clinical pharmacists initiating a SOP within a CPA should have appropriate competency assessment of the critical duties outlined in their scope. This ensures the provider or the facility with whom the CPA is entered into can determine the clinical pharmacist's readiness and abilities for their position.

There are a variety of ways to determine the individual pharmacist’s competency for establishing scope of practice, including an evaluation of past education and experience. The evaluation of competency may include one or more of the following items:

- Completion of a PGY1 Pharmacy Practice Residency
- Completion of a PGY2 Specialty Pharmacy Residency, in ambulatory care or areas with emphasis in primary care disease states/conditions
- Completion of a Post-Graduate Fellowship with an emphasis in primary care disease states/conditions
- Board Certification in Ambulatory Care or Pharmacotherapy (BCACP or BCPS)
- Experience providing direct patient care under a scope of practice (or collaborative practice agreement) in the primary care setting
- Evaluation through a Core Competency Assessment Form developed by the individual provider or facility with whom the CPA is being initiated (See Attachment B).
- Completion of a mentorship with a practitioner in a similar practice

D. **Professional Practice Evaluations**

The Professional Practice Evaluation (PPE) is an organized process carried out by an individual health care practitioner or select committee of healthcare professionals to evaluate the performance of other professionals in an ongoing manner. The PPE process of the pharmacist operating within a CPA should become an important part of quality assurance in the future for any practice site where a CPA is initiated. The PPE program should include both initial, focused professional practice evaluations (FPPE) and ongoing professional practice evaluations (OPPE), as indicated by defined triggering events. When evaluating the quality of care provided by clinical pharmacists practicing within a CPA, it is important that the PPE program evaluates the types of patients and spectrum of diseases and conditions seen by the clinical pharmacist. In recent years the Joint Commission has developed guidelines regarding
the use of PPEs. Many payers and other accrediting bodies have also mandated PPE, which has led to its use by many health systems as their primary mechanism for quality improvement. Typically directed at the observation of a particular medical staff member, the Joint Commission has developed six core areas of measurement:

- patient care
- medical/clinical knowledge
- practice-based learning and improvement
- interpersonal and communication skills
- professionalism
- systems-based practice

The Joint Commission recommends that the PPE process be developed and overseen by the health system or the individual provider with whom the pharmacist has initiated a CPA. Examples can be seen in Attachment C.

2. Patient Care Delivery by a Pharmacist within a CPA

A. Comprehensive Medication Management

Comprehensive Medication Management (CMM) encompasses the medication management of patients with chronic disease states. At a minimum, the clinical pharmacist should have a SOP to provide medication management for the following “core” disease states: anticoagulation, hypertension, hyperlipidemia, and diabetes. The goal is for the clinical pharmacist to expand his or her CMM SOP to include not only the “core” disease states, but, also, any additional chronic disease states, including but not limited to pain, heart failure, mental health, hepatitis C, hypothyroidism, gout, COPD, contraception, asthma, smoking cessation, and osteoporosis.

B. Modalities of Comprehensive Medication Management

i. Face to Face

A traditional direct patient care visit is conducted in the outpatient setting between a pharmacist and a patient. Face-to-face visits are best suited for new patients, patients requiring multiple complex interventions, patients with hearing or cognitive impairments, or patients who are difficult to reach by phone.

ii. Non Face-to-Face

A non-traditional direct patient care visit can be conducted over the telephone or by other electronic medium between a pharmacist and a patient. Various forms of non-telephonic visits currently exist and continue to be developed. Examples include commercial video conferencing programs (Skype™, FaceTime, etc.) as well as telemedicine programs designed for specific healthcare system use. Pharmacist-driven telephonic clinics contribute to the management of the complex patient who requires frequent medication adjustments, has consistent phone access, and prefers to limit trips to the medical center. Non face-to-face care is a core component of CMM; therefore, thorough documentation remains vital.
C. Methods of Referral

Clear and standardized processes for referral of patients to the clinical pharmacist should be established within the CPA. The most important thing to ensure is that the appropriate patient is referred to the clinical pharmacist for management. The infrastructure should always exist for the clinical pharmacist to refer to higher levels of care as needed. The referral method should be simple and avoid causing extra work for the referring provider or the clinical pharmacist. For all patients managed by the clinical pharmacist, it is important to develop guidance for discharge in case of frequently missed visits, failure to follow instructions, or continued demonstration of poor medication adherence despite intensive efforts by the clinical pharmacist. Continuity of care with the primary care provider should always be consistent.

Referrals for care from providers or team members to the clinical pharmacist can be accomplished through any of the following venues for CMM and/or disease management:

i. Formal consults

ii. Emails

iii. Patient self-referral

iv. Nurse referral (i.e. patients identified at team meetings such as huddles or interdisciplinary meetings)

v. Provider referral

vii. Population Management (i.e. patients identified by primary care that require follow-up based on a database such as the clinical dashboard)

D. Involvement of Trainees

Clinical pharmacists working within a CPA should advocate for the profession and work to spread knowledge of CMM to other pharmacists and providers. Precepting students, residents, and fellows or mentoring other clinical pharmacists within the CPA framework is strongly encouraged.

3. Business Models by Pharmacists within a CPA

Interests should be aligned for providers, patients, and insurers. Clinical pharmacists practicing within a CPA endeavor to achieve the “triple aim” as defined by The Institute for Healthcare Improvement (IHI): better patient care experience, better population health, and less per capita cost. Considering that 80% of patients leave a provider’s appointment with a prescription, pharmacists are uniquely positioned to improve healthcare quality and cost. There is an abundance of data showing improvements in outcomes, cost, or both when pharmacists are utilized in a variety of practice settings. Both cost avoidance and income-generating models may generally be considered as successful business models. While pharmacists are not currently recognized as providers under Medicare Part B, income can be generated through billing for services.

A. Income Generating

i. Incident-to billing: billing occurs for the clinical pharmacist under the physician’s NPI number who is physically present in the same office
ii. **Self-insured employer disease state programs**
   a) Clinical pharmacist or provider sets up individual contracts to see patients on a fee for service or cost avoidance model
   b) Clinical pharmacist or provider sets up individual contract to see patients on a per member per month to provide additional services
      1. Dedicated nurse educator
      2. Technology (Cardiocom, etc.)

iii. **Comprehensive Medication Management: use of specific CPT codes as a part of Medicare Part D**
   a) Community pharmacy
   b) Ambulatory care clinics, if contracted with the MTM program
      1. Third-party insurer contracts initiated specifically for clinical pharmacy services
      2. Diabetes Self-Management Education
         a) American Association of Diabetes Educator (AADE) or American Diabetes Association (ADA) accredited programs
            1. National Standards for Diabetes Self-Management Education
            2. Need an advisory panel of educators, coordinator, healthcare provider, community member
            3. Quality Improvement Plan
            4. Need ability to track progress of patient including attainment of goals or other quality metrics
               i. Both individual and group educational sessions
               ii. Many diabetes education curricula available for use
               iii. Can be multidisciplinary
         b) Insulin pump training
            1. Certification with the insulin pump company requires:
               i. Taking a certification exam
               ii. Being observed by certified product trainer for first insulin pump patient
            2. Work under an existing contract with a physician practice or an individual contract with an insulin pump company
   3. Professional continuous glucose monitor placement
      a) Any certified staff member can perform the insertion
      b) Monitoring insertion is a billable service with most insurers
      c) Data interpretation can only be billed by physicians, physician assistants, or nurse practitioners
   4. Injectable Long Acting Anti-Psychotic & Contraception medications
a) IM antipsychotic & contraception injections under the supervision of providers

5. Immunizations

6. Biometric Screening
   a) Partner with employers/institutions for a flat fee for service

7. Chronic Care Management
   a) Medicare beneficiaries with two or more chronic conditions
   b) Requires patient consent and 20 minutes of telephonic patient care
   c) A comprehensive care plan is created for all health issues and typically includes, but is not limited to, the following elements:
      1. Problem list
      2. Expected outcomes and prognosis
      3. Measureable treatment goals
      4. Symptom management
      5. Planned interventions & responsible person for each intervention
      6. Medication management
      7. Community/social services ordered
      8. A description of how services of agencies and specialists outside the practice will be directed/coordinated
      9. Schedule for periodic review and needed revisions of the care plan

8. Annual Medicare Wellness Visits
   a) No cost to patients
   b) Personalized prevention help plan
   c) Billed under the physician
   d) Annual wellness visits include:
      1. Health risk assessment
      2. A review of the patient’s medical and family history
      3. Developing or updating a list of current providers and prescriptions
      4. Height, weight, blood pressure, and other routine measurements
      5. Detection of any cognitive impairment
      6. Personalized health advice
      7. A list of risk factors and treatment options for the patient
      8. A screening schedule/checklist for appropriate preventive services.

<table>
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<tr>
<th>Billing Options</th>
<th>CPT Billing Codes</th>
<th>Practice Setting</th>
<th>Medicare Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes Self-Management Training</td>
<td>G0108 (individual visit)</td>
<td>All</td>
<td>G0108: $53.70</td>
</tr>
<tr>
<td></td>
<td>G0109 (group visit)</td>
<td></td>
<td>G0109: $14.30</td>
</tr>
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</table>
### (DSMT)

<table>
<thead>
<tr>
<th>Incident to physician: office visit</th>
<th>Physician- and hospital-based outpatient clinic</th>
<th>99211: $20.02</th>
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</thead>
<tbody>
<tr>
<td>Incident to physician: Transitional Care Management (TCM)</td>
<td>Physician- and hospital-based outpatient clinic</td>
<td>99496: $161.25-232.41 99495: $111.91-165.54</td>
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<tr>
<td>Medication Therapy Management</td>
<td>Pharmacy and self-insured employers, contract health plan</td>
<td>Variable</td>
</tr>
<tr>
<td>CMS Annual Wellness Visit</td>
<td>Physician-and hospital-based outpatient clinic</td>
<td>G0438: $173.41 G0439: $117.28</td>
</tr>
<tr>
<td>Chronic Care Management</td>
<td>Physician- and hospital-based outpatient clinic</td>
<td>Approximately $40 per patient per month</td>
</tr>
</tbody>
</table>

### B. Cost Avoidance

#### i. Transitions of care

a) These services are for an established patient who requires moderate or high complexity medical decision making during transitions from an inpatient facility to the patient’s home, or other community settings. In order to bill for these services, non face-to-face services must occur within 2 business days of discharge, and the patient must have a face-to-face visit with a physician, physician assistant, or nurse practitioner within 14 days of discharge. The non face-to-face service can be provided by a qualified healthcare provider, including a clinical pharmacist; however, all the billing is linked to the face-to-face visit. Goals of this service would be to decrease hospital readmissions, decrease medication errors, and increase medication adherence.

#### ii. Surrogate marker improvement

a) Better A1c, blood pressure, cholesterol, etc.
b) Cost avoidance can be extrapolated based on improved metrics
iii. *Accountable Care Organization (ACO)*  
   a) Quality measures / Star measures  
   b) Lower cost medication alternatives  

iv. *Patient-Centered Medical Home (PCMH)*  
   a) Work within an interdisciplinary team  
   b) Adjust and refill medications; make therapeutic substitutions  
   c) Patient education  
   d) Increase medication adherence  
   e) Decrease medication errors  

4. **Outcome Evaluation of Pharmacy Services within a CPA**

A. **Documentation**

Documentation of clinical pharmacy services is important for meeting quality improvement, patient care, and legal requirements, as well as ensuring safe transitions of care and appropriate justification for hiring needs. Methods of documentation vary based on practice environment, but should all achieve the end goal of evaluating outcomes of services provided. When documenting in the medical record, full notes, such as CMM, MTM, SOAP-style encounters, or abbreviated notes, such as pharmacokinetic consults, telephone call documentation or education consults, may be utilized depending on the service provided. Although the specifics may change, all clinical pharmacists should document patient encounters in the permanent medical record, including all appropriate information necessary for quality care provision. As it is well-understood by medical professionals, a SOAP format may be considered when appropriate. Appropriate documentation may also include intervention logs, whether site specific or federal/state-run. Practitioners may tally their contributions to care in a variety of ways; many barriers exist to standardized documentation due to differing facility requirements. Clinical pharmacists should implement an appropriate system for tracking pharmacist contributions, including any information necessary to ensure patient safety and justify/expand pharmacy services.

In order to evaluate outcomes of pharmacy services, documentation should adhere to best practices for both cost savings and clinical outcomes. Guidelines for best practices have been set forth by several overarching pharmacy organizations, including the Patient-Centered Primary Care Collaborative (PCPCC), ACCP, and the National Association of Boards of Pharmacy (NABP).

**Core elements for documentation include:**

- Documentation of the complete medication experience  
- Medication history  
- Active problem list with supporting data for indication of medication therapy
TPA Collaborative Practice Agreement Guidance

- Full assessment of medication therapy including medication related needs and drug therapy problems
- Specific plan including interventions, goals of therapy, monitoring, appropriate follow-up, and patient education provided.

Examples and recommendations of documentation are located in Attachment D.

B. Evaluation of Outcomes

Outcome evaluations have a central role in providing justification for clinical pharmacy services. Outcomes measures should be comprehensive and encompass clinical, humanistic, and economic areas of research. Pharmacists should work with the collaborating providers to establish what outcomes are beneficial to collect. In meeting with the collaborating providers, all parties should agree on what outcomes to be collected. These outcomes should align with the organization’s goals and quality standards. In addition to choosing outcomes that align with the organization’s goals and quality standards, pharmacists should also consider the feasibility of collecting those outcomes. Outcomes can be utilized to compare before and after clinical pharmacy services implementation. Additionally, benchmarks for outcomes can be set, and clinical pharmacy services can be measured with regards to meeting these benchmarks. While measuring outcomes is important, consider how collecting these outcomes will fit into the workflow. Achievement of outcomes measures holds pharmacists accountable and can provide justification for further clinical pharmacy services.

In addition to measuring outcomes for internal use, clinical pharmacists working within the CPA should measure outcomes for external purposes. This may include participating in research and scholarship to promote the advancement in processes of pharmacist-provided care to achieve optimal patient care outcomes that indicate quality health care.

Described below are examples of clinical, humanistic, and economic outcomes and may be useful for pharmacists to measure within a CPA. Some examples of outcome measures that have demonstrated the value of clinical pharmacists include, but are not limited to, chronic disease state management and comprehensive medication management. These services can be delivered in a variety of settings, such as community pharmacies, patient-centered medical homes, federally qualified healthcare centers, hospital-based/systems-based clinics, and US Department of Veteran Affairs clinics among others. A 2011 report by the Office of the Chief Pharmacist to the U.S. Surgeon General summarized outcomes of clinical pharmacy services in a variety of practice settings and disease states demonstrating clinical pharmacists’ value. These findings are reported in Appendix B, titled “Outcomes Repository Spreadsheet.” The report is available at: https://www.dmhc.ca.gov/Portals/0/AbouttheDMHC/RCI/PromisingBestPractices/20
Tennessee (TN) pharmacists currently working within a CPA have provided some outcomes evaluations for this paper. This list is a sampling, rather than a comprehensive representation of all documented clinical pharmacy service outcomes that have been demonstrated in TN. These include, but are not limited to:

i. **Humanistic Outcomes**

   * An evaluation of patients receiving diabetes management by clinical pharmacists within the PCMH model demonstrated patient satisfaction of the care that they received from pharmacists

Humanistic outcomes are patient reported outcomes (PROs) that measure patient (or surrogate) perspectives concerning a variety of topics such as physical, psychological or social functioning. More broadly, these can include patient health status and satisfaction measures. Humanistic outcomes may also include provider-generated measures such as satisfaction with clinical pharmacist services. Instruments used to measure humanistic outcomes may be generic (i.e., contain domains relevant to a broad population) or disease/population-specific. Many tools are available in varying length. It is important for clinical pharmacists to understand the targeted population, administration format, logistics, and copyright status prior to use. In addition, clinical pharmacists should learn about the reliability, validity, domains measures and accurate interpretation of PRO results before employing the instrument.

**Examples of generic instruments include:**

a) Short Form Health Survey (SF-36) - measures health status and outcomes from the patient's point of view  
b) Sickness Impact Profile (SIP) - measures quality of life and level of dysfunction that results from disability or illness  
c) EuroQOL (ED-5Q) - measures generic health status and quality of life  
d) COOP/WONCA charts - measures functional health status in primary care  
e) Duke Health Profile (DUKE) - measures functional health status and health-related quality of life during a one-week period for adults 18 years or older  
f) Nottingham Health Profile - measures patient's perceived emotional, social and physical health problems

**Examples of disease/population-specific instruments include:**

a) Diabetes  
   1. Problem Areas in Diabetes (PAID)
2. Diabetes Treatment Satisfaction Questionnaire (DTSQ)
3. Diabetes-39 Questionnaire (D-39)

b) Depression
   1. Patient Health Questionnaire (PHQ-9)
   2. General Health Questionnaire (GHQ)
   3. Beck Depression Inventory (BDI)

c) Asthma/COPD
   1. Chronic Respiratory Disease Questionnaire (CRDQ)
   2. Adult Asthma Quality of Life Questionnaire (AQLQ)

d) Cardiovascular Disease
   1. MacNew Heart Disease Health-related Quality of Life (MacNew)
   2. Seattle Angina Questionnaire (SAQ)

e) Pain
   1. Brief Pain Inventory

ii. Clinical outcomes

- A telehealth MTM program performed in between face-to-face clinical pharmacy visits achieved greater A1C reductions in patients with poorly controlled Type 2 Diabetes vs. patients who only received face to face clinical pharmacy visits.
- Clinical pharmacy diabetes management has resulted in mean A1C difference of 1.39% reduction from baseline, 42-62% of patients achieving A1C <7%, as well as reductions in BMI, weight, cholesterol markers, and blood pressure readings. Clinical pharmacy diabetes education alone without medication interventions has been shown to also be effective, achieving a mean A1C difference of 1.09% reduction from baseline.
- Clinical pharmacists conducting face-to-face MTM visits in an ambulatory care setting improved diabetes medication adherence, as well as reductions in A1C and LDL.

Clinical outcomes are measures of a patient’s health status. Clinical outcomes should focus on the health status of an individual patient as well as the population and how these have changed based on interventions to care. When selecting clinical outcomes to collect, identify those that will be most important to the organization. Examples of clinical outcomes include healthcare utilization including hospital admission and re-admission rates, emergency department visits, etc. Other clinical outcomes include physiologic outcomes including blood pressure, cholesterol levels, hemoglobin A1cs, etc. Additionally, pharmacists can measure outcomes related to appropriate medication use such as medication adherence, compliance with clinical practice guideline recommendations, safe use...
of medications in elderly patients, and identification and resolution of medication-related problems.

Multiple organizations have defined quality measures for healthcare providers. The Healthcare Effectiveness Data and Information Set (HEDIS) is a set of measures that has been developed by National Committee for Quality Assurance. Over 90% of healthcare plans, including Medicare, use HEDIS measures to evaluate quality of care for patients. HEDIS measures measure quality of care provided by healthcare providers, not specific to pharmacist-provided care but pharmacists can have an impact on these measures. Another example of quality measures is the Medicare Star Ratings. Medicare Star Ratings are used to evaluate Medicare plans that provide prescription coverage, including Medicare Advantage plans and Part D plans. While these ratings evaluate patient satisfaction with the plan, they also now include quality measures looking at adherence and appropriate use of medications. For example, one Star Rating states, “Percent of plan members with a prescription for diabetes medication who fill their prescription often enough to cover 80% or more of the time they are supposed to be taking the medication.” While developed to evaluate Medicare plans, with the addition of measures focused on adherence and appropriate medication use, pharmacists can have an impact on these measures as well.


With its goal to improve medication management and use, PQA has also defined quality measures which are available from: http://pqaalliance.org/measures/default.asp.

Additional examples of quality ratings are provided by the Agency for Healthcare Research and Quality (AHRQ). AHRQ provides the National Quality Measures Clearinghouse which provides thousands of quality measures in a free and searchable database available from: https://www.qualitymeasures.ahrq.gov/.

### iii. Economic Outcomes

- Clinical pharmacists embedded within Family Medicine clinics used a software program to document 1318 interventions over 7 months. The estimated dollars saved was calculated at $1,224,100 or $929 per intervention

Economic outcomes represent payer, societal, and stakeholder perspectives and may include, but are not limited to, reduction of cost per member per month, hospitalization and emergency room visits, pharmacy services return on investment, and revenue generation. It is important for clinical pharmacists to document
interventions in order to quantify cost savings and economic impact toward patient care. One method used to measure the value of the clinical pharmacist is by calculating the return on investment (ROI). Web-based resources designed to calculate economic outcomes of the clinical pharmacist could be purchased. Examples include:

a) Clinical Measures

b) Quantifi

Future research should be focused on demonstrating further clinical, humanistic, and economic evidence for pharmacy services within the CPA and on providing additional guidance for establishing these services in a comprehensive fashion. Some examples of future areas of research, as supported by national pharmacy associations including but not limited to ACCP, PCPCC, and the American Society of Health-System Pharmacists (ASHP), include:

i. Predictors of medication-related problems

ii. Clinical and Economic Value of CMM in the PCMH/ACO
   a) Clinical outcomes include but are not limited to medication adherence rates, number of adverse drug events prevented or resolved, and achievement of chronic disease state goals
   b) Economic outcomes include but are not limited to reduction of cost per member per month, hospitalization and emergency room visits, pharmacy services return on investment, and revenue generation.
   c) Humanistic outcomes include but are not limited to Health-Related Quality of Life (HR-QoL), patient and provider satisfaction, and personal productivity.

iii. Most effective and efficient model of care to provide Collaborative Drug Therapy Management (CDTM) and CMM
APPENDIX A

CPA/Scope of Practice Examples

- Attachment 1
- Attachment 2
- Attachment 3
- Attachment 4
APPENDIX B

Example of Initial Competency Evaluation

- Attachment 5
APPENDIX C

Examples of Professional Practice Evaluation FPPE/OPPE Documents

- Attachment 6
- Attachment 7
APPENDIX D

Examples and Recommendations of Clinical Pharmacy Documentation

- Attachment 8
- Attachment 9
- Attachment 10
- Attachment 11