

# A Systematic Approach to Consultant Pharmacy Services

Introduction to Regulatory Requirements with  
Related Policies and Procedures

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# **OVERVIEW OF CONSULTANT RESPONSIBILITIES**

## **RESPONSIBILITIES OF A CONSULTANT PHARMACIST**

**The responsibilities of a consultant Pharmacist vary considerably based on the type of practice setting**

### **I. The Four Primary Responsibilities in all practice settings include:**

- 1. Drug Regimen Review (D.R.R.) (now called Medication Regimen Review (M.R.R.))**
- 2. Medication Administration Review (Common Med Errors)**
- 3. Review of Charting Documentation**
- 4. The Storage of Medication ( Physical Inspection)**

### **II. Other Common Responsibilities of the Consultant Pharmacist**

5. Education
6. Drug interactions
7. Adverse Drug Reactions
8. Drug allergies
9. Drug usage in facility (Rx's/Patient/Month)
10. Antipsychotic Drug Use and Dosage Reductions
11. Benzodiazepine Use and Dosage Reduction
12. Tracking supporting diagnoses for each drug in use
13. Drug Use Evaluation (DUE) studies
14. Development of policies and procedures
15. Development of Treatment Protocols
16. Committee involvement for P & T issues, quarterly meetings and Infection Control
17. Identifying Pharmacy service issues that may negatively impact patient outcomes
18. Preparing the consultant report to the facility
19. Tracking the nursing and physician responses to consultant comments.
20. Formulary compliance for product shifting (Therapeutic Interchange)
21. Monitoring patient outcomes

### **III. Areas of Responsibility That Lend Themselves To Computerization**

1. Chart Review of Drug Therapy (DRR)
2. Preparation of monthly Consultant Report
3. Tracking the nursing and physician responses to consultant comments.
4. Drug interaction scanning
5. Drug Allergy scanning
6. Review of drug usage in facility (Rx's/Patient/Month)
7. Antipsychotic Drug Use and Dosage Reductions

8. Benzodiazepine Use and Dosage Reduction
9. Tracking supporting diagnoses for each drug in use
10. Drug Use Evaluation (DUE) studies
11. Formulary compliance for product shifting
12. Monitoring patient outcomes
13. Conducting industry research

#### ***IV. THE CONSULTANT PHARMACIST IN A NURSING HOME***

**TAKEN FROM F425 Rev Nov 2016**

##### ***SERVICES OF A LICENSED PHARMACIST***

The facility is responsible for employing or contracting for the services of a pharmacist to provide consultation on all aspects of pharmaceutical services. The facility may provide for this service through any of several methods (in accordance with state requirements) such as direct employment or contractual agreement with a pharmacist. Whatever the arrangement or method employed, the facility and the pharmacist identify how they will collaborate for effective consultation regarding pharmaceutical services. The pharmacist reviews and evaluates the pharmaceutical services by helping the facility identify, evaluate, and address medication issues that may affect resident care, medical care, and quality of life.

The pharmacist is responsible for helping the facility obtain and maintain timely and appropriate pharmaceutical services that support residents' healthcare needs, that are consistent with current standards of practice, and that meet state and federal requirements. This includes, but is not limited to, collaborating with the facility and medical director to:

- Develop, implement, evaluate, and revise (as necessary) the procedures for the provision of all aspects of pharmaceutical services;
- Coordinate pharmaceutical services if and when multiple pharmaceutical service providers are utilized (e.g., pharmacy, infusion, hospice, prescription drug plans [PDP])
- Develop intravenous (IV) therapy procedures if used within the facility (consistent with state requirements) may include determining competency of staff, facility used IV admixture procedures that address sterile compounding, dosage calculations, IV pump use, and flushing procedures;
- Determine (in accordance with or as permitted by state law) the contents of the emergency supply of medications and monitor the use, replacement, and disposition of the supply;
- Develop mechanisms for communicating, addressing, and resolving issues related to pharmaceutical services;
- Strive to assure that medications are requested, received, and administered in a timely manner as ordered by the authorized prescriber (in accordance with state requirements), including physicians, advanced practice nurses, pharmacists, and physician assistants;
- Provide feedback about performance and practices related to medication

- administration and medication errors;
- Participate on the interdisciplinary team to address and resolve medication-related needs or problems;
- Establish procedures for: conducting the monthly medication regimen review (MRR) for each resident in the facility:
  - addressing the expected time frames for conducting the review and reporting the findings, addressing the irregularities,
  - documenting and reporting the results of the review (See F428 for provision of the review.);
- Establish procedures that address medication regimen reviews for residents who are anticipated to stay less than 30 days or when the resident experiences an acute change of condition as identified by facility staff.

**NOTE:** Facility procedures should address how and when the need for a consultation will be communicated, how the medication review will be handled if the pharmacist is off-site, how the results or report of their findings will be communicated to the physician, expectations for the physician's response and follow up, and how and where this information will be documented.

In addition, the pharmacist may collaborate with the facility and medical director on other aspects of pharmaceutical services including, but not limited to:

- Developing procedures and guidance regarding when to contact a prescriber about a medication issue and/or adverse effects, including what information to gather before contacting the prescriber;
- Developing the process for receiving, transcribing, and recapitulating medication orders;
- Recommending the type(s) of medication delivery system(s) to standardize packaging, such as bottles, bubble packs, tear strips, in an effort to minimize medication errors;
- Developing and implementing procedures regarding automated medication delivery devices or cabinets, if automated devices or cabinets are used, including: the types or categories of medications, amounts stored, location of supply, personnel authorized to access the supply, record keeping, monitoring for expiration dates, method to ensure accurate removal of medications and the steps for replacing the supply when dosages are used, and monitoring the availability of medications within the system;
- Interacting with the quality assessment and assurance committee to develop procedures and evaluate pharmaceutical services including delivery and storage systems within the various locations of the facility in order to prevent, to the degree possible, loss or tampering with the medication supplies, and to define and monitor corrective actions for problems related to pharmaceutical services and medications, including medication errors;
- Recommending current resources to help staff identify medications and information on contraindications, side effects and/or adverse effects, dosage levels, and other pertinent information; and
- Identifying facility educational and informational needs about medications and providing information from sources such as nationally recognized organizations to the facility staff, practitioners, residents, and families.

**NOTE:** This does not imply that the pharmacist must personally present educational programs.

<b>DEFINITION OF COMMONLY USED TERMS IN LONG TERM CARE</b>	
<b>TERM</b>	<b>DEFINITION</b>
ACLF	ADULT CONGREGATE LIVING FACILITY (old term -see ALF)
A.M.D.A.	Formerly known as American Medical Director's Association – now “The Society for Post-Acute and Long-Term Care”
ADL's	ACTIVITIES OF DAILY LIVING - This term refers to the resident's ability to handle: ambulation, bathing, dressing, eating, grooming and toileting. The residents ability to deal with each of these ADL's will determine the type of assistance provided by a facility.
ADT	ADULT DAY TRAINING CENTERS - These are facilities that provide day programs for residents that have developmental disabilities, psychiatric disorders, Alzheimer's disease or dementias. Typically an ADT will specialize in a specific type of resident.
AHCA	AGENCY FOR HEALTHCARE ADMINISTRATION (Federal Agency) and AMERICAN HEALTH CARE ASSOCIATION (private agency)
AIMS	ABNORMAL INVOLUNTARY MOVEMENT SCALE - A test performed on all residents taking antipsychotic medications in a nursing home to rule out the possibility of "movement" side effects.
ALF	ASSISTED LIVING FACILITY - The most common name for facilities that provide living space and assistance for older people who can no longer manage a household. Assistance may include: meal preparation, maid service, laundry service, assistance with activities of daily living and medication supervision.
ASCP	AMERICAN SOCIETY OF CONSULTANT PHARMACISTS - the professional organization that represents all vendor and consultant pharmacists that deal with nursing homes, ALF's, ICF-DD's and correctional facilities
BEER'S DRUG	This term refers to a list of drugs that have a high incidence of adverse effects in the elderly. These drugs are broken down into 2 categories: The "High Severity" drugs which should not be used in the elderly and the "Low Severity" drugs which should only be used for short term treatments when the patient is monitored closely for adverse effects. These drugs are part of the Federal

	Guidelines (1999) and came from an article written by a Dr Beers in the Annals of Internal Medicine.
CARF	COMMISSION ON ACCREDITATION OF REHABILITATION FACILITIES - a non-profit organization that accredits behavioral health rehab and community service programs
CCRC	CONTINUING CARE RETIREMENT CENTER
CMS	CENTER FOR MEDICARE AND MEDICAID SERVICES - The Federal agency that oversees the Medicare and state Medicaid Programs
DMQA	DIVISION OF MEDICAL QUALITY ASSURANCE - This is a state agency that oversees the inspection of nursing homes in the state. They also represent the Federal government during these inspections. The name of this organization may vary from state to state but every state has a similar agency that provides annual inspections
DOH	DEPARTMENT OF HEALTH - Typically a State Agency that oversees healthcare programs in the state.
DRR	DRUG REGIMEN REVIEW - This is the term used to describe a Consultant Pharmacist's review of a resident's medical record. The Consultant Pharmacist reviews current drug orders, lab tests, doctors progress notes and nursing notes to ensure that the residents is free from drug interactions, allergies and side effects from their current medication. In addition, The Consultant looks for ways of reducing overall medication and or reducing doses of medication to the lowest effective dose. Now called Medication Regimen Review (MRR)
EDK	EMERGENCY DRUG KIT - A kit of drugs owned by the Vendor Pharmacy that are stored in a nursing home or ICF-DD to allow a limited number of medications to be started in the event of an emergency
F.A.C.T.	Florida Assertive Community Treatment Teams
F.A.D.O.N.A.	Florida Association Directors of Nursing Administration - LTC
F.A.P.	Facility Admission Profile - will be used for the Nursing Home Quality Indicators
FEDERAL INDICATORS	The Federal Indicators were designed to help the state surveyors determine if the Consultant Pharmacist was doing an adequate job in reviewing drug therapy in a facility. The original Federal indicators started in 1982 and identified where, when and how often charts needed to be reviewed. These

	initial indicators also addressed the type of lab work, patient monitoring (blood pressure & pulse) and appropriate diagnoses for specific drug therapies.
FIRST DATA BANK	First Data Bank is a private company that sells current price information to most Pharmacies, Insurance plans and state Medicaid programs. This information is provided in electronic format on a daily, weekly or monthly basis that is used by health care providers to update their computer databases.
FORMULARY	A list of drugs that typically provide a limited number of drugs in each therapeutic category. In a hospital the formulary items may be the only drugs stocked by the Hospital Pharmacy. In a LTC Pharmacy a formulary is typically the list of drugs that a Pharmacy will provide for a Per Diem rate. The use of a formulary is important to control drug costs in any facility.
GRTS	GERIATRIC RESIDENTIAL TRAINING SERVICE - A residential facility that specializes in services for elderly residents with psychiatric disorders
HCFA	HEALTH CARE FINANCE ADMINISTRATION - This is the former name for the agency that oversees Medicare and also state Medicaid programs. The new name for this agency is CMS
HHS	HEALTH & HUMAN SERVICES - The federal agency that oversees all Federal health care programs in the country
HIPAA	Health Insurance Portability & Accountability Act
ICF	INTERMEDIATE CARE FACILITY - Most often referred to in terms of a facility for developmentally disabled residents. The medical care is less acute in these facilities than in the typical nursing home.
ICF-DD	INTERMEDIATE CARE FACILITY FOR DEVELOPMENTALLY DISABLED - This is the more politically correct term for facilities that provide care to residents with developmental disabilities. Treatments often involve the treatment of seizure disorders, behavioral problems and birth defects
ICF-MR	INTERMEDIATE CARE FACILITY FOR MENTALLY RETARDED - This is the old term to describe a facility for the developmentally disabled. The newer term for these facilities is the ICF-DD
LOA	LEAVE OF ABSENCE - this means the patient can leave the facility for a family visit, doctors appointment etc but is still considered a resident at the facility.

LONG TERM ACUTE CARE HOSPITAL	This term describes a small number of hospitals in the country that take care of high acuity patients for an extended period. CMS describes these facilities as hospitals with an average stay in excess of 25 days.
MAR's	MEDICATION ADMINISTRATION RECORDS
MDS	MINIMUM DATA SET -this is a required document that is used in the nursing facility to evaluate their residents. This information is used to determine the residents RUG score which determines the payment by Medicare, it is used to create the OSCAR data which is used to evaluate care in a facility and is used to create the Quality Indicator information which is posted on the Medicare web site.
MEDICAID	Medicaid or Public Assistance is a State program designed to provide medical, dental and Pharmaceutical coverage for indigent patients. These programs are partially funded by Federal funds with the remainder of the funds coming from state budgets.
MEDICARE	Medicare is a Federal program that covers some medical costs for U.S. residents over the age of 65. Medicare Part A covers hospital costs and Nursing Home services after a resident is discharged from the hospital. Medicare Part B covers doctors appointments, Enteral supplements, Diabetic supplies, and a limited number of IV drugs for residents that don't require hospitalization.
OBRA	OMNIBUS BUDGET RECONCILIATION ACT - a Federal budget act that includes funding for a variety of federal programs. These annual budget acts often address funding to nursing facilities and Pharmacy services
OIG	OFFICE OF INSPECTOR GENERAL - A Federal agency that monitors Federal spending. This agency looks for fraud, abuse and waste as they relate to federal payments. One of this agency's responsibilities is to oversee the relationship between nursing homes and their vendors including labs, pharmacies, ambulance services and a number of other companies that collect federal funds.
OSCAR	ONLINE SURVEY AND CERTIFICATION ACTIVITY REPORT - This is a Federal report that compares key data from the MDS to create a report card for each nursing facility in the country. This report compares each nursing home to other facilities in the State, Region, and Nationally. This data is used by the facility, the Consultant Pharmacist and the state Surveyors to identify problem areas at the facility.

P&P	POLICY AND PROCEDURE MANUAL -The Pharmacy Vendor provides the facility with the Pharmacy P&P manual. This manual addresses all phases of ordering and receiving medication, the administration of medication and the destruction or return of discontinued medication. The Vendor Pharmacy may also provide an I.V. P&P manual that will describe how to administer IV medications.
PDR	PHYSICIAN DRUG REFERENCE - The PDR is a reference book that is often used by Physicians and Nurses as a source of drug information. The book contains the same information found in the drug manufacturer's package insert.
PER DIEM	This term refers to a method of billing a facility for drugs consumed. The Pharmacy will bill a daily charge or "per diem" for medications dispensed for certain payor groups (most commonly include the Medicare and Managed Care residents). The Pharmacy will most often create a list of drugs (a formulary) that will be the only drugs covered for this daily charge.
POS	PHYSICIAN ORDER SHEET - This form summarizes all current orders for a patient. This form is reprinted monthly and signed by the attending physician. This signature updates all current orders for another month. The POS is often provided by the Vendor Pharmacy.
PPD	PRICE PER DAY or PER PATIENT DAY - this is another term used to identify the daily cost of drugs. The price per day will actually include any per diem rate, the cost of non-formulary items and any risk share the facility owes
PPS	PROSPECTIVE PAYMENT SYSTEM - This is the Medicare program that started in July 1998. This program reimburses facilities for patient care based on the acuity of the patient's illness. Payment is based on the patient's RUG's score and varies somewhat depending on whether the facility is in a city or a rural community
PRIVATE PAY	This term is used to describe patients that are responsible for paying their own drug bills. These are typically patients who do not have insurance or their insurance does not cover drugs directly.
QAPI	QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT COMMITTEE - a committee in all nursing homes that coordinate all services in the facility (medical, nursing, dietary, pharmacy, laboratory, maintenance etc) which monitors overall service and measures performance improvement
QI	QUALITY INDICATORS - This is a Medicare program started in May 2002 which makes available to the public a way to compare services at all nursing homes in a community. There are 24 Quality Indicators used by the state survey teams -

	of these, 9 Quality Indicators will be posted on the Medicare Web Site for public viewing.
QIO	QUALITY CARE ORGANIZATION
QMRP	QUALIFIED MENTAL RETARDATION PROFESSIONAL - this term refers to an employ at an ICF-DD that coordinates the care of the facility's residents
RAI	RESIDENT ASSESSMENT INSTRUMENT - This term refers to a number of tools used by the facility to determine a residents care needs. This term usually includes the MDS, the RAP's and the residents care plan
RAP's	RESIDENT ASSESSMENT PROTOCOL - These are nursing tools that help the facility assess a residents health problems for further treatment
RISK-BAND	This concept is usually built into a Risk Share Per Diem Contract. The Risk Band defines a percentage of any over-use of the drug formulary that will be absorbed by the Pharmacy. As an example if the risk band = 10% the Pharmacy will absorb the first 10% of the drugs used over a pre-set rate before the Pharmacy and facility share any risk.
RISK-SHARE	This type of Per Diem contract requires both the Facility and the Pharmacy to share risk for excessive use of the formulary. If the actual drugs used exceeds a pre-set level the Pharmacy and Facility split the additional cost. If the actual drug cost is below a pre-set level the Pharmacy and Facility split the savings. In a Risk Share contract the rate will be adjusted (similar to a "True-Up" contract) but the facility will also be billed for excessive use for the previous 90 days.
RUGS	RESOURCE UTILIZATION GROUPS - There are 44 RUG categories that are used to determine the care needed by a resident in the nursing home. Medicare reimburses the facility for the treatment of their Medicare residents based on the residents RUG's score
SNF	SKILLED NURSING FACILITY - often pronounced "SNIFF" and refers to the typical nursing home
STEP-DOWN UNIT	This is another term used by hospitals to describe beds in the hospital that are used as nursing home beds. The more common term for these beds (or units) are Transitional Care Units.
SURVEYORS	The Surveyor is a state employee that may be a nurse, a Pharmacist, a Dietician or other healthcare professional who is responsible for reviewing care in a nursing home, ICF-DD or ALF. This surveyor inspects based on the Federal and State regulations that govern the type of facility being inspected. The state

	surveyor represent both the State licensing organization and also the Federal government when the facility takes Medicare residents.
TAR's	TREATMENT ADMINISTRATION RECORDS - the form used by nursing to document treatments provided to the residents. These forms are often provided by the vendor Pharmacy
TCU	TRANSITIONAL CARE UNIT - This is the common name for a nursing home unit in a hospital. These units are also called "step-down" units
TD	TARDIVE DYSKINESIA - an irreversible side effect of certain drug therapy (antipsychotics most often) that cause involuntary movements of the tongue, face and extremities
TI's	THERAPEUTIC INTERCHANGE - This term refers to the practice of switching one drug to another drug with similar effects. Typically, the new drug is chemically different from the original drug prescribed. LTC Pharmacies use Therapeutic Interchanges to improve drug therapy and help reduce drug costs in a facility.
TRIGGERS	Triggers refer to part of the resident's MDS evaluation. Certain questions on the MDS may "Trigger" additional evaluation of the patient. Example - an MDS question asks if a patient ever falls. A response of YES will trigger further evaluation (using the Resident Assessment Protocols) to attempt to determine if the falls are related to drugs, patient vision, a current disease such as Parkinson's etc.
TRUE-UP	This term is used in a Per Diem contract to allow the Pharmacy to adjust the Per Diem rate when the actual cost of drug falls below a pre-set level (typically the state Medicaid formula). A True-up adjusts the daily rate going forward but does not require the facility to pay back any charges for over use of the formulary.

**QAPI            Quality Assurance Performance Improvement. A newly-developed quality meeting for nursing homes, replacing the previous QA and PI meetings:**

- QA is a process of meeting quality standards and assuring that care reaches an acceptable level. Nursing homes typically set QA thresholds to comply with regulations. They may also create standards that go beyond regulations. QA is a reactive, retrospective effort to

examine why a facility failed to meet certain standards. QA activities do improve quality, but efforts frequently end once the standard is met.

- PI (also called Quality Improvement - QI) is a pro-active and continuous study of processes with the intent to prevent or decrease the likelihood of problems by identifying areas of opportunity and testing new approaches to fix underlying causes of persistent/systemic problems. PI in nursing homes aims to improve processes involved in health care delivery and resident quality of life. PI can make good quality even better.

**A COMPARISON OF SERVICES AND REQUIREMENTS OF DIFFERENT FACILITIES**

<b>Services</b>	<b>Nursing Home</b>	<b>Transitional Unit</b>	<b>ALF</b>	<b>ICF-DD</b>	<b>Correctional Facility</b>	<b>Group Home</b>
<b>Pharmacy Permit</b>	Institutional Class I	Under Institutional Class II	Special Permit (Optional)	Institutional Class I	Institutional Class II-B	No Pharmacy license
<b>Policy &amp; Procedure Manual</b>	required	required	optional (unless permitted)	required	required	optional
<b>Consultant Pharmacist Services</b>	required	required	Optional unless deficiency or ALF license	required	required	optional
<b>Frequency of RPh visits</b>	at least monthly	at least monthly (usually 2 x month)	optional	monthly	monthly	optional
<b>M.A.R. Reviews</b>	at least monthly	at least monthly	not required	at least monthly	at least monthly	not required
<b>Physical Inspection</b>	monthly preferred	monthly preferred	optional (unless permitted)	monthly preferred	monthly	optional
<b>Required Reports</b>	monthly irregularities to DON + quarterly summary report	monthly irregularities to DON + quarterly summary report	none - unless permitted then monthly inspection	Quarterly Chart review + monthly inspection	Monthly Inspection Report	None
<b>Emergency Kits</b>	Yes	Yes	No	Yes	Yes	No
<b>Floor Stock - OTC's</b>	Yes	Yes	No	Yes	Yes	Yes
<b>Floor Stock - RX Drugs</b>	No	Yes	No	No	Yes	No
<b>Floor Stock Controlled Substances</b>	No	Yes	No	No	Yes (with DEA license)	No

<b>Antipsychotic Dose Reductions</b>	2 separate quarters in first year	2 separate quarters in first year	MD must review yearly	MD must review yearly	No time requirement	No time requirement
<b>Anxiolytic Dose Reductions</b>	2 separate quarters in first year	2 separate quarters in first year	MD must review yearly	No time requirement	No time requirement	No time requirement