

[§482.25 Condition of Participation: Pharmaceutical Services

The hospital.... must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision....

§482.25(a)(1) - A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Interpretive Guidelines §482.25 and §482.25(a)(1)

Pharmaceutical services offered throughout the hospital must be under the direction of a pharmacist, who may be full-time, part-time, or consulting. This is required even in the case of a hospital that has a drug storage area instead of a pharmacy. The director must have documented training or expertise in hospital pharmacy practice and management. The hospital must have written criteria for the qualifications of the pharmacy director in accordance with the scope of services provided.

The extent of pharmaceutical services provided by the hospital determines whether a part-time director of the services is sufficient. Depending on the volume and complexity of the hospital's services, oversight may not require full-time on-site management at the hospital's pharmacy, but may be accomplished through regularly scheduled visits, and/or use of telecommunications in accordance with Federal and State law and accepted professional principles. If the hospital does not have a full-time pharmacist, it must be able to provide evidence of how a part-time or consulting pharmacist is able to perform all functions relating to developing, supervising and coordinating all pharmacy services activities.

In general, hospital pharmacies are staffed with registered pharmacists and pharmacy technicians who perform various functions, including, but not limited to, compounding, labeling, and dispensing of various drugs and biologicals.

There may be instances of small hospitals that do not have a pharmacy but utilize a drug storage area for dispensing pre-packaged drugs only. If the hospital has a drug storage area in lieu of a pharmacy, the day-to-day operations of pharmaceutical services must be under

the supervision of an individual who, if not a pharmacist, nevertheless has documented competency to oversee compliance with all the pharmaceutical services regulatory requirements (e.g., security, access to locked areas, etc.). The hospital must establish in writing the qualifications of the drug storage area supervisor.

The job description or the written agreement for the responsibilities of the pharmacist director should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services, including active leadership of those committees responsible for establishing medication-related policies and procedures.

Survey Procedures §482.25 and §482.25(a)(1)

- Does the hospital have a pharmacist who has been appointed to direct the pharmaceutical services?
 - Are there written criteria for the qualifications of the pharmacist director?
 - Is there evidence in the pharmacist's file that he/she satisfies the criteria?
- If the hospital has a drug storage area in lieu of a pharmacy, is there evidence the storage area is under competent supervision?
- Review the pharmaceutical services Director's file to verify that he or she meets the qualifications established by the medical staff and has been granted privileges as a pharmacist.
- If the Director is a part-time employee or consultant, ask him/her how much time/week is spent on developing, supervising and coordinating pharmaceutical services.
- Review the implementation of the pharmacy director's responsibilities by:
 - Reviewing minutes of meetings (if any) with facility staff regarding pharmaceutical services;
 - Reviewing the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development supervision and coordination of all the activities of pharmacy services;
 - Determining whether the pharmacy director/manager routinely evaluates the performance and competency of pharmacy personnel?
 - Ask the pharmacy director to describe how policies and procedures related to pharmaceutical services are developed, approved, and implemented. What is his/her role in this process?
 - Is there any evidence of problems within the pharmaceutical services that suggest lack of supervision?