

## 19. RESEARCH PATIENT CARE COSTS

### 19.2 Definitions

**Research Patient Care Costs.** The **costs of routine and ancillary services provided by hospitals** to individuals participating in research programs. The costs of these services normally are assigned to specific research projects through the development and application of research patient care rates or amounts (hereafter "rates").

**Research patient care costs do not include:**

- (1) the otherwise allowable items of personal expense reimbursement, such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of individuals, including inpatients, outpatients, subjects, volunteers, and donors,
- (2) costs of ancillary tests **performed in facilities outside the hospital on a fee-for-service basis** (e.g., in an independent, privately owned laboratory) or laboratory tests performed at a medical school/university not associated with a hospital routine or ancillary service ,
- (3) recruitment or retention fees or
- (4) the data management or statistical analysis of clinical research results.

#### Definitions:

**Hospital.** Includes all types of medical, psychiatric, and dental facilities, such as clinics, infirmaries, and sanatoria.

**Research Patients.** Inpatient and outpatient subjects, volunteers, or donors participating in a research protocol.

**Routine Services.** Regular room services, minor medical and surgical supplies, and the use of equipment and facilities, for which a separate charge is not customarily made.

**Ancillary Services.** Those special services for which charges are customarily made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology.

**Outpatient Services.** Services rendered to subjects/volunteers/donors who are not hospitalized.

**Usual Patient Care.** Items and services (routine and ancillary) ordinarily furnished in the treatment of patients by providers of patient care under the supervision of the physician or

other responsible health professional. Such items or services may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, or any other related professional health services. **These expenses are for care that would have been incurred even if the research study did not exist.** The patient and/or third-party insurance generally will provide for reimbursement of charges for "usual patient care" as opposed to not reimbursing those charges generated solely because of participation in a research protocol.

**Discrete Centers.** Groups of beds that have been set aside for occupancy by research patients and are physically separated from other hospital beds in an environment that normally permits an ascertainable allocation of costs associated with the space they occupy and the service needs they generate.

**Scatter Beds.** Beds assigned to research patients based on availability. These beds are not physically separate from non-research beds. Scatter beds are geographically dispersed among all the beds available for use in the hospital and are not usually distinguishable in terms of services or costs from other general service beds within the hospital.

**Cost-Finding Process.** The technique of apportioning or allocating the costs of the non-revenue-producing cost centers to each other and to the revenue-producing centers on the basis of the statistical data that measure the amount of service rendered by each center to other centers.