NIH Policy Manual

6352-2 - Research Patient Care Costs Supported by NIH Sponsored Agreements

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Transmittal Notice

A. Purpose

This issuance provides guidelines in the management of sponsored agreements that provide funds for the support of research patient care activities. In serving as the NIH implementation of the PHS Grants Administration Manual Chapter 6-50, Research Patient Care Costs, this issuance also provides supplemental guidelines for NIH-supported grants and awards and establishes the requirement for compliance with 45 CFR Part 74, Appendix E, Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts With Hospitals, for NIH-supported contracts. To utilize this issuance effectively, it should be used in conjunction with the two documents cited above since pertinent parts of these documents are not repeated herein.

B. Applicability

This issuance is applicable to all NIH-sponsored agreements that provide funds for reimbursement of research patient care costs.

C. References

1. PHS Grants Administration Manual Chapter 6-50, Research Patient Care Costs
2. "A Guide for Hospitals," DHHS, OASC-3.
3. Title 18 (Medicare Program), Social Security Act, Principles of Reimbursement for Provider Costs
4. Title 45, CFR Part 74, DHHS - Administration of Grants
5. NIH Manual Chapter 5202, Prior Approval of Use of NIH Grant Funds Including Rebudgeting

D. Definitions

1. Sponsored Agreement - For purposes of this issuance, means any grant, cooperative agreement or contract between the NIH and an awardee/contractor institution or organization.

2. Research Patient Care Costs - The costs of routine and ancillary services provided by hospitals to patients participating in research programs. The costs of these services are normally assigned to individual research projects through the development and application of research patient care rates or amounts (here-after collectively referred to as "rates").

   NOTE: Research patient care costs do not include 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 patients including inpatients, outpatients, subjects, volunteers, and donors.
3. Hospital - For purposes of this issuance the term "hospital", as referred to in the PHS Grants Administration Manual Chapter 6-50, will also cover all types of medical, psychiatric, and dental facilities such as clinics, infirmaries, sanatoria, etc.
4. Research Patients - Inpatients and outpatients admitted to a hospital primarily to participate in a research protocol.
5. Research/Service Patients - Inpatients or outpatients admitted primarily for the purposes of diagnoses or treatment according to established regimens, and who are also participating in a research protocol that may or may not be related to their condition.
6. Routine Services - The regular room, dietary and nursing services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made.
7. 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, pathology.
8. Outpatient Services - Services rendered to subjects who are not hospitalized.
9. 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 professional.

   Such items or services may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, or any other related professional health services. These expenses are for the care that would have been incurred even if the research study did not exist. The patient and/or the third party insurance will usually provide for reimbursement of charges for "usual patient care" as opposed to non-reimbursement for those charges generated solely because of participation in a research protocol.
10. Discrete Centers - A group 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.
11. Scatter Beds - "Scatter beds" are beds assigned to research patients based on availability. These beds are not physically separate from nonresearch 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.

12. 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.

E. Policy

NIH provides funds for the cost of research patient care through its various sponsored agreements. Research patients may receive routine services in discrete centers or scatter bed environments. Such patients may also receive various ancillary services either as inpatients or outpatients. With certain specific exceptions, as identified in Section I of this issuance, patient care costs whether expressed as a rate or amount are subject to negotiation by authorized staff of the Divisions of Cost Allocation in the ten Department of Health and Human Services Regional Administrative Support Centers.

F. Implementing Instructions

1. Allowability of Research Patient Care Costs under Sponsored Agreements - The determining factors for allowing research patient care costs as charges to sponsored agreements depend on the patient and the type of services received. If the patient is receiving service or care that neither differs from usual patient care nor results in expenses greater than those which would have been incurred if the study had not existed, then the patient is considered to be hospitalized for usual care purposes and the sponsored agreement will not support the costs. When the research extends the period of hospitalization beyond that ordinarily required for usual care, or imposes procedures, tests or services beyond usual care, whether in an inpatient or outpatient setting, the sponsored agreement may pay the additional costs. The grantee or contractor must decide whether, in fact, the hospitalization period, the tests, or the services have been extended beyond or added to what would ordinarily have been expected, and to what extent. Patient care costs for individuals who are receiving accepted treatment according to standard regimens would not ordinarily be an acceptable charge against the sponsored agreement. Similarly, in certain kinds of clinical trials where accepted treatments are compared against new therapies, research patient care costs generally may be charged to a sponsored agreement only insofar as they are measurements or services above and beyond those which constitute usual patient care and are specified by the study protocol.

2. Exceptions - NIH-authorized funds may be used to pay all costs (whether usual care costs or research care costs) for the entire period of hospitalization or research tests or services for patients who would not have been hospitalized or received such tests or services except for their participation in the research study. Any such exceptions should be documented in the records of the awardee or contractor.

   These patients may include:

a. Persons to whom no health advantages may be expected to accrue as a result of the hospitalization. Examples would be: normal controls for metabolic or other studies; persons with genetic or certain abnormalities of interest to the investigator; sick persons brought to the hospital solely for studies when they otherwise would not require hospitalization.
b. Sick persons of research importance to the investigator but without funds of their own or without funds available to them through a responsible third party to pay hospitalization expenses. This includes patients for whom some third party payer, such as city, county, or state government, might pay hospitalization expenses in some other hospital but has no responsibility to pay in the hospital in which the approved clinical research is being conducted.
c. Sick persons with limited personal funds or health insurance but who are not willing to spend their own money or use their hospital plan coverage at that particular time. (Fear of more urgent need in the future for both personal funds and health insurance might be one reason for the patient's reluctance to participate in the study.) The investigator has a special responsibility in making the decision to include patients in this third group with full charges to the sponsored agreement. Ordinarily, by guidelines laid down in this document the patient and/or third party would be expected to pay the total costs of the usual care portions of the hospitalization. However, as an exception to the general rule, the investigator may decide to pay the total expenses for hospitalization, research services, or tests from the sponsored agreement if this is required to secure timely cooperation of a valuable study patient not otherwise available.

3. Methods of Computing Research Patient Care Costs Chargeable to Sponsored Agreements - Reimbursement of research patient care costs incurred under NIH sponsored agreements will be computed using research patient care rates established by DHHS. Such rates must be shown in all requests and/or claims for the reimbursement of research patient care costs. Copies of the DHHS-negotiated research patient care rate agreements may be obtained by calling the Federal Assistance Accounting Branch, Division of Financial Management on (301) 496-5315.

   When provisional rates are used as a basis for the award and payment of research patient care costs, the amount awarded shall constitute the maximum amount which the NIH awarding unit is obligated to reimburse a hospital for research patient care costs under the sponsored agreement. Patient care, whether expressed as a rate or an amount, shall be computed in a manner consistent with the principles and procedures used by the Medicare program for determining the portion of Medicare reimbursement based on reasonable costs. The diagnosis related groups' (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs.

   The policy further provides that separate cost centers must be established for each discrete bed unit for purposes of allocating or distributing allowable routine costs to the

discrete unit. The allocation or distribution of allowable routine costs should be made during the normal "step down" of costs for Medicare purposes. Routine costs are funded by this discrete method or by a scatter bed method. Discrete bed reimbursement for routine care is based on a total dollar amount method. Scatter bed reimbursement is based on an average hospital per diem rate. All allowable costs for Medicare determinations are allowable in determining research patient care cost. Ancillary costs will be determined by applying the departmental (radiology, pathology, etc.) ratio of costs to charges to the actual departmental charges generated by the research patients. The charges for ancillary services provided to research patients must be on the same basis as charges made to any other patient for like services.

In addition to the routine cost rate and ancillary ratio of cost to charges determined from the cost finding process, offset rates must be negotiated where appropriate. These offset rates are negotiated to allow a credit to the patient care category for each research/service patient day, and to allow for the reduction from an average per diem for those items funded directly by the sponsored agreement. The types of offsets negotiated are as follows:

a. The offset for the discrete bed unit routine cost is normally the average cost of all routine beds in the hospital.
b. The offset from the routine per diem rate is a rate which allows for a reduction from the average routine per diem those items directly funded by the sponsored agreement, i.e., nursing or dietary services.

G. Other Elements of Cost

Reimbursement of other elements of cost, consistent with the needs of the sponsored agreement may be made in accordance with the cost principles prescribed in 45 CFR 74, Appendix E.

H. Indirect Costs

Indirect costs should not be paid on any cost component representing the cost of research patient care activities. However, a special indirect cost rate may be applicable to salaries and wages of employees who would not ordinarily be employed by a hospital unless an ongoing research function or activity (e.g., non-hospital types such as principal investigators, animal caretakers, etc.) is in place. Such special rates will exclude, for example, depreciation, operations and maintenance, housekeeping and other space costs for the discrete facilities which are already included in the direct cost component of research patient care.

Patient care rates (routine and ancillary) also include indirect costs related to "hospital-type" employees (nurses, medical technicians, etc.) supported as a direct cost under the sponsored agreement. Therefore, to preclude overrecoveries of costs similar to the aforementioned indirect costs, salaries and wages (S&W) of all "hospital-type" employees working on the sponsored agreement must be excluded from the S&W base used to claim indirect costs.

Related fringe benefits should also be excluded if such costs are part of the S&W base. If a total direct costs base is used to compute and claim indirect costs, the above-mentioned "hospital-type" salaries must be excluded from the base also, as well as any other base costs chargeable to the sponsored agreement through the application of research patient care rates.

When a hospital is the direct recipient of a sponsored agreement which provides support exclusively for research patient care activities, no indirect costs will normally be allowed as a separate cost element since all allocable indirect costs have been stepped down into the routine or ancillary activity costs contained in patient care rates.

I. Special Procedures for Certain Hospitals

1. Requirements for submission of research patient care proposals do not apply to hospitals which are awarded $25,000 or less in research patient care costs under each individual sponsored agreement for any single grant budget period or contract period awarded by any of the components of DHHS. If the hospital has a currently negotiated rate, that rate would apply to any patient cost awarded, regardless of amount. Hospitals which meet this condition will, instead, be subject to the following alternate procedures:

    a. If the hospital is a sub-awardee, the recipient of the sponsored agreement will be responsible for negotiating reasonable fees for research patient care services provided by the hospital.
    b. If the hospital is the direct recipient of a sponsored agreement, it must support its claims for the reimbursement of research patient care costs by preparing a research patient care rate computation for each fiscal year during which the costs are claimed. The computation must be based on section IX.B.23 of the Department's Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts With Hospitals (Appendix E to 45 CFR Part 74) and must conform to the proposal formats shown on pages 9 through 11 of the DHHS document, "A Guide for Hospitals." The computation, along with the supporting documentation described in the Guide, must be retained by the hospital for possible review and audit by, or on behalf of, the Department. The retention period shall be in accordance with the Department's records retention regulations (Subpart D of 45 CFR Part 74). The rates developed by the hospital will be treated as predetermined rates. However, the research patient care costs reflected in the hospital's expenditures reports based on these rates will be subject to adjustment if an audit or other review by, or on behalf of, the Department results in a reduction in the rates. A contracting officer may request the computation and supporting documentation on research patient care pursuant to FAR 15.804.

2. In the absence of a Research Patient Care Negotiation Agreement published by DHHS' Office of Procurement Assistance and Logistics, Office of the Assistant Secretary for Management and Budget/OS, the awarding agency may provide funds for research patient care costs based on the rates proposed by the recipient of the sponsored

agreement, provided that the amount awarded under the agreement does not exceed $25,000 for each hospital involved and the hospital(s) does not have any other DHHS awards which individually provide research patient care support in excess of $25,000.

J. Financial Responsibilities

Where the costs of patient care are funded by the sponsored agreement, and whether such costs are classified as usual patient care or research patient care, the amount recovered from third parties must be credited to the sponsored agreement. However, patient care charges must be adjusted to cost for both routine and ancillaries, pursuant to the principles of this issuance, prior to applying the third party recoveries. The recipient of the sponsored agreement is obligated to pursue recovery to the fullest extent possible and should be able to document such efforts.

K. Specific Information Required in Applications and Proposals Involving Research Patient Care Costs

To effectively review any anticipated need for research patient care costs, it is necessary for the application or proposal to include certain basic information and supporting data. Funds for research patient care can be used only after justification and supporting data have been reviewed and accepted by appropriate staff of the NIH awarding unit. The following information should be provided in application or proposal (competitive or non-competitive) that includes a request for research patient care costs:

Inpatient Costs - Scatter Beds

1. The name of the hospital(s) to be used, and the amounts requested for each

2. An indication of whether the hospital(s) has a currently effective DHHS-negotiated hospitalization rate agreement: if not, the basis to be used for calculating charges

3. A presentation of the research protocols under which patients will be hospitalized. In addition, the following information should be provided by protocol:

    a. The service or ward e.g., medicine, surgery, intensive care unit, coronary care unit, where inpatients will be located
    b. The number of patients anticipated
    c. The number of patient days anticipated
    d. The rate or basis on which the scatter bed costs have been calculated
    e. An indication of the anticipated charges per patient day for routine costs
    f. An indication of the anticipated charges per patient day for ancillary costs
    g. An estimated percentage of the total costs per patient day which will be charged to third party coverage

Inpatient Costs - Discrete Beds

1. The name of the hospital(s) to be used and the amounts requested for each

2. An indication of whether the hospital(s) has a currently effective DHHS negotiated hospitalization rate agreement; if not, the basis to be used for calculating charges

3. A presentation of the research protocols under which patients will be hospitalized

4. The number of beds in the discrete research unit

5. The basis for determining costs for the routine care requested

6. The anticipated occupancy rate of the beds requested with an indication of the number of patients that are expected to be "research" versus the number that are expected to be "research/service"

7. An indication of the average ancillary cost per day for "research" patients and "research/service" patients

8. An indication of the related costs, e.g., laboratory, drugs, that will be generated outside of the discrete unit

9. An estimate of the anticipated rate of third party recovery

Outpatient Costs

1. The name of the hospital(s) to be used and the amount requested for each

2. An indication of whether the hospital(s) has a currently effective DHHS negotiated hospitalization rate agreement; if not, the basis for calculating charges

3. A presentation of the research protocols under which outpatient are to be involved. In addition, the following information should be provided by protocol:

    a. The types of tests or procedures which will be performed
    b. The number of outpatients to be involved
    c. The number of outpatient visits
    d. An estimate of the average cost per visit

L. Program Requirements

An individual NIH awarding unit may adopt special implementing procedures to meet the specific needs of its own program provided that such procedures do not conflict with this issuance.

NOTE: The majority of NIH-supported discrete centers are being funded by the General Clinical Research Centers (GCRC) program of the Division of Research Resources, and the Division has developed detailed guidelines for the operation of such centers. Other BIDs

funding discrete centers might wish to utilize these guidelines in connection with their programs. Copies of the guidelines may be obtained by contacting GCRC staff.

M. Effective Dates

This policy is effective on date of release.

N. Additional Information

For further information on this chapter contact the Office of Acquisition Management and Policy. Telephone: (301) 496-6014. Information is also available at: http://grants.nih.gov/policy/nihgps/index.htm.

O. Additional Copies

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