Frequently Asked Questions about Patient Care Costs

And a Quick Guide to Patient Care Costs

Background from NIH Grants Policy Statement: The following definition should be kept in mind when answering questions regarding human research patient care costs. Human research patient care costs are 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.

Answers to the questions below are entered by each question.

1. Lab work or procedures done by a hospital that is NOT Fairview? Are these considered patient care? Each hospital must develop its own patient care rates which usually are their Medicare rates for each specific service it provides to research subjects. If other hospitals develop a patient care rate or use their Medicare rates, costs would be considered allowable patient care costs excluded from the application of F&A costs.

2. What about lab work that we send to a non-hospital lab? As the NIH policy statement says, costs of ancillary tests performed outside the hospital on a fee-for-service basis by an independent, privately owned laboratory or performed at a medical school/university laboratory are not patient care.

3. What about UMP (the pro-fee component) to procedures? As the NIH policy statement states, patient care costs do not include consulting physician fees. Ordinarily, physicians who are named as co-investigators or other key persons on a project will have their time on project reimbursed as effort on the project, fulfilling their time as part of their professorial duties to conduct research.

4. What about services performed at the VA hospital? The VA hospital must develop its own patient care rates for each specific service it provides to research subjects. Once the VA hospital develops a patient care rate, costs would be considered allowable patient care costs excluded from the application of F&A costs.

5. What about pharmacy dispensing fees to distribute pharmaceuticals for patients in a clinical trial? The answer to this question is that it depends on how the hospital treats these costs relative to its Medicare Cost Report. University of Minnesota Hospital-Fairview excludes these costs from its Medicare Cost Report meaning that these costs are not patient care costs. Additional information about the basis of these costs would be needed in order to determine
whether such costs could be treated as patient care costs when these costs are charged by other hospitals.

6. What about patient specimens that are received from another clinical site where Fairview Health Services is used to process these specimens for test results? Answer: Laboratory Medicine and Pathology has established a laboratory using Fairview personnel and equipment it purchased from Fairview. This laboratory serves as central laboratory for several national clinical trials and may be able to process these laboratory specimens. As such, these tests would not be conducted by a hospital owned laboratory and would not be considered patient care costs because these specimens are not those of our research subjects. These costs would subject to the application of F&A costs. Even if these specimens were processed by Fairview’s laboratories, these costs would not be patient care costs because these specimens are not those of our research subjects.

For further guidance, please refer to Chapter 19, Research Patient Care Costs, NIH Grants Policy Statement, October 1, 2010.

A QUICK GUIDE TO PATIENT CARE COSTS

Patient Care Costs Involving University of Minnesota Human Subjects

Services must be performed by University of Minnesota Medical Center-Fairview or another hospital with patient care rates (VA, HCMC, etc.) for human research subjects who are being seen at that hospital.

- Laboratory Services

- Procedures:
  - MRI’s
  - X-rays (Radiology)
  - Ultrasounds, etc.

Not Patient Care Costs

- Laboratory services performed on samples collected from patients of other hospitals, centers or projects, cell lines, or animal studies

- IDS (Investigational Drug Service) – University of Minnesota Medical Center -Fairview only. SPA management would need to review and determine status of IDS charges for other hospitals

- Laboratory work sent to an outside laboratory

- Laboratory work/tests performed through Advanced Research & Diagnostic Laboratories (ARDL) (Housed in Laboratory Medicine & Pathology)
• Other services/procedures NOT performed by a hospital

• UMP services

• CTSI services

• Patient parking