

Modification of Diet in Renal Disease Study

Manual of Operations

Volume 1, Chapter 7

Billing Information and HCFA Reimbursement



MCRD Manual of Operations

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TABLE OF CONTENTS

	PAGE
Section 7.1 Billing Information.....	1.7.2
Section 7.2 Reimbursement Coverage.....	1.7.3

APPENDIX

Appendix Information Required to complete the HCFA UB-82 Form.....	1.7.5
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MDRD Study Manual of Operations
Chapter 7. Billing Information and HCFA Reimbursement

Section 7.1 Billing Information

The Health Care Financing Administration (HCFA) and the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), NIH will be jointly funding the MDRD Study. Under the Interagency Agreement, HCFA and NIDDK agreed that NIDDK would have the lead responsibility for the safety and efficacy portion of the Study and the clinical trials that would be conducted. HCFA will determine the specific services and items to be reimbursed for patients participating in the clinical tests and the reimbursable amounts for these services, and will have the lead responsibility for the cost effectiveness portion of the Study. The major portion of the Study's research and administrative costs will be funded by NIDDK, and the costs of the services and items required by patients during the clinical trials will be reimbursed by HCFA through the Medicare trust funds.

The Division of Research and Demonstrations System Support (DRDSS) is a component within HCFA's Office of Research and Demonstrations (ORD) and will serve as fiscal intermediary for this project. DRDSS will make determinations on coverage and reasonable costs incurred by the clinical centers and will authorize the Treasury Department to issue payments for these services. The clinical centers will query DRDSS for answers to questions concerning coverage of services, billing, costs reporting and reimbursement under the Study.

The Study Coordinator will need to establish contact with the liaison person within the study center billing office as designated by the Reimbursement agreement. It will be necessary for the Study Coordinator to develop a method of communication with the local center's billing office designee to provide the necessary information for each clinic visit to allow for accurate billing.

The billing department designee will complete the HCFA UB-82 (HCFA-1450) forms and submit them for payment. Local procedures may require additional information; however, MDRD Form 29 and the clinical center face sheet will most likely contain all the required information. Any changes in the patients' study status, insurance information or address change should be reported by the Study Coordinator to the billing department designee. This will correct and update information being submitted to HCFA. (See Attachment I for the information required to complete the HCFA-1450 form).

Section 7.2 Reimbursement Coverage

I. General (as specified by the MDRD Reimbursement Manual).

The cost of services will be reimbursed, consistent with the reimbursement criteria approved for the Study, only if the following conditions are met:

- A. The services are required by the study protocol; or
- B. The services are required for the treatment of the underlying kidney disease and the patient is an active participant* in the Study; or
- C. The services are required because of complications arising from the treatment provided under the Study protocol; and
- D. The services are provided by one of the participating clinical centers, the MDRD Central Laboratories, or under arrangements with one of the participating clinical centers; and
- E. The patient is participating in the Screening, Baseline or the Follow up period, as required by the Study protocol; and
- F. The services are not paid in full by other insurance, including Medicare and Medicaid for Inpatient/Emergency Outpatient Care.

* Refer to part "E" for definition of participant.

II. Specific guideline and additional information are contained in the MDRD Reimbursement Manual in regards to the following:

- A. Covered services
 - 1. Outpatient services
 - 2. Inpatient services
 - 3. Dietary supplements
- B. Other Health Insurance and Routine care exclusions, and
- C. Noncovered Services and items.

III. The MDRD Study Reimbursement Manual also establishes the methodology and billing procedures to be followed by the study. Intermediary Letters #1, 2, and 3 (dated June 9, 1989; July 5, 1989; and July 5, 1989) from Edward J. Norwood provide additional details and clarification for the MDRD Study Reimbursement Manual and should be on file with the Reimbursement Manual.



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APPENDIX (continued)

- 51 Revenue Code
 - 001 Total charges
 - 250-258 Pharmacy
 - 270 Medical/Surgical Supplies
 - 300-307 Laboratory
 - 301 Lab charges
 - 305 Hematology charges
 - 307 Urology charges
 - 341 Nuclear Medicine
 - 510 Clinic charges
 - 730 EKG/ECG
 - 925 Pregnancy Test
- 52 S. Units
- 53 Charges (individual and total)
- 68 Insurance Identification Number (SSN if no third party coverage)
- 94 Necessary Remarks
- 95 Signature of person completing the claim and date