# Memorandum

Date OCT 24 1995

From June Gibbs Brown
Inspector General

Subject Reimbursable Patient Care Costs at the National Institutes of Health's Clinical Center (CIN: A-15-92-00011)

To

Harold E. Varmus, M.D.
Director
National Institutes of Health

The attached final report addresses the potential of charging for standard care provided to research patients at the National Institutes of Health's (NIH) Clinical Center.[1] Our review updated information contained in two previous reports by the General Accounting Office and NIH related to the question of whether standard care is provided at the Clinical Center.

Our report also addresses the question of whether NIH currently has the authority and necessary accounting information to bill for standard care. In addition, our report addresses data collection and other issues related to the feasibility of NIH charging for such care. We undertook the audit at the request of the former NIH Director, who told us she was interested in seeking additional sources of revenue to support activities of the Clinical Center. The draft report was addressed to Dr. Philip R. Lee, Assistant Secretary of Health.

We found standard medical care is provided at no charge to research patients at NIH when patients are admitted to controlled studies at the Clinical Center and to others when they are treated for a medical condition unrelated to the research. We believe, because of the nature of the medical procedures we reviewed, that if these patients were not at NIH, participating in research, they would be receiving the same or similar care at community hospitals or in doctors' offices and this care would be billed to medical insurers. It is this care that we believe is potentially billable to insurers if NIH had the authority to charge.

We could not quantify the amount of standard care provided at NIH, patients' ability to pay, or the feasibility of charging. We were unable to do this because NIH's financial and management information systems do not account for all costs of treating patients or distinguish between research and standard care. Also, NIH does not obtain any financial or health insurance information from patients.

We are recommending that NIH: (1) modify its accounting and information systems to collect the full cost of treating patients at NIH; (2) segregate research costs from nonresearch

[1] A 359-bed research hospital located at NIH in Bethesda, Maryland.

care costs by patient; (3) collect insurance and financial information from patients; (4) seek authority to charge for nonresearch care provided under controlled studies and to other patients participating in research protocols; and (5) develop a plan for using the authority to charge that includes meeting with representatives of major insurers to discuss potential reimbursement procedures.

In response to our draft report, the Public Health Service (PHS) told us it has forwarded our report to a workgroup which is reviewing activities of the Department of Health and Human Services under REGO II which includes operations of the Clinical Center. It asked that the report's conclusions and recommendations be considered as part of the workgroup's review. The PHS stated that once the workgroup has completed its review, it will revisit our recommendations in conjunction with those of the workgroup to determine an appropriate course of action. We agree with PHS' decision.

We would appreciate being advised within 60 days of the status of corrective actions taken or planned on each recommendation after the workgroup has issued its report. If you have any questions, please call me or have your staff contact Joseph J. Green, Assistant Inspector General for Public Health Service Audits, at (301) 443-3582.

Attachment

Department of Health and Human Services

# OFFICE OF INSPECTOR GENERAL

# REIMBURSABLE PATIENT CARE COSTS AT THE NATIONAL INSTITUTES OF HEALTH'S CLINICAL CENTER

JUNE GIBBS BROWN
Inspector General

OCTOBER 1995
A-15-92-00011

# EXECUTIVE SUMMARY

This final report addresses the potential of charging for standard care provided to research patients at the National Institutes of Health's (NIH) Clinical Center.[1] The objectives of our review were to update information contained in two previous reports by the General Accounting Office (GAO) and NIH related to the question of whether standard care[2] is provided at the Clinical Center and to determine if NIH currently has the authority and necessary information, including cost data, to bill for standard care. Our report also addresses data collection and other issues related to charging for such care. Our review was undertaken at the request of the former NIH Director, who told us she was interested in seeking additional sources of revenue to support activities of the Clinical Center.

## Background

The GAO and NIH issued reports discussing charging for care at the Clinical Center in 1977 and 1983. These reports stated that nonresearch medical care was provided to research patients at the Clinical Center and indicated that such care may be billable if NIH had the authority to charge patients' insurers. The NIH expressed concern that charging for nonresearch care could adversely affect NIH's ability to recruit and keep research patients. The GAO report stated current legislation is unclear with respect to whether NIH had authority to charge patients for nonresearch services. The GAO believed that if legislation were amended to include language specifically allowing patients at NIH to be charged for nonresearch services, it would have little or no detrimental effect on research. The NIH does not charge patients or their insurers for care at the Clinical Center.

Insurance companies' contracts with their covered members contain clauses that state they will not pay for health care provided to patients involved in research programs. In the section of the NIH report dealing with negotiations with insurers and Federal legislation, the NIH report described the relevant restrictions and practices of medical insurers and detailed two approaches to overcome them. According to the report, the first approach involved negotiation between the Government and medical insurers. The report included examples of how a nationally known "charity hospital" (St. Jude), a nonfederal research hospital, and other hospitals with NIH-funded clinical research centers, segregated research and nonresearch costs

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[1] A 359-bed research hospital located at NIH in Bethesda, Maryland.

[2] We use the terms, "standard care" and "nonresearch care" interchangeably throughout this report. We defined standard care, and nonresearch care, as medically necessary services that meet professionally recognized standards and are routinely or regularly provided to patients to alleviate or cure a medical condition or disease. Clinical research generally does not comply with such professionally recognized standards and practices.

before sending bills to patients' insurers and Medicare. The second approach involved legislation that would change the Internal Revenue Code. The change would, in effect, require insurers to pay for certain treatment costs in the NIH Clinical Center.

## Results of Review

Our review found that nonresearch services continue to be provided at no charge to patients. Such care is provided to those participating in controlled studies when the sole purpose of the study is to evaluate the effectiveness of various types of standard therapies and for evaluating the differences between standard and innovative (research) care. We also found that nonresearch services are provided, sometimes over many years, to research patients under what some NIH officials described as the full-service concept. Under this concept, NIH treats research patients' complete medical needs, including those medical conditions not related to the condition being studied. We agree with the conclusions in the GAO and NIH studies and believe that routine and necessary (standard) care, provided under controlled studies and to patients actively participating in research protocols, has the potential of being billed to third-party payers, i.e. medical insurers.

We did not quantify the dollar amount of nonresearch care provided at NIH or assess patients' ability to pay. We were unable to do this because NIH's financial and medical information systems do not distinguish between research and nonresearch care. Also, patient care costs are recorded both in the Clinical Center budget and the institutes' budgets making it difficult to compute a total cost of care comparable to that of private sector hospitals. In addition, NIH does not obtain any financial or health insurance information from patients.

The NIH officials we interviewed, on several occasions, acknowledged that many of the patients included in our review were receiving nonresearch care, but indicated that sometimes providing nonresearch care is a necessary incentive to recruit and keep patients in research and sometimes necessary to study the natural history of disease.

## Recommendations

We believe legislation is needed to allow NIH to charge and to require medical insurance companies, Medicare, and Medicaid to cover care at the Clinical Center. We are recommending, that NIH: (1) modify its accounting and information systems to collect the full cost of treating patients at NIH; (2) segregate research costs from nonresearch care costs, by patient; (3) collect insurance and financial information from patients; (4) seek authority to charge for nonresearch care provided under controlled studies and to other patients participating in research protocols; and (5) develop a plan for using the authority (when enacted) to charge that includes meeting with representatives of major insurers to discuss potential reimbursement procedures.

## Agency Response

The official Public Health Service (PHS) response is included in the Appendix of this report. In response to our draft report, the Assistant Secretary for Health stated that he is forwarding a copy to a workgroup chaired by Dr. Helen Smits, Deputy Administrator of the Health Care Financing Administration. This workgroup is reviewing the activities of the NIH Clinical Center and is looking at a range of options to develop more cost effective ways of doing business. The Assistant Secretary for Health has asked Dr. Smits to consider the report's conclusions and recommendations as part of her workgroup's review.

The Assistant Secretary for Health stated that once the workgroup has completed its review, the Office of the Assistant Secretary for Health will revisit the Office of Inspector General's (OIG) recommendations in conjunction with those of the workgroup to determine an appropriate course of action. The OIG agrees with this response.

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# BACKGROUND

The NIH is the principal biomedical research agency of the Federal Government. Its mission is to seek to improve the Nation's health by increasing the understanding of processes underlying human health, disability, and disease; advancing knowledge regarding: preventing, detecting, diagnosing, and treating disease; and disseminating research results for critical review and medical application.

The NIH Clinical Center, designed as a dedicated medical research facility, combines care provided under written plans of research, better known as research protocols, with laboratory research programs. Its primary purpose is the advancement of medical knowledge through research. Generally, only patients meeting certain criteria, for example; age, type of illness, and/or state of illness progression under investigation should be admitted for diagnostic tests and participation in a clinical study or trial.

Patients at the Clinical Center are generally referred to NIH by their physicians and are admitted to 1 of the 15 NIH categorical disease research institutes. Patients are generally admitted under screening protocols to determine if they are suitable for research and to determine their suitability for more narrowly defined research protocols. Patients are then treated under 1 or more of the Clinical Center's 811 active research protocols.

The Clinical Center has a support staff of 2,408 employees. In Fiscal Year (FY) 1993, more than 5,000 inpatients were admitted and 20,000 outpatients (85,000 visits) were seen at NIH's Clinical Center. The NIH does not request medical insurance information from patients, apply a means test (ability to pay), or have a patient billing system. The Clinical Center does not receive a direct appropriation from Congress. Rather, the Clinical Center receives financial support from the research institutes through the NIH Management Fund (Fund). Each institute's contribution to the Fund is based on the institutes' use of Clinical Center beds and other factors. According to an April 1994 report on NIH intramural research, prepared for Congress, of the $305 million expended on intramural research at NIH, $250 million was directly related to patient care at the Clinical Center.

While NIH does not have a patient billing system, it does (for budget purposes) have a system for allocating certain costs of providing care to the institutes having patients at the Clinical Center. This allocation system uses data on patients entered by Clinical Center staff into the Clinical Center's Medical Information System (CCMIS). Medical services provided to inpatients and outpatients (e.g., X-Rays, hospital beds, and laboratory procedures) are entered into the CCMIS and accounted for in the allocation system by patient within each institute by protocol. Neither the CCMIS nor allocation system identify the care provided as research, research related, or nonresearch care.

The institutes' costs related to maintaining patients in the Clinical Center (e.g., salaries of institutes' staff, travel expenses of patients, and administrative costs of each institute) are borne entirely by the research institutes and are not included in the Fund. The NIH does not maintain separate cost data on individual institute's direct and administrative costs that could be related to caring for patients at the Clinical Center.

## Previous Studies and Reports on Medical Reimbursement for Clinical Center Services

We reviewed two reports studying the question of reimbursement for nonresearch care provided at the Clinical Center. In 1977, GAO[3] issued a report dealing with the payment of care for research patients. The report included a discussion of a 1974 NIH study on the feasibility of charging for care. As part of its audit, GAO reviewed medical records of certain Clinical Center patients. The GAO reported that patients receive care at the Clinical Center without charge even though many of the services they receive are routine and not research related. In 1983, NIH conducted another feasibility study which found that nonresearch care is provided, but indicated that it may not be feasible from a research point of view to charge for such services.

Although both studies are quite old, we found that much of the information and concepts in both reports were useful and relevant to the current debate on this issue. When necessary, in analyzing the data in these studies, we updated information to reflect the current status of activities related to research care.

### GAO Report

The GAO concluded that many of the services patients receive at the Clinical Center are not always research related. The GAO noted that 80 of 152 Clinical Center patients sampled (during the 1974 feasibility study) were also being treated for their medical conditions for reasons not directly related to the research being conducted (i.e., not research). The patients required nonresearch care (at NIH or another hospital) during part of their stay at the Clinical Center; 55 of the 152 required nonresearch care for their entire stay. The GAO also stated that its medical advisor's review of 11 randomly selected Clinical Center patients' medical records (included in the 1974 feasibility study) found that all procedures performed on 7 patients were nonresearch in nature. For the remaining four patients, innovative medical methods were used to try to improve their medical condition and for the study of the effects of such medical methods.

During the 1974 study, NIH officials expressed a strong belief that recruitment of research patients would be hindered if NIH were to charge for services. To determine if recruitment

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[3] Services for Patients Involved in National Institutes of Health Supported Research: How Should They Be Classified and Who Should Pay for Them?--December 22, 1977--HRD-78-21.

would be affected, a questionnaire was prepared for all of the patients included in the study. Two questions dealt with whether patients would still come to NIH if they or their insurance companies were billed for nonresearch care. Of 80 patients who required hospitalization for their condition, 74 were available to respond to the 2 questions, 55 patients said they would still come, 6 patients said they would not come, and 13 either did not respond or said they were not sure. (Note, 64 of the 74 patients had medical insurance.) The GAO report provided examples of responses from its patient questionnaire:

-- "It's the best in the world."

-- "For further surgery would come here if had to pay because cannot get the kind of all round care as at NIH even when paying for it."

All six patients who stated they would not come to NIH cited financial problems as the reason. A Clinical Center official told GAO that he believed the exclusion of these patients could hamper research, but that such patients would agree to participate if NIH could selectively write off charges for routine care when the patients' participation in research was of major research significance. The study stated that NIH believed it could collect as much as $9 million annually if it charged.

As part of its review, GAO also contacted several large private insurance companies to discuss their standard exclusion clauses in insurance contracts. Such clauses exclude payment to Federal and State institutions. According to GAO, officials at the insurance companies explained the reason why payments to Federal and State institutions are excluded is because patients in such institutions are generally entitled to free care. One insurance company official told GAO, "He knew of no reason why any insurer would not pay for hospitalization costs of a patient admitted to the Center merely because it was a Federal hospital."

The GAO also considered whether NIH could charge for the care it provided. The Department of Health and Human Services' (Department) official position was that the PHS Act and related statutes provide no basis for charging for the care of research patients. The Department's position was that charging patients was "...inconsistent with congressional intent...." The GAO stated that, "Current legislation neither clearly permits nor clearly prohibits charging patients at the Clinical Center for nonresearch services." The GAO recommended that the PHS Act be clarified to specifically state whether study patients at the Clinical Center can be charged. The GAO believed that if legislation were amended to include language specifically allowing patients at NIH to be charged for nonresearch services, it would have little or no detrimental effect on research. The GAO felt that congressional intent relative to patients being charged was not clear and stated Congress should clarify existing legislation as to whether NIH could charge for nonresearch care. The GAO report stated it was not convinced that Congress is aware of:

- the extent of nonresearch services provided at the Clinical Center;

- the 1974 NIH study which indicated patients would come to the NIH Clinical Center even on a fee-for-service basis; and

- statements by officials of major insurance companies who GAO contacted suggesting conditions under which they would pay for services provided by the Clinical Center.

In addition to reviewing the provision of research and nonresearch care at the Clinical Center, GAO also reviewed care at 5 of the then more than 87 NIH grantees having clinical research centers grants. These NIH grantees provided both research services and nonresearch care to patients at nonfederal hospitals. The NIH guidelines required the grantee to separate services for patient care between research and nonresearch care based on the grantees' medical judgment. The grantees charge NIH for the research portion and charge insurers, or patients, for the nonresearch portion.

**NIH Committee Study**

In August 1983, NIH released a study on the feasibility of collecting third-party reimbursements on behalf of patients seen at the Clinical Center.[4] The study was conducted by a 10-member committee consisting of 9 NIH employees and a consultant. The report addressed clinical research at NIH, third-party payment practices and restrictions, strategies for overcoming restrictions through negotiation or legislation, and expected costs and yields from establishing a patient billing system. The NIH report indicated that NIH did not have the ability to obtain reimbursement from insurers or Medicare.

The NIH study indicated that charging for nonresearch care would make NIH a less attractive place to be hospitalized and a less attractive place to conduct research. The report stated that the side effects of billing patients for the potentially reimbursable aspects of their care would damage clinical research. According to the committee, if patients were billed for standard surgical care or drug therapy, they would have little incentive to travel to NIH to receive standard treatments available at comparable charges at any university medical center.

As part of the study, NIH identified several different categories of patients at the Clinical Center and made determinations as to whether the patients could be charged or whether insurance companies would pay for care provided in each patient category. The study concluded that services provided to some patients are of a purely research nature and do not contain nonresearch care while services provided other patients contain mainly standard care.

> Note - According to our medical advisor, some of these patients are those who volunteer for protocols involving controlled studies and clinical trials of standard therapies--they usually would require hospitalization for their illness

[4] Report of the Ad Hoc Committee on Third-Party Payments. This report responded to requests from the Office of Management and Budget and PHS.

> and some medical services provided to them is considered nonresearch care for their medical condition. Some of the patients would be receiving therapies (e.g., removing a cancerous growth) at a nonresearch hospital if they were not at the Clinical Center participating in a research protocol. These patients are normally selected to participate in trials because their condition (type of illness, state of illness or progression, and age) makes them ideal subjects for the type of research NIH conducts. During a clinical trial, research conducted on patients may involve a comparison of two or more standard (traditional) therapies for treating a cancerous growth or a comparison of a standard therapy to an investigational therapy.

The committee's report also explained that in conducting research, patients participate in clinical trials in which some patients are randomized for different treatment. Some are randomized for standard therapy (called the standard care arm of a protocol; as opposed to the research arm). These patients serve as a control group for others who are randomized to experimental approaches. While at NIH, some of these patients may be switched from standard care arms to research arms or from research arms to standard care arms (cross-over study).

According to the committee's report, some patients receive standard care at the Clinical Center and that this care could be subject to reimbursement. The committee stated that some patients receive the same treatment as they could receive in any hospital. The committee cautioned, however, that patients do so under research conditions. The report stated:

> "...Clinical Center patients...who receive the same therapy here that they would in any hospital but do so under special research circumstances. Patients are inconvenienced for long periods of time so that exacting studies can be carried out during the course of treatment. Ordinarily, if a patient simply went to his private physician for the same treatment, this would be done over a much shorter period of time. Free care is the compensation these patients receive for participating in research. If that carrot were removed, there would be little incentive to participate."

To determine the level of reimbursement that might be expected, NIH brought in a group from the Johns Hopkins Hospital to review patient information collected by the Clinical Center. The group estimated how much NIH could be reimbursed if it could bill insurers for inpatient cost; outpatients were not included. Data were collected and analyzed on all (331) inpatients at the Clinical Center on July 13, 1983. The group divided the 331 inpatients into "A" patients and "B" patients. The "A" patients were then divided into two groups: strictly research patients who would not be at the Clinical Center except for their voluntary participation in research, and patients who had some illness or condition which was being studied as part of their participation in a research protocol, but who would not have been hospitalized on July 13 were it not for participation in research. The "B" patients were those the team declared, based on the type of illness/disease and stage or severity of the case, would have been hospitalized at the time even if they were not at the Clinical Center. The report

showed that 65 percent of the patients were "A," and 35 percent were "B"--30 percent of the "B" patients had no insurance.

Not included in estimating possible reimbursement were:

- all "A" patients, even if they may have received incidental standard care;[5]
- "B" patients that were at the Clinical Center on July 13, but the team determined that their hospitalization was not necessary that day;
- services to "B" patients that the team believed insurers would disallow; and
- "B" patients without insurance and patients for whom NIH could not determine if they had insurance.

If NIH had the authority and were to bill only private insurers, based on the above criteria, the committee estimated, after deducting the cost of operating a billing system and deducting the usual patients' 20 percent co-insurance deductible, the residual financial gain to NIH would be between $3.4 to $3.7 million in 1983 dollars. If Medicare and other public insurers could also be billed, an additional $5.1 million could be received--a total of between $8.5 to $8.8 million. The report, however, questioned the rationale of charging Medicare and other Government-financed health insurance; it said there was not a net gain to the Government.

Another part of the feasibility study addressed restrictions and practices imposed by third-party payers. An examination of insurance plans in force by the Nation's largest insurance firms showed it would be impossible to obtain third-party payment without changes in the private insurance contracts then in force. The report listed the following restrictions found in insurance plans; payment is prohibited for: experimental drugs, procedures or treatment; services in a Government facility; and services for which the patient has no legal obligation to pay.

In addressing these restrictions, the committee's report indicated that legislation requiring insurers to pay for treatment costs at the Clinical Center was one solution. The NIH report also stated that insurers could be induced by legislation (e.g., changes in the Internal Revenue Code) to pay for treatment costs in Federal research hospitals as a condition for insurance premiums remaining a tax deductible expense for employers. Another approach, according to the report, would be to negotiate agreements with insurers.

The NIH report, in discussing ways of overcoming insurers' restrictions, provided examples of how two nationally known "charity hospitals" (St. Jude in Memphis, Tennessee, and City of Hope in Los Angeles, California) and a nonfederal research hospital, Rockefeller University Hospital (Rockefeller), in New York City, obtained reimbursement for standard care. These hospitals segregate research and therapeutic (nonresearch) costs before sending bills to the patients' insurers and Medicare--there was no billing of patients in excess of the insurance

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[5] Although the report did not mention patients in control groups, we assume that "A" patients would include those in control groups.

reimbursement. The majority of insurers including Medicare, Blue Cross, and Medicaid paid the hospitals on this basis.

Subsequent to the establishment of this system at St. Jude, the Tennessee legislature enacted a law to require insurers to pay St. Jude. The report stated, "Insurer cooperation with St. Jude reflects the small size of the hospital and a historic cooperation between the hospital and Blue Cross in the State." It took a California State law to require insurers to pay for nonresearch-related charges for which the patient had no obligation to pay at City of Hope. With respect to nonresearch-related charges at Rockefeller, the report indicated a law was not needed in New York to require that insurers pay Rockefeller for nonresearch care. Although the NIH report did not state these hospitals have some type of understanding with insurers, we believe the report implied the hospitals did have an understanding. We believe it also implied similar agreements could possibly be negotiated between NIH and insurers.

Before attempting negotiations with insurers, according to the report, NIH would have to adopt (in order to receive reimbursement) a series of procedures used by other hospitals that admit research patients. Such procedures include: (1) segregating research and therapeutic costs; (2) establishing patient liability for costs by law or regulation; and (3) establishing a cost/charge structure and billing process that assures insurers that they pay for no higher level for care at the Clinical Center than they pay elsewhere.

**Congressional Interest in Clinical Health Care**

The NIH Revitalization Act of 1993 (Public Law 103-43--June 10, 1993), directed the Department to conduct a study of third-party payers regarding the payment of costs of appropriate health services that are provided incidental to an individual's participation in certain clinical trials. The Act requires the Department to develop recommendations on the policies of third-party payers. The House of Representatives Conference Report 103-100, dated May 20, 1993, states:

> "The Conferees are concerned that much of the framework for the financing of clinical research is threatened by recent efforts to limit third-party payment for medical and hospital costs. This problem, which has progressed from the exclusion of payment for costs necessitated by the research to the exclusion of payment of any costs if research is conducted, has occurred not just with research on AIDS, but also with research on cancer and other life-threatening illnesses."

We do not know whether Congress will be willing to enact legislation that could allow NIH to charge certain patients and require insurers to reimburse patients for standard care provided at NIH.

## OBJECTIVE, SCOPE, AND METHODOLOGY

Our review was conducted at the request of the former NIH Director who asked us to determine if the Clinical Center is providing services that may be subject to reimbursement. In order to answer this question, we designed our review objectives to update two earlier studies performed by GAO and NIH that addressed the question of whether nonresearch services were provided at the Clinical Center; and if NIH has the authority and necessary information, including cost data, to bill for standard care. We read and analyzed the two reports issued by GAO and NIH after their studies. We did not quantify the amount of possible reimbursable care and the costs of providing such care at the Clinical Center because data was not readily available.

To determine what types of care have been provided and whether they are potentially reimbursable, we evaluated the standards used by private insurers, regulatory guidance, policies and procedures, and other Federal guidance. In addition, we reviewed policies issued by NIH, PHS, and the Department regarding reimbursement at the Clinical Center.

We selected for review at a NIH institute the medical records for 61 of 82 patients who received only pharmaceutical services in the second quarter of FY 1993. As part of our review, at this same institute, we also randomly selected medical records for 32 of 346 patients who received surgical operations at local hospitals that were paid for by NIH in the period January 1990-July 1994; later, we expanded our review and selected medical records for 41 additional heart surgery patients. The institute was selected because it had one of the highest percentage of patient costs not assigned to written research protocols in the CCMIS. We also reviewed the plans of care defined in selected Clinical Center protocols to determine if the plans were adequately documented, specified clear research objectives, or involved standard diagnosis and patient screening. We were assisted in our evaluation of medical records by OIG's medical advisor, a physician.

Reviews were conducted to determine whether standard care was evident in the planned activities. We also interviewed the clinical directors (or surrogates) of all institutes as well as the Acting Deputy Director of the Clinical Center and the Associate Director for Quality Assurance of the Clinical Center. Additionally, we interviewed the Chief of the Medical Records Department.

We conducted discussions to determine if the Clinical Center, under current statutes and regulations, could charge patients for services performed. Our review was conducted in accordance with generally accepted government auditing standards.

## RESULTS OF REVIEW

### The NIH Clinical Center Provides Nonresearch Care

We found standard medical care continues to be provided at no charge to some research patients at NIH. Such care is provided when patients are participating in controlled studies at the Clinical Center and to others when they are provided, under the full-service concept, treatments for their medical conditions which are unrelated to research. Because of the nature of the medical procedures, we believe that if these patients were not at NIH, participating in research, some would be receiving the same or similar care at community hospitals or in doctors' offices. It is this care that we believe is potentially billable.

We reviewed selected protocols for all the institutes. Based on our review, we concluded that nonresearch care is provided as an integral component in the execution of clinical research, or as a definable segment, such as a control group, or as "best available" or standard therapy arms in a clinical trial. Patients participating in research protocols contrasting the effectiveness of one standard therapy to another standard therapy, or contrasting standard therapies to experimental therapies, receive standard care that potentially could be charged to patients or their insurers.

Our review of Clinical Center protocols that contrast the effectiveness of different treatments showed that such protocols contain both research and standard care arms. The protocols require the innovative treatment be given to one or more groups of patients and standard treatment be given to what is called a control group--those patients enrolled in the protocol's standard care arm. For example, we looked at 1 NIH protocol (conducted off-site) which consisted of 3 arms (50 patients in each arm with symptomatic Human Immunodeficiency Virus infection). The control group received the acquired immune deficiency syndrome drug, Azidothymidine (AZT). The two other groups received a combination of AZT and another drug. If the patients in the control group were not participating in this protocol, they could have been treated by their personal physicians with AZT. If applicable, their insurance companies would have to reimburse the patients for the cost.

In another example of the provision of standard care, a protocol called for a randomized study comparing different treatments of 134 patients with melanoma. One group of patients (the control group) received a standard combination chemotherapy regiment consisting of Tamoxifen, Cis-Platinum and Dacarbazine. The other group received this same combination chemotherapy but in conjunction with Alpha-interferon and Interleukin-2.

In still another example, two research patients were being treated with investigational drugs for cancer. During the treatment they had unrelated heart problems. Both patients received urgent heart surgery; one required and received heart valve repair surgery and the other

patient received revascularization surgery--both standard therapies. We believe that if the patients were not participating in research protocols, they would have been treated by their personal physicians and their insurance companies could have reimbursed the patient for the cost.

We discussed our findings with NIH officials who acknowledged that nonresearch services are provided at the Clinical Center. However, NIH pointed out that some of the surgery patients were too sick to participate in research and the other patients received standard care under research conditions. According to NIH, these patients often incur travel costs and other inconveniences when volunteering to participate in research at NIH. If NIH was to charge insurers for the standard care related to research, NIH believes some patients may not be willing to participate. The NIH position is contrary to the results of the GAO survey which found that most patients would participate in research even if their insurance companies were billed. We believe the reasons given by these patients during the earlier survey are still valid today. The NIH continues to be recognized as one of the Nation's premier research facilities staffed by physicians and scientists who are in the forefront in the development of new and innovative medical technologies.

## The Clinical Center's Information Systems Do Not Provide Data Needed to Determine Cost or Type of Care Subject to Reimbursement

A reasonable estimate of the cost of care, whether it is research or nonresearch, is currently not possible because the Clinical Center's CCMIS collects only the costs of operating the Clinical Center and does not include costs borne by institute budgets, nor do they distinguish between research and nonresearch care by patient within protocols. We believe NIH should be aware of the costs associated with research protocols for reasons other than those related to billing. For example, cost data on research provided to Clinical Center patients is needed in assessing the full cost of Cooperative Research and Development Agreements (CRADA)[6] and in establishing resources consumed in developing new technologies and in transferring these technologies to the private sector, as well as providing cost information for managing clinical research. We believe that the system used to allocate patient costs to the various NIH institutes could be modified to identify research and nonresearch care.

The two NIH studies, conducted in 1974 and 1983, both estimated potential annual revenues of about $9 million if standard care was billed to Clinical Center patients. We believe current estimates would be higher because these earlier studies did not count research patients that received incidental standard care, outpatients and patients that NIH could not readily determine had insurance coverage. As noted earlier, we did not compute our own estimates of potential revenue because relevant data was not readily available.

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[6] The CRADAs are a collaborative mechanism intended to foster the private commercialization of useful technologies developed in Federal laboratories.

The following are the three major obstacles in the accounting and management systems that inhibited our ability to estimate revenues and that we believe need to be overcome before nonresearch care could be billed.

(1) **The NIH Does Not Capture the Full Operating Cost of the Clinical Center.** The NIH's information systems do not collect all the accounting information related to providing medical services to patients. While the CCMIS and allocation system collect and allocate the cost of operating the Clinical Center to individual NIH institutes, these costs do not include each institute's costs attributable to patients. For example, the salaries of the research institutes' staff who may treat patients, and the proportionate share of administrative costs of the institutes and NIH Administration, are not accounted for or paid through the Fund. Thus, the full costs of services provided to patients is not shown in the Fund's financial statements.

The NIH needs to determine all the costs of operating the research hospital. This should include costs currently captured by the CCMIS (used to allocate cost to the institutes) and the institutes' costs not currently captured by the Fund. Also, as mentioned in the Committee's 1983 report, for NIH to charge for nonresearch care, it would have to adopt a series of procedures used by other hospitals that admit research patients. Such procedures include segregating research and therapeutic costs and establishing a cost/charge structure and billing process that assures insurers that they pay for no higher level for care at the Clinical Center than they pay elsewhere.

Further analysis of costs is needed to identify those costs (administrative and direct) that are attributable to care at the Clinical Center. Finally, these costs should then be allocated to research protocols.

(2) **The NIH Does Not Know How Much Standard Care Is Provided.** The NIH does not have a system for identifying how much standard care is provided under the full-service concept or when care is provided that is incidental to research at the Clinical Center. Health care providers are not required to use codes identifying care as research or nonresearch when entering patient information into the CCMIS. We found that staff would have to review individual patients' medical records to identify and quantify the type of care given in protocols that include both nonresearch care for some patients and experimental care for other patients. However, according to NIH, a review of medical records may not always provide the needed information.

According to NIH officials, in "double blind"[7] clinical trials, patients' records will not always disclose the type of care (research or nonresearch) patients are receiving. New procedures would need to be developed to capture data related to standard care in these cases.

(3) **Patient Financial Information Is Not Collected.** The NIH does not know the number of patients with medical insurance or if patients have the ability to pay. The NIH does not ask patients when they are admitted if they have medical insurance or have the financial means to pay for standard medical services. This information is needed for NIH to make a determination as to the feasibility of establishing a billing system, acceptable to insurers, for standard medical services provided to patients.

## The NIH Does Not Have Legal Authority to Obtain Reimbursement for Nonresearch Care

We believe legislation is needed to give NIH authority to charge patients and their insurers for standard care, incidental to research, provided at the Clinical Center. Also, legislation is needed to establish patient liability to pay for such care and to require Medicare and Medicaid to pay.

We believe such legislation is needed to overcome insurers' restrictions on: reimbursing for care in research hospitals; standard care incidental to research; and when the patient is not legally obligated to pay for care. Officials at the Health Insurance Association of America told us that, generally, insurance reimbursement would not be made for research or medical services for which the patient is not legally obligated to pay. Similarly, section 1862(a) of the Social Security Act--Medicare--states that no payment can be made under part A or part B when there is no obligation for the patient to pay. Legislation could take several forms. Private insurers could, for example, be required, by legislation, to pay for certain treatment costs in Federal research hospitals as a condition for insurance premiums remaining a tax deductible expense for employers.

Whatever form legislation takes, we believe it should allow NIH flexibility in billing patients. It should allow NIH to enter into agreements with insurers just as St. Jude, City of Hope, and Rockefeller did. These hospitals do not bill patients for non-covered services or their share of deductibles and co-insurance. Another form of flexibility in billing could give the NIH Director authority to selectively write off charges for standard care when the patient does not have insurance or when it is concluded the patients' contributions may be of vital research significance.

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[7] Clinical trials in which neither the attending physician nor the patient know whether standard therapy, no therapy, or experimental therapy is being provided.

As discussed earlier, the NIH Revitalization Act directed the Department to develop recommendations on insurers' policies regarding paying for standard care incidental to an individual's participation in research. We believe our review of this issue supports the need for such recommendations regarding standard care provided at the Clinical Center.

**Discussions with Representatives of the Health Insurance Industry**

Prior NIH studies, and our interviews with NIH officials, revealed that NIH has not held discussions with representatives of major health insurance companies to explore the possibility of reaching an agreement relative to reimbursing NIH for standard care provided to patients at the Clinical Center. The GAO reported that its discussions with several large insurers revealed that exclusion clauses in their contracts would not preclude their paying for standard care at the Clinical Center. Insurance company officials, however, told GAO that insured and uninsured patients must be treated equally with respect to charges.

As discussed earlier in this report, we believe several hospitals have worked out an understanding with insurers regarding research patients. The 1983 NIH report suggested similar agreement could possibly be negotiated between NIH and insurers. Based on what GAO found in its discussions with medical insurers, we also believe that discussions with insurers may provide NIH with an opportunity to reach an understanding on billing and pave the way for legislation that would allow NIH to charge for certain services.

## CONCLUSION

The NIH's Clinical Center, a research hospital, provides free standard medical care when incidental to research or as part of a patient's participation in a protocol involving a controlled clinical study. The NIH stated that it has a practice of providing research patients medical services that are not related to the condition being studied. The NIH lacks legal authority to charge for the cost of care provided at the Clinical Center, legislation allowing it to charge for the cost of certain services is needed. We found however, that a reasonable estimate of the cost of care is not currently possible because the Clinical Center's accounting system and CCMIS do not collect all costs of operating the Clinical Center, nor do they distinguish between research and standard care by patient within protocols. We believe that the system used to allocate patient costs to institutes could be modified to identify nonresearch care.

Aside from the problems the absence of cost data presents with regard to billing for certain services, we believe NIH management should be aware of the total costs associated with research protocols for other reasons. For example, cost data on research provided to Clinical Center patients is needed in assessing the full cost of CRADAs and in establishing resources

consumed in developing new technologies and in transferring these technologies to the private sector, as well as providing cost information for managing clinical research.

## RECOMMENDATIONS

We recommend that NIH:

1. modify its accounting and information systems to collect the full cost of treating patients at NIH. (Costs should include the expenses related to the categorical disease institutes' attending physicians and other staff as well as administrative costs.)

2. segregate research costs from nonresearch care costs, by patient.

3. collect insurance and financial information from patients. (When admitting new patients and when re-examining former patients, admission staff should request medical insurance and financial information.)

4. seek authority to charge for nonresearch care provided under controlled studies and to other patients participating in research protocols.

5. develop a plan for using (when enacted) the authority to charge that includes meeting with representatives of major insurers to discuss potential reimbursement procedures.

## AGENCY RESPONSE

The official PHS response is included in the Appendix of this report. In response to our draft report, the Assistant Secretary for Health stated that he is forwarding a copy to a workgroup chaired by Dr. Helen Smits, Deputy Administrator of the Health Care Financing Administration. This workgroup is reviewing the activities of the NIH Clinical Center and is looking at a range of options to develop more cost effective ways of doing business. The Assistant Secretary for Health has asked Dr. Smits to consider the report's conclusions and recommendations as part of her workgroup's review.

The Assistant Secretary for Health stated that once the workgroup has completed its review, the PHS will revisit the OIG recommendations in conjunction with those of the workgroup to determine an appropriate course of action. The OIG agrees with this approach.

# APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

JUN 7 1995

TO: Inspector General, OS

FROM: Assistant Secretary for Health

SUBJECT: Office of Inspector General (OIG) Draft Report "Reimbursable Patient Care Costs at the National Institutes of Health's Clinical Center," A-15-92-00011, January 1995

The PHS has reviewed the subject OIG draft report. As you know, the Department is reviewing selected aspects of its operations under REGO II, including the operations of the Clinical Center at the National Institutes of Health (NIH). In this regard, a workgroup chaired by Dr. Helen Smits, Deputy Administrator of the Health Care Financing Administration, is reviewing the activities of the NIH Clinical Center and is looking at a range of options to develop more cost effective ways of doing business. We have forwarded your office's report along with other pertinent information to Dr. Smits and asked that the report's conclusions and recommendations be considered as part of her workgroup's review.

Once the workgroup has completed its review, we will revisit the OIG recommendations in conjunction with those of the workgroup to determine an appropriate course of action. Dr. Smits advises her report will be ready by the end of the calendar year. We will advise you of our plans shortly after that time. I hope this will be satisfactory and thank you for your cooperation in this important effort.

Philip R. Lee, M.D.

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