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HUMAN RESOURCES
DIVISION

RESTRICTED

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The Honorable John Conyers, Jr.
The Honorable Joshua Eilberg
The Honorable Tennyson Guyer
The Honorable Margaret M. Heckler
The Honorable Elizabeth Holtzman
The Honorable Henry J. Hyde
The Honorable Jerry M. Patterson
The Honorable James H. Scheuer
The Honorable Harold L. Volkmer
The Honorable Robert A. Young
House of Representatives

RELEASED

This is in response to your July 15, 1977, request for information on and an examination of several aspects of Government-funded sterilizations. In subsequent discussions with Congressman Young's office, we agreed to limit our effort to an examination of the administrative controls established by the Department of Health, Education, and Welfare (HEW) to assure compliance with its sterilization requirements. Also, as agreed with his office, we further limited our review to one HEW Regional Office and selected grantee activity in one State in that region as a result of recent initiatives announced by HEW to strengthen its sterilization requirements.

SCOPE OF REVIEW

We conducted our review at HEW Region III in Philadelphia, and at selected HEW grantees and their agents in Pennsylvania. We determined what actions HEW took to implement its April 1974 sterilization regulations (45 C.F.R. 205.35 and 42 C.F.R. 50.201) and, to a limited extent, how well HEW grantees and/or their agents were complying with these regulations for the following programs.

--Medicaid, Title XIX of the Social Security Act, administered by the Health Care Financing Administration,

1/Region III includes Delaware, Maryland, Pennsylvania, Virginia, West Virginia, and the District of Columbia.

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- Social Services, Title XX of the Social Security Act, administered by the Office of Human Development Services,
- Family Planning, Title X of the Public Health Service Act, administered by the Public Health Service, and
- Maternal and Child Health, Title V of the Social Security Act, administered by the Public Health Service.

These programs are operated through HEW grants to either State or private nonprofit agencies. Some of these agencies subcontract with other organizations for the provision of program services or for review and payment of claims.

STERILIZATION REQUIREMENTS

Nontherapeutic sterilization is defined in HEW regulations as a procedure or operation, the purpose of which is to render an individual permanently incapable of reproducing. Sterilizations to treat an existing illness or injury are classified as therapeutic sterilizations.

For nontherapeutic sterilizations, HEW:

- Prohibits using Federal funds for the sterilization of anyone under the age of 21 or legally incapable of consenting to the sterilization (mentally incompetent under State laws).
- Requires at least a 72-hour waiting period after informed consent is given by the patient before performing the sterilization.
- Specifies six basic elements necessary in obtaining informed consent:
 1. A fair explanation of the procedure.
 2. A description of the attendant discomforts and risks.
 3. A description of the benefits to be expected.
 4. Counseling concerning alternate family planning methods and the irreversibility of the procedure.
 5. An offer to answer any questions.

6. An instruction to the individual that he or she is free to withhold or withdraw his or her consent at any time without losing any benefits or care to which he or she is entitled.

The consent forms must be signed by the patient. The short form must include the signatures of an auditor-witness to the oral presentation and the person obtaining the consent.

SUMMARY OF FINDINGS

To implement the regulations, HEW Region III notified program grantees of the requirements, reviewed consent forms drafted by them, and required regular reporting of sterilizations. For the Medicaid program, HEW specifically reviewed some claims to assure appropriate consent forms were used and that State agencies had adequate controls. Currently, HEW Region III has no special effort for on-site sterilization review but includes it in its overall program monitoring.

From our review of HEW Region III records and procedures and a limited examination of grantee operations, controls established in Pennsylvania generally appeared to be working and no flagrant sterilization abuse was found. However, some problems were identified:

- Statistical reporting is inaccurate.
- HEW was lax in seeing that States promptly used in their Medicaid programs consent documents that complied with its regulations.
- Administrative controls and payment procedures for Medicaid may need to be strengthened to ensure that requirements are met for sterilizations done at the same time as a related surgical procedure, such as a Caesarian section.
- In Pennsylvania, consent documents for 10 of 129 approved Medicaid physician claims reviewed omitted one element of informed consent. These omissions appeared to be administrative oversights rather than deliberate abuse.
- Pennsylvania had not established adequate procedures to ensure that hospital and physician Medicaid claims were both denied when requirements were not met.

Also, we contacted several consumer and advocacy groups, such as Women's Medical Services and the Pregnancy Advisory Service, from the Philadelphia area. They had no evidence of sterilization abuse. In fact, one official indicated that some women experienced difficulty obtaining a sterilization because of the stringency of health care providers' procedures.

STATISTICAL REPORTING

For the first three quarters of calendar year 1977, Pennsylvania reported 2,944 Medicaid-funded nontherapeutic sterilizations at a cost of \$279,300. For the same period, Family Planning and Maternal and Child Health program grantees in Pennsylvania reported 140 and 21 sterilizations, respectively, but cost information was not reported. No sterilizations were done under Pennsylvania's Social Services program.

Reporting is inaccurate

During our review in Pennsylvania, we noted duplicate reporting in the numbers and cost of sterilizations. According to Public Health Service instructions, grantees report both arranging and paying for sterilizations. For example, a Maternal and Child Health grantee in Pennsylvania refers voluntary sterilization patients to a hospital and includes the referrals as sterilizations. Because the patients' operations were paid for with Medicaid program funds, the sterilization is also reported in the statistics of that program.

We also noted that some inpatient hospital sterilizations are counted more than once under the Pennsylvania Medicaid program. Occasionally, besides counting the primary physician claim, the assisting surgeon or anesthesiologist claim is counted as if it represented a separate sterilization. Under-reporting occurs because, under Medicaid in Pennsylvania, no sterilizations done on an outpatient basis are reported to HEW. Also, the State reports only the physician costs for inpatient sterilizations--hospital costs are not reported.

Our findings for each program follow.

MEDICAID

During 1975 and 1976, HEW regional personnel reviewed State consent forms and in each State examined a sample of claims submitted by Medicaid providers. HEW disallowed sterilization costs for fiscal year 1975, the first complete fiscal

year the regulations were in effect, for the District of Columbia and Maryland. Neither jurisdiction was using an approved consent form. The District had \$103,924 disallowed. Maryland had \$18,817 disallowed.

We found that due to the absence of close monitoring by HEW in West Virginia, the State's Department of Welfare is still using a consent form that relies only on an oral explanation of informed consent. The regulations stipulate that an oral explanation must be supported by a written summary. We brought this matter to the attention of the Regional Medicaid Director, and on January 30, 1978, West Virginia was informed by Region III that it was out of compliance.

Also, due to the lack of vigorous enforcement action by HEW, Maryland did not begin using an HEW-approved consent form for Medicaid until May 1977. Furthermore, Pennsylvania Medicaid providers have been permitted to use either a short or long form consent document. The short form does not comply with HEW requirements because the no-loss-of-benefits notation is at the bottom of the consent document rather than at the top. After we brought this matter to HEW Region III's attention, it obtained concurrence from the State to instruct providers to discontinue using the short form consent document.

Pennsylvania

In Pennsylvania, the Department of Public Welfare's Bureau of Medical Assistance administers the Medicaid program. Medicaid claims are processed by three separate entities, depending on the type of claim--hospital, inpatient physician, or outpatient physician.

Inpatient hospital claims

Physicians and nurses in the Bureau's Utilization Review Division review all hospital claims to see that sterilization requirements are met. The HEW Audit Agency examined the Bureau's operation during the summer of 1976. It found no substantive deficiencies. Our audit findings agreed.

Inpatient physician claims

All claims for inpatient hospital physician care are reviewed by a contractor, Pennsylvania Blue Shield. We randomly selected for review 193, or about 10.5 percent, of the 1,846 sterilization claims received during the third

calendar quarter of 1977. Of the 193, 131 were for nontherapeutic sterilizations and 62 were for sterilizations reportedly done for therapeutic reasons. For the 131, we found that:

- None were hysterectomies.
- Pennsylvania Blue Shield approved 129 for payment and correctly denied payment for 2 because the patients were under age 21.
- Each of the 129 approved claims was accompanied by a consent document and met age, waiting period, and signature requirements.
- Consent documents for 10 of the 129 approved claims omitted required indications that one of the elements of informed consent was met. However, these omissions appeared to be administrative oversights or "technical violations," rather than deliberate abuse. An HEW Region III Medicaid program representative told us that the 10 physician claims should have been denied because of the omissions. State instructions also require that claims for sterilizations be denied when consent documents are incomplete.

We found that the State's Utilization Review Division rejected four, approved three, and had not yet received three of the corresponding hospital claims for these 10 cases. The State acknowledges needing better procedures to see that physician claims for inpatient services are rejected when the corresponding hospital claim is rejected and vice versa. It plans to correct this when it automates its hospital claim processing operation, which is now manual.

As agreed, our medical consultant will review the 62 therapeutic procedures from our sample to determine their medical necessity. Also, as agreed, we will report these results separately--orally if no substantive problems are identified, otherwise in writing.

Sterilizations done with other procedures

During our review at Pennsylvania Blue Shield, we noted a potential problem that could exist in administrative control when a sterilization is done at the same time as a related surgical procedure. Under current Pennsylvania Medicaid regulations, a sterilization done in conjunction with a Caesarean section may not be identified.

Pennsylvania's regulations provide that the physician is only reimbursed for the major surgical procedure, when two or more related surgical procedures are done together. If a sterilization is done at the same time as a Caesarean section, the latter is considered the major procedure, and the physician is paid the rate for that procedure. He receives no additional payment for the sterilization.

Therefore, if a sterilization is done, it may not be recorded on the physician's claim form, and Blue Shield reviewers may have no indication that the sterilization was done. Also, even if the sterilization was identified by the physician, the absence of the consent form would not result in denying payment for the procedure according to Blue Shield and a State Medicaid official because no reimbursement is allowed under Pennsylvania Medicaid regulations.

On the other hand, State Utilization Review Division officials told us they would deny payment for that portion of the hospital cost related to a sterilization done at the same time as a Caesarean section if they knew the sterilization were done and requirements were not met. None of the sterilization cases we reviewed also involved a Caesarean section. Therefore, we did not determine the effectiveness of the State's controls in this area.

Outpatient claims

Medical Audit, part of the Pennsylvania Department of Public Welfare's Office of the Comptroller, reviews all outpatient claims, including those for sterilizations. Medical Audit's manual includes procedures for processing sterilization claims.

We did not review outpatient physician claims for sterilizations because they are not systematically identified among the approximately 4 million claims filed annually. State personnel estimated that less than 50 outpatient sterilizations, primarily vasectomies, are done yearly under Medicaid.

SOCIAL SERVICES

Family planning services are required to be offered by each State under its title XX program. Only one State in Region III--Virginia--has included sterilizations in its social services programs.

In Pennsylvania, the Department of Public Welfare, Bureau of Child Welfare, manages the Social Services family planning program. The Bureau contracts with the four Public Health Service title X family planning grantees to provide services. These contracts specifically prohibit funding of sterilizations.

PUBLIC HEALTH SERVICE

In September 1975, HEW's Deputy Assistant Secretary for Population Affairs requested each Public Health Service region to designate a sterilization liaison (1) to inform both regional office health services personnel and grantees of the regulations and Department directives on sterilizations, and (2) to monitor regional enforcement. Region III staff review statistical reports submitted by grantees and followup on cases which appear to be out of compliance, such as a reported nontherapeutic sterilization of a person under 21.

Public Health Service sterilization guidelines require that if any hospital or clinic it funds reports more than 100 sterilizations annually, an audit by its regional office is mandatory. For the programs we reviewed, no hospital or clinic in Region III reported more than 100 sterilizations to the Public Health Service during the first 9 months of 1977.

On-site review for compliance with the regulations for sterilization activity below the 100-case threshold is done in conjunction with overall project review. No separate records are kept unless deficiencies are noted. Therefore, we could not determine the adequacy of the scope and depth of the reviews. However, we noted that in 1976 Region III reported only three sterilization cases to the Secretary for not meeting regulations.

Title X Family Planning in Pennsylvania

Pennsylvania's title X grantees are four nonprofit family planning councils that subcontract with clinics and hospitals throughout the State to provide family planning services. We visited the council that serves the State's largest population area. This council has contracted with a hospital and a Planned Parenthood clinic to perform sterilizations. The council approves all sterilizations prior to the operation based on medical, financial, and social information. The council supplements HEW regulations by requiring a handwritten letter from the patient explaining the reasons for the sterilization and showing knowledge of its implications.

During the third quarter of calendar year 1977, the hospital and clinic having contracts with the council reported a total of 12 sterilizations. Our review of the hospital and clinic records showed that sterilization requirements were met in each of the 12 cases. <

Maternal and Child Health
Program in Pennsylvania

In Pennsylvania, the State's Department of Health, Bureau of Children's Services, administers the Maternal and Child Health program. As part of this program, the Bureau funds three Maternal and Infant Care projects which can pay for sterilizations. An HEW Region III representative said that all 21 sterilizations reported by these projects for the first 9 months of 1977 were referrals to other service providers for coverage under Medicaid. These referrals were reported because the Public Health Service requires information on sterilizations arranged or paid for. The Bureau also provides funds for family planning services under its Maternal and Child Health program. It contracts with the four title X grantees in the State to provide family planning services, but the contracts do not provide funds for sterilizations.

RECENT HEW INITIATIVES

On December 1, 1977, HEW announced proposed new sterilization regulations. Key provisions would

- require a 30-day period between obtaining consent and performing the operation,
- require the physician to sign a document stating he discussed the procedure with the patient just prior to the time of the operation,
- require prepayment review of consent forms, and
- prohibit hysterectomies as a nontherapeutic sterilization procedure.

HEW is accepting comments on the proposed new regulations for 90 days after the announcement.

The title X grantee contacted expressed concern over the 30-day waiting period proposed because a woman desiring a

post-partum sterilization may have to undergo two hospitalizations. For example, if a woman delivered early, 30 days may not have passed since the consent form was signed so she would have to make a return trip for the sterilization.

On November 1, 1977, HEW announced new efforts to combat unnecessary surgery, including hysterectomies. These steps include: encouraging second opinions, strengthening Professional Standards Review Organization monitoring of surgery, and developing criteria for certain surgical procedures, including hysterectomies.

OBSERVATIONS

We found no flagrant abuses of HEW's sterilization regulations in our review of selected grantee activities in Pennsylvania and controls generally appeared adequate. However, our review disclosed some actual and potential problems in administrative controls. Because of the limited nature of our review, we are not making any conclusions or recommendations. However, we are making some observations on matters we believe HEW might consider in developing and implementing its new sterilization regulations. These are

- seeing that grantees promptly use approved forms for documenting informed consent;
- ensuring that records for all HEW-funded sterilizations, whether done on an inpatient or outpatient basis, can be easily obtained and reviewed;
- seeing that criteria for sterilization claim denial are understood and consistently implemented by reviewers; and
- improving the accuracy of statistical reporting of sterilization activity.

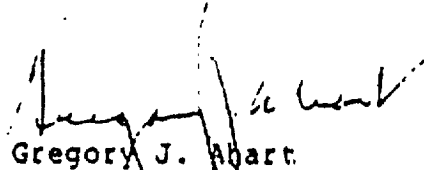
In addition, HEW should consider the problem of sterilizations done at the same time as other surgical procedures, such as Caesarean sections, from two aspects: (1) denial of Federal financial participation for at least part of the cost when it is known a sterilization was done without meeting requirements and (2) identifying cases in which sterilizations are done but not identified on the claim form or documents accompanying it. If providers were required to report by patient number each Medicaid funded sterilization--similar to

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the Public Health Service's reporting requirement--it would be easier to determine cases in which sterilizations were done at the same time as other surgical procedures.

As requested, we did not give HEW an opportunity to formally comment on this report. Its contents, however, were discussed with HEW Region III officials and headquarters staff responsible for administering the programs involved and their comments were incorporated where appropriate.

Also, as requested, this letter will not be released to HEW or the public until 1 day after you and the other requesters have received it.


Gregory J. Abart
Director