

April 2008

ORGAN TRANSPLANT PROGRAMS

Federal Agencies
Have Acted to
Improve Oversight,
but Implementation
Issues Remain





Highlights of [GAO-08-412](#), a report to the Ranking Member, Committee on Finance, U.S. Senate

Why GAO Did This Study

Media reports in 2005 and 2006 highlighted serious problems at organ transplant programs, calling attention to possible deficits in federal oversight. Two agencies in the Department of Health and Human Services (HHS) oversee organ transplant programs: the Centers for Medicare & Medicaid Services (CMS) oversees transplant programs that receive Medicare reimbursement, and the Health Resources and Services Administration (HRSA) oversees the Organ Procurement and Transplantation Network (OPTN), which manages the nation's organ allocation system. GAO was asked to examine (1) federal oversight of transplant programs at the time the high-profile cases came to light in 2005 and 2006 and (2) changes that federal agencies have made or planned since then to strengthen oversight. GAO interviewed CMS, HRSA, and OPTN officials and reviewed agency documents and data and a CMS draft proposal for sharing information with HRSA.

What GAO Recommends

GAO recommends that the Secretary of Health and Human Services direct (1) CMS to develop a methodology for conducting on-site surveys for Medicare reapproval to ensure that at least some programs meeting certain Medicare criteria are surveyed and (2) CMS and HRSA to establish a time frame for finalizing an agreement to share information from their oversight activities. HHS concurred with both recommendations.

To view the full product, including the scope and methodology, click on [GAO-08-412](#). For more information, contact Randall B. Williamson at (202) 512-7114 or williamsonr@gao.gov.

ORGAN TRANSPLANT PROGRAMS

Federal Agencies Have Acted to Improve Oversight, but Implementation Issues Remain

What GAO Found

Limitations in federal oversight of organ transplant programs existed when high-profile problems came to light in 2005 and 2006. These high-profile cases included, for example, a transplant program that lacked a full-time surgeon for over a year and had been turning down organs offered for patients at markedly high rates. At that time, CMS did not actively monitor heart, liver, lung, and intestine transplant programs, relying instead primarily on complaints to detect problems. CMS periodically monitored kidney transplant programs through on-site inspections, known as surveys, but the surveys reviewed compliance with requirements that had not been substantially updated in decades and were limited in scope. In addition, some programs were not actively monitored. At the same time, the OPTN actively monitored transplant programs for many types of potential problems and worked with the programs to resolve identified problems. The OPTN's monitoring activities, however, were not sufficient to promptly detect certain problems that prolonged the time that patients waited for transplants, such as inadequate staffing at transplant programs.

CMS, HRSA, and the OPTN have made or plan to make changes to strengthen their oversight of organ transplant programs, but the effectiveness of these changes will depend, in part, on implementation and information sharing by CMS, HRSA, and the OPTN. In 2006, after high-profile problems came to light, CMS began actively monitoring heart, liver, lung, and intestine transplant programs. In a more fundamental change, CMS published new regulations in 2007 that establish a single set of updated requirements for all Medicare-approved transplant programs and provide for periodic reviews of programs. The OPTN has been working with HRSA to develop and implement a set of indicators to better detect problems that prolong the time patients wait for transplants. However, neither CMS nor the OPTN has fully implemented these changes, and their full effect remains to be seen. In particular, CMS has not determined the extent to which it will conduct on-site surveys in its periodic reviews of programs for Medicare reapproval. Under the new regulations, CMS may choose not to conduct on-site reapproval surveys of programs meeting certain Medicare requirements. Not conducting these surveys may limit CMS's ability to monitor for compliance with other Medicare requirements and to detect problems like some of those involved in the high-profile cases. As of January 2008, CMS had not determined how it will choose which transplant programs to survey, if any, among those for which it has discretion. Further, while CMS, HRSA, and the OPTN recognize the value of sharing information about potential problems at transplant programs, how they will share additional information from their oversight activities has not been resolved. A definitive agreement between CMS and HRSA on this issue will better ensure that problems at transplant programs are detected and corrected in a timely manner.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
CoP	condition of participation
ESRD	end-stage renal disease
HHS	Department of Health and Human Services
HMO	health maintenance organization
HRSA	Health Resources and Services Administration
MPSC	Membership and Professional Standards Committee
NCD	national coverage determination
OPTN	Organ Procurement and Transplantation Network
UNOS	United Network for Organ Sharing

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United States Government Accountability Office
Washington, DC 20548

April 29, 2008

The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
United States Senate

Dear Senator Grassley:

Organ transplantation has become increasingly common, with over 28,000 organ transplants performed in the United States in 2007. Over 250 U.S. hospitals have organ transplant centers. Many of these centers operate multiple transplant programs that each specialize in the transplantation of a specific organ, such as the kidneys, heart, liver, lungs, intestines, or pancreas. Despite increases in organ donations, the demand for organs continues to exceed the available supply.¹ Over 6,000 people die each year in the United States while waiting for organ transplants. The scarcity of organs relative to demand emphasizes the need to ensure both the equitable allocation of organs and proper oversight of the organ transplantation system, including the programs that perform organ transplants.

Two agencies within the Department of Health and Human Services (HHS) are involved in overseeing the organ transplantation system. These two agencies have responsibilities that differ in some respects but overlap in others.

- HHS's Health Resources and Services Administration (HRSA) is responsible for overseeing the Organ Procurement and Transplantation Network (OPTN), a nonprofit network of transplant centers and others in the transplant community that was established in 1984 to manage the nation's organ allocation system. The OPTN's responsibilities include maintaining a list of individuals waiting for transplants, operating a computerized system for matching donated organs with individuals on the waiting list, and developing policies for how organs are to be allocated. The OPTN is administered by a nonprofit organization that has a contract

¹In 2007, 14,393 individuals (deceased and living) donated one or more organs.

with HRSA.² Historically, the OPTN's primary focus has been ensuring the equitable allocation of donated organs, and its policies include detailed allocation rules for matching donated organs with individuals on the waiting list.³ Its policies also address other areas related to transplantation, such as the training and experience of key transplant personnel and performance standards for transplant programs related to patient survival rates and transplant activity. More recently the OPTN's activities expanded to include monitoring members' compliance with federal regulations and OPTN policies. The OPTN monitors its members' compliance through various mechanisms, such as on-site reviews of transplant programs and regular reviews of organ allocations, and is responsible for reporting member noncompliance and any other issues affecting patient health or public safety to HRSA.

- HHS's Centers for Medicare & Medicaid Services (CMS)⁴ is responsible for regulating transplant programs that receive reimbursement under the Medicare program.⁵ CMS oversees fewer transplant programs than the OPTN because not all transplant programs participate in Medicare.⁶ In addition, CMS's range of requirements for Medicare-approved transplant programs differs from the OPTN's; for example, CMS does not have specific requirements for organ allocation procedures. At the same time, CMS's requirements address some areas in common with the OPTN, such as minimum qualifications for some transplant program personnel and patient survival rates. CMS has monitored some transplant programs by contracting with state agencies to conduct routine on-site inspections, known as surveys.

²The United Network for Organ Sharing (UNOS), a nonprofit organization, administers the OPTN under contract with HRSA. We use the OPTN to refer to the OPTN, UNOS, or both and OPTN officials to refer to OPTN officials, UNOS officials responsible for administering the OPTN, or both.

³The OPTN's expectations for its members are specified in OPTN policies and OPTN bylaws. In this report, we refer to both OPTN policies and OPTN bylaws as OPTN policies.

⁴CMS was known as the Health Care Financing Administration prior to June 14, 2001. In this report, we use CMS to refer to activities of both CMS and the Health Care Financing Administration.

⁵Medicare is a federal program that finances health care for people aged 65 years or older and for younger people with disabilities and people with end-stage renal disease (permanent kidney failure requiring dialysis or transplantation).

⁶Based on CMS and OPTN data, we estimate that about 80 percent of transplant programs are Medicare approved.

In 2005 and 2006, media reports of problems at several organ transplant programs drew attention to possible shortcomings in federal oversight, noting that some problems were not detected or addressed by the OPTN or CMS in a timely fashion. Three cases that occurred at different facilities in California received particular attention because of the seriousness of the problems involved. The OPTN's oversight brought one of the cases to light, while individuals alerted federal agencies or the media to the other cases.

- In 2003, a liver transplant program used one patient's high position on the waiting list to obtain a liver for someone else who was lower on the waiting list, bypassing more than 50 patients who had higher priority for the liver than the actual recipient. Medical records were falsified to conceal the switch, and the patient who had the highest priority for the liver later died without a transplant. A routine OPTN on-site review in 2005 led the transplant program's staff to review the case and self-report the problem to the OPTN.
- At another facility, the liver transplant program did not have a full-time transplant surgeon on staff even though it had led the OPTN and patients to believe otherwise. From mid-2004 until the program closed over a year later, the program lacked a full-time surgeon and had been turning down organs offered for patients on the waiting list at rates markedly higher than regional and national averages. A patient complaint in 2005 led to a CMS investigation that first uncovered the situation.
- In 2004, a health maintenance organization (HMO) notified over 1,500 of its enrollees waiting for kidney transplants that it would no longer pay for their transplants unless they were performed at a new kidney transplant program it was about to open. The new transplant program, however, was unable to properly handle the large influx of patients and did not provide contingency plans for patients to receive transplants through other programs. As a result, patients' access to transplants was impeded. A whistleblower contacted the media, and in May 2006, media articles about the situation alerted the OPTN and CMS to the problem.

Concerned that these recent issues at organ transplant programs could indicate more systemic problems, you asked us to examine federal oversight of the organ transplantation system. This report discusses (1) federal oversight of transplant programs at the time the high-profile cases came to light in 2005 and 2006 and (2) the changes that federal

agencies have made or planned since then to strengthen their capacity to detect and resolve compliance problems at organ transplant programs.⁷

Our review encompassed the OPTN's and HRSA's activities to oversee organ transplant programs and CMS's activities to oversee Medicare-approved organ transplant programs.⁸ To examine the OPTN's, HRSA's, and CMS's oversight activities, we reviewed relevant laws, regulations, policies, and other documents and interviewed OPTN and HRSA officials and officials from CMS's central office and from the 5 (of 10) regional offices responsible for overseeing the largest numbers of transplant programs. We also reviewed case files from the OPTN detailing the OPTN's review of and actions taken on compliance cases that occurred from 2003 through 2006, including the three high-profile cases;⁹ the OPTN's data on transplant programs that did not meet OPTN performance standards for clinical outcomes or transplant activity from January 2003 through October 2006; the OPTN contract with HRSA; CMS data on surveys of renal (kidney) transplant programs; CMS data on reviews of extra-renal (heart, liver, lung, and intestine) transplant programs conducted in 2006 and 2007;¹⁰ CMS complaint investigations of the three high-profile cases; and a CMS draft proposal for sharing information with HRSA. We examined the reliability of the data used in this report by

⁷For purposes of this report, we consider federal agencies' oversight of organ transplant programs to include the oversight activities conducted by CMS, HRSA, and the OPTN.

⁸We excluded from our review oversight of transplant programs under CMS's Medicaid program, the joint federal-state program that finances health care for certain low-income individuals. According to CMS officials, oversight of transplant programs that receive Medicaid reimbursement is handled by state Medicaid programs. We also did not examine the OPTN's, HRSA's, or CMS's oversight of organ procurement organizations, which are responsible for the retrieval, preservation, and transportation of donated organs.

⁹A total of 81 transplant centers had compliance cases from 2003 through 2006. We randomly selected 27 of the 81 centers and supplemented the random sample by including all additional compliance cases from transplant centers where the OPTN took strong enforcement actions from 2000 through 2006 that were not already included in the random sample (4 centers). Some transplant centers had multiple cases reviewed by the OPTN at that time; we reviewed all 43 cases associated with the 31 transplant centers we selected.

¹⁰Pancreas transplant programs are extra-renal transplant programs, but CMS officials stated that its surveys of renal (kidney) transplant programs are in effect reviews of pancreas transplant programs, noting that Medicare-approved pancreas transplants have largely been performed by Medicare-approved kidney transplant programs. For example, according to CMS, since 2003, no Medicare-approved pancreas transplant had been performed outside of a Medicare-approved kidney transplant program. For the purposes of this report, when we refer to CMS's monitoring of extra-renal transplant programs we mean its monitoring of heart, liver, lung, and intestine transplant programs.

performing appropriate electronic data checks and checks for obvious errors, such as missing data and data outside of expected ranges. We also interviewed officials who were knowledgeable about the data. We determined that the data we used were sufficiently reliable for our purposes. In addition, we conducted interviews with experts from associations representing transplant professionals about both CMS's and the OPTN's oversight of transplant programs. We conducted this performance audit from August 2006 through April 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

Limitations in federal oversight of organ transplant programs existed at the time high-profile problems came to light in 2005 and 2006. The nature of these limitations differed for CMS and the OPTN. CMS's oversight activities for both extra-renal and renal transplant programs were incomplete in several respects. For example, until 2006, CMS did not actively monitor extra-renal transplant programs; instead, the agency relied primarily on complaints to detect problems. CMS did periodically monitor renal transplant programs through contracts with state agencies to conduct on-site surveys and did act to resolve identified problems, but the surveys reviewed compliance with requirements that had not been substantially updated in decades and were limited in scope. In addition, some programs were not actively monitored. In contrast, the OPTN actively monitored for many types of noncompliance and poor performance and acted to resolve identified problems. The OPTN's monitoring activities, however, did not include methods capable of promptly detecting certain problems that prolonged the time that patients waited for transplants, such as insufficient staffing at transplant programs. For example, until media reports surfaced, the OPTN was not aware of such problems in two of the high-profile cases. The OPTN also did not always meet its goals for conducting on-site reviews, one component of its monitoring activities.

CMS, HRSA, and the OPTN have made or plan to make changes to strengthen federal oversight of organ transplant programs, but the effectiveness of the changes will depend in part on their implementation and the degree of information sharing that the agencies agree to undertake. In 2006, after high-profile problems came to light, CMS began

actively monitoring extra-renal transplant programs. In a more fundamental change, CMS published new Medicare regulations in 2007, establishing a single set of expanded and updated requirements for both extra-renal and renal transplant programs and procedures for periodic reviews of Medicare-approved programs. For its part, the OPTN, with HRSA's involvement, has taken steps to address previous shortcomings. For example, the OPTN has been working with HRSA to develop and implement a set of indicators to better detect problems that prolong the time patients wait for transplants. The effects of CMS's and the OPTN's changes remain to be seen, however, as not all changes have been fully implemented. In particular, CMS has not determined the extent to which it will include on-site surveys in its periodic reviews of transplant programs for Medicare reapproval. Under the new regulations, CMS may choose not to conduct on-site reapproval surveys of transplant programs meeting certain Medicare requirements. Not conducting such surveys may limit CMS's ability to monitor these programs for compliance with other Medicare requirements and to detect problems like some of those involved in the high-profile cases. As of January 2008, CMS had not determined how it will choose which transplant programs to survey for reapproval, if any, among those for which it has discretion. Further, CMS and HRSA have not determined how they will share information about potential problems at transplant programs. CMS developed a proposal outlining how the agencies could share such information, but the agencies have not yet finalized an agreement. Finalizing an agreement delineating the scope and a time frame for sharing information from their oversight of transplant programs is important to ensure that in the future problems at transplant programs are detected and corrected in a timely manner.

To increase opportunities for identifying potential problems at transplant programs, we are recommending that the Secretary of Health and Human Services direct the Administrator of CMS to develop a methodology for conducting on-site surveys for Medicare reapproval to ensure that at least some transplant programs meeting certain Medicare requirements receive an on-site survey, and that the Secretary direct the Administrators of CMS and HRSA to establish a time frame for finalizing an agreement for CMS, HRSA, and the OPTN to share information from their oversight activities.

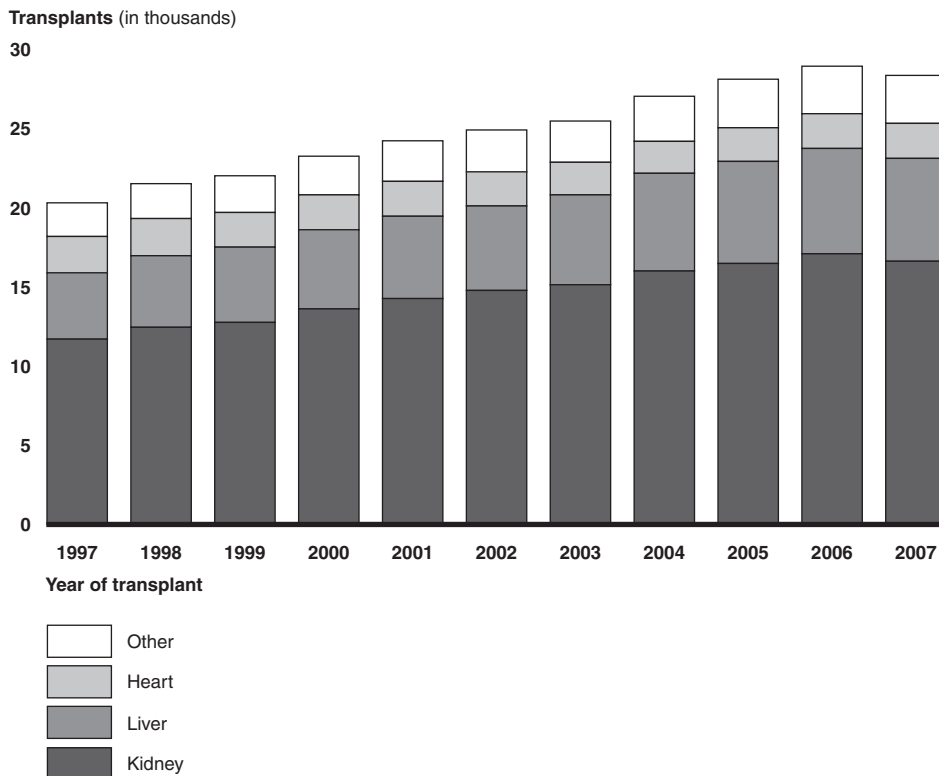
In commenting on a draft of this report, HHS concurred with our recommendations. HHS agreed that CMS should develop a methodology for conducting on-site surveys for Medicare reapproval, noting that CMS has developed an initial framework for doing so but that its implementation will depend on resources. HHS also agreed with our recommendation that HRSA and CMS establish a time frame for finalizing

an agreement to share information from their oversight activities. The comments noted that CMS would like to finalize an agreement with HRSA by June 30, 2008, and that even in the absence of a formal agreement, CMS and HRSA have shared information on several occasions.

Background

Organ transplants are becoming increasingly common. The 28,352 organ transplants performed in the United States in 2007 represent an increase of about 40 percent since 1997. (See fig. 1.) Kidney transplants are the most common procedure, accounting for almost 60 percent of transplants. Most transplanted organs come from deceased donors, but a significant portion (22 percent in 2007) come from living donors who may donate, for example, a kidney or a segment of liver or lung.

Figure 1: Number of Organ Transplants Performed, Calendar Years 1997–2007



Source: The OPTN.

Notes: Data are as of February 29, 2008. Other includes lung, pancreas, and intestine transplants as well as procedures involving the transplantation of multiple organs, such as kidney-pancreas and heart-lung transplants.

As of January 2008, 254 U.S. hospitals had a transplant center; collectively, these centers operated 844 individual transplant programs. (See table 1.) Nearly all states had at least one transplant center, but some types of transplant programs, such as lung or intestine transplant programs, were located in a limited number of states.

Table 1: Number of Organ Transplant Centers and Programs, 2008

Total number of organ transplant centers	254
Number of organ transplant centers with	
Kidney programs	245
Liver programs	126
Pancreas programs ^a	175
Heart programs	132
Lung programs	66
Heart-lung programs	54
Intestine programs	46
Total number of organ transplant programs	844

Source: The OPTN.

Notes: Data are as of January 23, 2008. Data on transplant centers that perform heart-lung transplants are captured in a separate category. Data on transplant centers that perform multi-organ transplants other than heart-lung transplants are captured under both organs involved.

^aPancreas programs include programs performing transplants of pancreas islet cells.

Organ Transplantation Process

The organ transplantation process involves the following steps.

Step 1: The process begins when a patient’s physician determines that an organ transplant may be necessary and refers the patient to a transplant program for evaluation.

Step 2: If the transplant program determines that the patient is a candidate for transplantation, the individual is registered on the national organ transplant waiting list maintained by the OPTN.

Step 3: When an organ becomes available, the local organ procurement organization enters information about the donor organ into a national computer system operated by the OPTN. The computer system generates a ranked list of potential recipients based on how closely their medical characteristics—such as blood type, organ size, and genetic makeup—

match the donor's, as well as on the urgency of their medical conditions, their time spent on the waiting list, and their proximity to the donor.¹¹

Step 4: Transplant programs whose patients appear on the list are contacted. The decision whether to accept an organ rests with the patient's transplant team. Because the length of time organs can viably be kept outside the body is limited, the transplant team has 1 hour to make its decision. If the organ is not accepted, it is offered to the center with the next patient on the list until the organ is placed.

Step 5: Once the organ is accepted for a potential recipient, a surgical team comes to the donor hospital to recover the organ. The recovered organ is transported from the donor to the recipient hospital for transplantation into the patient.

The OPTN's Role and Responsibilities

The OPTN was created pursuant to the National Organ Transplant Act, which called for HHS to provide by contract for the establishment and operation of the OPTN to manage the nation's organ allocation system.¹² Prior to that time, national policies regarding transplantation did not exist and organ allocation was carried out on an ad hoc basis. The OPTN's functions include maintaining a list of patients waiting for transplants, operating a system for matching donated organs with individuals on the list, establishing medical criteria for allocating organs, collecting and analyzing data on organs donated and transplanted, and conducting work to increase the supply of donated organs. The OPTN's members include all transplant centers and organ procurement organizations in the country; tissue-typing laboratories;¹³ professional scientific and medical organizations; and other organizations and individuals interested in organ donation or transplantation, such as organ donors, recipients, and their families. The OPTN's Membership and Professional Standards Committee (MPSC) is responsible for overseeing the compliance of OPTN members

¹¹Medical urgency is measured differently for different organs, according to criteria established by the OPTN, and may include such factors as life expectancy and intensity of current treatment.

¹²Pub. L. No. 98-507, § 201, 98 Stat. 2339, 2342 (1984) (codified as amended at 42 U.S.C. § 274). The Secretary of Health and Human Services delegated this responsibility to HRSA.

¹³Tissue-typing laboratories test potential donors and recipients for tissue compatibility. Tissue typing is routinely performed for all donors and recipients in kidney and pancreas transplantation to help match the donor with the most suitable recipients in order to decrease the likelihood of organ rejection.

with applicable federal regulations and OPTN policies. The OPTN collects most of the funding to cover its operating costs (estimated to be about \$25 million in 2006) from candidate registration fees paid by OPTN members; HRSA's funding for the OPTN is capped at \$2 million a year.¹⁴

From early in its history, the OPTN has been responsible for operating an equitable nationwide system of organ allocation. The OPTN develops detailed policies that govern the distribution of organs and other issues related to transplantation, such as the specific credentials required of transplant surgeons and physicians. HHS clarified the OPTN's oversight responsibilities in regulations implemented in 2000.¹⁵ The regulations require the OPTN to design plans and procedures for conducting ongoing and periodic reviews of all member transplant centers for compliance with the regulations and OPTN policies. The regulations also require the OPTN to advise the Secretary of Health and Human Services when the results of its reviews indicate noncompliance with the regulations or OPTN policies or otherwise indicate a risk to patient health or public safety.

While the OPTN is required to monitor transplant programs' compliance with its policies, OPTN policies are considered voluntary or advisory.¹⁶ To promote transplant programs' voluntary compliance with OPTN policies, the OPTN employs a confidential review process in which OPTN members evaluate the medical care provided by colleagues to determine compliance with OPTN policies and regulations.¹⁷ The OPTN emphasizes that its

¹⁴42 U.S.C. § 274(a).

¹⁵HHS initially published an OPTN final rule on April 2, 1998, 63 Fed. Reg. 16332 (to be codified at 42 C.F.R. pt. 121). The rule was later amended on October 20, 1999 (64 Fed. Reg. 56658), and then became effective on March 16, 2000.

¹⁶Under a 1986 addition to the Social Security Act, hospitals that participate in Medicare and Medicaid and perform organ transplants are required to be members of and abide by the rules of the OPTN. Pub. L. No. 99-509, § 9318, 100 Stat. 1874, 2009 (adding section 1138 to the Social Security Act) (codified as amended at 42 U.S.C. § 1320b-8). HHS interpreted this provision to require that to be considered a rule or requirement of the OPTN and therefore binding on participating hospitals, the rule or requirement must be formally approved by the Secretary. 54 Fed. Reg. 51802 (Dec. 18, 1989); see also 42 C.F.R. § 121.4(b)(2) and (c) (2007) (regulation providing framework for submission of OPTN policies to the Secretary for review and approval). As of February 2008, the Secretary had not approved any OPTN policies for this purpose. Although OPTN policies have not been formally approved by the Secretary, HRSA has indicated that certain data submitted to the OPTN are mandatory under 42 C.F.R. § 121.11(b)(2) and that failure to submit these data accurately and completely could be considered a violation of this section.

¹⁷This process is referred to in OPTN policies as confidential medical peer review.

confidential review process focuses on corrective action rather than punishment and is aimed at continuous quality and performance improvement. On its own, the OPTN can impose certain sanctions against noncompliant transplant programs, such as issuing a letter of warning or placing a program on probation. The OPTN can also request that the Secretary of Health and Human Services impose stronger enforcement actions, including terminating a program's ability to receive organs or reimbursement under Medicare.

HRSA's Oversight of the OPTN

The OPTN contract with HRSA includes several requirements related to the oversight of transplant programs. For example, the contract requires the OPTN to conduct on-site reviews of heart, liver, and lung transplant programs at least once every 3 years and to perform ongoing analyses of organ allocations.¹⁸ The OPTN is also required to submit monthly reports to HRSA describing transplant program-specific instances of noncompliance with OPTN policies and the status of corrective action plans. To ensure that the OPTN is fulfilling its responsibilities to monitor transplant programs' compliance, HRSA officials participate as ex officio nonvoting members on the OPTN's Board of Directors and committees, including the MPSC. According to HRSA officials, the agency's presence on OPTN committees helps ensure that the committees' recommendations are consistent with federal laws and regulations. In addition, HRSA officials said that they and OPTN officials communicate regularly about all aspects of the OPTN's performance, including monitoring transplant program compliance.

CMS's Role and Responsibilities

CMS is responsible for overseeing organ transplant programs that receive Medicare reimbursement for transplant services. At the time the high-profile cases came to light, CMS had different criteria and procedures for overseeing extra-renal and renal transplant programs participating in Medicare.

¹⁸The OPTN contract does not require on-site reviews of kidney transplant programs. Kidney transplant programs are different from other programs in that kidney allocation is determined, in part, by the amount of time the patient has been waiting, not the severity of the patient's illness. OPTN officials said that kidney transplant programs are reviewed on-site if they are part of a transplant center where the OPTN is reviewing other transplant programs.

-
- Extra-renal transplant programs participated in Medicare by meeting the criteria set forth in various national coverage determinations (NCD) published beginning in 1987.¹⁹ The NCDs provide that transplants of extra-renal organs for Medicare beneficiaries will be considered reasonable and necessary and therefore reimbursable under Medicare if they are performed in a facility that CMS approves as meeting specified criteria. For example, heart, liver, and lung transplant programs were required to have written patient selection criteria, perform a minimum number of transplants each year, and meet minimum patient survival rates. The NCDs for these programs did not include criteria for reevaluating the ongoing performance of Medicare-approved programs.
 - Renal transplant programs participated in Medicare by meeting regulatory standards for facilities furnishing end-stage renal disease (ESRD) services.²⁰ ESRD facilities include those providing dialysis services and renal transplant services.²¹ CMS monitored renal transplant programs' compliance with Medicare requirements by contracting with state survey agencies—generally state departments of health—to conduct routine on-site inspections known as surveys.²² If a survey found a facility to be out of compliance and if it had a major deficiency that went uncorrected, then the facility was subject to termination from the Medicare program.

In 2005, recognizing the need to update existing requirements for extra-renal and renal transplant programs and that the NCDs did not include criteria for reassessing the performance of extra-renal transplant

¹⁹Medicare NCDs were published extending coverage to participating and qualified facilities performing heart transplants in 1987, liver transplants in 1991, lung transplants in 1995, pancreas transplants simultaneous with or after kidney transplants in 1999, isolated intestinal and combined liver-intestinal transplants in 2001, and pancreas transplants alone in 2006. 52 Fed. Reg. 10935 (Apr. 6, 1987) (heart); 56 Fed. Reg. 15006 (Apr. 12, 1991) (liver); 60 Fed. Reg. 6537 (Feb. 2, 1995) (lung); CMS Program Memorandum, Transmittal A-99-16 (Apr. 1999) (pancreas simultaneous with or after kidney); CMS Program Memorandum, Transmittal AB-01-58 (Apr. 12, 2001) (intestinal and multivisceral, including combined liver-intestinal); and CMS Pub. 100-03, Transmittal 56 (May 19, 2006) (pancreas). Revised transplant volume requirements for heart, liver, and lung transplant programs were issued on October 11, 2000. CMS Program Memorandum, Transmittal AB-00-95 (Oct. 11, 2000).

²⁰See 42 C.F.R. pt. 405, subpt. U (2006).

²¹Most ESRD facilities are renal dialysis facilities, but a small subset of ESRD facilities operate renal transplant programs.

²²The state agencies are often responsible for surveying other types of health care facilities that require certification for participation in Medicare or Medicaid, such as nursing homes and home health agencies.

programs, CMS promulgated proposed regulations to establish a single set of Medicare requirements for both renal and extra-renal transplant programs.²³

Limitations Existed in Federal Oversight at the Time High-Profile Problems Came to Light

CMS's and, to a lesser extent, the OPTN's oversight of transplant programs was not comprehensive at the time high-profile problems came to light in 2005 and 2006. CMS did not actively monitor extra-renal transplant programs' compliance with criteria for Medicare approval. CMS monitored renal transplant programs through contracts with state agencies, but the surveys reviewed compliance with requirements that had not been substantially updated in decades and were limited in scope; also, not all programs were actively monitored. At the same time, the OPTN actively monitored transplant programs and took action to resolve identified problems, but its oversight activities fell short in some respects—the OPTN's monitoring did not include methods capable of promptly detecting problems at transplant programs that prolonged the time that patients waited for transplants, and the OPTN did not always meet its goals for conducting on-site reviews.

CMS's Oversight Was Limited and Inconsistent

CMS's oversight varied between extra-renal and renal transplant programs and was not comprehensive even for renal transplant programs, which received more oversight.

CMS Did Not Actively Monitor Extra-Renal Transplant Programs

At the time high-profile problems came to light in 2005 and 2006, CMS was not actively monitoring the ongoing compliance of Medicare-approved extra-renal transplant programs with the criteria specified in the NCDs, which included performing a minimum number of transplants per year and achieving a minimum patient survival rate.²⁴ Instead, CMS's procedure was to conduct only an initial review of an extra-renal program to determine if

²³CMS initially published a transplant center proposed rule for comment on February 4, 2005. 70 Fed. Reg. 6140. After a comment period, CMS published a final rule on March 30, 2007 (72 Fed. Reg. 15198) (codified at 42. C.F.R. pts. 405, 482, 488, and 498) that became effective on June 28, 2007.

²⁴Criteria for Medicare approval differed by program type. In its NCDs, CMS established the criteria that lung and intestine transplant programs should conduct at least 10 transplants per year, and heart and liver transplant programs should conduct at least 12 transplants per year. The criteria for 1-year survival rates for patients after transplantation were 69 percent or higher for lung transplant programs, 65 percent or higher for intestine transplant programs, 73 percent or higher for heart transplant programs, and 77 percent or higher for liver transplant programs.

it met the criteria in the NCDs at the time the program applied for Medicare approval. Once an extra-renal transplant program received Medicare approval, CMS generally did not assess the program's continued compliance with NCD criteria.²⁵ Although the NCDs for heart and liver transplant programs called for programs to submit an application for Medicare reapproval every 3 years, the NCDs did not specify and CMS did not otherwise establish a process for doing so, and programs continued to retain Medicare approval without reapplying.

To oversee extra-renal transplant programs' ongoing compliance with criteria for Medicare approval, CMS relied on programs to self-report significant changes and complaints from Medicare beneficiaries and others that would alert CMS to a potential problem. CMS officials or state surveyors conducted complaint investigations after receiving complaints against transplant programs or otherwise becoming aware of potential problems, such as through media reports. CMS officials in three of the five regions we contacted reported that they or state surveyors had investigated nine complaints against extra-renal transplant programs during the period of 2000 through 2006.²⁶ For example, one of the three high-profile cases initially came to light after CMS received a patient complaint about a liver transplant program. CMS officials investigated the complaint and discovered that this transplant program had not had a full-time surgeon on staff in over a year. After completing the complaint investigation, CMS withdrew Medicare approval from the transplant program, which closed shortly thereafter.

CMS Had a Process in Place to Monitor Renal Transplant Programs, but Some Programs Still Were Not Actively Reviewed

CMS's oversight of renal transplant programs was more active than its oversight of extra-renal transplant programs, although it also had limitations. CMS contracted with state agencies to periodically perform on-site surveys of renal transplant programs for compliance with Medicare requirements and had a process in place to resolve problems identified during these surveys. When state surveyors identified compliance problems with requirements during their reviews of renal transplant programs, CMS generally acted to resolve these problems by requiring programs to submit corrective action plans for coming back into

²⁵The earliest possible date of initial Medicare approval was 1986 for heart programs, 1990 for liver programs, 1995 for lung programs, and 2001 for intestine programs.

²⁶One CMS regional office reported conducting no complaint investigations of extra-renal transplant programs; another reported that it did not track them. CMS officials also reported conducting several complaint investigations of renal transplant programs.

compliance with requirements. According to CMS data, major problems were generally corrected within 90 days, and only one of the five CMS regional offices we contacted reported that CMS had withdrawn Medicare approval from a renal transplant program in its region since 2000 for failure to comply with Medicare requirements. This instance was the high-profile case involving an HMO that was unable to properly handle a large influx of patients to its program.

Although CMS had a process in place to periodically review renal transplant programs through state agency surveys of ESRD facilities, the surveys reviewed compliance with requirements that had not been substantially updated in decades and were limited in scope. Medicare regulations for ESRD facilities, including renal transplant programs, were initially published in 1976 and, according to CMS officials, had not been substantially updated since then.²⁷ For example, the regulations did not include a requirement that renal transplant programs achieve a minimum patient survival rate. Experts in the transplantation field have since recognized the importance of patient-centered, outcome-oriented performance measures, such as survival rates, and recommended their use.²⁸ In addition, while the Medicare requirements specified that renal transplant programs should perform a minimum number of transplants per year, CMS instructions to state surveyors did not call for them to verify that these numbers were achieved.²⁹

²⁷The Medicare requirements for ESRD facilities addressed issues relevant to all ESRD facilities, such as the maintenance of medical records; they also addressed a limited number of requirements specific to renal transplant programs, such as that the transplant program perform a minimum number of transplants per year, be under the direction of a qualified transplant surgeon or physician, and meet minimal service requirements, including participation in a patient organ allocation registry and provision of social, dietetic, and laboratory services.

²⁸See, for example, Institute of Medicine, *Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule* (Washington, D.C.: National Academies Press, 1999).

²⁹Other areas not addressed in the Medicare requirements for ESRD facilities included protections for the safety of living donors, which since 1990 have become the fastest growing source of kidneys for kidney transplants, and implementation of quality assessment and performance improvement programs, now widely used to improve delivery of health care services. CMS recognized the need both to expand and update its requirements for renal and extra-renal transplant programs and to standardize requirements for all types of programs, and began working on new requirements in 2000. CMS had published a proposed version for public comment but had not finalized or implemented these requirements when serious problems came to light in 2005 (the requirements were later finalized in March 2007).

Furthermore, CMS's process to review renal transplant programs did not ensure that all of these programs were actively monitored in practice. Our analysis of CMS data as of May 2007 showed that 31, or about 1 in 8, active, Medicare-approved renal transplant programs had been mistakenly classified as no longer participating in Medicare in CMS's survey database or had been mistakenly excluded from the database.³⁰ According to CMS officials, these programs would not have been surveyed again after these mistakes occurred. Our analysis showed that as of May 2007 the length of time since the 31 programs had last been surveyed ranged from about 4 to over 20 years; over three-quarters of these programs had not been surveyed in the previous 10 years. By comparison, most correctly classified programs had been surveyed in the previous 4 years, although 34 programs had not, and 9 of those programs had not been surveyed in the previous 10 years. CMS did not have survey frequency goals specific to renal transplant programs. However, CMS has acknowledged that not all state agencies achieved CMS goals for conducting surveys of all ESRD facilities (of which renal transplant programs are a subset).³¹ CMS officials emphasized that the CMS survey and certification budget had not been fully funded during fiscal years 2005 through 2007.

The OPTN's Oversight Was Active and Multipronged but Was Not Sufficient to Detect All Problems

The OPTN's oversight, while more active and extensive than CMS's oversight, also had limitations; most notably, its monitoring methods were insufficient to promptly detect problems affecting patients waiting for transplants.

³⁰Twenty-seven of the 31 programs were mistakenly classified as no longer participating in Medicare and 4 programs were mistakenly excluded from the survey database. According to CMS officials, the misclassifications likely resulted from state survey agencies mistakenly terminating the ESRD Medicare identification number for the renal transplant program when an associated dialysis program was closed or sold (a renal transplant program and a dialysis program within the same facility were tracked under the same ESRD Medicare identification number). Officials said that this misclassification did not affect renal transplant programs' ability to receive Medicare reimbursement because programs with terminated ESRD identification numbers could continue billing Medicare through their hospital identification numbers.

³¹CMS's goals for ESRD facilities have varied in recent years. For example, in fiscal years 2006 and 2007 CMS had a goal that state agencies assign high priority to surveys of a subset (10 percent) of low-performing ESRD facilities targeted by CMS, as well as a goal that state agencies survey all ESRD facilities every 3.5 years on average; in fiscal years 2004 and 2005 CMS had a goal that state agencies survey all ESRD facilities every 3 years on average.

The OPTN Actively Monitored for Many Types of Problems

The OPTN monitored transplant programs on an ongoing basis for numerous types of potential problems. The OPTN's oversight was conducted by both OPTN staff and by its MPSC, which includes OPTN members who are medical professionals from the field of transplantation. The OPTN's numerous activities to monitor compliance with OPTN policies included reviewing information on patients placed on transplant waiting lists, allocations of organs from deceased donors, physician credentials, and timely submission of required data. These reviews were generally scheduled to occur weekly or quarterly. The OPTN also monitored on a quarterly basis two key indicators of potential performance problems at transplant programs—lower-than-expected patient and organ survival rates and failure to perform any transplants during a specified period of time. In addition, the OPTN conducted periodic routine on-site reviews of heart and liver transplant programs to review patient medical records; the OPTN's goal was to conduct these on-site reviews once every 3 years.³²

The OPTN's monitoring activities identified many problems, ranging from minor anomalies with organ allocations to more significant problems, including one of the three high-profile cases. The case came to light after a routine OPTN on-site review led staff at the transplant program to self-report that a recipient of a liver transplant had inappropriately received the transplant ahead of others on the waiting list and that the program had falsified patient medical records in order to conceal its actions.³³ Our review of a sample of compliance cases showed that the OPTN most often identified members' noncompliance with OPTN policies through its routine on-site reviews (15 of 43 cases).

Our review of OPTN compliance cases and performance data and discussions with OPTN officials indicated that the OPTN took steps to resolve compliance and performance problems it identified during its

³²Until September 2005, the goal to conduct periodic routine on-site reviews was limited to heart and liver programs because patients' priority on the waiting list for these organs depended primarily on medical urgency. The September 2005 OPTN contract incorporated the OPTN's goal of conducting on-site reviews every 3 years and included lung programs in addition to heart and liver programs, after a policy change in which patients' priority on the waiting list for lung transplants would likewise depend upon medical urgency.

³³The OPTN's monitoring also detected performance problems involving low patient survival rates at another transplant program involved in a high-profile case, although this monitoring did not enable the OPTN to promptly identify the full scope of the problem. (A CMS complaint survey later found that the transplant program did not have a full-time transplant surgeon on staff.)

monitoring activities. As explained below, the OPTN's process for resolving members' noncompliance with OPTN policies differs from its process for resolving members' performance problems, such as lower-than-expected survival rates.

- **Noncompliance with OPTN policies.** OPTN officials emphasize that the OPTN works to resolve most cases of noncompliance without resorting to strong enforcement actions. Our review of a sample of compliance cases showed that the length of time for cases to be fully resolved varied and depended on the nature of the case. For example, a relatively minor case involving an organ allocation discrepancy was resolved within 4 months, while a case involving problems with medical record documentation took about 3 years to resolve. The three high-profile cases are examples of cases in which the OPTN took strong enforcement actions. After the individual transplant programs involved in these cases had announced that they would voluntarily close, the OPTN continued to review the cases and eventually declared two of the transplant centers that operated these transplant programs "Members Not in Good Standing" and imposed a lesser sanction of probation on the third transplant center.
- **Performance problems.** The OPTN flags for the MPSC's review transplant programs that are not achieving OPTN performance standards for survival rates or transplant activity, but these programs are not considered to be out of compliance with OPTN policies. Instead, the OPTN works with these programs until they meet the standards, sometimes sending peer review teams on-site to consult with the programs, or until problems are otherwise resolved (for example, if a program closes voluntarily). OPTN officials said that programs with low survival rates typically need to show improvement in outcomes before being released from review by the MPSC and emphasized that this can take some time. Of 72 cases the OPTN flagged for low survival rates in 2005, about 40 percent remained under review by the MPSC as of August 2007.

The OPTN's Monitoring Did Not Detect All High-Profile Cases and Was Not Always Timely

Although the OPTN conducted numerous types of monitoring activities, these activities did not incorporate methods capable of promptly detecting problems at transplant programs that prolonged the time that patients waited for transplants. For example, the OPTN regularly flagged programs for review that did not perform any transplants in a specified period of time.³⁴ While helpful in detecting completely inactive programs, this

³⁴The period of time ranges from 3 to 12 months, depending on the type of transplant program.

particular method did not identify more subtle problems, such as a transplant program that was understaffed and was turning down organs offered for patients at markedly high rates. At the two transplant programs with high-profile problems affecting patient access to transplants, enough transplants were conducted that the programs were not flagged as inactive programs. In addition, the transplants that did occur were successful enough that the programs were not flagged as experiencing performance problems at the time the problems came to light.³⁵ However, far fewer transplants were conducted than would be expected given the numbers of patients on the waiting list, reflecting problems with understaffing that ultimately affected patients' access to transplants at these programs.

Even though a targeted method for detecting these problems was not in place, separate pieces of information, if pieced together, could have alerted the OPTN to at least one of the high-profile incidents. The OPTN, however, missed opportunities to link these separate sources of information. For example, OPTN staff who handle patient transfers were aware that an HMO was attempting to transfer hundreds of patients to its new transplant program at an unprecedented rate and was experiencing problems with the transfers. However, they did not alert other appropriate OPTN staff to the possible need for a compliance review or to look into the situation by, for example, reviewing available data that indicated far lower-than-expected numbers of transplants at the new program. The problem eventually came to light after a whistleblower alerted the news media.

In addition to having insufficient methods to detect some of the high-profile cases, the OPTN was not always timely in conducting those monitoring activities that it performs on-site, namely routine on-site reviews and peer review site visits. Although the OPTN's goal was to conduct routine on-site reviews of heart and liver programs once every 3 years, it had fallen behind this schedule. In December 2006, 50 percent of continuously active heart and liver transplant programs had not been reviewed on-site in the previous 3 years and 38 percent had not been reviewed on-site in the previous 4 years. OPTN and HRSA officials attribute the delay in routine on-site reviews to HRSA's directive to the OPTN to study a new lung allocation policy. Additionally, in our review of

³⁵The OPTN had previously identified performance problems at one of these two programs, but the program's survival rates improved and the OPTN released the program from review a few months prior to the time that the staffing problem came to light.

performance data we observed that in some cases peer review site visits were not conducted on a timely basis. For about three-fourths of transplant programs (17 of 22) for which the MPSC recommended a peer review site visit from July 2005 through July 2006, the site visit had not yet occurred a year after being recommended. According to OPTN officials, a contributing factor in the delay was that the number of programs recommended to receive a peer review site visit significantly increased during 2005, resulting in a backlog.³⁶

CMS, HRSA, and the OPTN Have Acted to Strengthen Oversight, but the Full Effect of These Actions Will Depend on Implementation and Further Information Sharing

Since the high-profile cases came to light, CMS, HRSA, and the OPTN have made some changes and planned others to improve federal oversight of organ transplant programs; however, the full effect of these changes remains to be seen. CMS has begun monitoring extra-renal transplant programs and has finalized regulations that expand and unify Medicare requirements for all types of transplant programs and establish procedures for periodic review of transplant programs. The OPTN and HRSA are working to develop and implement a set of indicators to help the OPTN better identify problems that prolong the time patients wait for transplants. Implementation of CMS's new requirements is in its early stages, however, and CMS has not resolved the extent to which on-site surveys will be performed as part of its periodic reviews of programs for Medicare reapproval. Also, the OPTN's and HRSA's set of indicators has not yet been implemented. Further, while CMS, HRSA, and the OPTN have begun sharing basic transplant program data, how they will share additional information resulting from their oversight activities has not been resolved.

CMS Strengthened Oversight by Expanding Monitoring Efforts and Issuing New Regulations

CMS has made substantial changes to its oversight: the agency began monitoring extra-renal transplant programs and, most significantly, finalized new regulations that apply to all types of transplant programs and that require on-site surveys of all transplant programs applying for Medicare approval.

³⁶In 2005, the OPTN changed the way it identified programs for additional review. Before 2005, transplant programs flagged as having lower-than-expected outcomes in two consecutive quarterly reports were identified for additional review. As of October 2005, programs flagged as having lower-than-expected outcomes in one report were identified for additional review.

CMS Began Monitoring Extra-Renal Transplant Programs and Took Steps to Withdraw Medicare Approval from the Most Problematic Programs

After high-profile problems came to light, CMS began monitoring extra-renal transplant programs' compliance with existing Medicare NCD criteria in 2006. According to CMS officials, the agency's initial monitoring effort revealed that nearly all 242 Medicare-approved programs were complying with NCD criteria for meeting minimum survival rates. A number of programs, however, were not in compliance with the NCD annual transplant volume criteria, which specify that programs must conduct a minimum number of transplants each year. CMS continued to monitor extra-renal transplant programs and ultimately found that a total of 49 extra-renal transplant programs did not meet the NCD transplant volume criteria in 2005, 2006, or both. As a result, CMS notified 11 programs that agency officials viewed as the most problematic that they could lose Medicare approval for failure to comply with NCD criteria.³⁷ Ultimately, CMS withdrew Medicare approval from 1 of the 11 programs; of the remaining 10 programs, 2 withdrew voluntarily and 8 programs were implementing corrective action plans as of December 2007. (See table 2.)

Table 2: Status of the 49 Extra-Renal Transplant Programs That Did Not Meet NCD Volume Criteria in 2005, 2006, or Both

11	Noncompliant programs were notified by CMS that they could lose Medicare approval for failure to comply with NCD criteria
2	Programs voluntarily withdrew from Medicare
8	Programs submitted corrective action plans that were approved by CMS
1	Program submitted a corrective action plan that CMS rejected (Medicare approval was withdrawn)
38	Noncompliant programs were not notified by CMS
5	Programs voluntarily withdrew from Medicare
12	Programs improved and met transplant volume criteria in 2006
11	Programs met or were projected to meet transplant volume criteria in 2007
10	Programs were projected to remain out of compliance with volume criteria in 2007

Source: GAO analysis of information provided by CMS.

³⁷CMS officials reported that they reviewed circumstances at transplant programs on a case-by-case basis to decide which cases constituted egregious noncompliance, and that there were no explicit criteria with which to make this decision.

CMS Established New Requirements That Apply to All Types of Transplant Programs

In March 2007, CMS made a more fundamental change to its oversight by publishing final regulations establishing a new set of Medicare requirements specifically for organ transplant programs. The regulations include 13 core requirements known as Medicare conditions of participation (CoP). Whereas renal and extra-renal transplant programs were previously subject to different requirements and regulatory procedures, the new regulations provide a single set of CoPs and review procedures for all types of transplant programs. In addition, the new regulations both update and expand upon previous requirements. For example, the new CoPs incorporate an updated method for calculating survival rates that reflects current best practices. The CoPs also include entirely new requirements, such as those related to the protection of living donors. (See app. I for more information about the 13 CoPs.)

The new regulations also bring CMS requirements into substantial alignment with OPTN policies. Specifically, 10 of the 13 CoPs pertain to areas addressed in OPTN policies. In some instances, CMS incorporated OPTN policies into its requirements such that these policies are now enforceable under federal regulation for Medicare-approved transplant programs. In some areas, the new regulations impose additional requirements not covered by the OPTN. For example, while OPTN policies require transplant programs to provide social support services, CMS's regulations further require that social support services be furnished by a qualified social worker, as defined by CMS. In other areas, the new CMS requirements cover matters not addressed in existing OPTN policies. For example, one CoP requires programs to implement formal quality assessment and performance improvement programs—a requirement not paralleled in OPTN policies. There are also areas of OPTN policies, largely pertaining to organ allocation, which the CMS regulations do not address.

New Regulations Also Established Procedures for Reviewing Transplant Programs

In addition to updating and expanding requirements and more closely aligning them with OPTN policies, CMS's new regulations also subject transplant programs to initial and periodic reviews for compliance with the Medicare CoPs. Under the new regulations, all transplant programs seeking Medicare approval are required to apply for initial approval; programs that were previously Medicare approved must reapply.³⁸ As part of determining compliance with the CoPs, each transplant program that

³⁸Transplant programs that were Medicare approved as of June 28, 2007, were required to apply for approval under the new regulations by December 26, 2007, to maintain their Medicare approval until CMS could act on their applications.

applies for Medicare approval will undergo an on-site survey. Transplant programs that are in compliance with all CoPs will be approved for participation in Medicare for 3 years. Prior to the end of the initial 3-year approval period, CMS plans to reexamine data on three key requirements, which together compose one of the CoPs:³⁹

- Data submission: Transplant programs must submit OPTN-required data to the OPTN within specified time frames.
- Clinical experience: Transplant programs must generally perform at least 10 transplants over a 12-month period.
- Outcomes: Transplant programs must achieve expected survival rates.⁴⁰

If a program is found to be in compliance with the three requirements of this CoP, under the new regulations CMS may choose whether to conduct an on-site reapproval survey of the program's compliance with additional CoPs.

CMS plans to complete on-site surveys for transplant programs seeking initial Medicare approval over the course of 3 years. CMS officials reported that on-site surveys of transplant programs had begun as of August 2007. The agency is prioritizing the order in which these surveys will be conducted, so that programs that do not currently meet the clinical experience and outcomes requirements will receive the highest priority for surveys.⁴¹ According to CMS officials, the agency plans to complete these high-priority surveys by the end of fiscal year 2008; all initial surveys are planned to be completed by the end of fiscal year 2010. Until a new Medicare approval decision is made under the new regulations, currently

³⁹According to CMS officials, CMS also plans to monitor compliance with these requirements, and others with which compliance can be monitored using available data, on an ongoing basis during the 3-year approval period.

⁴⁰CMS will consider patient and graft survival rates to be unacceptable if the observed patient or survival rate is lower than expected and all three of the following are true: (1) the one-sided p-value is less than 0.05, (2) the number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and (3) the number of observed events divided by the number of expected events is greater than 1.5.

⁴¹According to CMS, for initial approval the agency generally will not approve programs that do not meet the data submission, clinical experience, and outcome standards, but the regulations also provide for the consideration of mitigating factors.

approved extra-renal and renal transplant programs will remain approved under the NCDs and requirements for ESRD facilities, respectively.⁴²

The OPTN and HRSA Have Taken Steps to Address Shortcomings in Detection of Problems

To address shortcomings in the OPTN's ability to detect problems affecting patients waiting for transplants, such as understaffing, the OPTN and HRSA, along with another HRSA contractor, are working to develop and implement a set of activity-level indicators. The set of indicators would be used to monitor programs for problems, such as understaffing, indicated by lower-than-expected activity levels in a manner similar to how the OPTN currently monitors programs for performance problems indicated by lower-than-expected survival rates. The set of indicators includes two existing indicators already developed by the OPTN, one of which, although available, was not previously reviewed by the MPSC, and a new organ acceptance rate indicator. The new indicator, which is intended to identify programs exhibiting lower-than-expected rates of organ acceptance, is a key component of the set of activity-level indicators and has been under development since January 2006. According to the OPTN, the organ acceptance rate indicator had been developed but not yet implemented for kidney and liver transplant programs as of February 2008.

With HRSA's encouragement, the OPTN has also taken steps to increase its capacity to conduct on-site monitoring activities and to improve internal communication. The OPTN substantially increased its staff in 2007 in order to get back on schedule in conducting on-site reviews once every 3 years. According to OPTN officials, the increase in staff will also help the OPTN address its backlog of peer review site visits and achieve its goal of conducting all peer review site visits within 3 months of the visit being recommended by the MPSC. To improve internal communication, the OPTN reported that since 2006, its leadership has emphasized the importance of shared communication, particularly across departments. As a result, according to the OPTN, staff responsible for managing the waiting list, including handling patient transfers, now meet frequently with staff responsible for monitoring policy compliance to share information about potential policy violations.

⁴²Transplant programs that want to continue to be Medicare approved, however, must be in compliance with the new regulations as of June 28, 2007, and must have submitted a request to CMS for Medicare approval under the CoPs no later than December 26, 2007.

**CMS, HRSA, and the OPTN
Have Yet to Fully
Implement Several
Measures to Improve
Oversight**

Although CMS, HRSA, and the OPTN have taken steps to improve oversight of transplant programs since the high-profile cases came to light, three important areas remain in progress.

- One key unresolved question is the extent to which CMS will conduct on-site reapproval surveys of transplant programs (as part of its new review procedures) after transplant programs gain initial Medicare approval under the new regulations. According to CMS's new regulations, CMS may choose not to conduct on-site reapproval surveys for transplant programs meeting data submission, clinical experience, and outcomes requirements. This means that CMS could potentially choose not to conduct any reapproval surveys for programs meeting these requirements. While CMS officials said that they see value in conducting reapproval surveys, just how CMS will apply its discretion remains unclear. As of January 2008, CMS officials said that the agency had not decided how many reapproval surveys it would conduct or how it would choose which programs to survey among those that meet the aforementioned requirements. They emphasized the agency's need to carefully consider resource constraints in making these decisions. A decision by CMS not to conduct an on-site reapproval survey at a transplant program means that compliance with some CoPs would not be reviewed unless there was a complaint investigation. As a result, problems at transplant programs unrelated to the data submission, clinical experience, and outcomes requirements—for example, a transplant program failing to provide required protections for living donors or to sufficiently staff its program—could go undetected. In two of the high-profile cases, staffing problems that ultimately affected patients' access to transplants would not have been detected by the outcomes indicator that CMS has now adopted, and the numbers of transplants performed per year at these programs exceeded or were close to CMS's clinical experience requirement.
- Additional questions remain regarding the extent to which CMS will accurately track on-site surveys to avoid the misclassification errors we identified in our review and complete the surveys on a timely basis. As a result of the new transplant regulations, renal transplant programs will no longer share Medicare identification numbers with dialysis facilities, and previously misclassified renal transplant programs will at some point receive a new accurate classification in CMS's survey database once they are approved. However, the potential for transplant programs to be mistakenly classified may remain because transplant programs within the same hospital will share one transplant center Medicare identification number, according to CMS officials. CMS officials said that they were highly aware of the need for their systems to accurately track the status of each transplant program separately. They said that they plan to test for

this capability in their new tracking system for transplant programs, which remains under development. What also remains to be seen is the extent to which surveys will occur on a timely basis. Prior to the new regulations, state agencies did not always meet CMS goals for surveying ESRD facilities. Now, under the new regulations, the responsibilities of state agencies that will be conducting on-site surveys of transplant programs will increase, since they will be required to survey both renal and extra-renal transplant programs.⁴³ With respect to initial approval surveys, CMS's stated plan is that high-priority surveys of transplant programs will be completed by the end of fiscal year 2008, but as of January 2008, CMS officials expressed some uncertainty about meeting this goal. Initial surveys of transplant programs have been given a relatively high priority in the state agency workload, but it is not definite that this high priority level will continue because CMS has revised state agency workload priorities in the past.⁴⁴ Further, the priority level for reapproval surveys is not yet known; a lower priority could affect how frequently surveys occur.

- The last unresolved question concerns the OPTN's and HRSA's planned organ acceptance rate indicator, which as part of a set of activity-level indicators, could potentially improve the OPTN's ability to detect transplant programs experiencing problems that prolong the time patients wait for transplants. According to the OPTN, the organ acceptance rate indicator for kidney and liver transplant programs has been developed but, as of February 2008, has not yet been implemented; HRSA officials expect the indicator to be in place within 1 year. HRSA and OPTN officials reported that they are considering developing organ acceptance rate indicators for transplant programs for other organ types. Before extending the indicator to other types of programs, however, the OPTN will first assess the effectiveness of the indicator at detecting potential problems at kidney and liver transplant programs, which perform larger volumes of transplants, and determine the feasibility of developing an indicator for programs with lower transplant volumes, such as heart and lung transplant programs.

⁴³On-site surveys in about half of the states will be conducted by state agencies; in the other states, CMS has assigned a contractor to conduct the surveys.

⁴⁴CMS sets priorities for state survey agency workload based on tiers, where Tier 1 is the highest priority and Tier 4 the lowest. In 2007, CMS prioritized surveys of transplant programs at Tier 2.

CMS, HRSA, and the OPTN Are Sharing Basic Data on Transplant Programs, but How They Will Share Additional Information from Their Oversight Activities Has Not Been Resolved

CMS, HRSA, and the OPTN have recognized the importance of sharing data on transplant programs with one another and have taken initial steps to share basic data. To help CMS assess programs' compliance with its new Medicare requirements, the OPTN (through HRSA) is now sending CMS certain basic transplant program data on a quarterly basis.⁴⁵ For example, the new Medicare regulations require transplant centers to be OPTN members, so the OPTN is providing data on the status of each transplant center's membership in the OPTN. (See table 3.)

Table 3: Medicare Requirements for Transplant Programs for Which the OPTN Is Providing Data to CMS

Medicare requirement	Data provided to CMS on each OPTN member
Transplant programs must be a member of the OPTN	OPTN membership status
Transplant programs must submit OPTN-required data to the OPTN within 90 days of OPTN deadlines	Member's compliance with OPTN data submission policies
The hospital in which a transplant program operates must have a written agreement with an organ procurement organization to receive organs	The organ procurement organization with which the transplant center has an agreement
Transplant programs must ensure that all individuals who provide services at the program, supervise services, or both are qualified to provide or supervise such services	The names of the primary surgeon and primary physician at the transplant program

Source: GAO analysis of Medicare CoPs for transplant centers and information from CMS and HRSA.

While this basic data sharing represents progress, CMS, HRSA, and the OPTN have additional information resulting from their oversight activities that could be shared. The exchange of this information is important because CMS and the OPTN conduct different monitoring activities and, as a result, may have different information about transplant programs that could be relevant to each other. For example, while both CMS and the OPTN conduct on-site reviews of transplant programs, the OPTN's on-site reviews focus largely on medical records review while CMS's on-site surveys are more broadly scoped. If the OPTN determined during an on-

⁴⁵ Another HRSA contractor is providing CMS with quarterly data on transplant programs' survival rates and transplant activity.

site review that the medical urgency assigned to patients by a transplant program was not supported by its medical records, this information could be of interest to CMS if this practice inappropriately reduced the chances of others on the waiting list to receive a transplant. As another example, the OPTN and HRSA are working to put into place their organ acceptance rate indicator, which CMS officials said they would be interested in using. Information from CMS's and the OPTN's investigations could also be potentially important to share. For example, if CMS investigated a complaint from a patient about the length of time he or she had been waiting for a transplant and determined that the delay was caused by the program failing to update the patient's health status, a violation of OPTN policy, the OPTN might want to flag the program for closer monitoring.

CMS and HRSA have recognized the importance of sharing information from their oversight activities, but the agencies have not yet reached agreement on how they would do so. CMS submitted a draft proposal to HRSA in April 2007 describing how CMS and HRSA could potentially share information about organ transplant programs. CMS and HRSA officials have since discussed the initial proposal, including possible revisions, but their progress has been slow. As of February 2008, CMS and HRSA had yet to reach agreement or establish a time frame for doing so. According to HRSA officials it had taken the agencies several months to better understand each other's oversight processes, and both agencies needed to further explore their information needs. CMS officials also indicated that further issues would need to be resolved before an agreement could be reached.

As part of any agreement to share information from their oversight activities, CMS and HRSA will need to determine precisely what information from their oversight activities they will share and at what point in their oversight processes they will share it. CMS and HRSA have discussed but not resolved these issues:

- **Nature of information to be shared.** It will be important for CMS and HRSA to determine specifically what information they will share from their oversight activities. For example, while CMS's initial proposal addressed how CMS and HRSA could share information from CMS's and the OPTN's investigations of serious complaints, such as those involving threats to patient health and safety, CMS and HRSA officials have since discussed whether to share information from all complaints. In addition, CMS and HRSA have not determined to what extent information from routine inspections, such as the OPTN's on-site reviews and CMS's on-site surveys, will be shared and at what level of detail. For example, CMS's

initial proposal called for CMS to notify the OPTN about its completed on-site surveys and to indicate whether the transplant program surveyed had a plan of correction, but it did not call for CMS to provide information on the deficiencies CMS found. HRSA officials have since expressed their interest in having this more detailed information.

- **Timing of information sharing.** A more difficult challenge that CMS and HRSA face is agreeing when to share information about potential problems at transplant programs. Officials from both CMS and HRSA consider the severity of the identified problem(s) with a program to be a key factor in determining the appropriate time for information sharing. In this regard, officials from both agencies stated a willingness to promptly share information on potentially serious problems. Agreeing on just when to exchange information on less serious problems has been more problematic for the agencies in part because of differences in their approaches to oversight. On the one hand, CMS officials emphasize their agency's obligation to investigate any indications of noncompliance with Medicare requirements and prefer to be notified as soon as possible if the OPTN discovers a potential problem indicating noncompliance with Medicare CoPs. On the other hand, HRSA officials have emphasized that the viability and success of the OPTN's performance improvement process depends upon transplant programs sharing openly about their practices or past events. HRSA officials contend that the possibility of such information being shared with CMS, a regulatory agency, could cause transplant programs to be less candid about discussing real or potential problems, making it more difficult for the OPTN to help them return to compliance.

Conclusions

CMS, HRSA, and the OPTN recognize the gaps in oversight that existed when serious problems were exposed at transplant centers and have taken significant steps to strengthen federal oversight. The actions they have taken will help improve standards for transplant programs and should improve detection of potential problems. These actions include CMS's issuance of new regulations that expand and update requirements for transplant programs. In addition, CMS plans to conduct on-site surveys of all transplant programs seeking initial Medicare approval under the new regulations and to regularly review certain transplant program data, which should reduce the chances of problems going undetected by the agency. Similarly, if the OPTN's and HRSA's efforts to develop and implement a set of activity-level indicators to detect problems that prolong the time patients wait for transplants are successful, the indicators will likely result in earlier detection of these more subtle problems.

The full effect of these planned improvements, however, is unknown at this time, and much has yet to be accomplished. While surveyors have begun conducting on-site surveys for initial Medicare approval, CMS expects these surveys may take 3 years to complete. CMS is still in the process of designing its tracking system for transplant programs, and it is important that the system include mechanisms to check that transplant programs remain accurately classified in the CMS survey database over time. The OPTN and HRSA are working on implementing their set of activity-level indicators for kidney and liver transplant programs. It will be important for the OPTN and HRSA to implement the activity-level indicators to the extent feasible to provide improved monitoring tools to detect problems affecting patient access to transplants like those involved in the high-profile cases in 2005 and 2006. Attending to these areas is critical for effective oversight, and we encourage CMS, HRSA, and the OPTN to continue their efforts to implement these initiatives.

Of more concern are two other issues. The first is how CMS will ultimately conduct on-site surveys for transplant programs seeking reapproval under the new Medicare regulations. Under the regulations, CMS may choose not to conduct such surveys for transplant programs meeting data submission, clinical experience, and outcomes requirements. Not conducting on-site reapproval surveys may limit CMS's ability to monitor these transplant programs' compliance with other Medicare CoPs, for example, whether transplant programs are providing required protections for living donors, and to detect problems like those involved in some of the high-profile cases. CMS has not yet developed a process to determine the scope of the transplant programs (number or type) to be included in reapproval surveys or the criteria for determining which, if any, transplant programs that meet the three requirements will receive such surveys. Given the potential importance of these reapproval surveys, we believe that having a methodology that ensures that CMS conducts surveys of at least some transplant programs meeting the three requirements is critical to maximize CMS's opportunities to identify potential problems in a timely manner.

We also have a concern about the pace of progress being made to share information about the oversight activities of CMS, HRSA, and the OPTN. Agency officials believe, as we do, that their ability to identify potential problems could be enhanced by sharing information resulting from their oversight activities. While CMS's draft proposal for sharing such information is an important first step in reaching an agreement on this issue, CMS and HRSA have yet to finalize an agreement or establish a time frame for doing so. Without a definitive time frame for reaching agreement, there is increased risk that the negotiation process among

these agencies could languish, and they could miss opportunities to detect and remedy problems with transplant programs. Furthermore, in developing an agreement, CMS and HRSA will need to fully articulate what types of information will be shared from their oversight activities and when they will share it. While we agree that there are challenges associated with reaching agreement on this issue, we also believe it is important to settle these issues and finalize a clear written agreement that maximizes information sharing as appropriate and better ensures that all parties are aware of critical information in time to take appropriate action. Once CMS and HRSA reach and implement an agreement, they may wish to periodically assess how effectively it is working for each of them to improve their oversight.

Recommendations for Executive Action

To improve federal oversight of organ transplant programs, we recommend that the Secretary of Health and Human Services:

(1) Direct the Administrator of CMS to develop a methodology for conducting on-site surveys of transplant programs seeking Medicare reapproval that ensures that at least some transplant programs meeting data submission, clinical experience, and outcomes requirements receive on-site surveys.

(2) Direct the Administrators of CMS and HRSA to establish a time frame for finalizing an agreement for the agencies to share information resulting from CMS's and the OPTN's oversight activities. The agreement should, at a minimum,

- specify the types of information CMS, HRSA, and the OPTN will share and
- specify at what point in CMS's and the OPTN's oversight processes this information will be exchanged.

Agency Comments

We received comments on a draft of this report from HHS. (See app. II.) The department concurred with both of our recommendations and commented that CMS recognizes the need to increase its oversight of organ transplant programs.

HHS agreed with our recommendation that CMS develop a methodology for conducting on-site surveys for Medicare reapproval to ensure that at least some programs meeting certain Medicare criteria are surveyed, noting that CMS has developed an initial framework for doing so but that

its implementation will depend on the resources available for survey and certification activities. CMS highlighted several factors the agency may use as part of a methodology to determine survey frequencies for individual transplant programs, including prior survey results, program changes, program indicators, and the time interval since the last survey.

HHS also agreed with our recommendation to establish a time frame for finalizing the agreement between HRSA and CMS to share information from their oversight activities, noting that HRSA and CMS have been working to develop and finalize such an agreement. Specifically, the department commented that CMS has conveyed a proposal to HRSA regarding the criteria and process that CMS would use in sharing information, and that CMS would like the agreement with HRSA to be finalized by June 30, 2008. HHS also noted that even though a formal agreement is not yet in place, CMS and HRSA have on several occasions already shared oversight information about particular programs.

The department also provided technical comments, which we incorporated as appropriate.

As arranged with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after its date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Administrators of CMS and HRSA, and appropriate congressional committees. We will also provide copies to others upon request. In addition, the report is available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or williamsonr@gao.gov. GAO staff who made major contributions to this report are listed in appendix III.

Sincerely yours,



Randall B. Williamson
Director, Health Care

Appendix I: Medicare Conditions of Participation for Transplant Centers

On March 30, 2007, the Centers for Medicare & Medicaid Services (CMS) published a final rule promulgating requirements for Medicare approval and reapproval of transplant centers to perform organ transplants. The regulations, which became effective June 28, 2007, delineate Medicare conditions of participation for heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers.¹ Table 4 presents a summary of the key requirements for each condition of participation.

Table 4: Summary of Medicare Conditions of Participation for Transplant Centers

Title of condition of participation	Summary of requirements
Organ Procurement and Transplantation Network (OPTN) membership	The transplant program must be located in a hospital that is a member of the OPTN and that abides by the approved rules and requirements of the OPTN.
Notification to CMS	The transplant program must notify CMS of any significant changes related to the program or changes that could affect its compliance with the Medicare conditions of participation.
Pediatric transplants	A transplant program seeking to perform pediatric transplants must apply for specific approval to do so.
Data submission, clinical experience, and outcomes requirements for initial approval	For initial Medicare approval: <ul style="list-style-type: none"> • The transplant program must submit required data to the OPTN within a specified time frame. • Adult heart, liver, lung, and intestine transplant programs must generally perform 10 transplants over a 12-month period; adult kidney transplant programs must perform at least 3 transplants over a 12-month period prior to their request for initial approval. • Heart, liver, lung, and kidney transplant programs must have acceptable patient and graft (transplanted organ) survival rates.^a
Data submission, clinical experience, and outcomes requirements for reapproval	To renew Medicare approval: <ul style="list-style-type: none"> • The transplant program must submit required data to the OPTN within a specified time frame. • Adult heart, liver, lung, intestine, and kidney transplant programs must perform an average of 10 transplants per year. • Heart, liver, lung, and kidney transplant programs must have acceptable patient and graft survival rates.^a
Patient and living donor selection	The transplant program must use written patient selection criteria and, if applicable, written living donor selection criteria. Patient selection criteria must assure a nondiscriminatory distribution of organs. Living donor selection criteria must be consistent with principles of medical ethics.
Organ recovery and receipt	The transplant program must have written protocols, including documentation of vital information, for recovery and receipt of organs from deceased donors and for living donor organ transplantation. The transplanting surgeon is responsible for ensuring the medical suitability of organs for transplantation into the intended recipient.

¹72 Fed. Reg. 15198 (codified in pertinent part at 42 C.F.R. pt. 482, subpt. E).

Appendix I: Medicare Conditions of Participation for Transplant Centers

Title of condition of participation	Summary of requirements
Patient and living donor management	The transplant program must have written patient and, if applicable, living donor management policies; keep patient waiting lists and medical records up to date; and provide social and nutritional services to patients and donors.
Quality assessment and performance improvement	The transplant program must develop, implement, and maintain a quality assessment and performance improvement program to monitor and evaluate its transplantation services.
Human resources	The transplant program must ensure that staff, including the program director, primary transplant surgeon and physician, clinical transplant coordinator, and living donor advocate are qualified and meet CMS-specified requirements.
Organ procurement	The hospital containing the transplant program must have a written agreement with an organ procurement organization designated by the Secretary of Health and Human Services.
Patient and living donor rights	The transplant program must protect and promote patient and living donor rights through the implementation of informed consent policies, and must notify patients about factors that could affect patient access to transplantation, such as termination of Medicare approval or that the program is served by a single surgeon.
Additional requirements for kidney transplant centers	Kidney transplant programs must furnish dialysis services and other care to end-stage renal disease patients.

Source: GAO analysis of Medicare hospital conditions of participation for transplant centers.

^aCMS will compare data on observed patient deaths and graft failures 1-year post-transplant to the expected number of deaths and graft failures 1-year post-transplant calculated by the Scientific Registry of Transplant Recipients, which uses risk-adjusted statistical models. CMS will consider patient and graft survival rates to be unacceptable if the observed patient or survival rate is lower than expected and all three of the following are true: (1) the one-sided p-value is less than 0.05, (2) the number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and (3) the number of observed events divided by the number of expected events is greater than 1.5.

Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
for Legislation

Washington, D.C. 20201

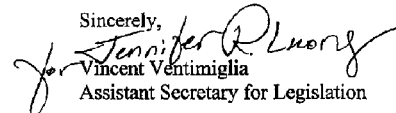
APR 14 2008

Randall Williamson
Acting Director, Health Care
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Williamson:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO) report entitled: "Organ Transplant Programs: Federal Agencies Have Acted to Improve Oversight but Implementation Issues Remain" (GAO 08-412).

The Department appreciates the opportunity to review and comment on this report before its publication.

Sincerely,

Vincent Ventimiglia
Assistant Secretary for Legislation

Appendix II: Comments from the Department
of Health and Human Services




DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: APR 14 2008

TO: Randall Williamson
Acting Director, Health Care
Government Accountability Office

FROM: Kerry Weems
Acting Administrator 

SUBJECT: Government Accountability Office (GAO) Draft Report: "Organ Transplant Programs: Federal Agencies Have Acted to Improve Oversight but Implementation Issues Remain" (GAO-08-412)

Thank you for the opportunity to comment on the subject GAO Draft Report. The purpose of the report was to examine--(1) Federal oversight of transplant programs at the time several high-profile organ transplant cases came to light in 2005 and 2006; and (2) changes that Federal agencies have made or planned since then to strengthen oversight.

The Centers for Medicare and Medicaid Services (CMS) recognizes the need to increase our oversight of organ transplant programs, and appreciates GAO's description of our considerable efforts over the past 18 months to strengthen oversight of hospital transplant programs, such as the following:

- **Review of Extra-Renal Programs under the National Coverage Determinations:** In 2006, CMS notified 11 extra-renal transplant programs that their Medicare approval was in jeopardy due to failure to comply with the National Coverage Determinations. As discussed in the GAO report, Medicare participation ended (either voluntarily or involuntarily) for 3 of those programs. The remaining 8 programs have submitted corrective action plans that were approved, and continue to be monitored, by CMS.
- **Release of Regulation Establishing Organ Transplant Conditions of Participation:** In March 2007, CMS published new Conditions of Participation (CoPs) for organ transplant programs. The CoPs established one set of 13 minimum requirements that all transplant programs must meet in order to participate in Medicare.
- **Development of Surveyor Guidance:** In 2007, CMS developed detailed guidance for surveyors who conduct the onsite review of transplant programs to assist in their determination of program compliance with the CoP. This guidance outlines the sources of evidence (e.g., policies, procedures, medical records) that surveyors will review to evaluate compliance with each Condition of the regulation.
- **Coordination between CMS and the Health Resources and Services Administration (HRSA):** In April 2007, CMS and HRSA began a dialogue to address the areas where our separate regulatory responsibilities intersect and discuss how coordination/collaboration

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could reinforce each agency's oversight efforts in this area. CMS and HRSA have agreed to exchange program information quarterly, and are continuing discussions about the exchange of case-specific information (e.g., complaints).

- **Survey Implementation:** In August 2007, CMS trained 66 surveyors to perform transplant program surveys. The onsite transplant surveys began in August 2007, and are ongoing. State survey agencies are conducting the surveys in most States, while a national contractor is conducting surveys in others.
- **Continued Improvement:** We continue to benefit from feedback from surveyors, professional associations, States, transplant programs, and the public as we review early survey experience and work to improve our interpretive guidance for surveyors.

The GAO report makes two recommendations for the CMS consideration. These recommendations and our responses to these recommendations are listed below.

Recommendation #1: CMS should develop a methodology for conducting on-site surveys for Medicare re-approval to ensure that at least some programs meeting certain Medicare criteria are surveyed.

CMS Response: The CMS concurs with this recommendation. We have already developed an initial framework for doing so, but implementation of the methodology will depend on the resources available for survey and certification (S&C) activities. As you may know, the current level of survey activity for transplant programs was initiated by CMS without explicit fiscal support from Congress. We sincerely hope that the necessary resources will be available to enable us to maintain this level of S&C frequency for transplant programs.

At the present time we are implementing onsite surveys based on a 3-year survey and certification cycle. This means that re-approval surveys will begin in fiscal year (FY) 2010 for those transplant programs first surveyed in FY 2007. Ideally, we would be able to continue the re-certification surveys on the same 3-year cycle, on average, depending on the budget.

However, as discussed in the GAO report, the regulation permits CMS to make future survey and compliance determinations based on other factors. Even with a 3-year survey cycle on average, we plan to adjust survey frequencies for any specific transplant program taking into account past compliance with regulatory requirements. For example, such factors may include the following:

- **Prior Survey Results:** In some cases, the findings from a prior survey would warrant more frequent or less frequent onsite review to verify that compliance with the CoP is maintained.
- **Program Changes:** On an ongoing basis, transplant programs are required to report significant program changes that may affect compliance with the CoP (e.g., key personnel changes, inactivity). Such reports may indicate a period of transition for a transplant program. CMS would want to consider reviewing transplant programs that have been through a significant transition since their last onsite survey to ensure that the CoP continue to be met.

Page 3 - Randall Williamson

- **Program Indicators:** Every 6 months, the Scientific Registry of Transplant Recipients (SRTR) publishes reports that provide key program information, such as: outcome data, how long individuals at that program wait for an organ transplant, how many individuals have received transplants, what the patient mortality rate at that program is for individuals on the waiting list, etc. These reports compare a program's information with others in their region and with the national average. We expect that these data would be used to develop indicators where potential issues may exist, and where an onsite review would be most important.
- **Interval Since the Last Survey:** After the first re-approval period, CMS will consider the time that has elapsed since a program's last onsite survey, as well as intervening complaints that have been substantiated through a complaint investigation.

Recommendation #2: Establish a timeframe for finalizing the agreement between HRSA and CMS to share information from our oversight activities.

CMS Response: The CMS agrees with this recommendation. CMS and HRSA have been working to develop and finalize an agreement regarding the sharing of information from our mutual oversight activities. We have made significant progress on the content and format for sharing transplant program data on a quarterly basis (as described in the GAO report), and we are hopeful that we are close to an agreement outlining the criteria and process for sharing case-specific notifications of program changes, complaints, and inactivity.

We have conveyed to HRSA a proposal regarding the criteria and process that CMS would use in sharing information regarding specific cases. This would include communicating at an early stage in cases of high-profile incidences, incidences of gross negligence, or a program's inactivity, and routinely sharing CMS survey findings that identify that a program is out of compliance with one or more Medicare CoP. The results of any other survey finding would be shared with HRSA upon request. We hope that the agreement can be finalized between CMS and HRSA by June 30, 2008.

Even though a formal agreement is not yet in place, neither CMS nor HRSA is waiting for such an agreement to work together in sharing information that results from our oversight activities. Since the onsite surveys have started, there have been several occasions where CMS and HRSA have discussed a particular program's status or investigated a complaint that has been referred to us.

We thank the GAO staff for their work in this important area of federal health care purchasing and oversight.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Randall B. Williamson, (202) 512-7114 or williamsonr@gao.gov

Acknowledgments

In addition to the contact named above, Kim Yamane, Assistant Director; Emily Beller; Susannah Bloch; George Bogart; Manuel Buentello; Linda McIver; Colin Smith; Stanley Stenersen; and Suzanne Worth made key contributions to this report.

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