



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.