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MEDICARE-APPROVED HEART TRANSPLANT CENTERS

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ABSTRACT

We analyzed data on Medicare-approved heart transplant centers from 1987 through 2000. Our report did not evaluate whether heart transplants were performed under unsafe conditions. It measures only whether centers continued to meet Medicare's initial volume and/or survival criteria.

Our analysis of these centers' performance found that many centers have performed at volume and survival rates below the minimum levels required for their initial Medicare approval, sometimes for several consecutive years. From 1987 through 2000, 69 of 90 Medicare-approved heart transplant centers failed, at least once, to meet the initial approval criteria for volume and/or survival rate. From 1992 to 2000, 15 percent of Medicare beneficiaries who received a heart transplant did so in a Medicare-approved center that fell below the initial approval However, the Centers for Medicare & Medicaid Services (CMS) rarely receives data from heart transplant centers on their volume and survival rate. The lack of data and lack of criteria for ongoing performance limits CMS's ability to provide effective oversight of heart transplant centers.

We recommend that CMS expedite the development of standards for continuing approved centers, as well as guidelines for what levels of performance trigger specific responses from CMS. We also recommend, in the short term, that CMS improve its oversight of centers by entering into an arrangement with the Health Resources and Services Administration for the regular exchange of volume and survival rate data.

EXECUTIVE SUMMARY

OBJECTIVES

To document whether Medicare-approved heart transplant centers continue to meet the initial 1-year volume and survival rate criteria required for Medicare approval.

To assess the Centers for Medicare & Medicaid Services's (CMS's) oversight of approved centers' performance on annual volume and survival rate.

BACKGROUND

In 1987, CMS published a coverage decision that allowed Medicare coverage for heart transplants performed in centers that are Medicare approved for heart transplants. By 2002, 99 heart transplant centers had been approved for Medicare reimbursement. In 1992, 294 Medicare beneficiaries received a heart transplant; by 2001, this number had increased to 494.

The 1987 coverage decision required centers to have performed heart transplants on at least 12 patients in each of the 2 preceding 12-month periods, and 12 patients prior to that, for a minimum total of 36 transplants. It also required centers to have achieved a 73 percent 1-year survival rate and a 65 percent 2-year survival rate. In 2000, CMS lowered the volume criteria from 36 to 12 transplants.

The 1987 coverage decision also required approved heart transplant centers to notify CMS about changes that would "affect the health and safety of patients...for example...a significant decrease in its experience level or survival rates." The 2000 update to the criteria did not change or clarify this requirement.

CMS has not established ongoing performance standards for Medicare-approved heart transplant centers. However, for the purpose of this study, we measured the historical performance of approved centers against CMS's initial approval requirements (12 annual procedures with a 73 percent 1-year survival rate). We reviewed volume and survival rate data for 90 heart transplant centers approved for Medicare coverage from 1987 through 1999. We obtained these data from the Scientific Registry of Transplant Recipients (Scientific Registry).

We reviewed all available files and applications for the 90 centers, including 70 letters that centers had sent to CMS in 2000. We mailed a questionnaire to 97 Medicare-approved centers and received 65 responses. We analyzed 1992 to 2001 Medicare payment data. We conducted six interviews with expert reviewers of applications for Medicare coverage and with transplant center representatives.

Our report did not evaluate whether heart transplants were performed under unsafe conditions. It measures only whether centers continued to meet Medicare's initial volume and/or survival criteria.

FINDINGS

From 1987 through 2000, 69 of 90 Medicare-approved heart transplant centers failed, at least once, to meet the initial approval criteria for volume and/or survival rate.

During this time period, 53 Medicare-approved heart transplant centers fell below a 73 percent 1-year survival rate at least once. Forty-five Medicare-approved heart transplant centers fell below an annual volume of 12 transplants at least once. Twenty-four Medicare-approved heart transplant centers fell below both initial criteria at least once.

From 1992 to 2000, 15 percent of Medicare beneficiaries who received a heart transplant did so in a Medicare-approved center that fell below the initial approval criteria for volume and/or survival rate in the year of their transplant.

In this 8-year period for which complete data are available, 583 of the 3,847 Medicare beneficiaries who received heart transplants received them in centers that did not meet CMS's initial approval criteria in the year of their transplant. Medicare paid $64 million for these transplants.

Over time, an increasing percentage of Medicare-approved heart transplant centers performed below the initial volume and/or survival rate criteria.

The percentage of Medicare-approved heart transplant centers that performed below the initial criteria rose from 15 percent in 1987 to 39 percent in 2000. In 1999 and 2000, the 2 most recent years for which data were available, slightly more than half of all approved centers fell below the initial approval criteria for volume and/or survival.

The lack of data and lack of criteria for ongoing performance limits CMS's ability to provide effective oversight of heart transplant centers.

CMS rarely receives data from heart transplant centers on their volume and survival rate. Nor does CMS regularly obtain such information from the Scientific Registry. Our assessment is based on discussions with CMS officials in the central and regional offices, our survey of centers, and our review of CMS files. For example, our survey results revealed that only 6 of 65 responding centers had notified CMS of any changes in their volume or survival rate at some point between 1997 and 2002. Yet, in 2000 alone, one-third of these 65 centers fell below the initial criteria for volume and/or survival rate.

Without volume or survival rate criteria for ongoing performance, CMS has little basis for taking enforcement actions. CMS has never withdrawn a center's Medicare-approval status, although 2 centers voluntarily terminated their programs in 2002. In our review of

CMS's files of approved centers, we found one example of CMS instituting a corrective action against a center for falling below the initial Medicare-approval criteria for volume and survival rate.

RECOMMENDATIONS

In its 1987 criteria for Medicare coverage of heart transplants, CMS identified initial criteria for volume and survival rate as key elements in ensuring patient quality. By not developing volume and survival rate criteria for continuing performance, as it committed to do in its 1987 coverage decision, CMS has limited its capacity to ensure that Medicare beneficiaries receive heart transplants "under conditions that are safe and effective."

CMS has taken some steps toward correcting this situation. It convened a public meeting with stakeholders in 1999, established a work group to evaluate the volume and survival rate criteria, and has made progress during the course of this inspection toward developing Conditions of Participation for Medicare-approved transplant centers. CMS has indicated that it will publish draft criteria early in 2004.

We present three recommendations that would enable CMS to improve its oversight of the volume and survival rate performance of Medicare-approved heart transplant centers.

- CMS should expedite the development of continuing criteria for volume and survival rate performance and for periodic recertification.

- CMS should develop guidelines and procedures for taking action when centers do not meet Medicare criteria for volume and survival rate.

- CMS should take immediate steps to improve its ability to maintain accurate and timely data on center performance.

COMMENTS ON THE DRAFT REPORT

CMS and the Health Resources and Services Administration provided comments on our draft report. These agencies agreed with our recommendations and described steps that they are taking to address them. We would like to address two points that they raise.

First, they raise concerns about our reliance on Medicare's volume and non risk-adjusted survival criteria as a basis for assessing performance. For this inspection, we focused on the Medicare coverage criteria established in 1987—and not yet revised—as measures of center performance. Newly approved centers must meet these criteria; it seemed reasonable to assess their continued adherence once they are Medicare-approved.

Second, the agencies indicate that the Department of Health and Human Services oversees transplant centers through the Organ Procurement and Transplantation Network (OPTN). While the OPTN's review of center operations and quality provide valuable

information, CMS is the accountable regulatory agency so far as Medicare participation is concerned. Nevertheless, we recognize the OPTN's important oversight role and intend to look more closely at it in the future.

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INTRODUCTION

OBJECTIVES

To document whether Medicare-approved heart transplant centers continue to meet the initial 1-year volume and survival rate criteria required for Medicare approval.

To assess the Centers for Medicare & Medicaid Services's (CMS's) oversight of approved centers' performance on annual volume and survival rate.

BACKGROUND

The Importance of Heart Transplants

Heart transplants have extended and improved the lives of thousands of people. Demand, however, continues to outpace the supply of available organs. From 1995 to 2001, over 26,000 people registered to be placed on a list of patients waiting for a heart transplant.[1] Of those on the list, 39 percent did not receive the needed heart transplant. The Secretary of Health and Human Services has launched several initiatives to increase awareness of the need for organ donation and thereby increase the number of transplant recipients.[2]

Medicare Coverage of Heart Transplants

CMS covers heart transplants for beneficiaries if the procedures are medically necessary and performed in centers that Medicare has approved for that purpose. Medicare began coverage for heart transplants in approved centers in 1987.[3] By 2002, 99 of 139 heart transplant centers in the United States had been approved for Medicare reimbursement. From 1992 to 2001, the annual number of Medicare beneficiaries who received heart transplants increased by 68 percent, from 294 to 494. During the same period, annual Medicare Part A heart transplant payments almost tripled, from $25 million in 1992 to $74 million in 2001.

From 1992 to 2002, the number of Medicare-approved heart transplant centers grew from 62 to 99. From 1992 to 2001, the total number of heart transplants performed in the United States remained relatively flat, rising from 2,170 to 2,202.

Volume and Survival Rate Criteria for Medicare Coverage

When it began covering heart transplants in 1987, CMS published a coverage decision describing criteria that transplant centers must meet to be eligible for Medicare payment, including criteria for volume and survival rate. CMS based these criteria on research that demonstrated that volume and survival rate were key indicators of a successful transplantation program. The decision announcing Medicare coverage of heart transplants stated that the survival rate criteria "are necessary to provide an adequately reliable measure

of the success of an applicant facility."[4] Later research supported the use of volume criteria to ensure better outcomes, finding that "the risk of mortality...is substantially higher in low-volume cardiac transplant centers."[5] The volume and survival rate criteria established for heart transplants preceded and influenced the criteria later developed for Medicare coverage of liver, lung, and intestinal transplants.

Table 1
Changes in Initial Volume and Survival Rate Criteria for Approval

Criteria	April 1987- October 2000	After October 2000
1. Volume	*Heart transplant centers applying for Medicare coverage must perform a minimum total of 36 transplants before a date the centers choose, referred to in the coverage decision and hereafter as the fiducial date:* • At least 24 transplants performed in the 24 months prior to the fiducial date. There must be at least 12 transplants in each of the two 12 months in this 2-year period. -and- • At least 12 transplants performed more than 24 months prior to the fiducial date. These 12 can be done at any prior time, with no yearly minimum.	• At least 12 transplants performed within the 12 months prior to the fiducial date. • Eliminated all other volume requirements.
2. Survival Rate	• At least 73 percent 1-year survival rate. The cohort of patients includes all transplants at the center, back to 1982. The volume criteria result in a minimum of 24 transplants with 1 full year of survival experience. -and- • At least 65 percent 2-year survival rate. Calculated for all transplants, back to 1982. The volume criteria result in a minimum of 12 transplants with 2 full years of survival experience.	• Unchanged survival rate and cohort. However, the volume criteria do not result in any minimum number of transplants with 1 full year of survival experience. • Unchanged survival rate and cohort. However, the volume criteria do not result in any minimum number of transplants with 2 full years of survival experience.

Source: OIG analysis of 1987 coverage decision and 2000 decision memorandum.

Among other criteria, Medicare approval requires centers to meet certain volume and survival rate criteria as of a date that centers choose, referred to in the coverage decision as the fiducial date. The fiducial date must be within 90 days of the date that a center submits its application and is the point from which all volume and survival rate data are calculated (see Table 1). The 1987 criteria did not include an ongoing performance standard.

In 2000, CMS published a memorandum that lowered the volume criteria for approval.[6] CMS "reasoned that volume could possibly serve as a proxy for the 2-year minimum experience requirement in addressing the issue of whether a new transplant center staffed with an experience[d] team might be expected to produce satisfactory outcomes." The 2000 criteria did not include an ongoing performance standard.

CMS has taken several steps to develop and institute performance indicators, such as volume and survival rate, for measuring the quality of the health care that Medicare beneficiaries receive in a variety of settings. For example, in January 2003, CMS published a final rule that established the Quality Assessment and Performance Improvement (QAPI) Program, which requires hospitals to keep data on performance indicators for improving health

outcomes and reducing medical errors. In 2002, CMS launched the National Nursing Home Quality Initiative, which uses performance indicators to highlight quality of care in nursing homes. The agency began reporting similar information for home health agencies in 2003.

Reporting Criteria for Volume and Survival Rate

In addition to establishing volume and survival rate criteria, the 1987 coverage decision required approved heart transplant centers to maintain data and submit information to notify CMS about changes to the transplant program that would "affect the health and safety of patients...for example...a significant decrease in its experience level or survival rates." The 2000 update to the criteria did not change or clarify this requirement. Because volume and survival rate are important indicators of quality, notifications of changes in these measures can serve as a vital oversight tool.

All heart transplant centers, regardless of their Medicare-approval status, must report volume, survival, and other transplant-related data to a Health Resources and Services Administration (HRSA) contractor, the Organ Procurement and Transplantation Network. Another HRSA contractor, the Scientific Registry of Transplant Recipients, analyzes and releases these data.

Initiatives to Evaluate Heart Transplant Centers After Approval

Although CMS has not developed procedures for a reapproval process or criteria for continuing performance, as it stated it would in the 1987 coverage decision, it has taken some steps to reassess the volume and survival rate criteria. CMS is in the process of developing Conditions of Participation for Medicare-approved transplant centers, including those performing heart transplants. CMS estimates it will publish the draft criteria early in 2004. As a part of this effort, CMS has a workgroup in place to evaluate the initial criteria for Medicare coverage and to determine criteria for ongoing approval.[7] In 1999, CMS convened a town hall meeting at which stakeholders offered their views on appropriate criteria for maintaining approval status, including criteria for volume and survival rate.[8]

SCOPE AND METHODOLOGY

Our study focuses on heart transplant centers approved for participation in Medicare from 1987 to 2000. We assess the performance of these centers against 2 of the criteria that Medicare adopted in 1987. We recognized that heart transplantation is a dynamic field and that measures of quality also are evolving. Because there are no continuing performance standards for centers, we considered Medicare's 1987 initial criteria to be a reasonable benchmark against which to measure continuing performance.

Our report did not evaluate whether heart transplants were performed under unsafe conditions. It measures only whether centers continued to meet Medicare's initial volume and/or survival criteria.

For this report we reviewed several sources of data related to the volume and survival rate criteria and the reporting requirement. Not every source contains data for each of the 99

heart transplant centers that CMS approved for Medicare, or for the entire period between 1987 and 2002. For example, data limitations prevented an analysis of how often centers met the 2-year volume and survival rate requirements. We note the time periods and number of approved centers for each of the data sources as they are referenced in the text.

Below, we summarize our data sources. Appendix B provides a more detailed methodology.

- **Center-specific performance data.** To determine the extent to which centers met or did not meet the initial Medicare coverage criteria for volume and survival rate performance, we analyzed annual 1-year volume and survival rate data for the 90 heart transplant centers approved for Medicare coverage between 1987 and 1999. For that time period, we compared each center's annual volume and survival rate with the initial criteria for Medicare coverage and calculated how many times each center fell below or met the criteria. Our analysis is similar to the criteria detailed in the 2000 coverage update, but calculates 1-year survival rates with a full year of follow up.
- **Review of files and applications of Medicare-approved centers.** To document the number of voluntary notifications centers sent to CMS and any communications CMS made to centers about performance and reporting expectations, we reviewed 91 files and 22 applications of approved centers that CMS has maintained. We also reviewed the 70 letters that centers sent to CMS in response to its 2000 letter reminding centers to report changes in their transplant programs.
- **Phone interviews and on-site visit with CMS central office.** To document the approval process, CMS's ongoing oversight, and communications between CMS central office and approved centers, we conducted six phone interviews and one on-site interview with CMS central office staff responsible for keeping track of and writing policy for heart transplant centers.
- **Phone survey of CMS regional offices.** To determine the role of CMS regional offices in the oversight of heart transplant centers and the extent to which regional offices communicate with centers and with CMS central office, we surveyed each of the 10 CMS regional offices responsible for overseeing Medicare-certified hospitals and for informing beneficiaries about insurance.
- **Survey of Medicare-approved heart transplant centers.** To validate and supplement information we gathered from CMS files and staff interviews, we mailed a written questionnaire to 97 Medicare-approved centers and received 65 responses.
- **Medicare claims data.** To calculate how many Medicare beneficiaries received a heart transplant and how much those transplants cost, we analyzed Medicare payment data. These data cover Medicare Part A payments for diagnostic-related group (DRG) 103 (heart transplants) from 1992 to 2000, a period for which we also received volume and survival rate data from the Scientific Registry.
- **Interviews with expert reviewers and transplant center representatives.** To document perspectives on Medicare coverage of heart transplants and issues that physicians and centers face in addressing volume and survival rate, we conducted six interviews with expert reviewers of applications for Medicare coverage and with heart transplant center representatives.

- **Literature review.** To further understand Medicare coverage of heart transplant centers and the volume and survival rate criteria, we reviewed relevant literature, including laws, regulations, policies, and guidelines, as well as journal articles.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

From 1987 through 2000, 69 of 90 Medicare-approved heart transplant centers failed, at least once, to meet the initial approval criteria for volume and/or survival rate.

The 1987 coverage decision for heart transplants stated that center "approval will be for a three year period and extensions of approval will require submission of a continuation application and will not be automatic."[9] CMS, however, never specified how centers were to submit continuation applications and never developed continuing performance standards for approved centers.

In the 1987 coverage decision, CMS justified its volume and survival rate criteria, explaining that "transplantation under such circumstances, and only under such circumstances is safe, effective, and widely accepted; that is, reasonable and necessary."[10] Through the year 2000, 45 of the 90 approved centers fell below the initial approval criteria for volume in at least 1 year after their approval, and 53 of the centers fell below the initial approval criteria for survival rate in at least 1 year after their approval (see Table 2).

Many Medicare-approved heart transplant centers fell below 12 procedures annually not just once, but in multiple years. For example, one center performed fewer than 12 procedures annually for 8 consecutive years, including 2 consecutive years in which it performed only 1 transplant. From 1987 through 2000, 17 centers performed 6 or fewer transplants in a single year, yet retained their Medicare approval status.

Table 2
Medicare-Approved Heart Transplant Centers
Performing Below the Volume and/or Survival Rate Criteria, 1987-2000

	Number of Centers Below Criteria		
	Below Volume *(fewer than 12 procedures)*	**Below Survival Rate** *(less than 73 percent)*	**Below Both in the Same Year**
At Least 1 Year Below Criteria	45 (50%)	53 (59%)	24 (27%)
3 or More Years Below Criteria	27 (30%)	13 (14%)	2 (2%)
3 or More Consecutive Years Below Criteria	17 (19%)	7 (8%)	2 (2%)

N=90. Source: OIG analysis of Scientific Registry of Transplant Recipients database as of 8/2/2002, containing volume and survival rate data from 1987-2000. These categories are not mutually exclusive: each cell is an independent summary of all applicable centers.

Additionally, many Medicare-approved heart transplant centers fell below a 73 percent 1-year survival rate multiple times (see Table 2). For example, 2 centers fell below the survival rate criteria for 4 consecutive years. Some centers had 1-year survival rates far below 73 percent: 6 centers had a 1-year survival rate of 50 percent or less. One center had a 1-year survival rate of 25 percent for a year in which 8 patients were transplanted. Another center

had a 1-year survival rate of 0 percent for a year in which the single patient transplanted died within the year.

Twenty-four centers fell below both volume and survival rate criteria in a single year. One center fell below both initial approval criteria in 4 consecutive years, but continued to be approved by Medicare.

This variance in transplant center performance has implications for beneficiaries. One effect is that many Medicare beneficiaries received transplants in low-performing centers that are located near approved centers that did meet Medicare's initial volume and survival rate criteria for approval. In the year 2000 alone, 35 Medicare-approved heart transplant centers fell below the initial approval criteria for volume and/or survival rate. Twelve of these centers, 34 percent, were located within 10 miles of a center that performed above both the initial volume and survival rate criteria in 2000.

From 1987 through 2002, 2 of the 99 approved centers voluntarily terminated their status by submitting a letter to CMS, requesting a change in their approval status to "voluntarily terminated." Some centers that retain their approval status, however, have performed at volume and survival rate levels below those of the two voluntarily terminated centers.

From 1992 to 2000, 15 percent of Medicare beneficiaries who received a heart transplant did so in a Medicare-approved center that fell below the initial approval criteria for volume and/or survival rate in the year of their transplant.

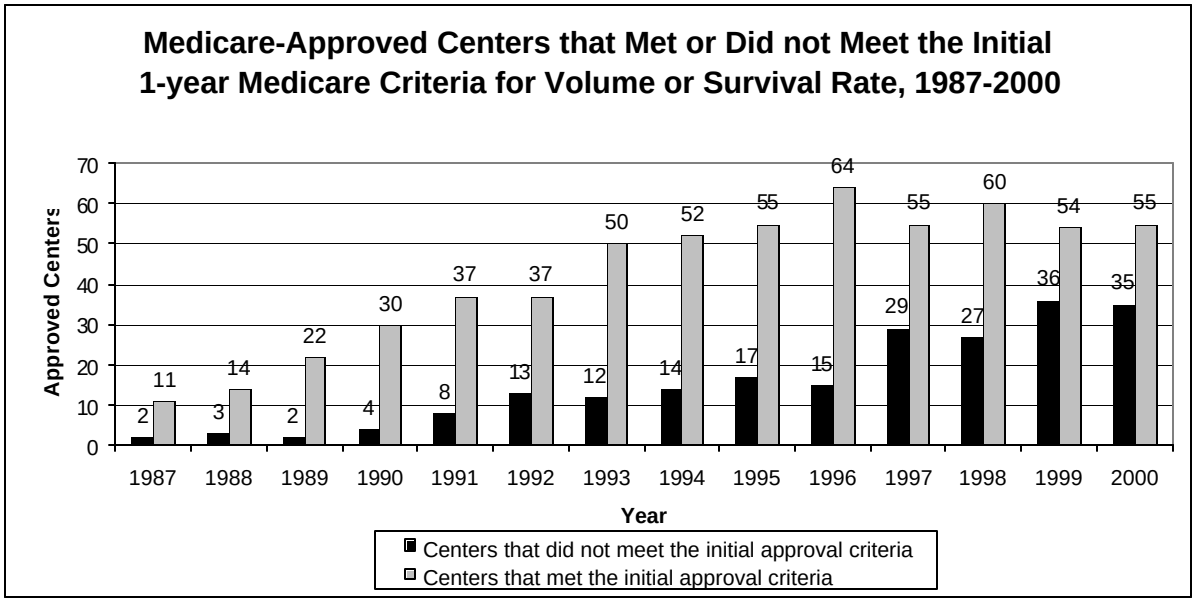
During the 8 years for which complete Medicare payment data were available, 583 of the 3,847 Medicare beneficiaries who received heart transplants received them in centers that did not continue to meet CMS's own research-based initial criteria for quality. These 583 beneficiaries' transplants accounted for $64 million in Medicare payments.[11] Medicare paid $25 million for 232 beneficiaries' transplants at centers that, after receiving Medicare approval, fell below the initial Medicare-approval criteria for volume; $32 million for 294 beneficiaries' heart transplants performed at centers that fell below the initial criteria for survival rate; and $7 million for 57 beneficiaries' heart transplants performed at centers that fell below both initial criteria.

The amount of Medicare payments going to centers that did not continue to meet the initial certification criteria increased fourfold, from $3 million in 1992 to $13 million in 2000. The number of Medicare beneficiaries receiving transplants at those centers similarly increased; it nearly tripled from 34 in 1992 to 98 in 2000.

Over time, an increasing percentage of Medicare-approved heart transplant centers performed below the initial volume and/or survival rate criteria.

The percentage of Medicare-approved heart transplant centers that performed below the initial Medicare-approval criteria for volume and/or survival rate rose from 15 percent (2 of 13) in 1987 to 39 percent (35 of 90) in 2000 (see Figure 1).

Figure 1



Source: OIG analysis of HRSA/Scientific Registry database as of 8/2/2002.

Of the 90 centers approved through 1998, 48 fell below the initial approval criteria for volume and/or survival rate in 1999 or 2000. In other words, in the 2 most recent years for which data were available, more than half of all approved centers fell below the initial approval criteria for volume and/or survival rate.

Due to the lack of growth in the number of organ donations, the total number of heart transplants performed in the United States during the 1990s stayed relatively flat. Even though the number of Medicare-approved heart transplant centers doubled in the 1990s (from 45 to 90), the total number of transplants performed in these centers grew by only 51 percent. Eighteen of the 65 centers responding to our survey, and 3 of the 6 expert reviewers and transplant center representatives we interviewed, told us that the stagnant donation rate has reduced the average number of transplants performed annually at Medicare-approved centers.

The lack of data and lack of criteria for ongoing performance limits CMS's ability to provide effective oversight of heart transplant centers.

The 1987 coverage decision requires Medicare-approved heart transplant centers to report to CMS when they experience "any events or changes which would affect [their] approved status…specifically…any significant decreases" in volume and/or survival rates. But CMS has not defined what level of decreases in volume and/or survival rate should trigger centers to report.

CMS rarely receives data from heart transplant centers on their volume or survival rate. Although the 1987 coverage decision requires approved centers to maintain and routinely submit data to CMS, this has not happened. The revised performance criteria issued in 2000 reiterated this requirement. In both the 1987 and 2000 coverage decisions, however, CMS did not specify what type of information centers should maintain or the format in which to submit it. In 1987, CMS stated that it would issue such instructions, but it has not done so.

CMS lacks a system to monitor centers' ongoing performance concerning volume or survival rates. We base this assessment on discussions with CMS officials in its central office and each of its 10 regional offices, as well as data gathered from our survey of Medicare-approved centers and through a review of relevant CMS files.

In our survey of 97 approved centers, we asked if they had notified CMS of any change in their volume or survival rate in the last 5 years. Of the 65 centers that responded, only 6 indicated that they had notified CMS of changes in their volume or survival rate at some point between 1997 and 2002. Yet, in 2000 alone, one-third of these 65 centers fell below the initial criteria for either volume and/or survival rate.

In our file review, we examined the files that were available in CMS's central office for 91 approved centers. In those files, we found no documentation of centers submitting volume or survival rate information, except for the centers' response to a specific request CMS made in 2000. In that year, for the first time in the 15 years of Medicare coverage, CMS mailed a letter to centers reminding them to report performance data. This letter triggered a one-time spike in reporting, which accounts for the majority of data on volume and survival rate that CMS has received from centers. Both before and after this spike in reporting, centers have reported little information to CMS concerning volume or survival rate.

CMS does not regularly obtain information from the Scientific Registry. As we noted in the background to this report, another source of data on center performance is available to CMS: The Scientific Registry of Transplant Recipients. The Scientific Registry is maintained under contract with the Health Resources and Services Administration. All heart transplant centers, regardless of their Medicare-approval status, report volume, survival, and other transplant-related data to the Organ Procurement and Transplantation Network on an

annual basis. Since 2000, these data have been made publicly available on the Scientific Registry website (http://ustransplant.org).

CMS does not have a system in place to receive these data directly from the Scientific Registry. CMS does not have an arrangement with the Health Resources and Services Administration for the regular receipt of these data. We found no indication that CMS routinely accesses the data on the Scientific Registry's website regarding heart transplant center performance.

Without volume or survival rate criteria for continuing performance of approved centers, CMS has little basis for taking enforcement action against approved centers that fall below the initial Medicare-approval criteria for volume and/or survival rate. The 1987 heart transplant coverage decision states "changes in the terms of approval may lead to prospective withdrawal of approval for Medicare coverage." CMS, though, has not determined what type and level of changes in volume and survival rate would lead it to withdraw Medicare approval. CMS also has not outlined steps it would take to address a low-performing center before withdrawing approval.

In its 2000 letter reminding centers to report program changes, CMS stated that centers must report when they fall below the initial criteria under penalty of withdrawal from the Medicare program (see Appendix C). However, CMS officials have since expressed a lack of certainty regarding CMS's authority to take such action, except in egregious cases, since clear guidelines for performance have not been developed. According to CMS officials and our review of all CMS files on heart transplant centers, CMS has never withdrawn a center's Medicare-approval status (although, as noted before, two centers voluntarily terminated their programs).

In our review of the files of 90 heart transplant centers that CMS possesses, we found 1 example of CMS taking action against a center for falling below the initial Medicare-approval criteria for volume and survival rate. In this case, CMS conducted an on-site review and instituted a corrective action plan in response to a national newspaper article that raised concerns about the center's survival rate. CMS had approved this center for Medicare less than 3 months before the article was published.

CMS has taken no actions to address approved centers that reported falling below the initial approval criteria. When CMS sent centers a letter in 2000 reminding them to report program changes, 70 out of the 91 centers that were approved at that time responded. However, CMS conducted no follow up on these responses or on the 21 centers that failed to respond to its letter.

RECOMMENDATIONS

Over the past 15 years, Medicare has covered heart transplants in many centers that, after approval, performed at levels below the initial approval criteria for volume and/or survival rate. In a recent period for which data are available—1992 to 2000—15 percent of the Medicare beneficiaries who received transplants received them in such centers. This is a significant concern given that CMS, in its 1987 criteria for Medicare coverage of heart transplants, identified the initial criteria for volume and survival rate as key elements in ensuring quality. In that statement of criteria, CMS noted the following:

> *We believe that the most appropriate means of assuring that Medicare beneficiaries receive heart transplants under conditions that are safe and effective is to provide coverage only at those facilities with demonstrated experience and success.*[12]

Our report did not evaluate whether heart transplants were performed under unsafe conditions. It measures only whether centers continued to meet Medicare's initial volume and/or survival criteria. However, by not developing volume and survival rate criteria for continuing performance, as it committed to do in its 1987 coverage decision, CMS has limited its capacity to ensure that Medicare beneficiaries receive heart transplants "under conditions that are safe and effective."[13]

CMS has taken some steps toward correcting this situation. It convened a public meeting with stakeholders in 1999, established a work group to evaluate the volume and survival rate criteria, and has made progress during the course of this inspection toward developing Conditions of Participation for Medicare-approved transplant centers. In its response to our draft report, CMS indicated that it will publish these draft criteria early in 2004**.** The development of the Conditions of Participation offers the opportunity for CMS to strengthen its ability to oversee the performance of Medicare-approved heart transplant centers.

We present three recommendations that would enable CMS to improve its oversight of the volume and survival rate performance of Medicare-approved heart transplant centers.

CMS should expedite the development of continuing criteria for volume and survival rate performance and for periodic recertification.

CMS stated its intention to do so in the 1987 coverage decision, in the 1999 town hall meeting, and in the 2000 memorandum that lowered the approval criteria. The updated criteria could specify the volume and survival rate that centers must meet to be eligible for Medicare approval, as well as the specific requirements and time periods that the recertification process involves. Upon determining the appropriate levels of performance and the procedures for maintaining continuing approval, CMS should clearly communicate them to all approved heart transplant centers.

CMS should develop guidelines and procedures for taking action when centers do not meet Medicare criteria for volume and survival rate.

Once CMS establishes clear criteria for performance, it could determine the performance threshold and corresponding steps necessary to take action if centers fail to meet the criteria. For example, it could define the extent to which centers can fall below the performance criteria without triggering CMS action. It also could develop guidelines that define when poor performance constitutes immediate jeopardy to patients, triggering review of the center's Medicare approval status. It could define the length of time over which low performance would warrant specific actions. CMS could establish levels of approval that would determine the degree of its oversight, develop corrective action plans for centers that fall below the criteria, and outline termination processes for centers that are unable to meet the criteria over time.

CMS should take immediate steps to improve its ability to maintain accurate and timely data on center performance.

Because the development and implementation of a new system for the approval, periodic recertification, and oversight of heart transplant centers may be lengthy, there are steps CMS can immediately take to improve its oversight of Medicare-approved heart transplant center performance. Obtaining Scientific Registry data is a first step toward the routine tracking and analysis of heart transplant center performance data. This would eliminate CMS's reliance on center reporting as the sole source of data on program changes.

While developing an arrangement for the regular exchange of performance data from the Health Resources and Services Administration, CMS could request or obtain the publicly available data on volume and performance since 1987 from the Scientific Registry. Using these data, CMS could identify instances in which centers fail to meet the ongoing criteria for volume and survival rate, once they are defined. With regular performance data coming from the Scientific Registry, CMS can be better informed in the future regarding its oversight efforts.

Moreover, CMS could use volume and survival rate data from the Scientific Registry for quality improvement efforts. It could make that data available to the public to encourage more informed decision-making by beneficiaries. Many of the centers that fell below the initial criteria are located a short distance from another center that meets or exceeds the initial approval criteria. This knowledge about the comparative quality of care of centers could facilitate the public's informed decision-making about their health care.

COMMENTS ON THE DRAFT REPORT

We received comments on our draft report from the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA).

These agencies agreed with our recommendations and described steps that they are taking to address them. In particular, we are encouraged that CMS and HRSA plan to publish a proposed rule that includes survival criteria for initial approval and reapproval of transplant centers. We are pleased that this proposed rule will include a process that CMS will follow if centers do not meet ongoing performance criteria.

We would, however, like to address two points that these agencies' comments raise.

First, the agencies raise concerns about our reliance on Medicare's volume and non risk-adjusted survival criteria as a basis for assessing center performance. For this inspection, we focused on the Medicare coverage criteria that were established in 1987—and that have not yet been revised—as measures of center performance. Newly approved centers are required to meet the volume and outcome criteria set forth in these coverage conditions. It seemed reasonable to us to assess their continued adherence to these criteria once they become Medicare-approved.

Second, the agencies indicate that the Department of Health and Human Services (HHS) oversees transplant centers through the Organ Procurement and Transplantation Network (OPTN). For example, they point out that any center that did not meet Medicare's volume and survival criteria would have been reviewed by the OPTN using risk-adjusted performance criteria. We recognize the important oversight role played by the OPTN and intend to look more closely at it in the future. Certainly the OPTN's review of center operations and quality serves a valuable purpose as one component of oversight. However, since CMS is the regulatory agency with responsibility for ensuring quality care for Medicare beneficiaries and for protecting the Medicare Trust Fund, it is the accountable agency so far as Medicare participation is concerned.

Input from a collegial, scientific organization is not the same as regulatory oversight of participating centers. HHS oversees the performance of the OPTN as a private contractor; that oversight does not extend to using that contractor for approval of centers for participation in Medicare.

APPENDIX A

AGENCY COMMENTS

DATE: JAN 20 2004

TO: Dara Corrigan
Acting Principal Deputy Inspector General
Office of Inspector General

FROM: Dennis G. Smith
Acting Administrator
Centers for Medicare
& Medicaid Services

Elizabeth M. Duke
Administrator
Health Resources and Services
Administration

SUBJECT: Office of Inspector General (OIG) Draft Report: *"Medicare-Approved Heart Transplant Centers,"* (OEI-01-02-00520)

Thank you for the opportunity to review the above-referenced draft report. We appreciate the OIG's assessment of the ongoing performance of the Medicare-approved heart transplant centers, and specifically, whether, once approved, these centers continue to meet initial approval criteria. We understand your concern that the performance of some heart transplant centers has dropped in the years following their Medicare approval. We do not, however, consider the findings presented in your report to be cause for public apprehension because they are based on non risk-adjusted data.

The Department of Health and Human Services (DHHS) can assure the public that, despite the OIG's findings, public health and safety have never been compromised. The DHHS has oversight of all heart transplant centers, including those receiving Medicare reimbursement, through the Organ Procurement and Transplantation Network (OPTN). The OPTN is operated by the United Network for Organ Sharing under contract with the Health Resources and Services Administration (HRSA) to coordinate and improve the Nation's organ procurement, distribution, and transplantation systems by: (1) maintaining a computer-based system to facilitate the organ matching and allocation process; (2) collecting data and conducting research on solid organ transplantation issues to improve the system; (3) evaluating organ transplant center effectiveness in prolonging and improving the quality of life for transplant patients; and (4) disseminating this information for use by patients and their families, physicians, payers, researchers, and other interested stakeholders.

To assess transplant center quality and operations, the OPTN uses review of risk-adjusted outcomes models with statistical and clinical significance; completion of comprehensive written surveys; and interviews and on-site audits with skilled transplant professionals. Any Medicare-approved transplant center found by the OIG study to fail Medicare's volume and non risk-adjusted survival criteria would have been reviewed by the OPTN using risk-adjusted performance criteria. Unlike the absolute volume and non risk-adjusted survival criteria used in the OIG study,

the OPTN performance criteria, using risk-adjusted models and tests of statistical and clinical significance, have greater predictive value for public health and safety purposes.

The problem with evaluating center performance on the basis of non risk-adjusted survival criteria is that the criteria do not take each center's patient mix into consideration. Therefore, failure to meet the existing Medicare survival criteria does not necessarily mean that a center has bad outcomes. For example, a heart center that selects mostly high-risk patients and has an observed 1-year patient survival rate of 70 percent, would fail to meet the existing 1-year patient survival criterion of 73 percent. If we risk-adjust the center's data and find that the center is expected to have a 1-year patient survival rate of 50 percent and that the difference between the observed and expected survival rate is both statistically (i.e., not due to random chance) and clinically significant, then the center's performance would be better than expected.

On the other hand, meeting the existing Medicare survival rate criteria does not necessarily mean that a center has good outcomes either. For example, a heart center that intentionally selects low-risk patients and achieves an observed 1-year patient survival rate of 80 percent would meet the existing Medicare 1-year survival rate criterion. If we risk-adjust the data and find that the center is expected to have a 1-year patient survival rate of 100 percent and that the difference between the observed survival rate and expected survival rate is both statistically and clinically significant, then the center's performance would be worse than expected.

Since the mutual goal of the DHHS and the OPTN is to assure access to quality organ transplantations, the OPTN works carefully with transplant centers to improve the centers' performances and outcomes before taking more extreme measures, such as requesting center inactivation or closure. Ultimately, all patients, including Medicare beneficiaries, benefit from this approach. The DHHS believes that the OPTN's approach to review of transplant centers reflects the most recent understanding of organ transplant technology and assures the public and all Medicare beneficiaries that the DHHS has always maintained appropriate oversight of heart transplant centers.

Further, we believe the OIG's findings may not accurately reflect the quality of organ transplantation in Medicare-approved heart transplant centers because the OIG used outdated criteria to evaluate the Medicare-approved heart transplant centers' ongoing performances. The existing Medicare approval criteria, which were developed in 1987 when heart transplantation was still in its infancy, no longer reflect the state-of-the-art in organ transplant technology.

The CMS and HRSA have long recognized the need to change the Medicare approval criteria for transplant centers. Therefore, we are pleased to report that the DHHS will soon publish a proposed rule that will include new survival criteria for initial Medicare approval and re-approval of transplant centers.

While the list of patients waiting for organ transplants grows longer every day, the DHHS and the organ and tissue donation community have focused largely on increasing the supply of transplantable organs. However, we believe it is equally important to ensure that transplants are

performed only in facilities where policies and procedures guarantee that healthy organs, once recovered, are not wasted. Further, we believe that the DHHS has an obligation to require transplant centers to demonstrate the experiences and expertise necessary to provide good outcomes in order to be Medicare-approved facilities.

Our specific comments on the OIG's recommendations are as follows:

OIG Recommendation

The CMS should expedite the development of continuing criteria for volume and survival rate performance and for periodic evaluation.

Response

We agree. A proposed rule is under development within the DHHS, offering new criteria CMS would use for the initial approval of all transplant centers, as well as new criteria CMS would use for the continuing evaluation and periodic re-approval (or disapproval) of all transplant centers.

Publication of this proposed rule for public comment is anticipated in early 2004.

OIG Recommendation

The CMS should develop guidelines and procedures for taking action when centers do not meet Medicare criteria for volume and survival rate.

Response

We agree. While the existing Medicare approval criteria limits CMS' ability to provide effective oversight of heart transplant centers once a center is Medicare-approved, the above-cited proposed rule includes provisions to address the operational issues of transplant center approval and re-approval. The proposed rule includes a process for transplant centers applying for initial approval and a process CMS would follow if the agency should find, during the re-approval process, that a transplant center did not meet the criteria for re-approval. During intervening years, CMS would have in place a process to ensure that approved centers are in compliance with all applicable rules. (Also see text of response below.)

OIG Recommendation

The CMS should take immediate steps to improve its ability to maintain accurate and timely data on center performance.

Page 4 – Dara Corrigan

Response

We agree. The HRSA has partnered with CMS in developing the proposed rule, including the proposed outcome measures to be used for initial approval and re-approval of transplant centers. The HRSA, as overseer of the contract for the Scientific Registry of Transplant Recipients (SRTR), has acted as a liaison to provide CMS access to SRTR data on transplant center performance. Following publication of the new transplant center regulations, HRSA will continue to provide regular reports to CMS, conveying data on transplant center volume and survival rates from SRTR.

APPENDIX B

METHODOLOGY

In 1987, Medicare published criteria that heart transplant centers must meet to be approved for coverage. Among other criteria, Medicare approval required centers to have transplanted 12 or more patients in the 12 months preceding the application and to have achieved a 73 percent 1-year survival rate. The coverage decision identified volume and survival rate as key indicators of quality and required centers to report if they fall below these criteria. Between 1987 and 2002, Medicare approved 99 heart transplant centers.

Number of Heart Transplant Centers Approved for Medicare, by Year of their Effective Approval

	Number of Approved Centers	
Effective Year of Approval	**Approved Per Year**	**Cumulative Total**
1986	13	13
1987	4	17
1988	7	24
1989	10	34
1990	11	45
1991	5	50
1992	12	62
1993	4	66
1994	6	72
1995	7	79
1996	5	84
1997	3	87
1998	3	90
1999	0	90
2000	4	94
2001	4	98
2002	1	99

Source: CMS website

For this report, we reviewed several sources of data related to the volume and survival rate criteria and the reporting requirement. Some approvals made were made retroactive to 1986. We were unable to access data for each of the 99 approved centers or for the entire time period between 1986 and 2002. In those cases, however, we noted the limitations of the data in the text.

Center-Specific Performance Data

We used Microsoft Excel and SAS®, a statistical analysis program, to review and analyze each center's 1-year volume and survival rate. Our data analysis covers every year from 1986, when Medicare retroactively attributed coverage, to 2000, the most recent year of data available. These data allow post-approval performance analysis of all 90 Medicare-approved heart transplant centers approved before the year 2000. These data allowed us to track how many centers per year met or did not meet the initial Medicare coverage criteria for volume and survival rate performance and to what extent they did not meet the criteria over time. Performance data represent only adult heart transplants.

We obtained each center's 1-year volume and survival rate data from the Health Resources and Services Administration (HRSA). HRSA synthesized volume and survival rate information from data it received from its contractor, the Scientific Registry of Transplant Recipients. The Scientific Registry collects, analyzes, and releases data on heart transplant centers, including volume and survival rate. We requested annual volume and survival rate data from 1986 to 2002, but HRSA staff who provided us with Scientific Registry data told us that data were incomplete, at the time of our request, for years after 2000 given the time it takes to input and analyze the data.

We also interviewed HRSA and Scientific Registry staff to find out the extent to which they validate data that centers report. They told us that they validate survival rate through comparing center reports with Social Security records. In turn, we attempted to validate the Scientific Registry data through comparing figures from the Scientific Registry and from the Organ Procurement and Transplantation Network (OPTN) another HRSA contractor that collects and manages data from heart transplant program. However, the Scientific Registry and OPTN calculate and publish their data differently, making comparisons difficult. Although OPTN has volume and survival rate data publicly available on the Internet, the data do not correspond with the calendar year time period on which we based our analysis. While the Scientific Registry gave us volume and survival rate for every year (January 1 to December 31), OPTN calculates data for a 3-year cohort, which it published on its website.

To determine the distance between centers, we used a SAS® program to calculate the distance between the geographic center of each zip code in which a heart transplant center is located; we did not use street addresses to calculate distances. The resulting distances are therefore approximate, not exact, center-to-center distances.

Incomplete volume and survival rate records and a lack of accurate data on the review and approval process for each center prevented several analyses, including: how often approved centers met the approval criteria at the time of their approval, and how often centers met the 2-year volume and survival rate. The 1-year criteria that we used to assess center performance are a lower threshold than using both the 1-year and the 2-year criteria for volume and survival rate.

CMS posts on its website the effective date of approval for each Medicare-approved heart transplant center. We used these dates to determine the effective year of approval for each approved center. Two of these dates were incorrect. Fairview University in Minneapolis, Minnesota and Clarian Health in Indianapolis, Indiana are incorrectly listed as approved in 1997. Both centers indicated, in response to our survey, that their effective dates of approval were 1986.

Review of Files and Applications of Medicare-Approved Centers

While on-site at CMS headquarters in Baltimore, we collected and reviewed all files associated with heart transplant centers, including center applications and CMS-center correspondence. CMS staff told us that they were unable to retrieve some files and documents. CMS did not have 8 files and 77 applications of the 99 centers with effective

approval dates between 1986 and 2002. In the process of moving office locations, CMS staff responsible for transplant facilities purged or stored documents, such as waivers, applications, and subsequent correspondence, in the Federal Archives.

Using an Excel spreadsheet, we documented what the available files and applications contained. We recorded the number of voluntary notifications centers sent to CMS and any communications CMS made to centers about the reporting criteria and performance expectations. If such notifications and communications existed, we documented the contents of those documents.

Two centers took steps to voluntarily terminate themselves from Medicare coverage. Although these steps occurred recently, in 2002, CMS staff told us that documents related to these steps to terminate are incomplete, similar to the other files. We extracted as much as was available and for greater details reviewed the two cases with CMS staff during our on-site visit.

We also obtained the letter CMS gave to heart transplant centers on June 6, 2000, to remind them of their obligation to report changes in their transplant program (see Appendix C). Seventy out of the 91 centers that Medicare had approved by that time responded to the 2000 letter. We reviewed the 2000 letter and centers' responses and documented how many centers reported significant decreases in their volume and survival rate.

Phone Interviews and On-Site Visit of CMS Headquarters

To document the approval process, CMS's ongoing oversight, and communications between CMS headquarters and approved centers, we conducted four phone interviews and one on-site interview with CMS headquarters staff in the Office of Coverage and Analysis Group (OCAG), who oversee the Medicare-approval process and post-approval performance of heart transplant centers. We also conducted two interviews with CMS staff from the Office of Clinical Standards and Quality (OCSQ), which is responsible for writing policy for heart transplant centers. In July 2001, policy decisions related to heart transplant centers were moved from OCAG to OCSQ=s Division of Institutional Quality Standards. OCSQ is currently in the process of reevaluating the existing standards and developing Conditions of Participation.

Phone Survey of CMS Regional Offices

We developed a telephone survey protocol for CMS regional office staff responsible for overseeing Medicare-certified hospitals, including those with Medicare-approved heart transplant centers. We inquired about the role of CMS regional offices in the oversight of heart transplant centers and the extent to which regional offices communicate with centers and with CMS headquarters in Baltimore. We interviewed the four CMS regional offices of OCSQ, and the nine regional offices from the Division of Survey and Certification (DSC). We also spoke with two regional offices in the Division of Beneficiary Health Plans and Providers (DBHPP), which provides information to Medicare beneficiaries about insurance.

APPENDIX B

Surveys to Medicare-Approved Heart Transplant Centers

We designed a written questionnaire and received 65 responses from the 97 approved centers that we were able to contact. Addressed to directors of each center's transplant programs, we mailed the survey twice to increase the response rate. We recorded the survey results on Microsoft Access template and aggregated the results using Access queries.

We used the survey results to validate and supplement the information we gathered from CMS files and regional/headquarter staff interviews. We asked centers about waivers they received for low volume and survival rate, any reports of program changes that they gave to CMS, and their experiences in meeting the performance criteria. We then compared the survey response with what we found in CMS's files.

Medicare Claims Data

Using SAS®, we analyzed claims data from the CMS Customer Information System (HCIS). Since 1992 to the present, CMS has used HCIS to summarize Medicare claims data. From HCIS, we extracted Medicare Part A payments captured under diagnostic-related group (DRG) 103, the DRG for heart transplants. The data cover 1992 to 2001, the earliest and latest years of data available. We recognize that other Medicare costs are associated with heart transplants, such as Part B payments, immunosuppressant drugs, and diagnostic procedures. However, we focused solely on the Part A, DRG 103 amount to calculate the number of Medicare beneficiaries receiving heart transplants in approved centers and their corresponding costs.

For 11 states, HCIS did not have center-specific information to calculate how many beneficiaries receive a heart transplant and how much those transplants cost. Because we used each center as the unit of analysis in matching center performance data with claims data, it is likely that we have undercounted the number of beneficiaries who received transplants in a center that did not meet the initial criteria for Medicare approval, and therefore, undercounted the costs for these transplants. For example, in 1998, we know that five centers in Texas, Utah, Virginia, Washington, and Wisconsin fell below the volume and/or survival rate criteria. However, HCIS did not contain center-specific information for these States in that year. As a result, we were unable to calculate the number of Medicare patients and associated costs given to those low performing centers using HCIS.

We conducted a separate analysis of those missing centers using Medicare Provider Analysis and Review (MEDPAR) data, which increased the total amount Medicare has paid for Medicare-approved centers below the initial criteria for volume and/or survival rate by 3 million dollars, and the total number of beneficiaries who received transplants in such centers by 33. We did not combine data from MEDPAR and HCIS due to discrepancies between the systems. These figures, however, would only increase the total dollars spent and beneficiaries affected.

Also, we identified eight heart transplant centers that changed their Medicare Provider Number. Five of these centers changed their Medicare Provider Number due to a merger

with another hospital. In those cases, because we used centers as our unit of analysis, such mergers did not affect our yearly totals. Three of these centers received Medicare payment despite being denied approval.

Interviews with Expert Reviewers and Transplant Center Representatives

We developed interview protocols and conducted interviews with three expert reviewers of applications for Medicare coverage and for three heart transplant center representatives. These interviews gave us insight into how, if at all, expert reviewers and centers communicate with CMS regional and headquarters staff about heart transplants, including the criteria to report program changes and performance expectations related to volume and survival rate. These interviews also allowed us to document the current and historical perspectives to Medicare coverage of heart transplants and issues that physicians and centers face in addressing volume and survival rate.

Literature Review

We performed a literature review, covering relevant laws, regulations, policies, and guidelines. We paid particular attention to the 1987 and 2000 coverage criteria that outline the conditions under which Medicare would cover heart transplants, including the requirements to meet initial volume and survival rate criteria and to report program changes to CMS. We also reviewed OPTN data and documents related to center performance and reporting requirements, given that OPTN has similar requirements it uses in overseeing heart transplant centers. We reviewed journal articles that address the link between volume and survival rates.

APPENDIX C

June 6, 2000

Dear Director:

This letter is being sent to all currently approved heart transplant facilities. It is being sent to remind you of your obligation to report certain changes, as described below, that may occur in your transplant program. This reporting requirement is a condition of continued Medicare payments under the national coverage decision establishing criteria for Heart Transplants. 52 Fed. Reg. 10935 (April 6, 1987)

Recently, we became aware of several instances in which major changes had occurred in various transplant programs. In most of these instances we were not directly notified by the facility of the changes that had occurred, but became aware of the changes at a much later date and through sources other than the facility. Failure to report these changes on a timely basis is unacceptable because it places Medicare beneficiaries at risk

Section 1862(a)(1)(A) of the Social Security Act prohibits payment for any expenses incurred for items or services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." In the case of heart transplant services, our national coverage decision prescribes criteria, including patient selection criteria, that facilities must satisfy in order for the transplants to be considered reasonable and necessary and, therefore, payable under title XVIII. A facility that wishes to obtain coverage of heart transplants must submit an application and supply documentation showing its initial and ongoing compliance with each of the criteria. 52 Fed. Reg. at 10946. You are required to report any changes related to a facility's transplant program that could affect the health or safety of patients selected for Medicare covered heart transplants or which would otherwise alter specific elements on a facility's application. These elements include, but are not limited to, the performance of less than 12 transplants in a twelve month period, a decrease in the 1 year and 2 year patient survival rates of 73 and 65 per cent, respectively, the loss of key members of the transplant team, transplantation of patients who do not meet the facility's patient selection criteria, or any other changes that could affect the performance of heart transplants performed at the facility. Changes from the terms of approval of your facility at the time of application could result in the Health Care Financing Administration's withdrawal of approval for Medicare coverage of transplants performed at your facility and/or denial of payment for transplants performed in a non-approved facility.

Please acknowledge receipt of this letter, and, pursuant to the above-referenced national coverage decision, please report any changes to your transplant program, as specified above, within 30 days from the date of this letter to the following address:

Bernadette Schumaker
Acting Director
Division of Integrated Delivery Systems
C4-25-02
7500 Security Boulevard
Baltimore, Maryland 21244

The collection of this information is authorized by OMB control number 0938-0490.

If you have any questions concerning this letter, please contact Claude Mone at 410-786-5666, by email at cmone@hcfa.gov, or Sandy Zachary at 410-786-4565, by email at szachary@hcfa.gov.

Sincerely,

Robert A. Berenson, M.D.
Director
Center for Health Plans and Providers

APPENDIX D

ENDNOTES

[1] Robert Wolfe et al., "Final Analysis for the Data Request from the ACOT Multicultural Issues Subcommittee Meeting of April 24, 2002," *Scientific Registry of Transplant Recipients Meeting Materials,* Table 2:13, 7.16.

[2] U.S. Department of Health and Human Services, "HHS Secretary Unveils Organ Donation Documentary" HHS press release, 9 April 2002. Retrieved from http://www.hhs.gov/news/press/2002pres/20020409.html, 12 July 2002.

[3] Criteria for Medicare Coverage of Heart Transplants, 52 FR 10,935, April 6, 1987.

[4] *Ibid.*

[5] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Medicare Coverage Policy, Transplant Centers: Re-Evaluation of Criteria for Medicare Approval,* Decision Memorandum, 26 July 2000.

[6] The 1-year and 2-year survival rates remained at 73 percent and 65 percent, respectively. The minimum number of transplants and the period of follow-up experience, however, changed with the volume requirements. These changes are reflected in Chart 1.

[7] Criteria for Approval of Facilities to Perform Covered Heart, Liver, Lung, Pancreas, and Intestinal Transplants, Unified Agenda, 67 FR 74,524, December 9, 2002.

[8] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Medicare Coverage Policy: Re-Evaluation of Criteria for Medicare Approval of Transplant Centers,* Summary of Town Hall Meeting, 1 December 1999.

[9] Criteria for Medicare Coverage of Heart Transplants, 52 FR 10,935, April 6, 1987.

[10] *Ibid.*

[11] In our analysis of Medicare claims data from CMS Customer Information System, we found eight provider numbers that did not match any of the ones associated with centers approved for Medicare. According to the CMS files we reviewed, one of these Provider Numbers matched a center that withdrew its application for Medicare approval in 1996. This center received payments from Medicare of $51,633 in 1992.

[12] Criteria for Medicare Coverage of Heart Transplants, 52 FR 10,935, April 6, 1987.

[13] *Ibid.*

ACKNOWLEDGMENTS

This report was prepared under the direction of Mark R. Yessian, Ph.D., Regional Inspector General for Evaluation and Inspections in Boston and Joyce M. Greenleaf, MBA, Assistant Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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