American Journal of Transplantation 2008; 8: 2496–2502
Wiley Periodicals Inc.

Special Article

doi: 10.1111/j.1600-6143.2008.02434.x

Transplant Center Regulations—A Mixed Blessing? An ASTS Council Viewpoint

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The Centers for Medicare and Medicaid Services (CMS) has developed a set of regulations that spell out the Conditions of Participation (CoPs) for provider hospitals that wish to be certified (and thus eligible for reimbursement) by Medicare for transplant services. The American Society of Transplant Surgeons (ASTS) Council has played a major role in providing CMS with advice and guidance in the development and ongoing implementation of these conditions through a process of fruitful dialogue. In this report, we highlight the events that led to the development of the regulations and describe the process to date in implementing the CoPs. We have raised some important questions regarding the effectiveness of the regulations for improving safety, and we have highlighted the cost associated with their implementation. This report has been vetted by and represents the opinions of the Council of the ASTS.

Key words: Medicaid, medicare, regulation

Abbreviations: ASTS, American Society of Transplant Surgeons; CMS, Center for Medicare and Medicaid Services; CoPs, conditions for participation; ESRD, end-stage renal disease; G, interpretative guidelines; MPSC, membership and professional standards committee; OPTN, organ procurement and transplantation network; RCA, root cause analysis; SRTR, scientific registry for transplant recipients.

Received 15 July 2008, revised 19 August 2008 and accepted for publication 20 August 2008

Introduction

The Centers for Medicare and Medicaid Services (CMS), which administers the Medicare and Medicaid programs, has promulgated and implemented a set of regulations for the certification of transplant centers. This is important because a significant proportion of transplant recipients in the United States are Medicare beneficiaries. Medicare reimburses transplant centers for transplantation services provided to Medicare beneficiaries, but only if the transplant center is Medicare certified. In order to be certified, the center must meet the Conditions of Participation (CoPs), which for transplant centers were published as a final rule in the *Federal Register* on March 30, 2007 with an effective date of June 28, 2007 (1). The following is a description of the process used to create and implement these regulations. We focus on the ongoing discussions between ASTS and CMS and raise important questions regarding the implementation of the rule.

Background

CMS is the largest single payor in the United States for health care services in general and for transplant services in particular. In addition, CMS acts not only as a payor, but also as a regulator. Most commercial payors follow CMS' lead regarding transplant center regulation. The CMS End Stage Renal Disease (ESRD) program is a key driver of the important role played by CMS as a transplant services payor in the United States. Under this program, almost all individuals in the United States who develop ESRD, regardless of age, are entitled to Medicare benefits, including renal transplantation, at a transplant center approved by CMS to perform kidney transplants. For nonrenal transplants, there is no similar entitlement, and patients in need of nonrenal transplantation must either demonstrate a period of permanent medical disability or be of at least 65 years of age in order to qualify for Medicare benefits.

Transplant centers must be certified by CMS for each organ type. In the past, Medicare certification was based on meeting certain volume and patient and/or graft survival rate requirements. Nonrenal transplant centers were required to submit an application to CMS for review by an expert panel. Issues such as patient selection criteria, patient management procedures and the hospital's commitment to the transplant center were considered. For renal

programs only, there was an on-site review requirement that included areas such as the transplant center's policies, governing body and the availability of social work and dietician services.

Under the Organ Procurement and Transplantation Network (OPTN) contract with federal authorities mandated by the National Organ Transplant Act of 1984, United Network for Organ Sharing has responsibility for quality assurance in the organ transplant community. All programs that do not obtain Medicare certification must be approved by the OPTN to be designated to receive organs. This approval includes a review of the education, training and experience of a primary surgeon and of a primary physician for the transplant program to determine that they meet OPTN criteria. OPTN bylaws require that all programs meet the criteria for a primary surgeon and physician regardless of Medicare certification. The OPTN membership approval may include a site review designed to ensure that the necessary resources and personnel are available to provide transplantation services.

Transplant centers are responsible for evaluating potential transplant recipients in order to determine whether they are candidates for transplantation. The OPTN Final Rule states that a candidate is someone who has been identified as medically suited to benefit from an organ transplant, and as soon as patients are deemed to be candidates, they are to be placed on a waiting list for deceased donor transplantation. If contraindications develop, transplant centers are responsible for removing candidates from the waiting list or for making them temporarily inactive. Transplant centers are required to report updated candidate and recipient information to the OPTN. These data are in turn analyzed by the Scientific Registry of Transplant Recipients (SRTR) on an ongoing basis and published twice a year on a public website (www.ustransplant.org). Separately, the OPTN oversees the transplant center performance by monitoring SRTR center-specific reports on a quarterly basis. In these reports, center-specific data are compared to expected risk-adjusted outcomes, using three well-defined criteria adopted by the OPTN for quality assurance. If a program has results that meet all three criteria, the OPTN Membership and Professional Standards Committee (MPSC) commissions a group of reviewers who investigate potential causes for inferior outcomes and then report back to the MPSC. Based on their findings, the MPSC makes recommendations regarding the necessary steps required to improve outcomes. The OPTN continues to monitor the performance until outcomes are improved. If serious deficiencies persist and are not corrected, the OPTN may take actions against the transplant center, including a letter of warning, a letter of reprimand, declare the transplant center to be on probation or declare it to be a 'member not in good standing'. If the problem is serious enough, the OPTN may recommend that the Department of Health and Human Services removes the transplant program's 'designated status', which will deny the transplant center access to deceased donor organs for transplant (2,3).

Several unfortunate events in the past few years led federal authorities and members of the media to question the effectiveness of existing Medicare and OPTN quality safeguards. For example, the *Los Angeles Times* reported that organs allocated by the OPTN for patients awaiting liver transplantation at a California transplant center were not being accepted for those candidates, reportedly because no surgeon was available to perform the transplants, despite the fact that the transplant center was both an OPTN-approved and Medicare-certified center (4). Separately, certain patients on the waiting list at another transplant center in California were reportedly bypassed for the benefit of an individual patient with less priority on the same waiting list, without any explanation and, more importantly, without any disciplinary action from either the OPTN or CMS (5). Finally, a California healthcare organization had accepted the transfer of a large number of patients awaiting kidney transplantation from another California transplant center and formed its own waiting list, without having the administrative infrastructure to support this waiting list or the ability to transplant these patients as organs became available (6). The media attention generated by these and other incidents (Table 1) caused CMS to more closely examine their current processes for the oversight of transplantation quality and to finalize the requirements that had been published in CMS' proposed regulation in February 2005 (described below).

Process

After some initial discussions, CMS published a proposal for CoPs in the *Federal Register* on February 4, 2005 (7). This comprehensive proposal included requirements that were considered inappropriate by many in the transplant community. As a result, a joint task force was formed

Table 1: Highly publicized sentinel events

Year	State	Sentinel event	Headline	Publication
2002	New York	Living liver donor death	The ultimate sacrifice	*TIME*
2003	North Carolina	Blood type incompatible heart transplant	A death at duke	*NEJM*
2005	California	Potential recipients not offered allocated organs	Organs refused while patients die	*L.A. Times*
2007	Illinois	HIV/HCV transmission	Four transplant recipients contract HIV	*N.Y. Times*

comprising members of the ASTS, the American Society of Transplantation and the International Society for Heart and Lung Transplantation. The task force examined the contents of the CMS proposal and after several face-to-face meetings and discussions with CMS submitted a comprehensive set of responses and recommendations during the comment period (8). The final rule, including CMS' response to a plethora of public comments (including those from the ASTS), was subsequently published in the *Federal Register* on March 30, 2007 (1). The final rule included volume and outcomes requirements for initial certification and recertification of transplant centers, as well as requirements for processes for the evaluation of potential recipients and donors and for the care provided to transplant recipients.

In essence, all transplant centers were allowed to continue Medicare participation as long as they applied for and received the initial approval under the new regulations. A letter indicating the desire by the transplant center to undergo initial evaluation under the new requirements was to be sent no later than 180 days following the effective date of the final rule. As part of these requirements, transplant centers were required to achieve or exceed expected 1-year survival graft and patient survival outcomes. Beyond these outcomes requirements, a site review process was outlined that relied heavily on documentation of policies and procedures and medical record documentation requirements. It was not sufficient for a transplant center to demonstrate that it had the proper manuals of operations and protocols in place. CMS reviewers would need to be shown documentation that for a sample of individual medical records reviewed, the transplant center's policies and protocols had been followed. Therefore, a transplant center could theoretically be completely compliant with the rules relating to policies and procedures, but could be found to be noncompliant if documentation in the individual medical record was incomplete or insufficient.

Although the joint task force still had some fundamental disagreements with the final rule, it was felt to be a clear improvement over the initial proposal, particularly since CMS had responded favorably to many of the comments from the joint task force. For example, CMS eliminated or modified inappropriate requirements in the areas of organ recovery, notification to patients on the waiting list and informed consent. It also clarified due process rights available to transplant centers in the event of an unfavorable review and provided for the consideration of mitigating circumstances when outcome and volume criteria were not met. The joint task force was disbanded following publication of the final rule in the *Federal Register* on March 30, 2007, but ASTS continued to monitor the process.

Once the final rule was published, CMS began its implementation process, which included drafting a set of interpretive guidelines (IGs) to be used by surveyors performing the on-site review of each program. The exact language used in the IGs is extremely important, since the guidelines are used by surveyors to interpret the final rule and to determine whether transplant centers meet the regulatory requirements (Table 2).

When the first set of draft IGs was made available, the ASTS felt that they deviated from the final rule in several areas. Members of the ASTS Executive Committee met and corresponded with CMS in order to make the agency aware of areas of concern (9). CMS responded by amending the language in the IGs to better reflect the intent of the final rule. Specifically, the agency eliminated several requirements and modified others to provide transplant centers with increased flexibility in the areas of multidisciplinary care, verification of patient selection criteria, continuing education for clinical staff and availability of tissue typing services among others. In addition, the agency clarified the roles of the transplant surgeon and transplant coordinator. A third and final version of the IGs was issued to surveyors in June 2008, which addressed a number of concerns that remained after the second draft, and these final IGs replaced all previous versions.

The most recent changes made by CMS in response to ASTS comments include clarification that surveyors must limit their review to the effective date of the new CoPs, recognition that meetings are not required to document multidisciplinary care and that this can be documented through entries in the patient chart, clarification that the compliance survey does not encompass care provided in outpatient clinics, clarification that postdischarge care can be provided by the local physician and a provision for increased flexibility in documentation of team involvement in living donor assessments. During a recent visit to CMS, the agency shared with ASTS the results of the first set of surveys (without revealing the names of the transplant

Table 2: CMS CoP final rule section headings

482.68	Special requirements for transplant centers
482.72	OPTN membership
482.76	Pediatric transplants
482.80	Data submission, clinical experience and outcome requirements for the initial approval of transplant centers
482.82	Data submission, clinical experience and outcome requirements for the reapproval of transplant centers
482.90	Patient and living donor selection
482.92	Organ recovery and receipt
482.94	Patient and living donor management
482.96	Quality assessment and performance improvement (QAPI)
482.98	Human resources
482.100	Organ procurement
482.102	Patient and living donor rights
482.104	Additional requirements for kidney transplant centers
488.61	Special procedures for the approval and reapproval of organ transplant centers

Table 3: Summary of initial transplant center surveys—most frequently cited deficiencies

Percent of transplant centers deficient	Deficiency
42%	Organ receipt: verification of ABO and other vital data
27%	Written documentation of transplant multidisciplinary patient care planning
24%	Components of quality assessment and performance (QAPI)
24%	Transplant team—identified and responsibilities described
22%	Written documentation of discharge multidisciplinary patient care planning
20%	Written documentation (patient's medical record) of selections criteria used to waitlist patient

centers) and identified areas where transplant centers have frequently been found to be out of compliance with the requirements (Table 3). As of this writing, CMS has begun its surveys using the third and final versions of IGs that incorporate many additional suggestions from ASTS. The ASTS is continuing a dialogue with CMS regarding the IGs, and it is not unlikely that additional changes may be made in the future, as the conduct of surveys reveals areas requiring further clarification.

Discussion

While the motivation behind the CMS process and its general direction is laudable, there are areas of concern that may have to be addressed if potential harm is to be avoided. Everyone in the transplant community would surely agree that the regulations that govern Medicare certification of transplant centers will increase the standardization of care. It is clear that the dialogue and interaction between ASTS and CMS have led to a much improved set of guidelines. The dialogue must continue, and CMS has indicated that it plans to continue to involve the ASTS in the implementation of the new regulations.

The principal remaining areas of concern relate to (a) potential unintended consequences of the 'process' measures that are the focus of the site surveys, (b) the potential impact of the outcomes measures used by CMS and (c) the costs of implementation.

As the surveys unfold, important questions remain about the implementation of the new Medicare 'process' requirements. First, will the implementation of regulations that govern transplant center processes truly lead to improved safety and quality? Would these regulations have prevented the lapses that generated substantial media attention? Did CMS conduct a 'root cause analysis' of these events in adopting the final regulations? In a 'root cause analysis' (10), a sentinel event is analyzed from various perspectives, and the recommendations that arise from such analyses are based on a scientific evaluation of causality (Table 4). To our knowledge, no such analysis has been performed by CMS of the various sentinel events that led to these regulations.

Table 4: Elements of a 'root cause analysis' (RCA)

Define	Define the problem(s) that led to sentinel event
Data	Gather relevant data/evidence
Cause and effect	Establish causal relationships with defined problem(s)
Identify cause(s)	Identify cause(s) that if removed will prevent recurrence
Unintended consequences	Make sure that solution(s) does (do) not create other problems
Recommend	Recommend solution(s) that meet goals and objectives
Implement	Implement the recommendations
Observe	Observe effect of solution(s)

Certainly, the regulations will lead to better documentation, since this is clearly a main focus. CMS seems to be particularly focused on mandating that many processes be documented in each patient's medical record. The documenting process does not necessarily mean improved processes; it just means that the process is documented better. More importantly, will the documentation burden itself siphon valuable resources away from care of patients? These questions can only be answered by studying the effect of the regulations on safety and quality.

This issue is particularly acute with respect to the informed consent requirements. While the CoPs focus heavily on informed consent, the subtleties of the informed consent process can be difficult to capture in a top–down approach to all circumstances. Again, the focus is on documentation in the medical record that recipients and donors have received the necessary educational materials for informed consent. Along these lines, a living donor advocate must play a central role in this function for living donors. Theoretically, this all makes sense. However, there is a growing literature on health care communication and literacy that has shown that true informed consent is extremely variable, even when the same tools are used with different patients. There are cultural issues, beyond language barriers, that may result in health information illiteracy. These issues require appropriate studies designed specifically to assess transplant healthcare literacy in both recipients and living donors. One could make an argument that a transplant center may have the best documentation possible, yet their recipients and living donors are not giving truly informed consent. Even with a living donor advocate with the best intentions, it is hard to imagine that the level of understanding of such a complex set of circumstances by

the living donor can be truly evaluated without very sophisticated tools.

Moreover, while one of the primary objectives of the CoPs seems to be improving outcomes, the standards for measuring those outcomes may not be optimal and could impede the delivery of care. The only outcomes that are measured and required for CMS certification are 1-year patient and graft survival, as measured using reports generated by the SRTR for the purposes of MPSC review. But many have made the point that the SRTR center-specific outcomes reports were not meant to be used as a bright line test to determine whether a transplant center should be allowed to perform transplants or not. Instead, the pattern of SRTR outcomes was designed to be used by the OPTN MPSC to determine when peer-review-based quality assurance mechanisms should be put into play at the transplant center. These mechanisms are designed to determine whether advice may be offered to help the center improve its outcomes.

The calculations used by CMS for transplant center certification that determine whether a program's results are significantly lower than expected utilize a one-tailed statistical test, in addition to requiring that there be three failures more than expected and that the ratio of observed to expected failures be greater than 1.5. These criteria are identical to those used by the OPTN MPSC for its quality assurance determinations. As good as SRTR risk-adjustment methodologies may be, they do not and cannot account for all clinical parameters that may affect outcomes. For example, some transplant centers are performing kidney transplants after antibody desensitization in cases of positive HLA crossmatch due to sensitization or in cases of ABO blood type incompatibility between donor and recipient. The published literature supports such procedures (11,12), even though the results are inferior to transplants in patients who do not need desensitization. Since the SRTR cannot adjust for this factor (because data are unavailable from the OPTN on which patients are receiving this treatment), the expected outcome for such cases will be higher than those when the information were included. Therefore, will programs attempting to transplant highly sensitized patients using experimental protocols, with necessarily higher losses, be punished, even if this meets approved standards for research? This is just one example of the type of incomplete risk adjustment that could results in a transplant center failing to achieve and/or maintain CMS certification.

There are two levels used by CMS to determine how deviations from the outcomes standard will affect certification. A 'condition' level citation is deemed grounds for termination of a center's certification; for instance, a transplant center may receive a termination letter (which may be publicly available) if its most recent outcomes fail to meet standards and if more than one outcomes report over the past 2 years fails to meet the standards. Although the rule provides for 'mitigating circumstances' in order to prevent such an unfavorable certification decision, the requirements for mitigating circumstances are undefined, and it is unclear what type of 'corrective action plan' can avert termination. The lag in data reporting by centers and analysis by SRTR makes it unrealistic that a transplant center can 'correct' its outcomes within the 210 days provided. The ASTS has registered these concerns with CMS.

The focus on outcomes as the *a priori* requirement for CMS certification will have implications that could harm the service delivery to higher risk patients. This focus may result in transplant centers shying away from difficult cases that are not risk adjusted and from more marginal donors if their characteristics are not risk adjusted. The directions coming from the Department of Health and Human Services appear to be inconsistent. On one hand, transplant centers are encouraged and organ procurement organizations are mandated by the Health Resources and Services Administration, which is the federal agency responsible for the oversight of the OPTN, to maximize the number of organs transplanted from all donors, including marginal donors, while the CMS CoPs seemingly castigate transplant centers that take more risk with donor organs resulting in worse outcomes. Society benefits from the use of marginal donors compared to other options (death, prolonged dialysis, etc.), but the center may suffer because its lower observed outcomes will not be reflected in lower expected outcomes. Similarly, although current deceased donor organ allocation policies for most organs except kidneys are based on some form of a 'sickest first' policy, transplanting the sickest patients is certain to result in worse outcomes. Although outcomes are risk adjusted, it is clear that not all risk predictors are included in these analyses.

The ASTS feels that centers should be given an opportunity to produce data concerning patient characteristics that are not currently collected by the OPTN (and are therefore cannot be evaluated by the SRTR) and that are associated with a higher risk of graft failure and/or death, as part of an acceptable demonstration of 'mitigating circumstances'. In addition, we suggest that the periodic review of requirements for data submission to the OPTN should include identification of such presently uncollected factors, so that these might be evaluated by the SRTR for inclusion in subsequently updated risk-adjustment models.

Finally, these new regulations have costs that must be acknowledged. The implementation and monitoring required to meet the requirements of the final rule, especially the documentation requirements, have resulted in added costs to transplant centers without any additional funding, outside of allowable costs under the Organ Acquisition Cost Center provisions (13,14). Several centers have noted the need to add at least two to three individuals to their

Table 5: Timeline of interactions between ASTS and CMS related to transplant center CoPs

Feb. 4, 2005	Proposed CoPs published in the *Federal Register*	CMS
Feb. 6, 2005	Analysis of proposed rule	ASTS
March 22, 2005	Meeting with CMS—clinical Standards Group	ASTS, AST
April 11, 2005	Recommended revision for CoP regulatory language	ASTS
May 18, 2005	Formal comments submitted	ASTS, AST, ISHLT
June 12, 2006	Meeting with CMS—clinical Standards Group	ASTS
March 30, 2007	Final rule published in the *Federal Register*	CMS
April 2, 2007	Analysis of final rule—addressed & unaddressed issues	ASTS
May 18, 2007	Letter to CMS requesting response to unaddressed issues	ASTS
June 21, 2007	Written response to ASTS	CMS
Aug. 27, 2007	Meeting with CMS—survey & certification group	ASTS
Aug. 31, 2007	Letter to CMS	ASTS
Sept. 21, 2007	Draft interpretive guidelines (IGs) available	CMS
Oct. 1, 2007	Analysis of draft IGs	ASTS
Oct. 11, 2007	Preliminary views on draft IGs to CMS	ASTS
Oct. 25, 2007	Conference call with CMS—survey & certification group	ASTS
Nov. 1, 2007	Formal comments on draft IGs to CMS	ASTS
March 6, 2008	Additional comments submitted on draft IGs to CMS	ASTS
March 19, 2008	Written response to ASTS	CMS
March 21, 2008	Analysis of CMS response and revisions to draft IGs	ASTS
April 1, 2008	Revised draft IGs available	CMS
April 10, 2008	Meeting with CMS—survey & certification group	ASTS
May 12, 2008	Comments submitted on revised draft IGs	ASTS
May 12, 2008	Comments submitted on survey protocol	ASTS
June 9, 2008	Written response to ASTS	CMS
June 13, 2008	Advance copy of final IGs released	CMS

programs for the purposes of implementing and monitoring the regulations. Other centers have noted the need to incorporate the processes involved in the regulations into their electronic medical records requiring further information systems personnel. These costs can be estimated to be in the hundreds of thousands of dollars in additional annual expense. In the current environment of falling reimbursements and rising costs, particularly for higher acuity recipients and more marginal donors, it is difficult to support the costs associated with these regulations. This issue has not been addressed to date and requires further discussion.

A recent report from the U.S. Government Accountability Office (GAO) to Senator Charles Grassley, Ranking Member of the U.S. Senate Committee on Finance states that federal agencies have acted to improve the oversight of organ transplant programs, but that implementation issues remain. The report focuses on requirements for recertification and on redundancy of oversight, particularly of volume/outcome and process requirements. This comprehensive report (15) recommends that CMS should develop a methodology for conducting on-site surveys for Medicare recertification (i.e. recertifications that begin after the first 3-year phase-in of initial certifications by CMS) in addition to data and outcomes requirements. The GAO also recommended that a time frame should be established for finalizing an agreement between CMS and the Health Resources and Services Administration to share information from their respective oversight activities.

Conclusions

The transplant center CoPs will undoubtedly enhance the standardization of the documentation of care provided to transplant candidates, transplant recipients and living donors in the United States. The ASTS has provided advice to CMS over the past 3 years (Table 5) regarding implementation of the new requirements. In this report, we have chronicled the evolution of the regulations that now govern transplant center certification by CMS. We have also described the ongoing process utilized by CMS to implement these regulations. We have raised important questions about the impact of the regulations on the safety and quality of care provided to transplant patients, questions that can only be answered through further study. In this, CMS, transplant caregivers and patients are all on the same page, desiring to advance the quality and outcomes of transplant services. To this end, the ASTS will continue to engage CMS in a dialogue to constructively move the process forward.

Acknowledgment

We gratefully acknowledge Katrina Crist, MBA, ASTS Executive Director, for her immense help in coordinating and facilitating all the interactions between ASTS and CMS.

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