

Building a business plan to support a transplantation pharmacy practice model

ERIC M. TICHY, NICOLE A. PILCH, LONNIE D. SMITH, ANGELA Q. MALDONADO, AND DAVID J. TABER, ON BEHALF OF THE AMERICAN SOCIETY OF TRANSPLANTATION PHARMACY COMMUNITY OF PRACTICE, THE AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS SECTION OF CLINICAL SPECIALISTS AND SCIENTISTS TRANSPLANTATION/IMMUNOLOGY NETWORK, AND THE AMERICAN COLLEGE OF CLINICAL PHARMACY IMMUNOLOGY/TRANSPLANTATION PRACTICE AND RESEARCH NETWORK

Am J Health-Syst Pharm. 2014; 71:751-7

Pharmacists have been part of the multidisciplinary transplantation care team for more than four decades. The first article detailing the pharmacist's role on the transplantation team was published in this journal in 1976.¹ Since the 1970s, a pharmacist's presence within the transplantation team has transitioned from a novelty, to a standard of clinical care, and, most recently, to a federally mandated position.

In 2011, a description of the pharmacist's role as part of the multidisciplinary transplantation team was published as a White Paper in the *American Journal of Transplantation*.² The paper outlined the roles of the pharmacist in the inpatient, ambulatory care, and research settings and described the training required to be competent in these settings. Moreover, the American Society of Health-System Pharmacists (ASHP) has recognized the field of transplantation pharmacy by endorsing and accrediting postgraduate year 2 (PGY2) residency training programs in this area.³ This is an important

step in the evolution of training, as it ensures that transplantation pharmacy residents are meeting specific standards and receiving the highest quality of training. The number of PGY2 transplantation residency programs has increased dramatically in the past 10 years, growing from fewer than 6 programs to almost 30 programs in 2013, and the majority of these programs are now ASHP

accredited. The expansion of the transplantation residency programs allows the discipline to continue to grow and achieve increasingly higher standards of excellence for pharmacy services provided to both living donors and recipients.

As transplantation has become increasingly regulated, the cost of care has risen. Excellent patient and graft survival rates are no longer just clinical goals but are now federally mandated. Therefore, as clinical leaders identify the need to strengthen their transplantation pharmacy teams to sustain excellent outcomes, it is critical that they overcome common stumbling blocks: the ability to translate available evidence to an individual practice site and the ability to develop a strong business case to convince financial decision makers to support the establishment or expansion of transplantation pharmacy services.⁴ Herein, we describe business planning aspects that can be used by pharmacy clinicians, managers, and leaders to implement new or

ERIC M. TICHY, PHARM.D., BCPS, is Senior Clinical Pharmacy Specialist, Solid Organ Transplant, and Director, Postgraduate Year 2 Pharmacy Residency—Transplant, Department of Pharmacy, Yale-New Haven Hospital, New Haven, CT. NICOLE A. PILCH, PHARM.D., M.S.C.R., BCPS, is Clinical Specialist, Solid Organ Transplantation, and Clinical Assistant Professor, Department of Pharmacy and Clinical Sciences, South Carolina College of Pharmacy, Medical University of South Carolina, Charleston. LONNIE D. SMITH, PHARM.D., is Manager, Department of Solid Organ Transplant, and Director, Postgraduate Year 2 Pharmacy Residency—Transplant, University of Utah Hospitals and Clinics, Salt Lake City. ANGELA Q. MALDONADO, PHARM.D., BCPS, is Clinical Pharmacy Specialist—Transplant Services, Vidant Medical Center, Greenville, NC. DAVID J. TABER, PHARM.D., BCPS, is Director, Clinical Research, and Assistant

Professor of Surgery, Medical University of South Carolina.

Address correspondence to Dr. Tichy (eric.tichy@ynhh.org).

Edward Zavala, M.B.A., and Jennifer Milton, B.S.N., M.B.A., CCTC, are acknowledged for their critical review of this manuscript.

This article represents the opinion of the Immunology/Transplantation Practice and Research Network of the American College of Clinical Pharmacy (ACCP). It does not necessarily represent an official ACCP commentary, guideline, or statement of policy or position.

The authors have declared no potential conflicts of interest.

Copyright © 2014, American Society of Health-System Pharmacists, Inc. All rights reserved. 1079-2082/14/0501-0751\$06.00.

DOI 10.2146/ajhp130555

expanded transplantation pharmacy service opportunities.

Regulatory requirement for transplantation pharmacy. The need to demonstrate compliance with regulatory and practice requirements is a powerful motivating factor in health care. The requirement of transplantation pharmacists' involvement is well codified in the bylaws of the transplantation regulatory bodies as well as the practice standards promulgated by professional associations.^{2,5,6} The Organ Procurement and Transplantation Network (OPTN) is a unique public-private partnership that links all of the professionals involved in organ donation and transplantation.⁷ The OPTN is administered by the United Network for Organ Sharing (UNOS) under contract with the Department of Health and Human Services.⁸ Bylaws developed by UNOS specify the exact criteria that each transplantation program must follow in order to be compliant with the standards. These bylaws were amended in 2004 to recognize and identify the roles and responsibilities of the pharmacist as an essential member of the transplantation team. Specifically, these bylaws mandate that "all transplantation programs should identify one or more pharmacists who will be responsible for providing pharmaceutical care to solid organ transplant recipients."⁹ The transplantation pharmacist should be the designated member of the team to serve as the drug information expert and should be responsible for ensuring the adherence to institutional protocols, screening requirements, preventing drug interactions, and providing patient and caregiver education, along with additional responsibilities as outlined by the transplantation center.⁸

In addition to the UNOS requirements, the Centers for Medicare and Medicaid Services (CMS) has conditions of participation that every transplantation program must meet

if Medicare is to serve as the payer for transplant patients. Every three years, CMS performs formal site reviews at all CMS-approved transplantation centers or those seeking to become CMS approved to ensure that these centers meet the established conditions of participation.¹⁰ The document specifically states "a transplantation center must identify a multidisciplinary transplantation team (composed of individuals from medicine, nursing, nutrition, social services, transplant coordination, and pharmacology) and describe the responsibilities of each member of the team." The document does not specifically state that a pharmacist must be the team member from pharmacology. However, in an open comment session, CMS did refer to the UNOS bylaws for details on the specifications of the pharmacist in filling that role.¹⁰ An updated version of the interpretive guidelines was published in 2008.¹¹ Important updates outlined in this document include the need for all members of the multidisciplinary team to document all activities in the medical record and to be involved with the care of both donors and recipients throughout all distinct phases of the donation and transplantation processes (i.e., pretransplantation evaluation phase before listing, perioperative period, immediate post-transplantation hospital admission, and discharge process).

In addition to the updated interpretive guidelines, CMS published a set of documents in September 2008 to assist centers in planning for surveys, specifying that the inpatient pharmacy will be toured and the designated transplantation pharmacist will be interviewed during the CMS visit.¹² To ensure proficiency, pharmacist personnel files are reviewed to evaluate the pharmacist's transplantation-specific training, current competency, and continuing education related to transplantation. Transplantation centers not

meeting these requirements have been required to implement corrective action plans, often leading to the expansion of transplantation pharmacy services or the addition of transplantation pharmacy personnel.

The CMS regulations mandated that programs' observed patient and graft survival outcomes must fall within expected risk-adjusted outcomes. These outcomes data are published twice yearly, and graft and patient survival rates at one year have become the gold standard used by regulators and payers to determine if transplantation centers are performing at acceptable levels. This has implications for center of excellence (COE) designation by commercial payers and may result in impaired access to transplantation for patients who are not Medicare beneficiaries.¹³ Thus, one-year patient and graft survival rates have become paramount to transplantation centers' overall activity levels and financial health. Therefore, drug-related complications can have severe regulatory and multimillion-dollar consequences to programs, as even one patient or graft loss in the first year can result in sanctions or the loss of COE designation.

Financial justification for clinical pharmacy services. Although the transplantation pharmacist role is mandated by regulations, the primary long-term measure of any initiative in many health care organizations is the cost required to maintain the service over time. Positive financial performance should allow for continued investment and growth in the service line. Perhaps the largest threat to transplantation pharmacy services is the relatively high salary of the pharmacist.⁴ The inherent challenge in justifying a clinical pharmacy position from a financial standpoint is the difficulty in quantifying direct and indirect outcomes attributable to pharmacotherapy interventions initiated by pharmacists. Therefore, we outline

several opportunities to enhance transplantation center revenue as well as cost-containment measures that can be utilized to justify transplantation pharmacy services. These opportunities can be divided into two categories: revenue generating (capturing transplantation-related costs or charges, billing for services, filling prescriptions for transplant-related medications in outpatient pharmacies) and cost avoidance (reducing drug cost during inpatient hospitalization, reducing outpatient medical costs, decreasing length of hospital stay).

Medicare cost report. The largest primary payer of organ transplantation in the United States today is Medicare. Medicare reimburses hospitals that are certified transplantation centers for costs associated with the acquisition of organs for transplantation to Medicare beneficiaries. Medicare covers organ acquisition costs, which include all costs associated with the organ donor and recipient before admission to a hospital for the transplant operation (i.e., pretransplantation services), as well as hospital inpatient costs associated with the donor. At the end of each year, each transplantation center files a cost report that is reconciled by Medicare to ensure that all costs are allowable as defined in Medicare regulations and policy.¹³

Notably, for pharmacy administrators who may not be familiar with the transplantation center cost report, the process is similar to the reimbursement process for postgraduate year one pharmacy residents. Medicare requires that transplantation hospitals allocate only the portion of costs that relate to the time spent on allowable organ acquisition activities (i.e., organ acquisition costs) on the Medicare cost report. Institutions are required to use a reasonable basis to allocate costs to appropriate cost centers for pretransplantation-, posttransplantation-, and nontransplantation-related

activities. The capture of pretransplantation-related costs associated with personnel salaries is vital for every transplantation center. Tools such as time studies are used to quantify the amount of time that transplantation coordinators, social workers, financial coordinators, and administrative staff spend working in the pretransplantation phase or on donor management. These salary costs are Medicare allowable and should be captured for partial reimbursement via the cost report. As both Medicare and UNOS have implemented policy mandating the participation of a transplantation pharmacist in the pretransplantation phase for recipients and in the care of living organ donors during all phases, it is vital that transplantation centers include the salaries of pharmacists, including PGY2 pharmacy residents, in these time studies. A substantial portion of a pharmacist's salary can be offset and will vary by each institution's percentage of Medicare-covered organ transplants, the number of donors managed, and the amount of pretransplantation pharmacist involvement.¹²⁻¹⁴

Billing for services. Although there are a limited number of transplantation pharmacists who are currently pursuing this route, there is opportunity for pharmacists practicing in the posttransplantation outpatient phase to bill for their services. Maldonado and colleagues¹⁵ demonstrated that billing for outpatient transplant pharmacy services using facility-fee or technical-fee billing in one year (208 pharmacist visits) resulted in increasing outpatient reimbursement by nearly \$10,000, or roughly \$100 per visit. This increase in reimbursement, along with other factors described herein, was used to substantiate the case for clinical pharmacy services in the outpatient posttransplantation clinic.

Transplantation specialty pharmacy. Hospitals and health systems with outpatient pharmacy

and transplantation pharmacist involvement have an opportunity to generate revenue and reduce fragmentation of the health care delivery process by implementing transplantation specialty pharmacy (TSP) prescription services. These services are initiated at the time of discharge after transplantation, and the goal is to create a system that allows patients to remain with their hospital's outpatient (retail) pharmacy for refills and maintenance medications after transplantation surgery. The continually increasing cost of medications and the complexity of pharmacy billing and reimbursement have discouraged many retail pharmacies from participating in the Medicare Part B or "specialty" market and have allowed the business to be absorbed by specialty pharmacies and retail chains. Over the past 30 years, "specialty" pharmacy has done approximately \$100 billion in business annually and has become a major force in health care quality and innovation.¹⁶ Immunosuppressive medications are often considered specialty pharmacy medications with many payers, requiring a specific expertise in billing and reimbursement that many health-system pharmacies do not possess. Additional contracting requirements and restrictions may also apply to this subset of medications, further complicating the dispensing and reimbursement processes.

Successfully capturing this outpatient business and referring patients to a robust internal pharmacy program allow for the generation of significant revenue and additional resources (often staffing). Successful transplantation pharmacies also provide mail-order service, as this increases the odds of retaining patients outside the immediate geographic area and allows patients to remain within the system for long-term maintenance medication needs. The University of Michigan recently described its success in instituting a TSP that produced a \$4.7 million

margin in 2011 alone.¹⁷ Support from the transplantation center and hospital leadership and having an educated pharmacy staff willing to embrace the hurdles and opportunities available through a TSP service line are critical elements to the success of a TSP. Institutions that have successfully developed a TSP service line and maintained patients within their own system have been able to use this revenue as financial justification for maintaining and often increasing clinical pharmacy services.

An important aspect of all pharmacy programs today is the need to provide resources and services for underfunded or unfunded patients. The expense of long-term medication needs after transplantation can result in patients going without medications, stretching medications to be taken differently than prescribed, or foregoing other important household expenses to pay for medications. Almost all manufacturers offer patient assistance programs that provide medication for free or at significantly reduced costs after a financial disclosure and evaluation process. These programs are fairly standardized across manufacturers, but with the level of documentation required and the responsibility of continually updating eligibility every 6–12 months (depending on the manufacturer), they can be resource intensive and difficult to staff without dedicated resources. Creating a program that tracks the savings of these medication expenses and enables those resources to be put toward dedicated patient assistance and financial support team members is critical for success. This model has been developed and tested in numerous health systems around the country and provides a level of patient care and medication adherence that benefits both transplantation and pharmacy alike and positively impacts published outcomes data.

Drug cost avoidance. Payments for transplantation are packaged

into case rates or diagnostic-related groups. A majority of commercial payers extend the case rate to include up to the first three months after transplantation. Programs must cautiously examine their expenses to retain profitability. The medications used within the field of transplantation are very expensive, and many have a narrow therapeutic range.

Antibody stewardship. Oftentimes, the antibody induction and rejection treatment agents used associated with transplantation (antithymocyte immune globulin, alemtuzumab, basiliximab, i.v. immune globulin, and rituximab) are within the top 20 medications, in terms of annual costs, for hospital systems. Thus, the use of clinical pharmacy services to ensure the most efficient and effective use of these medications is important to include in a business model aimed at expanding pharmacy services for this population of patients.

Multiple publications have demonstrated the success of drug cost avoidance programs in improving the financial ability to care for transplantation patients. By shifting doses of the induction therapy agent rabbit antithymocyte immune globulin from the inpatient to the outpatient setting, McGillicuddy et al.¹⁸ demonstrated a \$230,867 improvement in net margin for 85 patients over a 14-month period, with no differences in clinical outcomes (delayed graft function, acute rejection, graft loss, or opportunistic infections) as compared with a historical control group. The same group of authors demonstrated significant cost savings by implementing a similar strategy (shifting the use of medications from the inpatient to the outpatient setting) with additional high-cost antibody medications, including basiliximab and rituximab.¹⁸ Thus, antibody stewardship strategies to maximize the efficient use of high-cost antibody therapy can have profound effects on the net margins of transplantation centers and hospital systems.

Low-dose valganciclovir for cytomegalovirus prophylaxis. Multiple publications have reported similar efficacy for cytomegalovirus prophylaxis with valganciclovir at 450 mg orally daily compared with valganciclovir 900 mg daily.^{19–21} As the 2012 wholesale acquisition cost of this medication alone was over \$1800 for a one-month supply, this one intervention can lead to significant cost savings for both the patient and the transplantation center.

Generic agents for maintenance immunosuppression. The use of generic formulations of immunosuppressive agents, namely tacrolimus and mycophenolate mofetil, can reduce out-of-pocket costs for the patient while lowering the acquisition costs of these agents for health systems. If the change from brand-name to generic products is made in an appropriate and systematic fashion, with the rigor and monitoring required of all drugs with a narrow therapeutic range, brand-to-generic substitution can occur with similar efficacy and toxicity.^{22–27}

All told, there are numerous well-established strategies published in the literature to reduce costs and increase net margins through the efficient use of transplantation medications. These strategies should be an important part of the business model developed to justify and increase comprehensive transplantation pharmacy services. Strategies should be tracked to ensure that they are implemented safely and that the cost savings or revenue generation can be accurately captured and used to justify the new pharmacy services.

Quality outcomes. From a pharmacotherapy perspective, transplantation recipients are among the most complex of all inpatient populations to manage.²⁸ Clinical transplantation pharmacists combine the principles of several subspecialties to be effective members of the multidisciplinary transplantation patient care team. This includes optimization of

pharmacotherapy across the continuum of care from the presurgical evaluation through the perioperative period and advancing through long-term care in the outpatient setting for adult and pediatric transplant recipients and living donors. Knowledge of drug delivery systems, pharmacoeconomics, drug information and drug literature evaluation, statistics, immunology, pharmacokinetics, pharmacology, pharmacogenomics, pathophysiology, pharmacotherapy, pharmacovigilance, regulatory standards, and medication safety is a necessity. Transplantation pharmacists have substantial expertise in the management of novel and traditional immunosuppression and incorporate this with other subspecialties such as infectious diseases, cardiology, hepatology, nephrology, pulmonology, endocrinology, hematology, pediatrics, internal medicine, and critical care in order to manage patients with multiple comorbidities.²

In addition to direct patient care responsibilities, transplantation pharmacists are involved in quality- assurance and process-improvement measures. These typically involve developing transplantation medication-use protocols, ensuring adherence to protocols during the transplantation process, and proactively measuring protocol-related outcomes through data collection, which results in continuous modifications to protocols over time. The data collection involved with evaluating the effectiveness of protocols is often the basis of clinical research with the transplantation center, with the transplantation pharmacist taking an important lead in these projects. The results often prove meaningful to peer institutions and have contributed to the growing literature describing methods for optimizing patient outcomes.²³

Outpatient clinical pharmacy services. The implementation of transplantation pharmacy services in outpatient clinics has been shown

to improve patient outcomes, as demonstrated in several studies. Chisholm and colleagues²⁹ evaluated the cost savings associated with implementing a clinical pharmacist-led patient assistance program in a kidney transplantation clinic. In the first year of the program, a total of 61 patients were enrolled, and \$124,793 in costs were avoided secondary to acquisition of immunosuppressants through industry-sponsored patient assistance programs. The estimated cost incurred for pharmacist time was \$16,650. The impact of clinical pharmacy services on transplantation outcomes and adherence was evaluated in a subsequent study by Chisholm-Burns and colleagues.³⁰ In this study, 24 kidney transplantation recipients were provided intense clinical pharmacy services aimed at adherence, medication education, and medication access ($n = 12$), while the control group ($n = 12$) received standard care. The intervention group had a higher mean \pm S.D. adherence rate compared with the control group ($96.1\% \pm 4.7\%$ versus $81.6\% \pm 11.5\%$, $p < 0.001$). Improved adherence ($>80\%$ adherence) was sustained longer in the intervention group versus the control group in those patients who eventually became nonadherent (mean 11 months versus 9 months in the control group, $p < 0.05$).

Several centers have also implemented outpatient transplantation pharmacy services to increase their outpatient pharmacy revenue and improve patient outcomes by (1) developing additional disease management services (pharmacist-run collaborative diabetes, anticoagulation, hypertension, and hepatitis C clinics), allowing for quick, concise referrals yielding immediate results, or (2) utilizing pharmacists to provide the pathway for patients to return to the community pharmacy to fill their prescriptions (including those for immunosuppressants).³¹ These outpatient transplantation pharmacist

models can aid in improving the continuity of patient care from the inpatient to the outpatient setting.

The impact of a comprehensive inpatient and ambulatory pharmaceutical care program on posttransplantation medication compliance was also described by Klein et al.³² The investigators conducted a prospective, randomized controlled trial to evaluate the effect of a 12-month pharmaceutical care program on posttransplantation medication adherence in 50 liver transplant recipients. Methods used to assess adherence in this study included medication-event monitoring system caps, serum immunosuppressant concentrations, pill counts, self-reports, and the Morisky questionnaire. In addition to routine clinical care, patients randomized to the intervention group received pharmaceutical care services provided by a dedicated hospital pharmacist. The pharmacist began meeting with patients approximately one week before discharge, discussing dosing instructions, possible adverse effects, and monitoring and discharge instructions. This review occurred three or four times before discharge. At discharge, these patients also received written information about their medications, a discharge plan, and a diary for documenting vital signs and laboratory test values. During the first year posttransplantation, patients met with the pharmacist on a quarterly basis to review medication changes, laboratory test values, and any drug-related problems. The investigators found that patients who were randomized to receive pharmaceutical care had a higher mean \pm S.D. adherence rate (defined as the number of days with the correct number of bottle openings divided by the number of monitored days multiplied by 100) compared with controls ($90.2\% \pm 6.2\%$ versus $80.8\% \pm 12.4\%$, $p = 0.015$). Adherence as measured by pill counts showed large inpatient and interpatient

variability, especially in the control group. However, the median compliance rate was significantly higher in patients who received pharmaceutical care. Target serum immunosuppressant levels were achieved in a significantly higher proportion of patients receiving pharmaceutical care compared with controls (78% versus 51%, $p < 0.001$).

Medication reconciliation. Taber and colleagues³³ recently described a quality-improvement initiative that included pharmacist-managed medication reconciliation, discharge medication dispensing, and outpatient medication-use education. They found a 47% reduction in 30-day readmissions and a 40% reduction in medication safety issues while maintaining a 3-day median length of hospital admission for kidney transplant recipients. This finding was notable, considering the patient population was mostly composed of deceased-donor, African-American, and high-immunologic-risk kidney transplant recipients. Other findings included a 25% reduction in acute rejection and a 9% reduction in cytomegalovirus infection.

In a similar quality-improvement initiative, Maldonado and colleagues³⁴ demonstrated a dramatic reduction in mean length of stay (from 7.8 days to 3.4 days, $p < 0.001$) with no impact on readmission and an overall one-year cost savings of \$279,180 at a transplantation center that performed approximately 50 kidney transplants annually. A transplantation pharmacist was added to the transplantation service to comply with Medicare requirements. The transplantation pharmacist was involved with medication reconciliation, patient education, transition of care management, and medication management in the inpatient and outpatient settings for all phases of the transplantation process, with the majority of effort focused on the perioperative and posttransplantation phases. As

with the intervention by Taber et al.³³ transitioning medication-use education to the outpatient setting was a critical element of the initiative and largely coordinated by the transplantation pharmacist.

In a recently published prospective controlled trial, Musgrave and colleagues³⁵ demonstrated the importance of the transplantation pharmacist being formally involved in the medication reconciliation process during transitions of care. This study found that the transplantation pharmacist prevented 191 medication errors (mean, 3.0 per patient) and discovered another 72 errors (mean, 1.1 per patient) in the follow-up ambulatory care setting. It is clear from the robust studies published in this area that the development or extension of transplantation pharmacy services should incorporate the implementation and tracking of quality outcomes that are designed to demonstrate the true role of the transplantation pharmacist.

Conclusion. Recognition of the role of the transplantation pharmacist by governing bodies such as CMS and UNOS has transitioned the role of the transplantation pharmacist from a novelty to a necessary member of the multidisciplinary transplantation team. While the salary cost of transplantation pharmacy personnel can seem daunting, there are several strategies that can be implemented to defray these costs and create opportunities for previously untapped revenue generation. Moreover, transplantation pharmacy expertise can lead to cost savings that can cover the salary investment by severalfold in addition to the added benefit to patient care. The regulatory, financial, and quality measures discussed herein can serve as pillars to support the transplantation pharmacy practice model. Transplantation recipients are among the most pharmacologically complex patients in health care today, and business plans should be

created to justify the development of robust pharmacy teams at transplantation centers.

References

1. Mitchell JF. Pharmacist involvement as a member of a renal transplant team. *Am J Hosp Pharm.* 1976; 33:55-8.
2. Alloway RR, Dupuis R, Gabardi S et al. Evolution of the role of the transplant pharmacist on the multidisciplinary transplant team. *Am J Transplant.* 2011; 11:1576-83.
3. American Society of Health-System Pharmacists. Required educational outcomes and objectives for postgraduate year two (PGY2) pharmacy residencies in solid organ transplant. www.ashp.org/menu/Accreditation/ResidencyAccreditation.aspx (accessed 2011 Nov 23).
4. Schumock GT, Stubbings J. How to develop a business plan for pharmacy services. Lenexa, KS: American College of Clinical Pharmacy; 2007.
5. Costanzo MR, Dipchand A, Starling R et al. The International Society of Heart and Lung Transplantation guidelines for the care of heart transplant recipients. *J Heart Lung Transplant.* 2010; 29:914-56.
6. Kidney Disease: Improving Global Outcomes (KDIGO) Transplant Work Group. KDIGO clinical practice guideline for the care of kidney transplant recipients. *Am J Transplant.* 2009; 9(suppl 3):S1-157.
7. Title42C.F.R.121 Organ Procurement and Transplantation Network. www.gpo.gov/fdsys/granule/CFR-2011-title42-vol1/CFR-2011-title42-vol1-part121/content-detail.html (accessed 2011 Nov 23).
8. United Network for Organ Sharing (UNOS). Attachment 1 to appendix B of the UNOS bylaws; designated transplant program criteria. UNOS-Appendix B- Attachment I-XII-1-91. www.unos.org/docs/Appendix_B_AttachI_XIII.pdf (accessed 2011 Nov 23).
9. Centers for Medicare and Medicaid Services. 42 CFR 405,482,488, and 498 Medicare program; hospital conditions of participation: requirements for approval and re-approval of transplant centers to perform organ transplants; final rule. *Fed Regist.* 2007; 72:15197-279.
10. Centers for Medicare and Medicaid Services. Advance copy—organ transplant program interpretive guidelines; 2008. www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter08-25.pdf (accessed 2011 Dec 1).
11. Centers for Medicare and Medicaid Services. Advance copy—organ transplant program state operations manual (SOM) and survey protocol; 2008. www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter09-09.pdf (accessed 2011 Dec 1).
12. Abecassis MM, Burke R, Cosimi AB et al. Transplant center regulation—a mixed blessing? An ASTS Council viewpoint. *Am J Transplant.* 2008; 8:2496-502.

13. Abecassis M. Organ acquisition cost centers. Part I: Medicare regulations—truth or consequence. *Am J Transplant.* 2006; 6:2830-5.
14. Centers for Medicare and Medicaid Services. 42 CFR 412.100—Special treatment: renal transplantation centers. http://edocket.access.gpo.gov/cfr_2004/octqtr/pdf/42cfr412.100.pdf (accessed 2011 Dec 23).
15. Maldonado AQ, Seiger TC, Urann CL et al. Billing for outpatient transplant pharmacy services. *Am J Health-Syst Pharm.* 2012; 69:144-7.
16. Suchanek D. The rise and role of specialty pharmacy. *Biotechnol Healthc.* 2005; 2(5):31-5.
17. Hlubocky JM, Stuckey LJ, Schuman AD et al. Evaluation of a transplantation specialty pharmacy program. *Am J Health-Syst Pharm.* 2012; 69:340-7.
18. McGillicuddy JW, Taber DJ, Pilch NA et al. Clinical and economic analysis of delayed administration of antithymocyte globulin for induction therapy in kidney transplants. *Prog Transplant.* 2013; 23:33-8.
19. Gabardi S, Magee CC, Baroletti SA et al. Efficacy and safety of low-dose valganciclovir for prevention of cytomegalovirus disease in renal transplant recipients: a single-center, retrospective analysis. *Pharmacotherapy.* 2004; 24:1323-30.
20. Park JM, Lake KD, Arenas JD et al. Efficacy and safety of low-dose valganciclovir in the prevention of cytomegalovirus disease in adult liver transplant recipients. *Liver Transpl.* 2006; 12:494.
21. Weng FL, Patel AM, Wanchoo R et al. Oral ganciclovir versus low-dose valganciclovir for prevention of cytomegalovirus disease in recipients of kidney and pancreas transplants. *Transplantation.* 2007; 83:290-6.
22. Momper JD, Ridenour TA, Schonder KS et al. The impact of conversion from Prograf to generic tacrolimus in liver and kidney transplant recipients with stable graft function. *Am J Transplant.* 2011; 11:1861-7.
23. McDevitt-Potter LM, Sadaka B, Tichy EM et al. A multicenter experience with generic tacrolimus conversion. *Transplantation.* 2011; 92:653-7.
24. Spence MM, Nguyen LM, Chan J. Evaluation of clinical and safety outcomes associated with conversion from brand-name to generic tacrolimus in transplant recipients enrolled in an integrated health care system. *Pharmacotherapy.* 2012; 32:981-7.
25. Alloway RR, Sadaka B, Trofe-Clark J et al. A randomized pharmacokinetic study of generic tacrolimus versus reference tacrolimus in kidney transplant recipients. *Am J Transplant.* 2012; 12:2825-31.
26. Heavner MS, Tichy EM, Yazdi M et al. Clinical outcomes associated with conversion from brand-name to generic tacrolimus in hospitalized kidney transplant recipients. *Am J Health-Syst Pharm.* 2013; 70:1507-12.
27. Marfo K, Aitken S, Akalin E. Clinical outcomes after conversion from brand-name tacrolimus (Prograf) to a generic formulation in renal transplant recipients. *P&T.* 2013; 38:484-8.
28. Granko RP, Poppe LB, Savage SW et al. Method to determine allocation of clinical pharmacist resources. *Am J Health-Syst Pharm.* 2012; 69:1398-404.
29. Chisholm MA, Vollenweider LJ, Mulloy LL et al. Cost-benefit analysis of a clinical pharmacist-managed medication assistance program in a renal transplant clinic. *Clin Transplant.* 2000; 14:304-7.
30. Chisholm-Burns MA, Spivey CA, Garrett C et al. Impact of clinical pharmacy services on renal transplant recipients' adherence and outcomes. *Patient Prefer Adherence.* 2008; 2:287-92.
31. Schuh MJ, Crumb DJ, Dubois J. Building a pharmacist-managed pharmacotherapy medication therapy management practice. *Consult Pharm.* 2011; 26:404-13.
32. Klein A, Otto G, Krämer I. Impact of a pharmaceutical care program on liver transplant patients' compliance with immunosuppressive medication: a prospective, randomized, controlled trial using electronic monitoring. *Transplantation.* 2009; 87:839-47.
33. Taber DJ, Pilch NA, McGillicuddy JW et al. Improved patient safety and outcomes with a comprehensive interdisciplinary improvement initiative in kidney transplant recipients. *Am J Med Qual.* 2013; 28:103-12.
34. Maldonado AQ, Weeks DL, Bitterman AN et al. Changing transplant recipient education and inpatient transplant pharmacy practices: a single-center perspective. *Am J Health-Syst Pharm.* 2013; 70:900-4.
35. Musgrave CR, Pilch NA, Taber DJ et al. Improving transplant patient safety through pharmacist discharge medication reconciliation. *Am J Transplant.* 2013; 13:796-801.