## Preliminary Request for the Board of Pharmacy Specialties to Consider a New Specialty February 6, 2012

1. Name of the practice area of the proposed specialty.

Solid Organ Transplantation Pharmacy Practice

2. Description of the specialty practice area, the work of pharmacists engaged in it, and its overall impact on society.

The solid organ transplantation pharmacy practice area focuses on the pharmaceutical care of solid organ transplant patients. Transplant pharmacists practice as members of interprofessional health care teams in a variety of settings, including adult and pediatric medical intensive care units (ICU), surgical ICU, inpatient acute care, outpatient ambulatory care clinics, academic settings, pharmaceutical industry, and research institutions. As summarized in a joint position paper from the American Society of Transplantation Transplant Pharmacy Community of Practice and the American College of Clinical Pharmacy Immunology/Transplantation Practice and Research Network (AST and ACCP – see

http://www.accp.com/docs/prns/imtr/Role\_of\_Transplant\_Pharmacist\_Alloway\_AJT\_2011.pdf), the fundamental activities of transplant pharmacists include:

- Prospective pharmacokinetic, pharmacodynamic, and therapeutic drug monitoring evaluation of all drug and non-drug therapy in the transplant recipient;
- Coordinate development, implementation, adherence and outcome measures of departmental policies and procedures and drug therapy protocols;
- Perform medication reconciliation, medication therapy management and discharge counseling;
- Provide education and training to members of the transplant team and practitioners in training;
- Facilitate cost containment strategies, pharmacotherapy optimization, and participation in quality assurance programs to maximize patient and center specific outcomes;
- Provide pre-and post-transplant medication education;
- Lead and assist with clinical and pharmacoeconomic research;
- Identification, management, and prevention of medication-related adverse events;
- Monitoring every stage of medication therapy to improve all aspects of effectiveness;
- Documentation of education provided and pharmacotherapeutic recommendations in the medical record;
- Provision of consultation to institutional committees (e.g., Pharmacy and Therapeutics Committee) regarding immunosuppressant and immunomodulating pharmacotherapeutic agents; and
- Coordinating and providing outpatient medication therapy management.

In addition, many transplant pharmacists are involved in teaching pharmacotherapy to pharmacy students, medical students, pharmacy/medical residents, fellows, and other health care practitioners. A number of transplant pharmacists are also involved in health services (outcomes), basic, and/or translational research.

Transplant pharmacists possess specialized knowledge and experience in the care of transplant patients. Many have completed formal, post-graduate residency training in solid organ transplant practice environments. They possess unique knowledge of the epidemiology and pathophysiology of solid organ transplant; the pharmacotherapy of transplant patients; the application of pharmacokinetics, pharmacodynamics, and pharmacogenomics to transplantation; operational and clinical systems designed to assure medication safety; patient/parent/caregiver counseling to optimize medication adherence; and long term disease prevention and health maintenance in patients receiving life-long immunosuppressants. They also contribute to, and evaluate, biomedical literature pertinent to immunology and transplant pharmacotherapy.

Safe and optimal pharmacotherapy in the solid organ transplant setting requires contributions from all members of the specialized health care team. Pharmacists have been recognized as an essential member of that interdisciplinary team (1,2). In addition to the AST-ACCP position paper noted above, in 2004, the United Network for Organ Sharing bylaws were amended to recognize pharmacists as an essential part of the patient care team. In 2007, the Centers for Medicare and Medicaid Services published Medicare Conditions for Participation for organ transplant programs stating that in order for transplant programs to be reimbursed for their services by Medicare, programs must have a designated, qualified expert in transplant pharmacology as a member of the multidisciplinary transplant team. This transplant pharmacology expert must be involved in every patient's care at varying phases of the transplant process in order to maintain transplant center accreditation (3,4). Within the context of team care of transplant patients, transplant pharmacists have been found to have a high impact on increased medication compliance and improved outcomes in transplant patients (5-8).

3. Estimates of potential numbers of pharmacists who might seek such certification (using available data such as number of residents and residency programs, organizational member surveys, and evolving practice and environmental changes in the profession expected to support the specialty practice).

The AST lists 169 pharmacist members in its Transplant Pharmacy Community of Practice. The ACCP Immunology/Transplantation PRN now includes more than 330 active members. Despite considerable overlap in the membership of these two groups, we estimate that there are more than 500 pharmacists now practicing in solid organ transplantation due to the increasing demand secondary to the CMS mandates. In addition to this existing pool of practitioners, ASHP listed in November 2011, 18 current PGY-2 solid organ transplant residency training programs with a total of 29 solid organ transplant residency and fellowship training programs in the nation. Taken together, we believe that the number of current and future transplant pharmacists is sufficient to support establishment of this new specialty area. Finally, in an October 2011 survey of ACCP members, 76% of 160 respondents (or 122) indicated their belief that solid organ transplantation pharmacy practice should be recognized as a new specialty.

4. Potential sources of financial resources to develop and implement the specialty prior to receipt of candidate fees.

The organizations listed below support consideration by BPS of this request for recognition of the proposed specialty. A firm commitment to providing resources to help develop and implement the specialty is in place from at least one of the organizations listed. It is expected that each of the organizations listed, and perhaps others, will actively consider its role in financial support and resource development in any and all next steps should BPS move forward in its process of recognition of this proposed specialty.

5. Name(s) and contact information of the requestor(s).

Michael S. Maddux, Pharm.D., FCCP Executive Director American College of Clinical Pharmacy 13000 W. 87<sup>th</sup> St. Parkway, Suite 100 Lenexa, KS 66215

E-mail: mmaddux@accp.com Telephone: (913) 492-3311 Paul W. Abramowitz, Pharm.D., FASHP Executive Vice President and CEO American Society of Health-System Pharmacists 7272 Wisconsin Ave. Bethesda, MD 20814

E-mail: <u>pabramowitz@ashp.org</u> Telephone: (301) 657-3000

## References:

- 1. Mitchell JF. Pharmacist involvement as a member of a renal transplant team. Am J Hosp Pharm. 1976 Jan;33(1):55-8.
- 2. Martin JE, Zavala EY. The expanding role of the transplant pharmacist in the multidisciplinary practice of transplantation. Clin Transplant 2004;(18)12:50-4.
- 3. [UNOS] United Network for Organ Sharing. 2007. Attachment I to Appendix B of UNOS ByLaws: Designated Transplant Program Criteria [online]. Accessed on May 18,2009. URL: http://www.unos.org/policiesandBylaws2/bylaws/UNOSByLaws/pdfs/bylaw 122.pdf
- 4. Centers for Medicare & Medicaid Services. Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re- Approval of Transplant Centers To Perform Organ Transplants. Federal Register / Vol. 72, No. 61 / Friday, March 30, 2007 / Rules and Regulations [Online] Accessed on May 15, 2009. http://www.cms.hhs.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf
- 5 De Bleser L, Matteson M, Dobbels F, Russel C, De Geest S. Interventions to improve medication—adherence after transplantation: a systematic review. Transplant Int 2009;22:780-797.
- 6. Chisholm MA, Mulloy LL, Jagadeesan M, DiPiro JT. Impact of clinical pharmacy services on renal transplant patients' compliance with immunosuppressive medications. Clin Transplant. 2001;15(5):330-6.
- 7. Chisholm MA, Mulloy LL, Jagadeesan M, Martin BC, DiPiro JT. Effects of clinical pharmacy services on the blood pressure of African-American renal transplant patients. Ethn Dis. 2002;12(3):392-7.
- 8. Burckart GJ. Transplant pharmacy: 30 years of improving patient care. Ann Pharmacother 2007;41:1261-1263.