

ASN News

ASN'S NEWEST STAFF MEMBERS

Lauren Maza joined the ASN in May as the CME Project Manager. She will serve as a link between the ASN staff and the ACCME. She comes to ASN from the Accrediting Council for Independent Colleges and Schools (ACICS), where she reviewed applications related to accreditation and led onsite visits to member schools. Prior to ACICS, Lauren worked on educational programs for Community Associations Institute and for Meridian International Center.

Marissa Carter joined the ASN in May as the Communications and Education Intern. She will be assisting both the education and communication teams with various projects in preparation for Renal Week 2007. She is currently in her junior year of college at Howard University and is majoring in Journalism.

RENAL WEEK UPDATE

Abstract Information

Thank you to all ASN members who submitted abstracts for Renal Week 2007. Once again, we have received a record number of abstracts.

In late August, all presenting authors received a letter regarding the status of the submitted abstracts. If you are a presenting author and did not receive a letter about the abstract by August 24, please send an email inquiry to support@marathonmultimedia.com or fax to 507-334-0126.

Stay tuned to the ASN website in early October for ASN's Program-and-Abstracts Online, which will include the complete program and abstracts for Renal Week.

POLICY AND PUBLIC AFFAIRS UPDATE

FDA Anemia Management Hearing

The Food and Drug Administration (FDA) will convene a meeting on September 11, 2007, to ask two panels of experts whether Epopren, Aranesp, and Pro-

crit are safe when used in patients with anemia caused by kidney failure. The FDA held a similar meeting in May 2007 to look at safety of these drugs when used in cancer patients with anemia.

On April 26, 2007, ASN was present at a meeting at which the American Association of Kidney Patients (AAKP), the Renal Physicians Association (RPA), and the National Kidney Foundation (NKF) expressed concerns regarding the FDA's recent black-boxed warning and emphasized the fact that cancer patients and kidney disease patients have different needs and their anemia treatments should be managed accordingly.

NIH Work Group Reviews Peer Review Process

The Peer Review Working Group of the Advisory Committee to the Director of National Institutes of Health (NIH) is evaluating comments from academic societies on how best to manage and enhance the peer review system in an era of flat funding and increased application rates. The committee's goal is to assess NIH's peer review process in light of the "increasing breadth and complexity of science" and, in particular, solicit feedback on the pace, efficiency, and effectiveness of the process. The work group also reviewed a regulation to allow multiple principal investigators and commented on a new strategic plan for the National Center for Research Resources (NCRR).

NIH highlights six questions that address the challenges, core values, and criteria of the peer review process, challenges to NIH's system of research support, solutions to these challenges, and the effectiveness of the peer review system in supporting investigators at specific points in their career development. The request for information (RFI) and full set of questions can be found on the NIH website.

NIH also posted a RFI in the June 2007 *Federal Register* regarding its regulations affecting the definition of princi-

pal investigator. According to the RFI, NIH proposes to revise "the definition of principal investigator to mean one or more individuals designated by the grantee in the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the project, rather than limiting the role of principal investigator to one single individual." In addition, NIH proposes altering "the conditions for multiple or concurrent awards to permit the Department of Health and Human Services Secretary to evaluate, approve and make one or more awards pursuant to one or more applications."

The NCRR requested input on its strategic plan for 2009–2013. The center is charged to provide researchers with the tools and training necessary to effectively perform research across the entire research spectrum, from basic science to animal studies to patient-oriented clinical trials. Some programs under NCRR's purview include the Clinical and Translational Science Awards (CTSA), career development for clinical researchers, and programs for underserved states and institutions studying health disparities. Of particular concern to NCRR are ways in which it can respond to the new trends in biomedical research, what new research resources the center should develop in the next five to eight years, how the CTSA program can be improved to ensure its success, how the center can support institutions that predominantly serve minority and underserved populations, and how it should collaborate with federal and private institutions to expand and enhance the center's programs. The full set of questions can be found on the NCRR website.

CMS Announces a Clinical Trials Determination and Alters Clinical Trial Policy

The Centers for Medicare & Medicaid Services (CMS) announced the reopening of its Clinical Trial Policy national coverage determination, and issued a

proposed decision memorandum for public comment.

“This proposed decision will address ambiguities about Medicare coverage in research studies and what items and services are reasonable and necessary for beneficiaries participating in clinical research studies,” CMS Acting Administrator Leslie V. Norwalk said. “We look forward to comments from the public on all aspects of this proposed policy, which will expand access for Medicare beneficiaries while providing important patient protections.”

The new action follows a July 2007 CMS final Clinical Trial Policy Decision Memorandum on coverage of items and services used by beneficiaries in clinical trials, which made few changes to the existing policy (No. 132 HCDR 7/11/07).

The agency said its proposal clarifies the standards that CMS believes are important to patient safety and good outcomes. “It also allows study sponsors or principal investigators to certify that their study has met these standards,” the agency said.

The two changes to CMS’ Clinical Trial Policy include:

- A clarification that Medicare will provide reimbursement for items

and services used for a clinical research trial “if they would be covered outside of the clinical research trial.”

- Adoption of a “Coverage with Evidence” clause to provide Medicare payment for items and services in clinical research trials for which there is “some evidence of significant medical benefit, but for which there is insufficient evidence to support a ‘reasonable and necessary’ determination” as long as the clinical trial meets requirements stated in the national coverage determination.

CMS held an Open Door Forum in August on this action. CMS plans to make a final determination and issue a final decision memorandum by October 19, 2007.

PUBLICATIONS UPDATE

CJASN to be Indexed by PubMed’s MEDLINE

The *Clinical Journal of the American Society of Nephrology* (CJASN) was selected in late June by the National Institute of Health’s National Library of Medicine (NLM) to be indexed and in-

cluded in PubMed’s MEDLINE. According to MEDLINE Executive Editor Sheldon Kotzin, citations from the articles indexed, the indexing terms, and the abstracts printed in *CJASN* will be included in the database. All past issues will also be indexed as soon as possible. MEDLINE will make *CJASN*’s citations and abstracts available worldwide *via* the Internet.

JASN has been indexed since its first issue, which published in July 1990.

According to NLM’s website, MEDLINE is a bibliographic database containing “over 15 million references to journal articles in life sciences with a concentration on biomedicine.” MEDLINE covers publications from 1950 to the present and currently provides citations from approximately 5000 journals in 37 languages. Between 2000 and 4000 references are added each day, five days each week; 623,000 references were added in 2006.

MEDLINE is a part of Medlars. More information about Medlars can be found at www.nlm.nih.gov/pubs/factsheets/intlmedlars.html. More information about MEDLINE can be found at www.nlm.nih.gov/pubs/factsheets/medline.html.