

December 15, 2004

Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 314G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

We are writing to express our thoughts on CMS-1427-P – Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2005 Payment Rates. We are concerned that CMS's criteria for new technology to qualify for transitional pass-through payment under the OPPS system is negatively impacting access to and reimbursement for new technology for women.

As you know, the Society for Women's Health Research is the nation's only not-for-profit organization whose mission is to improve the health of all women through research, education and advocacy. The Society advocates increased funding for research on women's health; encourages the study of sex differences that may affect the prevention, diagnosis and treatment of disease; promotes the inclusion of women in medical research studies; and informs women, providers, policy makers and media about contemporary women's health issues.

The Society believes that under the current restrictive interpretation of the rule governing traditional pass-through payments for medical devices, women's health is being compromised. As you know, in 1999 Congress required HHS to provide pass-through payments for new medical devices, drugs and biologics, as long as they were first paid after 1996 as a hospital outpatient service and their costs were not insignificant in relation to the amount payable for the relevant outpatient service.

However, in implementing this provision, CMS has allowed only surgically implanted devices to qualify for pass-through payment. This decision denies women reimbursement for, and thus access to, devices that could improve their health but are implanted through natural body openings and orifices rather than through surgery. This harms patients by


preventing them from utilizing less-invasive, less costly non-surgical treatment alternatives, which we believe CMS should be encouraging rather than discouraging. Areas of medicine particularly impacted by CMS interpretation are gynecological, urologic, colorectal, and gastrointestinal procedures.

The Society recommends that CMS broaden its interpretation of the transitional pass-through payment provision to include coverage of medical devices that are inserted in the body as well as those which are surgically implanted. Thank you for your continued efforts to improve the health of the women and men of our nation.

Sincerely,

A handwritten signature in cursive script, reading "Phyllis Greenberger".

Phyllis Greenberger, MSW
President and CEO

A handwritten signature in cursive script, reading "Martha Nolan".

Martha Nolan
Vice President, Public Policy