June 6, 2005

Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mailstop: C1-12-28
7500 Security Boulevard
Baltimore, MD 21244

To Whom It May Concern:

On behalf of the Society for Women's Health Research, we are responding to the Centers for Medicare & Medicaid Services (CMS) solicitation of comments on the Draft Guidance for the Public, Industry, and CMS Staff on "Factors CMS Considers in Making a Determination of Coverage with Evidence Development." We appreciate having this opportunity and hope that you will take our comments into consideration.

The Society is the nation's only not-for-profit organization whose mission is to improve the health of all women through research, education and advocacy. We advocate for increased funding for research on women's health; encourage the study of sex differences that may affect the prevention, diagnosis and treatment of disease; promote the inclusion of women in medical research studies; and inform women, providers, policy makers and media about contemporary women's health issues.

As CMS makes decisions about extending national coverage for items and services with coverage linked to a requirement for prospective data collection (or "coverage with evidence development"), we urge the agency to ensure that any such data collection includes the study and examination of biological sex differences between women and men. As noted in the draft guidelines, there are many cases in which the benefit of a technology or service will be evident in a specific patient population, such as women and minorities. In order for members of these groups to benefit accordingly, the appropriate data collection and analysis must be performed to ensure that any important sex differences are understood and can be factored into CMS's reasonable and necessary coverage decisions.

Scientists have long known of the anatomical differences between the sexes, but only within the past decade have they begun to uncover significant biological and physiological differences between the sexes. Sex differences have been found everywhere from the composition of bone matter and the experience of pain to the metabolism of certain drugs and the rate of neurotransmitter synthesis in the brain.

In April 2001, the Institute of Medicine (IOM) of the National Academy of Sciences released a report entitled, "Exploring the Biological Contributions to Human Health: Does Sex Matter?" The report, initiated and supported by the Society and released by the National Academy of Sciences, found that sex differences important to health and human disease occur in the womb and throughout the life span, affecting behavior, perception, and health.

Regardless of the IOM report and efforts by the scientific community to include women in clinical research, it is challenging to get participants to enroll in clinical trials. For fifteen years, the Society has worked to increase the number of women in medical research. Several years ago, we launched our "Some Things Only A Woman Can Do" campaign to educate women about and encourage them to participate in clinical trials. Recently, the Society has added to this campaign to address issues related to the elderly women population served by CMS, which we believe is of critical importance since there is very little data on women and drugs and devices in this age category. The Society has discussed with CMS the benefits that this expanded educational program may provide to coverage with evidence development. With the Society's expertise and experience running the previous "Some Things Only A Woman Can Do" campaign, we would be delighted to run a 1-year program focusing on elderly women and clinical trials.

The draft guidance specifically asks questions to be addressed by the Public. The Society has several comments to provide in two areas: "Factors Considered in Applying CED" and "Evidence Development Methods."

Factors Considered In Applying CED

The Society believes that sex differences criteria are critically important for consideration in applying coverage with evidence development decisions as medical research data has repeatedly shown. Several recent studies have revealed significant sex differences between men and women in the treatment and diagnosis of various diseases. For example, the CMS draft guideline mentions colon cancer. In a May 2005 study conducted by the University of Michigan, the National Cancer Institute, the University of Minnesota Cancer Center, the National Naval Medical Center and the Walter Reed Army Medical Center, it was determined that sex differences between men and women exist with respect to this disease, and that colonoscopy is the best screening method for women. According to Phillip Schoenfeld, M.D, assistant professor in the Division of Gastroenterology in the Department of Internal Medicine at the University of Michigan Medical School, these findings illustrate that "…Medical research conducted in men cannot routinely be applied to women. Women may be at a disadvantage if medical research is focused on men because women have unique biological differences that may require different diagnostic tools or treatments."

Another example of sex differences can be found in the diagnosis and treatment of Attention- Deficit/Hyperactivity Disorder (ADHD). A recent study showed that women with ADHD often display different symptoms than men, which causes the condition to

remain undiagnosed. Further, women in the study displayed greater emotional symptom improvement than men when treated with the same drug.

The draft guidance poses the question of whether focus should be placed only on newer technologies and services, or on the entire spectrum. We believe that in terms of the Society's "Some Things Only A Woman Can Do" campaign, it is critical to look at the entire spectrum of technologies and services, not merely newer ones. Previously, many decisions were made based on young males, and did not examine the Medicare population, particularly older women.

Evidence Development Methods

The Society appreciates the study designs under consideration and feel that each could better answer the question of why men and women differ biologically. Regardless, the Society believes that these designs often lose opportunities to examine sex differences, even when women are included in studies. Further, clinical trial designs need to include women in all types of clinical research, not merely in phase III clinical trials. Finally, a concerted effort should be made to report all data from trials, whether the results are positive, negative, or merely neutral, and this information should be stored in a repository of some kind so that it will continue to be available in the future.

Further, the Society believes that CMS should require a database, in order to delve into the comparative effectiveness of drugs and devices, a subject important to both women and men. A great deal of information on sex differences remains unknown; making the right choices difficult. We believe that databases should be required whenever possible to help improve this situation.

As CMS evaluates the quality of a proposed study design, we believe it is crucial that all of these proposed designs directly examine sex differences and report this data to CMS.

Thank you for providing this opportunity to comment on CMS's draft guidance on "Factors CMS Considers in Making a Determination of Coverage with Evidence Development." We hope that you will take our comments into consideration. If you have any questions, please feel free to contact Martha Nolan at 202-496-5007.

Sincerely,

Phyllis Greenberger
President

Martha Nolan
Vice President of Public Policy