September 5, 2013

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS Proposed Rule (CMS-1601-P) Section III(A) Regarding Changes to IDE Coverage Process

Dear Ms. Tavenner:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), below are comments submitted on CMS’ Proposed Rule, Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule and Other Revisions to Part B for CY 2014.

ISASS is an international, scientific and educational society organized to discuss and assess existing strategies and innovative ideas in the clinical and basic sciences related to spine surgery to enhance patient care. Our comments focus specifically on proposed changes to the procedures and standards for Medicare coverage of items and services furnished during Investigational Device Exemption (IDE) clinical trials.

As a professional society dedicated to the treatment of spine disorders, our members often participate in prospective IDE clinical studies to evaluate the safety and clinical efficacy of new or emerging technologies or procedures. The proposed changes to the Medicare coverage process for these studies threaten the timely enrollment and execution of clinical trials, particularly with respect to spinal technologies. Below, we describe our concerns with the proposed changes and offer recommendations to better protect important clinical research.
Transitioning to a Superiority Endpoint Does Not Make Sense for Many Spinal Studies

One proposed change to the Medicare IDE coverage process would shift the requirements for automatic coverage consideration to include the design of an acceptable superiority endpoint. While ISASS recognizes CMS’s intent to encourage more robust evidence development, this requirement may be appropriate for some specialties and technologies; however, it is inappropriate in many cases for spinal surgery.

Unlike for other indications and treatment types, clinical studies that involve the insertion of spinal devices cannot be controlled to placebo. For example, it would be unethical to perform a sham procedure for the purpose of clinical evidence development. As a result, manufacturers of spinal implants typically control against the current standard of care in IDE studies. In many cases, the object of the clinical study is to identify less invasive surgical treatment options that yield comparable safety and efficacy. Requiring a superiority outcome against the current standard of care would set an unrealistic bar for clinical evidence development and likely would reduce innovative clinical research in these areas.

ISASS recommends that CMS maintain the current requirements for Medicare coverage of IDE studies and not implement the change with respect to superiority. If CMS nonetheless elects to change this requirement, we respectfully recommend that CMS develop a dual process with respect to study design. In a future rule, CMS should identify indications and procedures for which superiority study design is not practical and allow coverage with appropriate IDE study design for non-inferiority.

Centralizing the Medicare IDE Coverage Process

ISASS is also concerned that CMS’s proposal to centralize Medicare clinical study review and coverage determinations will negatively impact clinical study enrollment and completion. In the proposed rule, CMS put forward a proposal to transition from a MAC-based review process to a centralized CMS process. Under the proposed centralized process, one requirement for centralized coverage determination is the submission of “IRB approval letter(s).”

Our members’ experiences as clinical study investigators shows that each study site has a different timeline for study preparation, IRB submission, IRB approval, and patient enrollment. In some studies, the first site can have IRB approval and begin treating patients before other sites even submit to an IRB. If CMS requires the completion of all IRB approvals across all clinical study sites before it begins a review for coverage determination, this process will slow down patient recruitment, enrollment, and treatment. If study enrollment is not delayed for the first sites, these sites may limit enrollment to non-Medicare patients while awaiting CMS review for coverage. Either scenario would conflict with the original intent of providing Medicare coverage during clinical studies.
For these reasons, ISASS recommends that CMS maintain the current MAC-based coverage determination process. While not perfect, MAC-level review provides the best option for addressing individual site readiness for patient enrollment. Alternatively, CMS may wish to consider allowing centralized coverage determination for the entire IDE study upon approval of the first site IRB with the requirement that individual site coverage requires IRB approval for that site, in addition to the other requirements.

Thank you again for providing this opportunity for public comment.

Sincerely,

Luis Pimenta, MD, PhD
ISASS President

Gunnar B.J. Andersson, MD, PhD
Co-Chair
ISASS Public Policy Committee

Frank M. Phillips, MD
Co-Chair
ISASS Public Policy Committee