

June 3, 2005

Mark B. McClellan, M.D., Ph.D.  
Centers for Medicare and Medicaid Services (CMS)  
Department of Health and Human Services  
Attention: CMS – 3064 – P  
PO Box 8015  
Baltimore, MD 21244-8015

Re: **CMS – 3064 – P**

Dear Dr. McClellan:

The American Academy of Orthopaedic Surgeons (AAOS/Academy), representing over 19,000 Board certified orthopaedic surgeons, welcomes the opportunity to comment on the proposed rule *Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations*, as published in the Federal Register on February 4, 2005.

Orthopaedic surgeons are frequent users of musculoskeletal tissues and tissue products. Tissues are, of course, donated at the same time and through the same consent process as are organs. The Academy, our surgeons, and our patients are exceptionally grateful for the altruistic tissue donations made by so many each year. We support donation protocols for organ procurement organizations (OPOs) that are informed, responsive to donor and donor families' needs, and enhance donation rates in order to maintain the nation's supply of organs and tissues.

The Academy wishes to bring to the attention of the CMS an issue that may have an unintended effect on the donation of tissues for implantation. We are concerned that without delineating the differences between a "for-profit" and "non-profit" entity, the consent process may not be fully informed, and donation rates may subsequently be affected. The AAOS notes that within the context of organ and tissue procurement, the public may be unaware of the benefits provided by both for-profit and non-profit associated entities.

The AAOS would like to impress upon the CMS that significant contributions are made by both non-profits and for-profits in the tissue safety field. Altruistic missions and the delivery of quality products are facets of both for-profits and non-profits. Both types of organizations contribute to the scientific body of knowledge, advancing safe processing

techniques through research and development. Society as a whole benefits from these mutual efforts.

There has been much lay press coverage over the past years that has prominently featured the negative aspects of OPOs and tissue processors. We believe that acknowledging the contributions of both for-profit and non-profit associated entities will facilitate a truly informed consent process.

It would be detrimental to the entire tissue supply, and more importantly, to our patients' health, if the availability of tissue for orthopaedic patients became compromised as a result of a lack of information or misperception regarding a distinction between for-profit and non-profit associated entities.

We thank you for this opportunity to express our concern, and we look forward to working with you on future initiatives.

Sincerely,

A handwritten signature in cursive script that reads "Stuart Weinstein". The signature is written in black ink and is positioned above the typed name and title.

Stuart L. Weinstein, MD  
President