



September 2, 2014

The Honorable Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Revisions to the Sunshine Act Under the Medicare Physician Fee Schedule for CY 2015, CMS-1612-P

Dear Administrator Tavenner:

On behalf of the members of the Healthcare Leadership Council (HLC), I would like to take this opportunity to express our deep concern with the CMS proposal to delete the continuing medical education (CME) exclusion in the Sunshine Act final rule.

HLC is a not-for-profit membership organization comprised of chief executives of the nation's leading healthcare companies and organizations. HLC is committed to advancing a consumer-centered healthcare system that values innovation and provides affordable, accessible, high-quality healthcare to all Americans.

Collaboration among industry, healthcare professionals, and scientists has been at the heart of most of the advances in U.S. healthcare over the past several decades. Appropriate collaboration, education, and training between non-industry healthcare professionals and scientists and industry -- guided by clear principles and conducted for the benefit of patients -- drives medical innovation, meaningful health outcome improvements, and economic growth for our nation.

For the past few years, concerns about undue influence of industry on healthcare have presented an increasingly complex challenge to medical research, education, communication, and innovation efforts. With this in mind, the National Dialogue for Healthcare Innovation (NDHI), an HLC initiative, brought together varying perspectives to discuss issues that affect innovation and patient care. NDHI then identified four principles to provide a basic framework to help guide collaborative efforts and maintain the confidence and trust of all participants in our healthcare system, including patients, providers, payers, industry, researchers, academia, and government. A copy of the principles is enclosed.

Collaboration through CME and CE are vital components of our healthcare system and allow our nation's doctors and healthcare providers to remain up to date with the latest in medical science. However, it is important to America's doctors that they have clear rules that provide a safe harbor from Open Payments reporting when they participate in accredited CME and CE. This is what we understand was intended by Congress and exists in the Final Rule as it currently stands, and we would encourage you to create a similarly clear "safe harbor" for all healthcare professionals and CME/CE at the conclusion of this process.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary R. Grealy".

Mary R. Grealy
President

Enclosure: NDHI Principles



NATIONAL DIALOGUE FOR Healthcare Innovation

A Joint Statement on 21st Century Collaboration for Healthcare Advancement

Collaboration between industry, healthcare professionals, and scientists has been at the heart of most of the advances in U.S. healthcare over the past several decades. Appropriate collaboration between non-industry healthcare professionals and scientists and industry -- guided by clear principles and conducted for the benefit of patients -- drives medical innovation, meaningful health outcome improvements, and economic growth for our nation.

For the past few years, concerns about undue influence of industry on healthcare have presented an increasingly complex challenge to medical research, education, communication, and innovation efforts. With this in mind, the National Dialogue for Healthcare Innovation (NDHI) has brought together varying perspectives to discuss issues that affect innovation and patient care. NDHI has identified four principles to guide collaborations designed to advance medical technology, innovation, and patient care. These principles do not replace or subsume the important existing guidelines and codes that have already been developed by professional societies, trade associations, government agencies, academic medical centers, or individual companies. They do, however, provide a basic framework to help guide collaborative efforts and maintain the confidence and trust of all participants in our healthcare system, including patients, providers, payers, industry, researchers, academia, and government.

- 1. The benefit of patients:** Collaborations at any level, from the research lab to the doctor's office, must aim to benefit patients and put patients' interests first.
- 2. The autonomy of healthcare professionals:** Healthcare professionals and scientists must be free to assess independently multiple sources of information and treat each patient in a manner consistent with the patient's needs and best medical practice. This is vital to preserve the public's trust in the innovation process and in our healthcare system.
- 3. Transparency:** Patients and all those involved in healthcare should have reasonable access to relevant and meaningful information about how academic institutions, researchers, healthcare professionals, and medical products companies engage in collaborative relationships. Transparency builds trust between patients and the healthcare professionals who serve them.
- 4. Accountability:** All participants across healthcare must be responsible for their actions. External regulation is important here, but internal self-regulation with recurrent training and communication is essential to this effort.

The organizations agreeing to this statement and participating in the National Dialogue for Healthcare Innovation comprise a diversity of voices, but share a common goal – to promote the American innovative spirit so that new advances in medicine and medical technology can continue to make the journey from concept to the practice of medicine for the benefit of patients. In order to do this, we seek to preserve and enhance an environment that fosters innovation of new products, practices, and ideas. This must happen with the participants in these collaborative activities understanding the importance of principles such as patients' best interests, autonomy of healthcare professionals, transparency, and accountability. Such principles will help achieve the dual goals of encouraging medical innovations that save, extend, and improve lives, while maintaining the trust in the collaboration process.

Developed and endorsed by the following organizations:





NATIONAL DIALOGUE FOR Healthcare Innovation

Additional endorsements:

Alliance for Aging Research
American Association of Colleges of Osteopathic Medicine
American Association of Neurological Surgeons
American College of Osteopathic Neurologists and Psychiatrists
American College of Osteopathic Surgeons
Association of Clinical Research Organizations
Federation of State Medical Boards
Johnson & Johnson
Kansas Association of Osteopathic Medicine
Men's Health Network
Merck
Osteopathic Physicians and Surgeons of Oregon
Pfizer
Stryker
Society for Women's Health Research
South Carolina Osteopathic Medical Society
The Congress of Neurological Surgeons
Vanderbilt University School of Nursing
WomenHeart: The National Coalition for Women with Heart Disease

Individual endorsements:

Dennis Ausiello, M.D. (Harvard Medical School & the Massachusetts General Hospital)
Eugene Braunwald, M.D. (Harvard University School of Medicine and Brigham & Women's Hospital)
William N. Kelley, M.D. (University of Pennsylvania School of Medicine)
Ralph Snyderman, M.D. (Duke University School of Medicine)
Bruce Wilkoff, M.D. (Cleveland Clinic)