



February 13, 2017

VIA ELECTRONIC MAIL

Jerry A. Menikoff, MD, JD
Director, Office for Human Research Protections
U.S. Department of Health & Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Jerry.Menikoff@hhs.gov

Dear Dr. Menikoff:

The Physician Clinical Registry Coalition would like to commend your office for finalizing the rule on the Federal Policy for the Protection of Human Subjects (“the Final Rule”). We particularly appreciate the clarity that the Final Rule provides on the single IRB review mandate, revisions to the Common Rules’ informed consent requirements, and numerous other modifications.

However, we are disappointed that the Final Rule: (1) does not expand the exemption for data collection activities covered by the HIPAA rules to include business associates and researchers that comply with those rules; (2) does not adopt the proposed exclusion for certain quality improvement/benchmarking activities, and (3) does not include the proposed exemption for the use of identifiable private information for secondary research when notice of such use is given.

We do appreciate that the preamble to the Final Rule provides clarification on the application of the Common Rule to clinical data registries in response to the mandate in Section 511 of the Medicare Authorization and CHIP Reauthorization Act (“MACRA”). We do not necessarily agree, however, that this clarification fulfills the intent of the statutory directive. At a minimum, the guidance should be published in a separate, accessible medium and format. And, while it covers many ways in which the Common Rule applies or does not apply to clinical data registries, it does not provide the comprehensive guide contemplated by Section 511 of MACRA.

We would appreciate the opportunity to meet with you and others in your office to discuss our concerns about the Final Rule and the need for follow-up actions to further clarify the application of the Common Rule to clinical data registries. Please contact Rob Portman at rob.portman@powerslaw.com if you would be willing to meet with representatives of the Coalition about these important issues.

Jerry A. Menikoff, MD, JD
February 13, 2017
Page 2

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION

AMERICAN ACADEMY OF NEUROLOGY

AMERICAN ACADEMY OF OPHTHALMOLOGY

AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY

AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS

AMERICAN COLLEGE OF EMERGENCY PHYSICIANS

AMERICAN COLLEGE OF RHEUMATOLOGY

AMERICAN COLLEGE OF SURGEONS

AMERICAN GASTROENTEROLOGICAL ASSOCIATION

AMERICAN JOINT REPLACEMENT REGISTRY

ANESTHESIA QUALITY INSTITUTE/AMERICAN SOCIETY OF ANESTHESIOLOGISTS

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

AMERICAN SOCIETY OF PLASTIC SURGEONS

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

AMERICAN UROLOGICAL ASSOCIATION

GIQUIC/ AMERICAN COLLEGE OF GASTROENTEROLOGY

NORTH AMERICAN SPINE SOCIETY

SOCIETY OF INTERVENTIONAL RADIOLOGY

SOCIETY OF NEUROINTERVENTIONAL SURGERY

SOCIETY FOR VASCULAR SURGERY

THE SOCIETY OF THORACIC SURGEONS