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January 4, 2016

Jerry Menikoff, M.D., J.D.
Office for Human Research Protections (OHRP)
Department of Health and Human Services
1101 Wootton Parkway, Suite 200, Rockville, MD 20852

Re: HHS–OPHS–2015–0008

Dear Dr. Menikoff,

The Society of Hospital Medicine (SHM), representing the nation's nearly 50,000 hospitalists, appreciates the opportunity to provide comment on the proposed changes to the Common Rule (HHS-OPHS-2015-0008). SHM applauds this effort to modernize the Common Rule, seeking to enhance protection of human subjects while promoting research and we respectfully submit the following comments.

Hospitalists are front-line providers in America's hospitals, providing care for millions of hospitalized patients each year. In their role, hospitalists manage the clinical care of acutely ill, hospitalized patients, while working to enhance the performance of hospitals and healthcare systems. The unique position of hospitalists within the healthcare system affords them a distinctive role as leaders on systems, process, and quality improvement in their hospitals—quality improvement efforts are a central feature of the specialty. As such, these proposed changes to the Common Rule, specifically the new exclusions categories, are of particular interest to the many hospitalists who are intimately involved with Quality Improvement efforts and research.

Explicit Exclusion of Activities From the Common Rule

IV. Quality Assurance and Quality Improvement Activities

The NRPM creates a new section of the regulations that would explicitly exclude certain activities from the Common Rule. Most pertinent to SHM is the fourth category of excluded activities, which covers quality assurance or improvement activities. This category excludes activities that are limited to data collection and analysis only, and quality assurance activities that only involve the implementation of practices that are already accepted with a goal of improving delivery or quality of treatments or services. We fully support the goal of streamlining some quality improvement efforts through the establishment of a categorical exclusion, but want to point out that QI consists of much more than what is included in this exclusion.

According to the proposed rule, quality improvement is defined as, *"activities designed only to improve the implementation of a practice that is already accepted, not to evaluate the effectiveness and value of the accepted practice itself..."* Whether not including all QI activities within the exclusion was intentional or not, we feel it is important to correctly define quality improvement activities as involving interventions directly intended to impact patient-centered outcomes by measuring those outcomes, acting upon those measures, and assessing the effectiveness of activities on those outcomes. Quality improvement efforts are much broader based than what appears to be the case in the proposed rule. To guard against misconceptions, we recommend that the title of category recognize this and state "**Certain** Quality Assurance and Quality Improvement Activities".

Additionally, while we recognize the classification of research versus QI is not always straightforward, the proposed regulations have specific wording that may result in limiting the scope of what is not considered research. Despite all of the exemption categories contained in the current Common Rule having been carried over to the proposed Rule in one or another form, individual IRBs may read into this change more than was intended. It is unclear in the proposal whether most QI activities that are not included in this exclusion category will remain exempt under Common Rule standard, which presents a substantial risk that institutions and IRBs may view anything not falling under the exclusion as being subject to full IRB review and oversight.

It should be made clear within each exclusion category that some of the current Common Rule's exemptions have now become exclusions under the NPRM (and thus subject to no administrative or IRB review), while anything currently exempt will remain so under the NPRM's exempt categories section. In other words, the QI activities that are not considered "excluded" under "the 4th category" are still exempt despite not being granted the newly proposed exclusion. It should also be clarified that despite the proposed exclusion categories, expedited review is still possible for anything not falling under an exclusion (and is even streamlined by virtue of not having to be renewed annually).

Failure to improve clarity of how the exclusions operate alongside exemptions could detrimentally impact operational processes and quality improvement strategies by causing confusion about whether these activities are excluded, exempt or neither, which would thwart to overall intent of creating categorical exclusions.

SHM appreciates the opportunity to provide comments on the proposed changes to the Common Rule. If you require any additional information or clarification, please contact Josh Bowell, Director of Government Relations at jboswell@hospitalmedicine.org or 267-702-2635.

Sincerely,

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