

December 7, 2015

[VIA OVERNIGHT DELIVERY]

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RE: *iCompare and FIRST Trials*

Drs. Carome, Hall, Wolfe, and Almashat,

This letter is in response to your November 19, 2015 correspondence regarding the *iCompare* and *FIRST* trials. The Accreditation Council for Graduate Medical Education (ACGME) is committed to ongoing assessments of our requirements based on the most up-to-date evidence to foster a safe learning environment serving the best interests of patients, residents, and fellows.

The ACGME's support of the two large, multicenter clinical trials to investigate the impact of duty hour standards on patient safety and resident education will be elements of the ACGME's scheduled five-year review of whether the Institutional and Program Requirements are achieving their intended goals to foster a safe learning environment.

The ACGME's current duty hour accreditation requirements were developed in 2011 based on the best available evidence at the time. These requirements are based on the findings and recommendations of the 2010 ACGME Task Force on Quality Care and Professionalism, which conducted a thorough investigation of published evidence on duty hours and sleep science, heard testimony from experts and patients, and was informed by the 2009 Institute of Medicine (IOM) report, *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*.

The 2009 IOM report 1) noted that, “Prospective studies that have attempted to evaluate the effects of duty hours on patient safety generally have had sample sizes that lacked sufficient power to determine whether significant changes in errors (especially preventable adverse events), mortality, or other measures of patient harm occurred,” 2) outlined the ongoing need for additional prospective studies so that the “consideration of any future adjustments to duty hours would then have a more comprehensive database as a foundation for recommendations,” and 3) called for the ACGME and other stakeholders to “foster research studies across multiple institutions to examine the effects of duty hour changes and practices.”

Since the 2009 IOM report and the implementation of the new ACGME duty hour requirements, a number of studies have been conducted to assess the impact of the additional standards instituted in 2011. The preponderance of this new published research suggests that the additional 2011 duty hour requirements may not have had an incremental benefit in patient safety, and that there might be significant negative impacts to the quality of physician education, professional development, and socialization to the practice of medicine.

To further investigate these issues, the ACGME provided seed funding and agreed to waive specific duty hour requirements for two national, large, independent, multicenter trials. The ACGME granted these waivers to allow for the collection of data, evaluating the impact of the 2011 duty hour requirements on patient safety, along with the welfare and education of resident physicians. The iCOMPARE trial for internal medicine and the FIRST trial for general surgery were designed so that researchers can compare control groups using the current requirements with test groups following more flexible duty hour requirements. Furthermore, the ACGME would have access to multicenter trial information that would inform the question of whether there are specialty-specific differences in the impact of duty hour requirements. The waivers were granted for the length of each research trial (June 2016 for the completion of the FIRST trial, and July 2017 for the completion of the iCOMPARE trial).

The ACGME did NOT waive the central requirements for duty hours that have been in place since 2003 for all specialties, and for internal medicine since the early 1990s. The requirements limiting the total number of hours per week remain in effect for all trial participants (i.e., 80 hours per week—averaged over four weeks; one day off in seven—averaged over four weeks; and 24-hour in-house call duty no more frequently than every third night). Compliance with these requirements is monitored annually in the Next Accreditation System for all programs across all specialties, including those participating in these two trials. In addition, all first year (PGY-1) residents are required to have real-time, on-site, direct supervision in which a more experienced clinician bears the responsibility for patient care. The un-waived requirements also allow fatigued residents to hand off patients at any time, recommend napping after 16 hours of duty, and provide adequate sleep facilities and/or safe transportation options for residents who may be too fatigued to safely return home.

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December 7, 2015*

The ACGME was not involved in the design or implementation of the FIRST or the iCOMPARE trials beyond the waiver requirements, and will not be involved in the interpretation of their results. Nevertheless, the ACGME understands that both duty hour study protocols were reviewed by the Institutional Review Board (IRB) of the institution affiliated with each principal investigator. The ACGME also understands that the iCOMPARE trial was funded by the National Institutes of Health (NIH).

The ACGME is committed to the highest quality of patient care and resident/fellow learning. Wherever possible, the ACGME will continue to support and facilitate well designed, IRB-reviewed, multicenter educational trials with aims to scientifically test elements of the educational process that have the potential to enhance the quality and effectiveness of graduate medical education programs, and the safety and quality of care rendered to our patients today, and tomorrow.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas J. Nasca". The signature is written in a cursive style with a large, sweeping initial "T".

Thomas J. Nasca, MD, MACP
Chief Executive Officer

cc: Mr. John Duval
Chair, ACGME Board of Directors

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services

The Honorable Karen B. DeSalvo
Acting Assistant Secretary for Health, HHS