Chapter 4 The Process for Developing the 2011 Duty Hour Standards

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Introduction

In 2008, the common duty hour standards instituted in 2003 had been in effect for 5 years, and the ACGME was prepared to explore refinements that would be based on programs', institutions', and residents' experience with the 2003 standards. Concurrently, the Institute of Medicine announced that at the request of elected officials and the Agency for Healthcare Research and Quality (AHRQ) it had convened an expert group to deliberate about resident hours and conditions to optimize patient safety.[1] The ACGME decided that it would await the release of the IOM report,[2] scheduled for December 2008, and initiate a comprehensive, multifaceted process to develop new standards for duty hours, supervision, and professionalism. A key attribute of the approach would be an explicit commitment to provide all interested and affected stakeholders with the opportunity for input into the revisions of the common requirements.

ACGME Task Force on Quality Care and Professionalism

The ACGME adopted a process for the development of new standards for duty hours, supervision, and professionalism that sought to ensure that all interested and affected stakeholders had the opportunity to provide input. After the release of the IOM report, in February 2009, the ACGME charged a 16-member ACGME Task Force with the process of deliberating on the new common requirements for resident duty hours. Initially named the *Duty Hours Task Force*, one of its first actions was to change its name to the *ACGME Task Force on Quality Care and Professionalism*, to reflect the complexity and comprehensiveness of the issues being addressed. The Task Force comprised 12 national leaders in graduate medical education, 3 residents, and 1 nonphysician public representative with experience in consumer advocacy.

The members of the Task Force were drawn from the Council of Review Committees (CRCs) and the ACGME Board of Directors and included program directors, department chairs, and designated institutional officials (DIOs), hospital administrators, and residents/fellows. The CRC consists of the chairs of each of the 27 specialty-specific Review Committees and the Institutional Review Committee, 2 ACGME directors and nonvoting observers from the Royal College of Physicians, the Council of Medical Specialty Society's Organization of Program Director Associations, and the Veterans Administration.[3] The Council is responsible for the content of the Common Program Requirements, which it must review and revise at least every 5 years and as needed.[4] All members (with the exception of the public member) had extensive current or recent experience in graduate medical education, collectively representing more than 250 years of activity in training future physicians. Susan Day, MD, chair of the ACGME Board of Directors, and E. Stephen Amis Jr, MD, FACR, chair of the CRC, served as cochairs, and Thomas Nasca, MD, MACP, chief executive officer of the ACGME, served as vice-chair.

The membership represented a host of specialties, including internal medicine, pediatrics, family medicine, emergency medicine, surgery, pulmonary disease and critical care, neurosurgery, vascular surgery, diagnostic radiology, anesthesiology, ophthalmology, obstetrics and gynecology, colon and rectal surgery, and nephrology. Members felt this spectrum of medical, surgical, and hospital-based disciplines capably represented the interests of those specialties not on the Task Force. The participation of residents and fellows also created generational diversity and brought to the table the perspectives of individuals

TABLE 1 **Task Force on Quality Care and Professionalism Members**

E. Stephen Amis Jr, MD, FACR, Chair, Council of Review Committees and Task Force Co-chair; University Chair, Department of Radiology, Albert Einstein College of Medicine and Montefiore Medical Center, Bronx, New York
Susan Day, MD, Chair, ACGME Board of Directors and Task Force Co-chair; Chair and Residency Program Director, Department of Ophthalmology, California Pacific Medical Center, San Francisco, California
Thomas Nasca, MD, MACP, Task Force Vice-chair; Chief Executive Officer ACGME and ACGME International LLC, Chicago; Professor of Medicine, Jefferson Medical College, Thomas Jefferson University, Philadelphia, Pennsylvania
Paige Amidon, Public Member, ACGME Board of Directors
Jaime Bohl, MD, Staff Surgeon, Department of Colon and Rectal Surgery, New Orleans, Louisiana. Dr Bohl served as a resident representative.
Lois Bready, MD, Professor, Department of Anesthesiology and Associate Dean for Graduate Medical Education, University of Texas Health Science Center San Antonio, San Antonio, Texas
Ralph Dacey Jr, MD, Henry G. and Edith R. Schwartz Professor and Chair, Department of Neurological Surgery, Washington University School of Medicine, St Louis, Missouri
Rosemarie Fisher, MD, Attending Physician and Associate Dean for Graduate Medical Education, Yale-New Haven Hospital, Yale University, New Haven, Connecticut
Timothy Flynn, MD, FACS, Chair-Elect, ACGME Board of Directors; Professor, Department of Surgery, and Senior Associate Dean for Clinical Affairs, University of Florida College of Medicine, Gainesville, Florida
Stephen Ludwig, MD, Professor of Pediatrics and Emergency Medicine, and Designated Institutional Official, The Children's Hospital of Philadelphia, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania
Robert L. Muelleman, MD, FACEP, Professor and Chairman, Department of Emergency Medicine, University of Nebraska Medical Center; Medical Director, Emergency Medical Services, Nebraska Medical Center, Omaha, Nebraska
Janice Nevin, MD, MPH, Senior Vice President and Associate Chief Medical Officer, Christiana Care Health System; Associate Professor, Jefferson Medical College, Wilmington, Delaware
Meredith Riebschleger, MD, Fellow in Pediatric Rheumatology, University of Michigan Health System - Mott Children's Hospital, Ann Arbor, Michigan. Dr Riebschleger served as a resident representative.
William J. Walsh III, MD, MPH, Research Fellow, Division of Pulmonary and Critical Care Medicine, University of Utah, Salt Lake City, Utah. Dr Walsh served as a resident representative.
George Wendel Jr, MD, Professor and Residency Program Director, Department of Obstetrics and Gynecology, University of Texas Southwestern Medical School, Parkland Memorial Hospital, Dallas, Texas
Thomas V. Whalen, MD, MMM, CPE, FACS, FAAP, Chairman, Department of Surgery, Lehigh Valley Health Network; Professor of Surgery, Penn State University College of Medicine/The Milton S. Hershey Medical Center; Adjunct Associate Professor, Uniformed Health Services University of the Health Sciences, Allentown, Pennsylvania

currently in training. The public member, Paige Amidon, ACGME public director, played a critical role representing the voice of the patient and the public at large. A complete listing of Task Force members is provided in TABLE 1.

The Task Force was charged with reviewing the available evidence pertaining to the existing requirements, the findings of the IOM's 2008 report on resident duty hours,[2] and other relevant information and to make recommendations for new common standards. The group conducted a comprehensive review of duty hour standards, resident supervision, and related issues.[5] It also considered more than 100 written position statements by the organizations and individuals in the academic community, heard oral testimony, received 3 comprehensive external reviews of the literature that the ACGME had commissioned expressly for this purpose, and conducted multiple additional fact-gathering sessions. On behalf of the Task Force, the ACGME conducted a survey of residents, medical school faculty, program directors, and DIOs.

International Duty Hour Symposium

The first step in developing refined standards for resident duty hours entailed information gathering. A key event was an International Duty Hour Symposium that took place in conjunction with the annual ACGME Educational Conference in March 2009. Approximately 200 individuals participated in the symposium.[6] This began the process of soliciting the perspectives of residents, program directors, DIOs, faculty, ACGME review committee members, and others with a stake in graduate medical education. Participants heard from experts on sleep loss and performance and were briefed by representatives from other nations that have regulated resident hours and by members of the committee who developed the IOM duty hour recommendations. The symposium also addressed the issue of potential federal regulation of resident duty hours.

Attendees discussed ways to improve the ACGME's approach to monitoring duty hours and supervision arrangements that would enhance resident learning and ensure safe and effective care. An important concept that emerged during the symposium was the need to develop duty hour standards that would be sensitive to differences among specialties and levels of training, to ensure safe patient care in settings with resident participation while allowing for acquisition of competence for independent practice, and the professional development of physicians.

Duty Hours Congress

In June 2009, the Task Force and the ACGME convened a 2-day Duty Hours Congress, held in Chicago.[7] Before the event, the ACGME invited the GME community and other stakeholders to provide written commentary on the impact of the current duty hour requirements and to make recommendations for the upcoming revision of the standards. Most respondents also provided opinions on the recommendations contained in the 2008 IOM report on resident duty hours. More than 100 organizations responded to the request, including all of the major professional organizations representing the specialties and most of the major organizations in health care and medical education, such as the American Medical Association and the American Hospital Association. Organizations representing students, residents, and the public also submitted commentary.

During the Duty Hours Congress, the Task Force heard 67 oral presentations as a follow-up to the written opinions. Some disciplines collaborated and chose to present a consensus statement; others presented individually. Task Force members had the opportunity to question the presenters. The Duty Hours Congress provided the necessary foundation for the Task Force to begin its work, though additional information gathering would continue for several months.

Task Force Meetings and Fact Gathering

During the 2009–2010 academic year, the Task Force met an additional 11 times, with 6 meetings entirely devoted to fact gathering from multiple experts. Topics were essentially grouped into 5 areas, including history and background of duty hour restrictions, needs of the medical profession, patient safety (including the perspective of the patient), sleep physiology, and research. A list of presenters and organizations providing testimony in these sessions is found in TABLE 2.

The remaining 5 Task Force meetings were devoted to reviewing testimony and developing the recommendations. While the initial time line called for draft requirements to be presented at the February 2010 ACGME Board Meeting, the Task Force appreciated the complexity of the issue and recognized that added work was needed to refine the revisions. This work was completed at meetings held in Chicago in April and June 2010.

The Task Force met personally with representatives of 72 groups, which included experts on fatigue mitigation, patient safety,

TABLE 2 **Presenters to the ACGME Task Force on Quality Care and Professionalism**

Lawrence Opas, MD, Associate Dean, Graduate Medical Education and Designated Institutional Official, USC/LAC + USC Medical Center *Cost Impact of Duty Hour Change*
Lucian Leape, MD, Harvard School of Public Health *Training Physicians for the New World of Health Care*
James Bagian, MD, Chief Patient Safety Officer, Director, National Center for Patient Safety Department of Veteran Affairs *Fatigue Mitigation: Is It Just About Resident Duty Hours?*
Mark Chassin, MD, President, The Joint Commission *The Joint Commission, Patient Safety, and Duty Hours During Physician Training*
Doug Carlson, ACGME Legal Counsel *Duty Hours and the Law*
Dewitt Baldwin Jr, MD, ACGME Scholar in Residence; and Steven R. Daugherty, PhD, Director, Education and Testing, Kaplan Medical *Past Date, Present Correlates, and Future Directions: Toward a Better Understanding of Residency Education*
Dewitt Baldwin Jr, MD, ACGME Scholar in Residence; Steven R. Daugherty, PhD, Director, Education and Testing, Kaplan Medical; and Patrick M. Ryan, MD, Research Consultant, ACGME *Beyond Work and Sleep: Variations in Residency Training*
Ingrid Philibert, PhD, MBA, Senior Vice President, Field Activities, ACGME *The 2003 ACGME Common Duty Hours Standards: Development, Implementation, and Promoting Compliance—Lessons Learned*
Timothy Johnson, Senior Vice President, Greater New York Hospital Association *Resident Duty Hour Limitations: Observations From New York*
David Dinges, PhD, Professor of Psychology and Psychiatry, and Chief, Division of Sleep and Chronobiology, University of Pennsylvania School of Medicine *Sleep Research and Resident Duty Hours*
David Dinges, PhD, Professor of Psychology and Psychiatry, and Chief, Division of Sleep and Chronobiology, University of Pennsylvania School of Medicine *Fatigue Management Overview*
Charles Czeisler, PhD, MD, Baldino Professor of Sleep Medicine, and Director, Division of Sleep Medicine, Harvard Medical School *Medical and Genetic Differences in the Impact of Sleep Loss on Performance: Implications for Work Hour Standards*
Javier A. Gonzalez del Rey, MD, MEd, Director, Pediatric Residency Program, Cincinnati Children's Hospital *The Recommendations of the IOM Consensus Committee to Optimize Residents' Hours and Work Schedules to Include Patient Safety: A Pediatric Program Director's Perspective*
Susan Sheridan, Consumers Advancing Patient Safety *Keeping Patients Safe: Passion, Courage, and the Power of Partnership*
Lenora Janacek, Save the Patient *The Life You Save May Be Your Own*
Helen Haskell, Mothers Against Medical Error *Resident Working Conditions: We Have Questions*

sleep physiology, quality improvement, transitions of care, and impact of the New York State duty hour standards. Finally, the members studied the IOM's 2008 report, ''Resident Duty Hours: Enhancing Sleep, Supervision, and Safety'' (the 2008 IOM report),[2] and engaged in in-depth discussions with the authors of that report.

Literature Reviews

In addition to hearing directly from experts and other persons invested in the GME system, the ACGME commissioned 3 comprehensive literature reviews of US and international peer-reviewed articles relevant to resident duty hours, supervision, and the

working environment; sleep physiology, sleep and deprivation, fatigue and well-being; moonlighting; causes of medical errors, and the effect of the 2003 duty hour standards, presented as Appendix A through C of this monograph.[8–10] A request for proposals was released in April 2009: eight proposals were submitted to the ACGME, and 3 were selected for authorization to proceed and receive funding. Analysis and synthesis of key elements and themes were the main focus of each review. The authors were asked to identify significant gaps in data and to recommend areas of needed research. Each review applied a quality index based on relevance, sample size, and methodology in order to determine which articles would be included. An annotated bibliography was produced to accompany each review. The reviews addressed the conceptual frameworks underlying proposed changes in the duty hour limits, the effect of varying resident duty hours and schedules on patient safety, and duty hours and related topics such as supervision and workload.

Consensus Building

After assimilating the evidence, the Task Force began the process of drafting and reaching consensus for the revised standards. A drafting subcommittee produced the framework. This process resulted in 3 options with varying degrees of specialty- and training-level specificity. The decision was made to move forward with a framework based primarily upon level of training. Although specialty-specific requirements were desirable for some areas, the Task Force was not prepared to generate 27 different versions of the duty hour standards. In addition, the members were concerned that the complexity of specialty-specific requirements for all areas might be confusing for residents working across specialties, such as family medicine and emergency medicine, and for transitional year residents, as well as for sponsoring institutions that would need to monitor compliance.

The 3 major categories in which themes were identified—duty hours, professionalism and personal responsibility, and supervision—were used as subthemes for drafting the new standards. Each member of the Task Force was assigned to 1 of 3 writing groups and initial requirements were drafted. The writing groups considered scientific evidence, including the IOM recommendations, expert testimony, and the practical experience of its members when drafting the new requirements.

Each writing group brought its product to the entire Task Force for review, and the members discussed every requirement line by line and word by word during several roundtable meetings. The Task Force strove to reach full consensus for each requirement, and the members voted on the exact wording. Dissent by 3 members was necessary for a veto and further discussion.

Approval Process

In June 2010, the Task Force presented its recommendations for enhancing the 2003 resident duty hour standards. A key aim was to expand the focus beyond duty hours and to set forth new standards for supervision, safety, and professionalism. After soliciting and reviewing comments from major stakeholders in the GME community and general public, the group chose to:

- Establish more restrictive limitations on continuous shift hours for first-year residents;
- Require the creation of mandatory transportation and in-hospital sleep facilities for resident physicians who may be too tired to drive home safely;
- Include all moonlighting in the 80-hour weekly limit; and
- Enhance the requirements for graded supervision of residents.

The 2011 duty hour, supervision, and safety standards did not receive special treatment with regard to the approval process for ACGME program requirements, despite the increased

magnitude of public attention and scrutiny from the GME community. Under the ACGME's policies and procedures for standards revisions, all significant revisions of any program requirement are sent to the Committee on Requirements (COR) before submission to the Board of Directors.[7] The COR considers the content, clarity of language, general reasonableness, and impact for the proposed requirements; makes any necessary modifications; and returns the document to the submitting committee or council for response. The Committee then submits the proposed revised requirements to the Board of Directors, which has ultimate responsibility for approving revisions. In addition, all changes in ACGME accreditation standards are posted for a 45-day period of public comment.[4] The committee or council proposing the revision must consider and respond to all comments. For the 2011 duty hour and professionalism standards, the CRC delegated that responsibility to the Task Force, which discussed all comments and considered making additional changes to the requirements during another roundtable consensus-building session.

Once the Task Force developed a document that met the spirit of their goals for improved resident education, with concomitant increases in resident and patient safety, the standards were subjected to the process of public notice and comment that is expected for any revision of the ACGME program requirements.[4] This included the development of an impact statement that addresses the effect of revision on resident education, patient care, and institutional resources, facilities, and services. The impact statement recognized that changes in residency requirements may affect how patient care is delivered and the allocation of resources within the sponsoring institution. The draft standards documents, including the impact statement, were forwarded to the CRC, who submitted the draft requirements to the ACGME Board for approval.

After approval by the Board, the new standards were posted on the ACGME website for 45 days, as required by policy.[4] Stakeholders were notified of the posting and advised to submit comment if they desired, and the ACGME received comments from more than 1000 organizations and individuals. On August 29, 2010, the Task Force convened for the last time to review the comments received. Because of the constructive nature of the comments, the standards were reevaluated and revised in some areas. This final revision was endorsed by the CRC and Committee on Requirements before being submitted to the ACGME Board for review and approval. On September 27, 2010, the Board of Directors approved the new standards addressing professionalism, supervision, and duty hours. The new standards were scheduled to become effective July 1, 2011.

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