Statement of Justification/Impact for the Final Approval of Common Standards Related to Resident Duty Hours

September 2002

In June 2002, the ACGME granted preliminary approval to new standards for resident duty hours, to be incorporated into the "Common Program Requirements," and a set of added standards defining the obligations of sponsoring institutions, to be incorporated into the Institutional Requirements. Both will become effective in July 2003. The standards limit resident duty hours in all specialties to 80 hours per week, averaged over four weeks. Other elements include a 10-hour rest period between duty periods, and a 24-hour limit on continuous duty time, with up to 6 added hours for the transfer of care and didactic activities. The new standards incorporate the existing requirements that one day in seven must be free of patient care responsibilities, and that in-hospital call must be scheduled no more frequently than every third night. The new standards require that when residents take call from home and are called in, time spent in the hospital must be counted toward the weekly limit. Through the Institutional Requirements, the ACMGE emphasizes the role of the sponsoring institution in overseeing compliance with the standards, and putting in place systems to ensure that education has priority over service in the allocation of residents' time. After preliminary approval of the common standards, the ACGME began to solicit comments to clarify and refine the standards prior to final approval and implementation. Comments were received from the ACGME's appointing organizations, the resident education and program director community and the general public. They are considered in this impact statement.

1. The rationale for the development of common duty hour standards

The impetus for developing common duty hour standards and enhanced Institutional Requirements for "Resident Supervision, Duty Hours, and Work Environment" are changes in health care delivery that have increased patient acuity; growing public attention on residents' hours; and data from the study of sleep deprivation that show a potential negative effect on residents' clinical and educational performance. As the accrediting body for 7,800 residency programs, the ACGME is the entity to which the community looks to address the issue of resident hours. Congress and the Department of Health and Human Services recognize the ACGME's role in fostering education and safe patient care, by requiring programs that receive Medicare graduate medical education payments to be accredited.[1] The American Board of Medical Specialties requires completion of an accredited program for Board certification, and state licensing agencies make completion of one or more years in an accredited program a prerequisite for licensure. Illinois specifically compels hospitals by statute to comply with the ACGME's duty hour requirements.[2] Maintaining the public's trust and that of its officials and institutions requires the ACGME to take the leadership in addressing duty hours.

The present initiative builds on a 20-year history of addressing resident hours. In the early 1980s, the ACGME requirements for Internal Medicine and Pediatrics first included language on duty hours, and in 1987, the ACGME adopted several duty hour requirements for all specialties. These standards have been enforced over the years, and a number of specialties have set more restrictive requirements, including five that have set a limit on weekly resident hours. Because patient safety, education and resident well-being are not just related to the number of duty hours, the standards need to be viewed in the context of the ACGME's comprehensive approach to accreditation that specifies educational curricula, require residents to be supervised, and measure attainment of educational goals, including assessment of residents' qualifications to perform procedures.

The organizations in the graduate medical education and health care community have contemplated the issue of resident hours for some years. Several have provided policy recommendations that include a weekly limit, with some going as far back as the late 1980s.[3,4,5] In 1989, New York State, which accounts for approximately 15 percent of all residents[6], implemented duty hour regulations across all specialties that include a weekly limit on resident hours. In addition to support from the medical education community, the public's support for limits on duty hours is an important factor in the decision. Given the concerns about the effects of sleep

deprivation on patient safety, education and resident well-being, failure to act could be interpreted as the profession abrogating its responsibilities and ignoring the evidence on sleep and performance. The result could be regulation of resident hours, and there have been calls for legislative or regulatory intervention.[7,8] One attribute of accreditation is that it offers greater flexibility and opportunity for input than a regulatory approach.[9]

2. The Rationale for the Enforcement Provisions Related to Resident Duty Hours

The ACGME promotes adherence to its standards by monitoring and citing programs that fail to meet them. It takes adverse actions in cases of significant noncompliance, including probation and, after ensuring the program due process and a fair hearing, withdrawal of accreditation. Across all standards, the rate of adverse actions against programs is 8 percent.[10] Statistics on enforcement of the duty hour standards has shown fluctuation in the percentage of programs and institutions cited annually. Overall the percentage of programs cited for failure to comply with the standards is declining, although in a few disciplines – predominantly surgical specialties – it has remained largely stable.[11] Information on compliance collected in the future will be more meaningful due to the existence of a uniform set of standards that permits a true comparison across specialties.

To prevent residents from spending many months or even years of their education in programs that do not comply with the duty hour standards, a critical element of the compliance effort involves shortening the time frame for addressing duty hour citations, through all RRCs and the IRC requesting progress reports and action plans from programs that have been cited. RRCs are also expected to shorten the timeframe for withdrawing accreditation from programs that fail to come into substantial compliance with the duty hour standards in a timely manner. For the most serious violations, the ACGME may invoke the procedure for Rapid Response to Alleged Egregious Accreditation Violations or Catastrophic Institutional Events, which provides for an immediate site visit, and the potential for serious accreditation consequences if the allegation is confirmed.

3. Sleep Deprivation and Its Effects

Advances in scientific research have produced data on sleep deprivation and its effects that is relevant to residents' clinical and educational performance. Many studies have shown that sleep deprivation negatively influences performance in experiments and field studies involving residents, reaching back three decades.[12,13,14,15,16] In 1971, Friedman et al. found that first-year residents who were post-call made more errors than rested residents in reading standardized electrocardiograms.[17] The literature on sleep loss and performance does not uniformly find impairment in residents. One reason is that the various aspects of cognitive performance are influenced differently by sleep loss. Studies show that acuity on performance tests requiring prolonged vigilance deteriorates fairly rapidly with sleep deprivation, while performance on most psychomotor tests, reaction times, and short-term recall is not affected.[18] Residents' post-call status also was not a significant factor in variation on scores on in-service exams in one study,[19] potentially because both acute and chronic sleep deprivation is present in resident cohorts.[20]

The ACGME duty hour standards take into account the difference between acute and chronic sleep deprivation. They address acute sleep loss by placing a limit of 24 hours on continuous duty, and cap weekly duty hours and require rest periods to deal with chronic sleep deprivation. A benefit of a weekly limit is that it provides an easily understood metric, yet from the multiple perspectives of promoting safe care, education and resident well-being, a weekly limit alone may not be adequate, because it fails to account for differences in intensity between comparable periods. The standards thus emphasize supervision faculty involvement; mandate education of faculty and residents about sleep deprivation; and require that residents are monitored for sleep deprivation and relieved of clinical responsibilities if they show signs of fatigue that may compromise performance.

4. Effect of the Standards on Education and Learning

One advantage of standards set by the profession is that they can avoid a narrow definition of limits on duty hours that may interfere with residents' education. When New York State implemented regulation limiting resident hours, a study found "an open-ended workday and competing considerations confronting residents when deciding to leave the hospital – including concerns about leaving patients at critical junctures in their care, regard for the workload of their colleagues, and uneasiness about the educational consequences."[21] In the European Community, limits on duty hours for all physicians produced the findings that some education and patient care activities were moved to "non-documented" work hours,[22] and that the quality of education diminished, without effective monitoring of the residents' work load.[23,24,25] The ACGME's standards seek to avoid such a narrow definition, and to emphasize education. The added period of up to six hours at the end of 24 hours of continuous duty allows for the transfer of patient care and for educational debriefing. It also preserves flexibility in scheduling didactic activities and avoids exclusion of post-call residents from educational offerings, required continuity clinics and participation of surgical residents in the "first case of the day." A narrow focus is not optimal, because as future physicians, residents are expected to demonstrate professionalism and responsibility for patients, and need to learn that these activities are not necessarily discharged during pre-determined hours. At the same time, enforcement needs to distinguish between legitimate educational considerations, and hours above established norms used to meet service obligations.

5. Effect of the Standards on the Various Accredited Specialties

The standards define the minimum that must be met by all accredited programs. They do not detract from the existing program requirements in specialties that have established more stringent limits. Instead, they are intended to serve as a "floor" on which RRCs can define standards that reflect the patient safety and educational considerations of their discipline. The common requirements include several existing ACGME standards, and it is expected that programs comply with these, as would have occurred in the absence of the new standards. One standard that received extensive comment is the required 10-hour rest period, with many noting that this will complicate scheduling in many specialties and is not aligned with New York State's 405 regulations, which specify 8 hours of rest. In many specialties, the new standards will have little or no effect. Internal Medicine, the largest accredited specialty representing more than 20 percent of all physicians in residency,[26] limited duty hours to 80 per week more than 10 years ago. Other disciplines virtually never approach 80 hours per week or impinge on the other requirements. However, several predominantly surgical specialties have expressed concerns that limiting duty hours to 80 per week may constrain residents' educational opportunities.

To provide for added time beyond 80 hours to allow residents to participate in educationally meaningful activities, the standards allow programs to request an exception of up to 10 percent above the weekly limit. Programs may apply for this exception with the endorsement of their sponsoring institution's Graduate Medical Education Committee. Approval will be granted by the RRC. In the rare instance where a specialty believes its programs cannot conduct their educational activities within the 80-hour limit, the ACGME in the future will provide an opportunity for the RRC to petition for an exception. This option will not be available prior to the implementation of the new standards, to allow programs time to demonstrate compliance with the new standards. Specialty-wide exceptions will require the approval of the ACGME Program Requirements Committee and the Board of Directors, and will be granted for a limit of up to 88 hours per week. Beyond that, exceptions may be granted only for the years of training beyond the third graduate year, up to a limit that reflects the average number of hours per week worked by the practitioners in that specialty. All exceptions will require a sound educational rationale, and information on how safe patient care and education will be promoted. They must be based on evidence that all hours, not just the added amount, contribute to resident learning.

6. Effect of the Standards on Patient Care

Some of the comments suggested that reductions in resident hours would result in a reduction of the quality of

care in teaching institutions, similar to the results of several studies of the effect of duty hour limits in New York State.[27,28,29] One study found a reduction in the timeliness of services and diagnostic tests, and a higher rate of complications after adjusting for differences in severity of illness.[30] There have also been concerns about a loss of professionalism in physicians trained under regulated duty hours, with future physicians comfortable working in an hourly setting, but less familiar with the obligations they have to their patients.[31] At a limit of 80 hours per week, residents should be able to continue to contribute meaningfully to the provision of care, and gain an understanding of the dedication the public expects from physicians, while being more rested and alert.

Promoting safe and effective patient care is a major impetus for the limits on duty hours. At the same time, no single intervention, including reducing resident hours, can ensure patient safety, because it is influenced by multiple factors. In 2001, the Institute of Medicine recommended a broad-based, systems approach to patient safety. [32] Thus, the common duty hour standards must be viewed as one element in a system to enhance the safety of patient care. Implementation of the duty hour limits in a way that is attentive to the overall patient care and learning environment will result in enhanced patient care quality and improved education, while a narrow interpretation that only focused on the number of hours worked may be detrimental to patient care.

Any approach to reduce resident hours with the intent of promoting patient safety, and resident learning and well-being must address resident moonlighting. Residents in many disciplines moonlight, often in settings not affiliated with the residency program, although "in-house" moonlighting is gaining in popularity. At the same time, any decision about moonlighting is destined to be controversial, because it must balance residents' personal liberties against the interests of protecting residents, their patients and their ability to devote sufficient time and energy to their education. The "educational value" of moonlighting has been debated, though education is not the reason residents moonlight. While debt is frequently cited as a factor in the "need to moonlight," research has found only a weak relationship between educational debt and moonlighting.[33] In addition to financial pressures (not limited to educational debt), reduced call schedules in the program and perceived shifts in career opportunities contribute to residents' decisions to moonlight.[34] The solution of counting hours spent in in-house moonlighting toward the weekly duty hour limit affirms that resident alertness is an important consideration for patient safety in teaching institutions that extends to patient care activities. It also guards against institutions inappropriately using in-house moonlighting to replace patient services formerly provided by the residents as part of the educational program. It may likely curtail the hours residents are available to provide clinical care in teaching institutions external to their educational program.

7. Effect of the Standards on Program Directors and Faculty

Many comments on the new duty hour standards focused on the need for faculty to assume duties formerly held by the residents, and the added burden this will place on academic physicians. The added responsibilities are not limited to patient care. The educational role of faculty will expand under the new standards, because reductions in hours will diminish the availability of residents to educate junior colleagues and medical students. The standards emphasize the role of program directors and faculty in recognizing and intervening in instances of residents exhibiting signs of fatigue. Symptoms that can be recognized by others include reduced vigilance, poor communication, lethargy, poor mood and nodding off.[35] If residents confirm these symptoms relate to sleep deprivation, faculty should reassign care. Residents should also request to be relieved when their limits have been reached, with faculty supporting these decisions. A related matter is the role of programs in educating residents about moonlighting, as resident may not be aware about its medical-legal implications and risks.

In many programs, the new duty hour standards will increase faculty responsibilities, at a tine when many clinical faculty members already feel burdened. Although clinical care and teaching are fulfilling activities, there is evidence that professional rewards for clinical faculty lag behind those of their colleagues who focus on research. Clinical faculty members also report lower satisfaction with academic practice than faculty primarily focused on research.[36] Teaching institutions will have to give consideration to enhancing their

systems for developing, motivating and rewarding faculty members who devote their energies to patient care.

8. Effect of the Standards on Residents

Information from the application of duty hour limits in New York State showed the positive effect of the standards on the residents included less fatigue, more time for reading, and family and personal pursuits.[37] A study of obstetrics-gynecology residents after the implementation of the duty hour regulations found a marked improvement in resident life-style, very little change in in-service exam scores and quality of patient care.[38] Of surgical residents in New England surveyed in the early 1990s, 72 percent thought there was a need for some level of limiting of resident duty hours.[39] The majority of the comments from residents expressed support for the new requirements. At the same time, their support is tempered by concerns from residents in surgical specialties that the limits on duty hours may interfere with their operative and patient care experiences. There are also comments about the effect of the ACGME's efforts to restrict resident moonlighting, by requiring prospective approval and counting "in-house" moonlighting toward residents' weekly duty hours.

The added involvement of the faculty in teaching junior residents and medical students after a reduction in resident hours will likely benefit junior residents and medical students. There are concerns with the current, widely accepted educational model that places this responsibility largely on more senior residents. Functioning as teachers gives residents the opportunity to test their knowledge, but it produces conflicting obligations.[40] These include learning needs that are similar to those of their junior colleagues, and the expectation that they teach materials they have just learned. Their role as supervisors compels them to ensure that junior residents "get the work done," which may occur at the expense of teaching them. Finally, residents' priority is meeting their patients' needs, and responsibility for the learning needs of junior colleagues may compete with this.

9. The Effect of the Standards on Teaching Institutions

The duty hour standards emphasize the responsibility of sponsoring institutions for creating an appropriate learning environment. This role is not limited to coordinating and monitoring programs' compliance. Sponsoring institutions play a vital role in creating an environment within their residency programs that promotes safe patient care and high-quality learning. They will need to assume additional responsibilities, including educating residents and faculty about sleep deprivation and fatigue. While the duty hour standards will have little or no effect in many specialties and in a number of programs in each specialty, in other programs they will necessitate significant changes in some programs. In programs with long duty hours, necessary changes may include decreasing the frequency of in-house call to no more than every fourth night or implementing night float systems, in which some residents' work 8 to 12 hours nightly to cover the evening and overnight hours. All of these initiatives will carry costs that will accrue to the sponsoring institutions, discussed in the section dealing with the cost impact of the new duty hour standards.

10. Effect of the Duty Hour Standards on the ACGME

Promoting compliance with the duty hour standards has the potential of increasing the workload of RRCs and the ACGME staff. The extent to which this will occur is not known at present, and this could be one of several elements of the process of implementing the duty hour standards on which it will be important to develop a metric and collect data. Such changes in the accreditation process are part of the ACGME's established process, in which it regularly amends its standards and monitors enforcement to accommodate changes in medical practice, educational theory and methodology, and other factors. One example is the implementation of the six general competencies. In the case of duty hours, as changes in the clinical environment made resident hours a growing concern, the ACGME responded by formulating more comprehensive duty hour standards and enforcement practices. It has also enhanced its effort to educate its constituencies about the issue.

The ACGME has assessed its internal practices to ensure timely, consistent and fair enforcement of the duty

hour standards. To further enhance this, the Monitoring Committee will review RRCs' performance in applying the duty hour standards to guard against inadequate attention or lax enforcement of the standards by a given RRC. A final element for further enhancing the functioning of the accrediting process related to the resident duty hour standards is the formation of a dedicated ad hoc ACGME Subcommittee on Resident Duty Hours, and charging it with coordination of the implementation of the ACGME's comprehensive approach to duty hours.

11. The Cost Implications of the Common Duty Hour Standards

While little or no change will be required in some programs, in others and in most sponsoring institutions, the standards will necessitate change and carry potentially significant costs. Reducing residents' duty hours will require patient care activities to be transferred to other providers, and the costs – financial, time and opportunity – and challenges resulting from this transfer merit further attention. Having faculty assume added responsibility seems a natural solution, but transferring work to clinical faculty is complicated by the fact that this group already feels constrained and its members do not believe themselves able to assume much added burden. Another strategy calls for replacing residents with non-physician providers. This approach increased cost in the limited number of models available in the literature, and is discussed below.

A number of comments on the Work Group's report noted the absence of comprehensive, detailed information on the cost of the new duty hour standards. The reason for absence of cost data is the dynamic nature of this information, which must take into account the differences in local costs for both residents and their replacement providers, variations in patient care reimbursement methods that range from fee-for-service to full capitation; variation in state practice statutes and the extent to which non-physician providers are able to bill, and offsets in the cost of replacing residents from savings resulting from reduced diagnostic charges, length of stay, and other changes in the approach to care. Nationally or even for a given sponsoring institution, the global impact of this is difficult to quantify, and examples of institutional assessments of resident replacement costs are lacking to date, with most studies reporting data from individual clinical areas. For example, Franzini et al. in 1999 estimated the cost of educating residents in an anesthesiology program at $75,070 per resident per year, less than the value of services provided by each resident, estimated at $103,436 per year.[41] Other studies have produced similar results that overall have supported the contention that residents are lower cost providers of services than the practitioners that can replace them.[42,43] There are two examples of state-wide cost estimates specific to initiatives to reduce resident hours. The cost of additional staffing under New York State's duty hour regulation was estimated at more than $358 million in 1989.[44] A sizable portion was not related to reductions in duty hours but to increased faculty staffing to maintain continuous, on-site supervision of residents in several specialties. A 1990 study of the cost of a mandate by the California state legislature to limit resident work hours produced an estimated net cost of compliance with the proposed requirements, of approximately $75 million per year.[45] Weekly hours vary across specialties and hospital types, with hours the highest for general surgery, obstetrics-gynecology, surgical subspecialties and anesthesiology. However, duty hours for all specialties except dermatology and pathology, and all hospital types, exceeded 80 hours per week at some time. It is important to note that, unlike efforts to reduce the number of residency positions, limiting resident hours does not affect Medicare direct graduate medical education reimbursement. The reduced hours may produce reductions in rotations at some teaching hospitals, which would diminish the resident and intern to bed ratio and thus the indirect medical education payment, though this effect is very difficult to quantify prospectively.

All residents spend some amount of time performing activities that have relatively little relation to their education. Three categories of this work need to be considered. The first are tasks that do not require a licensed provider, which are addressed through the Institutional Requirements that stipulate that sponsoring institutions must provide services such as phlebotomy, diagnostic results reporting, and patient transport. Cost constraints in many teaching hospitals appear to have reduced the level of these services available, especially during night and weekend hours. Work in the second category includes activities that are potentially redundant and could be eliminated through re-engineering of the teaching environment, such as use of digitized radiological films that eliminate waiting on film retrieval. Efforts to do this are just being initiated, and may be

years away from producing data that will allow quantification of their effect. The third type entails repeated performance of activities that require a licensed provider, but that residents have become competent in. These activities need to be performed intermittently to maintain skills. The frequency with which this is necessary varies with the type of activity and with the ability and learning style of the individual resident.

Even when funding for replacement providers is available, replacement may not be an option because of shortages in health professionals. In the mid-1990s, a pilot program in New York State provided for temporary funding for replacement providers for programs that reduced their resident complement. Programs still experienced difficulties in finding replacement providers that were willing to work the hours and in the settings previously occupied by residents. Replacement of residents with non-physician providers is also complicated by state practice acts, and by the fact that most mid-level practitioners cannot perform the full range of activities that can be performed by a physician,[46] and by findings from the European community that showed that it is difficult to focus reductions in resident hours solely on "non-educational work."[47]

For some programs and institutions, the adoption of the new duty hour standards may create financial and/or operational hardships. Recognizing this, what is needed is credible, consistently collected information that allows an assessment of the magnitude of these costs across institutions. The ACGME will also solicit feedback to monitor the extent of these hardships, and will report the findings to its member organizations and appropriate federal entities. In order to secure additional resources in an environment of fiscal constraints, it may be necessary for the academic community to make legislators and the general public aware of the importance of appropriate funding of teaching hospitals' educational mission. More important, given the costs of the replacement options for resident services, what may be needed is a rethinking of care in teaching settings and the roles residents play in it. This is discussed further in the section on "learning laboratories."

12. Effect of the Standards on Continuity and Transfer of Care

An important element of resident education is learning how to provide patient care independently and competently, including how to foster continuity of care and how to appropriately transfer care to others. Both are critical in private or other practice settings. An important issue for residency programs involves allowing sufficient time for exchange of information at patient "hand-off," to allow this process to be completed from the patient care perspective, and to allow residents to become familiar with the exchange of information required to appropriately transfer the responsibility for direct patient care from one physician to another. To better address the issue of patient hand-off, research is needed about the process of transfer of information, and how to safeguard against missed information that could lead to medical errors, potentially using "human factor engineering." Appropriate patient hand-off is applicable in all health care settings, but it is especially critical in settings where learners are present (residents, and medical, nursing and students in other health professions).

After New York State implemented regulation of resident hours, some studies found continuity of care to be negatively affected.[48,49] There is some evidence from the European community that more frequent changes in the health care team lead to additional errors because of missed information during patient hand-off,[50] but scientific research in this area has yet to be done and strategies to provide for effective information exchange at patient hand-off are also lacking. Until they have been developed and tested, the existing practices, such as morning report, will continue to be the best approach for transferring information at patient hand-off. The ACGME also addresses this through standards that emphasize residents' responsibility for continuing care, requirements for back-up support "when patient care responsibilities are especially difficult or prolonged," and the added period of up to 6 hours for the transfer of care at the end of a continuous duty period.

13. The Existence of Learning Laboratories for Duty Hours

For the past 13 years, New York State has functioned as a learning laboratory for limitation of duty hours, because state regulation has placed limits on resident hours.[51] Years of experience with the regulation have

demonstrated that regulation is no ready solution, and that reducing resident hours is not easy. The ACGME cites residency programs in New York State with some regularity for violations of its requirements relating to duty hours. Between January 1998 and June 2001, 68 residency programs in New York State received such citations.[52] A report released in June 2002 indicated that the New York State Department of Health cited 54 of the state's 82 teaching hospitals for some degree of violation of New York's duty hour standards.[53] In the European nations, gains in resident working conditions, such as fewer working hours, shorter shifts and a day off after being on duty, seemed to have gained these advantages by a reduction in working hours with educational value, rather than by a reduction in routine work.[54] In addition, compliance with the European work hour limits for practicing was estimated to require a significant increase in the number of physicians, associated with an unsupportable rise in costs. The solution has been either a reduction in performance or performing work in "undocumented" hours, resulting in physicians to face a "conflict of legality and legitimacy."[55]

What has been lacking from both the New York and European experience is comprehensive data on the effect of the regulations, and information on what constituted effective, broadly applicable models for how to respond to limits on resident duty hours. In 1993, a study of the implementation of New York duty hour regulations recommended that studies be conducted to "determine staffing strategies that optimize quality of care for patients, as well as medical education and quality of life for house officers."[56] In 2002, these studies are just being initiated across the nation. They include research at Brigham and Women's Hospital, Boston, to assess the performance of a group of first-year residents in internal medicine working a standard intensive care unit schedule vs. a second group working a schedule capped at 12 hours, and other efforts. Their findings will be available in the future to refine the standards and institutional approaches to address resident duty hours in the contexts of creating an appropriate learning and patient care environment in settings where residents learn.

Knowledge about how institutions and programs create a better learning environment will need to be disseminated to allow others to learn from these models. The ACGME, its RRCs and the IRC are in an excellent position to identify and evaluate innovative models. They need to seek out this information in their review activities, evaluate these approaches, and disseminate information on those that have the most potential for wider adoption and adaptation. To date, the evidence from the field suggests there is a dearth of innovative approaches to address resident hours, and a clear need for research to develop new models of care in teaching settings that do not rely exclusively or nearly exclusively on residents to provide patient services. Efforts to re-design care in teaching settings may be the ultimate solution, but will require years to develop and test. The teaching hospital community needs more rigorous, formal approaches to develop functioning models of how institutions can improve the educational environment for their residents and the care process for their patients. The AAMC is currently working on such models, in collaboration with the Institute for Healthcare Improvement (IHI), for a grant from the Agency for Healthcare Research and Quality to formally address the issue of re-engineering in teaching settings. These activities to address resident duty hours on a larger scale by re-engineering the work of residents or the overall patient care activities in teaching settings can only be achieved through well thought-out, collaborative efforts within the academic community. An added undertaking for the ACGME, to be shared with the other organizations in the academic community, is fostering the development of these models for care in a system in which resident duty hours are capped.

14. The Need for a Uniform Metric to Assess the Effect of the Common Duty Hour Standards

In several places throughout this impact statement, the point was made that the effect of the new standards cannot be quantified at this time, as critical data elements are lacking. Thus, this impact statement lacks information on the impact of the new standards in important areas. An important component of the process to address resident duty hours will be collection of detailed information on resident hours; the components needed to comply with the standards and the associated costs; and the effect of the standards on education, patient care, access, patient safety, and resident well-being. Absence of this information from New York State's effort to regulate duty hours has reduced the value of this "learning laboratory" in offering guidance to the current national effort to address duty hours. This suggests a need for the collection of comprehensive data

to assess the effect of the common duty hour standards, beginning prior to the effective date of the standards, to allow an assessment of the state of resident education in the United States prior to the implementation of the duty hour reforms. It needs to apply a uniform metric to allow assessment across different specialties, types of programs, institutions and data collection and accounting practices. The data collected must be broader than merely counting resident hours, because the ACGME's experience with enforcement has shown that excessive resident hours are often a symptom of inadequate attention to the educational demands of residency, with citations often pertaining to the interface between duty hours and the overall learning environment for residents.

In the effort to define the data elements to be collected, prior studies can offer guidance, such as Lewin/ICF study that projected the impact of a 1989 mandate by the California state legislature to limit resident work hours. This sought answers to four questions: (1) the hours currently worked above the 80-hour weekly limits; (2) the mechanisms needed to comply with the new duty hour limitations; (3) the cost of compliance; and (4) the possible means for financing these costs within the constraints of the current patient service revenue-based system for payment of resident education? These areas can suggest the data elements to be collected. Developing an applicable, uniform metric will be complicated, and will benefit from the involvement of experts in education, patient care, and teaching hospital financing. Some information can be collected in conjunction with the accreditation site visit and associated ACGME activities. Site visitors interview 12,000 to 15,000 residents annually about their educational experience, and a survey will soon reach all residents of programs scheduled for accreditation review in a given year. Both data collection methods will use standardized questions regarding duty hours. Other data will need to be collected separate from the site visit. As the academic community seeks to assess the impact of the new standards, it would be best served by working with a standard set of data elements and a uniform metric to maximize the utility of the information.

15. Rationale for the Effective Date for the Common Duty Hour Standards

The rationale for the requested effective date of July, 2003, in large part is based on the need for program institutional efforts to re-engineer patient and educational practices in those programs where the implementation of the new standards requires a reduction in resident hours.

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[1] 42 CFR > 413.86 (Direct graduate medical education payments) refers to payments 'for the costs of approved residency programs.' 42 CFR > 413.86(a)(1).

[2] 'Hospitals licensed under this Act shall comply with the duty hour requirements for residents and interns established by the Accreditation Council for Graduate Medical Education.' 210 ILCS 85/6.14.

[3] Executive Council, Association of American Medical Colleges. Resident Supervision and Hours: Recommendations of the Association of American Medical Colleges. Journal of Medical Education. 1988; 63:417-426.

[4] Association of American Medical Colleges. AAMC Policy Guidance on Graduate Medical Education: Assuring Quality Patient Care and Quality Education. October 2001; Washington, DC.

[5] American Medical Association, Resident Physician Working Conditions. Report of the Council on Medical Education, CME Report 9-A-02, May, 2002; Chicago, IL.

[6] ACGME Data, July 2002, resident in New York State accounted for 14,950 of 95,250 residents in accredited program in Academic Year 2001/2002.

[7] 107th CONGRESS, 1st Session, H. R. 3236. The Patient and Physician Safety and Protection Act of 2001, November 6, 2001.

[8] Petition to the Occupational Safety and Health Administration (OSHA) filed by Public Citizen, the American Medical Student Association and the Committee of Interns and Residents (CIR); April 30, 2001.

[9] Agency for Healthcare Research and Quality, Evidence Report/Technology Assessment, No. 43, "Making Health Care Safer: A Critical Analysis of Patient Safety Practices," Table 55.2, A Comparison of non-local methods to

promote patient safety practices, page 606.

[10] ACGME Accreditation Data, July 2002.

[11] ACGME Accreditation Data for 1999, 2000 and 2001. ACGME, May 2002.

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