

Office of the President

Gary A. Ezzell, PhD Associate Professor Radiation Oncology Mayo Clinic Arizona 5777 E. Mayo Blvd. Phoenix, AZ 85054

Phone: 480-301-5413 Fax: 480-301-7687

Email: ezzell.gary@mayo.edu

June 8, 2012

American Association of Physicists in Medicine Statement on The Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Bill (H.R. 2104)

Chairman Upton, Ranking Member Waxman, Subcommittee Chairman Pitts, Subcommittee Ranking Member Pallone and members of this distinguished committee the American Association of Physicists in Medicine¹ (AAPM) commends you for this hearing to examine why we must establish standards for medical imaging and radiation therapy technologists.

AAPM is grateful for the bipartisan leadership of Reps. Whitfield and Barrow -- along with 20 Members of the full committee and 10 from the health subcommittee -- for supporting the *Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Act* (H.R. 2104). **AAPM strongly supports immediate passage of the CARE Act (H.R. 2104).**

Passage of the CARE legislation is critical to ensuring that essential standards for medical imaging and radiation therapy professionals are established.

The use of medical radiation occurs in radiology and radiation oncology practices with millions of people receiving that radiation to their benefit annually. Patients and the public may see the results of medical radiation, but few understand the details of the process and most assume that everyone who performs an imaging or radiation therapy procedure is competent and appropriately educated and trained. However, that is not always the case.

Each patient procedure is a complex multi-system process, in which each system involves a combination of technology and human actions. This process requires the coordination and participation of teams of clinical staff: physicians, medical physicists, dosimetrists, radiation therapists, radiologic technologists, information system engineers, linear accelerator and other vendor related engineers, nursing and support staff – all of these individuals and all of their effort must be focused on the diagnosis or treatment of each patient.

Qualifications of Personnel

Qualifications required for radiation team members are state regulated (by some but not all states) and widely variable. In many states, most of the team members including the Medical Physicist, Radiation Therapist and Medical Dosimetrist, have no specific qualifications required.² The CARE legislation - H.R. 2104 will require that minimum standards for personnel who perform, plan, evaluate, or verify patient dose for medical imaging examinations or radiation therapy procedures be established. **The intent**

¹ The American Association of Physicists in Medicine's (AAPM) is the premier organization in medical physics; a broadly-based ² There are specific requirements for individuals to use radioactive materials defined by the NRC and Agreement States. These address the use of radioactive materials only (not x-ray producing equipment) and do not specify the

of the bill is to cover all subspecialties of clinical medical physics. We believe that passage of this bill will enhance patient safety in the use of medical radiation. Thus, we urge that ALL individuals involved in these procedures be included in this legislation. The Federal Government pays for a substantial portion of these radiation-related medical services in the United States, and thus has a strong interest to assure that the procedures are properly administered by qualified staff.

The Medical Physicist

Medical physicists are uniquely positioned across medical specialties due to our responsibility to connect the physician to the patient through the use of radiation producing technology in both diagnosing and treating people. The responsibility of the medical physicist is to assure that the radiation prescribed for imaging and radiation therapy is delivered accurately and safely.

AAPM has devoted a substantial part of its energy to the creation and recognition of the Qualified Medical Physicist, or QMP. These physicists have a unique combination of education in the principles of physics, radiobiology, human anatomy, physiology and oncology through a graduate degree, as well as clinical training in the applications of radiation physics to medicine, such as the technologies of medical imaging and treatment delivery, radiation dose planning and measurement, as well as safety analysis and quality control methods. Following this, an individual demonstrates competence in his/her discipline by obtaining board certification (currently offered for ionizing radiation imaging and radiation therapy through the American Board of Radiology). Certification is a rigorous, multi-year process that requires considerable supervised clinical experience as well as passage of written and oral examinations. The AAPM recognizes a Qualified Medical Physicist for the purpose of providing clinical medical physics services, as an individual who is board-certified in the appropriate medical subfield and has documented continuing education.

Current Challenges

All of the efforts mentioned are aimed at providing safer, more accurate and more effective patient procedures using medical radiation and we will continue to work toward achieving the absolute minimum error rate. However, there are some challenges we face in trying to meet these goals:

- While the AAPM has a clear definition of a Qualified Medical Physicist, there is no consistent national recognition of this credential.
- Medical physicists are licensed in only 4 states (TX, NY, FL, HI) and regulated at widely varying levels in the other 46 states.

As we stated in our letter dated April 7, 2010 to then Chairman Pallone as follow up to the February 26, 2010 Hearing on *Radiation Use in Medicine: An Overview of the Issues*, accreditation is very important and perhaps is the mechanism that could ensure that qualified individuals are staffed in appropriate numbers, and perform procedures based on national consensus guidelines. Accreditation must be tied to reimbursement in a hybrid of the *Mammography Quality Standards Act of 1992*³ (MQSA) (P.L. 102-539) and *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA) (P. L. 110-275), MIPPA models.

The difference between MQSA and MIPPA is in the prescriptiveness of the regulations. MQSA is much more prescriptive and MIPPA, much less so. We believe that the required qualifications for individuals to deliver radiation should be mandatory by federal legislation. This is consistent with the CARE legislation – H.R. 2104.

³By MQSA we mean as amended by the Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (MQSRA).

It is clear that MIPPA as currently in place does NOT require consistent qualifications for individuals who are involved in the delivery of medical radiation, especially in the case of medical physicists. **Thus immediate passage of CARE legislation - H.R. 2104 is necessary**. Legislation should specify that the medical community develop minimum staffing levels by qualified individuals and specific practice guidelines to be followed. This means that it would be expected that the medical community adopt consensus standards of practice by which uniform national accrediting would be accomplished. Subsequently, a robust combination of mandatory qualifications and consistent accreditation, required for payment by the Centers for Medicare & Medicaid Services (CMS), would improve patient safety and care.

Future Directions

Although rare, medical errors can be devastating. We all wish that no one ever made a mistake, even more so, no event that could injure another person. But errors still can and do occur due to a combination of unlikely events occurring sequentially or simultaneously, many times under unusual circumstances that involve the complex systems in the delivery of this type of medical care.

AAPM stated in our <u>testimony in 2010 before this subcommittee</u> that significant effort has been placed and progress is being made in the following areas, but that we can and must do more to improve the quality of care and increase patient safety. This is still true today. We continue to believe that together we all (medical radiation team members, professional associations, manufacturers and government) must:

- 1. Provide robust, consistent, and financially stable education, training and clinical experience for the Qualified Medical Physicist in clinical practice. To achieve this, we must:
 - continue strong support for the AAPM 2014 initiative, which will meet the goal of requiring
 every candidate who applies to take the American Board of Radiology medical physics exams to
 receive structured didactic medical physics education and complete an accredited clinical
 residency prior to completing the certification exam beginning in 2014 and
 - obtain recognition for medical physics residency programs for Centers for Medicare & Medicaid (CMS) reimbursement equivalent to that of physician residencies.
- 2. Strive for nationally consistent recognition of the Qualified Medical Physicist and equivalent competency for all medical radiation team members;
 - pass H.R. 2104, Consistency, Accuracy, Responsibility and Excellence (CARE) in Medical Imaging and Radiation Therapy Act and specifically require that all medical physicists involved in medical imaging and radiation therapy be included in the bill and
 - facilitate consistent implementation of CARE nationally.
- 3. Provide national practice guidance in radiation oncology and medical imaging based on consensus and consistent minimum quality standards. Standards must:
 - recognize qualified individuals; specifically the Qualified Medical Physicist,
 - establish minimum staffing levels,
 - require that Qualified Medical Physicists be involved in the supervision of the processes that determine image quality and patient dose/exposure,
 - define procedure-specific guidance, including explicit process communication within and beyond the medical team, and
 - undergo periodic review with timely amendment or replacement when necessary.
- 4. Establish a rigorous minimum standard for accrediting clinical practices that specifically includes the oversight of dose and quality assurance for medical imaging and radiation therapy technology. This standard should require that:

- sites have work performed per national practice guidance by qualified individuals with appropriate staffing levels,
- additional accreditation requirements are established for highly specialized procedures, and
- practice reviews are performed by qualified individuals.
- 5. Link Centers for Medicare & Medicaid (CMS) reimbursement to rigorous practice accreditation for all medical imaging and radiation therapy practices to insure steps one through four above are followed.
- 6. Create a national data collection system to learn from actual and potential adverse events in the medical use of radiation. The system must:
 - allow reporting by medical staff and manufacturers and others in a complete and consistent manner,
 - be searchable to identify patterns, risks and corrective actions and to provide education, and
 - require a partnership between all involved (federal and state government, manufacturers, users, patient advocates).
- 7. Improve the effectiveness of product clinical quality, application and integration review in the regulatory equipment clearance process by partnering with the U.S. Food and Drug Administration (FDA), the International Electrotechnical Commission, (IEC) and manufacturers.

Conclusion

In summary, the AAPM believes that patient safety in the use of medical radiation will be increased through: consistent education and certification of medical team members, whose qualifications are recognized nationally, and who follow consensus practice guidelines that meet established national accrediting standards. That is why we urge you to move *The Consistency, Accuracy, Responsibility and Excellence in Medical Imaging and Radiation Therapy Bill* (H.R. 2104) forward for quick passage in this session and look forward to working with you on other legislation to further secure quality patient care.

If you have questions or would like to discuss further, please contact me or Lynne Fairobent, Manager of Legislative and Regulatory Affairs at 301-209-3364 or via email: lynne@aapm.org.

Sincerely,

Lay a Gell

Gary A. Ezzell, Ph.D., FAAPM