CMS Releases Final Rule on Direct Supervision

On May 7, the Centers for Medicare & Medicaid Services (CMS) released the Final Rule for Part II Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction. The new final rule permits trained nuclear medicine technologists in hospitals to prepare radiopharmaceuticals for nuclear medicine without the constant presence of a supervising physician or pharmacist, which promises to speed services to patients, particularly during off hours. This new rule finalized the previously proposed change of removing the term "direct" from the current requirement at §482.53(b)(1) and will go into effect on July 12. In material released with the final rule, CMS stated: "We received several comments on our proposed change to §482.53, primarily from professional organizations, hospitals, and hospital systems, and individual nuclear medicine technologists. All commenters were supportive of the proposed change with no commenters opposed."

Section §482.53(b)(1) had originally required that in-house preparation of radiopharmaceuticals be performed by or under the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy (i.e., one of these professionals would have to be physically present in the hospital and immediately available during preparation of all radiopharmaceuticals). Hospitals had reported to CMS that direct supervision requirement is extremely burdensome when the presence of a pharmacist or physician is required for the provision of off-hour nuclear medicine tests requiring only minimal in-house preparation of radiopharmaceuticals. As a result of comments from SNMMI and other groups, CMS explained in its 2013 Proposed Rule that: "We propose to revise the current requirement at §482.53(b)(1) by removing the term 'direct.' The revised requirement would then require that in-house preparation of radiopharmaceuticals be performed by, or under the supervision of, an appropriately trained registered pharmacist or doctor of medicine or osteopathy. The revision to 'supervision' from 'direct supervision' would allow for other appropriately trained hospital staff to prepare in-house radiopharmaceuticals under the oversight of a registered pharmacist or doctor of medicine or osteopathy, but it would not require that such oversight be exercised by the physical presence in the hospital at all times of one of these professionals, particularly during off-hours when such a professional would not be routinely present." CMS estimated that U.S. hospitals will save $76.8 million with this change (calculated as 1.6 million off-hour procedures × $192/h salary for MD/DO/PharmD × 15 min for direct supervision).

Centers for Medicare & Medicaid Services
SNMMI

Update on Kinevac Shortage

On May 23, Bracco Diagnostics Inc. (Monroe Township, NJ) published a customer letter with updates on continuing challenges in Kinevac (sincalide injection) availability. All remaining Kinevac inventory was depleted in April, with all unfulfilled orders placed on a back order list. In the customer letter, Kim Giordano, Bracco vice president and general manager for nuclear medicine, provided background on the shortage of the pharmaceutical, which is used in hepatobiliary imaging in more than 630,000 U.S. patients each year. The contract manufacturer for Kinevac, Jubilant Hollister–Stier has experienced manufacturing delays and interruptions and has been unable to achieve a routine production schedule. Issues have focused on general compliance review at the manufacturing site and "do not relate specifically to the quality or safety of Kinevac."

Bracco has been working with the U.S. Food and Drug Administration to support a product shortage review and define a manufacturing pathway for Kinevac. Giordano noted that SNMMI, the American College of Radiology, and members of the nuclear medicine community "have communicated to the authorities the clinical relevance of Kinevac and expressed their concern about this product shortage. We appreciate your continued advocacy for this important product."

Bracco anticipates that the next Kinevac lot will be commercially available in the third quarter of 2014. Distribution may be limited, with supplies rationed until sufficient inventory has been replenished through a routine production schedule. More definitive timelines will be released by Bracco as they become available.

Bracco Diagnostics Inc.

New DOE Commission on National Labs

On May 20, U.S. Department of Energy (DOE) Secretary Ernest Moniz announced the launch and initial membership of the Commission to Review the Effectiveness of the National Energy Laboratories, a congressionally mandated committee that will evaluate the effectiveness of the 17 DOE national laboratories. "The Energy Department's national laboratories are a leading force in driving U.S. scientific and technological innovation and advancing the department's science, energy, environmental, and national security missions," said Secretary Moniz. "I want to thank the commission members for their expertise and look forward to working with them to ensure we leverage the national laboratories' unique capabilities to fulfill our missions."

This independent commission will examine the priorities of the labs to determine whether these are in line with the broader strategic priorities of the DOE. The commission will conduct a 2-part study, with the first phase scheduled to be complete in February 2015. The Commission will be cochaired by Jared Cohon, PhD, President Emeritus and Professor of Civil and Environmental

Engineering at Carnegie Mellon University, and T.J. Glauthier, MBA, president of TJG Energy Associates, LLC. Other commission members include: Norman Augustine, MSE, chair of the U.S. Human Space Flight Plans Committee, NASA, and former chair, Lockheed Martin; Wanda Austin, PhD, president and CEO, The Aerospace Corporation; Charles Elachi, PhD, MBA, director of the Jet Propulsion Laboratory, NASA; Paul Fleury, PhD, Frederick W. Beinecke Professor of Engineering and Applied Physics, Yale University; Susan Hockfield, PhD, professor of neuroscience and president emerita, Massachusetts Institute of Technology; Richard Meserve, JD, PhD, president, Carnegie Institution for Science and chair of the Environmental Stewardship Subcommittee of the Secretary of Energy Advisory Board; and Cherry Murray, PhD, dean, Harvard School of Engineering and Applied Sciences.

U.S. Department of Energy

Joint Commission Delays Change Implementation

In December 2013, the Centers for Medicare & Medicaid Services (CMS) updated its interpretive guidelines and survey procedures for Medicare Condition of Participation, which addresses maintaining hospital facilities, supplies, and equipment at an acceptable level of safety and quality. CMS guidance clarifies the circumstances in which a hospital may adjust its maintenance, inspection, and testing activities for facility and medical equipment from those recommended by manufacturers. As a result of this clarification, The Joint Commission announced on May 16 that 2 new elements of performance for deemed status hospitals are needed. In the first element, hospitals must inspect, test, and maintain the following in accordance with manufacturers' recommendations: medical lasers, imaging and radiology equipment (whether used for diagnostic or therapeutic purposes), and new medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies. Documentation of maintenance history may include: records provided by the hospital's contractors, information made public by nationally recognized sources, and/or records of the hospital's experience over time. In the second element, hospitals must inspect, test, and maintain new operating components of utility systems in accordance with manufacturers' recommendations when insufficient maintenance history exists to support the use of alternative maintenance strategies.

The Joint Commission also announced that implementation of changes to standards for diagnostic imaging services, first published in December 2013, would not be effective as planned on July 1, 2014. Instead, these and other changes will be phased in by 2015. Initial standards changes were to focus on CT, nuclear medicine (including PET), and MR services, with a second phase focusing on fluoroscopy, minimum qualifications for clinicians who perform imaging exams, and cone-beam CT in dental offices and oral–maxillary surgery practices. The current goal is to implement all revised standards by July 2015, with an accompanying release of a comprehensive set of requirements. The delay in implementation stems from stakeholder feedback pointing out areas in which changes were either problematic or unclear. In the interim, the Joint Commission will be collecting additional information on several critical areas of radiation safety, including: documentation of radiation dose, annual equipment performance evaluations by a medical physicist or MR scientist, and minimum qualifications for radiologic technologists who perform CT examinations.

The Joint Commission

2014 National AD Plan

The U.S. Department of Health and Human Services (HHS) on April 29 released *The National Plan to Address Alzheimer's Disease [AD]: 2014 Update* and reviewed progress toward accomplishing goals set in the 2011 National Alzheimer's Project Act. The 2014 Plan was developed with input from experts in aging and AD from federal, state, private, and nonprofit organizations, as well as caregivers and individuals with the disease. The plan outlines goals to: find ways to prevent and effectively treat AD by 2025, enhance care for AD patients, expand support for individuals with dementia and their families, improve public awareness, and carefully track data to support these efforts.

Highlights of achievements in the past year include: identification of 11 AD risk genes, identification of new insights into disease pathways and possible drug targets, training and support on dementia to more than 23,000 health care providers, focused and coordinated public–private efforts that have reduced inappropriate use of antipsychotics among long-stay nursing home residents with dementia by almost 14%, and funding to states for development of dementia-capable long-term services and support systems. The 2014 plan outlines the following action steps to be led by HHS to better research, treat, and prevent AD: acceleration of efforts to identify the earliest stages of AD and to develop and test targets for intervention; moving research and care forward by increasing collaboration in science, data sharing, and priority setting among AD experts, health care providers, and caregivers; expansion of current work to strengthen dementia care guidelines and quality measures, including meaningful outcomes for people with dementia and their families; helping health care providers to better address ethical considerations related to caring for people with dementia, including how to balance privacy, autonomy, and safety; and enhancing support for global collaboration on dementia.

HHS noted in the plan that it will expand its work to identify imaging and biomarkers through the public–private Alzheimer's Disease Neuroimaging Initiative. This partnership will help identify and monitor disease progression, even in early and presymptomatic stages. The Accelerating Medicines Partnership (AMP) will enhance this effort through a government, industry, and nonprofit federation focused on identifying and validating the most promising biological targets of AD. AMP proposes to identify biomarkers that can predict clinical outcomes by incorporating selected biomarkers into 4 National Institutes of

Health–funded clinical trials. AMP will then support a large-scale analysis of donated AD patient brain tissue samples to validate biologic targets previously shown to play key roles in disease progression and to improve understanding of the molecular pathways involved in the disease to identify new therapeutic targets. The complete *National Plan to Address Alzheimer's Disease: 2014 Update* is available at: http://aspe.hhs.gov/daltcp/napa/NatlPlan2014.shtml.

U.S. Department of Health and Human Services

Global Radiopharmaceutical Outlook

Medical Radiation Strategic Intelligence Experts (MEDraysintell; Louvain-la-Neuve, Belgium, and Lalaye, France) provided details on May 5 on their projection that the global nuclear medicine market will reach $24 billion by 2030, with an annual average growth rate of 11%. This growth will be driven by expansion in the therapeutic radiopharmaceutical market. In the proprietary report, *Opportunities in Nuclear Medicine, Edition 2014*, MEDraysintell points to encouraging results with ^{223}Ra-dichloride. First-quarter 2014 revenues for Xofigo (Bayer Healthcare; Leverkusen, Germany) reached $49 million, an increase of 24% over the last quarter of 2013, with projected U.S. sales of >$200 million for all of 2014.

In 2013 ~60% of the world market value was based on ^{99m}Tc; ^{18}F-FDG accounted for 20% and therapeutic radiopharmaceuticals for only 4% of the market. Increasing use of PET in cardiology and neurology procedures was also cited as a driver in industry growth, although overall average annual expansion of only 5% is predicted for diagnostic radiopharmaceuticals. The 800-page report provides an overview of data on more than 300 radiopharmaceuticals and radionuclides and more than 130 companies and institutions active in the nuclear medicine market. More information and a table of contents are available at: www.medraysintell.com/Nuclear_Medicine.html.

Medical Radiation Strategic Intelligence Experts

NIH Women's Health Initiative: Health and Financial Success

The National Institutes of Health (NIH) announced on May 5 that an in-depth analysis of final data from one of the Women's Health Initiative (WHI) Postmenopausal Hormone Therapy Trials found that investment in WHI resulted in a return of $140 in net economic value for each dollar invested in the trial. The WHI, sponsored by the NIH National Heart, Lung, and Blood Institute, was a multifaceted 15-y research program to address the most common causes of death, disability, and poor quality of life in postmenopausal women, including cardiovascular disease, cancer, and osteoporosis. An article by a consortium of WHI investigators in the May 6 issue of *Annals of Internal Medicine (*2014;160:594–602) looked at disease incidence, direct medical expenditure, quality-adjusted life years (a measure of disease burden, including quality and length of life), and net economic return on investment for an estrogen plus progestin clinical trial between 2003 and 2012. The researchers' analysis was based on a disease simulation model that used an estimate of approximately 39.1 million combined hormone therapy–eligible women. The analysis found that the guidance provided by the WHI clinical trial results led to: 76,000 fewer cases of cardiovascular disease, 4.3 million fewer combined hormone therapy users, 126,000 fewer breast cancer cases, 145,000 more quality-adjusted life years, and direct medical expenditure savings of $35.2 billion. However, the analysis also concluded that guidance provided by these WHI clinical trial results led to 263,000 more fractures (hip, vertebral, and other osteoporotic fractures). The researchers calculated the total net economic return of the trial, which cost $260 million in inflation-adjusted dollars, at $37.1 billion.

National Institutes of Health

ANSTO to Increase ^{99}Mo Production

The Australian Nuclear Science and Technology Organisation (ANSTO) announced on May 13 its intention to triple the country's production of ^{99}Mo and "become a major world supplier of radiopharmaceuticals." ANSTO reported that work has begun on a new $168 million nuclear medicine manufacturing facility at the organization's southwestern Sydney campus. "World demand for nuclear medicine is growing as more countries develop modern medical systems, but at the same time supplies are under threat—with the research reactors that produce around 70% of this medicine due to shut in the next few years," said Ian Macfarlane, Australian Minister for Industry. "By investing in this new facility, the Australian Government has positioned Australia as a global leader in the manufacture of nuclear medicines." ANSTO currently produces about 550,000 doses of ^{99}Mo annually. The project will use low-enriched uranium and will include a nuclear medicine manufacturing plant and a waste treatment plant. The target date for operational activities is 2016.

Australian Nuclear Science and Technology Organisation