Enhanced Privacy Standards

The U.S. Department of Health and Human Services (HHS) announced on January 17 changes in requirements for privacy and security safeguards for consumer health data. The final rule enhances a patient's privacy protections, provides individuals new rights to their health information, and strengthens the government's ability to enforce the law. In the past, Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules have focused on health care providers, health plans, and other entities that process health insurance claims. The most recent changes expand many of the requirements to business associates of these entities, such as contractors and subcontractors, that receive protected health information. Some of the largest breaches reported to HHS have involved business associates. Penalties have been increased for noncompliance based on the level of negligence, with a maximum penalty of $1.5 million per violation. The changes also strengthen the Health Information Technology for Economic and Clinical Health (HITECH) Breach Notification requirements by clarifying when breaches of unsecured health information must be reported to HHS.

Individual rights have been expanded to ensure that a patient can ask for copies of his or her electronic medical record in an electronic form and that individuals who pay by cash can instruct their provider not to share information about their treatment with their health plans. The final omnibus rule sets new limits on how information is used and disclosed for marketing and fundraising purposes and prohibits the sale of an individuals' health information without permission.

The final rule also "streamlines" individuals' ability to authorize use of their health information for research purposes. The rule makes it easier for parents and others to give permission to share proof of a child's immunization with a school and gives covered entities and business associates up to 1 y after the 180-d compliance date to modify contracts to comply with the rule.

The final omnibus rule is based on statutory changes under the HITECH Act, enacted as part of the American Recovery and Reinvestment Act of 2009, and the Genetic Information Nondiscrimination Act of 2008, which clarified that genetic information is protected under the HIPAA Privacy Rule and prohibits most health plans from using or disclosing genetic information for underwriting purposes.

U.S. Department of Health and Human Services

NIH AD Cooperative Study

The National Institute on Aging (NIA), a part of the National Institutes of Health (NIH), announced on January 14 the award of funding for 4 major research projects to be conducted by the Alzheimer's Disease Cooperative Study (ADCS), a national consortium of academic medical centers and clinics set up by NIH in 1991 to collaborate on development of AD treatments and diagnostic tools. In these projects, the ADCS will test drug and exercise interventions in individuals in the early stages of the disease, examine a medication to reduce agitation in individuals with Alzheimer dementia, and test a cutting-edge approach to speed testing of drugs in clinical trials. PET and MR brain imaging will play key roles in at least 2 of the 4 studies.

The ADCS will receive $11 million in fiscal year 2013, and the effort could total as much as $55 million over the projected 5-y span of the project. The consortium, coordinated by the University of California, San Diego, and led by Paul Aisen, MD, includes more than 70 research sites in the United States and Canada, with a focus on advancing studies of interventions that might not otherwise be tested by industry. In addition to testing new therapies, the ADCS mission includes design of new instruments for use in clinical studies and the development of novel and innovative approaches to AD clinical trial design and analysis. The ADCS also works to enhance the recruitment of minority groups into AD studies. To date, the ADCS has conducted 30 studies (23 drug studies and 7 instrument development protocols).

"The ADCS is a key initiative in the federal program to discover, develop, and test new Alzheimer's treatments and diagnostic tools. Over the years, it has proved invaluable in advancing our understanding about the disease and how to conduct research in this challenging area," said NIA Director Richard J. Hodes, MD. "I am particularly excited that this round of studies will use what we have learned by testing interventions presymptomatically, as early as we can in the development of the disease, where we now think the best hope lies for keeping Alzheimer's at bay."

National Institute on Aging

NRC Licensing Decision on $^{223}RaCl_2$

Pursuant to a November 20 report from its Advisory Committee on the Medical Uses of Isotopes (ACMUI), the U.S. Nuclear Regulatory Commission (NRC) announced in January that licensing of $^{223}RaCl_2$ is appropriate under Title 10 of the Code of Federal Regulations (10CFR) Part 35, Subpart E "Unsealed Byproduct Material—Written Directive Required." Under these regulations, physicians who are approved for the use of any β-emitter or any photon-emitting radionuclide with a photon energy $<$150 keV under 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required," or 10 CFR 35.396, "Training for the parenteral

administration of unsealed byproduct material requiring a written directive," can be authorized for medical use of $^{223}RaCl_2$.

In its summary statement, ACMUI noted that $^{223}RaCl_2$, "currently a nonapproved investigational agent undergoing clinical trials in the United States and elsewhere, represents a first-in-class, α-particle–emitting therapeutic" with indications for treatment of skeletal metastases in advanced, castrate-resistant prostate cancer, delivering high biologically effective doses to malignant cells in bone with relative sparing of hematopoietic marrow and other normal tissues. In making its recommendation to expand licensing to authorized users of radiopharmaceuticals, the committee noted that "$^{223}RaCl_2$ does not differ significantly in terms of clinical use and management, radiation safety, and logistics from currently approved radiopharmaceuticals." The complete ACMUI report is available at: http://pbadupws.nrc.gov/docs/ML1232/ML12326A568.pdf.

U.S. Nuclear Regulatory Commission

Advanced Imaging and Declining Cancer Rates

The Medical Imaging & Technology Alliance (MITA) released a statement on January 17 based on material from the *Cancer Facts & Figures 2013* report released by the American Cancer Society (ACS). The statement focused on the contribution of medical imaging technologies to declining U.S. cancer death rates. MITA called for expansion of Center for Medicare & Medicaid coverage for both CT colonography to detect colon cancer and low-dose CT lung imaging to detect lung cancer in at-risk populations. "Medical imaging today is essential to diagnosing and treating a variety of cancers at a relatively low cost," said Gail Rodriguez, MITA executive director. "To continue this positive trend and further increase access to early disease detection, Medicare and insurers must cover imaging procedures, such as CT colonography and low-dose lung CT, which are medically proven to reduce mortality by improving early disease detection."

The new ACS report found that cancer death rates decreased from their peak of 215.1 per 100,000 individuals in 1991 to 173.1 per 100,000 in 2009. Death rates continue to decline for lung, colorectal, breast, and prostate cancers. Clinical study results cited in detail by MITA suggest that with the utilization of advanced medical imaging technologies death rates will continue to decline. "The proof lies in the statistics: advanced medical imaging promotes early detection and more effective treatment, ultimately saving lives," said Rodriguez. "It is critical that policymakers keep the evidence in mind when making future coverage decisions that will impact access to life-saving technologies."

The Medical Imaging & Technology Alliance

American Taxpayer Relief Act

On January 1, both the Senate and the House of Representatives passed H.R. 8, the American Taxpayer Relief Act of 2012. This legislation most notably avoided across-the-board tax increases that were set to take effect on January 1. H.R. 8 also blocked for 1 y a scheduled 27% cut in reimbursements for Medicare physicians. This "patch" will be paid for by cuts and adjustments to other provider payments.

According to the Congressional Budget Office, the cost of this 1-y patch will be $25.1 billion over 10 y, and Medicare offsets and other provisions would reduce spending by $25.7 billion over the same time period. Congress has attempted to work on the challenges of the Sustainable Growth Rate (SGR) requirements and pass a permanent fix to the annual threat of significant reimbursement cuts but have been unable to agree on a solution. As a result they have instead relied on a series of temporary patches. To help pay for the current 1-y SGR freeze, Congress approved increasing Medicare's equipment utilization assumption for advanced imaging services from 75% to 90%, effective with the 2014 Medicare Physician Fee Schedule.

A summary of health care–related provisions in the American Taxpayer Relief Act of 2012 is available on the SNMMI site at: http://interactive.snm.org/docs/Payment%20Offsets.pdf.

SNMMI

Neurologists Plan to Use Amyloid Imaging

A large majority of the nation's top neurologists say they would use a recently approved amyloid detection brain scan to evaluate their patients for Alzheimer disease (AD) if the scan were paid for by health insurance, according to a survey recently published in the *Journal of Alzheimer's Disease* (2013;33:445–450). The survey results were also covered in a press release from the Oregon Health & Science University (OHSU) Brain Institute. The survey did not specifically mention ^{18}F-florbetapir, recently approved by the U.S. Food and Drug Administration for PET estimation of β-amyloid neuritic plaque density in patients with cognitive decline. Instead, the instrument asked participants to base their responses on the assumption that "some form of amyloid imaging is U.S. Food and Drug Administration approved, available at your institution, and covered by insurance."

Given these assumptions, more than 83% of neurologists surveyed responded that they would use the scan to evaluate their patients for AD. Reimbursement was clearly a critical factor in these assumptions. "As with all new medical technologies, cost will undoubtedly be an important factor in initial uptake of amyloid imaging," said Eran Klein, MD, PhD, lead author of the article and an assistant professor of neurology at OHSU. "Nonetheless, it is clear from our survey that experts in the field of dementia currently see clinical value in testing for brain amyloid and plan to add it to their tools for understanding and diagnosing Alzheimer's dementia."

The survey also found that 92% of responding neurologists believed patients should be counseled on the

meaning of potential results before undergoing imaging. Approximately 77% of neurologists planned to use the scan to bolster confidence in diagnosis of AD, and 73% planned to use the scan to rule out the disease. Younger neurologists were more likely to use such scans than older neurologists. All respondents with fewer than 5 y of experience indicated that they planned to use amyloid imaging, whereas 70% of neurologists with 20 y or more in practice planned to use the scans. The survey instrument is available for review at: www.j-alz.com/issues/33/klein_supplement.pdf.

Journal of Alzheimer's Disease

NIH Launches PD Biomarker Initiative

A new initiative launched on January 15 by the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health, is designed to accelerate the search for biomarkers in Parkinson disease (PD) by improving collaboration among researchers and encouraging patients to become involved in clinical studies. The Parkinson's Disease Biomarkers Program (PDBP) will support efforts to invent new technologies and analysis tools for biomarker discovery, to identify and validate biomarkers in patients, and to share biomarker data and resources across the PD community.

"Our goal is to accelerate progress toward a robust set of biomarkers for PD by supporting researchers who have strong leads or innovative approaches, bringing them together, and making it easier for them to share and analyze data across studies," said NINDS director Story Landis, PhD.

Nine research teams have been funded through the program so far. These include groups from Emory University (Atlanta, GA), University of Pennsylvania (Philadelphia), Johns Hopkins University (Baltimore, MD), University of Texas Southwestern Medical Center at Dallas, Pennsylvania State University (University Park), Battelle Pacific Northwest Laboratories (Richland, WA), Brigham and Women's Hospital/Harvard University (Boston, MA), University of Alabama at Birmingham, and University of Washington (Seattle). Four of the initial projects are associated with the NINDS Udall Centers of Excellence for Parkinson's Disease Research.

To support collaboration across these projects and others, the PDBP is introducing a new online data sharing platform, the Data Management Resource (DMR), which was developed by the NIH Center for Information Technology. PDBP investigators are required to share data through the DMR. In the future, this requirement will also apply to investigators funded through the NINDS Udall Centers. Investigators not funded through these programs will be able to access data and request biologic samples, and will be encouraged to submit their own samples. Biologic samples submitted through the PDBP will be banked by the NINDS Human Genetics Repository at the Coriell Institute for Medical Research (Camden, NJ).

The DMR will post updates about ongoing research, including notices about studies that are actively recruiting and results funded through the PDBP. "This Web site is not just a database, but a way to communicate with the public and the research community about our progress," said Katrina Gwinn, MD, PhD, of NINDS.

National Institute of Neurological Disorders and Stroke

Enrollment in Tech Programs

The American Society of Radiologic Technologists (ASRT) announced on January 14 the results of a recent study showing that the number of students entering radiographic technology programs decreased in 2012 but rose slightly for nuclear medicine programs. The report, titled *ASRT Enrollment Snapshot of Radiography, Radiation Therapy, and Nuclear Medicine Technology Programs*, indicated that an estimated 15,675 radiography students entered programs in 2012 compared with 16,454 in 2011, representing a 4.7% decrease. The number of students entering nuclear medicine programs jumped from 1,175 in 2011 to 1,407 in 2012, a 19.7% increase. The report is based on the results of an annual survey of programs in the United States and Canada.

Many training programs remain at capacity. According to the survey, radiography program directors reported turning away 16,323 qualified students in 2012. Nuclear medicine programs passed on 232 student applicants. "According to the study results, future enrollment numbers will depend on the discipline," said ASRT Director of Research John Culbertson. "For example, 89% of radiography program directors said they'll likely keep entering class enrollment numbers the same in the coming years. . .and almost 18% of nuclear medicine program directors reported that they'll increase enrollments." The survey also outlined job placement rates for recent program graduates. Almost 85% of radiography students found employment in their respective disciplines within 6 mo of graduating in 2011. However, only 57.2% of nuclear medicine students found employment within that period. "The job placement rates highlighted in this survey are comparable to what we've found in our vacancy rate data, which shows that the job market is still very tight," said Culbertson.

The ASRT has published the training program survey for 12 y. As a result, the new report includes a summary of longitudinal enrollment trends from 2001 to 2012.

American Society of Radiologic Technologists

Revised CMS Guidance for Stage 2 Meaningful Use

On January 8, the Centers for Medicare & Medicaid Services released new guidance regarding the Stage 2 criteria for the Medicare and Medicaid Electronic Health Record Incentive Programs, also known as meaningful use. The revised guidance (summarized in

a brief FAQ available at: https://questions.cms.gov/faq.php?id=5005&faqId=7731) clarifies confusion over the fact that a single Provider Enrollment, Chain, and Ownership System (PECOS) code did not exist for the entirety of radiology. It also clarifies which radiologists are eligible to apply for a hardship exception to avoid Medicare payment adjustments in 2015. Under the revised guidance, the PECOS code now lists radiology as including diagnostic radiology, interventional radiology, and nuclear medicine.

SNMMI

Molecular Imaging Workshop in India

A 1-day preconference workshop on "Molecular Imaging in Oncology" was held on November 21 ahead of the International Conference on Radiation Biology 2012 at the Advanced Centre for Treatment Research and Education in Cancer in Mumbai, India. The aim of the workshop was to introduce the fundamentals and various applications of molecular imaging, along with hands-on demonstrations of various imaging techniques. The first session reviewed applications of nuclear imaging in clinical oncology and preclinical studies. The second session was dedicated to the principles, techniques, and in vitro and in vivo applications of bioluminescence, fluorescence, and multimodal imaging, including nanotechnology. The talks were followed by a laboratory demonstration of microscopy, preclinical PET, and fluorescence imaging techniques.

Sushmita Chatterjee MSc
Mumbai, India
Rao V.L. Papineni, PhD
Branford, CT

IN MEMORIAM

Paul Numerof, PhD 1922–2013

Paul Numerof, PhD, a nuclear pioneer and member of the Manhattan Project research team, died on January 12 in St. Louis, MO. He grew up in Philadelphia (PA), the son of Russian immigrants. He graduated from Temple University and enlisted in the U.S. Army in World War II. His interest in chemistry led to an invitation to join more than 2,500 chemists, physicists, mathematicians, and others in Los Alamos, NM, for what would become the Manhattan Project. Numerof led a team that developed the process for preparation of weapon-grade uranium.

At the end of the war, he enrolled in Carnegie Institute of Technology and completed a doctorate in chemistry. He then worked for E.R. Squibb and Sons in early medical isotope investigation and sales and went on to lead the Squibb Division of Nuclear Medicine. He developed small nuclear isotope generators for hospital use and lectured and published widely on medical isotopes. After 25 years with Squibb, retiring as vice president of the Hospital Division, Numerof left to serve as a private consultant for major corporations. He developed techniques to neutralize hazardous chemicals spills for industries and emergency response units. He taught college level mathematics, management, and marketing, and became a full professor at Pace University. In 1990, he moved to Vail, CO, where he was an ardent hiker, skier, and naturalist, as well as a popular lecturer and tutor at Vail Mountain School and Colorado Mountain College.

He traveled the world to every continent, including Antarctica, which he visited twice. He was a lover of classical music and an admirer of Native American art. With his wife, he established The Collector's Room, a gallery in Vail.

In 2007 Numerof published a memoir of his participation in and perceptions of the Manhattan Project, titled *In August 1945*.

Arthur Weis, JD, PhD 1922–2013

Arthur (Art) Weis, JD, PhD, founder and chair of the board of Capintec, Inc. and a pioneer in the development of nuclear medicine, died on January 20. Capintec has been a global consultant and supplier of nuclear medical equipment and systems for almost half a century.

Weiss entered the U.S. Naval Academy in the last year of World War II and was a graduate of the Rensselaer Polytechnic Institute. He received his JD from Rutgers Law School and became a patent attorney, later inventing a nuclear thermionic fuel cell that was used as a power supply for spacecraft launched in the 1960s. In addition to his longtime career at Capintec, he served as president and director of Brevatome USA, Inc. and was a consultant to the French Atomic Energy Commission, the Italian Atomic Energy Commission, and numerous Japanese companies in nuclear power and nuclear medicine.

In 2008, Weis received the SNMMI Presidential Distinguished Service award in recognition of continual dedication to the society. In 1993, Weis was featured in an interview in Newsline (*J Nucl Med.* 1993;34[6]:30N–32N), where he drew on his deep experience in the field to provide prescient insights into the future of the field. "The future of nuclear medicine obviously is dependent on the development of new radiopharmaceuticals, but you can't compete with static imaging modalities like CT and MRI. You've got to be able to do things that they can't and do them very cost effectively. That means reliance not so much on pretty pictures but useful information," he told the interviewer. Weis went on to predict the