CMS and Intermediaries Begin Accepting NOPR Claims

On June 19 implementation of the National Oncologic PET Registry (NOPR) advanced as the Centers for Medicare & Medicaid Services (CMS) and fiscal intermediaries (FIs) began accepting patient claims from providers participating in the program. The NOPR officially began accepting patient records on May 8. On May 19 CMS issued the anticipated Transmittal 956 change request 5124, which officially instructs providers on how and when claims for Medicare reimbursement may be submitted for coding and billing (www.cms.hhs.gov/transmittals/downloads/R956CP.pdf). To assist providers, CMS also prepared a Medical Learning Network article in its *MLN Matters* format (www.cms.hhs.gov/MLNMattersArticles/downloads/MM5124.pdf). The article contains a basic outline of the NOPR provisions, steps for compliance, warnings about potential pitfalls and challenges, and additional online references and resources.

The transmittal document included the following instructions:

- Carriers only: Carriers shall pay claims for PET scans for beneficiaries participating in a CMS-approved clinical trial submitted with an appropriate CPT code from section 60.3.1 (Chapter 13 of the CNM Manual System) and the QR (item or service provided in a Medicare-specified study) modifier.
- FIs only: In order to pay claims for PET scans on behalf of beneficiaries participating in a CMS-approved clinical trial, FIs require providers to submit claims with ICD-9 code V70.7 in the second diagnosis position on the CMS-1450 (UB-92), or the electronic equivalent, with the appropriate principal diagnosis code and an appropriate CPT code from section 60.3.1. Effective for PET scan claims for dates of service on or after January 28, 2005, FIs shall accept claims with the QR modifier on non-inpatient claims.

Additional information on registering to participate in NOPR is available at the registry Web site at: www.cancerpetregistry.org/.

Centers for Medicare & Medicaid Services

Reported Thyroid Cancer Rise Tied to Better Diagnosis

In an article published in the May 10 issue of the *Journal of the American Medical Association* (2006;295:2164–2167), Davies and Welch from the Veterans Affairs Medical Center (White River Junction, VT) examined trends in thyroid cancer incidence, histology, size distribution, and mortality in the United States from 1973 to 2002. The researchers performed cohort evaluations of patients with thyroid cancer during this period using the Surveillance, Epidemiology, and End Results (SEER) program and data on thyroid cancer mortality from the National Vital Statistics System. They found that the reported incidence of thyroid cancer increased from 3.6 per 100,000 in 1973 to 8.7 per 100,000 in 2002—a 2.4-fold increase. Almost the entire increase was attributable to papillary thyroid cancer, with no significant change in the incidence of the less common histologic types, including follicular, medullary, and anaplastic thyroid cancer. Papillary thyroid cancer increased in incidence from 2.7 to 7.7 per 100,000 over the 30-year study period—a 2.9-fold increase. SEER did not begin collecting data on tumor size until 1988, and between that date and 2002, 87% of the increase in thyroid cancer consisted of tumors $\leq$2 cm. Mortality from thyroid cancer ($\sim$0.5 deaths per 100,000) did not change during the study period.

The authors noted, "Increasing cancer incidence. . .may also reflect changing pathological criteria or increased diagnostic scrutiny." They concluded that "the increasing incidence of thyroid cancer in the United States is predominantly due to the increased detection of small papillary cancers. These trends, combined with the known existence of a substantial reservoir of subclinical cancer and stable overall mortality, suggest that increasing incidence reflects increased detection of subclinical disease, not an increase in the true occurrence of thyroid cancer."

Journal of the American Medical Association

Delays in Radioisotope Transport

Medical and transportation leaders from around the world expressed concerns about continued timely delivery of radioisotopes across international borders at an International Atomic Energy Agency (IAEA) meeting held May 8–12 at IAEA headquarters in Vienna, Austria. High costs and increasingly complex and varied regulatory requirements were among key elements driving the delays.

Industry representatives warned of growing numbers of cargo refusals and delays in international shipments of radioactive material. "Hospitals and patients need the international shipments to arrive on time, especially if the isotope has a short shelf-life," said Paul Gray of Nordion. Gray cited radioiodine, essential in so many nuclear medicine applications, as an example. "If we get an order from a hospital in the afternoon, we'll produce the isotope and arrange to fly it out that night," he said.

"If the iodine misses the flight it becomes useless."

The actual number of blocked or delayed shipments is not known. Routes in Europe, Pacific Asia, and the Mediterranean are among those where denials and delays have occurred. Jim Stewart, Transport Radiological Advisor, United Kingdom Department of Transport, noted that in some cases medical isotopes are forced by idiosyncratic storage and in-flight requirements to travel 3 times the direct distance. Stewart noted that one challenge is an inability to accurately gauge the extent of the problem. "[We have received about] 100 reports of denied shipment in 3 months, and that's not a comprehensive picture. We've only started dealing with this issue. Something dramatic needs to be done. The problem is getting worse," he said at an IAEA briefing.

David Brennan, assistant director of the Dangerous Goods and Safety International Air Transport Association, reported that these difficulties are compounded by the fact that fewer carriers are willing to take on radioactive shipments, thus fewer routes are available. In other cases, a country's regulatory controls may create bottlenecks that effectively block shipments. The commercial incentives for airlines to carry radioactive materials have diminished as the cost of additional regulatory control has increased. For example, some countries have multiple levels of regulatory controls, such as requiring a dedicated storage area for radioactive materials, employing a radiation protection advisor, and/or banning radioactive materials when animals are also on the flight.

Shipments of medical and industrial radioactive material are regulated by countries and the airline industry in accordance with the IAEA International Regulations for the Safe Transport of Radioactive Material. "Radioactive material is very safely transported, based on standards developed by the IAEA which have been operating for 43 years," said Michael Wangler, IAEA Unit Head, Safety of Transport of Radioactive Materials. However, these rules do not preclude individual countries, air carriers, and cargo handlers from imposing additional restrictions and regulations.

The weeklong meeting included discussions of the extent of the problem and strategies to improve the flow of information and formulate solutions. A full conference report is expected later in the year.

International Atomic Energy Agency

NIH Launches Rare Disease Initiative

On May 5 the National Institutes of Health (NIH) announced the launch of the first clinical studies in its Rare Diseases Clinical Research Network (RDCRN). More than 20 trials and studies are expected to open in the next few months at about 50 sites across the United States and in several other countries, including the United Kingdom, Japan, and Brazil. A rare disease is defined by NIH as a disease or condition affecting fewer than 200,000 persons in the United States. About 6,000 such disorders have been identified, affecting an estimated 25 million Americans. Few drug companies conduct research into rare diseases because of difficulties in recouping development costs for treatments targeted at small, geographically dispersed populations.

"By studying the genetic component of these rare diseases, we hope to be able to better predict the course of the illnesses and provide more effective, personalized treatments for those afflicted," said Elias A. Zerhouni, MD, NIH director. "Ultimately, this individualized approach, completely different from how we treat patients today, will allow us to prevent or to promptly treat the complications arising from these genetic disorders."

The RDCRN has received 5-year funding awards totaling $71 million and is coordinated primarily by 2 NIH components: the Office of Rare Diseases and the National Center for Research Resources. A central data and technology coordinating center and 10 research consortia will investigate a variety of diseases including Angelman, Rett, and Prader–Willi syndromes; myelodysplastic syndrome and other bone marrow failure conditions; lymphangioleiomyomatosis, rare genetic disorders of the airways, and other rare lung diseases; episodic ataxia, Andersen–Tawil syndrome, and nondystrophic myotonias; several vasculitides; urea cycle disorders; antiphospholipid syndrome and other rare thrombotic diseases; rare pediatric liver diseases; and rare genetic steroid defects.

"Increased collaboration among researchers investigating rare diseases will not only lead to discoveries that will help prevent and treat these conditions, but may also produce medical advances that will benefit the population in general," said Stephen Groft, PhD, director of NIH's Office of Rare Diseases. It is anticipated that imaging, including nuclear medicine techniques, will be an integral part of many of these investigations.

For more information about the RDCRN, see www.ncrr.nih.gov/clinical/cr_rdcrn.asp.

National Institutes of Health

HHS Health Information Technology Recommendations

The American Health Information Community (AHIC) unanimously approved and delivered 28 recommendations on May 16 to U.S. Department of Health and Human Services Secretary Mike Leavitt for consideration. The group made recommendations on how to make health records digital and interoperable while protecting patient privacy and the security of those records.

The group recommended that:

(1) The Health Information Technology Standards Panel (HITSP) identify and define standards for (a) secure messaging between patients and clinicians, such as secure e-mail to allow a patient to receive a doctor's advice outside a traditional office visit; (b) reporting results from laboratory testing, so lab results can travel

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444 patients treated over a 40-year period (223 with lung metastases only, 115 with bone metastases only, 82 with both lung and bone metastases, and 24 with metastases at other sites). Routine treatment involved administration of 3.7 GBq ^{131}I after withdrawal of thyroid hormone treatment, every 3–9 months for 2 years and then once each year until complete disappearance of metastatic uptake. Thyroxine treatment was given at suppressive doses between courses of ^{131}I treatment. The authors found that negative imaging studies (negative total-body ^{131}I scans and conventional radiographs) were attained more frequently in those who were younger, had well differentiated tumors, and/or had limited disease. Most negative studies (96%) were obtained after administration of 3.7–22 GBq ^{131}I. Almost half of negative studies were not obtained until more than 5 years after initiation of treatment of metastases. Only 7% of patients who achieved a negative study experienced subsequent tumor recurrence. Among patients who achieved a negative study, overall survival at 10 years after initiation of therapy was 92% but was only 19% in those who did not achieve a negative study. The authors concluded that radioiodine treatment is "highly effective in younger patients with ^{131}I uptake and small metastases" and that these patients should be treated until the disappearance of any uptake or until a cumulative activity of 22 GBq has been administered.

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with patients; and (c) electronic registration and patient history information to replace the medical clipboard;

(2) The Certification Commission for Health Information Technology (CCHIT) incorporate HITSP standards as criteria for product certification on an ongoing basis, to ensure interoperability; and

(3) A subgroup be formed to frame privacy and security issues relevant to innovations in technology and medicine.

The AHIC also unanimously adopted all CCHIT criteria for certification of ambulatory electronic health records (EHRs). The Office of the National Coordinator for Health Information Technology entered into a $2.7 million contract with the CCHIT last year to develop and test criteria for certification of health information technology, which began in April of 2006. The CCHIT will expand certification to inpatient EHRs in 2007. Standards for transmission and security of images and associated patient information are covered under many of these recommendations and agreements. For information about the AHIC and its workgroups and the complete recommendations, visit www.hhs.gov/healthit/ahic.html.

U.S. Department of Health and Human Services

Last "Radium Girl" Marks 100th Birthday

On May 28 Mae Keane, the last surviving "radium girl," celebrated her 100th birthday in Middlebury, CT. She was among a number of young women in the 1920s who worked in factories and shops decorating watch and clock faces with radioluminescent paint. Keane began at the Waterbury (CT) Clock Company in 1924, earning $18 per week or 6 cents for each dial painted. There, like women in New York and Pennsylvania performing similar tasks, she routinely "pointed" her brush by moistening it with her lips before re-dipping it into the paint.

"I don't think the bosses even knew it was poison," Keane told a reporter from the *Waterbury Republican-American*. "The foreman would tell us it was very expensive and to be careful. We had no idea. But when they did find out, they hid it." Keane worked in the factory for only a few months, but during that period she began to experience dental, dermatologic, and ophthalmologic problems. Many of her colleagues who remained on the radium painting line at the factory died before 1928, and others lingered on with increasingly debilitating radiation-induced illnesses that have been chronicled in many articles and several historical books.

In response to the traditional query about the reasons for her longevity, Keane replied that she had never smoked, loved to walk and dance, and enjoys caramels, chocolates, and an occasional apricot sour or Bailey's Irish Cream.

Waterbury Republican-American