HHS and Laptop Scanner HIPAA Violation

The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) announced on November 25 an agreement to settle with Lahey Hospital and Medical Center (Burlington, MA) on potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules. On August 11, 2011, Lahey had notified OCR that a radiology information system laptop supporting a portable CT unit had been stolen from an unlocked treatment room during overnight hours. The laptop contained protected health information (PHI) on 599 individuals. OCR's subsequent investigation identified widespread noncompliance with HIPAA requirements, including failure to conduct risk analyses for electronic PHI (ePHI), failure to physically safeguard the workstation, "failure to implement and maintain policies and procedures regarding the safeguarding of ePHI maintained on workstations utilized in connection with diagnostic/laboratory equipment," lack of unique user names for identifying and tracking workstation users, failure to implement procedures to record and examine activity at the workstation, and impermissible disclosure of PHI.

As a result of the settlement, Lahey will pay $850,000 and will adopt "a robust corrective action plan" to correct deficiencies in its HIPAA compliance program; provide OCR with a comprehensive, enterprise-wide risk analysis and corresponding risk management plan; report certain specified events; and provide evidence of compliance. "It is essential that covered entities apply appropriate protections to workstations associated with medical devices such as diagnostic or laboratory equipment," said OCR Director Jocelyn Samuels. "Because these workstations often contain ePHI and are highly portable, such ePHI must be considered during an entity's risk analysis, and entities must ensure that necessary safeguards that conform to HIPAA's standards are in place."

In addition to the $850,000 settlement, Lahey must address its history of noncompliance with the HIPAA Rules by providing OCR with a comprehensive, enterprise-wide risk analysis and corresponding risk management plan, as well as reporting certain events and providing evidence of compliance.

HHS offers tips on how to protect and secure health information when using mobile devices at www.healthit.gov/providers-professionals/your-mobile-device-and-health-information-privacy-and-security.

U.S. Department of Health and Human Services

2014 National Health Expenditure Data Released

On December 2, the Centers for Medicare & Medicaid Services (CMS) released a report in the journal *Health Affairs* indicating that per capita health care spending grew in 2014 by 4.5% and that overall health spending grew by 5.3%. CMS noted that those rates of increase were lower than in most years prior to passage of the Affordable Care Act. Consumer out-of-pocket spending grew by only 1.3% in 2014, which CMS attributed to increased numbers of individuals with health coverage. Spending on prescription drugs grew by 12.2% in 2014, compared to only 2.4% growth in 2013, fueled largely by spending for new medicines, particularly for specialty drugs such as those used to treat hepatitis C. On a per enrollee basis, overall spending increased by 3.2% in private health insurance and 2.4% for Medicare but decreased by 2.0% in Medicaid. Additional data highlights from the report included:

- Total private health insurance expenditures (33% of total health care spending) reached $991.0 billion in 2014 and increased 4.4%.
- Medicare spending, which represented 20% of national health spending in 2014, grew 5.5% to $618.7 billion.
- Medicaid spending accounted for 16% of total spending on health and grew 11.0% in 2014 to $495.8 billion. An estimated 6.3 million newly eligible enrollees were added to Medicaid in 2014.
- Households and the federal government accounted for the largest shares of spending (28% each), followed by private businesses (20%) and state and local governments (17%).

The CMS report is available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html and in the January issue of *Health Affairs*.

Centers for Medicare & Medicaid Services

CMS Denies Coverage for ^{18}F-NaF PET

As anticipated, the Centers for Medicare & Medicaid Services (CMS) issued a final decision memo on December 15 determining that "the evidence is sufficient to determine that use of a NaF-18 positron emission tomography (PET) scan to identify bone metastasis of cancer is not reasonable and necessary to diagnose or treat an illness or injury or to improve the functioning of a malformed body member" and so will not be covered. The decision memo continued reimbursement for ^{18}F-NaF PET under coverage with evidence development (CED) until December 15, 2017. The purpose of this CED extension is to "allow confirmatory analyses to be performed and resulting evidence to be published [in peer-reviewed journals] to definitely answer the following question: Does the addition of NaF-18 PET imaging lead to a change in patient management to more appropriate palliative care, a change in patient management to more appropriate curative care, improved quality

of life, or improved survival?" All other indications for ^{18}F-NaF PET will remain nationally noncovered.

The National Oncologic PET Registry, which has led CED efforts in PET imaging, is considering options for collection of additional data that CMS may consider sufficient to answer these questions. The complete final decision memo is available at www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=279&bc=AAAAAAAAAAEAAA%3d%3d&.

Centers for Medicare & Medicaid Services

SNMMI Comments on 2016 Final Rules for HOPPS and MPFS

On December 16, SNMMI submitted letters with comments to the Centers for Medicare & Medicaid Services (CMS) on the 2016 Final Rules for the Hospital Outpatient Prospective Payment System (HOPPS) and the Medicare Physician Fee Schedule (MPFS). These letters were submitted in response to a CMS request for comments by a December 29 deadline. In the HOPPS letter, SNMMI commented on Ambulatory Payment Classification (APC) restructuring for nuclear medicine services, OPPS treatment of new Current Procedural Terminology and Level II Healthcare Common Procedure Coding System codes, Off-Campus Provider-Based Departments, CMS Offset File, and Q9969 Code. Although SNMMI met with CMS earlier in 2015 with concerns about APC restructuring, SNMMI recommendations were not included in the Final Rule. In the MPFS letter, SNMMI commented on 2016 identification of potentially misvalued services, colon transit imaging, and Appropriate Use Criteria (AUC). SNMMI noted in an online statement that it supports the CMS decision to delay the AUC provision and adopt policies regarding claims-based reporting requirements in the CY 2017 and CY 2018 rulemaking cycles.

SNMMI

Imaging in Privately Insured Patients, 2007–2013

In a study published in the December issue of the *Journal of the American College of Radiology* (2015;12:1380–1387), Horný et al. from Boston University (MA) reported on a study designed to determine whether increases in utilization of advanced diagnostic imaging for privately insured patients in 2011 were the beginning of an upward trend in imaging growth or merely an anomaly in what had appeared to be a declining trend beginning in 2008. The study looked at out- and inpatient data on CT, diagnostic ultrasound, MR, and PET imaging from 2007 through 2013. Calculated data included numbers of procedures per person-year covered by private health insurance, proportion of office and emergency visits that resulted in imaging, average payments per procedure, and total payments per person-year covered by private health insurance. Results showed that outpatient utilization of CT and PET imaging decreased in both 2012 and 2013 and that outpatient utilization of MR imaging increased slightly in 2012 but decreased in 2013. Outpatient utilization of diagnostic ultrasound increased each year throughout the study. Inpatient utilization of all imaging modalities except PET decreased in 2012 and 2013. Adjusted payments for all imaging modalities increased in 2012 and then dropped significantly in 2013 (except for diagnostic ultrasound, where adjusted payments increased in 2013). The authors concluded that "the trend of increasing utilization of advanced diagnostic imaging seems to be over for some, but not all, imaging modalities. A combination of policy (e.g., breast density notification laws), technologic advancement, and wider access seems to be responsible for at least part of an increasing utilization of diagnostic ultrasound."

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Achievement in Basic Science Applied to Nuclear Medicine (1993), the Ernest H. Swift Lectureship at the California Institute of Technology (1999), the American Chemical Society Award for Creative Invention (2006), the Carothers Award for outstanding contributions and advances in industrial applications of chemistry (2006), the Jacob Heskel Gabbay Award in Biotechnology and Medicine (2006), and the SNMMI Georg Charles de Hevesy Nuclear Pioneer Award (2009). Upon his retirement, the MIT Department of Chemistry established an endowed lectureship for junior faculty in his name, a reminder of his commitment to mentoring junior faculty.

Davison is survived by Lynne Davison, his wife of 21 years; 5 children; 2 stepchildren; 16 grandchildren; and 3 great-grandchildren. A memorial service is planned for March.