CCH Health Care Compliance LETTER

Volume 11, Issue 16 health.cch.com August 5, 2008

Senate pursues IT use to improve health care quality, reduce costs

Panelists at a recent Senate Finance Committee hearing agreed that health information technology can not only help reduce health care costs and improve quality, but also can improve the way the government pays for Medicare services.

"Many observers believe that widespread use of [information technology (IT)] would improve health care quality and efficiency," Senate Finance Committee Chairman Max Baucus (D-Mont.) said at a July 17, 2008, hearing to explore health care reform options. "Unfortunately, health care has been slow to adopt IT," he continued. Ranking member Charles Grassley (R-Iowa) noted the systems are expensive to install. "While it's clear that electronic patient records will improve efficient health care, the economics have not proven attractive to doctors. We need to think about how to make adoption of electronic records more attractive to those who will use them," Grassley added.

Federally-funded research center. Project Hope Senior Fellow Gail Wilensky suggested that a federally-funded clinical research center could produce information on comparative clinical effectiveness based on data gleaned from electronic health records. Then the government could use this research to change its Medicare reimbursement system to realign financial incentives, rewarding the clinicians and institutions that provide quality care, create efficiencies, promote healthy lifestyles, and "do it right the first time."

Congressional Budget Office Director Peter Orszag said that a significantly expanded comparative effectiveness effort, combined with changes in financial incentives, "holds substantial potential" for reducing health care costs and improving the quality. RAND Principal Researcher Richard Hillestad added that providing comparative effectiveness data is another incentive for moving forward with the adoption of health IT. "We need this level of evaluation," according to Kaiser Foundation Health Plan Chairman and Chief Executive Officer George Halvorson.

Research findings. In 2005, RAND released research estimating that the efficiency savings enabled by health IT could reach approximately $80 billion per year once adopted by 90 percent of hospitals and physicians. According to RAND, 20 to 25 percent of hospitals and 10 to 15 percent of physician offices had adopted systems that could achieve some of the goals of IT, including reduced test duplication, lower-cost drug utilization, better scheduling, reduced paper-record handling, improved claims and billing administration, reduced handwriting-based errors, improved management of chronic illness, and improved continuity of care for those patients seeking care away from their primary provider. ■

CCH Washington Bureau, July 17, 2008.

Wolters Kluwer Law & Business

Lost or stolen tapes, laptops lead to HHS' first HIPAA Resolution Agreement

HHS has entered into a Resolution Agreement with Seattle-based Providence Health & Services (Providence) to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules. This is the first time HHS has required a Resolution Agreement from a covered entity. Under the agreement, Providence will pay $100,000 and implement a detailed Corrective Action Plan (CAP) to ensure that it will appropriately safeguard identifiable electronic patient information against theft or loss. Providence's cooperation with the Office of Civil Rights (OCR) and CMS allowed HHS to resolve this case without the imposition of civil money penalties.

HIPAA violations. On several occasions between September 2005 and March 2006, backup tapes, optical disks, and laptops, all containing unencrypted electronic protected health information (PHI), were removed from the Providence premises and left unattended. The media and laptops were subsequently lost or stolen, compromising the PHI of over 386,000 patients. HHS received over 30 complaints about the stolen tapes and disks after Providence alerted patients to the theft.

CAP. The CAP requires that Providence: (1) revise its policies and procedures regarding encryption and physical safeguards governing off-site transport and storage of electronic media containing patient information, subject to HHS approval; (2) train workforce members on the safeguards; (3) conduct audits and site visits of facilities; and (4) submit compliance reports to HHS for a period of three years. ■

HHS Press Release, July 17, 2008.

OCR announces Privacy Rule enforcement results

Since the compliance date of April 14, 2003, HHS' Office of Civil Rights (OCR) has received over 37,223 complaints under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, resolving over eighty percent of these complaints. HHS has investigated and resolved over 6,648 cases by requiring changes in privacy practices and other corrective actions by the covered entities. In another 3,290 cases, HHS investigations found no violation. In the balance of resolved cases (20,644), HHS found that the complaint was ineligible for enforcement under the Privacy Rule because: (1) OCR lacked jurisdiction under HIPAA; (2) the complaint was untimely, withdrawn, or not pursued by the filer; or (3) the activity described did not violate the Rule.

Common enforcement issues and entities. The compliance issues most frequently investigated by HHS are: (1) impermissible uses and disclosures of protected health information (PHI); (2) lack of safeguards of PHI; (3) lack of patient access to their PHI; (4) uses or disclosures of more than the minimum necessary PHI; and (5) lack of or invalid authorizations for uses and disclosures of PHI. The most common types of covered entities that have been required to take corrective action are private practices, general hospitals, outpatient facilities, group health plans and health insurance issuers, and pharmacies.

Referrals. As of June 30, 2008, OCR has made over 436 referrals to the Department of Justice for criminal investigation involving knowing disclosure or obtaining of PHI in violation of the HIPAA Privacy Rule. In addition, over 250 referrals have been made to CMS for investigation of potential violation of the HIPAA Security Rule.

Educational outreach. Outreach by OCR to covered entities and consumers occurs through educational conferences, a toll-free call line, and an interactive website. HHS has had over 5.5 million visits to its Privacy Web pages and over 4.3 million visits to the frequently asked questions on the Privacy Web pages. Announcements and educational information have been distributed to over 18,000 subscribers through HHS' Privacy listserv. ■

HHS Press Release, June 30, 2008.

Experts identify issues encountered when disclosing PHI

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits the use and disclosure of protected health information (PHI) to treat patients; identify, locate, and notify family members and certain other individuals of a patient's location, general

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CCH Health Care Compliance Letter is published 24 times a year by CCH, a Wolters Kluwer business, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is $305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO *CCH Health Care Compliance Letter*, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A.

condition or death; obtain the services of disaster relief agencies such as the American Red Cross; carry out public health activities and prevent or lessen serious and imminent threats to health or safety, Chana Feinberg, Health Information Management director at Unity Health System in Rochester, New York explained during a teleconference sponsored by the American Health Information Management Association. She also noted that patients have the right to access their own medical records for inspection or copying upon written request and may request an amendment or a correction to their PHI.

A disclosure occurs when a covered entity (a provider, facility or organization covered by HIPAA) releases, transfers or divulges information to anyone who is not part of that entity. An authorization is required for the use or disclosure of PHI, however, there are a few exceptions, noted Aviva Halpert, chief HIPAA officer at Mt. Sinai Medical Center in New York City. Exceptions are made for statutory requirements, public health, education, emergencies, limited law enforcement, institutional review board (IRB)-approved waiver for research, and identification of a deceased person or cause of death. The exceptions include: (1) treatment; (2) payment to health care providers for their services; and (3) health care operations. Examples of health care operations include: audits, quality assurance and risk management, Feinberg added.

Accounting of disclosures. According to Feinberg, individuals have a right to receive a list of all disclosures of PHI made by a covered entity in the six years prior to the date on which the accounting is requested, a right that's referred to as an accounting of disclosures. Exceptions to this right include disclosures that are made: (1) for treatment, payment, and health care operations; (2) to the patient; (3) to persons involved in the patient's care or to notify family members or friends of the patient's location, general condition or death; (4) for national security and intelligence purposes; and (5) prior to the April 14, 2003, the HIPAA Privacy Rule compliance date, she noted.

"Minimum necessary" disclosure. A covered entity must make reasonable efforts to limit the use or disclosure of PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request, Feinberg said. According to Feinberg, the minimum necessary rule does not apply if the use or disclosure is: (1) for treatment, (2) to the patient or individual to whom the PHI belongs, (3) made pursuant to an individual's authorization, (4) to HHS to comply with HIPAA, (5) required for compliance with the standardized transactions, or (6) required by law.

Disclosure during emergencies. Decisions on whether to disclose information should never interfere with care, the speakers emphasized. Feinberg stressed that providers should exercise their best judgment, making sure the disclosures would be in the best interest of the patient, adding that providers can require the patient or a personal representative to send a written authorization after the fact. "The privacy rule was not designed to interfere with the provision of health care or the coordination of disaster relief efforts that are needed to respond to situations such as Hurricane Katrina or like disasters," she added.

Other patient issues. Adoptions present many challenges related to disclosures of PHI, including proof of identity, access to the mother's record, and access to the chart of a minor. To further complicate the issue, the parents may be divorced, separated or neither may have custody. "Both parents have equal access rights even if they are divorced unless it is deemed that giving access to one or both of them would be harmful to the minor," Halpert noted.

If a minor is emancipated or if the content to be accessed is for sexually related treatment (e.g., pregnancy, sexually transmitted disease, etc.) his or her PHI may not be disclosed even to a parent without the minor's authorization, Halpert said.

Although some psychiatric patients may not be competent to authorize disclosure of their PHI, in which case their personal representative would provide authorization, a psychiatric condition in and of itself would not preclude a patient from signing authorization, Halpert noted. As long as he or she understands what is happening, an adult psychiatric patient may authorize disclosure of PHI. A separate authorization is required, however, for all releases of psychotherapy notes, Halpert said, explaining that a psychotherapy note is a note that is maintained separately by a therapist, is not part of the medical record

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On The Front Lines

An Analysis of the New Schedule H (IRS Form 990) and Proposed Instructions – Are Hospitals Ready for Increased Disclosures? Part II

By Albert Y. Lin, LLM, CPA, Health Care Compliance Advisory Board Member

To prepare the compliance officer for increased disclosure requirements in the revised Form 990 (U.S. Return of Exempt Organizations) Part I of this Article introduced the new Schedule H (Hospitals) that tax-exempt hospitals and hospital systems will need to file beginning with the 2008 tax year (with only a part required for 2008 and the full Schedule H to be completed for the 2009 tax year). It focused on the detailed charity care and community "cost" reporting requirements, and guides the compliance officer through a discussion of the Schedule H itself and the accompanying Draft Instructions and Worksheets.

Part II of this Article covers the remainder of Schedule H, which includes reporting of bad debt, Medicare information, and collection practices, as well as management company, joint venture, and facility disclosures.

III. Reporting Community Building Activities

Lines 1-10 of Part II, "Community Building Activities," permit reporting of costs related to more general community enhancement activities that promote the health of the community. These may include costs related to physical improvements and housing, economic development, community support, environmental improvements, leadership development and training, coalition building to address health and safety issues, community health improvement advocacy, workforce development (i.e. recruitment of staff to medical shortage areas), and other broad categories of community benefit.

IV. Reporting Bad Debt, Medicare, & Collection Practices

Part III, Bad Debt, Medicare, & Collection Practices, is divided into three parts - Part A, reporting bad debt expense information, Part B, reporting Medicare information, and Part C, reporting collection practices.

a. Part A - Bad Debt Reporting

With respect to Part A, the intent is to provide a clear distinction between "true" bad debt and charity care. The organization must state whether it reports bad debt pursuant to Healthcare Financial Management Association (HFMA) Statement No. 15, and must provide the actual text of the audited financial statement footnotes that describe accounting for bad debts. The HFMA Statement sets forth commonly-followed guidance on recordkeeping, valuation, and disclosure for bad debts. The Draft Instructions make it clear, however, that the American Institute of Certified Public Accountants and the IRS have not adopted the HFMA standards and do not require it.[26]

In its response to these Draft Instructions, however, the AHA mentions that many organizations do not have footnote language in financial statements relating to bad debt expense or other designations and should not be required to create footnotes to satisfy this disclosure requirement.[27]

Line 2 of Part A requests reporting of bad debt expense at cost (i.e. again, not the actual charge written off, but the cost of such charges). Organizations using their own cost accounting system should enter the estimated cost of patient care services attributable to charges written off to bad debt. Alternatively, Worksheet A[28] may be used to calculate bad debt based on a cost to charges method (which in turn refers to the same Worksheet 2 to calculate a cost ratio to apply to bad debt attributable to patient accounts).

Line 3 of Part A asks for an estimate of the amount of costs reported in Line 2 that can "reasonably be attributed" to patients who would likely qualify for financial assistance under the hospital's charity care policy, but for whom insufficient information was obtained to make an eligibility determination. Reasonable methods to make this determination could include record reviews, assessment of charity care applications, and demographic analysis.[29]

Line 4 of Part A requires disclosure of the financial statement footnote provision related to bad debts, and the costing methodology used in Lines 2 or 3 (i.e. cost accounting method or Worksheet

A method). Somewhat confusingly, Line 4 also asks for the "rationale for including other bad debt amounts in community benefit," which seems contradictory as bad debt "is not to be reported in the Table [for Line 7] under any circumstances."[30]

This is evidently a place to justify the amount of bad debt as a community benefit even though it is not intended to be treated as such.

b. Part B - Medicare Reporting

Line 5 first requires disclosure of all net patient service revenue from payments received or accrued for Medicare services performed for Medicare patients. Any revenue related to subsidized health services or direct graduate medical education (GME) reported earlier under the prior community benefit sections are excluded. Only revenues relating to Medicaid Part A, related to inpatient hospital services, and Medicaid Part B, related to outpatient hospital, home health, and physician services, are reported in Line 5.

Line 6 requires entry of all Medicare allowable costs associated with services to Medicare beneficiaries generating the revenue listed in Line 5. These costs may be determined by using a Worksheet B,[31] which draws information from the Medicare Cost Report and backs out costs associated with subsidized health services and direct GME costs.

The difference between Line 5 and Line 6 is entered on Line 7, and Line 8 allows the organization to justify any shortfall (excess of Medicare costs over revenues) as community benefit, even though the organization is explicitly told not to enter such amount in the Line 7 table. The AHA's comments noted that the IRS did not provide guidance on exactly what explanation the IRS would find useful in showing which portions of the shortfall make up community benefit.[32]

Moreover, the AHA has asked for clarification on the ability to use multiple methods of cost reporting as Medicaid cost reports do not include all subsets of Medicare programs.[33]

c. Part C - Collections

Practices Line 9a requires disclosure of whether the organization has a written debt collection policy. Line 9b asks if such written debt policy, if any, has provisions on collections practices to be followed for patients meeting eligibility criteria for charity care or financial assistance. The Draft Instructions suggest that these provisions might include procedures for internal review of accounts prior to initiating legal actions or retention of an outside collections agency.[34]

V. Reporting Information on Management Companies & Joint Ventures

Particularly burdensome for large multiple-tiered healthcare systems will be Part IV, Management Companies & Joint Ventures, which requires disclosure of the filing organization's ownership or participation in joint ventures, partnerships, corporations, limited liability companies, and other entities. The disclosure rules are triggered if:

1. the filing organization's current officers, directors, trustees, key employees (including physicians who have staff privileges with one or more of the organization's hospitals) own in the aggregate more than 10 percent of the profits interest (if a partnership) or 10 percent of stock (if a corporation), and
2. the joint venture, partnership or corporation either (i) provides management services used by the organization in its provision of medical care, or (ii) provides medical care, or owns or provides real, tangible, or intangible property used by the organization or by others to provide medical care.

These entities do not include publicly traded entities or entities in which the sole income is passive investment income (i.e. interest or dividends).

VI. Reporting Information on Facilities

More specific disclosures related to actual physical facilities comprise Part V, Facilities Information. The filing organization must list the name and address of each facility (defined as a campus, or component thereof), building, structure or other physical location or address where the organization provides medical or hospital care.[35]

Reported facilities include facilities either operated directly or indirectly through another organization. The AHA has commented that such a broad definition may be administratively burdensome and urges the IRS to limit its definition of a facility to an "entity that is licensed or certified as a hospital."[36]

Part V contains checkboxes to indicate what services are provided at each facility. Preparers may check multiple services. Choices include licensed hospital, general medical and surgical services, children's hospital, teaching hospital, critical access hospital (pursuant to state designation through a State Medicare Rural Hospital Flexibility Program), research facility, research, 24-hour emergency room (ER) services, non-24 hour ER services, and other.

VII. Reporting Additional Supplemental Information

Part VI, Supplemental Information, serves as an additional schedule, in part to remind organizations of further information requested in the earlier Parts, and in part to solicit more substantive information. Question 1 of Part VI contains reminders about questions related to financial eligibility criteria, bad debt expense financial statement disclosures, rationale for any shortfalls/bad debt as community benefit, collections practices, and costing methodology explanation (all requested in earlier Parts).

Questions 2-8 of Part VI can be seen as broad-based "community benefit" questions designed to see if organizations follow best practices procedures. Question 2 asks how the organization assesses community need for the health care services it provides. Question 3 requests disclosure of how the organization informs and educates patients and persons about eligibility for federal, state, or local governmental health care programs, pursuant to its charity care policy. Various options for dissemination are suggested, including posting of the policy, providing a copy of the policy or summary during the intake process, providing a copy at discharge, or discussion with the patient.

Question 5 asks generally how community building activities (reported in Part II) promote the health of the communities served. Question 6 is a free-for-all question, offering the opportunity to provide any other information relevant to how the organization benefits the community, including structure of the governing board, extension of medical staff privileges to all qualified physicians, or allocation of surplus funds to patient care, medical education, and research improvements.

Question 7 asks a deceptively simple question - how the organization, if part of an "affiliated health care system," promotes the health of the communities. An "affiliated health care system" is defined as a system that includes affiliates under common governance or control, or that cooperate, in providing health care services to the community. This encourages required adequate disclosures of organization structure in affiliated health care systems.

Finally, Question 8 requests identification of all states in which the organization (or a related organization) files a community benefit report.

VIII. Conclusion

While Schedule H of the revised Form 990 is brief at four pages, an in-depth review of the accompanying Draft Instructions clearly demonstrates the need for the compliance officer's review well before the first complete Schedule H is filed in 2010. The first mandatory portion to complete will be the Facility Information portion, which may be an extensive undertaking for the larger system with multiple physical facilities, particularly if the final Instructions do not limit the definition of "facility" as commentators propose. The compliance officer should discuss the Schedule H with internal and outside accountants and determine if the reporting and cost systems of the organization provide means to accumulate the new information required by Schedule H. The table provided for Question 7, Charity Care and Certain Other Community Benefits at Cost, along with data for Part II, Community Building Activities, may take the most time to complete, especially if the internal accounting processes currently do not take into account such figures. In the meantime, the IRS hopefully will release final instructions this year that may take into account many helpful comments received from organizations and compliance professionals. ■

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[26] See 2008 Schedule H Form 990 Instructions - Draft ("Draft Instructions"), at 9-10. The redesigned Form 990 and Draft Instructions are available at: http://www.irs.gov/charities/article/0,,id=181091,00.html. The public comments have been made available at http://www.irs.gov/charities/article/0,,id=181965,00.html. Note that the "old" redesigned Schedule H was originally issued as of June 14, 2007 (identified by "20XX"), at the upper right corner, and was superseded by the December 19, 2007, version (with "2008" at the upper right corner).

[27] Letter from American Hospital Association to IRS, at 6 (May 15, 2008), *available at* http://www.aha.org/aha/letter/2008/080515-cl-irs-990.pdf (hereinafter "AHA Letter").

[28] Draft Instructions at 9.

[29] *Id.* at 10.

[30] Draft Instructions at 7.

[31] *Id.* at 11.

[32] AHA Letter at 6. The AHA suggests that the Draft Instructions be modified to state "An organization's rationale may have any reasonable basis, including the amount of the shortfall that might otherwise have been used to support the programs included in Parts I or II, an estimate of the income range of the organization's Medicare patients, an estimate of the number of Medicare patients also eligible for the Medicaid program (dual eligibles), or whether the organization reports the amount of Medicare shortfall to any state government authority identified in Part IV, Line 8, or any other government authority." *Id.*

[33] AHA Letter at 7.

[34] Draft Instructions at 12.

[35] *Id.* at 13.

[36] AHA Letter at 8.

and would contain the content of a session as opposed to the facts of a visit.

Cultural issues also can come in to play, according to Halpert, who noted that end-of-life decision-making varies by culture. Japanese Americans often prefer to have a terminal diagnosis disclosed to the family who would then decide what to tell the patient. "This would be a breach of HIPAA and a way would have to be found to accommodate both the law and the needs of the patient," she said.

State law ramifications. State law preempts HIPAA if it is more stringent than HIPAA. Determining whether the state law is more stringent, however, requires careful comparative analysis, Halpert explained. Because laws vary from state to state, it's best to check on the state websites and check with legal

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counsel, she advised. Areas that are generally the province of the state include public health reporting, health department access to medical records, and patient access laws. States also have different registry reporting requirements.

Other exemptions. PHI in cases of workers' compensation is exempt from HIPAA, while prisoners have limited civil rights. A covered entity may disclose a prisoner's PHI without authorization to the correctional institution or law enforcement personnel if the information is needed to provide health care. PHI also may be disclosed to notify a family member of a soldier's location, general condition, or death. ■

CCH Washington Bureau, July 9, 2008.

Privacy rule has negative impact on biomedical research

The privacy rule of the Health Insurance Portability and Accountability Act (HIPAA) is causing a negative impact on the advance of biomedical research and the search for treatments, according to a report by the Association of Academic Health Centers (AAHC) entitled "HIPAA Creating Barriers to Research and Discovery." The AAHC report describes the unintended, disruptive consequences of the privacy rule, including confusion for patients, misinterpretation by research participants, barriers to patient recruitment, and burdensome administrative procedures that increase research costs.

Findings. The AAHC findings are based on focus group discussions of researchers and compliance personnel at five major academic health centers. Of particular significance to researchers is that HIPAA particularly affects access to stored tissue and genetic data sets, data warehouses and medical records, and community research. Community research, which is vital in large collaborative research efforts, is becoming increasingly difficult as community physicians are reluctant to engage in research due to the burdensome HIPAA requirements.

Recommendations. The AAHC recommends: (1) the HIPAA Privacy Rule be revised to defer to the existing and well-established Common Rule, the existing federal policy for the protection of human subjects; (2) HHS revise the rule through its Office of Civil Rights; and (3) Congress implement a national genetic privacy act or include it in a revision of HIPAA to help resolve current conflicts between state privacy acts and HIPAA that now hamper tissue bank and genetic research.

"Protection of the patient and health information is always paramount when it comes to research conducted at academic health centers throughout the nation," according to AAHC President Dr. Steven A. Wartman. "We now know that the privacy rule is having a serious and detrimental impact on research and ultimately patients. Solutions to problems generated by the privacy rule, as outlined in this report, should be pushed forward to protect privacy while ensuring the nation's biomedical research endeavors do not suffer in the near or long term." ■

AAHC Press Release, June 16, 2008.

Employment

House amendment expands ADA reach

By a 402-17 vote on June 25, 2008, the House of Representatives overwhelmingly passed the ADA Amendment Act (H.R. 3195), which clarifies the definition of "disability" and could potentially grant millions of workers protections under the Americans with Disabilities Act (ADA). Lawmakers say the bill, supported by a broad coalition of employer groups and disability rights advocates, is necessary to reverse a series of Supreme Court decisions that have narrowed the definition of who is covered under the Act.

Definitions. Supporters note that the Supreme Court's decisions have narrowed the definition of disability to the point that people with serious conditions such as epilepsy, cancer, diabetes and cerebral palsy have failed to meet the ADA's definition of disability. Workers with disabilities who are able to reduce the impact of their disabilities with items such as eyeglasses, hearing aids or medications may not qualify for ADA protections. As a result, plaintiffs in 2004 lost 97 percent of ADA employment discrimination claims that went to trial. The legislation clarifies the definition of "disability," containing a nonexhaustive list of examples of what it means to be substantially limited in a major life activity. The bill defines "substantially limits" as "materially restricts," rather than the Supreme Court's more restrictive interpretation. House Majority Leader Steny Hoyer (D-Md.), the sponsor of the bill, remarked, "The purpose of this legislation was to restore the intent of Congress to cover a broad group of individuals with disabilities under the ADA and to eliminate the problem of courts focusing too heavily on whether individuals were covered by the law rather than on whether discrimination occurred."

Implications for employers. Under the bill, it would be illegal for an employer to discriminate against an employee because of the worker's actual or perceived impairment, regardless of whether the worker is disabled. Impairments that are transitory and minor are excluded from coverage. The bill's backers say it strikes a balance between employer and employee interests by clarifying that employers need not provide accommodations to a worker who is only "regarded as" having an impairment. ■

CCH Washington Bureau, June 25, 2008.

Correction

In Volume 11, Issue 15 of the Health Care Compliance Letter, in the article entitled, "Gift card plan would not violate Stark law," (on page 8), the law referenced in the first paragraph was erroneously cited as 42 U.S.C. §1128(a)(5). The correct citation is 42 U.S.C. §1320a-7a.

Ethics

PhRMA code on interactions with health professionals revised

Reflecting the continuing commitment of America's pharmaceutical research and biotechnology companies to pursue policies and practices that best serve the needs of patients and the healthcare community, the Pharmaceutical Research and Manufacturers of America (PhRMA) Board of Directors has adopted measures to enhance the PhRMA Code on Interactions with Healthcare Professionals. The newly revised PhRMA Code, which builds on improvements made in the previous 2002 version, is part of an ongoing effort to ensure that pharmaceutical marketing practices comply with the highest ethical standards.

Code changes. The revised PhRMA Code, which will take effect in January 2009, reaffirms that interactions between company representatives and healthcare professionals "should be focused on informing the healthcare professionals about products, providing scientific and educational information, and supporting medical research and education."

The revised Code: (1) prohibits distribution of noneducational items (such as pens, mugs and other "reminder" objects typically adorned with a company or product logo) to healthcare providers and their staff; (2) prohibits company sales representatives from providing restaurant meals to healthcare professionals, but allows them to provide occasional meals in healthcare professionals' offices in conjunction with informational presentations; (3) includes new provisions that require companies to ensure that their representatives are sufficiently trained about applicable laws, regulations and industry codes of practice that govern interactions with healthcare professionals; and (4) provides that each company will state it's intentions to abide by the Code and that company chief executive officers and compliance officers will certify each year that they have processes in place to comply, a process patterned after the concept of the Sarbanes-Oxley Act compliance mechanisms. ■

PhRMA press release, July 10, 2008.

In the News

House panel approves health IT protection bill

The House Energy and Commerce Committee approved legislation by voice vote on July 23, 2008, to improve health information technology. The bill, entitled "Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008" (H.R. 6357), or the "PRO(TECH)T Act," aims to strengthen the quality of health care, reduce medical errors and costs, and further protect the privacy and security of health information. The bill would (1) require notification when protected health information is breached, and (2) extend federal privacy law to entities that do business with providers, such as quality review organizations and newer entities that store and manage a provider's electronic health information allowing the federal government to bring enforcement actions against bad actors.

CCH Washington Bureau, July 24, 2008.

Amerigroup settles marketing practices litigation

Amerigroup Corporation announced a comprehensive settlement agreement in principle that would conclude its civil *qui tam* litigation related to certain marketing practices of its former Illinois health plan. In 2007, a judgment against Amerigroup and its Illinois subsidiary resulted in a civil amount of approximately $334 million plus fees. Under the terms of the proposed settlement, Amerigroup will pay $225 million to the United States and the State of Illinois, plus approximately $9 million in legal fees, and will not admit any wrongdoing. Additionally, in connection with the settlement, the company would enter into a corporate integrity agreement with the HHS Office of Inspector General. Amerigroup would report a one time charge for the settlement of approximately $199 million net of the estimated tax benefit, in the second quarter ending June 30, 2008. The company would pay the settlement from restricted funds previously established to cover costs related to the judgment.

Amerigroup Press Release, July 22, 2008.

Medical review responsibilities transferred

The responsibility for measuring and preventing improper payments to acute inpatient prospective payment (IPPS) hospitals and long term care hospitals (LTCHs) has been transferred from quality improvement organizations (QIOs) to fiscal intermediaries (FIs), Medicare administrative contractors (MACs), and Comprehensive Error Rate Testing (CERT) contractors. This change will allow the QIOs to concentrate on improving patient quality of care and maintaining quality improvement and provider assistance efforts. CERT contractors began reviewing claims to measure error rates for IPPS hospital and LTCH claims on April 1, 2008. FIs and MACs will begin reviewing IPPS hospital and LTCH claims this summer to determine the appropriate payment due and prevent or reduce improper payments. FIs and MACs will perform medical review of these claims on a prepayment or post-payment basis to ensure that the services provided are covered, correctly coded, and reasonable and necessary services. Claim adjustments will be made as necessary. FIs and MACs also will conduct provider feedback through their medical review departments based on findings from medical review of IPPS hospital and LTCH claims.

CMS Fact Sheet, July 9, 2008.