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On The Front Lines 4

Getting in touch with your inner regulatory artist: Creative responses to nine privacy problems you never thought about and are probably glad you didn't, Part 1

by Stephen Miller, JD, Health Care Compliance Editorial Advisory Board Member

Physician Self-Referral 1

- Experts respond to questions about latest self-referral rules

EMTALA 3

- CMS finalizes EMTALA community call plans and on-call list rules

Tax-Exempt Organizations 8

- Profit/nonprofit hospitals provide similar charity care

Wolters Kluwer Law & Business

Experts respond to questions about latest self-referral rules

The new physician self-referral regulations contained in the fiscal year (FY) 2009 Inpatient Prospective Payment System (IPPS) final rule have generated numerous questions. A group of experts, including two CMS officials, addressed many of these questions at a teleconference sponsored by the American Bar Association. They focused their comments on stand-in-the-shoes provisions, under arrangements, per-click compensation and set-in-advance requirements.

Where you stand depends on where you sit. Lisa Ohrin, deputy director of CMS' Center for Medicare Management, Chronic Care Policy Group, Division of Technical Payment Policy, provided an overview of the "stand in the shoes" (SITS) provision, which provides that only a physician who has an ownership or investment interest in a physician organization (PO) is deemed to stand-in-the-shoes of that PO. An exception to the ownership provision is titular ownership, when there is no ability or right to receive financial benefits of ownership or investment, including, but not limited to, profit distributions, dividends and sale proceeds, Ohrin noted. Under permissive SITS - a nonowner physician (and titular owners) may, but is not required, to stand in the shoes of his or her PO, Ohrin said. In addition, Ohrin explained that CMS has proposed some Entity SITS provisions, under which the designated health service (DHS) entity would stand in the shoes of an organization in which it has a 100 percent ownership interest.

Andrew Wachler, principal of Wachler & Associates, Royal Oak, Michigan, said CMS revised the SITS regulations to provide that a physician will "stand in the shoes" of his or her physician organization for purposes of applying the rules that describe direct and indirect compensation arrangements. Under Stark Phase III, if the primary function of the organization is to provide physician services it is probably a PO, Wachler added. "Physician ownership is key," he said.

Under arrangements. Don Romano, director of CMS' Center for Medicare Management Division of Technical Payment Policy, explained that in the FY 2009 IPPS final rule, CMS has restricted under arrangement (UA) transactions by changing the definition of "entity furnishing DHS." He emphasized that "this term is central to a Stark Law analysis." He also noted that under the Stark Law, a physician may not refer to an entity that furnishes DHS if the physician (or immediate family member) has a financial relationship with the entity unless a Stark exception applies. Previously, he noted, an entity was considered to furnish DHS only if it was the person or entity to which CMS made payment for the DHS.

Under the new regulations, a person or entity is considered to be furnishing DHS if the person or entity has performed services that are billed as DHS, or has

continued on page 2

presented a claim to Medicare for the DHS, Romano said. The new definition becomes effective October 1, 2009.

"There are a lot of arrangements out there that are probably going to have to be modified," said Linda Baumann, a partner with Arent Fox in Washington, D.C. She added that when one entity performs a DHS service that is billed by another, both entities are furnishing DHS.

Performed services. CMS did not provide a definition of what it means to "perform" the services billed as DHS, Baumann said, adding that the word "perform" is to have its common meaning. CMS states that a service is "performed" by a physician or organization if the physician or organization does the medical work and could bill for the service, but has contracted with a hospital that bills for the service instead. "That's clearly a case in which the entity is performing the service," she said.

Baumann also noted that physician-owned device companies do not necessarily "perform the DHS" and that, at this point, they "aren't the entities furnishing the DHS on this basis alone." She pointed out that the preamble to the final rule does note that there might be further proposed regulations on this issue. Not all UA transactions are prohibited, according to Bauman. "This was not intended to stop UA transactions," she said. Physicians can protect their financial relationship with a company that furnishes DHS with an ownership or compensation exception, as appropriate, she added.

Physician ownership in UA entity. Baumann noted that if an entity is currently providing services to a hospital under arrangement and the entity has a physician owner, as of October 1, 2009, the physician will either have to be able to satisfy an ownership exception, such as that for rural providers or publicly traded securities. Other than that, she said, the physician should make no referrals to the hospital or divest his or her ownership interest in the UA entity, she advised.

Baumann said that CMS is requesting comments on the need for an exception for an ownership/investment interest in one or more types of physician-owned service providers – to be issued as a proposed rulemaking. Ohrin asked conference participants to submit these comments directly to her or Romano. Romano explained that the 2009 effective date could give CMS enough time to make a change. CMS also could delay the effective date if there is need for that, he added.

Per-click. Per-click compensation is now prohibited in all space and equipment leases to the extent that the charges reflect services provided to patients referred by the lessor to the lessee, Baumann said. Compensation for the rental of office space or equipment may not be determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients referred between the parties, she noted. "You're going to have to watch out in space and equipment leases," Baumann stressed.

The new restrictions have been delayed but will become effective October 1, 2009.

Set in advance. The Phase III rule also contained an interpretation that the "set in advance" requirement in many Stark exceptions prohibited, during the first year of an agreement's term, the amendment of the rental charges in space and equipment leases and compensation paid to a physician in a personal services agreement, Baumann explained. Parties who sought to modify such payments had to terminate the initial agreement and enter into a new agreement, but they could not enter into a new agreement until after the first year of the original term, and the new lease term had to be for at least one year. "It was quite a conundrum," Baumann noted.

In the final rule, these parties can amend "set in advance" compensation provisions in an agreement during the agreement's term if all the requirements of an applicable exception are met, Baumann said. The requirements of an applicable exception are: (1) the revised rental charges or other compensation has to be determined before the amendment is implemented, (2) the formula has to be sufficiently detailed to allow objective verification, and (3) the agreement has to be in place for one year.

According to Ohrin, CMS might provide more guidance on this subject in its Frequently Asked Questions. ■

CCH Washington Bureau, Sept. 9, 2008

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Requests for information about article submission and comments from readers are welcome and should be directed to Susan Smith at susan.smith@wolterskluwer.com, Tel. 847-267-2780, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

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CMS finalizes EMTALA community call plans and on-call list rules

CMS has adopted changes to the regulations governing the Emergency Medical Treatment and Labor Act of 1986 (EMTALA) to include rules for community call plans and amend the regulations governing the on-call list. The regulations, effective October 1, 2008, were included in the fiscal year 2009 inpatient prospective payment system (IPPS) final rule.

Transfer of unstable inpatients. In the 2009 IPPS proposed rule, CMS expressed its intent to revise EMTALA regulations to "clarify" that, when an unstable patient was admitted at one hospital and, subsequently, was transferred in an unstable condition via an appropriate transfer to a facility with specialized capabilities, the "receiving hospital" had an EMTALA obligation to accept the individual so long as the transfer was appropriate and the receiving hospital had the capacity to treat the individual.

Numerous commenters opposed the proposal because, rather than being a clarification, the proposal represented a significant policy change, reopening EMTALA for the admitting hospital. Admitting hospitals, after admitting the individual, would then be required to abide by the regulations governing an appropriate transfer when it transferred the inpatient to the hospital with special capabilities. The commenters questioned whether such a policy change was necessary, as it would be unlikely that a hospital would knowingly admit an individual with an unstabilized emergency medical condition whom they did not have the ability to stabilize.

CMS agreed that implementing the proposed inpatient EMTALA changes would have significant consequences for both admitting and receiving hospitals and, therefore, withdrew the proposed rule.

CMS clarified that if an individual:

- presented to the admitting hospital that had a dedicated emergency department,
- was provided an appropriate medical screening examination and was found to have an emergency medical condition, and
- was admitted as an inpatient in good faith for stabilizing treatment of an emergency medical condition,

then the admitting hospital would meet its EMTALA obligation to that individual, even if the individual remained unstable. A hospital with specialized capabilities would not have an obligation under EMTALA to accept a transfer of that individual from the referring hospital in these circumstances.

Community calls. CMS finalized the regulations that would permit hospitals to meet the EMTALA requirement for maintaining an on-call physician list by participating in a formalized community call plan among hospitals, and retained all but one of the proposed call plan elements described in the proposed rule. The requirement that hospitals demonstrate evidence that they have analyzed the specialty on-call needs of the community to be served by the call plan was removed because the proposed requirement would be duplicative of the existing requirement that a hospital must assess the call plan annually. The amended regulations require a call plan to include:

- clear delineation of on-call coverage responsibilities;
- defined, specific geographic areas to which the call plan applies;
- the requirement that any local and regional Emergency Medical Services (EMS) system protocol formally include information on community on-call arrangements;
- a statement specifying that, even if an individual arrived at a participating hospital that was not designated as the on-call hospital, the participating hospital continues to have an EMTALA obligation to provide (1) a medical screening examination on all individuals who present to the hospital seeking treatment, (2) stabilizing treatment within its capability; and (3) an appropriate transfer as needed; and
- annual reassessment by participating hospitals.

Physician on-call requirements. Language stating that a hospital was required to maintain an on-call list "in a manner that best meets the needs of the hospital's patients" was removed. The regulations have been amended to state that an on-call list must be maintained "in accordance with the resources available to the hospital" and include sufficient guidance that a hospital is ob-

continued on page 7

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Getting in touch with your inner regulatory artist: Creative responses to nine privacy problems you never thought about and are probably glad you didn't, Part I

by Stephen Miller, JD, Health Care Compliance Advisory Board Member

Creativity is a term not often embraced by compliance professionals, after all, we spend our days toiling in what many consider to be a mundane and rigid world of federal and state statutes, regulations, guidance and rules. Our reputations are built on making others understand, or at least follow, rules that are idiosyncratic at best and logic-defying at worst. Many a compliance officer balks at the request to be "creative" in solving problems, viewing it as an invitation to skirt the intent of a rule.

The real world of health care operations sometimes demands a little creativity from our profession; often you just can't combine patient needs, operational efficiency and legal imperatives without adding a little catalyst - creativity. There may not be a better example of this than when addressing patient privacy issues and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The Privacy Rule is a study in balance. For example, the rule has to strike a balance between the paradoxical desires of patients for personal privacy and to have family, loved ones and friends involved in their care. It balances the important social need to have faith in the confidentiality of highly personal and sensitive information and the needs of health care providers for open communication to promote high quality health care. Often the right balance can't be struck without being operationally creative.

This two part article addresses nine scenarios in which meeting the requirements of the Privacy Rule, operational demands and patient needs requires careful regulatory analysis, thoughtful planning, and a little creativity.

Shadowing Programs, Mentoring Programs and Take Your Child to Work Day, - Theme and Variation

A major tenet of the HIPAA Privacy Rule is that patient information can only be used for "treatment," "payment," and "health care operations" (TPO) unless the patient has provided explicit written authorization, or one of many regulatory exceptions applies. A second major concept is that only the minimum amount of information necessary should be used and disclosed to accomplish a given purpose. These two rules, "TPO" and "Minimum Necessary," combine to form the bedrock of the Privacy Rule's regulatory scheme. They also create gaping chasms though which many activities that were time honored traditions in some organizations can get lost.

Under these rules one potentially problematic activity is the proverbial "shadowing program," and its variants, the "mentoring program" and "Take Your Child to Work Day." The idea of having a health care provider "shadowed"while meeting with patients is not unheard of, but does present challenges under the Privacy Rule. Whether it is a "nurses' day shadowing program," when a politician or community leader learns more about the daily rigors of being a direct care provider, a "mentoring program," when a physician that wants to introduce an eager college student to the rewards of the practice of medicine, or "take your child to work day," when a person learns about career opportunities in the health care field, each of these scenarios falls in gaps in the Privacy Rule. They are not clearly permitted under TPO, are problematic under the "minimum necessary" rule and, yet, are not clearly prohibited either. Moreover, there does not appear to be an individual regulatory exception to match to these programs. Each of these activities serves a legitimate beneficial purpose and shouldn't be quietly eliminated because of a desire to reduce risk. They also should not be ignored or chalked up to the old, vexing, adage "everybody does it." Instead, with the application of diligent regulatory analysis, sound controls and a little compliance creativity, you can reduce risk, meet patient needs and gain the benefits that these programs provide to society.

The Regulations

When analyzing these programs, its important to keep the regulation's basic approach to using and disclosing

health information in mind. Under the Privacy Rule, health care providers may only use or disclose patient information for purposes authorized by the regulations. This is reflected in the regulations at 45 CFR §164.502, Uses and Disclosures of Protected Health Information: General Rules, which states:

> (a) *Standard*. A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

The regulation then goes on to lay out the basic analytical frame work for determining whether a use or disclosure is appropriate:

> (1) *Permitted uses and disclosures*. A covered entity is permitted to use or disclose protected health information as follows:
> (i) To the individual;
> (ii) For treatment, payment, or health care operations, as permitted by and in compliance with §164.506;
> (iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of §164.502(b), §164.514(d), and §164.530(c) with respect to such otherwise permitted or required use or disclosure;
> (iv) Pursuant to and in compliance with a valid authorization under §164.508;
> (v) Pursuant to an agreement under, or as otherwise permitted by, §164.510; and
> (vi) As permitted by and in compliance with this section, §164.512, or §164.514(e), (f), or (g).

In other words, using and disclosing protected health information (PHI) is only appropriate for treatment, payment, or health care operations purposes, unless the patient specifically has authorized the disclosure in a HIPAA compliant writing, or another regulatory exception applies. To use or disclose PHI for a shadowing or mentoring program or for a "take your child to work day" event, the health care provider must be in a position to demonstrate that the event qualifies as either "TPO," that the facility has written authorization from the patient, or another regulatory exception applies.

It is almost indisputable that these programs will not meet the definition of "treatment" at 45 CFR §164.501:

> *Treatment* means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

An individual accompanying a treatment provider to learn more about the health care profession does not relate to the actual provision of care to the patient. Similarly, these programs are wholly unrelated to "payment."

"Health care operations" may provide more fertile ground because it contains language that addresses training programs:

> *Health care operations* means any of the following activities of the covered entity to the extent that the activities are related to covered functions:
> [(1)...]
> (2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, *conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals*, accreditation, certification, licensing, or credentialing activities;

[45 CFR §164.501]

In response to a frequently asked question on the issue of training, the Office for Civil Rights responded as follows:

> **Q:** Do the HIPAA Privacy Rule's minimum necessary requirements prohibit medical residents, medical students, nursing students, and other medical trainees from accessing patient medical information in the course of their training?
>
> **A:** No. The definition of "health care operations" in the Privacy Rule provides for "conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers." Covered entities can shape their policies and procedures for minimum necessary uses and disclosures to permit medical trainees access to patients' medical information, including entire medical records.

While a "mentoring program" may be more closely related to the "training of students," shadowing programs and "take your child to work day" are much less likely to fall under a reasonable interpretation of this regulation.

The following are three approaches to these programs. These are not the only approaches to these challenges and

continued on page 7

Figure 1. Notice and Authorization of Voluntary Participation in Nurses Day Program

On Nurses' Day, ______________________________, Good Heart Health System will be providing our community leaders with an opportunity to better understand and appreciated the demands and needs of the nursing profession. Good Heart is inviting a small number of its patients to participate in this event. Those who participate will help improve the quality of nursing care for everyone in New Jersey.

Participation in this event is strictly voluntary. Your care and payment for your care will not be affected if you do not decide to participate. You are free to decline this invitation.

If you decide to participate:

An invited state or local official or community leader will be assigned to spend an hour with the nurse that provides care to you. You will be introduced to and have an opportunity to meet and speak with the state or local official or community leader ("Guest");

The Guest will accompany the nurse when he or she is providing care to you to learn about how nurses do their jobs;

The nurse will explain your condition, course of treatment and other relevant information about you to the Guest so that the Guest can understand the nurse's role in caring for you.

Protection of your privacy:

A Guest will only be assigned to your nurse if you choose to participate in this event and sign the attached authorization form;

The nurse will ask for your permission before allowing the Guest to enter your room; the Guest will not be in your room at times when your physical privacy might be compromised.

If you decide to participate, you may decide to discontinue participation in the program at any time for any reason. Simply tell your nurse you no longer want to participate.

The Guest will not be permitted in your room during discussions with you about your care unless you first verbally agree.

What information may we give to the Guest?

The nurse will tell the Guest about your condition ("diagnosis"), the care that you are receiving ("course of treatment"), information about past health problems that affect your care ("history") and the expectations for your recovery ("prognosis"). This may include a discussion of diagnostic tests (laboratory, radiology etc.) that you received or will receive, the results of those tests and how your care is affected by the results.

Again, your decision to participate in this event is strictly voluntary. To participate, you must sign below and complete and sign the attached Authorization form. Your care will not be affected if you choose not to participate. If you have any questions about this program, or have a concern about your privacy, you can call Good Heart's Chief Compliance and Privacy Officer at ______________________.

To Participate:

I have read and understand the above information and choose to participate in the Good Heart Health System Nurses' Day Program.

______________________________ ______________________________

Name Date of Birth

should be carefully considered in design and operation. Any approach you consider should be approved in advance by qualified legal counsel.

Shadowing Programs: the Nurse's Day Scenario.

Too often the communities that health care providers serve don't have a good understanding of what it's like to work everyday "in the trenches" as a direct care provider. Shadowing programs are an effective tool to illustrate what health care workers do on a daily basis and demonstrate the value of the service they provide. In a shadowing program, a local dignitary, politician or other prominent community member ("guest") is assigned to shadow a nurse for a day to learn more about his or her job. The guest will have potential access to the nursing unit, including patient rooms, the nurse's station and patient charts, clinical reports and physicians. Potential access to PHI will be substantial.

There are several potential solutions to this problem. First, you could try to fit the shadowing program into the definition of "health care operations" and its reference to training. Given the lack of on-point language, many compliance officers and their counsel will be uncomfortable with this option. A second possibility is to treat the guest as a visitor under the regulatory exception found at 45 CFR §164.510(b) *Standard uses and disclosures for involvement in the individual's care and notification purposes - (1) Permitted uses and disclosures*. In this case, clinical staff would request patient permission before entering the room with the guest, and attempt to limit exposure to PHI as much as possible. There is a significant problem with relying on this regulation, however. In reality the guest is not a person involved in the care of the patient as intended by the regulation. Reliance on this regulation is risky at best.

The more conservative approach is to design a program, with appropriate documentation, training and safeguards that relies on the authorization requirement. In this case, the guest would only come into direct contact with patients that have authorized his or her participation the program in advance through a HIPAA compliant authorization form. The program would involve the following:

1. **Program scope.** The program would be limited to clinical units in which patient authorization can be obtained at least one day in advance and it would exclude participation by patients who have conditions that receive special protection under law such as human immunodeficiency virus, sexually transmitted diseases, substance abuse, or behavioral health issues.
2. **Notice.** The patient would receive a notice explaining the program to the patient and emphasizing that his or her participation in the program is purely voluntary. The notice would clearly state that a decision by a patient not to participate in the program would in no way effect his or her health care or payment for his or her health care services. The notice would inform the patient that he or she may "opt-out" of the program at any time. (See Figure 1 on page 6 for an example notice.)
3. **Prior authorization.** Patients would be asked to authorize their participation at least one day in advance. The patient's authorization would be in the form of a HIPAA compliant writing that would authorize the health care provider to share their information with the guest. The name and address of the guest would appear on the form, and the patient would be provided with a copy of the form at the time that he or she sign it. (See Figure 2 in Part II of this Article for an example authorization form.)

Conclusion

Part I of this Article introduced the operational demands placed on an entity attempting to meet the requirements of the Privacy Rule and provide open communication to promote quality health care. It focused on the regulations related to uses and disclosure of PHI and the interplay between the Privacy Rule and shadowing programs for health care facilities. Part II of this Article will cover other scenarios that would come under scrutiny under the Privacy Rule, including mentoring programs, children in the workplace, media access, staff family members as patients, staff as patients, physician access to electronic-PHI, executive officer access to PHI, and fundraisers. ■

Stephen Miller, JD, Chief Compliance and Privacy Officer, oversees the administration of Capital Health System's Corporate Compliance Program. His responsibilities include developing policies and procedures designed to ensure CHS' compliance with all federal, state and local laws. He also oversees compliance audits and annual and risk specific compliance training for CHS employees. He earned his Bachelor of Arts degree from West Virginia Wesleyan College and his Juris Doctor degree from Widener University School of Law, Harrisburg, Pennsylvania. He is a member of CCH Health Care Compliance Editorial Advisory Board.

EMTALA (cont.)

ligated to provide on-call services based on the resources it has available at the time, including the availability of specialists. The language change does not limit a hospital's ability to set expectations that physicians be on call. Although a physician who wanted to avoid on-call obligations or a hospital that did not want to apply such obligations uniformly could attempt to excuse noncompliance by claiming that the physician was not "available" as a resource, the community call plan would help hospitals diversify their own on-call coverage and ease the burden on those physicians who are providing continuous on-call coverage. ■

Final rule, 73 FR 48434, 48654, Aug. 19, 2008, Health Care Compliance Reporter, ¶700,075

Tax-Exempt

Profit/nonprofit hospitals provide similar charity care

"We don't see much of a difference between nonprofit hospitals and for-profit hospitals," said Theresa Pattara, a staff member of the office of Senate Finance Committee (SFC) ranking member Charles E. Grassley (R-Iowa), at an American Health Lawyers Association program on September 12 in Washington D.C.

Governance. Grassley believes the Internal Revenue Service (IRS) has the authority to ask questions about governance and management. If challenges to the IRS's authority to ask such questions continue, the staffer observed, legislation is very likely to be introduced to give the IRS that right more clearly. Grassley is willing to give the IRS whatever it needs to ensure exempt organizations are in compliance with the tax law, Pattara emphasized

Charitable care. Pattara encouraged nonprofit hospitals to "get their information out there." She mentioned that it would take a minimum of 15 months for Congress to receive the data after the organizations submit their returns. "We need some way to measure what nonprofit hospitals are doing in terms of charitable care" to entitle them to all the tax breaks they receive. How to "measure" charity care or community benefits is the question, Pattara added.

RHIOs. The IRS continues to wrestle with the way it wants to treat regional health information organizations (RHIOs), Stephen Nash, partner, Holme Roberts & Owen LLP, Denver, Colorado remarked. RHIOs exchange health information electronically across organizations and information systems. The problem for the IRS, according to Nash, is that RHIOs did not exist four or five years ago, there are numerous types, and many have applied for tax-exempt status. The IRS is temporarily shelving the initial review of RHIOs applications for exempt status while in the process of evaluating this new form of organization and developing its analytical framework, Nash reported. ■

CCH Washington Bureau, Sept. 12, 2008

In the News

CMS announces revised RAC rollout timeline

CMS has announced a revised timeline for the nationwide rollout of the permanent Medicare recovery audit contractors (RAC) program. Rollout will begin in October 1, 2008, with a second wave in March 1, 2009, and the final wave August 1, 2009. All of these dates are flexible and could be pushed back a week or two. The RAC program must be implemented in all 50 states by January 1, 2010, as required by the Tax Relief and Health Care Act of 2006. CMS indicates that hospitals will not see demand letters or requests for medical records until January 2009 because of the process RACs must follow to operationalize the program. Hospitals in the RAC demonstration states might begin to receive medical record requests sooner than in other states as systems are in place.

CMS News Release, Sept. 9, 2008

ADA Amendments Act passes House and Senate

The Senate has passed a bill (S. 3406) that would expand the scope of the Americans with Disabilities Act (ADA). The House overwhelmingly approved a similar bill (H.R. 3195) in June and approved the Senate version on September 17. President Bush is expected to sign the bill into law. The bill, which was sponsored by Orrin Hatch (R-Utah) and Tom Harkin (D-Iowa), would significantly increase the number of Americans protected by the ADA by expanding the Supreme Court's definition of "disability" under the Act. The bill would retain the requirement that an impairment must "substantially limit a major life activity" to be considered a disability, but would clarify and expand what it means to be substantially limited in a major life activity. The bill contains a nonexhaustive new category of major bodily functions as major life activities.

CCH Chicago Bureau, Sept. 17, 2008

Senators seek incentives for quality of care

Health care providers should be rewarded based on the quality of care they provide, rather than the volume of services, according to high-ranking members of the Senate Finance Committee. Medicare and Medicaid spending are projected to rise from 4.6 percent of the economy to 6 percent within 10 years under current policies, and continue rising to 12 percent of gross domestic product by 2050. "With health care costs growing this quickly, we simply cannot afford to continue paying for inappropriate or inadequate medical care," said Sen. Max Baucus (D-Mont.) during a September 9 committee hearing. Peter Lee, executive director of national health policy for the Pacific Business Group on Health, recommended making routine Medicare claims data available to qualified quality reporting organizations so that employer-sponsored and individually-sponsored health benefit plans can lower premiums by using aggregate claims data across multiple beneficiaries. He also called for a national initiative to measure and compare the effectiveness of drugs, devices and procedures.

CCH Washington Bureau, Sept. 9, 2008