

# Health Care Compliance LETTER

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by William P. Schurgin, Esq. and Kristen McGurn, Esq.

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## Release of allegedly misleading health care reform information halted by CMS

All Medicare Advantage (MA) and Medicare prescription drug plans have been ordered by CMS to immediately discontinue any mailings regarding current health care reform legislation to Medicare beneficiaries, as well as remove any related materials from their website. The order followed CMS' discovery that an insurance company was contacting enrollees, alleging that current health care reform legislation could hurt seniors and disabled individuals causing them to lose important benefits and services as a result of the legislation.

**Potentially misleading information.** "We are concerned that the materials sent to our beneficiaries may violate Medicare rules by appearing to contain Medicare Advantage and prescription drug benefit information, which must be submitted to CMS for review," said Jonathan Blum, acting director of CMS' Center for Drug and Health Plan Choices. "We also are asking that no other plan sponsors are mailing similar materials while we investigate whether a potential violation has occurred."

"We are concerned that, among other things, the information in the letter is misleading and confusing to beneficiaries, who may believe that it represents official communication about the Medicare Advantage program," said Blum. Specifically, CMS is investigating whether the company inappropriately used the lists of Medicare enrollees for unauthorized purposes.

**GOP response.** House Republican Leader John Boehner (R-OH) responded to the memorandum by criticizing actions of the Obama Administration to impose what he referred to as a gag order on critics of the \$500 billion in Medicare cuts proposed by the congressional Democrats. He released a statement contending, "It is outrageous that the Obama Administration is trying to keep seniors in the dark about the consequences of congressional Democrats' costly government-run health care bills."

**CMS investigation.** CMS is currently investigating the released information because the communications claim to convey legitimate Medicare program information about an individual's specific benefits or other matters, but instead offer "misleading or confusing opinion and conjecture by the plan about the effect of health care reform legislation on the Medicare Advantage program and other information unrelated to a beneficiary's specific benefits," according to CMS. The communications ultimately urge enrollees to contact their congressional representatives to protest the proposals referenced in the letter. These communications are potentially contrary to federal regulations and guidance for the MA and prescription drug programs and other federal law, including the Health Insurance Portability and Accountability Act (HIPAA). ■

*CMS Memorandum, Sept. 21, 2009, Health Care Compliance Reporter, ¶350,180*

### OIG: localities not fully prepared for pandemic influenza

An evaluation of ten selected localities revealed that they were not fully prepared for the distribution and dispensing of vaccine and antiviral drugs in response to an influenza pandemic. The Office of Inspector General (OIG) has identified and described eight broad components of vaccine and antiviral drug distribution and dispensing planning:

- (1) **Receiving and staging** involves identifying locations where vaccines and antiviral drugs will be received and staged, and developing procedures necessary to deliver them to dispensing sites.
- (2) **Dispensing** involves administering medications, identifying facilities at which dispensing will occur, and developing procedures to operate and staff these sites.
- (3) **Tracking** involves managing vaccine and antiviral drug inventories by implementing inventory management systems at state or local stockpiles, receiving and staging locations, and dispensing sites.
- (4) **Vulnerable populations** refer to groups, such as the homeless, prison inmates, and nursing home residents, which may not have access to traditional dispensing sites.
- (5) **Priority groups** are typically defined by occupation or health status (e.g., health care personnel, pregnant women). While HHS has developed preliminary guidance regarding priority group definitions, states and localities are responsible for implementing this guidance appropriately.
- (6) **Security** for vaccines and antiviral drugs involves protecting these medications at state or local stockpiles and receiving and staging locations through the point of dispensing.
- (7) **Storage** involves ensuring that the proper environmental conditions are maintained at state or local stockpiles and receiving and staging locations until the medications are dispensed.

- (8) **Transportation** involves moving the medications from state or local stockpiles and receiving and staging locations to dispensing sites.

**Distribution and dispensing components.** According to the OIG's study, the ten selected localities had not addressed most of the eight components and 89 preparedness items that measure the extent of preparedness within each of the eight components. None of the localities had started planning in all eight components. The selected localities' plans to distribute and dispense vaccines and antiviral drugs generally were not actionable. For instance, they did not estimate staffing needs, and when they did, they had not accounted for absenteeism rates in their estimates.

The selected localities moreover varied to the extent to which they addressed the distribution and dispensing components. While all the localities addressed at least one preparedness item in two or more of the components, no locality addressed at least one preparedness item in all eight components.

The selected localities addressed the highest percentage of preparedness items in the Receiving and Staging component and Dispensing component, and addressed the lowest percentage of preparedness items in the Security, Storage and Transportation components.

**Exercises, After Action Reports, and Improvement Plans.** The selected localities conducted exercises related to drug distribution and dispensing and, between September 2006 and July 2008, varied in the extent to which they exercised the components and the number of components tested.

However, nine localities did not create both After Action Reports and Improvement Plans for all of their exercises. After Action Reports typically include the exercise objectives, participant observations, and general recommendations to improve future performance. Improvement Plans identify specific corrective actions necessary to improve the plan, assign the actions to responsible parties, and establish target completion dates to

incorporate the lessons learned during the exercise.

**Collaboration with community partners.** All selected localities collaborated with community partners, such as educational institutions, state or local emergency management agencies, and hospitals, to develop and exercise their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic.

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**Recommendations.** It was recommended that the Centers for Disease Control (CDC) work with states to:

- Improve local preparedness by: (1) determining why localities appear to be in the early stages of planning, and provide assistance to improve preparedness; (2) prioritizing the planning areas where states should focus pandemic influenza funding to improve local preparedness; and (3) placing special emphasis on ensuring localities develop actionable drug distribution and dispensing plans.
- Ensure that localities consistently create both After Action Reports and Improvement Plans to enhance their preparedness.
- Facilitate information sharing and collaboration about existing pandemic influenza planning and encourage the use of existing resources. For example, the CDC should encourage using the Lessons Learned Information Sharing Web site to share not only After Action Reports but also planning documents and promising practices.

The CDC agreed with the second and third recommendations, yet did not indicate whether it agreed with the first recommendation, although it stated it planned to use some of the suggested actions to address this recommendation. ■

*OIG Report, No. OEI-04-08-00260, Sept. 2009*

### Resolution reached regarding auxiliary aids for deaf patients

After the Office of Civil Rights (OCR) found that a hospital violated the Rehabilitation Act of 1973 (Act) by failing to provide an auxiliary aid or sign language interpreter to a deaf patient that sought treatment in the emergency room, a resolution agreement was reached between HHS and the hospital. During the deaf patient's visit he was accompanied by his 11-year-old son; the patient and his son requested a sign language interpreter and the patient's wife called the hospital and asked that one be

provided. Despite the hospital's assurances that one would be provided, no interpreter ever arrived. The patient's medical history, consent for treatment, diagnosis, medication, and discharge instructions were all conveyed through the patient's son. The hospital had a policy in place at the time of treatment that stated that it will provide a qualified interpreter to a hearing impaired person to facilitate the delivery of quality patient care. In addition, the hospital had one portable telecommunication device for the deaf (TDD) for use in the emergency room, which was not utilized.

The OCR found that the hospital failed to provide appropriate auxiliary aids adequate to afford the patient effective communication. Further, the hospital's failure to provide the patient with an interpreter was inconsistent with the hospital's own policy regarding situations which require a qualified interpreter, such as obtaining medical histories and consent for treatment, making a diagnosis and giving medication indications, and discharge instructions.

As a result of the finding that the patient was deprived of an equal opportunity to benefit from the services the hospital provides, the hospital agreed to the provisions of a resolu-

tion agreement with the OCR and to become compliant with the Act. Under the agreement, the hospital must (1) provide deaf or hard-of-hearing patients and companions with full enjoyment of hospital services, and not deny services, privileges, facilities, advantages, and accommodations; (2) designate an individual to coordinate compliance with the Act; (3) develop procedures to address complaints of discrimination; and (4) develop a notice of nondiscrimination and inform patients, companions, and personnel of the contents of the notice. Further, the hospital agreed to specific requirements as to which situations require an interpreter or auxiliary aids to be made available to a patient and the time frames in which they must be provided in emergency and scheduled visits. The hospital also is required to revise its policies and procedures within 60 days to ensure that effective communication is provided to deaf or hard-of-hearing patients and companions and to maintain a log of requests for auxiliary aids to submit to the OCR periodically along with compliance reports. ■

*Office for Civil Rights Letter of Findings, Sept. 1, 2009, Health Care Compliance Reporter, ¶370,032*

*Resolution Agreement, Sept. 1, 2009, Health Care Compliance Reporter, ¶370,033*

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# The ADA Amendments Act: Expanded Disability Challenges for Health Care Employers

by William P. Schurgin, Esq. and Kristen McGurn, Esq.

*This year, over sixteen years after the employment provisions of the Americans with Disabilities Act (ADA) first went into effect, the Americans with Disabilities Amendments Act of 2008 (PubLNo 110-325) (ADAAA) has changed the landscape of disability discrimination in the workplace. The ADAAA significantly broadens the definition of disability under the ADA, states that employers should generally not consider mitigating measures when assessing whether an employee is entitled to the statute's protection, and requires employers to change the way they evaluate whether a worker has a disability and how they handle medical impairments in the workplace.*

## Background

In 1990, Congress passed the Americans with Disabilities Act (PubLNo 111-336) (ADA), ushering in a new era of protection for individuals with disabilities. The ADA prohibits discrimination against persons with disabilities in employment, government programs and services, public accommodations and services, and telecommunications. Today, approximately 20 percent of all employment discrimination charges filed with the Equal Employment Opportunity Commission (EEOC) arise under the employment provisions of the ADA.

Over the past 20 years, however, many disability rights advocates have contended that the ADA has not fulfilled the statute's purpose of creating a more inclusive workplace for people with disabilities. The concerns raised by these disability advocacy groups revolved largely around a series of the United States Supreme Court decisions that limited the definition of disability under the ADA.

In September, 2008, Congress responded to these concerns by passing the ADAAA, which went into effect on January 1, 2009. The ADAAA moved swiftly through Congress with strong bipartisan support. Employer groups, recognizing the bipartisan support in Congress for amending the ADA, worked to negotiate compromise language. The ADAAA significantly expands the universe of individuals entitled to protection from workplace discrimination due to a disability. As a result, many healthcare workers who would not have been considered to have a disability under prior law will now be entitled to the protections of the Act.

## The Expanded Definition of "Disability" Under the ADAAA

The original ADA defined "disability" to include an individual who:

- has a physical or mental impairment that substantially limits one or more major life activities; or

- has a record of impairment; or
- is regarded as having an impairment; or
- has a relationship or association with someone who has a known disability.

The ADAAA retains the same definitional language as the original statute but explicitly states that "disability" must be construed broadly so that the statute's coverage applies "to the maximum extent." In this regard, the statute states that the question of whether an individual's impairment is a disability under the ADAAA "should not demand extensive analysis."

The ADAAA also flatly rejects several Supreme Court rulings that Congress believed led lower courts to incorrectly exclude many people with disabilities from the protections of the statute. Going forward, this means that many of the court cases that had analyzed "disabilities" under the ADA will be of little value under the ADAAA. As a practical matter, until a new body of law develops under the ADAAA, health care employers will need to consider almost any medical or mental condition a potential disability under the ADAAA - other than truly transitory illnesses and injuries.

## "Major Life Activities"

In *Toyota Motor Manufacturing, Kentucky, Inc. v. Williams*, 543 U.S. 184 (2002), the Supreme Court defined "major life activities" as activities that are of "central importance" to daily life. The ADAAA expands the definition of "major life activities" to specifically include: standing, lifting, bending, reading, concentrating, sleeping, thinking, working, caring for oneself, seeing, hearing, eating, walking, speaking, breathing, learning and communicating. The ADAAA also includes as "major life activities" the "operation of major bodily functions," such as the "immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions."

Congress' expansive view of what constitutes a major life activity now includes the ability to lift, bend, sleep, work,

read, concentrate and think, as well as the operation of major bodily functions. This broader definition will result in many more conditions now being considered as major life activities than under the original ADA.

### “Substantially Limits”

The U.S. Supreme Court also held in *Toyota v. Williams* that the term “substantially limits” must be “interpreted strictly.” According to the Court, to be substantially limited in performing a major life activity under the ADA, “an individual must have an impairment that prevents or severely restricts the individual” from performing a major life activity. The language of the ADAAA specifically rejects this Supreme Court standard. While Congress retained the “substantially limits” language in the statute, it declared the standard announced in *Toyota v. Williams* too restrictive and instructed the EEOC to issue new regulations defining “substantially limited” more broadly than the Supreme Court’s holding.

To date, the EEOC has not issued a formal proposed rule. However, in a draft proposed rule circulated in June, 2009, the EEOC proposed deleting its current regulatory language that instructs courts to consider “the condition, manner and duration” of an impaired individual’s performance compared to an average person to determine if that individual is “substantially limited.” The EEOC, at that time, however, did not provide an alternative analytical method for determining when the standard is met. While it is not clear when a formal proposed rule will be published or exactly what guidance it will provide on this important issue, the EEOC’s actions to date signal that any new regulation will set a much lower standard for determining when an individual is “substantially limited in a major life activity” than past court rulings.

### Mitigating Measures and Conditions in Remission

The ADAAA explicitly overrules the Supreme Court’s decision in *Sutton v. United Airlines*, 527 U.S. 471 (1999), which held that mitigating measures should be considered in assessing whether an employee is entitled to protection under the ADA. Now, employers must evaluate impairments in their unmitigated state. Accordingly, in determining whether an individual has a protected disability, health care employers must generally ignore the ameliorative effects of any medications, prosthetics, corrective surgery, hearing aids, mobility devices and other measures that help the worker to correct or avoid a substantial limitation on a major life activity. Health care employees will now be considered to have a protected disability even if their impairments’ substantially limiting effects are completely corrected by mitigating measures. In other words, even if someone is completely asymptomatic, as long as she takes medication, the employer will need to evaluate whether she has a disability in the absence of medication.

Similarly, the ADAAA specifically protects individuals with episodic impairments even when their conditions are in remission as long as the impairment, when active, would substantially limit a major life activity. As a result, employees with conditions that are presently entirely asymptomatic, such as asthma, migraine headaches or allergies, may now be able to claim the statute’s protections if they meet the threshold requirements of the Act.

### Employees “Regarded As” Having a Disability

Under the ADA, an employee is entitled to protection from discrimination if – whether or not he is in fact disabled – his employer “regarded” him as disabled. The ADAAA significantly expands the number of workers who can claim that their employer “regarded” them as disabled. Under the ADAAA, employees may be “regarded as” having a disability if they suffer discrimination because of an actual or perceived mental or physical impairment, whether or not the impairment limits, or is perceived to limit, a major life activity. Therefore, under the ADAAA, the employer does not need to act based on a perceived disability, but only upon a perceived impairment to risk potential liability under the “regarded as” prong.

For example, a health care worker who is subject to a 25-pound lifting restriction may have a “regarded as” claim even if the condition was not found to be a substantial limitation of any major life activity. The worker could claim under the ADAAA that her employer regarded her as having an “impairment” and took adverse action against her in light of the restriction if, for example, it assigned her to another position. This claim could be made without regard to whether the impairment was in fact a disability or whether the employer had formed an opinion about the scope of the impairment.

There is one critical key limitation to bringing “regarded as” claims under the ADAAA. In this regard, the ADAAA specifically excludes from the “regarded as” definition any minor and transitory impairment with an actual or expected duration of less than six months. Accordingly, short term illnesses and injuries that are expected to last less than six months are not protected by the “regarded as” prong of disability. A likely future battleground will be whether this critical limitation applies in a broader sense to all disability based claims.

### A Greater Focus For Health Care Employers: When a Person with A Disability is Otherwise Qualified and What Constitutes a Reasonable Accommodation

Given the ADAAA’s expanded definition of disability, health employers should expect more frequent requests for reasonable accommodation and disability-related

claims. In turn, the focus of health care employers will likely shift to whether an individual is otherwise qualified to perform the essential functions of the job with or without reasonable accommodation. Importantly, the ADAAA only addressed the definition of disability and did not change existing case law, regulations or other guidance that apply to determining when an individual with a disability is otherwise qualified and/or what constitutes a reasonable accommodation.

### How do you Determine if Someone is Otherwise Qualified?

To be a “qualified” individual under the ADA, an individual must be able to perform the essential functions of the position held or desired, with or without a reasonable accommodation. The essential functions of a position are those basic duties that an employee must be able to perform based on factors such as 1) the reason the position exists, 2) the number of employees available to perform the function, and 3) the degree or expertise required to perform the function.

Though not conclusive proof, the EEOC has indicated that it will consider the employer’s judgment and a job description written before advertising or interviewing for a job as evidence of an essential function of a job. Accordingly, prudent healthcare employers should regularly review their job descriptions and other related documents to ensure that they accurately describe the essential functions of the job and other legitimate job qualifications such as experience and certification. In addition, to the extent that there are objective production requirements for a job, those standards should also be spelled out by the employer.

### What Constitutes Reasonable Accommodation?

The EEOC describes a reasonable accommodation as “any change or adjustment to a job or work environment that permits a qualified applicant or employee with a disability to participate in the job application process, to perform the essential functions of a job, or to enjoy benefits and privileges of employment equal to those enjoyed by employees without disabilities.” In this context, in 2007 the EEOC published a fact sheet on the application of the ADA to health care employees. This fact sheet, available at [www.eeoc.gov/facts/health\\_care\\_workers.html](http://www.eeoc.gov/facts/health_care_workers.html), sets forth a number of important points related to reasonable accommodation, including:

- An employer is not required to provide a reasonable accommodation unless an employee asks for one (except when the need for the accommodation is obvious).
- Once an employee asks for a reasonable accommodation, the employer should engage in an interactive process with the employee to determine what is needed and why.

- A health care provider may not rely on its own experience knowledge as a medical professional in making the decision to grant or deny a requested accommodation.
- If an employer rejects an employee’s requested accommodation for a legitimate reason, the employer *must* offer an alternative reasonable accommodation, if one exists.
- If more than one reasonable accommodation exists, the employer may choose the least costly or difficult to provide option, as long as the accommodation is effective.
- Light duty programs do not always satisfy reasonable accommodation requirements.

The fact sheet also reiterates the understanding that absent an undue hardship, employers are required to provide qualified individuals with a disability with reasonable accommodations that would permit employees to perform their essential job functions. Employers are not required, however, to accommodate an employee by removing essential functions from a position.

### The Importance of Manager Training

Training supervisors and managers to recognize and respond to accommodation requests is another important tool that should be considered by health care employees. In this regard, health care supervisors need to be sensitive to the fact that under the new broader definition of disability adopted by the ADAAA, common sense conclusions can result in potential liabilities. Accordingly, the ability to recognize what could be considered a protected disability and how to respond to questions and requests related to such conditions is critical.

### Conclusion

The ADAAA has changed the playing field for evaluating and responding to disability discrimination issues in the health care workplace. As a result, health care employers need to carefully reevaluate their existing procedures for addressing disability issues in the workplace. In doing so, employers should place particular emphasis on the reasonable accommodation process and delineating essential job functions and legitimate job qualifications.

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### New PPS proposed for renal dialysis facilities

CMS has proposed a new prospective payment system (PPS) for facilities that provide dialysis services to Medicare beneficiaries who have end-stage renal disease (ESRD). The proposed PPS would provide single bundled payments to dialysis facilities and would improve care by establishing performance standards for dialysis facilities and also contain the rapid growth in spending. "Combining a fully bundled prospective payment system with required performance standards would encourage facilities to operate more efficiently and ensure that beneficiaries receive high quality care, while saving dollars for both beneficiaries and the Medicare program," said Jonathan Blum, director of the CMS Center for Medicare Management.

Pursuant to the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (PubLNo 110-275), the new PPS must trim 2.0 percent of the estimated payments that would have been made in 2011 under the previous payment scheme. The PPS will be effective January 1, 2011, and would provide for a four-year transition (phase-in) period under which facilities would receive a blend of payments under the prior case-mix adjusted composite payment system and the new ESRD PPS.

**Quality incentive program.** The proposed PPS would provide for a quality incentive program (QIP) that would apply to renal dialysis services furnished on or after January 1, 2012, and would help ensure that ESRD facilities furnished high quality care to their patients by instituting financial incentives that would tie a facility's Medicare payment rate to how well the facility performed on quality of care measures. Facilities that do not meet or exceed minimum performance standards in a period determined by HHS would receive payment reductions of up to 2.0 percent of the payments otherwise made. The payment reductions would apply with respect to the year involved and would not be taken into account when computing future payment rates.

The PPS would provide for measures and performance standards for health care categories, such as measures on anemia management and dialysis adequacy. The data needed to calculate these measures would be collected from Medicare claims submitted by ESRD providers and facilities on a patient-specific basis, which is the only complete provider and facility level data set available to CMS at this time. For this reason, CMS is proposing to adopt only two anemia management measures and one dialysis adequacy measure.

Other quality measures would include, to the extent feasible, measures specified by the Secretary of HHS, including measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula). CMS is not proposing to adopt any measures in these categories at this time since it is not currently collecting data that would allow determination of provider and facility-specific performance with respect to these categories of measures. ■

*Proposed rule, 74 FR 49922, Sept. 29, 2009, Health Care Compliance Reporter, ¶730,074*

## EMTALA

### EMTALA duty to stabilize not triggered by transfer order

A claim of failure to stabilize a patient under the Emergency Medical Treatment and Active Labor Act (EMTALA) requires more than the mere order to transfer, but the actual transfer of the patient. An end-stage renal disease dialysis patient had arrived at the emergency room of the hospital, and complained of chest pain and bleeding. The emergency room doctor ordered various tests, and discussed the patient's condition with a nephrologist at the hospital. The nephrologist subsequently ordered the patient's admission to the "medicine floor" with further orders for tests and a blood transfusion the next morning.

Early the next morning, a hospital surgeon evaluated the patient, and recommended that the patient be transferred to another hospital for surgery. Upon receipt of the recommendation, the nephrologist ordered the transfer as soon as possible. Before the patient was transferred, however, he died.

#### **EMTALA stabilization provision.**

To establish a violation of the stabilization provision in EMTALA, the family was required to prove that: (1) the hospital was a participating hospital covered by EMTALA that operated an emergency department, (2) the patient arrived at the hospital seeking treatment, and (3) the

hospital transferred the patient without first stabilizing the emergency medical condition. The family asserted, among other things, that EMTALA imposed an unqualified duty to stabilize once it was determined that the patient had an emergency medical condition; and, alternatively, even if the duty to stabilize applied only when a patient was transferred, "transfer" did not require a patient to physically leave the hospital, but only for a physician to enter an order of transfer.

Contrary to the family's arguments, the duty to stabilize under EMTALA does not impose a standard of care prescribing how the physicians should treat the patient's condition. EMTALA is not a federal malpractice statute. Rather, the law prescribes a precondition the hospital must satisfy before it may transfer the patient. Therefore, a hospital cannot violate the duty to stabilize unless it transfers a patient. A "transfer" is defined as the movement of an individual outside a hospital's facilities at the direction of any person employed by the hospital.

While the nephrologist did order the transfer of the patient to another hospital, the order did not effectuate a "transfer" because the patient never left the hospital's facilities. Given that no transfer occurred, the family failed to establish a stabilization claim under EMTALA. ■

*Alvarez-Torres v. Ryder Memorial Hospital, Inc., 1st Cir., Sept. 4, 2009, Health Care Compliance Reporter, ¶800,727*

## Anti-Kickback

### Ambulance service contracts not subject to OIG sanctions

In recent advisory opinions, the Office of Inspector General (OIG) stated that it would not impose administrative sanctions on two municipalities related to contracts with private ambulance companies to provide exclusive primary response for emergency ambulance calls. According to the OIG, even though the arrangements could potentially implicate the anti-kickback statute, both of the arrangements contained factors that mitigated the risk of federal health care program fraud and abuse.

The arrangements called for the ambulance companies to annually reimburse the municipalities for their costs incurred in operating 911 dispatch centers and, with one municipality, for it to monitor the company's performance. These kinds of arrangements would be considered prohibited remuneration under the Anti-Kickback Statute pursuant to section 1128B(b) of the Social Security Act because the companies were required to pay an annual remittance as part of their exclusive contract when some of those costs would be reimbursable under federal health care programs.

However, the risk of fraud or abuse is mitigated because the arrangements: (1) are part of comprehensive regulatory schemes to manage the delivery of emergency medical services; (2) provide compensation for the approximate costs of dispatch services; (3) fees are not related to volume or value of the referrals; (4) are limited to emergency medical services; (5) would not adversely impact competition; (6) inure to public rather than private benefits; and (7) do not represent a fundamental change in the delivery of emergency response services. Therefore, the proposed arrangements would not constitute grounds for the imposition of sanctions under the exclusion authority of the Act. ■

*OIG Advisory Opinion, No. 09-14, Aug. 27, 2009, Health Care Compliance Reporter, ¶500,219*

*OIG Advisory Opinion, No. 09-15, Aug. 27, 2009, Health Care Compliance Reporter, ¶500,220*

## In the News

### National Quality Forum annual report released

The National Quality Forum (NQF), contracted to measure performance by HHS, submitted its annual report to Congress in March 2009. The NQF is called on to: (1) formulate strategy and priorities for performance measurement, (2) create an endorsement process for quality measures, (3) maintain consensus endorsed measures, (4) promote electronic health records, (5) fill in measurement gaps, (6) create a website, and (7) present an annual report. The NQF created a group of leaders to set the national priorities and goals of improving health, encouraging people to manage their health and make care decisions, improving safety and reliability of care, ensuring well-organized, appropriate and compassionate care, and eliminating overuse. Further, with the new seven-step consensus development process, 400 quality measures were endorsed. Over the next year, the focus of the NQF's efforts will be to determine the 20 conditions that account for 90 percent of Medicare costs.

*Notice, 74 FR 46594, Sept. 10, 2009, Health Care Compliance Reporter, ¶760,370*

### Combined bargaining units not exempt

A state fund and a private insurer's agreement to offer the company's provider network to the fund's insureds were exempt from antitrust and unfair competition laws because there was no "post-formation conduct." When the fund dissolved its network for certain treatment, it required physicians to contract with the company's network to continue to provide those services and accept payment at a lower rate. While the physicians claimed that this constituted price fixing and "unreasonably restrained or eliminated competition," the trial court found that the fund was allowed to contract with a private company and reimburse at a lower rate pursuant to the Cartwright Act and Labor Code. Although the physicians argued that the two groups each formed contracting units amounting to "post-formation conduct," subject to antitrust regulations, the fund had dissolved its contracting unit and nothing prevents one efficient bargaining unit to be formed.

*Henstorf v. State Compensation Insurance Fund, Cal. App. 2d, Sept. 4, 2009, Health Care Compliance Reporter, ¶800,728*

### Repeal of antitrust exemption introduced

Senator Patrick Leahy (D-Vt.), Chairman of the Senate Judiciary Committee, introduced the Health Insurance Industry Antitrust Enforcement Act of 2009 (HR 3596) on September 16, 2009, which would repeal the exemption for insurance companies from federal antitrust litigation. The 1945 McCarran-Ferguson Act (15 U.S.C. §1101 et seq.), which gives states the authority to regulate the "business of insurance," presently exempts the business of insurance from federal antitrust laws. HR 3596 would repeal in part the McCarran-Ferguson Act with respect to the antitrust exemption for health insurance and medical malpractice insurance providers. The exemption for the most egregious forms of antitrust violations—price fixing, bid rigging, and market allocations—would be repealed. For antitrust concerns that would otherwise fall under a litigation-intensive rule of reason analysis, the McCarran-Ferguson antitrust exemption would still apply.

*CCH Chicago Bureau, Sept. 16, 2009*