HIGHLIGHTS

Health Care Quality, Fraud/Abuse Top List of Health Law Issues for 2008
Patient care quality will be the top health law issue in 2008 because quality concerns drive so much of the debate over how to improve, and finance, the nation’s health care delivery system, according to an informal survey of members of BNA’s Health Law Reporter’s editorial advisory board. Fraud and abuse, which ranked first in HLR’s 2007 Top 10 survey, is a close second. Rounding out this year’s Top 10 issues are health information technology, taxation, health care reform, Medicare, antitrust, labor and employment, corporate governance, and medical staff issues. Page 5

IRS Releases Final Revised Form 990; Changes Reflect Comments on Draft
The final Form 990 for tax-exempt organization reporting, released by the Internal Revenue Service, retains most of the format and queries of an earlier draft of the form while incorporating a series of modifications and much of the added flexibility sought by the large number of individuals and health care organizations that filed comments on the draft, the IRS says. Page 44

Health Plans Must Show Enrollee Deception Before Canceling Policies
California law requires that a health plan seeking to rescind an enrollee’s coverage first must demonstrate that a misrepresentation or omission on the application was willful, or show that the plan made reasonable efforts to ensure the information on the application was accurate and complete before issuing the contract, a state appellate court rules. Page 27

No Insurance Coverage for Legal Fees Arising From Antitrust Investigations
An insurance policy does not provide coverage for over $2.3 million in legal fees incurred by an insured hospital system in connection with federal and state antitrust investigations of a joint venture in which the insured has a 43 percent ownership interest, a New York appellate court decides. Page 20

Court Won’t Enjoin Lawsuit Seeking Damages for Exclusion From Network
Providers allegedly injured by exclusion from health insurance networks may pursue damages claims against two affiliated insurers under the Arkansas Any Willing Provider statute, a federal trial court rules. Page 32

Doctor Who Resigned Before Panel Hearing Failed to Exhaust Remedies
A physician who ended a medical executive committee’s administrative process by resigning during an early stage of its investigation failed to exhaust his administrative remedies and, therefore, could not succeed on claims against the MEC, a federal court in Colorado holds. Page 37

CMS Issues Final Rule Delaying Effective Date of Certain Stark Rules
The Centers for Medicare & Medicaid Services issues a final rule delaying until Jan. 1, 2009, the applicability of the anti-markup provisions under Stark physician self-referral rules with respect to certain services performed in certain locations. Page 22

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MEDICAL STAFF: A California appeals court upholds a verdict and damages award in a physician’s retaliatory discharge lawsuit. Page 35

MEDICAID: A Missouri appeals court rules for Kansas hospitals seeking higher Medicaid reimbursement. Page 34

PROVIDER REGULATION: The Ninth Circuit upholds an arbitrator’s ruling barring a hospital’s mandatory flu immunization program. Page 41

ARBITRATION: The Third Circuit rules that hospitals may sue in a fraud case against a medical transcription firm. Page 19

PROFESSIONAL LIABILITY: “Pure opinion” testimony is not subject to the Frye evidence test, the Florida Supreme Court rules. Page 39

DRUGS AND DEVICES: A federal court invalidates a Maine law limiting the sale of physician prescription data. Page 20

PLAN REGULATION: The EEOC issues a final rule allowing a link between retiree health benefits and Medicare. Page 30

PROFESSIONAL LIABILITY: Submission to a medical review panel is not a prerequisite for a claim alleging negligent maintenance, a Louisiana appeals court rules. Page 40

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Lead Report

Outlook 2008

Health Care Quality, Fraud and Abuse
Top List of Health Law Issues for 2008

Patient care quality, which affects all sectors of the health industry and is a focal point for setting reimbursement and assessing compliance, will be the top health law issue in 2008, according to an informal survey of members of BNA’s Health Law Reporter’s editorial advisory board.

Advisory board members, asked to rank the key issues for health care providers in the coming year, said quality of care issues will edge out fraud and abuse, which ranked first in HLR’s 2007 Top 10 survey, because quality concerns drive so much of the debate over how to improve, and finance, the nation’s health care delivery system.

For 2008, health information technology and taxation place third and fourth, while health care reform—energized by the upcoming elections but occurring primarily in the states—places fifth. Medicare, antitrust, labor and employment, governance, and medical staff issues round out the rest of the Top 10 list.

Several other issues—including alternative dispute resolution, public health, and transactions and financing—received honorable mention while board members gazing into their crystal balls said retail medicine, medical tourism, and e-discovery will raise important health law issues in coming years.

Following are the issues board members ranked highest among their concerns for 2008.


“All health care sectors are affected by the growing movement to focus on quality relative to service performance, reimbursement methodology, accountability, and compliance enforcement. Whether it is future health policy efforts or current corporate accountabil-

ity, quality is the driving issue for 2008,” Dombi said. He is with the Center for Health Care Law, National Association for Home Care, in Washington.

Wall, with Capella Healthcare Inc. in Nashville, Tenn., said “the Office of Inspector General, Joint Commission, Department of Justice, and Centers for Medicare and Medicaid Services . . . they are all in on the act.”

According to Douglas A. Hastings, with Epstein Becker & Green PC in Washington, quality is the “health care issue of the decade.”

The focus on quality creates “an opportunity for the best performers in the industry to create a profound transformation and then to open up best practices through transparency of data and collaborate to spread positive change,” Hastings said.

2. A close second, fraud and abuse enforcement from multiple directions commands attorney attention.

3. Health information technology, while promising to improve quality and lower costs, poses challenging legal questions.

4. Continuing pressure on exempt health care organizations keeps taxation hot.

5. Health care reform moves onto the list with election year proposals and system-wide challenges.

6. The Medicare program continues to have wide-ranging legal ramifications.

7. Increased enforcement of antitrust laws, both by government and private litigators, is predicted.

8. Continued pressure by unions and workforce challenges keep labor and employment issues in the forefront.

9. Corporate governance initiatives challenge the fortitude and competencies of board members faced with new oversight responsibilities.

10. Changes in physician/hospital relationships brought about by economics and regulatory proposals keep medical staff issues on attorneys’ radar screens.

Thomas W. Mayo called quality a “hydra-headed” issue. “Besides the usual stuff about how to measure quality, we have pay for performance (P4P), the transparency of quality information and ratings, patient safety/medical errors, electronic medical records and other IT matters, and Medicare and Medicaid reimbursement issues; the list just goes on and on,” he said. Mayo, of counsel to the firm of Haynes and Boone LLP in Dallas, also teaches internal medicine at a University of Texas medical school and law at the Southern Methodist University Dedman School of Law.

Robert L. Roth, with Crowell & Moring LLP in Washington, said 2007 may have been the turning point in the quality debate as both public and private payers increasingly committed to the “paymentization and compliancization” of quality.

W. Reece Hirsch, with Sonnenschein Nath & Rosenthal LLP in San Francisco, agreed, citing CMS’s recently issued report to Congress on value-based purchasing, the OIG’s move toward enforcement consequences for poor-quality care, and the fact that the plat-
form of every presidential candidate speaks to health care quality in some way.

Wall in Tennessee and Elisabeth Belmont of Maine-Health in Portland, Me., said quality of care and patient safety failures, once the turf of state regulators, are targets of fraud investigations by both DOJ and the OIG.

Not only does the OIG have “quality of care on its 2008 Work Plan but Inspector General [Daniel R.] Levinson announced that it was at the top of the OIG’s enforcement priorities,” Belmont said. Levinson has said that the OIG will expand its efforts to enforce quality of care in residential treatment facilities, psychiatric centers, facilities that treat people with development disabilities, and hospices, she said.

Other board members said that, while some federal initiatives are under way, they see most of the action occurring in the states. Mark A. Kadzielski, with Fulbright & Jaworski LLP in Los Angeles, said “At least 10 states in the past several years have adopted laws mandating the reporting of medical errors and are actively gathering data on the National Quality Forum’s ‘Never Events,’ paving the way for similar reforms in other states in 2008.”

Of course, the downside of mandatory error reporting is increased regulatory oversight and potential media scrutiny, Kadzielski said, “but so far, health facilities seem to have weathered that storm.” Some are becoming more transparent about disclosing errors to patients, families, and, when appropriate, the public, he added.

Activities at the state level “stand in sharp contrast to the inept handling of the federal regulatory process under the Patient Safety and Quality Improvement Act of 2005,” he continued. “No draft regulations for this important federal quality law have been issued some 30 months after President Bush hailed this legislation as a major part of health care quality reform,” he said.

Kadzielski said progress is impeded in part because resources are inadequate at most health care regulatory agencies on both the federal and state levels, “while programs designed to fine providers for quality errors, or to cut reimbursement for poor quality providers under the rubric of ‘value purchasing’ are just coming onto the regulatory scene.

“2008 will be a very interesting time to watch how the government increasingly levies financial penalties against health care providers in more areas than ever before. Healthcare facilities especially have to fight back against these penalties, whatever their amounts, or run the risk of being seen as easy targets for regulators to hit repeatedly,” Kadzielski added.

According to Crowell & Moring’s Roth, tying payment to quality “may, at last, cause all of the talking to give way to action.

“For the past forever, including last year, I identified quality of care as an issue where there was much handwringing but little action. The Medicare FY 2008 Inpatient Prospective Payment System Final Rule may have changed this by identifying certain ‘never events’ for which hospitals will not get paid despite having to provide additional services,” Roth said.

“If public and private payers can successfully fashion payment solutions for their quality concerns, the changes in the quality arena are likely to be significant as quality is transformed into a routine payment and compliance issue,” he added.

Stephanie W. Kanwit, special counsel to America’s Health Insurance Plans in Washington but speaking for herself, focused on the tie-in between quality and health IT. Advances in care quality “are premised on providing more and more relevant information to consumers, as well as on fostering the adoption of more effective treatments,” she said. This includes payment incentives to physicians and other providers to recognize and reward quality performance and reduce the overuse of inappropriate or unnecessary services.

Currently, some one-third of primary care physicians with health plan contracts have quality incentives in those contracts, Kanwit said. In addition, the Medicaid program as well as private health plans are testing and adopting P4P initiatives and Medicare has done demonstration programs, she said.

“Everybody’s talking about quality, but we have to watch carefully to see who is doing something.”

T.J. SULLIVAN, DRINKER BIDDLE & REATH LLP, WASHINGTON

Meanwhile, key stakeholders—including consumer groups, health plans, and more than 135 physician associations—are collaborating to promote a uniform strategy to measure and report provider performance, she added.

Hirsch, however, had a comment on P4P programs that no other board member made. “It is a bit disingenuous” to term the federal P4P an incentive program when CMS “essentially deducts from dollars that hospitals already have earned for services provided.” As a result, he said, CMS proposals to base Medicare hospital payments on quality measures will continue to generate controversy.

Kanwit said a correlative to P4P is how to get consumers current and objective information on which health care services provide the best value. A big issue is the need for an independent entity to set priorities for research to compare the effectiveness of new and existing drugs, devices, procedures, and therapies and distribute the results in a useful form to patients and clinicians, she told BNA.

Quality of care and the transparency of information about that care go hand in hand, she said. “Promoting quality improvement has to be grounded on the concept of an ‘informed consumer.’ There’s truly a ground swell, both public and private, for greater transparency,” Kanwit said.

Fredric J. Entin, of Foley & Lardner LLP, Chicago, said quality now is widely recognized as a health system board fiduciary responsibility.

Boards of directors have been put on notice to make immediate and serious efforts to understand their hospital’s ability to monitor and provide quality care. Entin said, citing Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors, the September 2007 joint report by the OIG and the American Health Lawyers Association (AHLA).

“There providers that fare well will not only have better control of the way in which patients are cared for but, increasingly, outcomes will be measured. On the commercial insurance front, more payers will be imple-
menting P4P-based contracts that will evolve from input- to outcomes-based payment,” Entin said.

Hirsch noted the links between quality and health IT, observing that employers are beginning to sponsor personal health records (PHRs) for employees as well as disease management programs to help manage the cost of health benefits.

While the information maintained in PHRs could make an employer’s disease management program more effective, proposing to use it for this purpose will create inevitable tension in the area of medical privacy, he said. “How can the employer obtain access to that information without offending privacy laws or the privacy expectations of employees?” he asked.

T.J. Sullivan, with Drinker Biddle & Reath LLP in Washington, had the last word. “Medical errors and hospital-borne infections have simply got to be reduced. Where the requisite pressure will come, however, remains to be seen. Price shopping by patients may remain a pipe dream, but outcomes measures and infection rates could easily drive consumer decisions,” he said.

“Everybody’s talking about quality, but we have to watch carefully to see who is doing something,” he added.

2. Fraud and Abuse. Board members ranked fraud and abuse at or near the top of their concerns because they expect 2008 to see increased administrative, regulatory, investigative, and prosecution activity. According to Kirk J. Nahra, of Wiley Rein LLP, Washington, “The fight against health care fraud rages on.”

“While, once upon a time, there was the possibility that health care fraud would be a ‘flavor of the month’ to be put aside when the next hot topic came up, it is clear that the fight against health care fraud is here to stay. The government is putting more resources into this fight, and has more expertise on health care fraud issues, than ever before,” he said.

The need to comply with the latest round of Stark law regulations, the OIG’s use of enforcement to advance the quality agenda, and DOJ’s use of deferred prosecution agreements (DPAs) to monitor medical device companies accused of taking kickbacks as some of the reasons board members said they expect an active year in federal enforcement.

With CMS expanding its use of demonstration project authority to empower recovery audit contractors and program safeguard contractors with bounty rewards for uncovering fraud and abuse, the industry should expect an active year in federal enforcement, they said.

Several board members observed that the present-ment requirement of the False Claims Act is headed to the Supreme Court in Allison Engine Co. v. Sanders. Presenting the question whether the FCA applies to subcontractors or just to the entity actually presenting a claim to the government, Allison Engine is not a health care case but “looks like a blockbuster with some real effect on the health care industry riding on the outcome,” according to Richard Raskin, with Sidney Austin in Chicago.

Sanford V. Teplitzky, with Ober Kaler in Baltimore, agreed, pointing out that there has been “no letup in the number of qui tam cases filed” and reports by Justice and the OIG confirm that health care investigative and enforcement priorities are, in large measure, driven by these cases.

Expanding the FCA to downstream contractors could mean more valuable government and private industry resources will be diverted to responding to cases that “in the majority of situations amount to unsubstantiated rumors and allegations containing incomplete and often inaccurate facts,” he said.

States’ enactment of false claims legislation as required by the Deficit Reduction Act (DRA) will only exacerbate this situation and significantly increase the time, effort, and money health care companies that conduct business in more than one state will have to expend in responding to allegations of health care fraud or abuse, Teplitzky added.

Jack A. Rovner, with Neal, Gerber & Eisenberg LLP in Chicago, said he also expects increased government investigation and enforcement of fraud and abuse laws generally and FCA activity in particular.

“Political pressure, especially in an election year, coupled with the 2006 Medicare Part D reconciliation process, which was delayed but should be well under way in early 2008, should spur intensified ‘investigations’ of ‘overpayments’ to Medicare private plans and Medicare providers, of improper Medicare private plan marketing—especially through agents and brokers, and enrollment improprieties,” he warned.

“The fight against health fraud rages on. The government is putting more resources into this fight, and has more expertise on health care fraud issues, than ever before.”

Kirk Nahra, Wiley Rein LLP, Washington

Eric Tuckman, with Advisory Health Management Group, Manhattan Beach, Calif., said he sees 2008 bringing “more novel and aggressive uses of fraud and abuse laws to improve patient care quality.

“Use of the FCA will continue in cases of marginal quality or the provision of unnecessary services, but identifying these cases more often will occur from sophisticated data mining techniques able to reveal heretofore unknown trends or patterns of practice,” Tuckman predicted.

Hirsch said he expects the OIG to continue to refine its new theories of liability relating to quality of care. For example, he said, the OIG/AHLA Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors “clearly highlighted that liability for failure of care or medically unnecessary care may be imposed upon organizations that neglect appropriate supervision and oversight of clinical services.

According to Roth, another factor motivating the aggressive use of the fraud laws is that the government “continues to be enamored by the quick policy-changing results that can be achieved through enforcement actions.” In his comments, Roth renewed last year’s criticism that regulatory agencies are allowing government enforcers to displace regulatory guidance
and agency decisionmaking with criminal and highly punitive FCA civil actions.

The result, he said, is that providers and payers have developed a siege mentality, while the government’s obligation to exercise thoughtful restraint in exercising its great power continues to wane. This can be seen, for example, in the penalties for failing to comply with the FCA education requirement in the DRA, Roth said. These are “Draconian and include debarment, nonpayment of claims, treble damages, penalties and, in some cases, attorneys’ fees and costs.”

Nahra expressed similar concerns. “There is a real risk that the government’s expertise—and willingness to be aggressive and push the envelope—is creating a situation where, in many situations, there isn’t a fair fight.” Government tactics are very aggressive and sometimes, as in the KPMG case, they get shot down, he said.

“But even in those situations, it is long after the fact, meaning that companies and individuals have already gone through the wringer,” Nahra said. “The result is that the government increasingly is using its aggressiveness and market clout to push a result that it otherwise would not be able to get,” he added.

“The government should focus its attention on the many situations where there is real bad behavior, rather than simply using its clout to get more money in borderline situations, Nahra said.

In Raskin’s opinion, increased fraud enforcement will stem, in part, from the fact that “2008 is an election year and no elected official or prosecutor wants to be seen as soft on fraud. The issue cuts across political parties and, better yet, enforcement pays for itself . . . and more.” The pharmaceutical and device sectors are likely to be hardest hit, he predicted.

Tuckman said he sees fraud and abuse statutes being “interpreted in such a way as to challenge utilization practices relative to Medicare patients when lengths of stay are reduced below community standards or when P4P programs are misused and go beyond quality considerations.”

Also of concern to some board members is the government’s use of deferred prosecution agreements or nonprosecution agreements under which companies are required to retain monitors who are paid by the companies, but who report directly to the government.

“To the extent that certification of OIG compliance agreements can be viewed as ‘corporate integrity agreements light,’ these agreements, which are in addition to CIAs, should be viewed as ‘CIAs on steroids,’” Teplitzky said. Under these agreements, monitors are involved in the company’s everyday operations and even must approve every consultant relationship, the attorney said. The health care industry “should not be surprised to see the use of deferred prosecution agreements expand to other areas,” he said.

What concerns Katherine Benesch, with Duane Morris LLP in Princeton, N.J., is that use of DPA monitors and overseers “has removed the management of health care organizations from experienced providers.” One hopeful sign, she said, is that four members of Congress, including Rep. Bill Pascrell (D-N.J.), are asking for House Judiciary oversight over DOJ’s use of DPAs and monitors, and for legislative controls over how the monitors get picked and paid, which—according to Teplitzky—is handsomely. It has been reported that former U.S. Attorney General John Ashcroft’s law firm could earn as much as $52.2 million serving as a monitor in a case against a medical device company, he said.

Similar concerns are triggered by the Recovery Audit Contractor (RAC) Program created by the Tax Relief and Healthcare Act of 2006, which uses these third parties to uncover fraud and overpayments in federal health care programs.

“Medicare is experimenting with a wide variety of time- and cost-efficient compliance enforcement measures to pick off the low hanging fruit among allegedly abusive health care providers,” Dombi said. “From expanded use of demonstration project authority to empowering RACs and program safeguard contractors with bounty rewards, 2008 promises to be an active year,” he said.

According to Teplitzky, industry terms these activities “RAC attacks.” Early results—RAC personnel identified more than $303.5 million as improper payments in the first 18 months of the program, according to the government—have encouraged CMS to expand the program nationwide during 2008, well ahead of the 2010 date mandated by Congress, he said.

The continued expansion of hospital ownership by physicians . . . likely will engender a closer look at the long-standing rationale for the whole hospital exemption.”

ERIC TUCKMAN, ADVISORY HEALTH MANAGEMENT GROUP, MANHATTAN BEACH, CALIF.

With payment tied to a percentage of recoveries, “early RAC reports have included significant and substantial recovery demands. Under the program, payments to the RACs are based upon the initial recovery demand, not upon the actual repayments, if any, following appeals. In fact, a number of providers have successfully appealed the initial RAC recovery amounts,” he said.

“More recently, CMS has announced a number of limitations on the activities of RACs which hopefully will reduce the angst and turmoil caused by these entities, but only time will tell,” Teplitzky said.

Changes to the Stark law in the Stark II Phase III regulations published in September generated numerous comments, but Sullivan said that while Stark arguably has been the number one issue since 1988 or 1989, “now the emperor has new shoes.” With the introduction of an expanded “stand in the shoes” doctrine for relationships involving physician practice members, hospitals and integrated delivery systems are being forced to reevaluate many of their long-standing arrangements with physicians, he said.

Belmont said she sees the goal of the Phase III regulations—both proposed and effective—and the host of proposed changes to the Stark regulations in the 2008 Medicare Physician Fee Schedule as being to “dramatically limit physicians’ financial relationships with other health care providers.”

Entin said this could result in significant disruption to existing physician/hospital relationships as what had been understood to be legal and mutually beneficial is
revised. Hirsch said that in California the stand-in-the-shoes doctrine has caused medical foundations to restructure the form, if not the substance, of professional services agreements with affiliated medical groups.

The new rules have “left many issues unanswered and raised significant new questions,” Teplitzky said. Of perhaps greatest importance is the damage the regulations could do to academic medical centers around the country, he said. “CMS issued a one-year delay on the application of the regs to AMCs, but the issues remain to be resolved,” he told BNA.

Hirsch said the effective date delay itself is “actually quite limited in scope.” It does not apply “where a non-profit hospital is contracting with a physician group and the entities are not both affiliated in the same health care system . . . or to contracts between an academic hospital and a physician group that is not part of the AMC.” As a result, he said, the stand-in-the-shoes rule still will lead to the restructuring of many common hospital-physician relationships.

Another problem that remains to be tackled is the blurring of the line between Stark and Medicare/Medicaid reimbursement represented by the 2008 Medicare Physician Fee Schedule regulations, board members said.

“The fee schedule’s ‘anti-markup’ rules for diagnostic tests that are purchased or performed at a site other than the office of the billing physician have created as much consternation, confusion, and controversy as any rules in recent memory,” Teplitzky said.

“CMS’s final rule would also have significantly altered the ‘same building’ test for ancillary designated health services performed by a physician group,” he added. “If it had been left standing, this would have required many physician group practices to institute substantial changes—including perhaps finding new and larger office space—to avoid serious, yet unintended, violations of the Stark rules.”

“Although CMS just announced that the new anti-markup provisions, except for anatomical pathology services performed in a centralized building, have been deferred until January 2009, CMS is not finished with this issue,” he said.

The Federal Register notice says that during the delay they will potentially issue clarifying guidance and new proposed rules, he said, adding “this issue is far from over.”

Tuckman said he foresees possible changes to the Stark law’s whole hospital exemption. “The continued expansion of hospital ownership by physicians, both with regard to specialty hospitals and well as general acute care facilities, likely will engender a closer look at the long-standing rationale for the whole hospital exemption,” he predicted.

“The news for providers on the enforcement front is not all bad, however,” Teplitzky said. Industry consideration of the OIG’s voluntary disclosure program should increase during the coming year with beneficial consequences, Teplitzky said.

“Results continue to demonstrate the benefit of that program under certain limited circumstances,” he said. “Specifically, a majority of the filings under that program have been referred by the OIG to the Medicare fiscal intermediaries and carriers and durable medical equipment carriers for a simple overpayment recovery. Of the cases that remain, a small minority were settled with the imposition of a CIA,” he said.

3. Health Information Technology. Health information technology ranked high on board members’ lists because of its promise and challenges. While it promises to help improve quality and reduce costs in the long term, short-term challenges relating to fraud, tax, and financing—all in the face of feasibility and technological hurdles—abound, they said.

To Howard Burde, with Blank Rome LLP in Philadelphia, health IT is the answer to reducing health care costs. “The only way to increase insurance levels is to reduce duplicative utilization by sharing information.” Short of cutting provider reimbursement, there are no real alternatives, he said.

According to Hirsch, the Department of Health and Human Services clearly is on board. Its willingness to use the Medicare program’s leverage is seen in developments such as the recently introduced bipartisan legislation to spur physician adoption of e-prescribing technology and the HHS initiative to incentivize physicians to adopt HIT systems with additional Medicare reimbursement, he said.

“HHS has the ability to use both carrots and sticks to move forward the cause of health care IT in 2008,” Hirsch said.

But Wiley Rein’s Nahra warned that developing health information technology “presents an enormous challenge.” Nahra co-chairs a federal advisory work group preparing recommendations for the American Health Information Community on how the government can best support interoperable electronic health information exchange while protecting personal health information.

“The HIT marketplace is proceeding far faster than the ability of the regulatory system to keep pace,” he told BNA. There are extremely complicated regulatory challenges and the difficulty of resolving them threatens to delay realistic progress, he said.

Belmont said 2008 will be a time of emerging uses of health information technology beyond traditional treatment and payment activities. Health information will be used for P4P programs, to achieve transparency that helps consumers make decisions about price and quality; for provider profiling; and for quality and utilization review programs. It also will be used in business analytics to test existing constructs for uses and disclosures of health information under privacy and security and intellectual property laws as well as contractual relationships among providers, payers, and other parties, she said.

These secondary uses of health data will require resolution of issues related to access, use, and control and ongoing monitoring of involved stakeholders, particularly at the local level, Belmont continued. Furthermore, evolving issues such as health record banking, implementation of regional health information organizations (RHIOs) for the exchange of health information, and the growing use of personal health records (PHRs) continue to keep the electronic health record (EHR) landscape in flux, she said.

There is “lots of talk” about how good EHR and a national health information infrastructure will be for the country, Rovner said, “but little help on how to pay for it; how to get the industry stakeholders to cooperate, rather than war, over its implementation; and, perhaps most vexing, how to find a viable economic model to pay for the investment to develop it.”
Rovner said he sees the economic failures of several initiatives, such as RHIOs, as underscoring the struggle to find a viable economic structure to justify the necessary investment. Furthermore, he said, continuing disputes among health care stakeholders, including payers, hospitals, physicians, other providers, employer group health plan sponsors, government, and consumer privacy advocates, “over who owns and who controls electronic health records will, as with the economic changes, continue to forestall effective development of interoperable EHRs.”

J. Mark Waxman, with Foley & Lardner LLP in Boston, expressed similar concerns about the potential financial consequences of HIT development. “With interest rates at a low level over the past several years, and managed care rates climbing, the overall environment has been strong. But if interest rates begin to rise, and pressures to spend on capital for IT remain strong while keeping prices fairly stagnant, will we see hospital margins erode, or weaker systems disappear?” he asked.

“HHS has the ability to use both carrots and sticks to move forward the cause of health care IT in 2008.”

W. Reece Hirsch, Sonnenschein Nath & Rosenthal, San Francisco

In any case, failing to act quickly enough to develop a regulatory framework could mean the marketplace develops without appropriate controls, Nahra said. “Much like the need to test Medicare alternatives, we need to find a realistic means of encouraging swift development and adoption of HIT, while at the same time developing a realistic regulatory structure, even if it is not a perfect regulatory structure,” Nahra said.

HIT advances “are absolutely critical to promote both quality and efficiency of operations, as health plans work with physicians and other health care providers to spread the use of both EHRs and PHRs,” according to AHIP’s Kanwit.

Kanwit said PHRs are truly “the wave of the future” and will have “an enormous positive impact on costs and quality throughout the system by preventing errors and adverse drug interactions.” AHIP has worked with the Blue Cross and Blue Shield Association to develop a model health plan PHR and operating rules that make the PHRs portable, so consumers who change health plans can take them with them, she told BNA.

“E-prescribing is also a key initiative,” Kanwit said, as health plans and pharmacy benefit managers work to develop tools to help physicians prescribe electronically, including allowing checking of patient histories and information about generic alternatives to be provided.

But these health plan IT initiatives work well only when they are truly interoperable, which HHS defines as the ability to communicate and exchange data accurately, securely, and effectively with other IT systems, she said. “In other words, they can’t operate in silos,” with hospitals and other providers unable to share data.

“It’s the classic VHS/Beta problem,” Nahra said, referring to the videotape recording war between two rival incompatible formats in the 1970s and ‘80s. “If we had the ability to say today that we are going to create VHS instead of Betamax so everybody should buy VHS then everyone could buy the same system. But it doesn’t exist right now. So doctors and hospitals are deciding that they need electronic medical record (EMR) systems for their own operations and are not yet worried about sharing that information. They can’t wait for that capability.”

Kanwit indicated the scope of the problem, saying studies show “only about a quarter of physicians use some form of EMRs, with fewer than that using what would be called a ‘fully operational’ system that would allow collection of patient information electronically, online ordering of lab tests, and electronic display of test results.”

A lot of this is because many physicians do not want to spend a lot of money today “when they may buy a Betamax that will have only a brief shelf life and quickly be replaced by the competition, Nahra said. “But there is no solution to this dilemma today; it’s just our reality.”

Despite the “Beta problem,” Burde said that “virtually every major acquisition by a health care provider or payer, or by state or federal programs involves health IT.” In fact, he said, the largest procurement in health care in the coming year will be the joint DOD/VA EMR system. “The standards used for that acquisition will affect the entire health care industry,” Burde said.

The DOD/VA acquisition “is a big deal because they are at least going to link among the VA hospitals,” Nahra said.

Board members generally were pessimistic about achieving HIT interoperability anytime soon. Rovner, for example, predicted that we will “continue to hear lots of talk, but not a lot of meaningful action.” Still, he said, “the incentives will continue and activity will be high.”

Entin agreed, but said “the fragmented nature of health care IT will continue to be a roadblock to the implementation of technology solutions beyond the four walls of a single hospital or system.”

One perhaps unwelcome result, Rovner predicted, is that said’s appetite to enforce privacy, security and transactions rules under the Health Insurance Portability and Accountability Act will grow along with the rise of electronic health information and its accompanying privacy and data security concerns.

Hirsch agreed, saying that, “although there have been no public announcements regarding the OIG’s security audit of Piedmont Hospital in Atlanta in the spring of 2007, 2008 is likely to see some degree of stepped-up HIPAA security enforcement.” CMS has contracted with PricewaterhouseCoopers to conduct covered entity security audits, and the OIG reportedly plans to conduct at least two more, he told BNA.

4. Taxation. Tax considerations, especially those affecting exempt health care organizations, again make this issue a Top 10 concern for health lawyers in 2008, board members said. As Tom Mayo put it, “Nonprofit health care will continue to be under the microscope in 2008.”

Wall agreed. “As long as Chuck Grassley is in the Senate there will be hearings that put tax-exempt providers under the microscope. The government will continue to require more reporting of data to establish
proof of community benefits to justify avoiding the tax
man,” Wall said.
In addition, “the state and local revocation of tax ex-
emption, emerging corporate governance principles, con-
gressional scrutiny and legislation on hospital bill-
ing and collection practices will continue to transform
the face of traditional community tax exempt hospi-
tals,” he added.

John J. Durso, with Ungaretti & Harris in Chicago,
concurred, predicting that “the never-ending battle
challenging the tax-exempt status of providers will con-
tinue” both at the federal level, with executive compen-
sation questions, the new Form 990, and Government
Accountability Office investigations, and at the state
level, with attorney general investigations and property
tax challenges.

Tuckman said that, “while 2008 may not bring a na-
tional standard regarding quantitative requirements for
charity care and community benefits, it is quite likely
we will see further legislative and regulatory action in
the states to mandate a definition of these components
and set specific levels for compliance.”

Although there are “bona fide industry arguments re-
ating to the elements that should be included in any
computation of charity or community benefits, estab-
lishing minimal standards will constitute clear and
simple compliance guideposts and enable regulators
and the public to determine which institutions are ap-
plying the revised standards effectively,” Tuckman
said.

Tuckman also said he expects private litigation to
change from challenging overall institutional policies
relative to billing and charity care to attacking the ac-
tual implementation of these policies. The increase in
the number of uninsured “as well as a significant in-
crease in the number of under-insured individuals
makes it certain” that there will be more private and
class action lawsuits in this area, he predicted.

“Finally, we may see regulators shift their focus from
individual community benefit and charity care determi-
nations to investigating whether exempt entities are uti-
lizing their overall assets for the benefit of the commu-
nity,” he said. “The existence and maintenance of large
positive balance sheets may also trigger governmental
review of whether the public is receiving maximal ben-
eficial use of these exempt assets,” he added.

According to Michael W. Peregrine, with McDermott,
Will & Emery LLP in Chicago, “the role of the federal
government in the oversight of nonprofit health care fa-
cilities will continue to evolve with the ongoing interest
of the Senate Finance Committee and the continued re-
consideration of the community benefit standard—and
its ‘community board’ component—for determining tax
exemption eligibility.

“We also can expect to see continued focus on execu-
tive compensation, from both the IRS—with the expec-
tation of additional formal reports from the IRS and its
analysis of the data from the community benefit compli-
ance checks of 2006—and state charity officials, who
can be expected to be aggressive in terms of their re-
view of potentially problematic compensation arrange-
ments,” Peregrine added.

Sullivan said tax issues remain high on his Top 10 list
this year “if only for the sheer volume of developments
percolating through Congress, the IRS, and state and
local authorities.

“Last year, providers no sooner got over the shock of
Illinois Attorney General Lisa Madigan’s ill-fated pro-
posal to require tax-exempt hospitals to provide 8 per-
cent charity care when the minority staff of the Senate
Finance Committee issued a Discussion Draft featuring
the proposal that all tax-exempt hospitals should be re-
quired to provide free care up to a certain income level
and should be required to provide charity care account-
ning for no less than 5 percent of their revenues or ex-
penses,” Sullivan said.

“While neither of these proposals is likely to become
law as is, the continuing legal battles over property tax
exemption at Carle Foundation and Provena Covenant
Medical Center in Illinois ultimately may force a legis-
lative solution there,” Sullivan continued. “Once Pan-
dora’s Box is opened, the hospital community cannot be
certain of a perfect outcome.

“While this may be the worst of times for legislation,
it is the best of times for exempt hospitals to strengthen
their charity care and community benefit records,” he
said, adding “It’s all going public soon.

The new IRS Form 990 and Schedule H will finally
bring about comparable national reporting for all non-
profit hospitals’ charity care and community benefit
records. With the Form 990 already routinely available
on the Web, the expanded content and specificity
means the amount of sunshine and opportunity for out-
side scrutiny has never been higher,” Sullivan said.

“All the new emphasis on measuring and reporting
charity care and community benefit occurs against the
backdrop of continuing governmental and public scruti-
tiny of executive compensation, benefits, and govern-
ance practices throughout the nonprofit sector. Hospi-
tals ignore these tax issue—and the need to tell their
story in the most positive way possible—at their own
peril,” he said.

Belmont agreed, saying that, while Forms 990 “have
long been subject to public disclosure, they have be-
come increasingly important as a comprehensive report
on the activities and operations of tax-exempt health
care organizations, including both financial and nonfi-
ancial matters.

“Because the redesigned Form 990 probes much
deeper into hospital operations and community benefit
practices, and because it requires more information on
the core form with respect to the compensation of offic-
ers, directors, and key employees, health law prac-
titioners likely will have greater involvement in the
review of those compensation arrangements,” Belmont
said.

5. Health Care Reform. The last serious attempt at na-
tional health care reform was more than a decade ago,
but board members asked to rank the key issues for
health care providers in the coming year think the time
has come for another round.

While few said they expect significant reform at the
federal level prior to 2009, many said they expect the
dialogue spurred by the upcoming elections and state
initiatives to make health care reform a significant fea-
ture of the health care legal landscape for 2008.

“Everybody knows the health care system is broken,”
Mayo said. “The uninsured and under-insured and
what to do about them will no doubt be fueled by the
presidential race,” he said, adding, “the media are all
over this issue and will keep it in front of us throughout
2008.”
According to Hastings, “When health policy is hot, health law issues follow, both in the form of legislative and regulatory actions and in the form of transactions and new arrangements structured to capitalize on business opportunities created by policy actions. The inevitable changes will mean more work for lawyers.”

Being in the middle of a presidential election cycle means that at the federal level we will “only see the trailers for real reform, not the movie,” Burde predicted. Kadzielski was equally pessimistic, citing the “debacle” over the State Children’s Health Insurance Program and saying the funding crises on meaningful health care reform legislation in Congress is a major problem.

“Whether anyone on the federal level will have the courage to take action on these health care issues in an election year is highly doubtful. Yet it is critical that action occur,” Kadzielski said.

While payers and providers are watching the national debate, they are responding to market opportunities and changes on a state-by-state basis, Burde said. The only real health care reform is taking place in the states, with “interesting approaches being implemented in Tennessee, Georgia, and Florida,” Burde said.

Mayo agreed, predicting that in the absence of any meaningful action from Congress, the states will continue to improvise.

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**“When health policy is hot, health law issues follow, both in the form of legislative and regulatory actions . . . and new arrangements structured to capitalize on business opportunities.”**

**DOUGLAS HASTINGS, EPSTEIN BECKER & GREEN PC, WASHINGTON**

Mark Waxman also concurred, saying that, while the election—and the health reform platforms of the candidates—is the No. 1 story for 2008, it will be notable “as much for the conversation it produces as for the resulting gridlock on any meaningful legislation along the way.”

Waxman predicted that “one hot topic will be whether Massachusetts-style health reform can be successful even in Massachusetts where the financial challenges are now becoming evident.”

Raskin was more hopeful. While it may be 2009 before specific federal legislation is proposed, health care companies and providers would do well to keep a close eye on the national political debate reinvigorated by the Massachusetts insurance experiment and presidential campaign proposals. “Health care reform is back on the agenda,” he said.

Rovner said he sees a half dozen key issues that could and should be addressed as part of a broad reform initiative, including measures to address the problem posed by the under- and under-insured, the cost of Medicare and Medicaid, quality and pay-for-performance issues, and health IT and a national health information infrastructure.

“It is not clear that any of these will get done by the new administration and new Congress, but there will be lots of talk, debate, ideas, concepts, promises and attacks until the election,” he said.

Roth said he sees only inaction. Health care reform will be the “top fizzle issue in 2008,” he said.

“There seems to be absolutely no momentum towards comprehensive health reform at the federal level. This stems from several factors, including the highly partisan mood in Congress, the jockeying of the two major parties on health care for the 2008 election, the efforts being made at the state level to try to address the problem of the uninsured, and the perceived lack of coherent voter disapproval focusing on any particular issue,” Roth said.

As a result, Roth said, state experimentation will continue to shape the debate while smaller changes command significant attention. An example of the latter is all the attention being paid to the Medicare sustainable growth rate formula used for physician payment rates, he said.

“I doubt something will get done, but only after significant discussion” as the parties seem more focused on finding wedge issues for the campaign rather than on achieving bipartisan policy goals, Roth said. “The slim Democrat majority in the Senate prevents any significant partisan action and bipartisan action does not look likely,” he added.

Any reform will need to deal with the employer’s role in health insurance, several attorneys said. “On the one hand, you have states, like Massachusetts, that are forcing employers to be more involved,” Nahra said. “On the other, constant cost pressures are creating real economic tensions for even the biggest employers, witness, for example, the auto industry where health care costs are deal-breakers with the unions. This seems to be a system facing chaos. Moreover, there are real legal issues about employers’ ability to control costs through employee behavior.

“Employers are interested in wellness programs that encourage better employee behavior, but there are real legal restrictions, including privacy laws, that put pressure on the idea of the ‘one size fits all’ employer-sponsored coverage, where all employees, within the range of choices, pay the same price.” Charging employees with problem behavior higher premiums might reduce costs, but will trigger a debate on whether this is appropriate, he said.

“I think costs and legal land mines will lead to real pressure to permit employers to be more active in this area as one way to help preserve an employer-sponsored system that seems on the verge of collapse,” Nahra said.

Jack Rovner had similar concerns. “There is a lot of enthusiasm for ‘forced’ wellness initiatives by employers,” he said. The 2007 HIPAA wellness program rules, for example, which take effect this year, allow health insurers and employers to provide real financial incentives to encourage and reward healthy behavior, he said. “But how will these programs be reconciled with Americans with Disabilities Act requirements (at least as the Equal Employment Opportunity Commission seems to interpret them) that appear to conflict with the wellness rules? How will these programs be managed to avoid HIPAA Privacy Rule violations when employers may want hard data to show whether the programs are working, including who in the company is using them.”
and who in the company may need ‘encouragement’ to use them?”

In picking health care reform as a key issue, Mayo said that employers “seem finally to understand this is their issue, too. The middle class also eventually will figure out that their insurance coverage isn’t nearly as good as they thought it was. Sooner or later, these forces will converge and this will be the ‘perfect storm’ issue well into the next decade.”

Wall was willing to predict a few consequences. “Despite all of the lofty policy discussions in Washington about safety, consumer choice and expanded coverage,” what all of the industry groups who lobby Congress will push for is funding, he said.

“Managed care plans will fight to preserve the huge gains that they have made during the Bush Administration while physicians will fight to avoid further cuts in payments. Adequate funding for traditional Medicare and Medicaid will continue to be the top issue that will cause the phone in the typical congressional office to ring off the hook,” Wall continued.

“Look for a Republican administration to expand some of the concepts that came along with Medicare Part D, which should favor managed care and big drug companies,” he said. “If the Democrats take office, expect a larger share of the nation’s GNP to go into health care spending, which should benefit providers,” he said.

6. Medicare. Medicare, according to board members, retains its spot on the Top 10 because it will continue to be a central component of the health care delivery system with ramifications—whether related to reimbursement, fraud prevention, or quality and technology innovation—across the board.

Mayo summed it up: “It’s so big, and it’s so large a part of the debate about health reform, and there’s so much going on—between absorbing the changes wrought by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), Part D, or changes in reimbursement policies—that Medicare will continue to be a central feature of the health law industry.”

Roth agreed. “Medicare is simply too vast and important. The big question is whether Congress will change the funding level for Part C, Medicare Advantage, and whether these programs will continue to be embraced by beneficiaries, providers, and private payers, and will actually reduce the growth rate for Medicare costs,” he said.

Nahra cited the importance of Medicare because of its dominant financing role. “There are pressure points everywhere—Medicare, Medicaid, private employer-sponsored insurance, individual coverage, etc. I put Medicare at the top of the list, mainly because it is the biggest chunk of that issue,” he said.

“We are in constant exploration of whether there are new models to make this system work. In addition, there continues to be a systemic tension between encouraging reasonable alternatives and providing so many restrictions to these alternatives that they are not likely to be sufficiently useful,” he said.

He acknowledged that there are fraud risks associated with some of these alternatives, but said that there is “a real possibility that these experiments will fail simply because the regulatory requirements—on issues that clearly matter less than the potential fraud—will get in the way of achieving effective results.”

He said it is difficult to look at the Medicare system as it now stands and have anything other than substantial concern about its future. “Developing an effective means of testing realistic alternatives—with appropriate but not undue regulatory requirements—will be a key challenge in the years ahead,” he said.

Hirsch said Medicare’s importance also stems in part from the leverage it affords in forcing change and innovation.

According to Benesch, “Medicare and Medicaid are ‘hot-button’ issues for several reasons. First, all of the fraud laws relate back to Medicare and Medicaid as the basis of many problems. Second is the problem of cost and the uninsured.”

Federal reimbursement policies “create incentives that determine who gets what care, and who can and cannot afford treatment,” she said. “While policymakers wrestle with how to pay for medical care, more and more of the population goes without. Thus, the results of these debates are of paramount importance in terms of the effectiveness of our health care system to care for those who need it the most,” she said.

Kanwit said Medicare is important because of its successes. “The Part D drug program is working well, giving beneficiaries a choice of plans, including prescription drug plans (PDPs) and Medicare Advantage plans with drug coverage, and many offer enhanced benefits, including coverage in the gap, low premiums, and zero or reduced deductibles,” she said.

“One Medicare issue of importance to health plans participating in Medicare Advantage and Part D involves the scope of federal preemption under Section 1395w-26(b)(3) of the Medicare Act, 42 U.S.C. § 1395w-21 through 28, as amended by the MMA,” Kanwit continued.

“Currently on appeal to the U.S. Court of Appeals for the 11th Circuit in Dial v. HealthSpring of Alabama Inc. is the question whether the MMA is a ‘complete preemption’ statute, thus affording federal jurisdiction over removed claims that otherwise would arise under state law. In the case, health plans claim the statute offers both complete preemption and ‘ordinary preemption’—preempting state laws governing areas the MMA reserved to the federal government,” she said.

Dombi cited developments with Medicare Advantage during 2008, whose growth will change as reimbursement level are threatened with further reductions. “This will lead to changes in health care provider business with shifts in network relationships and potentially expanded traditional fee-for-service Medicare,” he said.

Belmont said she is anticipating a new CMS clinical trials policy on when and under what circumstances Medicare will reimburse for associated routine costs. Belmont said this policy could clarify when research is, and is not, covered.

“CMS will likely try to resolve some of these issues in 2008, perhaps in the form of rulemaking. Because research is becoming more and more commonplace in hospital settings, the compliance issues surrounding the policy, whatever it may turn out to be, will be significant for all who work with hospitals or clinical trial sponsors,” Belmont said.

Sullivan said the sleeper issue is “whether Congress will again pick up the issue of specialty hospitals and try to determine, in lieu of free market forces, who will
be the winners and who will be the losers in the potential growth of physician owned single specialty hospitals, a movement opposed by acute care general hospitals.”

7. Antitrust. Board members ranking antitrust a top issue for health care lawyers cited increasing private litigation and stepped-up federal enforcement as issues that will keep competition concerns in the forefront in 2008.

Toby G. Singer, with Jones Day in Washington, said antitrust will stay hot because the Federal Trade Commission’s decision in Evanston Northwestern Healthcare, finding a hospital merger violated federal antitrust laws, has reinvigorated antitrust enforcement with respect to both hospital and health plan mergers. Private plaintiffs have discovered health care as well, litigating everything from exclusion from health plan networks to nurse wage-collusion cases,” she added.

Hastings agreed antitrust enforcement is up. “After Evanston, hospital mergers are being scrutinized more closely again, with second requests stemming from pre-merger notification requirements on the increase,” he said. “Constant consolidation on the one hand and expansion into new markets on the other creates antitrust issues that will make headlines,” he said.

Entin said that, while the outcome of the FTC challenge to the Evanston Northwestern Healthcare merger “was widely anticipated” in light of the FTC decision not to require divestiture, it is unclear whether success in the case will further embolden the agency.

“Was this just an academic victory or can the industry expect more challenges post-merger?” asked Sullivan. Sullivan thinks it can. Antitrust enforcement, which was “always one of the big three until the 1990s, appears to be on the upswing,” at least at the FTC, he said, adding that the commission’s retrospective review of the Evanston Northwestern merger and its compromise outcome likely signal an era of increased activism on hospital consolidation.

Although the antitrust laws also were invoked as part of the scrutiny of group purchasing organizations earlier in the decade, recent activity appears to have shifted to a consumer protection focus while the antitrust aspect has quieted,” he said.

Citing the cyclical nature of hospital merger and acquisitions, Tuckman predicted that, as financial performance recedes, it is inevitable 2008 will see more hospital transactional activity.

“These transactions have gotten and will get increased scrutiny from antitrust enforcement officials using nontraditional means of assessing the anti-competitive impact, increasing the likelihood of contested challenges,” Tuckman said.

Rovner said the Evanston decision “appears to mark the return of aggressive government antitrust enforcement in health care and signals an analytical shift from earlier unsuccessful government enforcement actions involving hospital mergers.”

This new analytical approach, which moves away from relying on patient discharge data and instead uses data on managed care organization contracting “appears realistically to capture the nature of to whom providers sell their services and focuses provider competition on their ‘real’ customers—the insurers that pay for most of the services they sell,” Rovner said.

“Look also to DOJ interest in health plan mergers as provider political opposition to payer consolidation builds pressure for government action,” he added.

Raskin said “critical antitrust issues facing health care companies in 2008 will include disputes between acute care and specialty hospitals, ‘bundling’ of products and services, authorized generics, health plan mergers, hospital mergers, and physician networks.”

Kanwit said she expected some big pharmaceutical-related antitrust developments. “First, the MMA requires brand name drug manufacturers to file certain agreements with the FTC, including settlement agreements between generic drug companies and brand names that pay compensation to the generic patent challenger in return for refraining from launching the generic product for a period of time,” she said.

The commission has been very negative on these “reverse payment” settlements and their implications for drug costs, she said.

“Second, the FTC is also coming out with an authorized generics study which should be interesting, given the prevalence of generics in the market,” she said.

8. Labor and Employment. Labor and employment issues will continue to preoccupy health care providers in 2008 as workforce shortages and union initiatives put added pressure on hospital operations and bottom line, board members said.

According to Hastings, “the slowing of the economy, more and more employed physicians, continued staffing shortages and other workforce issues, and increased union activities at hospitals will add up to a robust year in health care labor and employment law.”

“Sullivan agreed there is “little evidence to suggest that recent activism by labor unions will slow any time in the near future. There is too much at stake.” Hospitals employ huge work forces, Sullivan continued, and represent big opportunities for unions. “With labor shortages at least in the nursing area, that means continued pressure for these employers,” he said.

Dombi added that “skilled health care staff remain in short supply while health care unions such as the Service Employees International Union are gaining strength in numbers and political power.” This year, he predicted, “unionization efforts and the collective bargaining strategies will trigger a new era in health care affecting health care businesses and involving both federal and state legislatures."

Kadzielski also cited the unionization of health care employees as a major challenge for providers. “Unions have figured out that American businesses can ‘outsource’ many different types of jobs to overseas companies, except those in the labor-intensive health care sector,” he said.

“This is a very high-stakes endeavor for both unions and hospitals, with a winner-take-all outcome in literally every circumstance,” he said.

“In 2008, the next shoe—corporate campaigns—will drop more frequently,” Kadzielski added. Through these initiatives, unions will continue to hit health care institutions in the pocketbook, spending significant resources to challenge hospital plans for development, new buildings, etc.,” he said.

Durso agreed that providers will continue to grapple with unions seeking to organize workers, noting they have been active in exposing alleged uninsured billing inequities and, in some communities, are leading the
challenge to the tax-exempt status of the nonprofit providers whose workers they are trying to organize.

Wall said the looming shortage of health care workers goes beyond the much discussed nursing shortage. “An overlooked developing story is the crisis that many communities will face when the physicians in their 50s and 60s begin to retire. Many hospitals, especially those in small rural communities, are finding it impossible to recruit specialists such as cardiologists and orthopedic surgeons,” he said.

In addition, “increased enforcement of immigration law is making it more difficult to recruit foreign born physicians,” he said. “With medical school entering classes not expanding, who is going to take care of the baby boomers who will be retiring in record numbers over the next 20 years?”

9. Governance. Governance issues arising from quality, fraud, and tax concerns that will increasingly be brought to the board room for review also will be a central focus for health care attorneys in 2008, HLR board members said. For members of boards of health care institutions, “the plate keeps getting more full,” Entin said.

“Whether as a result of the OIG’s challenge to nonprofit boards to monitor and understand quality, the IRS’s focus on financial transparency to satisfy their communities that they are deserving of the benefits of tax exemption, or because Sarbanes-Oxley issues remain a core board responsibility, compliance with a broad portfolio of rules unique to health care continues to be squarely on boards’ agendas,” he said.

Because of these rules, boards will need to examine existing structures and charters to determine whether they are capable of handling their ever-expanding agenda, Entin added.

Belmont said boards are being told to increase their scrutiny of quality and compliance and that they will need to a determine whether they have processes in place to effectively monitor these key concerns.

According to Entin, this means that individual False Claims Act liability now is a risk for board members, high-ranking officers, and legal counsel for health care organizations. “Boards, along with their legal counsel, must ensure that proper oversight occurs and that they make immediate and serious efforts to understand their hospital’s ability to monitor and provide quality care,” he said.

John D. Blum, with Loyola University School of Law Institute for Health Law in Chicago, predicted that the OIG’s new focus on quality issues in governance combined with related issues of patient safety and ongoing matters concerning community benefit “will place increasing pressure on the board in its trustee and fiduciary roles.”

Even the IRS is climbing aboard the “corporate governance bandwagon,” Sullivan said, noting that, while most of the IRS’s activities will be limited to education about best practices and sunshine, there still is room for improvement of actual practices in many health care organizations.

“IRS activity and finance committee scrutiny is just one more indication that, no matter from what perspective health care organizations are viewed, good governance can protect against a lot of ills, while governance weaknesses can be very destructive,” he said.

Peregrine commented that the new IRS’s new Form 990 places corporate governance of tax-exempt organizations front and center. “The attention paid to corporate governance issues is consistent with the agency’s overall efforts respecting corporate governance initiated in 2007 with the release of draft governance guidelines,” he said.

The importance of the initiative was underscored in the public comments of IRS Commissioner Steven Miller that promoted governance as a new “pillar” of the IRS’ compliance and education activity for the tax-exempt sector, Peregrine said.

“The governance-related provisions incorporated within the redesigned Form 990 include those relating to board size and structure, conflicts of interest management, director independence, intra-board relationships, audit committee practice, written governance policies, and the role of governance in the preparation and review of the form,” he said.

For members of boards of health care institutions, “the plate keeps getting more full.”

FREDRIC J. ENTIN, FOLEY & LARDNER LLP, CHICAGO

In addition, Peregrine said, “while increasing attention will be placed on the board’s obligation to oversee quality of care, the standards applicable to such oversight will remain fluid for the foreseeable future as both providers and regulators work to balance the benefits of such oversight—including government’s related role—with the risk that such oversight could create a new and unnecessary burden on the board.”

Peregrine also said he expects that state charity officials, the IRS, and the courts “will increasingly look to the Panel on the Nonprofit Sector’s Principles of Self Regulation as de facto ‘best practices’ for nonprofit organization governance.” He predicted that, “whether by resolution of corporate controversies, new bar association/policy group publications, or through avenues, there will be a continued focus on the role of the general counsel and increased access to the governing board.”

Raskin agreed, saying health care systems and companies will continue to face governance pressures. “In particular,” he said, “public companies can expect continued SEC scrutiny of options practices as well as review of international operations under the Foreign Corrupt Practices Act,” he said.

10. Medical Staff. Medical staff issues, too, will keep health care law practitioners busy throughout 2008, according to HLR advisory board members.

Sullivan said that peer review, credentialing, contracting, call coverage, and physician/hospital alignment issues will continue to be hot.

Waxman said he believes legal issues concerning hospital-physician relationships will move to the forefront. He specifically said that doctors and hospitals are exploring different model relationship structures, with the result that employed physicians and practice acquisitions are “making a fairly strong comeback.”

Hastings said that “changes in the way health care is delivered due to population demographics, technology,
Gazing into their crystal balls, several HLR advisory board members took a stab at predicting issues that will be facing health care law practitioners within the next several years.

**Retail Clinics.** As health care costs continue to rise, look for retail health clinics to proliferate, Elisabeth Belmont said. Embraced by large retail merchants such as Wal-Mart, CVS, Target, and RiteAid, and major health systems such as Aurora Health, Geisinger, and Sutter Health, they are growing in popularity with consumers because they have low overhead; provide convenient, affordable basic care in short visits; have transparent pricing; and provide for effective communication, she said. Various compliance and risk management issues “come with this territory,” Belmont said. In particular, she said, regulation of retail clinics, whether under new or existing laws, will keep health lawyers busy.

Howard Wall also cited the rise of retail health clinics. “The offer of cheap flu shots and free generic drugs is drawing consumers into chain-operated clinics and drug stores that will also be able to provide annual sports physicals for kids and other services families need at a fraction of the time and cost of traditional medical care.”

**Medical Tourism.** Patients unable to find affordable quality care in the United States increasingly will go abroad. In some cases, the treatments they seek are unavailable in the United States because they have not been approved; in others, the cost of the procedure is simply prohibitive here.

Howard Burde said U.S.-educated doctors increasingly will treat American patients in nearby islands and South America. He added, however, that medical tourism also is inbound. “With the rise of wealthy classes in countries with health care systems less well-developed than ours, individuals are seeking care in the United States in increasing numbers,” he said. American hospitals are actively pursuing these patients, while businesses are forming to facilitate these opportunities, Burde said.

Jack Rovner predicted medical tourism could “explode” in the next four to five years. He foresees U.S. citizens obtaining elective health care overseas covered by U.S. insurers.

“The economics and the emergence of quality ‘Western-style’ facilities in the United Arab Emirates, India, Southeast Asia and elsewhere may . . . make going overseas an attractive option for ‘luxury’ care at much lower cost than in the U.S.,” he said.

Fred Entin agreed. “Millions of uninsured and under-insured patients, large and small employers, and third-party payors will consider care abroad as they look for affordable non-emergency procedures and treatments, some of which are not even available in the United States,” he said.

Entin predicted globalized health care will raise questions of professional liability, privacy, licensure, benefit plan design, taxation, insurance regulation, accreditation, and quality. Additionally, he said, many U.S.-based providers are forming alliances with and investing in overseas operations. The growing opportunity American health care providers have to deliver care to citizens from all over the world will encourage many others to broaden the definition of the communities they serve, he said. He added that, while many kinds of health care require local services, “increasingly, many diagnostic procedures can be done remotely from any place in the world.”

**E-Discovery.** Litigation-related issues were on the minds of several board members, with Richard Raskin and John Blum both foreseeing complex discovery issues. With the development of electronic health records, management of discovery—especially e-discovery—will gain in importance, they said. Managing “e-discovery can become all-consuming,” Raskin said.

Belmont also sounded a warning, saying e-discovery “creates new opportunities for disclosure of information not anticipated by both providers and patients.” Unlike in other industries, health care records are often in the possession of independent physicians, labs, pharmacies, hospitals and payers, making records administration and e-discovery requirements much more challenging, she said.

Belmont also cautioned that hospitals need to be careful in responding to requests from private insurers for information about treatments received by their insureds and, more generally, about the hospital’s policies and protocols because their responses may be discoverable in a subsequent malpractice action. She said she anticipates this type of activity will become “more mainstream.”

Belmont also is concerned about discovery of metadata, or hidden tags inserted in electronic documents. Metadata, allows litigants to trace changes in the documents and identify the person who made or edited each entry, she said.

It also can lead to problems maintaining privilege. “Responses to e-discovery requests need to be carefully controlled so that databases of privileged peer review and quality assurance data are not inadvertently disclosed; metadata can show, for example, exactly who has access to the peer review databases and plaintiff’s counsel can use this information in order to argue that the requirements of the privilege were not satisfied,” she noted.

**Internet ‘Care.’** Howard Burde expects Internet-related legal issues to arise in light of the growing proliferation of health care Web sites. He noted that Google and Microsoft are continuing to develop such sites. “Consumer response will tell us whether Americans are ready to treat their health care and health care information like other kinds of information,” he said. He also predicted that the incentive to use the Internet to explore health issues “will rise with the cost of health care.”
and other factors is causing a radical shift in the locations and economics of health care delivery. Hospitals and physicians, who used to have independent relationships governed by historical medical staff rules, now are required to collaborate to a much greater extent to meet evolving care protocols and quality standards, yet at the same time are acting more and more as competitors in the increasingly outpatient-based delivery environment.”

Wall said that both the “rise of specialty hospitals and other physician-owned entities that compete with hospitals and increasing physician resistance to following EMTALA on-call requirements will continue to be trigger points in the rift between hospitals and their staffs.”

However, by far the most talked about “hot” medical staff issue for 2008 is the Joint Commission’s revision of Medical Staff Standard 1.20. So controversial has it been that the version of MS 1.20 scheduled to take effect July 1, 2009, is actually the third attempt in four years to finalize the standard.

The current version draws the most criticism on two points: (1) its mandate that certain requirements be included in the medical staff bylaws and (2) provisions that allow the medical staff to bypass the medical executive committee (MEC) and take issues directly to the hospital’s governing body.

Benesch said that, while the medical staff arena is one health care issue that has not had a lot of activity, that is likely to change in light of MS 1.20, which is “poised to create new animosities between the medical staff organization, its executive committee, and the hospital, and a lot of work for medical staff leaders, hospital administrators and medical staff attorneys.”

Benesch also challenged the Joint Commission’s assertion that the provisions will improve the quality of care. In fact, they will have the opposite effect, she asserted.

“It will be interesting to see whether or not the Joint Commission comes to its senses and revises this rule,” Benesch said. Given the overwhelmingly negative industry reaction to the current draft, it “is hard to believe” that the standard will take effect in its current form, she added.

Kadzielski said that the “adoption of new standard MS 1.20 has sent hospitals into a tizzy. In effect, by mandating wholesale bylaw changes to conform to new MS 1.20 by mid-2009, the Joint Commission has antagonized health care providers unnecessarily.”

Amending medical staff bylaws is very complicated, usually requires a supermajority vote, and can take anywhere from six months to two years to complete, he said. Furthermore, amending staff bylaws could require corresponding amendments to the hospital governing body’s bylaws, he added.

The process that allows the medical staff to bypass the MEC and go directly to the governing board also is particularly troublesome, Kadzielski said. Although Joint Commission officers have stated the provision should get little use, Kadzielski said that the fact it exists at all will prompt more and more medical staff members to use it. This, in turn, will lead to confusion as the board must decide whom to listen to—the medical staff or the MEC. It comes down to “damned if you do, damned if you don’t” for the board when it is forced to take sides, he added.

The process, moreover, defeats the whole purpose of having a medical executive committee, which is elected by the medical staff to represent it before the board, he pointed out. Although some have suggested that the provision is needed to curtail board-controlled MECs, Kadzielski said that he has never seen one. He also noted that most medical staff bylaws already spell out a process for removing members of the MEC who the staff believes are not representing their interests.

Overall, he said, the new provisions are confusing. While he is hoping for clarification from the Joint Commission, Kadzielski called the idea that the Joint Commission will return to the October 2006 version “a non-starter.” The Joint Commission simply will not scrap two years of work, he said.

Nevertheless, he observed, the controversy “comes at a time when the Joint Commission senior leadership is being replaced. What the new leadership team will do to respond to this and other pressing issues will certainly be an important health care development in 2008.”

Hirsch said he is hopeful the commission will reconsider Standard MS 1.20 so that extensive revisions to many organizations’ medical staff bylaws will not be required.

The Joint Commission’s revised MS 1.20 is “poised to create new animosities between the medical staff organization, its executive committee, and the hospital, and a lot of work for medical staff leaders, hospital administrators and medical staff attorneys.”

KATHERINE BENESCH, DUANE, MORRIS LLP, PRINCETON, N.J.

Although compliance is not required until July 2009, if the standard is not modified medical staffs will probably need to begin the amendment process in 2008, given the lead time typically needed to secure medical staff approval to incorporate new substantive categories and related processes into bylaws, he said.

Wall added that the Joint Commission’s actions “will put hospital administrators and medical staff leaders on a collision course in 2008.” Revised MS 1.20, in particular, “seems to further emphasize the autonomy of the medical staff, weaken the traditional role of the MEC, and add confusion over shared responsibility in an organization in which the hospital board of trustees is ultimately responsible,” he said.

Wall also foresees difficulties with meeting the Joint Commission’s Jan. 1, 2009, implementation date for the revised Leadership Chapter, which “requires better communication over quality of care and patient safety, and requires organizations to manage conflicts effectively.”

He sounded a positive note, however, saying, “I for one hope that the necessity of addressing the Joint Commission standards will create a forum to allow a dialogue between hospital administration, board lead-
ers, and physicians that will lead to a better understanding of each others’ position and create opportunities to address the overriding issue of providing safe, quality health care in a hospital setting.”

Blum said he sees the MS 1.20 debate continuing but, like Wall, is optimistic the new provisions will facilitate an era of dialogue and cooperation between medical staffs and hospital governing bodies. In short, he said, this may be what is needed to prompt the two entities to work together to improve quality.

Blum acknowledged that many fear the new standards will add fuel to the ongoing tensions between medical staffs and hospitals over turf by empowering medical staffs to be more aggressive.

But rather than lead to more divisiveness, revised MS 1.20 may instead prompt “bridge-building,” Blum said. It could compel hospital boards to be more sensitive to the needs of the medical staff and to be more conciliatory and inclusive when addressing internal issues, he said.

**Honorable Mention: Alternative Dispute Resolution.** Kanwit predicts the overhaul of the entire medical liability system. Noting that “medical practice is still driven to some extent by fear of litigation” with the result that “dollars are wasted on defensive medicine” and a liability system that doesn’t serve the needs of either patients or providers, Kanwit said it is “likely there will be some changes to the system soon.”

She highlighted a few changes that have been suggested, including taking medical malpractice cases out of the judicial system and creating special “health care courts” or a dispute resolution process with independent third-party review designed to provide fair compensation for injuries and quick resolution of claims.

Benesch added that the idea of utilizing alternative dispute resolution in medical malpractice disputes is not new. Insurers, however, are unlikely to support wide use of such programs, she said. But ADR is on the rise in just about every other aspect of health care, Benesch said.

It is common today to find claims that arise out of practice group breakups and physician employment going to arbitration, she said. Arbitration is very big in managed care also, she said, and mandatory ADR clauses can be found in contracts between device/drug makers and research organizations that conduct clinical trials. In these areas, she said, more disputes are going to arbitration than to court.

**Honorable Mention: Transactions and Financing.** Wall said he expects finance and transactional developments to be areas to watch in 2008. “Wall Street is reeling and the credit markets are very tight. The impact of this is likely to linger into 2008,” he said.

Roth agreed. “It is always important to follow how capital markets view the health care system,” he said.

According to Wall, “With the credit market now much more limited, major tax-exempt financings at facilities with less than premium ratings may get put on the shelf. This may force capital-starved stand-alone facilities to consider selling or joint venturing with for-profit partners,” he said.

Private equity firms also may find it harder to finance “go private” deals, so strategies like one-time dividends and stock buybacks used to finance facility and system expansion may continue as companies struggle to bring value to shareholders. “When the public markets again turn to health care, as the markets have always done over the past 30 years, a strong group of old and new faces will be ready to meet the demand of the public investors, Wall said.

**Honorable Mention: Public Health.** Blum was one of several board members who cited ongoing public health issues and concerns as meriting continued attention by health lawyers in 2008.

“Attention spans may be short but there are still many post-Katrina issues out there along with MRSA infections, flu season, obesity etc. All have legal implications,” Blum said.

Wall cited a declaration by the Institute of Medicine that the nation’s system of emergency care is in crisis and is less able to withstand a major natural or man-made disaster than it was in 2001.

“From legitimate government efforts such as preparing the nation for pandemic flu on one extreme, to over-reaching, governmental intrusions in the rights of individuals and businesses like the New York ban on trans fats or state-wide or community-wide smoking bans in private buildings and outdoor spaces, public health issues will continue to be a focus of lawmakers and regulators, Wall said.

**Honorable Mention: Biotechnology.** Benesch and other board members predicted that biotechnology-related issues will come to dominate health care law. Advances in biotechnology will “change the paradigm of medical practice,” she said.

John Blum agreed, saying that issues concerning stem cell research will continue to arise through 2008 and beyond.

Benesch said biotechnology will affect all areas, from quality analysis to medical records. Moreover, she said, as the practice of medicine becomes more highly specialized scientifically, some adjudications may become difficult for traditional courts.

On the other hand, advances in biotechnology may eliminate some political/bioethical issues, Benesch said. She cited stem cell research in particular. Now that scientists have announced that they can produce stem cells without harvesting them from human embryos, the ethical/political/legal issues surrounding them may go away, she said.

Alternative Dispute Resolution

Appeals Court Says Hospitals May Sue In Fraud Case Against Transcription Firm

Hospitals alleging fraud and unjust enrichment claims against a medical transcription company, its subsidiary, and current and former officers are not required to arbitrate their claims, a federal appeals court ruled Dec. 13, 2007 (South Broward Hospital District v. Medquist Inc., 3d Cir., No. 07-2076, 12/13/07).

The U.S. Court of Appeals for the Third Circuit said South Broward Hospital District and other hospitals allegedly overcharged for medical transcription services by Medquist Inc. and its wholly owned subsidiary Medquist Transcriptions were entitled to pursue their claims in court because the Medquist defendants waived their right to compel arbitration.

The appeals court agreed with a federal trial court’s decision that the defendants made a tactical decision to litigate the claims brought against them in the U.S. District Court for the District of New Jersey and that their subsequent decision to try, instead, to compel arbitration came too late.

Even though arbitration is favored under the Federal Arbitration Act, the Third Circuit said Medquist’s delay in asserting its intent to compel arbitration satisfied the applicable standard for finding waiver of arbitration rights in cases where an arbitration demand comes long after the suit is commenced and where the case already has been litigated extensively.

The trial court, which issued its decision in March, refused to dismiss the proposed class action fraud complaint brought by Medquist’s hospital customers. While it refused to compel arbitration, the trial court ruled that Racketeer Influenced and Corrupt Organizations Act claims against the corporate defendants had to be dismissed. RICO claims asserted against individual Medquist officers were allowed, however, to proceed (16 HLR 476, 4/1/07).

The trial court also dismissed claims alleging negligent misrepresentation, negligent supervision, unfair business practices under New Jersey and California law, and other torts, finding they either sought relief unavailable outside of the service contracts Medquist and the hospitals signed or involved professional services not governed by the two states’ consumer protection laws.

The lawsuit involves claims brought by South Broward, Children’s Hospital of Los Angeles, Northbay Healthcare Group, Partners Healthcare Systems Inc., Riverside Healthcare Systems LP, and West Hill Hospital. In addition to the corporate defendants, the lawsuit also named four of their officers: Ronald Scarpone, Michael Clark, John Suender, and Brian Kearns.

The hospitals challenged the defendants’ billing practices, saying they “artificially inflated invoices for transcription services” by using a number of different computer programs to calculate the number of characters and lines transcribed. The hospitals alleged that the defendants also employed a system to prevent them from discovering the allegedly fraudulent billing practices, the trial court said.

Arbitration Waived. After the trial court said the case could remain in a judicial forum, the defendants appealed, arguing that the lower court erred in refusing to enforce the arbitration provision. The appeals court found, however, that the lower court properly resolved the issue.

The third Circuit noted that a finding of waiver usually involves situations where discovery has commenced and it would be prejudicial to the other party to require arbitration at that point. Prejudice can stem from other factors as well, however, the appeals court said.

“Although the District Court did not entertain motions for summary judgment, Medquist twice tested the sufficiency of the pleadings with motions to dismiss,” the appeals court said. “The fact that the parties did not engage in discovery normally precludes a finding of waiver, but here it is outweighed by Medquist’s tactical decision to litigate extensively in federal court before seeking to compel arbitration,” it added.

“Medquist made a tactical decision to forgo moving to compel arbitration pending litigation of the motions to dismiss” exposing the hospitals “to extensive litigation expense” and allowing Medquist to attempt to obtain “a total victory in federal court” while presuming to preserve its right to compel arbitration, the court said.

“Nothing in the cases cited by Medquist entitles it to expose the hospitals to such delay, expense, and prejudice and then move to compel arbitration. Medquist may have expressed its preference for arbitration, but that fact does not reduce the prejudice caused to the hospitals by its tactical decision not to move to compel arbitration,” the court continued.

“It moved to the arbitration alternative only when its preferred option proved unsuccessful. In this case, it was too late,” the appeals court concluded.

The court’s decision is available at [http://op.bna.com/] Vol. 17, No. 1) 19
Antitrust

Legal Fees

Insurance Policy Does Not Provide Coverage For Legal Fees Arising From Antitrust Probes

A

n insurance policy does not provide coverage for over $2.3 million in legal fees incurred by an insured hospital system in connection with federal and state antitrust investigations of a joint venture in which the insured has a 43 percent ownership interest, the New York Appellate Division, Second Department, decided Dec. 11, 2007 (Catholic Health Services of Long Island v. National Union Fire Insurance Co. of Pittsburgh PA, N.Y. App. Div., No. 2006-09875, 12/11/07).

The joint venture was the target of the antitrust investigation, according to the Appellate Division, which held that the joint venture was not an “insured” as defined in the policy at issue. Thus, the insurer had no obligation to defend the plaintiff in connection with the antitrust investigations.

In 1998, Catholic Health Services of Long Island Inc. and its five subsidiary hospitals entered into a joint venture agreement with several other parent corporations and their subsidiary hospitals. The purpose of the joint venture was to deliver cost-effective quality health care on Long Island. The plaintiff provided 43 percent of the state capital for the venture, which was called Long Island Healthcare Network (LIHN).

In October 1998, the plaintiff purchased a not-for-profit insurance policy from National Union Fire Insurance Company of Pittsburgh PA. The policy identified the insured as the plaintiff and its five subsidiary hospitals and provided defense coverage for “claims” against an insured for “wrongful acts,” which included violations of the Sherman Act or similar federal or state law.

In November 2002, the New York attorney general launched an antitrust investigation of LIHN. Associated interrogatories served on LIHN defined LIHN broadly to include not only LIHN but also any entity owning at least 20 percent of LIHN. The Department of Justice subsequently also served interrogatories on LIHN.

The plaintiff incurred legal fees of $2,300,877.77 in connection with these state and federal probes. In this suit, the plaintiff argued that its insurance policy provides coverage for the legal fees because the subpoena and interrogatories issued to LIHN were “claims” within the meaning of the policy.

The insurer denied coverage and won a summary judgment declaring that it was not obligated to defend the plaintiff in the underlying antitrust investigations.

Appellate Court Affirms. The appellate court, affirming, endorsed the lower court’s ruling that the plaintiff incurred attorneys’ fees and costs only “indirectly and solely by virtue of an independently imposed contractual obligation contained” in the joint venture agreement, which required it to pay a share of the fees proportionate to its ownership interest in the joint venture—43%.

The court noted that insurance coverage “extends only to named entities and/or individuals defined as insured parties under the relevant terms of the policy.” Since LIHN “is not named, described, or otherwise referred to as an insured in the policy, the coverage provisions of the policy are inapplicable and there is no duty to defend.”


Drugs and Devices

Pharmaceuticals

Federal Court Invalidates Maine Law Limiting Sale of Physician Prescription Data

BOSTON—Adhering closely to an opinion issued by a federal court in New Hampshire in 2007, a federal judge in Maine Dec. 21, 2007, struck down a new state law that would have restricted the sale of physician drug prescription data (IMS Health Corp. v. Rowe, D. Me., No. cv-07-127-B-W, 12/21/07).

Provisions of the law “that seek to restrict the use and disclosure of commercial information violate the free speech guarantee of the First Amendment,” said Judge John A. Woodcock Jr., of the U.S. District Court for Maine. He issued a preliminary injunction enjoining enforcement of the unconstitutional portions of the law, which was to have taken effect on Jan. 1.

Defenders of the Maine statute argued that it differed from the New Hampshire law, which prohibited any sale of prescriber information for commercial purposes, because it contains an “opt-out” provision requiring Maine prescribers to seek confidentiality protection that prevents pharmaceutical companies from using their individualized prescribing information to market them or others.

But Woodcock found that the opt-out provision did not make a difference. “The notion that prescribers have the legal right to restrict access to their own work product is appealing and the opt-out provision makes the question closer than the one” before the U.S. District Court for New Hampshire, he said.

“Nevertheless, at its heart, the law operates by making illegal the transfer of truthful commercial information for particular uses and disclosures, and as such, the law must withstand” the intermediate scrutiny test for commercial speech, Woodcock said.

Similar Case Currently on Appeal. Woodcock noted that the decision of the U.S. District Court for New Hampshire in IMS Health Corp. v. Ayotte (16 HLR 555, 5/3/07) currently is before the First Circuit, but that oral arguments have not been heard and a decision would not be issued before the effective date of the Maine law.

Maine Attorney General G. Steven Rowe (D) took an “understandable position” of rejecting the court’s suggestion that the state stay implementation of the law pending a First Circuit ruling, Woodcock commented,
but he noted that Vermont, which enacted a similar law this year, apparently has agreed to stay implementation until the First Circuit rules.

Sean Flynn, counsel to the National Legislative Association on Prescription Drug Prices and professor at American University’s Washington College of Law, told BNA Dec. 26 that the court basically followed the New Hampshire ruling, which now is subject to a “vigorous appeal” before the First Circuit. “I think this is headed to appeal as well,” he added.

Flynn said he felt both courts should have shown “appropriate deference to state legislatures” and that the cases had “very minimal First Amendment implications.”

A call to Rowe’s office for comment was not immediately returned.

**Sale of Records.** Objections to the current practices of firms like IMS center on the fact that pharmacies sell prescriber-identifiable records to IMS and similar organizations without prescriber consent. In turn, IMS and the other organizations sell the information about prescribing by individual physicians to pharmaceutical companies, which use it to target their marketing to the prescribers.

Under the Maine law (L.D. 4), enacted by the Legislature in June, “a carrier, pharmacy or prescription drug information broker may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies a prescriber who has filed for confidentiality protection.” The measure was aimed at stemming the practice of data mining, the use of prescribing information for marketing purposes.

Three health information firms filed suit in August, asking the court to strike down the law. IMS Health, Source Healthcare Analytics, and Verispan argued that the statute would restrict vital health care information from public view and would fail to reduce costs or promote health care (16 HLR 1084, 9/13/07).

**Law Held to Fail ‘Narrow Tailoring’ Test.** Applying the same “intermediate scrutiny” test used by the New Hampshire court to determine whether the limit on truthful commercial speech was permissible, Woodcock found that the state’s interest in protecting prescriber data from marketers is “narrow,” that the law “only marginally advances the governmental interest in prescriber privacy,” and that the statute “substantially fails” the criterion that it be as narrowly tailored as possible.

In a joint statement, the three firms said they were “pleased” with the ruling. “We believe that restrictions on the dissemination of information of crucial public interest are neither good healthcare policy nor consistent with our society’s core beliefs in the free flow of information,” Robert H. Steinfeld, IMS senior vice president and general counsel, said.

The Maine law is “inconsistent with the national trend toward more transparency in healthcare practices,” IMS Vice President Randy Frankel added. “It’s vital that provider-level prescription information remain accessible, as it has proven value in efforts to monitor safety and manage quality, treatment variability and healthcare costs.”

**Employment Issues**

**Damages**

**Ohio Court Holds Valid CRNA’s Contract To Pay Liquidated Damages Upon Breach**

A n Ohio court Dec. 21, 2007, declared enforceable a liquidated damages provision in a contract between a certified registered nurse anesthetist (CRNA) and a group of practicing anesthesiologists delineating the terms of their agreement to pay for her advanced training in exchange for her promise to remain with the practice for a specified period of time (Physicians Anesthesia Service Inc. v. Burt, Ohio Ct. App., No. C-060761, 12/21/07).

The Ohio Court of Appeals, First District, overturned a trial court’s conclusion that the liquidated damages provision was an unenforceable penalty. It said in a per curiam opinion that the contract at issue passed the state supreme court’s three-part test for determining the validity of a liquidated damages clause.

The court noted that the provision at issue contemplated that, if Heather Burt failed to complete her required tenure, Physicians Anesthesia Service Inc. (PAS) would suffer foreseeable damages because of the significant costs of finding a replacement for her due to a serious shortage of and high demand for CRNAs. It would have been difficult to predict the exact amount of those damages at the time the contract was executed, it said, and the contract was not otherwise unreasonable or unconscionable.

**Suit for Breach.** PAS claimed that Burt breached a contract by which it supplied her with a lump-sum student-support loan in exchange for her promise to work for PAS for three years following her graduation from a masters’ degree program. Burt resigned from PAS approximately two-thirds of the way through her required tenure.

As per the agreement, Burt made arrangements to repay the remaining balance on her loan. However, she disputed the validity of her obligation to pay liquidated damages. The relevant clause in the contract read: “[Burt] shall also owe PAS an additional 50% of the amount remaining [on the loan] as liquidated damages to compensate PAS for the loss of her services, the expense of holding a position for [Burt], the expense of recruiting another [student nurse anesthetist] or CRNA to fill the position, and expense of utilization of [a temporary replacement] CRNA until such time as another CRNA is hired to fill the position left vacant by [Burt’s] resignation. Payment shall be due within 5 days at PAS office.”

Burt moved for summary judgment on PAS’s breach of contract and unjust enrichment claims, arguing that she had repaid the principal and interest due on her student loan and that the liquidated damages provision was an unenforceable penalty under Ohio law. The trial

Text of the court ruling is available at http://op.bna.com/hl.nsf/?Open=deln-7a8lyt.
court granted summary judgment for Burt even though it found that she still owed PAS about $118 in unpaid interest.

The appellate court reversed, saying that the trial court erred when it entered judgment for Burt after finding her liable for unpaid interest. “If interest payments remained unpaid,” it said, “Burt was not entitled to judgment as a matter of law.”

Further, the court reversed the trial court’s conclusion that the liquidated damages clause was unenforceable as it was intended only to deter Burt from breaching the contract. When a party challenges a liquidated damages clause, the court must “step back and examine it in light of what the parties knew at the time the contract was formed and in light of an estimate of the actual damages caused by the breach,” it said, quoting the Ohio Supreme Court.

Penalty Versus Damages. According to the appellate court, the state high court has declared that “[w]here the parties have agreed upon an amount of damages in unambiguous terms, that amount is to be treated as liquidated damages and not as a penalty if (1) the actual damages would be uncertain in amount and difficult to prove; (2) the contract as a whole is not so manifestly unconscionable, unreasonable, and disproportionate in amount as to indicate that it does not express the true intention of the parties; and (3) the contract is consistent with the conclusion that the parties intended that damages in the agreed-upon amount would follow the breach of the contract.”

Here, the appellate court said, the evidence indicated that PAS’s actual damages from the breach would be uncertain and difficult to prove. For example, PAS’s vice president testified in an affidavit that the shortage of CRNAs had prompted many anesthesia practice groups to enter into contracts to pay for the education of potential employees in exchange for their future employment. The costs of replacing such a person after breach of the agreement depended on market conditions at the time of the breach, he said.

In addition, the court concluded that, as a result of the breach, “PAS would be forced to expend a significant but undeterminable amount of time and resources to seek out replacement CRNAs, to shift work schedules, and to locate temporary replacements hired at costs of 150% to 200% of a permanent CRNA employee’s salary.”

The court concluded that the liquidated damages clause was valid and, therefore, that PAS was not required to prove the actual damages it incurred in replacing Burt. Additionally, it said that the amount specified in the contract—50 percent of the remaining balance—“was reasonably related to the amount of time remaining in Burt’s employment obligation and was a reasonable prediction of the amount of potential damages to PAS.”

Mary Jill Donovan and Michael P. McCafferty, of Donovan Law in Cincinnati, Ohio, represented PAS. Trudie E. McAdams, of Montgomery, Rennie & Jonson in Cincinnati, represented Burt.

Fraud and Abuse

Physicians

CMS Issues Final Rule Delaying Effective Date of Certain Stark Rules

T he Centers for Medicare & Medicaid Services Dec. 28, 2007, issued a final rule delaying until Jan. 1, 2009, the applicability of the anti-markup provisions under Stark physician self-referral rules with respect to certain services performed in certain locations.

The delay applies to provisions in Section 414.50, as revised at 72 Fed. Reg. 66222, except with respect to: (1) the technical component of a purchased diagnostic test and (2) any anatomic pathology diagnostic testing services furnished in space that is utilized by a physician group practice as a “centralized building” (as defined at Section 411.351) for purposes of complying with the physician self-referral rules and (ii) does not qualify as a “same building” under Section 411.355(b)(2)(i).

The final rule will be published in the Jan. 3 Federal Register.

CMS said it was concerned that the definition of “office of the billing physician or other supplier” may not be entirely clear and could have “unintended consequences.” The agency said in the notice that during the next 12 months, it plans to issue clarifying guidance as to what constitutes the “office of the billing physician or other supplier” or propose additional rulemaking, or both.

The provisions were included in the final physician payment rule published Nov. 27, 2007 (16 HLR 1346, 11/8/07). After CMS published the final rule with comment period, CMS said it “received informal comments from various stakeholders” who alleged that the application of the rule is unclear with respect to whether certain types of space arrangements meet the definition of the “office of the billing physician or other supplier.”

Further, CMS said, some of these stakeholders asserted that patient access may be disrupted significantly due to the alleged inability of physician groups to render services in a cost-effective manner if medical office space that satisfies the “same building” test in Section 411.355(b)(2)(i) for purposes of the physician self-referral rules in Part 411, Subpart J, and other medical office space in which patients are seen and that complies with the physician self-referral rules is subject to the anti-markup provisions in revised Section 414.50.

“That is, physician groups allege that, in situations in which they are subject to the anti-markup provisions and are limited to billing Medicare for the amount of the net charge imposed by the performing supplier, because they will not be able to realize a profit and will not be able to recoup their overhead costs, they will not be able to continue to provide diagnostic testing services to the same extent that they are currently providing such services,” CMS said.

CMS made clear that the provisions of the Nov. 27, 2007, final rule with comment were effective Jan. 1. “However, the date of applicability of the provisions of § 414.50, as revised at 72 FR 66222, with respect to certain services furnished in certain locations, as described herein, are delayed until January 1, 2009.”
False Claims Act

Hospital, Nursing Home Groups File Brief Urging High Court to Reverse FCA Decision

Two health care provider organizations joined a friend-of-the-court brief in the U.S. Supreme Court seeking reversal of a decision that the groups said expands the scope of the False Claims Act, the American Hospital Association announced Dec. 20, 2007 (Allison Engine Co. v. United States ex rel. Sanders, U.S., No. 07-214, brief filed 12/20/07).

The American Hospital Association and the American Health Care Association (nursing homes group) joined the U.S. Chamber of Congress Dec. 20 in urging the high court to reverse a decision by the U.S. Court of Appeals for the Sixth Circuit. That appeals court determined that presentment of a false claim directly to the government is not a universal requirement for liability under the FCA.

The Supreme Court agreed to review the Sixth Circuit’s reversal of the district court’s determination that 31 U.S.C. § 3729 requires a showing that a false claim must be presented to the government for liability to attach and the whistleblowers, two former employees of a subcontractor for Allison Engine Company, failed to make that showing. The whistleblowers filed an FCA qui tam action alleging Allison Engine and two other subcontractors were aware that certain generator sets in the construction of missile destroyers did not comply with contract specifications and U.S. Navy regulations.

Circuit Conflict. The Sixth Circuit’s decision in Allison conflicts with the majority opinion by Judge (now Chief Justice) John G. Roberts Jr., United States ex rel. Totten v. Bombardier Corp., 380 F.3d 488 (D.C. Cir. 2004), according to John T. Boese, with Fried, Frank, Harris, Shriver & Jacobson LLP, Washington, in an October 2007 FraudMail Alert. In Totten, the U.S. Court of Appeals for the District of Columbia Circuit held that the text and structure of the FCA require presentment to the government, Boese said.

The Third, Eighth, and Eleventh Circuits specifically followed the Totten majority holding, but Allison adopted the view that although the FCA expressly requires presentment to the government for direct submissions of false claims, all that is required for a violation is that the claim was paid with “government money,” Boese said.

Boese is the counsel of record in another friend-of-the-court brief for the Washington Legal Foundation, a nonprofit public interest law and policy center in Washington, which also was filed in support of petitioners in Allison. The WLF brief argued that by eliminating “pre-sentment,” the Sixth Circuit expanded the scope of the FCA far beyond anything intended by Congress.

In situations such as Allison, there is no basis for liability under the FCA because the government has suffered no direct loss to the treasury because of the fraud, the Washington Legal Foundation brief said.

Treble Damages. “[T]he Sixth Circuit never explained how the United States can recover treble damages when it, in fact, suffers no financial loss,” the Washington Legal Foundation brief said. “If there is no immediate financial detriment to the Federal Treasury, the treble damages and penalties awarded to the United States under the [FCA] become a pure windfall to the Government, thus unmooring the FCA from its roots as a remedial statute designed to protect the Government from fraud on the Federal fisc.”

Further, although the lawsuit did not involve health care providers, the Supreme Court decision may have ramifications for the health care industry, the AHA brief argued.

“If presentment to the government is not required . . . then any person or company that submits claims to those who receive Federal money (including government contractors, Federal grantees, Medicare providers and beneficiaries, and a host of other entities) could be open to FCA liability for treble damages and mandatory penalties because of their ‘mere association’ with government funds even though their claims are never submitted to the government,” Boese said.

Medicare Payments. According to the AHA brief, hospitals receive Medicare payments from the government through a prospective payment system based on predetermined national and regional rates for caring for a patient with a particular diagnosis, similar to firm-fixed-price government contractors and federal grantees.

Skilled nursing facilities also receive Medicare payments through a prospective payment system. The payments are used by health care providers to cover a variety of costs arising out of a patient’s care, including cost of supplies and services provided by third-party vendors, the brief said.

“If a hospital or skilled nursing facility is allegedly overcharged by a vendor, that overcharge has no effect on payments by the Government under the prospective payment system, yet under the Sixth Circuit’s theory the vendor may nonetheless become the subject of a qui tam lawsuit,” the AHA brief said. “The qui tam relator will therefore effectively be assigned the right to sue the hospital’s or skilled nursing facility’s own supplier, dragging the health care provider into a burdensome investigation and complex litigation for what would otherwise be a straightforward commercial matter to be resolved between the hospital and the vendor.”

Although the Allison decision appeared to adopt a position that was faithful to the language of the FCA, the majority’s holding critically misstated the basis for liability under the FCA, the AHA brief said. The Sixth Circuit’s expansion of the FCA contradicts the language and the fundamental purpose of the FCA, which require proof of a causal link between the fraud and a direct financial loss to the federal treasury, the brief added.

Taxpayers Against Fraud Executive Director Joseph E.B. White told BNA that the high court likely will embrace a plain language reading of the FCA by holding that FCA liability applies any time federal government funds are stolen, regardless of whether a claim was ac-
tually presented to a federal government employee or official. However, even if the Supreme Court goes off course and reads a "presentment" requirement into the FCA, the decision will have little to no impact on FCA health care cases, White said.

**Little Effect.** "In the Medicaid context, State Medicaid agencies not only act as agents of the federal government, but are required to pass along the claims to the federal government," White said. "In the Medicaid context, Medicare contractors coordinate closely with federal government employees on both the payment and approval of Medicare claims. In short, while the Court may embrace a supposed 'presentment' requirement into the FCA, the decision will have little effect in the closely regulated and monitored government healthcare programs."

Nevertheless, the AHA brief concluded that the Sixth Circuit’s statutory analysis is fundamentally flawed and those flaws expand the statute far beyond its intended purpose.

The Supreme Court therefore should hold that the "harsh penalty and meddlesome" qui tam provisions of the FCA are properly reserved for situations where the government is presented with a false claim, not federalizing allegedly fraudulent transactions involving funds traceable in some way to the federal government, the AHA brief concluded.

The FCA is a broad statute, but it has clear and critical limits, the Washington Legal Foundation said. The fact that the federal government has an interest in a program is not relevant, nor is the fact that the government may have funded the program, the Washington Legal Foundation said.

"For liability to attach under the FCA, what is critical is that the fraud result in a direct loss to the Federal Treasury," the Washington Legal Foundation brief concluded. "‘Presentment’ of a claim made false by the fraud provides that critical link. Because the Sixth Circuit’s test for FCA liability did not include this critical link, the judgment of the court of appeals should be reversed."

Jonathan S. Franklin (counsel of record) and Caroline M. Mew, with Fulbright & Jaworski LLP, Washington; Robin S. Conrad and Amar D. Sarwal, National Chamber Litigation Center Inc., Washington; Melinda Reid Hatton and Maureen Mudron, American Hospital Association, Washington; and Priscilla Shoemaker, American Health Care Association, Washington, are counsel for the AHA amici curiae.


### HHS OIG
### Agency Solicits Suggestions
### For New Safe Harbors, Fraud Alerts

The Department of Health and Human Services Office of Inspector General is soliciting suggestions for new anti-kickback safe harbors and special fraud alerts.


The OIG annually solicits such comments, as required by the Health Insurance Portability and Accountability Act of 1996.

Anti-kickback safe harbor provisions protect specific types of business practices and arrangements that might otherwise be treated as criminal offenses or be subject to administrative sanctions by the OIG.

In addition to recommending new safe harbors, commenters are invited to suggest modifications to existing provisions.

OIG special fraud alerts are issued periodically to provide guidance to the health care provider community about potentially fraudulent or abusive practices.

The **HHS OIG notice is available at [http://oig.hhs.gov/authorities/docs/07/SafeHarborDec2007.pdf]**.

### Excluded Individual
### HHS OIG Approves Excluded Individual’s Proposed Arrangement for New Invention

An individual who was excluded from Medicare and Medicaid for five years got the green light from the Department of Health and Human Services Office of Inspector General to give his adult children a license for the life of the patent for his new invention for sale or lease in the United States, according to Advisory Opinion No. 07-17, released Dec. 26, 2007.

The individual was concerned that the proposed arrangement would be indirectly furnishing the invention or causing claims for it to be submitted to the federal health care programs.

Based on the facts submitted in the request, the OIG said the proposed arrangement would not violate his exclusion and would not constitute grounds for the imposition of administrative sanctions.

The OIG wrote that the arrangement would not result in the individual directly submitting claims for his invention to federal health care programs, and that he would not directly furnish any items or services that would be reimbursable by federal programs.

Under the proposal, the individual would turn over the intellectual property associated with the invention to a new company created by his adult children that would be completely independent from the individual. The new company would be responsible for manufacturing the invention and leasing or selling it to independent distributors who would then lease or sell the invention to health care providers or suppliers. These providers or suppliers would submit claims to third-party payers, including federal health care programs.

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**The AHA-Chamber of Commerce brief is available at** [http://op.bna.com/hl.nsf?Open=jthn-7aapy8]

**The Washington Legal Foundation brief is available at** [http://op.bna.com/hl.nsf?Open=jthn-7aadq2]
“In this scenario, we believe that the intervening and independent entities . . . together with your certifications that you would have no relationship—financial or otherwise—with [the new company], would sufficiently attenuate you from any claims submitted to Federal health care programs by downstream providers or suppliers [and that] you would not be indirectly furnishing the Invention or causing claims for it to be submitted to Federal programs in violation of your exclusion,” the opinion stated.

“[T]here is little risk that federal funds would make their way back to you through” the new company, the opinion said.


False Claims Act

Court Finds HHA Violated False Claims Act, Triples Payment to Medicare to $4.7 Million

A federal district court in Louisiana Dec. 18, 2007, held that a home health agency and its owner, previously found to have violated the Stark Act, also violated the False Claims Act and ordered them to pay a total of almost $4.7 million in damages and fines (United States ex rel. Roberts v. Aging Care Home Health Inc., W.D. La., No. 02-2199, 12/18/07).

The U.S. District Court for the Western District of Louisiana found that Aging Care Home Health Inc. and its owner, Janice Davis, knowingly submitted false cost report certifications and claims for payment to the Medicare program. The district court also found that after obtaining payment from Medicare for services performed under a prohibited referral, Aging Care and Davis failed to refund all collected amounts on a timely basis.

Five cost report certifications between 1999 and 2003 that Aging Care submitted to Medicare for five physicians violated Stark II and were false and material to the Medicare program’s decision to pay, the district court found. Therefore, the court determined, Aging Care and Davis both presented a false claim for payment and relied on a false record to obtain payment from Medicare.

Inducing Referrals. Whistleblowers Becky Roberts and Lori Purcell, former employees of Aging Care, filed the FCA qui tam complaint, alleging the HHA and its owner billed Medicare as a means of inducing physician referrals in violation of the anti-kickback law, the Stark law, and the FCA. The government partially intervened in the action alleging Aging Care violated the Stark law and anti-kickback law.

The government claimed that Aging Care’s financial relationship with five referring physicians violated Stark II. The evidence showed that Aging Care paid the physicians in accordance with compensation arrangements and the physicians signed patient plans of care, the district court found.

In February 2007, the district court declined to adopt the report and recommendation of the magistrate judge on the government’s motion for partial summary judgment. The court held that Aging Care and Davis vio-

lated Stark II and were liable to the government under theories of payment by mistake and unjust enrichment.

The court ordered the defendants to pay $427,504 with post-judgment interest. The government then moved in a second motion for partial summary judgment for a finding that Aging Care and Davis violated the FCA, arguing that their Stark II violations were made “knowingly” and, thus, also constituted violations of the FCA.

Prohibited Payments. The government presented evidence that Davis engaged in conduct designed to conceal Aging Care’s prohibited payments to its physicians. Since the facts about her conduct in attempting to conceal prohibited payments were not presented to the court by the government in its first motion for partial summary judgment, the court accepted as a matter of law the facts as presented by the government.

Based upon the evidence and testimony presented by the government, the court found that Davis and Aging Care acted with knowledge that they were violating the Stark laws with regard to their payments to the physicians, their presentation of claims to Medicare, and their failure to refund Medicare amounts received.

Accordingly, there was no genuine issue of material fact for trial, and the court determined that the government was entitled to summary judgment on its claim that Aging Care and Davis violated the FCA.

The district court previously determined the government’s damages to be $427,504. Thus, the district court found, under the FCA, the United States was entitled to recover three times its single damages, a total of nearly $1.3 million. The district court also imposed a fine of $5,500 for each false claim contained in the 615 claims for payment and the five false cost certification reports submitted to Medicare for a total fine of $3.4 million.

The district court also found that the government was entitled to post-judgment interest under 28 U.S.C. § 1961(a) computed daily and compounded annually until the government is paid in full on the total amount of $4.7 million.

Steven C. Thompson and S. Layne Lee, with Moore, Walters, Thompson, Thomas, Papillion & Cullens, Baton Rouge, La., and Don H. Johnson, with Johnson & Placke West Monroe, La., represented Roberts and Purcell.

Albert G. Alec Alexander III, assistant U.S. attorney with the Western District of Louisiana, Lafayette, La., and Sara McLean and Brian R. Young, Department of Justice, Washington, represented the United States.

Michael Jay Fontenot, with Davenport, Files & Kelly LLP, Monroe, La., and Elizabeth Zink Pearson and Lucian Bernard, with Pearson & Bernard, Covington, Ky., represented Aging Care and its owners.

The opinion is available at http://op.bna.com/hl.nsf/r/ [Open=fhln-7a4nz]

Fraud Settlements in Brief

Atlanta Hospital Will Pay $26 Million

An Atlanta hospital has agreed to pay the federal government $26 million to resolve allegations it overcharged Medicare for outpatient visits between 2000
and 2005, the Department of Justice announced Dec. 21, 2007.

The government charged that Saint Joseph’s Hospital of Atlanta violated the False Claims Act by inappropriately coding certain services as inpatient admissions when the services should have been billed as outpatient visits, DOJ said in a news release. Other violations also were covered by the settlement, DOJ noted. Saint Joseph’s also entered into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General as part of the settlement.

The case initially was brought by qui tam relator (whistleblower) Tami Ramsey, who had worked at the hospital as a registered nurse, according to the DOJ release. Ramsey will receive nearly $5 million as the relator’s share in the case.

California’s Orange County Pays $7 Million

Orange County, Calif., paid the United States $7 million to resolve allegations that one of its health care divisions submitted false claims to Medicare, the U.S. Attorney’s Office for the Central District of California announced Dec. 20, 2007.

A federal False Claims Act investigation of the county’s Health Care Agency (HCA), Behavioral Health Services Division (OCHCA), a participating Medicare provider, found that between 1990 and 1999, OCHCA billed Medicare for psychiatric evaluations performed by OCHCA personnel that did not meet requirements governing Medicare reimbursement, a press release said. Under Medicare, psychiatric or evaluative interviews are reimbursable only if performed by physicians, or by clinical psychologists and licensed social workers who are under the direct personal supervision of a physician.

The government’s investigation also revealed that OCHCA had repeatedly billed Medicare for activities that did not qualify as covered mental health services, the release said. In addition, the government found that OCHCA improperly billed for, and was paid for, dispensing self-administered methadone to drug-addicted patients, which is a noncovered service.

Health Care Policy

Congressional Roundup

Bush Signs Medicare/SCHIP, Fiscal Year 2008 HHS Funding Bills


The new law provides doctors with a 0.5 percent pay increase through June 30, cancelling a 10.1 percent cut that was scheduled to take effect Jan. 1. Congress will have to address the issue again in mid-2008 to avoid yet another payment cut for doctors from taking effect July 1.

The measure contains numerous provisions extending current Medicare payment policy, including an extension to June 30 of the nursing home therapy cap exception. It also includes a permanent freeze at 60 percent of the compliance threshold for inpatient rehabilitation facilities, regulatory relief for long-term care hospitals, and extension of the qualified individual, or QI program.

The agreement also reflects the political reality that Democrats are not likely to get a bill passed and signed by Bush to reauthorize an expanded SCHIP program. Two such bills already have been vetoed by the president, and Democrats had hoped to limit the extension of SCHIP funding to Sept. 30 to force Republicans to vote on the program immediately before the 2008 elections.

The House passed sweeping legislation in August providing numerous changes to Medicare policy, including a two-year payment increase for doctors, as well as $50 billion over five years for SCHIP reauthorization. By comparison, the bill passed by the Senate and House this week contains no new policy, a six-month physician payment fix, and an SCHIP program extension.

HHS Funding Bill. President Bush Dec. 26, 2007, signed an omnibus fiscal 2008 funding bill (H.R. 2764) that includes $65.6 billion for the Department of Health and Human Services—$1.5 billion above the 2007 funding level.

The Senate Dec. 18, 2007, approved, 76-17, House amendments that set funding levels for many federal departments and agencies, including HHS and the departments of Labor and Education. The House Dec. 17 voted 253-154 to approve the legislation.

The bill rejected $859 million in funding cuts for HHS under Bush’s proposed budget. Instead, the appropriations bill increased funding for health programs, including for the National Institutes of Health, according to a bill summary from the House Committee on Appropriations.

Bush Nov. 13 vetoed an earlier version of the appropriation bill, saying that its inclusion of $150.7 billion in discretionary spending made it too expensive. The House failed to override the veto Nov. 15.

Under the new version of the appropriations bill, NIH will receive $29.2 billion, an increase over the president’s request of $28.9 billion. The appropriations bill vetoed by Bush sought to add $1.1 billion to the NIH budget, bringing the medical research agency’s budget up to $30 billion.

The House combined departmental appropriations included in the omnibus legislation a vote on an amendment for war funding. The legislation did not include funding for the war in Iraq, as the president has requested. Following the Senate vote Dec. 18 adding in war funding, the omnibus legislation was sent back to the House for a final vote. The House gave final congressional approval Dec. 19.

For a complete report on federal and state health care policy initiatives, refer to BNA’s Health Care Policy Report. For a complete weekly report on proposed and final changes in the Medicare program, refer to BNA’s Medicare Report. Subscription information is available from BNA’s customer service office, 800-372-1033.
Health Information

HIPAA

No Right to Sue Official Over Alleged Failure to Adequately Investigate Claims

A federal court Dec. 6, 2007, ruled that it lacked jurisdiction over a lawsuit alleging an official with the Department of Health and Human Services' Office of Civil Rights failed to adequately investigate allegations of improper disclosure of medical information (Cain v. Mitchell, W.D. Mo., No. 4:06-cv-897, 12/6/07).

The U.S. District Court for the Western District of Missouri held that the Health Insurance Portability and Accountability Act does not create a private right of action to challenge actions by OCR or regulated providers. Even if HIPAA allowed federal courts to review OCR investigations, claimants would be required to pursue and exhaust administrative remedies first, the court added.

The lawsuit addressed allegations by Timothy G. Cain that OCR and investigator Steven Mitchell violated HIPAA in failing to take action against Kansas City Veterans Administration Medical Center in conjunction with the alleged disclosure of Cain's medical information to medical center staff in November 2004.

Although OCR investigated Cain's complaint, that the disclosure violated HIPAA's privacy rule, it ultimately found there was no violation. Cain then filed his lawsuit, alleging Mitchell did not investigate the case fully and that his conclusions were not consistent with the applicable legal requirements.

In finding the lawsuit had to be dismissed, the court began by citing the majority position that HIPAA provides no right for allegedly injured parties to sue providers or the officials responsible for enforcing the statute. While HIPAA imposes requirements on the Department of Health and Human Services, health plans, and health care providers involved in the exchange of health information, "district courts have universally held that HIPAA does not create a private right of action," the court said.

"In this case, plaintiffs assert that Timothy Cain's personal medical file was disclosed in violation of HIPAA and requests that this Court review the investigation of the Office of Civil Rights conducted by Steven Mitchell," the court said. "First, plaintiffs have no jurisdiction here as HIPAA creates no private cause of action as stated above."

"Second, the Court has no authority to review the investigator's decision not to enforce any penalties against the hospital under the Administrative Procedure Act," it continued. "Even if the Court could review Mitchell's investigation, plaintiffs have not exhausted administrative remedies below by filing a complaint regarding the inadequacy of Mitchell's investigation and then following the channels to appeal that decision thereafter," it concluded.


Privacy

AG Says Tennessee's Stringent Law Governs Disclosures of State-Held Data

RALEIGH, N.C.—The federal Health Insurance Portability and Accountability Act allows for more stringent state restrictions on the use or disclosure of individually identifiable health information, the Tennessee attorney general said in a Dec. 14, 2007, opinion (No. 07-165).

Therefore, according to AG Robert E. Cooper Jr. (D), a more stringent Tennessee law, regarding the release of individually identifiable health information in state Medicaid files held by the state Department of Human Services, governs. State Medicaid law (Tenn. Code Ann. Section 10-7-501, et seq.) prohibits the release of information maintained in those files except for purposes directly connected with the administration of the program, Cooper said in the opinion.

According to Cooper, HIPAA generally prohibits the disclosure of individually identifiable health information by covered entities, which includes the state Department of Human Services. However, he said, certain exceptions are provided under that federal law.

On the other hand, federal Medicaid regulations (42 C.F.R. 300 et. seq.) require states to limit the use or disclosure of information covering applicants and recipients to purposes directly connected with the administration of the program, according to Cooper. Tennessee enacted its law to implement those provisions, he said.

HIPAA provides that a more stringent state law related to the privacy of individually identifiable information overrides a use or disclosure otherwise permitted under the federal law, Cooper said in the opinion.

Cooper’s opinion was issued in response to an interpretive request filed by Virginia Dodge, Tennessee’s commissioner of human services.

Health Plan Regulation

Coverage

Health Plans Must Show Enrollee Deception Before They Can Cancel Policies, Court Rules

OS ANGELES—California law requires that a health plan seeking to rescind an enrollee’s coverage first must demonstrate that a misrepresentation or omission on the application was willful, or show that the plan made reasonable efforts to ensure the information on the application was accurate and complete before issuing the contract, a state appellate court ruled Dec. 24, 2007 (Hailey v. California Physicians’ Service, d/b/a Blue Shield of California, Cal. Ct. App., No. G035579, 12/24/07).

The decision by the California Court of Appeal, Fourth District, in the closely watched case reversed a
trial court summary judgment in favor of Blue Shield of California. However, more significantly, it marked the first appellate level opinion on the scope of a 1993 statute prohibiting the practice of “post-claims underwriting.”

That practice is at the heart of a number of individual and class action lawsuits, covering thousands of enrollees, now pending in lower courts around the state.

“This is going to force them [the health insurance companies] to change their practices,” said Michael G. Nutter, an Orange County, Calif., attorney representing the couple that sued Blue Shield.

Decision Supports DMHC Position. “The appellate decision supports the DMHC position that health plans have the obligation to conduct the proper medical underwriting upfront,” Cindy Ehnes, director of the Department of Managed Health Care (DMHC), said in a statement e-mailed to BNA.

“Consumers, who are paying higher and higher premiums for health care, need to be assured that the companies will give them a fair evaluation before coverage is extended. This way, people won’t be afraid that if they use their coverage, they could lose it—leaving them with huge medical bills or canceling coverage unfairly, leaving them uninsurable,” Ehnes added.

Health plans in California for years have rescinded health policies, citing misrepresentations or omissions that the plans discovered, generally after reviewing applications of enrollees who filed large claims for medical treatment.

Blue Shield and its supporters insisted at oral arguments before the appeals court in September that plans were entitled to “investigate” applications after a covered individual filed a claim, and to revoke coverage if misrepresentations were found.

Plans also have argued that rescission is legal in the case of misrepresentations or omissions, regardless of whether such errors were intentional.

But consumer groups, plaintiffs’ attorneys and especially the Department of Managed Health Care (DMHC), which regulates managed health plans in California, argued that, absent a showing of “willful misrepresentation,” the practice violated Health & Safety Code Section 1389.3, which the Legislature enacted in 1993.

Relying on Application Not Enough. Specifically, the statute prohibits rescinding or canceling coverage because of the plan’s failure to complete medical underwriting and resolve all questions arising from the application prior to issuing a contract, unless there is a showing of willful misrepresentation.

Blue Shield and its supporters argued that it had the right to rely on information provided on applications, without having to conduct a more detailed examination of the applicant’s medical history, to meet the statute’s underwriting requirement.

The three-justice panel of the appellate court disagreed.

“Blue Shield contends health plan providers may complete the ‘medical underwriting’ required under section 1389.3 by simply taking the submitted application and assigning values to the risks disclosed,” Justice Richard Aronson wrote in the decision. “We are not persuaded the Legislature intended such a narrow construction,” he added.

The case stemmed from a lawsuit Cindy and Steve Hailey brought against Blue Shield in January 2003, claiming, among other things, that Blue Shield’s 2001 rescission of their policy violated Section 1389.3’s post-claims underwriting prohibition.

Blue Shield issued the policy in 2000, but in February 2001 initiated an investigation of Steve Hailey’s health history, after receiving a claim for health services provided to him. In March 2001, Steve Hailey sustained life-threatening injuries in an automobile accident.

Then in June 2001, Blue Shield notified the couple it was rescinding the coverage, citing misrepresentations on their application. The Haileys filed suit demanding reinstatement; Blue Shield cross-complained, arguing the couple was responsible for any payments the plan made for Steve Hailey’s medical care.

A trial court granted Blue Shield’s motion for summary judgment, and ordered the Haileys to pay the company $104,194, the amount the plan paid to Steve Hailey’s providers.

Cindy Hailey said she believed the application sought only information relating to her own health, not that of her husband Steve, or their son. She returned the application to a Blue Shield agent, who asked Cindy Hailey some questions regarding her own health history, “but did not go over any of the application’s questions and did not inform her the application’s health questions also applied to Steve and their son,” the court noted.

Prior Medical Records. The problem could have been averted if the agent or Blue Shield’s underwriter had simply asked Cindy Hailey if she included information on her husband or son, Aronson wrote.

“Blue Shield also might have determined a problem existed had it contacted the Hailey’s primary care physician or previous health insurer, ’’ since the Haileys executed a release authorizing Blue Shield to obtain medical information from their doctors and previous health plan as part of their application, he added.

“Blue Shield apparently had no difficulty using this release to obtain Steve’s medical records after he filed his initial claim,” Aronson noted.

“Although the Legislature did not define ‘medical underwriting,’ we do not believe it intended to equate the term with whatever steps a plan took to evaluate the applicant based on its own marketing decisions or other considerations,” Aronson noted.

“Thus, in order to effectuate section 1389.3’s purpose, and in light of the equitable nature of rescission, we interpret ‘medical underwriting’ to require a plan to make reasonable efforts to ensure a potential subscriber’s application is accurate and complete,” he concluded.

In fact, plans have a duty to ensure they have “all the necessary information to accurately assess the risk before issuing the contract,” if they wish to preserve the right to later rescind if they cannot show willful misrepresentation, the court asserted.

Bad Faith, Infliction of Emotional Distress Claims. “Because Blue Shield failed to demonstrate it made reasonable efforts to ensure the Hailey’s application was accurate and complete as part of its precontract underwriting process, and the Haileys raised a triable issue of fact whether they willfully misrepresented Steve’s physical condition when they applied for coverage, we reverse the judgment,” the court ruled.
The appellate court also lent support to critics of health plans’ rescission practices, finding that a triable issue of fact existed as to whether Blue Shield acted in bad faith, and also that the Haileys adequately alleged a cause of action for intentional infliction of emotional distress.

Specifically, the court said that facts presented by the Haileys raised the inference that Blue Shield delayed its rescission decision. Such facts “raise the specter that Blue Shield does not immediately rescind health care contracts upon learning of potential grounds for rescission, but waits until the claims submitted under the contract exceed the monthly premiums being collected,” Aronson wrote.

“In other words, a health care service plan may adopt a ‘wait and see’ attitude after learning of facts justifying rescission by continuing to collect premiums while keeping open its rescission option if the subscriber later experiences a serious accident or illness that generates large medical expenses,” Aronson wrote.

Consumer advocates and plaintiffs’ attorneys have charged for some time that at least some health plans in California have systems in place to scrutinize for errors or omissions those applications of enrollees who file large claims for treatment, with the aim of rescinding those policies, and thus avoiding payment of the claims.

That same “wait and see” attitude also might open the plan to liability for intentional infliction of emotional distress, he added.

**Court’s Reversal Not Unexpected.** The appellate court’s reversal was not unexpected, given the line of questioning the three justices exhibited at the Sept. 25 oral arguments. Aronson, as well as Justices William F. Rylaardsam and Raymond J. Ikola sharply questioned attorneys for Blue Shield on what constituted medical underwriting within the context of Section 1389.3.

All three expressed skepticism at the time that simply evaluating whether to issue a policy.

In addition to the appellate court’s reversal of the trial court’s judgment in its favor, Blue Shield also faces the release, probably in January 2008, of a survey DMCH has conducted on the health plan’s rescission practices.

A similar survey prompted DMHC in March to fine Blue Cross of California $1 million (16 HLR 392, 3/29/07).

And in December, the California Department of Insurance said it was seeking $12.6 million in fines against Blue Shield, because of violations regarding health care rescissions and “irresponsible” claims processing (16 HLR 1519, 12/20/07).

Blue Shield termed the department’s action as inconsistent, unfair, and not within its authority, and said it would challenge the fines in the agency’s appeals process, and potentially later in court.

**Blue Shield Statement.** Tom Epstein, vice president of public affairs for Blue Shield, said in a Dec. 24 statement that the company was “pleased that the court ruled in our favor on the most important legal question before it—that the law does not require proof of intentional misrepresentation before a policy can be rescinded if the plan completed initial underwriting before the policy was issued.”

“We look forward to proving at trial that our underwriting was appropriate and that the Haileys misrepresented numerous important facts on their application,” Epstein said. “Decades of court decisions support the legal principle that insurers can rely on representations made by individuals in their signed applications when evaluating whether to issue a policy.”

“Since the overwhelming majority of people fill out their applications properly, requiring health plans to disbelieve all applicants by verifying the truth of every answer is inappropriate and unnecessary,” he continued. “If the courts were to change their view and require insurers to verify every answer on millions of applications for health coverage, the process of obtaining individual coverage would take much longer, would be much more expensive and the number of uninsured would rise.”

Epstein said that Blue Shield rescinds a “miniscule” number of policies and “we never rescind a policy unless the misrepresentations made by an applicant about his health history were significant. We do not ever rescind for minor mistakes and rescissions are a necessary part of our efforts to control costs for all our members.”

Epstein said Blue Shield supports legislation that would eliminate rescission “by guaranteeing health coverage for all.”

Nutter told BNA Blue Shield must decide whether to seek review by the California Supreme Court. If the plan decides not to do so, or if the high court declines to review the appellate court ruling, the case would revert to the trial court, he added.

“The appellate decision supports the DMHC position that health plans have the obligation to conduct the proper medical underwriting upfront,” Cindy Ehnes, director of DMHC, said. “Consumers, who are paying higher and higher premiums for health care, need to be assured that the companies will give them a fair evaluation before coverage is extended. This way, people won’t be afraid that if they use their coverage, they could lose it—leaving them with huge medical bills or cancelling coverage unfairly, leaving them uninsured.”

**BY TOM GILROY**

The full text of the court decision is at [http://www.courthome.ca.gov/opinions/documents/G035379.PDF](http://www.courthome.ca.gov/opinions/documents/G035379.PDF)

**ERISA**

**District Court Denies City’s Motion for Stay In Employer Health Care Expenditure Case**

The U.S. District Court for the Northern District of California Dec. 28, 2007, denied a motion by San Francisco seeking a stay of an order that prevented a local ordinance requiring employee health care expenditures by local businesses to take effect as planned on Jan. 2 (Golden Gate Restaurant Association v. City and County of San Francisco, N.D. Cal., No. C 06-06997 JSW, stay denied 12/28/07).

In an opinion by Judge Jeffrey S. White, the court said that the city’s filing of a notice of appeal in the U.S. Court of Appeals for the Ninth Circuit Dec. 27, along with a concurrent motion for a stay pending appeal, divested the district court of jurisdiction to grant a stay.
Once a notice of appeal is filed, it said, a district court no longer has jurisdiction over the matter being appealed.

The court’s action followed its Dec. 26 decision in which White ruled that the Employee Retirement Income Security Act (ERISA) preempted the San Francisco Health Care Security Ordinance, at least insofar as the latter requires employers to make minimum health care expenditures on behalf of covered employees.

White in that decision ruled that the health care expenditure requirements of the ordinance were preempted “because they have an impermissible connection with employee welfare benefit plans.

“By mandating employee health benefit structures and administration, those requirements interfere with preserving employer autonomy over whether and how to provide employee health coverage, and ensuring uniform national regulation of such coverage,” White said.

The action challenging the ordinance was filed against the city by the Golden Gate Restaurant Association in November 2006. The GGRA is a nonprofit trade organization that promotes the interests of the restaurant industry in the San Francisco Bay Area.

The San Francisco Central Labor Council, Service Employees International Union Healthcare Workers—West, Service Employees International Union Local 1021, and Unite Here! Local 2, intervened in support of the ordinance and filed a separate appeal from the district court’s decision.

In rejecting the request for an immediate stay—which would have had the effect of allowing the new law to take effect—the court cited the rule of exclusive jurisdiction. While this rule is not absolute, a decision to grant a stay generally must serve to maintain the status quo, the court said.

In this case, it said, the city moved for a stay of its Dec. 26 order that declared that ERISA preempted the San Francisco Health Care Security Ordinance, which would have taken effect Jan. 2. Thus, the court noted, granting the stay would modify—not preserve—the status quo pending appeal. Therefore, the exception to the exclusive jurisdiction rule does not apply in this case.

Even if it found that the stay was warranted, the district court could not act to modify the status quo, it concluded. “[H]ere, the stay would reverse the status quo and enable what the Court considers to be a preempted local ordinance to take effect,” it said.

San Francisco City Attorney Dan Herrera has vowed to continue defending the ordinance, and his office filed both the notice of appeal and the motion for a stay concurrently in both the district court and the Ninth Circuit. The city argued that ERISA does not preempt the ordinance because the latter “allows employers to comply with the health care spending requirement without adopting an ERISA plan or altering an existing ERISA plan.”

GGRA, on the other hand, called the district court’s decision “the right ruling.” Several unions that intervened in the district court filed a separate appeal with the Ninth Circuit Dec. 27.

In addition to Herrera, the city is being represented by Vince Chhabria, of the Office of the City Attorney, San Francisco. GGRA is being represented by Richard C. Rybicki, of Dickenson Peatman & Fogarty, Napa, Calif., and Patrick Sutton, of Dickenson Peatman & Fogarty, Santa Rosa, Calif.

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Retiree Benefits

EEOC Issues Final Rule Under ADEA Allowing Retiree Health Benefit-Medicare Link

More than four years after announcing a proposed rule to do so, the Equal Employment Opportunity Commission Dec. 26, 2007, issued a final rule creating an Age Discrimination in Employment Act exemption to permit employer-sponsored retiree health benefits to be altered, reduced, or eliminated when the recipient becomes eligible for Medicare or comparable state health benefits programs (72 Fed. Reg. 72938).

The new rule emerged from EEOC’s concern that its previous interpretation of the ADEA was encouraging the elimination or erosion of employer-provided retiree health benefits. Under the prior EEOC policy, an employer that chose to provide retiree health benefits had to prove either that the benefits available to Medicare-eligible retirees were the same as those provided to retirees not yet eligible for Medicare or that the employer was expending the same costs for both groups of retirees.

The position set out in the final EEOC rules has had widespread support in the employer, labor union, and benefits community, but has been sharply opposed by AARP, the older Americans’ advocacy organization, which argued that it discriminated against older workers.

“Labor unions, benefits experts, and public and private sector employers all agreed that the commission’s prior policy would have a deleterious effect on the provision of employer-sponsored retiree health benefits, especially given the numerous other factors negatively impacting the availability of such benefits,” EEOC said. “Public comments filed in response to the commission’s [proposed rule] only buttress this conclusion.”


Flaws in Previous Policy. In a preamble to the final rule, EEOC observed that under its prior policy employers could avoid the “complex comparisons” required by the old rule “by simply eliminating retiree health benefits entirely.” Alternatively, employers could comply with the prior rule by reducing health care coverage provided to retirees not yet eligible for Medicare, the commission said. EEOC therefore published a notice of proposed rulemaking in July 2003 to create a “narrow” ADEA exemption to allow employers to coordinate retiree health benefits with an individual’s eligibility for Medicare or for comparable state programs covering former public employees not subject to Medicare (12 HLR 1123, 7/17/03).

EEOC emphasized that its final rule concerns only the ADEA and does not affect “any non-ADEA obligation” that employers may have to provide health benefits under Medicare or any other law. “Although employers are under no legal obligation to offer retiree health benefits, some employers choose to do so and
themselves provide retirees with access to affordable health coverage at a time when private health insurance otherwise might be cost prohibitive,” EEOC said. “Because the commission has determined that its prior policy created an incentive for employers to reduce or eliminate retiree health benefits, the agency has concluded the public interest is best served by an ADEA policy that permits employers greater flexibility to offer these valuable benefits.”

Responses to Comments. EEOC received 44 comments from organizations in response to its July 2003 notice, with 27 expressing support for the proposed ADEA exemption, the commission said. EEOC also received approximately 30,000 letters from individuals, most of these a form letter opposing the proposal and expressing concern that if coordination of retiree health benefits was allowed, employers would reduce or even eliminate private benefits for Medicare-eligible retirees.

Responding to a comment that the proposed rule’s language on “eligible for” Medicare or a comparable state program was too vague, EEOC said the final rule clarified “the exemption would apply whether or not a particular enrollee actually enrolls” in Medicare or a comparable state program, “as long as the retiree was eligible for such benefits.”

In response to two organizations’ comments that EEOC should clarify that its rule does not affect ADEA coverage of non-health retiree benefits, such as life insurance or disability programs, the commission said it added language to the final rule explaining that it only applies to retiree health benefits and no other retiree benefits. EEOC also revised a question-and-answer section in an appendix to the rule to make the same point. “In light of those revisions, the commission concludes that adding a definition of retiree health benefits is unnecessary,” EEOC said.

Several comments asked that EEOC clarify how its new rule applies to existing employer-sponsored retiree health plans, but EEOC said no revision to the proposed rule is needed on that point. “It is the commission’s intention to allow employers to continue the practice of coordinating retiree health benefits with Medicare eligibility with as little disruption as possible,” EEOC said. “The commission does not believe that additional changes to the rule are required to achieve this result.”

Among the negative comments from organizations that did not support EEOC’s proposed rule, many suggested the commission lacked statutory authority for issuing such a rule. Others contended that such an exemption is inconsistent with the ADEA’s “primary purposes,” the commission observed. EEOC pointed out that Section 9 of the ADEA empowers the agency to establish such “reasonable exemption” as it “may find necessary and proper in the public interest.”

“Nor is the commission persuaded that the rule is inconsistent with the primary purposes of the ADEA,” EEOC added. “Given the continuing decline in the availability of employer-provided retiree health benefits, and the disincentive to provide such benefits created by the Third Circuit’s ruling [in Erie County Retirees Ass’n v. County of Erie, 220 F.3d 193 (3d Cir. 2000) (9 HLR 1254, 8/10/00)], and the commission’s prior policy, this final rule reasonably addresses a problem confronting older Americans. The commission is persuaded that, in order to comply with the commission’s prior policy, many employers would reduce the overall level of health benefits they offer to retirees or cease providing such benefits altogether, leaving many retirees without access to affordable health coverage.”

EEOC believes it has provided the “strong and affirmative showing required” to justify an ADEA exemption, supported by a “comprehensive study” of the relationship between the ADEA and retiree health benefits before it published the proposed rule and meetings with a “wide range” of interested parties, the commission said.

Supreme Court Petition Pending. EEOC said it had agreed not to publish the final rule until after a federal district court in Pennsylvania resolved a suit filed by AARP that challenged the commission’s authority to issue the exemption. In June, the U.S. Court of Appeals for the Third Circuit upheld summary judgment for EEOC, holding the agency properly exercised its power under Section 9 of the ADEA (16 HLR 714, 6/7/07). After the Third Circuit declined to rehear the case en banc, AARP asked the U.S. Supreme Court to stay the appeals court ruling but the justices declined. AARP’s petition for Supreme Court review of the Third Circuit ruling, filed Nov. 20, 2007, still is pending.

The final rule can be accessed at the http://edocket.access.gpo.gov/2007/E7-24867.htm on the Web.

Reimbursement

Court Refuses to Certify Class of Providers in Suit Over Insurer’s Reimbursement Caps

A chiropractic group failed to show that its claims against an insurance company, alleging systematic reimbursement reductions on personal injury protection (PIP) claims, were suitable for certification as a class action, a federal trial court ruled Dec. 4, 2007 (Shenandoah Chiropractic PA v. National Specialty Insurance Co., S.D. Fla., No. 07-60492-CIV, 12/4/07).

The U.S. District Court for the Southern District of Florida ruled that Shenandoah Chiropractic PA could pursue its individual contract-based claims against National Specialty Insurance Co., based on its allegations of improper and unreasonable reductions in payment, but that the claim notice provision of the Florida PIP auto insurance law rendered the individual provider’s claims ill-suited for class action treatment.

Determining whether the insurers’ claims payment practices were reasonable depended on the circumstances of individual provider claims and was not subject to resolution on a declaratory judgment motion seeking to hold the company’s practices unreasonable “across-the-board,” the court said. Declaratory relief is not available, the court added, “because the fact finder must, on a case by case basis, construe the term ‘reasonable’ and determine whether or not the insurer’s evaluation of the bills submitted fits the definition of ‘reasonable.’”

The state PIP law also stipulates that each claim be accompanied by a pre-suit demand letter that specifies the nature of the claim and includes documentation, the court noted. In this case, the court said, the demand letter provided by Shenandoah could not satisfy the notice.
Provider Contracting

Federal Court Says It Will Not Enjoin Lawsuit Seeking Damages for Exclusion From Network

Providers allegedly injured by exclusion from health insurance networks may pursue damages claims against two affiliated insurers under the Arkansas Any Willing Provider (AWP) statute, a federal trial court ruled Dec. 5, 2007 (Arkansas Blue Cross and Blue Shield v. St. Vincent Infirmary Medical Center, E.D. Ark., No. 4:07CV813, 12/5/07).

The U.S. District Court for the Eastern District of Arkansas said it would not enjoin a state lawsuit brought by St. Vincent Infirmary Medical Center and other providers who claimed damages under the Arkansas AWP statute for a period of time during which the law was the subject of an injunction. The court said it lacked jurisdiction over the claims brought by Arkansas Blue Cross and Blue Shield and USAble Corp., seeking to prevent the providers from bringing a damages action under the AWP law in state court.

The federal court specifically ruled that the insurers could not prevail on their claims that the All Writs Act gave the federal court authority to block state law actions that they said involved issues that were decided previously by other federal courts in AWP law preemption litigation. That litigation involved a series of federal court actions and rulings interpreting the validity of state AWP laws in the face of charges that such laws were preempted by the Employee Retirement Income Security Act.

That litigation, which generated an injunction barring enforcement of the Arkansas AWP law in 1997, culminated in an April 2003 ruling by the U.S. Supreme Court, Kentucky Ass’n of Health Plans Inc. v. Miller, 538 U.S. 329 (2003) (12 HLR 532, 4/3/03). The high court ruled that the Kentucky AWP law, which is designed to prevent health plans from excluding providers that are willing to participate under the plan’s terms, is not preempted by the Employee Retirement Income Security Act.

Kentucky’s AWP law was similar to the Arkansas law, the trial court said. The Arkansas injunction was finally lifted in 2005.

Thereafter, the insurers filed a lawsuit seeking a ruling that the injunction preventing enforcement of the Arkansas AWP statute should nonetheless remain in place. The providers opposed that action and counterclaimed seeking damages for the time they were excluded from the insurers’ networks. That action was dismissed without a ruling on the AWP counterclaims, and the providers then sued in state court.

New Lawsuit Filed. The insurers then filed the instant action in federal court, arguing that prior federal court decisions had resolved the state law damages issue and that the court could, therefore, enjoin the state court actions under the All Writs Act. The court, however, disagreed.

It ruled that an injunction under the All Writs Act was not necessary or appropriate given that the federal Anti-Injunction Act severely limits the ability of federal courts to interfere with state court proceedings. Although an injunction may be permissible if it is “necessary to protect or effectuate the federal court’s judgments,” that situation was not present here, the court said.

“In Prudential Ins. Co. of America v. National Park Medical Center Inc.,” this court found that the AWP was pre-empted by ERISA and enjoined the State of Arkansas from enforcing the AWP statute from January 31, 1997 to August 2, 2005,” the court noted. “In the state court action, the Providers seek damages from BCBS and USAble for their refusal to allow the Providers to be included in the BCBS and USAble healthcare networks,” it added.

Although a federal court has the authority to enforce its injunctions, this theory does not support jurisdiction of a court to issue an injunction to enforce an order the court did not make, the court ruled. Because the federal court never ruled on the propriety or availability of damages based on the providers’ AWP counterclaims, there is no basis for concluding that the court now may block those claims in a state court case, the court said.

Solvency

Federal Court Remands Case to State Court, Holds MA Plan Solvency Law Not Preempted

The U.S. District Court for the Northern District of Florida determined that Florida’s requirement that an insurer maintain a level of surplus relates to plan solvency. The court said allowing the state to enforce its regulation against Universal Health Care Insurance Co. does not hinder the operation of MMA. The only issues presented concern Florida law, the district court concluded, and, accordingly, no federal question jurisdiction existed.

“Universal does not make a convincing argument for the exercise of federal jurisdiction under the standard. [T]he liquidation petition does not depend on the construction of federal law,” Judge Stephan P. Mickle wrote. “In fact, there are no federal regulations setting surplus standards for Medicare Advantage insurers or provisions governing liquidation.”

State Law Controlling. The district court also found that Congress yielded to the states’ authority to regulate insurers and, in particular, Medicare Advantage insurers with respect to licensing and solvency issues. Florida law is controlling on those issues and is not preempted, the court found.

The Florida Department of Financial Services filed the lawsuit in state court to take immediate possession of Universal and liquidate its business for failure to meet the surplus requirements of state law. Under Florida’s statute (section 624.408), life and health insurers must maintain a surplus not less than the greater of $1.5 million or 4 percent of the insurer’s total liabilities plus 6 percent of the insurer’s liabilities relative to health insurance.

Universal removed the case to federal court on grounds that the Florida surplus requirements are completely preempted by MMA. Universal argued that federal jurisdiction exists because the case involved a substantial issue of federal law.

The district court found that Florida’s regulation does not relate to benefit requirements, treatment providers, coverage determinations, or similar matters that Congress preempted states from regulating under the MMA. Florida surplus requirement is a law related to plan solvency within the meaning of MMA, the district court concluded.

The district court remanded the case to Florida Circuit Court, Second Judicial Circuit, in Leon County, Fla., and denied all other motions as moot.

Michael G. Tanner and Stuart Fraser Williams, with Tanner Bishop, Jacksonville, Fla., represented Florida and the state Department of Financial Services. Mark Monroe Barber, with Broad & Cassel, Tampa, Fla., represented Universal.


### Long-Term Care

#### Mergers and Acquisitions

**Carlyle Buyout of Manor Care Completed After Lifting of Michigan Restraining Order**

CINCINNATI—The nursing home company Manor Care Inc. Dec. 21 announced that the private equity firm the Carlyle Group had completed its $6.3 billion acquisition of Manor Care.

Manor Care said that a temporary restraining order filed Dec. 20 in Michigan had been dissolved. The TRO had been instigated by the Service Employees International Union.

Earlier, West Virginia’s Health Care Authority had lifted a stay on a license transfer for the sale of seven Manor Care nursing homes.

SEIU, which has contested the buyout nationwide, contends the Carlyle Group will recoup the cost of acquiring Manor Care, the nation’s largest nursing home chain, by trimming patient services and employee compensation. The union represents about 1,100 of Manor Care’s 60,000 employees.

Carlyle, a global investment firm based in Washington, D.C., agreed to buy Manor Care in July but needed to obtain new titles on the operating licenses from states where it has nursing homes.

On Dec. 17, 2007, the buyout was approved by Pennsylvania health care regulators.

**West Virginia Action.** The West Virginia regulatory action on the takeover went through several rounds. Although the state granted a certificate of need (CON) approving the sale in October, the following month SEIU District 1199 requested a stay of that decision and reconsideration of the CON, which the state health care authority granted.

A reconsideration hearing was held Dec. 14, where Manor Care’s attorneys asked the authority to “immediately re-institute” the CON or, alternately, lift the stay on the license transfer, arguing that it was costing investors $1 million a day and that SEIU District 1199 had not demonstrated any irreparable harm it would suffer if the stay was resolved.

West Virginia’s three-member health care authority agreed with these arguments in its order lifting the stay, saying that while they were not in a position to know the precise financial harm to Manor Care, “it is clear that the harm is immediate and substantial if the stay is not dissolved.”

However, the board did not reaffirm its initial decision regarding the CON, thereby withholding final regulatory approval for the deal. The agency said it would allow both sides to file briefs until Jan. 7, 2008, as agreed following the Dec. 14 hearing, and then decide on whether to grant the CON.

Dissolving the West Virginia stay allowed Manor Care to close the deal, Manor Care’s chief operating officer Stephen L. Guillard said in a prepared statement issued after the state’s decision.

Since the deal was announced, it has been “one of the most heavily reviewed and scrutinized transactions ever in the health care sector,” and it has met the regulatory requirements in the 32 states where Manor Care operates, Guillard said.
SEIU District 1199 spokeswoman Jennifer Farmer said the union was disappointed by the West Virginia ruling. "Now more than ever, states, especially West Virginia, should hold hearings and fully investigate what Carlyle’s specific operational plans are to improve care and staffing,” she said.

Toledo, Ohio-based HCR Manor Care owns more than 550 nursing homes, assisted living facilities, rehabilitation clinics, and home care agencies.

BY BEBE RAUPE

Medicaid

Reimbursement

Missouri Court Rules for Kansas Hospitals Seeking Higher Medicaid Reimbursement

T. LOUIS—The Missouri Court of Appeals Dec. 18, 2007, ruled in favor of two Kansas hospitals that filed a lawsuit against the Missouri Department of Social Services claiming that DSS had improperly reimbursed out-of-state hospitals for Medicaid services at a lower rate than in-state hospitals (Overland Park Regional Medical Center v. Department of Social Services, Mo. Ct. App., No. WD67544, 12/18/07). Judge Ronald R. Holliger, Missouri Court of Appeals, Western District, said that the hospitals and DSS had a valid agreement for reimbursement, and that DSS failed to properly calculate reimbursements to the out-of-state hospitals. Holliger also said that the trial court should have used a 10-year statute of limitations in calculating the damages award rather than a five-year statute of limitations, and should have awarded the hospitals prejudgment interest.

The court remanded the lawsuit to the circuit court with instructions to modify its judgment to apply the 10-year statute of limitations and to include prejudgment interest from the date the original petition was filed, June 9, 2004.

The hospitals were Overland Park Regional Medical Center and Menorah Medical Center, both located in Kansas near the Missouri border. Each had an agreement with DSS to provide inpatient services to Missouri Medicaid beneficiaries.

A spokeswoman for DSS said that the department’s attorneys still were reviewing the ruling and had no comment.

Procedural Background. Holliger noted that the hospital first filed a declaratory judgment action in June 2004, seeking an injunction and damages, and arguing that the out-of-state reimbursement method violated the state statute requiring reimbursement for the reasonable cost of care, and violated the U.S. Constitution and other federal laws.

The declaratory judgment action followed upon a 2003 decision by the Missouri Circuit Court, Cole County, which threw out the out-of-state reimbursement method, and required DSS to reimburse out-of-state hospitals for the reasonable cost of care. DSS rescinded the regulation containing the invalid method and replaced it with a new regulation in October 2004.

After DSS repealed the regulation containing the invalid method, it filed a motion to dismiss the hospital’s claim for declaratory judgment, arguing that it was protected by sovereign immunity, and that the lawsuit was moot because the old regulation was no longer in force. But the trial court held that sovereign immunity was waived for contractual causes of action. It granted DSS’s motion to dismiss, but invited the hospitals to refile their lawsuit as a breach of contract action.

The hospitals then did so, claiming that DSS had improperly reimbursed them between April 1, 1994, and Oct. 30, 2004. The trial court found for the hospitals, awarding damages for underpayments for five years, but holding that damages for the previous years were barred by the statute of limitations. It awarded Overland Park Regional $913,000, and Menorah $641,000.

The hospitals appealed the amount of the damages award and the denial of prejudgment interest. DSS cross-appealed, arguing that its provider agreements with the hospitals were not contracts, and that the lawsuit should have been barred because the hospitals had failed to exhaust their administrative remedies.

Stipulated Facts. According to Holliger, the agreements between the hospitals and DSS provided that they be reimbursed for the “reasonable cost of the care or reasonable charge for the services.”

The agreements themselves did not specify reimbursement rates, but DSS regulations did set forth the rates and the methodology for determining reimbursement, as authorized by state statutes, he said.

Between April 1, 1994 and Oct. 30, 2004, only in-state hospitals were reimbursed for their reasonable cost for services. Holliger said. Hospitals located out of state were reimbursed by a different method that was based on out-of-date weighted averages for Missouri hospitals, and which did not adjust for inflation each year, unlike the method for in-state hospitals.

Holliger said that Overland Park Regional would have been paid and additional $1.3 million over the period under the in-state reimbursement method, and Menorah would have received an additional $782,000.

Agreement a Contract? DSS claimed that the trial court erred in finding that the provider agreements with the hospitals were contracts, arguing that the agreements were governed by statutes and regulations, that no provision of the agreement had been breached, that the agreements did not contain payment provisions, and that they had not been negotiated between the parties.

But Holliger brushed aside as inapplicable the cases cited by DSS in favor of the argument that the agreements were not contracts. He noted that the agreements did refer specifically to reimbursement rights, and that they incorporated by reference the statutory requirement that the hospitals be reimbursed for the reasonable cost of care. That requirement was “precisely the obligation that Hospitals allege was breached,” he wrote.

And the fact that the parties did not negotiate the provider agreements did not imply that they were not contracts, Holliger said, but rather that they were contracts of adhesion.

Administrative Remedies. DSS also claimed that the hospitals’ claims should have been barred because they did not exhaust their administrative remedies, citing a
case which suggested that, because the out-of-state method was still in force at the time the lawsuit was originally filed, the hospitals should have availed themselves of administrative remedies.

But Holliger noted that the hospitals’ original petition was a declaratory judgment action regarding the application of an agency rule. Missouri statutes give courts the power in such cases to issue declaratory judgments concerning rules whether or not the plaintiff has first sought relief from the agency, he said.

Holliger also said that DSS no longer had jurisdiction to hear claims regarding the rule once it had been withdrawn.


Tennessee

Non-Attorney May Represent Person Denied Medicaid Eligibility, State AG Says

RALEIGH, N.C.—An individual who is not an attorney may represent a person appealing the denial of Medicaid eligibility, Tennessee’s attorney general said in a Dec. 18 opinion (No. 07-166).

According to Robert E. Cooper Jr. (D), such representation is authorized under federal law and, as Tennessee accepts federal funding for its Medicaid program, the state must comply with such authorization. Therefore, representation by non-attorneys at administrative Medicaid hearings would not violate Tennessee’s law against the unauthorized practice of law (Tenn. Code Ann. Section 23-3-103) as it would in other situations.

However, Cooper said, if the legal assessments and advice regarding the application of federal or state laws relating to Medicaid eligibility offered by non-attorneys to a person seeking eligibility are performed for “valuable consideration” and require the “professional judgment of a lawyer,” such conduct would violate the state law.

According to Cooper, the situation would be no different if the representation services are provided by a non-attorney who has expertise in a pertinent subject matter of the law such as a certified senior adviser, certified estate planner, certified charitable adviser, or certified long-term care counselor with a working knowledge of the Medicaid laws.

Cooper rendered his opinion following an interpretive request by Virginia T. Lodge, the state’s commissioner for human services.


Medical Staff

Physicians

Court Upholds Verdict, Damages Award In Doctor’s Retaliatory Discharge Lawsuit

A doctor terminated by a medical group and health plan was properly awarded $200,000 on retaliatory demotion and discharge claims brought under California law, a state appeals court ruled in a decision posted Dec. 20, 2007 (Woods v. Southern California Permanente Medical Group, Cal. Ct. App., No. B193021, filed 11/20/07).

The California Court of Appeal, Second District, ruled that a jury did not return an inconsistent verdict when it ruled that Dr. Mark Woods was an employee of both Southern California Permanente Medical Group and Kaiser Foundation Health Plan who was entitled to pursue retaliatory discharge and wrongful demotion claims under Cal. Bus. & Prof. Code § 2056.

The appeals court affirmed a jury verdict and post-trial order that upheld the jury’s decision finding the medical group and plan took adverse action against Woods in retaliation for “advocating medically appropriate patient care” and that the action violated public policy enunciated in Section 2056.

The fact that the jury, in a special verdict form, wrote “No” where it was asked whether Woods was an employee of the medical group, and “Yes” where it was asked whether Kaiser and the Medical Group were a “single employer” of the physician, did not mean that Woods was not an employee of the Medical Group, the court said.

Rather, the jury’s response reflects its determination that Woods was employed by the medical group and foundation, together, as a single employer, the appeals court said. “The jury’s finding that the Medical Group was not Dr. Woods’s employer was merely a finding that the Medical Group, standing alone, was not his employer—rather, the Medical Group, together with Kaiser, were the single employer of Dr. Woods,” the court said.

“Because Woods was an employee of the Medical Group and Kaiser, he was entitled to sue in tort for their retaliatory conduct in violation of the public policy set forth in section 2056,” the court added.

Problems at Hospital ER. The lawsuit involved allegations that Woods was subject to discipline, and eventually terminated, because he reported lapses and weaknesses in care while serving as an emergency room physician at Kaiser Permanente Bellflower Hospital in Bellflower, Calif.

The court cited administrative citations by state regulators that supported Woods claims that the facility failed to provide appropriate medical screening examinations, stabilizing treatment for emergency medical conditions, and care in the emergency room without regard to the patients’ ability to pay.

“Kaiser-Bellflower’s policy was to keep patients waiting in the emergency room until they left without treatment,” the court said, adding that “between 1999 and 2006, more than 5,000 patients were sent home without receiving medical screening exams.” Kaiser, the court continued, “intentionally understaffed and under-
stocked the hospital” to increase profits and decrease the number of patients availing themselves of the emergency room care.

Woods, who allegedly complained about these conditions, was placed on administrative leave in November and December of 2003, was transferred in November 2004 to another Kaiser hospital, was suspended again in April 2006, and was terminated three months later, the court said.

Woods filed his original action in March 2004, prevailing on both his statutory and common law causes of action charging that the employment actions by the medical group and plan violated California public policy favoring the reporting of inappropriate patient care.

Although his status as an “employee” was challenged on appeal, the appeals court said the jury’s verdict was consistent with the conclusion that the medical group and plan constituted a “single employer” of Woods. “The jury’s finding the Medical Group was not Dr. Woods’ employer was merely a finding that it alone was not Dr. Woods’ employer; it was not an exoneration of defendants,” the court concluded.

The court’s decision is available at http://op.bna.com/hlnsf/r?Open=psts-7a9nbw.

Medicare

Reimbursement

Court Dismisses Challenge to Denial Of Medicare Payment for Depreciation

A federal district court Dec. 12, 2007, dismissed a hospital’s challenge to the denial of Medicare reimbursement claims arising from the treatment of depreciation following a merger of two facilities (UPMC St. Margaret Hospital v. Leavitt, W.D. Pa., No. 06-1237, 12/12/07).

Adopting a report and recommendations made in November by Magistrate Judge Robert C. Mitchell, the U.S. District Court for the Western District of Pennsylvania determined that the administrative decision to deny Medicare reimbursement to UPMC St. Margaret Hospital by the health and human services secretary was based on substantial evidence. The district court found that the denial of reimbursement was not arbitrary, capricious, or an abuse of discretion.

The administrator of the Centers for Medicare & Medicaid Services reversed a determination by the Provider Reimbursement Review Board that the fiscal intermediary improperly disallowed the loss on disposal depreciable assets resulting from the statutory merger of St. Margaret Memorial Hospital, in Allegheny County, Pa., and the University of Pittsburgh Medical Center (UPMC), in Pittsburgh, which became UPMC St. Margaret in 2006.

Parties Related. The CMS administrator found that the parties to the transaction were related through control. Applying the related party principles at 42 C.F.R. § 413.17, the administrator found that there was a continuity of control that resulted in the parties to the merger being related.

In addition, the administrator found that UPMC St. Margaret failed to show that there was a bona fide sale of its depreciable assets and it did not secure an appraisal before the closing date of the transaction, another indication that the hospital was not concerned with receiving reasonable consideration for its depreciable assets. Finally, no documentation supported the hospital’s conclusion that the assumption of debt was fair consideration for the hospital’s assets, and the administrator concluded that the transaction was not a bona fide sale for the recognition of a loss on the disposal of assets.

On appeal, the hospital argued that the administrator’s conclusion that “between related corporations” can refer to pre-merger and post-merger entities is inconsistent with the regulation and not entitled to any deference. The district court, however, found that UPMC St. Margaret did not point to any authority in support of its argument and, thus, the government’s interpretation was entitled to deference.

The hospital also argued that, even if CMS’s new interpretation of the regulations on mergers and related organizations were a permissible reading of the language, such a change only could be adopted through notice-and-comment rulemaking. The district court disagreed, finding that interpretive rules and statements of policy, which only state what the administrative agency thinks a statute means, are exempted from the notice and comment requirement of the Administrative Procedure Act and, thus, the HHS secretary was not required to comply with the notice and comment provisions.

Members Appointed. The district court also found that the predecessor, St. Margaret Memorial Hospital (SMMH) gained the power to appoint 10 of 16 members of UPMC St. Margaret’s board of directors, the president, three vice presidents, and the controller of SMMH. All of those members carried over to the merged entity and the merger agreement provided that the board would exercise control during the integration period.

Consequently, the court found, the secretary’s conclusion that the scope of control was “significant” was supported by substantial evidence and was entitled to deference. Finally, the court rejected UPMC St. Margaret’s contention that the secretary’s conclusion that the transaction was not bona fide was not supported by substantial evidence.

The district court found that by the hospital’s calculations, UPMC St. Margaret acquired $86 million in cash or cash equivalent for less than $71 million and, as the secretary argued, paid nothing for the hospital buildings and equipment despite their appraised value of $36 million. The court determined that the secretary’s conclusion that the transaction was not bona fide was supported by substantial evidence in the record, including the hospital’s appraisal.

Accordingly, the district court denied UPMC’s objections to the magistrate judge’s report and recommendations. The court granted summary judgment to the HHS secretary.

Samuel W. Braver, with Buchanan Ingersoll & Rooney PC, Pittsburgh, represented UPMC St. Margaret. Albert W. Schollaert, assistant U.S. attorney, Pittsburgh, represented the HHS secretary.

CMS Actions in Brief

CMS Issues DSH Allotments, Payment Limits

The notice provides explanations on how CMS determined the allotments based on provisions under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The notice provides two charts with the DSH allotment figures that went into effect Dec. 28.

The CMS notice also announced final 2006 and preliminary fiscal 2008 limitation on aggregate DSH payments that states may make to institutions for mental diseases (IMDs) and other mental health facilities. The notice provides two additional charts with the IMDs allotment figures that go into effect Dec. 28. The Federal Register notice is available on the Web at [http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/E7-24486.pdf].

HHS Proposes DAB Review Rule
The Department of Health and Human Services issued a proposed rule Dec. 28, 2007, recommending changes in the regulations governing administrative review by the HHS Departmental Appeals Board to allow the secretary to review final decisions and to correct errors in the application of law or deviation from published guidance.

The rule, published in the Federal Register (72 Fed. Reg. 73708), would amend regulations governing administrative review by the DAB. The current regulation under 45 C.F.R. Part 16 does not specifically require the DAB to follow published guidance and does not call for secretarial review of the DAB’s final decisions.

According to the proposed rule, as the DAB’s jurisdiction has increased, the issues for DAB review have grown in complexity and significance, and there has been considerable growth in the volume of cases as well. While the board had considerable expertise in departmental programs, under the current rules, the DAB does not have access to the full range of policy considerations that the secretary and the relevant agency components may have in interpreting applicable statutes and regulations, the proposal said.

Peer Review

Doctor’s Resignation Before Panel Hearing Constituted Failure to Exhaust His Remedies

A physician who ended a medical executive committee’s (MEC) administrative process by resigning during an early stage of its investigation failed to exhaust his administrative remedies and, therefore, could not succeed on claims against the MEC, a federal court in Colorado held Dec. 13, 2007 (Catholic Health Initiatives, Colorado v. Gross, D. Colo., No. 06-cv-01366-REB-BNB, 12/13/07).

The U.S. District Court for the District of Colorado granted summary judgment to the Medical Executive Committee of Catholic Health Initiatives Colorado and two of its individual members (collectively, the MEC) on Dr. Robert C. Gross’s complaint that they breached the implied duty of good faith and fair dealing and violated his due process rights in connection with actions taken during an investigation of Gross’s practice at Centura Health-St. Thomas More Hospital. The court also granted summary judgment for the hospital on three out of four claims Gross alleged against it.

In an opinion by Judge Robert E. Blackburn, the court said that it did not have subject matter jurisdiction over Gross’s claims against the MEC because the physician failed to exhaust the administrative remedies set forth in the hospital’s medical staff bylaws. It rejected Gross’s argument that the exhaustion doctrine was inapplicable in his case because administrative remedies were unavailable to him. The court said that the only reason Gross never received the notice and hearing contemplated by the bylaws was his unilateral resignation before the investigation reached that stage.

Investigation Started. Gross executed a physician recruitment agreement with Centura in 2003. In 2006, Catholic Health Initiatives, Colorado, doing business as Centura Health-St. Thomas More Hospital, brought suit against the doctor alleging breach of contract. Gross responded by filing counterclaims against Centura and third-party claims against the MEC. Both of these parties raised the affirmative defenses of waiver and failure to exhaust remedies and moved for summary judgment.

The MEC is the organization authorized by Centura to oversee medical staff functions, including credentialing and ensuring adherence to the medical staff bylaws. After receiving independent peer review of the care provided by Gross to several patients, the MEC invited the physician to respond to questions posed by the reviewer and to appear at a Nov. 3 MEC meeting. Gross went to the meeting, answered the questions, and presented his position.

On Nov. 10, the MEC sent Gross a letter that required him to obtain an investigation of his surgical skills by the Center for Personal Education for Physicians (CPEP). Pending the outcome of the CPEP evaluation, the MEC recommended that Gross voluntarily withdraw his privileges for surgical cases in which bowel anastomosis was contemplated or that he continue to perform such procedures only with the assistance of a proctor under certain specified conditions.
The MEC warned Gross that if he chose not to follow the “requirements and recommendations” outlined in the letter, then it would be forced to take further action, which could include a summary suspension of his privileges to perform bowel surgery. It also requested a response to its letter within 24 hours.

In a subsequent series of letters, Gross resigned—twice—from the medical staff, then attempted to withdraw his resignation. The MEC responded that it considered his resignation final and informed Gross that he would have to reapply to obtain medical staff membership at the hospital.

**Exhaustion Required.** Gross’s lawsuit claimed that the MEC’s actions breached its duty of good faith and fair dealing and violated his right to due process. The MEC, on the other hand, argued that Gross’s failure to exhaust administrative remedies barred the action. The court agreed with the MEC.

Generally, if “complete, adequate, and speedy administrative remedies are available, a party must pursue those remedies before filing a lawsuit concerning an administrative action,” the court said. This requirement, moreover, is usually applicable to challenges to actions taken by professional review committees under the Colorado Professional Review Act, Colo. Rev. Stat. §§ 12-36.5-101-12-36.5-203.

The peer-review process at a private hospital, including Centura, is an extension of the authority of the Colorado State Board of Medical Examiners, the court said. Therefore, as recently held by the Colorado Supreme Court in Crow v. Penrose-St. Francis Healthcare System, 169 P.3d 158 (Colo. 2007)(16 HLR 1292, 10/25/07), “a physician must exhaust all peer review committee administrative remedies before seeking relief in court.”

Here, the medical staff bylaws provided for a variety of procedures for resolving issues of professional competence, conduct, or discipline, the court said. Gross claimed that the MEC failed to abide by the notice and hearing requirements of the bylaws when it sent the Nov. 10 letter and when it refused to allow him to withdraw his resignation.

According to the court, it was undisputed that the MEC did not provide Gross with a notice of a right to a hearing in the Nov. 10 letter; however, it said, the letter did not trigger Gross’s hearing rights under the bylaws and, therefore, the MEC was not required to give him such notice.

The court noted that the bylaws contained specific provisions concerning investigations and routine corrective actions, under which a physician is not entitled to a hearing during such proceedings. The Nov. 10 letter “clearly” indicated that the investigation of Gross’s competency was ongoing, and even its “request for voluntary compliance” did not trigger Gross’s right to a hearing, the court said.

Moreover, Gross’s resignation interrupted the investigatory process, the court found. “To exhaust his administrative remedies, Dr. Gross was required to permit the preliminary proceedings outlined in the November 10th letter to proceed,” it wrote. “If those proceedings progressed to the point where a hearing was required, then Dr. Gross would have been required to complete the hearing process, assuming the MEC continued to follow proper procedures,” it said.

According to the court, the “path through the administrative process is laid out clearly in the By-Laws, and the November 10th letter indicated that the MEC had barely begun to progress down that path. Although the MEC had followed proper procedures to this point, Dr. Gross unilaterally interrupted the administrative process by submitting his two letters of resignation.”

**Hospital Defendants.** The court also granted summary judgment for the hospital on three of the four claims asserted against it by Gross. The first two claims paralleled those against the MEC—breach of the duty of good faith and fair dealing, and violations of due process—and were decided on the same ground. Gross’s other claims were for tortious interference with existing business opportunity and tortious interference with prospective business advantage. The affirmative defenses of waiver and failure to exhaust administrative remedies were inapplicable to these claims, the court said.

Gross’s allegation of tortious interference with an existing business opportunity concerned his practice at another hospital after he left Centura. He alleged that, at that time, members of the Centura’s medical staff and administration “made disparaging and false statements” about him that contributed to the termination of his medical staff privileges at the second hospital. The court concluded that Centura did not establish its entitlement to judgment as a matter of law on this counterclaim.

However, the court granted the hospital’s motion for summary judgment on Gross’s claim for tortious interference with a prospective business advantage. The counterclaim was based on a report made by Centura to the National Practitioner Data Bank (NPDB) that Gross had resigned his medical privileges while under investigation or to avoid an investigation. Because the undisputed facts in the record indicated that the hospital’s statements were true, the hospital was immune from liability in a civil action based on the report, the court said.

The court also granted Centura’s motion for summary judgment on its breach of contract claims. In a Dec. 17 order, the court scheduled a pretrial conference concerning the remaining issues in the case for Feb. 8.


Due Process

Doctor Claims Denial of Due Process Arising From Use of Withdrawn Allegations

A university hospital physician is seeking U.S. Supreme Court review of a decision that affirmed his recommended termination by a peer review panel that was based, in part, on withdrawn allegations of misconduct (Al-Jurf v. Board of Regents, U.S., No. 07-780, petition filed 12/10/07).

Dr. Adel Al-Jurf asserted in his petition for a writ of certiorari to the Iowa Court of Appeals that the panel’s reliance on the withdrawn allegations, and its failure to notify him that it intended to do so, violated his due process rights. He claimed that he “was also deprived of the right to know that the . . . incidents, and the rationale for their admission and consideration, would form the basis of the decision to impose the ultimate sanction of termination.”

As a result, Al-Jurf said, he “was deprived of the opportunity to develop a trial strategy to rebut the covert purpose for which they were offered.” Thus, he not only was deprived of the constitutionally required notice, but also of “the concomitant right to present his side of the story in direct response to the purposes for which the incidents were offered,” Al-Jurf argued.

Disciplinary Proceedings. Al-Jurf was a tenured general surgeon at the University of Iowa Hospitals and Clinics (UIHC). After a series of incidents, the chair of the department of surgery made a disciplinary complaint regarding Al-Jurf to the University of Iowa Office of Affirmative Action. This led to the appointment of a faculty judicial commission to hear the complaints.

At a fact-finding hearing before the commission, the university’s attorney submitted documentation of a series of problems between Al-Jurf and members of the hospital’s anesthesia department. However, in his closing remarks, the attorney made clear that he was not seeking findings from the panel regarding those particular incidents. Nevertheless, the commission relied on them to find a “pattern of repeated behavior” by Al-Jurf that violated the university’s standards of professional behavior.

These and other incidents, the commission said, demonstrated that Al-Jurf routinely vilified, distressed, and interfered with the work of colleagues, created a hostile educational environment for student residents, and compromised patient care. It recommended that he be terminated from his position. The university’s president accepted the findings and recommendations, although he acknowledged that the anesthesia department incidents could not “form an independent basis for the discipline in this case.”

The university’s board of regents, the trial court on judicial review, and the Iowa Court of Appeals affirmed Al-Jurf’s termination. The Iowa Supreme Court denied review. According to Al-Jurf’s petition, the trial court, also, detailed the anesthesia department incidents in holding that substantial evidence existed to support the physician’s termination.

Al-Jurf asserted that the Supreme Court should accept review “to clarify the due process rights afforded to . . . tenured state employees with a protected property interest in their employment.” Although he acknowledged that the case does not present “a conflict of authority among the courts or a unique or unsettled question of law,” Al-Jurf maintained that it gives the high court an opportunity to “correct an injustice.”

Thomas J. Duff, of the Duff Law Firm PLC, Des Moines, Iowa, filed the petition.

Professional Liability

Malpractice

‘Pure Opinion’ Testimony Not Subject To Frye Evidence Test, Florida Court Says

The Frye test for determining whether proposed expert evidence is reliable does not apply to expert testimony concerning a causal link between trauma and fibromyalgia, and “even if it did, such testimony satisfies it,” the Florida Supreme Court decided Nov. 21, 2007 (Marsh v. Valyou, Fla., No. SC06-118, 11/21/07).

Resolving a split among Florida circuit courts of appeals, the state’s supreme court held that the expert causation testimony was based on generally accepted methodology—differential diagnosis—and that disagreement about the conclusions drawn was “pure opinion” and was not subject to Frye analysis.

“Once the Frye test is satisfied through proof of general acceptance of the basis of an opinion, the expert’s opinions are to be evaluated by the finder of fact and are properly assessed as a matter of weight, not admissibility,” the court wrote.

Justice Harry Lee Anstead concurred in the majority’s holding, but for an additional reason: Frye, he said, “did not survive the adoption of Florida’s Evidence Code.” The evidence code, Anstead wrote, “was intended to apply a straightforward relevancy test to expert evidence and in essence to establish a rule favoring admissibility once relevancy was established.”

The First District Court of Appeals held that Frye applied and excluded the evidence. In a similar case, the Second District Court of Appeals held Frye did not apply, and allowed the evidence.

Parsing Through Twilight Zone. Jill Marsh was in four car accidents over a three-year period. She claimed the accidents caused fibromyalgia, a syndrome characterized by pervasive pain and fatigue. She sued the defendants, including Avis-Rent-a-Car.

Avis moved to preclude Marsh from presenting expert testimony that the accidents caused her fibromyalgia, arguing that the testimony did not meet Frye’s standard for admissibility because the premise that trauma can cause fibromyalgia had not been generally accepted in the scientific community.

“Many years ago,” the court said, the U.S. Court of Appeals for the District of Columbia Circuit recognized that, “Just when a scientific principle or discovery crosses the line between experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized.” The point for recognition, the court in Frye said, is when the theory has “gained general acceptance in the field.”
\textit{Daubert} and Federal Rule of Evidence 702 have “superseded the Frye test” in federal and many state courts, the court said. But the Florida Supreme Court has “repeatedly reaffirmed [its] adherence to Frye.”

Frye, the court said, “only applies when an expert attempts to render an opinion that is based upon new or novel scientific techniques. . . . Frye is inapplicable in the vast majority of cases.”

The expert testimony in this case was not “new or novel,” the supreme court held: Fibromyalgia is “widely accepted” as a diagnosis. Marsh’s experts based their diagnoses and opinions about the causes of her fibromyalgia on good methodology, the court said: a review of her medical history, clinical physical examinations, their own experience, published research, and differential diagnosis.

‘Pure Opinion.’ Expert opinion based on experience and training is “pure opinion testimony,” the court said, and is not subject to Frye analysis. Pure opinion testimony, the court explained, “is analyzed by the jury as it analyzes any other personal opinion or factual testimony by a witness.” Testimony causally linking trauma to fibromyalgia “is based on the experts’ experience and training [and] is pure opinion testimony admissible without having to satisfy Frye.”

The defendants, the court said, did not challenge the experts’ methodology of differential diagnosis, which the court has previously ruled is a generally accepted method for determining specific causation. Instead, the court said, the defendants challenge the experts’ conclusion that trauma caused Marsh’s fibromyalgia.

But under Frye, the court said, it is the scientific principles and methodologies underlying the conclusion that are subject to Frye; “’the opinion of the testifying expert need not be generally accepted as well.’”

Trial courts “must resist the temptation to usurp the jury’s role in evaluating the credibility of experts and choosing between legitimate but conflicting scientific views,” the court warned. “A challenge to the conclusions of Marshes’ experts as to causation, rather than the methods used to reach those conclusions, is a proper issue for the trier of fact,” the court said.

\textit{Frye Test Satisfied.} Even if the expert testimony linking fibromyalgia to trauma were subject to Frye, the testimony satisfied the test. “Numerous published articles and studies recognize an association between trauma and fibromyalgia. That experts disagree was not dispositive,” the court said: “’Frye does not require unanimity. While the precise etiology of fibromyalgia may not be fully understood,’ the court found that Marsh demonstrated the reliability of her experts’ testimony and it should have been admitted.

Justice Raoul G. Cantero III dissented. “Whether trauma can ever cause fibromyalgia is a subject of much debate and therefore the view that it can has not been generally accepted,” Cantero wrote. “I cannot agree with the majority that the jury should be left to sort out contentious and complex disputes about medical causation where experts in the relevant scientific community have been unable to agree.”

\begin{quote}
The court’s decision is available at \url{http://www.floridasupremecourt.org/decisions/2007/sc06-118.pdf}
\end{quote}

\section*{Negligence}

\textbf{Medical Review Panel Not Prerequisite For Claim Alleging Negligent Maintenance}

\textbf{Allegations that a plaintiff suffered foot and ankle injuries when the X-ray template from a defectively maintained machine fell on her foot did not need to be submitted to a medical review panel prior to filing suit, the Louisiana Court of Appeals held Nov. 21, 2007 (Duplessis v. Tulane University, La. Ct. App., No. 2007-CA-0647, 11/21/07).}

Defendant Tulane University, as the owner of the Tulane University Hospital and Clinic and the Tulane Institute of Sports Medicine, filed an exception of prematurity to the plaintiff’s action, arguing that the Louisiana Medical Malpractice Act (LMMA) required pre-suit review of the complaint by a special panel. A trial court agreed with the hospital and dismissed plaintiff Leslie Duplessis’s suit for damages.

In an opinion by Judge Dennis R. Bagneris Sr., the appeals court reversed. It held that Duplessis was not required to submit her claims to review prior to filing suit because the action was governed by general tort law, not the LMMA.

\textbf{Defective Device.} Duplessis was undergoing an X-ray procedure when, she alleged, an X-ray template fell from the machine onto her foot. She maintained that the device that held the template in the machine was defective and that the hospital’s maintenance department negligently failed to properly maintain, inspect, and/or repair the dangerous or defective condition of the template holder.

The hospital, on the other hand, said Duplessis’s injury was caused by the negligence of a health care provider—the X-ray technician—while she was performing an action connected to medical care or treatment. The court disagreed.

The court explained that the LMMA was intended to govern all claims of medical malpractice filed against health care providers who are enrolled in the Louisiana Patient Compensation Fund. However, it emphasized that the act applies only to claims that arise from medical malpractice and that all other tort liability on the part of health care providers is governed by general tort law.

In Coleman v. Deno, 813 So. 2d 315 (La. 2002), the state supreme court set out a six-part test to determine whether a claim sounds in medical malpractice or general negligence, the court said. An analysis of Duplessis’s complaint revealed that it sounded in general tort law.

First, the court found that particular wrong alleged by the plaintiff did not result from any dereliction of a treatment-related professional skill, since she contended that the template simply fell from the holder device.

Second, it said, no medical expert testimony will be needed to determine whether the maintenance personnel were negligent when they failed to repair the X-ray device after having been warned of its dangerous condition.

Third, the “pertinent acts or omissions” in the case did not implicate or require an assessment of Duplessis’s medical condition, the court said.
Fourth, the complaint alleged that Duplessis’s injury was due to the failure of the maintenance department to maintain the X-ray machine, and not that it arose in the context of a physician-patient relationship, the court said.

Fifth, the court noted, the injury could have occurred even if the plaintiff had not been seeking treatment at the time. Even “a visitor to the hospital, who was near the faulty equipment, could have suffered the same injury,” it observed.

The court concluded that all five factors weighed in favor of finding that the plaintiff’s allegations sounded in general negligence, not medical malpractice. The sixth factor, whether the tort was intentional, was not an issue in this case, it added.

The court held that, since the action sounded in general tort, not medical malpractice, the convening of a medical review panel was not a prerequisite to the filing of the suit. Therefore, the dismissal was inappropriate.


The opinion is available at http://op.bna.com/hl.nsf/r/Open=mapi-7a2ayf] on the Web.

Provider Regulation

Hospitals

Ninth Circuit Upholds Arbitrator’s Ruling Barring Hospital’s Flu Immunization Program

The U.S. Court of Appeals for the Ninth Circuit Dec. 21, 2007, upheld an arbitrator’s ruling that a Seattle hospital may not implement unilaterally a mandatory flu immunization program covering nurses and other employees (Virginia Mason Hospital v. Washington State Nurses Association, 9th Cir., No. 06-35073, 12/21/07).

Affirming a lower court’s grant of summary judgment to the Washington State Nurses Association, which represents between 600 and 700 registered nurses at Virginia Mason Hospital, the appeals court found that the arbitrator made a plausible interpretation of the collective bargaining agreement, he properly inferred a duty to bargain over terms and conditions of employment, and the ruling does not violate public health policy.

“[W]hile there is little doubt that the sort of mandatory immunization policy that Virginia Mason favors would enhance the aggressive infection control procedures and professional standards that state and federal regulations require, the hospital has not demonstrated that the converse is true and that the arbitrator’s decision requiring Virginia Mason to bargain with union representatives before implementing such a policy is directly incompatible with either the state and federal regulations at issue or the public policies underlying them,” Judge Ronald M. Gould wrote for the appeals court.

Judges William C. Canby and Susan P. Graber joined in the opinion.

Flu Shot Program Made Mandatory. Virginia Mason had long recommended that its employees get flu shots to reduce the chance of transmitting the influenza virus to elderly patients and those with compromised immune systems. The hospital in 1998 implemented a voluntary program providing free flu shots to all employees. After six years of running the program, the staff immunization rate was only 55 percent.

Virginia Mason decided in September 2004 to make the flu immunization program mandatory effective with the start of 2005. The hospital announced that proof of flu vaccination would be a requirement of fitness for duty except if the employee had a religious objection or a documented vaccine allergy. A memorandum warned that employees would face termination unless they got an annual flu shot or agreed to take prophylactic antiviral medication at their own expense.

Due to a shortage of flu vaccine, the hospital postponed implementation of the program until late 2005. In the meantime, the Washington State Nurses Association filed a grievance alleging that the hospital’s unilateral implementation of the program violated the bargaining contract.

An arbitrator ruled in favor of the union in August 2005, finding that, as a condition of employment, the flu vaccination program was a mandatory subject of bargaining and that it was not covered by the contract’s management rights clause. The arbitrator also found that the issue was not waived under the contract’s “zipper clause,” which waives all issues not discussed during bargaining or included in the contract. The arbitrator found that the patient care priority clause did not apply because the immunization program would primarily affect employees and would only have an indirect effect on patient care.

Virginia Mason asked the U.S. District Court for the Western District of Washington to vacate the arbitrator’s ruling, but the court granted summary judgment to the union. The district court denied the union’s motion for an award of attorneys’ fees as a sanction against the hospital for suing in bad faith.

The hospital later implemented a policy requiring nurses who refused to get an annual flu shot to either take prophylactic antiviral medication or to wear face masks when dealing with patients during flu season. A National Labor Relations Board administrative law judge found in October 2006 that the unilateral change did not violate the National Labor Relations Act because it was a narrow policy central to the purpose of running a hospital and therefore was not a mandatory subject of bargaining.

Arbitration Rulings Entitled to Deference. “We recognize Virginia Mason’s commendable desire to protect its vulnerable patients from infection with the flu,” Gould said. He also acknowledged, “as the arbitrator did,” that many experts recommend that health care workers get flu shots. However, Gould found that the parties chose arbitration to resolve grievances and that arbitration rulings are entitled to considerable deference and may be vacated only if they fail to draw their essence from the contract or violate explicit, well-defined public policy.

The hospital argued that three contract provisions—the patient care priority clause, the management rights...
clause, and the zipper clause—allowed it to implement the mandatory immunization policy without bargaining with the union. But Gould found that the arbitrator “did not ignore the plain language of any of these clauses,” that he thoroughly analyzed each of them, and that his interpretation “was not implausible.”

The arbitrator “viewed the dispute as requiring him to determine whether the mandatory immunization policy should be characterized as a ‘personnel policy’ that Virginia Mason could implement unilaterally” under the management rights clause “or a ‘condition of employment’ that must be submitted to collective bargaining” pursuant to the contract’s preamble and its union recognition clause, Gould said. He found that although the arbitrator’s interpretation of the management rights clause was “narrow,” it was not implausible because it was based on the terms of the contract.

Virginia Mason argued that the arbitrator exceeded his authority by interpreting the contract’s preamble and union recognition clause to require a general duty to bargain over terms and conditions of employment, which is not stated explicitly in either provision. However, Gould found that the arbitrator properly inferred a duty to bargain “in light of his understanding of the foundational labor law principle that management must bargain with recognized union representatives over terms and conditions of employment, a principle that is embodied in both statutory and judge-made law and that has become well established in all industries with unionized employees, including the health care industry.”

The hospital also argued that the arbitrator’s ruling conflicts with public policy embodied in state and federal regulations regarding infection control in hospitals and state professional standards for nurses and that hospitals could be held liable for employees’ passing flu to patients. But the hospital failed to cite even “a single example of a hospital facing legal action because a patient contracted the flu from a health care worker,” Gould said. “Nor has Virginia Mason provided any evidence of its inability, or the inability of peer institutions that do not require flu immunization of all employees, to comply with the state and federal regulatory regimes on infection control,” Gould said.

“The hospital has offered evidence of a developing medical consensus around mandatory flu immunization policies for health care workers, but no corresponding legal or regulatory consensus in support of such policies has yet emerged,” Gould said. He found that only one state—Arkansas—requires flu shots for health care workers and that the requirement is limited to long-term care facilities.

“The more general policies that already are in place both federally and in Washington to encourage infection control in hospitals do not specifically militate against the arbitrator’s requirement that Virginia Mason engage in collective bargaining before imposing such a policy on its nurses as a condition of employment,” Gould said. He observed that there also is “a clearly established public policy requiring employers to bargain with union-represented employees over conditions of employment” and that the mandatory immunization program would have resulted in the termination of employees who failed to meet its requirements.

Finally, the appeals court affirmed the denial of the union’s request for attorneys’ fees, finding that Virginia Mason’s arguments “were not frivolous and were not made for vexatious or oppressive reasons.”

Howard N. Goodfriend and Devin T. Theriot-Orr of Edwards, Sieh, Smith & Goodfriend in Seattle represented the hospital. Lawrence Schwerin of Schwerin Campbell Barnard in Seattle represented the union.

*The text of the decision may be accessed at http://op.bna.com/dlrcases.nsf?Open=smgk-7a7ttf.*

**Hospitals**

**Oklahoma County Liable for Medical Care Provided to Inmates, State Court Decides**

County officials in Oklahoma must pay hospitals that treat inmates for medical conditions regardless of whether the inmates had those conditions at the time they were incarcerated, the Oklahoma Supreme Court ruled Dec. 18, 2007 (HCA Health Services of Oklahoma Inc. v. Whetsel, Okla., No. 104227, 12/18/07).

The state high court, rejecting arguments of Oklahoma County, Okla., officials who claimed they should not be responsible for certain hospital charges, ruled that county officials may recover those charges from inmates under state law, but cannot avoid paying for them in the first instance simply because they were associated with a preexisting condition.

The ruling affirmed a state trial court decision finding HCA Health Services of Oklahoma Inc. could pursue claims for over $2.2 million in charges for medical care provided to county inmates between February 2003 and September 2006 in a lawsuit filed against Sheriff John Whetsel and others.

Federal and state laws require Oklahoma to provide medical treatment to inmates and state law requires counties to assume primary responsibility for paying for such treatment, the court said. With respect to treatment for preexisting conditions, the state has primary responsibility subject to a right of reimbursement from the treated inmate, the court added.

In reaching its decision, the court considered two Oklahoma statutes, 57 Okla. Stat. 2001 § 52 and 19 Okla. Stat. 2001 §§ 746. “Section 52 spells out generally the duty of providing medical care and the more generalized duties of the county” to provide inmates with medical care, while Section 746 details the procedures for payment for that care, the court said.

The provisions of Section 746 “clearly identify two parties from whom a provider may seek payment for medical treatment—the inmate and the custodial county,” the court said. “We firmly reject County’s notion that for conditions that pre-exist county’s custody the statute places sole liability on the inmate,” it added.

Although other states place primary responsibility for paying for treatment of preexisting conditions on the inmate, Oklahoma does not, the court said. And while providers may recover their treatment costs directly from inmates, they are not required to do so, it added.

“It is absolutely clear from the legislative text that responsibility is placed on both the inmate and the county without declaring any precondition for invoking the liability of either,” the court continued. “Without establishing primary liability or a precondition for invocation of secondary liability, the Oklahoma legislature has cre-
Grassley also has questioned the quality of care at such specialty hospitals to care for the sickest and most expensive patients. He said doctors who self-refer to such facilities are cherry-picking the most profitable patients and leaving community hospitals who self-refer to such facilities are cherry-picking the most profitable patients and leaving community hospitals to refer to other facilities created an unlevel playing field and stifled fair competition among hospitals.

“AHA also called it a myth that specialty hospitals provide higher quality care to patients, saying there was little difference in outcomes between community hospitals and smaller, doctor-owned facilities.


Stock Options

Minnesota Appeals Court Allows Probe Into Options Backdating at UnitedHealth

A state trial court properly rejected a bid by UnitedHealth Group Inc. to quash the Minnesota attorney general’s civil investigative demand (CID) to look into UnitedHealth’s possible statutory violations arising from stock options backdating, the Minnesota Court of Appeals affirmed Dec. 4, 2007 (UnitedHealth Group Inc. v. State, Minn. Ct. App., No. A06-2013, 12/4/07).

In an unpublished opinion by Judge Gordon Shumaker, the court said the CID specifies sufficient legal grounds for investigating UnitedHealth’s stock option practices.

In related matters, two days after the court’s opinion was issued, former UnitedHealth chief executive officer and board chairman William McGuire agreed to pay a record $468 million to settle Securities and Exchange Commission backdating charges.

Five Statutes. According to the court, in March 2006, the Wall Street Journal ran an article that raised questions about stock options backdating at UnitedHealth, among other companies. In the wake of the report, the concern’s stock option practices fell under both media and regulatory scrutiny, among other consequences.

In this case, in June 2006, the Minnesota attorney general served UnitedHealth with a CID under Minn. Stat. § 8.31, which allows it to investigate state law violations involving certain unlawful business practices. In the CID, the AG said it had reasonable grounds to believe UnitedHealth had violated one or more of five state statutes: the securities act, the business corporation act, the truth-in-advertising act, the consumer fraud act, and the deceptive trade practices act. The CID asked UnitedHealth to answer interrogatories and produce documents dating back to 1997. The lower court denied the company’s request for a protective order to quash the CID and the appeals court affirmed.

Statutory Authority. On appeal, UnitedHealth argued that the AG lacked power to investigate. Rejecting that contention, the appeals court explained that the CID is valid provided the AG has reasonable grounds to be-
lieve that UnitedHealth’s backdating practices violated any one of the statutes specified in the CID, and authority to prosecute that violation. On that basis, it concluded that the AG has authority to demand pre-
complaint discovery under the Minnesota False State-
ments in Advertisement Act (MFSAA). “Our holding does not indicate that [UnitedHealth’s] alleged backdat-
ning activities violate any other statute listed in [the
AG’s] CID or under section 8.31.”

The court also cited a Minnesota administrative rule
defining advertising in the securities context as proxy
statements, shareholder reports, and other required fil-
gings. It said that to the extent the public relies on Unit-
edHealth’s financial statements and other documents in
deciding whether to invest in the entity, “these docu-
ments are advertisements under the MFSAA.”

The court acknowledged that securities dealers are
the direct sellers of a company’s stock, and therefore,
the most direct advertisers. Nonetheless, it empha-
sized that securities dealers must rely on the company’s
representations regarding its financial condition. In this
case, UnitedHealth, “as the sole source of corporate in-
formation passed to its stockholders, is at least an indi-
rect advertiser of its financial health and value. . . . As a
publicly traded company, UnitedHealth also engages in
practices that induce the public to purchase its stock.”

Saying the entity—“at least indirectly”—
disseminates advertisements within the scope of the
MFSAA, the court allowed the AG’s investigation to pro-
ceed.

UnitedHealth was represented by Marianne D. Short,
Peter W. Carter, Thomas P. Swigert, Katie C. Pfeifer,
and Gretchen A. Agee of Dorsey & Whitney, Minneapo-
lis. The AG was represented by Lori Swanson, Michael
J. VanSelow, and Jennifer L. DeKarske of St. Paul,
Minn.

**Taxation**

**Exempt Organizations**

**IRS Releases Final Revised Form 990; Changes Reflect Comments on Draft**

The release of the final Form 990 has been widely antici-
pated by the tax-exempt hospital sector, which sub-
mitted many of the comments IRS received on the draft,
in part because of the expected impact the major
changes in the return will have on the sector, which
now will be providing a significantly greater amount of
both hard data and anecdotal information on commu-
nity benefit, executive compensation, charity care, bond
use, joint ventures, and other business relationships.

Anticipation has been heightened as well, however,
because the affected hospitals and their tax profes-
sionals needed to know the final reporting ground rules
to ensure the appropriate information and documentation
was compiled and retained. The final form answers one
particularly nagging question—concerning who must
file Schedule H—saying only licensed hospitals are cov-
ered.

The service also modified the implementation plan
for two schedules of significant interest to nonprofit
hospitals that commenters had said posed the largest
documentation and compliance challenge. Transition
relief included by the service allows nonprofit hospitals
to report for the 2008 tax year only part of the informa-
tion sought on Schedule H, applicable to hospitals, and
Schedule K, covering tax-exempt bonds. These sched-
ules will be fully applicable for the 2009 tax year, IRS
did.

Lois G. Lerner, IRS director of exempt organizations,
said in a statement, “We believe the transition relief we
are providing is appropriate and meaningful, and will
ease the concerns raised by commenters.”

Other major changes noted by the service include
changes made to the form’s summary page, to its sec-
tion on governance matters, and to the individual
schedules, including those relating to hospitals, execu-
tive compensation, related organizations, and tax-
exempt bonds, the service said.

The next step is instructions, which the IRS plans to
release early in 2008. “We are continuing to work with
the nonprofit sector to complete the new form’s instruc-
tions,” Lerner said.

**Specific Changes Outlined.** According to the service,
major changes outlined in the final Form 990 included
elimination of ratios, percentages and other metrics
from the summary page; incorporation of a two-year
summary of financial information comparing the cur-
rent and prior years; and a reordered core form that
moves the exempt organization’s description of its pro-
gram service accomplishments to page two, imme-
diately after the summary.

In addition, a new checklist of schedules has been
added to let charities know which schedules they need
to file since some had complained of potential confu-
sion associated with Form 990 changes. All the trigger
questions are now on one page so that organizations
will know right away which schedule they have to file,
the IRS release said.

The compensation and governance sections also have
been revised to address concerns expressed in com-
ments, Lerner said. The new form retains the use of
Form W-2 and Form 1099-MISC amounts, but provides
for separate reporting of other compensation, such as
contributions to retirement plans and health plans.

Specifics about compensation were in Schedule J, Le-
erner said, but some smaller- and medium-sized organi-
zations wanted information about retirement plans and
health plan contributions returned to the core form. That information was pulled back into the core form, but in order to reduce burden, organizations will be allowed to estimate those parts of compensation.

While larger exempt organizations must still file Schedule J, that new schedule also eliminates reporting of de minimis fringe and expense amounts, IRS said. In addition, although group exemption returns will be allowed for the 2008 tax year, the IRS remains concerned about transparency, Lerner said.

IRS does ask new questions about governance in the final Form 990, but Lerner said where new questions are asked, in a concession to the sector, there is a distinction made between governance questions required by statute and those that are just good governance policies.

**Bad Debt.** One of the more controversial issues—whether to include reporting of bad debt and the Medicare shortfalls that hospitals experience as part of providing a community benefit—was resolved by excluding bad debt from Part I of Schedule H. However, Part III of the schedule has been revised to include additional reporting of bad debt expense information outside of Part I. A previous billing and revenue table that the sector did not like has been eliminated, Lerner said.

“With respect to bad debt expense, the reporting is quite a bit different from the June draft,” said Ron Schultz, senior technical adviser in the exempt organizations division at IRS. “In June we asked one question—how do you determine the amounts included in bad debt expense? In this form we are asking for lot more bad debt expense information.”

The new Part III requires a hospital to report aggregate bad debt expense at cost; provide an estimate of how much is attributable to a patient; describe who qualifies for financial assistance under its charity care program; and provide a rationale for what portion of bad debt it believes should constitute community benefit.

The scheduled new part III also will collect Medicare shortfall information that is outside of Part I.

T.J. Sullivan, with Drinker Biddle in Washington, noted that the IRS reached a “practical compromise on reporting of bad debt and Medicare shortfalls” and said he was “pleased to see that the IRS has chosen to make Schedule H applicable only to state licensed hospitals and on a corporation by corporation basis.”

“This is a win-win outcome for the IRS and for the tax-exempt hospital community, as it will allow all stakeholders to report and all analysts to see once and for all what each hospital entity is doing in the way of community benefit and will allow meaningful comparisons to be made facility by facility, geographically, and over time,” he added.

**More Disclosure Coming.** Thomas K. Hyatt, with Ober Kaler in Washington, called the final form “a significant step forward towards attaining all three of the IRS’s expressed goals of increasing transparency, promoting accountability, and lessening the burden on filing organizations.” He said that “one of the real accomplishments of the final revision is that it backed off from raising best governance and operational practices to the level of de facto requirements.

“In most cases, the new form simply asks about whether the organization follows various practices and then gives the organization the opportunity to explain what it does and why. The final form gives organizations a much better chance to tell their story in their own terms and smart nonprofits will take full advantage of that opportunity,” he said.

The form also clarifies the IRS’s approach to exempt hospital accounting for bad debt and Medicare shortfalls, one of the most contentious aspects of the revision and comment process, Hyatt noted. “One of the most contentious issues has been resolved. Hospitals will now have the opportunity to report both bad debt and Medicare shortfalls on Schedule H,” Hyatt said.

James R. King, with Jones Day in Columbus, Ohio, agreed that the final form contains a number of improvements, specifically noting the elimination of the requirement that exempt hospitals report billings, collections, and proprietary information on hospital charges. Nevertheless, he said, the final form represents a “quantum leap toward greater disclosure” of the amounts and kinds of transactions, relationships, and activities carried out by exempt hospitals.

“Overall, the new form is much more disclosure-oriented than the June draft. It is replete with directions to describe one thing or another. There is more, and more pointed, and more detailed disclosure here, regarding more areas than has ever been the case. It’s hard to see an area of potential noncompliance the IRS didn’t hit and hit hard,” King said.

One example, King said, was in the final Schedule L, which used to be about loans and now is denoted Transactions with Interested Persons. “This schedule wants a description of any business transaction involving an ‘Interested Person’ including the name of the person, the business relationship, and the amount, and whether or not it involves any sharing of revenues. This means each and every transaction will now be subject to public scrutiny as well as IRS review,” King said.

**Reaction.** The American Hospital Association and Catholic Healthcare Association reacted positively to revisions made by IRS.

“We are heartened that IRS has responded to the overwhelming sentiment expressed by 307 Members of Congress, the AHA and the vast majority of hospitals that filed comments that Medicare underpayments and patient bad debt be included on a community benefit reporting form,” AHA said in a statement. “This allows for greater opportunity for hospitals to illustrate the full value of the programs they provide to their communities.”

AHA also praised the IRS for eliminating some of questions “unrelated to community benefit, particularly the chart labeled ‘Billing Information.’” AHA also said it appreciates the one-year filing delay for Schedule H.

“While we are concerned that, absent instructions and worksheets for Schedule H, hospitals will be seriously hampered in their efforts to collect and report the information required, we will continue to work with IRS to monitor hospitals’ progress and advocate for more time if IRS delays encumber hospitals’ data collection efforts,” AHA said.

Sister Carol Keehan, CHA’s president and chief executive, said the new Schedule H “will provide a standardized way for hospitals to describe, both qualitatively and quantitatively, the ways in which they benefit their communities.”

CHA said that it appears the IRS made many of the revisions sought by the association and others in the nonprofit sector. Although IRS did not end up including
a community benefit category for community building programs specifically designed to eliminate the root causes of illness and disease, the final Schedule H does contain a new table for hospitals to highlight these activities, CHA noted.

Independent Sector, which represents 600 of the largest charities in the United States, said in a statement that the form is “a major step in fulfilling the nonprofit community’s commitment to accountability and transparency,” and includes many of the improvements it requested in its comments to IRS on the proposed form.

“Nonprofits can now describe their exempt purpose and accomplishments on the first two pages of the Form, and there are other improvements in financial, compensation, and governance information and in specific schedules,” it said. The new form will facilitate accurate, complete, and consistent reporting and will be easier for most organizations to complete, it said.

Sen. Charles Grassley (R-Iowa), ranking Republican on the Senate Finance Committee, said the new form will provide for more consistent transparency from tax-exempt groups.

“Under the current setup, some groups are very transparent and others are secretive or lackadaisical about what they file,” he said.

On nonprofit hospitals, Grassley said it is good to see a clearer, more uniform definition of community benefit. “Some hospitals use a very loose definition, and this will help them focus,” he said. But he added he was disappointed that the revised Schedule H for hospitals will be voluntary for the first year.

He said he also was disappointed that IRS was not doing more to make sure nonprofits accurately report the amount of money going to their charitable purpose. “The IRS easily could have done more to help donors readily understand where their money goes,” said Grassley, adding that he plans to revisit that issue.

**By Peyton M. Sturges and Diane Freda**


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**In Brief**

**BNA Audioconference on Clinical Trial Billing**

BNA is presenting an audioconference on “Practical Advice on Clinical Trial Billing Under the Mostly Unchanged CMS Policy” Jan. 9, 2008, from 1 p.m. to 2:30 p.m. EST. The program will feature F. Lisa Murtha, managing director for Huron Consulting Group, and John E. Steiner Jr., chief compliance officer for UK HealthCare, Lexington, Ky. For more information or to register, go to [http://legaledge.bna.com/Pagemanager.aspx?pageId=7053](http://legaledge.bna.com/Pagemanager.aspx?pageId=7053). To register by phone, call 800-372-1033, option 6, then sub-menu option 1, and tell the reservationist the title, day, and time of the audioconference. The price is $199 for BNA subscribers, $259 for nonsubscribers.

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CONGRESSIONAL CALENDAR

Senate

Passed, Dec. 18, 2007, S. 2499, to amend titles XVIII, XIX, and XXI of the Social Security Act to extend provisions under the Medicare, Medicaid, and SCHIP programs.

House

To reconvene Jan. 3, at noon.

Passed by a vote of 411-3, Dec. 19, 2007, S. 2499, to amend titles XVIII, XIX, and XXI of the Social Security Act to extend provisions under the Medicare, Medicaid, and SCHIP programs, clearing the measure for the president; the Medicare, Medicaid, and SCHIP Extension Act of 2007. Also, passed S. 1916, to amend the Public Health Service Act to modify the program for the sanctuary system for surplus chimpanzees by terminating the authority for the removal of chimpanzees from the system for research purposes.

Suspended the rules and passed, Dec. 17, 2007, S. 2484, to rename the National Institute of Child Health and Human Development as the Eunice Kennedy Shriver National Institute of Child Health and Human Development, clearing the measure for the president.

Reports and Testimony

S. 901, to amend the Public Health Service Act to provide additional authorizations of appropriations for the health centers program under Section 330 of such act, with an amendment in the nature of a substitute.

S. 1551, to amend the Public Health Service Act with respect to making progress toward the goal of eliminating tuberculosis, with an amendment in the nature of a substitute.

Government Accountability Office Reports:

- State Children’s Health Insurance Program—Program Structure, Enrollment and Expenditure Experiences, and Outreach Approaches for States That Cover Adults (GAO-08-50).
- Centers for Medicare and Medicaid Services: Internal Control Deficiencies Resulted in Millions of Dollars of Questionable Contract Payments (GAO-08-54).

Bills and Resolutions

S. 2499 (MEDICARE/MEDICAID/SCHIP), to amend titles XVIII, XIX, and XXI of the Social Security Act to extend provisions under the Medicare, Medicaid, and SCHIP programs, and for other purposes; BAUCUS; considered and passed, Dec. 18, 2007.

S. 2510 (QUALITY ASSURANCE), to amend the Public Health Service Act to provide revised standards for quality assurance in screening and evaluation of gynecologic cytology preparations, and for other purposes; LANDRIEU; to the Committee on Health, Education, Labor, and Pensions, Dec. 18, 2007.

S. 2515 (EMERGENCY PREPAREDNESS), to amend the Public Health Service Act to establish a comprehensive national system for skilled construction workers to assist first responders in disasters; REID; to the Committee on Health, Education, Labor, and Pensions, Dec. 18, 2007.

S. 2522 (HEALTH CARE COVERAGE), to amend the Social Security Act to guarantee comprehensive health care coverage for all children born after 2008; ROCK-EFELLER; to the Committee on Finance, Dec. 19, 2007.


S. 2526 (INFECTION PREVENTION), to protect health care workers and first responders, including police, firefighters, emergency medical personnel, and other workers at risk of workplace exposure to infectious agents and drug resistant infections, such as MRSA and pandemic influenza; MENENDEZ; to the Committee on Health, Education, Labor, and Pensions, Dec. 19, 2007.

H.R. 4736 (MEDICARE), to amend Part B of Title XVIII of the Social Security Act to repeal limiting charges under Medicare for nonparticipating physicians and to preempt state laws that prohibit balance billing; FEENEY; jointly, to the committees on Energy and Commerce and Ways and Means, Dec. 17, 2007.

H.R. 4778 (MEDICARE), to amend Title XVIII of the Social Security Act to exempt negative pressure wound therapy pumps and related supplies and accessories from the Medicare competitive acquisition program until the clinical comparability of such products can be validated; GONZALEZ; jointly, to the committees on Energy and Commerce and Ways and Means, Dec. 17, 2007.

H.R. 4790 (MEDICARE), amend Title XVIII of the Social Security Act to provide for standardized marketing requirements under Medicare Advantage and the Medicare Prescription Drug Program and to provide for state certification prior to waiver of licensure requirements under the Medicare Prescription Drug Program, and for other purposes; CASTOR; jointly, to the committees on Ways and Means and Energy and Commerce, Dec. 18, 2007.

H.R. 4836 (DIABETES), to reduce the incidence, progression, and impact of diabetes and its complications and establish the position of national diabetes coordinator; INSLEE; jointly, to the committees on Energy and Commerce, Oversight and Government Reform, Agriculture, and Education and Labor, Dec. 18, 2007.
CONGRESSIONAL CALENDAR

Continued from previous page

H.R. 4849 (HEALTH CARE DISPARITIES), to prohibit discrimination in federal assisted health care services and research programs on the basis of sex, race, color, national origin, sexual orientation, or disability status; RICHARDSON; to the Committee on Energy and Commerce, Dec. 19, 2007.

H.R. 4879 (MEDICARE), to amend Title XVIII of the Social Security Act to include screening computed tomography colonography as a colorectal screening test for purposes of coverage under Medicare, and for other purposes; CUBIN; jointly, to the committees on Energy and Commerce and Ways and Means, Dec. 19, 2007.

H.R. 4899 (MENTAL HEALTH), to amend the Public Health Service Act to provide grants for community-based mental health infrastructure improvement; KENNEDY; to the Committee on Energy and Commerce, Dec. 19, 2007.

H.R. 4915 (VETERANS’ HEALTH), to amend Title 38, United States Code, to expand access to hospital care for veterans in urban areas, and for other purposes; PRYCE of Ohio; to the Committee on Veterans’ Affairs, Dec. 19, 2007.

REGULATORY CALENDAR

Final Rule

Centers for Medicare & Medicaid Services issued a final rule that eliminates federal Medicaid payment for the costs of certain school-based administrative and transportation activities because the secretary of health and human services has found that these activities are not necessary for the proper and efficient administration of the Medicaid state plan and are not within the definition of the optional transportation benefit. Based on these determinations, under the final rule, federal Medicaid payments no longer will be available for administrative activities performed by school employees or contractors, or anyone under the control of a public or private educational institution, and for transportation from home to school. In addition, the final rule responds to public comments received on the Sept. 7, 2007 proposed rule. The final rule becomes effective Jan. 1 (72 Fed. Reg. 73635, 12/28/07).

Proposed Rule

CMS published a notice of proposed rule making that would amend departmental regulations governing administrative review by the Departmental Appeals Board (DAB) and certain other administrative review regulations to ensure that the final administrative decision of the department reflects the considered opinion of the secretary of health and human services. The proposed rule would amend DAB regulations to require that the board follow published guidance that is not inconsistent with applicable statutes and regulations and would permit the HHS secretary an opportunity to review DAB decisions to correct errors in the application of law, or deviations from published guidance, in such disputes. The proposed rule would make technical changes to the regulations at 45 CFR Part 16. Also, the proposed rule would revise the procedures for Head Start Idaho appeals by applying the current 60-day time limit for final decisions to the board’s decision. Forward comments to HHS by Jan. 28 (72 Fed. Reg. 73708, 12/28/07).

Notices


CMS announced the final federal share disproportionate share hospital (DSH) allotments for federal fiscal year (FFY) 2006 and the preliminary federal share DSH allotments for FFY 2008. The notice also announced the final FFY 2006 and the preliminary FFY 2008 limitations on aggregate DSH payments that states may make to institutions for mental disease and other mental health facilities. In addition, the notice includes background information describing the methodology for determining the amounts of states’ FFY DSH allotments (72 Fed. Reg. 73831, 12/28/07).

CMS announced an additional physician election period for physicians who currently are not participating in the competitive acquisition program (CAP) for Medicare Part B drugs for calendar year 2008. The additional physician election period begins on Jan. 15, and ends Feb. 15. Physicians who elect to join the CAP during the additional election period will enter into a physician election agreement effective April 1 through Dec. 31 (72 Fed. Reg. 73841, 12/28/07).

CMS announced the scheduled expiration dates of the current contracts between CMS and out-of-state quality improvement organizations (QIOs) responsible for review in Vermont, Wyoming, Maine, Alaska, Idaho and South Carolina. The notice also specifies the period of time in which in-state QIOs may submit a proposal for those contracts. Interested offerors may submit a proposal to perform the QIO work in any of the states listed in the announcement. The request for proposal will be made available to all interested offerors through the Federal Business Opportunities Web site [http://www.fedbizopps.gov] (72 Fed. Reg. 73842, 12/28/07).

CMS published a notice listing its manual instructions, substantive and interpretive regulations, and other Federal Register notices that were published from July through September 2007 relating to Medicare and Medicaid. The notice provides information on national coverage determinations affecting specific medical and health care services under Medicare and identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that potentially may be covered under Medicare. The notice also includes listings of all approval numbers from the Office of Management and Budget for collections of information in CMS regulations and also in-
cludes a list of Medicare-approved carotid stent facilities. In addition, the notice includes a list of the American College of Cardiology’s National Cardiovascular Data Registry sites, active CMS coverage-related guidance documents, and special one-time notices regarding national coverage provisions. Also, included in the notice is a list of National Oncologic Positron Emissions Tomography Registry sites, a list of Medicare-approved ventricular assist device (destination therapy) facilities, a list of Medicare-approved lung volume reduction surgery facilities, a list of Medicare-approved clinical trials for fluorodeoxyglucose positron emissions tomography for dementia and a list of Medicare-approved bariatric surgery facilities (72 Fed. Reg. 73989, 12/28/07).

CMS announced a town hall meeting to be held Feb. 21, in accordance with Section 503 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to discuss fiscal year (FY) 2009 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system. Interested parties are invited to the meeting to present their comments, recommendations and data regarding whether the FY 2009 new medical services and technologies applications meet the substantial clinical improvement criterion. Registration for the meeting closes Feb. 14. The meeting will be held in the auditorium at CMS headquarters, 7500 Security Blvd., Baltimore (72 Fed. Reg. 73845, 12/28/07).

CMS announced that the Advisory Panel on Ambulatory Payment Classification Groups will meet March 5-7. Agenda items for discussion during the meeting include: reconfiguring APCs, evaluating APC weights, packaging devices and drug costs into APCs, removing procedures from the inpatient list for payment under the OPPS, using single and multiple procedure claims data, and addressing other APC structure technical issues. The meeting will be held in the auditorium at CMS headquarters, 7500 Security Blvd., Baltimore. The panel’s information line is (877) 449-5659 or (410) 786-9379 (72 Fed. Reg. 73843, 12/28/07).


CMS announced the annual adjustment in the amount in controversy (AIC) threshold amounts for administrative law judge (ALJ) hearings and judicial review under the Medicare appeals process. The adjustment to the AIC threshold amounts will be effective for requests for ALJ hearings and judicial review filed on or after Jan. 1. The 2008 AIC threshold amounts are $120 for ALJ hearings and $1,180 for judicial review (72 Fed. Reg. 73438, 12/27/07).

CMS published a notice that describes the methodology and process the agency is using for determining the amounts of certain states’ remaining SCHIP funding shortfalls during federal fiscal year (FY) 2007, in accordance with the provisions of the U.S. Troop Readiness, Veteran’s Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007. The notice also contains the amounts of the additional allotments to be provided to states to eliminate such FY 2007 funding shortfalls (72 Fed. Reg. 71915, 12/19/07).

Health and Human Services, Office of Inspector General published its annual notice soliciting proposals and recommendations for developing new and modifying existing safe harbor provisions under the federal anti-kickback statute (Section 1128B(b) of the Social Security Act), as well as developing new OIG special fraud alerts. The notice was published in accordance with Section 205 of the Health Insurance Portability and Accountability Act of 1996. Forward comments to the OIG by Feb. 19, 2008 (72 Fed. Reg. 71868, 12/19/07).

MEETINGS


Seventh Strategic Medicare Compliance and Administration Summit, Feb. 11-12, Washington (The Center for Business Intelligence, 500 W. Cummings Park, Suite 500, Woburn, Mass. 01801, 800-817-8601) [http://www.cbinet.com].


Listed below are the headlines and page numbers of selected articles in this issue followed by World Wide Web sites providing related information.

Appeals Court Says Hospitals May Sue in Fraud Case Against Transcription Firm (p. 19)  
http://op.bna.com/hl.nsf/r?Open=psts-7a3lpc

Insurance Policy Does Not Provide Coverage for Legal Fees Arising From Antitrust Probes (p. 20)  

CMS Issues Final Rule Delaying Effective Date of Certain Stark Rules (p. 22)  
http://op.bna.com/hl.nsf/r?Open=bbrk-7aemcy

Court Finds HHA Violated False Claims Act, Triples Payment to Medicare to $4.7 Million (p. 25)  
http://op.bna.com/hl.nsf/r?Open=jthn-7a4nzj

Health Plans Must Show Enrollee Deception Before They Can Cancel Policies, Court Rules (p. 27)  
http://www.courtinfo.ca.gov/opinions/documents/G035579.PDF

Court Refuses to Certify Class of Providers in Suit Over Insurer’s Reimbursement Caps (p. 31)  
http://op.bna.com/hl.nsf/r?Open=psts-7a3r8q

Federal Court Will Not Enjoin Lawsuit Seeking Damages for Exclusion From Network (p. 32)  
http://op.bna.com/hl.nsf/r?Open=psts-7a3myy

Federal Court Remands Case to State Court, Holds MA Plan Solvency Law Not Preempted (p. 32)  
http://op.bna.com/hl.nsf/r?Open=jthn-79rmgp

Missouri Court Rules for Kansas Hospitals Seeking Higher Medicaid Reimbursement (p. 34)  
http://www.courts.mo.gov/courts/courts/pubopinions.nsf/6735e1bedd146c485825661f004bc8f4/50b6d73b36f361f6b8f76c94?OpenDocument

Court Upholds Verdict, Damages Award in Doctor’s Retaliatory Discharge Lawsuit (p. 35)  
http://op.bna.com/hl.nsf/r?Open=psts-7a9nbw

Medical Review Panel Not Prerequisite for Claim Alleging Negligent Maintenance (p. 40)  
http://op.bna.com/hl.nsf/r?Open=mapi-7a2qyj

Ninth Circuit Upholds Arbitrator’s Ruling Barring Hospital’s Flu Immunization Program (p. 41)  
http://op.bna.com/dircases.nsf/r?Open=smgk-7a7ltf

IRS Releases Final Revised Form 990; Changes Reflect Comments on Draft (p. 44)  
http://www.irs.gov/charities/article/0,,id=176813,00.html

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Index-Summary updates for Health Law Reporter are available on a monthly basis.  
http://www.bna.com/current/hlr/

BNA HEALTH CARE PRODUCTS

The following is a site featuring current news, analysis, and source material prepared by the Health Care Information Division at BNA. It includes links to sample issues of BNA health care products.

BNA’s Professional Information Center on Health Law, Regulation and Policy  
http://healthcenter.bna.com

BNA’s Health Care Daily Report  

BNA’s Health Law & Business Library  

Life Sciences Law & Industry Report  

Medical Devices Law & Industry Report  

Medical Research Law & Policy Report  

BNA CONTACTS

BNA’s World Wide Web Home Page  
http://www.bna.com

BNA Customer Relations, e-mail  
customercare@bna.com

BNA PLUS, e-mail  
BNAPLUS@bna.com