Top Ten Health Law Issues for 2009

After a 15-year hiatus, healthcare has risen to the top of the national, political agenda. In order to keep its members on the cutting edge of what they must know and track, the American Health Lawyers Association (AHLA) must foresee and analyze emerging health law trends. To that end, AHLA sent a survey listing 22 potentially important health law topics to 1,659 of its members. The respondents were asked to select the top ten and rank-order them. The survey had a respectable 10% response rate. Below, you will find each suggested health law topic in the order that it was ranked by survey respondents. Each section summarizes the issue and provides a brief explanation as to why this topic may be significant for health lawyers in 2009.[1]

1. Healthcare Reform and the Uninsured – *Peter Leibold, AHLA*

Healthcare reform and the uninsured ranked first on AHLA's survey of the Top Ten health law issues of 2009. After the election of Barack Obama and his selection of former Senator Tom Daschle as Department of Health and Human Services (HHS) Secretary, the momentum for healthcare reform is as strong as it has been since the Clinton effort of 1993-1994.

While skeptics and fiscal hawks might doubt that the United States has the fiscal wherewithal to tackle healthcare reform during a ferocious economic downturn, numerous leaders, including Senator Daschle, reject this conclusion and believe that health reform is essential to addressing the underlying causes of the nation's economic weakness.

Members of Congress are not shying away from the challenge either. Senator Baucus, the Chairman of the Finance Committee, has released a white paper entitled *A Call to Action: Health Reform 2009*. In it, Senator Baucus advocates for action and broadly outlines a reform proposal that is not dissimilar from President-Elect Obama's proposal during the campaign. Senator Kennedy also has appointed three subgroups to craft a health reform proposal for the Senate Health, Education, Labor, and Pensions Committee.

Private healthcare advocacy groups have also demonstrated renewed political will to tackle this complex, important subject. In December 2008, America's Health Insurance Plans (AHIP) released a health reform plan for universal coverage and cost containment. While it has been subject to criticism from certain provider groups, like nurses, the plan demonstrates AHIP's willingness to be involved in crafting a final health reform proposal.

If enacted, health reform will have massive implications for health lawyers. New statutes and mechanisms for delivering care will increase the importance of health lawyers and their craft as the new system is rolled out. Providers, plans, and the government will be subject to new rules and expectations, and this will affect the practice of health law for years to come.

2. Impact of Economic Downturn on Healthcare Providers' Operations and Fiscal Health

and

3. Capital Finance for Healthcare Facilities – *Cynthia Conner, AHLA*

Two of the Top Ten issues, capital finance for healthcare facilities and how the economic crisis is affecting these organizations, are so closely intertwined that they are better addressed together rather than as separate topics. The headlines spell out the impact of the downturn in the economy on the

healthcare industry: "Hospitals Feel Effects of Economic Crisis, AHA Survey Finds," "Chicago Hospital Hangs For Sale Sign, Citing Credit Crunch," "Credit Crunch Hits Hospitals," "Financial Crisis Hits Healthcare Companies." Contrary to traditional wisdom, not only is healthcare NOT recession proof, in the current economy, it would not appear to be recession delayed or moderated either.

The same factors that drive the bleak financial outlook for the economy as a whole are having a serious impact on the entire healthcare system. One by-product of consumers' economic insecurity has been a pullback in their use of non-essential healthcare services, as seen in declines in elective procedures, such as hip and knee replacements, and screening procedures such as colonoscopies[2] and an increase in patients who are foregoing preventative care and medications because they can no longer afford co-pays and deductibles. A recent survey by the American Hospital Association (AHA) indicated that over the last three months, elective procedures have dropped 6% below projected levels, admissions are down 8%, and uncompensated care rose 8% between third quarter 2007 and the third quarter 2008. Rising unemployment also affects managed care organizations, as they endure membership losses in their large commercial accounts or lose the employer-based commercial accounts entirely.

Many hospitals have become dependent on investment income to supplement inadequate government compensation. With the dip in the stock market, tapping into cash reserves to fund operations or capital expenditures is no longer a safe option. The rising cost of borrowing can't be passed on immediately to government or private payors because payment rates are set several years in advance. Other cost-cutting measures, such as salary reductions and staff cuts, are not viable for healthcare facilities, given the shortage of healthcare workers and the impact that these measures would have on the quality of care. Many healthcare organizations have survived the crisis thus far by delaying or canceling capital investments. As the situation worsens however, many hospitals have resorted to employee layoffs, and at least 53% of hospitals are considering staff reductions to weather the economic storm. Under more dire circumstances, hospitals have been forced to sell all of their assets or have had to declare bankruptcy.

With their own solvency and survival at stake, healthcare providers are doing whatever they can to collect on unpaid bills. Some facilities and medical providers report that bad debt has increased from 60-75% over the past year. AHA provides guidelines on debt collection practices, which recommend that each patient receive financial counseling with appropriately trained staff and that costs be reasonable. Legislation in some states mandates some debt collection practices, such as requiring providers to allow patients to pay in installments, prohibiting them from foreclosing on a patient's home, and offering a grace period during which patients can negotiate their bills before they are sent to collection.

The healthcare sector's financial insecurity will translate into changes for healthcare attorneys in the year ahead, and affect the nature of the work that they do for their healthcare clients. With the credit crunch M & A work in healthcare has decreased significantly, but clients will need more help with bad debt collection. Healthcare lawyers will also have to assist their clients in coming up with creative strategies to raise capital, including leasing rather than purchasing new equipment, selling non-core assets like medical office buildings and then leasing them back, and engaging in more aggressive philanthropic efforts.

4. Quality Efforts –
Peter Leibold, AHLA

Both Presidential candidates critiqued our current healthcare system as lacking in value because our quality measures are not consistent with the amount that our nation spends on healthcare each year. We spend more than any other nation in the world, and the multitude of areas in which our health indicators lag those of other industrialized countries is distressing. A 2007 Commonwealth study found that compared with five other nations—Australia, Canada, Germany, New Zealand, and the United Kingdom—the U.S. healthcare system ranks last or next-to-last on five dimensions of a high performance health system: quality, access, efficiency, equity, and healthy lives.

Ever since the publication of the Institute of Medicine's two seminal works, *To Err is Human: Building a Safer Health System and Crossing the Quality Chasm: A New Health System for the 21st Century*, those studying health system change have focused on the enormous challenges of improving the quality of our nation's healthcare delivery system.

In the past several years, health policy experts like John Wennberg, M.D. of Dartmouth and the incoming Director of the Office of Management and Budget, Peter Orszag, Ph.D. have presented significant evidence that

3. Capital Finance for Healthcare Facilities

4. Quality Efforts

while Medicare expenditures vary enormously by geographic region, the quality of care was no better, and often worse, in areas where expenditures were higher. The disconnect between expenditures and quality has led these experts and others to advocate for changes to clinical practice patterns and reimbursement methodologies that emphasize quality care.

This research has already resulted in significant private and public sector efforts to improve quality: The Centers for Medicare and Medicaid Services' (CMS) decision not to pay additional amounts for eight, and soon to be eleven, "never events" or hospital-acquired conditions; the Medicare Hospital Gainsharing Demonstration program authorized by the Deficit Reduction Act of 2005; the new PROMETHEUS payment system that makes efforts to improve quality by using evidence based case rates; CMS' decision to launch a National Nursing Home Quality Initiative; and the recently enacted final regulations to implement the Patient Safety and Quality Improvement Act of 2005, to name only a few.

In this year's survey, AHLA's members recognized that these efforts to improve quality will only increase in the years ahead, and as these efforts proliferate, health lawyers will have to analyze the impact of these initiatives on their clients' regulatory compliance, reimbursement compliance, and potential for liability, among other legal issues. The health system's overdue efforts to improve quality certainly make it one of the hottest health law issues of 2009.

5. Stark and Hospital/Physician Relations – *Jason Christ, Epstein Becker & Green, Washington, DC*

Regulatory clarifications announced in 2008 combined with CMS auditing and government personnel changes may form the "perfect storm" for Stark related matters in 2009.

Restructuring in Response to Regulatory Changes: Certain "under arrangements" and per click/percentage based leases will need restructuring to meet a Stark exception or will need to be unwound by October 1, 2009. Specifically, in the calendar year 2008 Inpatient Prospective Payment System (IPPS) Rule, CMS adopted modifications to the Stark regulations such that, effective October 1, 2009, a joint venture between a hospital and a physician group in which the hospital pays the joint venture to provide a hospital "technical" service, will be considered an entity that performs the designated health service. As such, the physicians' ownership in the joint venture must satisfy a Stark ownership exception or select from a list of somewhat unappealing choices that include: (1) divestiture; (2) restructuring; or (3) halting referral streams. Currently, litigation has been filed challenging CMS' authority to make such a rule and the outcome of this litigation is unclear. Similarly, per click and percentage based equipment and space lease arrangements will no longer be permitted under the new rules. Like under arrangement joint ventures, these leasing changes prompt restructuring or ending relationships found not commercially viable under the new regulations.

Auditing and Enforcement—the DFRR: In 2007, CMS began its initiative to implement a survey to investigate the investment/ownership and compensation arrangements between physicians and hospitals to determine whether they are in compliance with the Stark Law and implementing regulations. The "Disclosure of Financial Relationships Report" (DFRR) was designed to be a mandatory survey for 500 hospitals selected by CMS. The extensive worksheet contains eight worksheets and covers direct and indirect physician investment and ownership in a hospital; payments to the hospital by physician ownerships; a listing of each rental, personal service, and recruitment arrangement between a hospital and physicians; and a series of questions targeting information on other types of compensation arrangements, including non-monetary compensation or medical staff incidental benefits that exceeded published limits and charitable donations by a physician to a hospital. The survey must be completed, certified by a hospital officer, and submitted to CMS within 60 days. In 2008, CMS stated in the preamble to the IPPS proposed and final rules that it intends to use the DFRR to both "identify arrangements that may not be in compliance" and "help future rulemaking." In the preamble to the 2009 final IPPS Rule, CMS stated that if appropriate, it would release hospital DFRR data to the HHS Office of Inspector General or the Department of Justice. Given that CMS' estimates of the time needed to fill out the survey have increased dramatically, hospitals and their counsel should begin in 2009 preparing for the release of this audit tool and taking immediate steps to ensure that all physician relationships are compliant.

Political climate: Finally, there are at least two significant practical changes that may affect Stark rulemaking next year. First, two CMS regulators who have been instrumental in creating the recent Stark rules have announced they are leaving the agency. Second, the incoming administration may push a universal or expanded healthcare coverage agenda. Assuming the government expands its role as payor, it is highly likely the govern-

ment will increase scrutiny of physician relationships accordingly.

6. State and Federal Efforts to Reduce Medicaid Payments

– Bianca Bishop, AHLA

With at least 43 states projecting sizeable budget shortfalls and many seeking federal assistance to weather the nation's economic downturn, healthcare safety net programs like Medicaid will face significant cost containment pressures for the foreseeable future. New York, California, Florida, and Illinois are among the states with substantial budget gaps where deep cuts in services, including Medicaid, are likely. Consumer group Families USA reported that eight states have enacted or are considering cuts to reduce eligibility or limit enrollment in Medicaid; twelve states and the District of Columbia have enacted or are considering reducing Medicaid benefits; five states have enacted or are considering increasing Medicaid recipient's out-of-pocket costs; and thirteen states and the District of Columbia have reduced or are considering reductions in payments to Medicaid providers.

At the federal level, CMS issued a pair of new regulations at the tail-end of 2008 designed to give states more flexibility in designing their Medicaid benefit packages and impose additional cost-sharing on certain Medicaid populations. The rules, which implement provisions of the Deficit Reduction Act of 2005 and the Tax Relief and Healthcare Act of 2006, are the latest in a series of regulations to implement the Bush administration's goals of aligning Medicaid more closely with private market insurance and giving states more control over their Medicaid benefits packages. But critics of the new regulations have argued the rules are really a veiled attempt to cutback on benefits and shift costs under the guise of increasing state flexibility.

Hospitals and other healthcare providers already are feeling the ripple effects of these cost containment efforts, which are likely to only intensify over the coming year.

7. Re-employment of Physicians by Hospitals – *William H. Thompson, Hall Render Killian Heath & Lyman PC, Indianapolis, IN*

There is renewed interest on the part of hospitals and health systems (and physicians) in the Physician Employment Model. Increasingly, hospitals are employing primary care and specialty physicians alike. In the late 80's and early 90's, hospitals targeted mostly primary care physicians in anticipation of a gatekeeper model under a managed care or capitated system of reimbursement. The terms of many of these transactions involved guaranteed salaries and significant payments for goodwill as part of the practice acquisitions. However, a reimbursement system based on capitated payments did not gain the traction first anticipated and the results of this earlier physician employment strategy were mixed at best. To be sure, lessons were learned by both the hospitals and the physicians, particularly with regard to culture, practice management, compensation methodologies, and regulatory constraints. These lessons are being applied today as the Employment Model reemerges as the model of choice for many hospitals and physicians.

The motivating factors behind the renewed interest in the Employment Model have changed somewhat from the managed care era. Physicians are finding it harder and harder to expand (or even maintain) their practices in today's environment. Declining reimbursement, higher overhead, stiff competition, and the mandate to adopt expensive information technology have all made it more difficult for independent practices to be financially successful. Hospitals and health systems face similar challenges. Many have invested significant human and capital resources in what remains of high margin services, such as cardiovascular services, cancer services, and orthopedics. In order to generate a return on this investment and to ensure high quality services, hospitals must have a dedicated workforce of primary and specialty care physicians whose interests are aligned with those of the hospital. Where in the past the model of choice may have been a joint venture or some type of compensation arrangement, these models have become increasingly difficult due to regulatory constraints and changes in reimbursement policy. Thus, a renewed interest in the Employment model has emerged as way to align incentives around quality improvement, patient safety, efficiency and economic success.

Thanks to certain statutory and regulatory exceptions under both the Anti-Kickback and the Stark Statutes, the direct Employment Model is relatively straight forward from a legal perspective. It is likely however that permutations of the direct Employment Model will develop over time, including such models as wholly or partly owned group practices, leased physician employees, jointly employed physicians and other quasi-employment arrangements. As these models develop, they undoubtedly will strain the extent of the current exceptions. Once again, presenting a new set of challenges for the members of AHLA. The legal work related to structuring an Employment Model and related permutations will keep health lawyers extremely busy in 2009.

8. Vendor-Healthcare Professional Relationships

– Bianca Bishop, AHLA

The relationships between pharmaceutical and device companies and healthcare professionals has continued to receive intense scrutiny from enforcement agencies, lawmakers, and the media fueled by concerns about conflicts of interest and the potential for illegal kickbacks. In April 2008, a special task force of the Association of American Medical Colleges urged all academic medical centers "to accelerate their adoption of policies that better manage, and when necessary, prohibit, academic-industry interactions that can inherently create conflicts of interest and undermine standards of professionalism."

Effective January 2009, the Pharmaceutical Research and Manufacturers of America adopted a revised voluntary code on vendor interactions with healthcare professionals. The revised code is intended to strengthen ethical standards governing vendor gift-giving and marketing practices, including more detailed standards regarding the independence of continuing medical education and additional comprehensive guidance on speaking and consulting arrangements.

While no federal legislation has been enacted as of yet, a number of states have passed or proposed legislation regarding vendor gifts and marketing, including most recently Massachusetts, which enacted a law requiring pharmaceutical and device manufacturers, among other things, to disclose any economic benefits provided to physicians and other healthcare providers in excess of $50. The state plans to post this information on its website. The Medicare Payment Advisory Commission (MedPAC) also has issued recommendations calling on Congress to require drug and device firms to report the details of their financial dealings with the healthcare sector to HHS. MedPAC said this information should be made publicly available in a searchable, online database.

Given this flurry of activity, AHLA members not surprisingly ranked vendor-provider relationships among the Top Ten health law issues for 2009. Health and life sciences lawyers undoubtedly will continue to be called on to help structure effective compliance programs and address the ramifications of suspect interactions.

9. Electronic Health Records

– Bianca Bishop, AHLA

The widespread adoption of health information technology (HIT) is viewed as an essential cornerstone of reforming the healthcare system, improving quality of care, and facilitating other initiatives like personalized medicine. The incoming administration already has signaled its commitment to advancing the adoption of an electronic health information infrastructure and exchange. President-Elect Obama said he plans to seek funding for HIT as part of a broad stimulus package to boost the nation's flagging economy.

While HIT legislation at the federal level has stalled, states have accelerated the pace of enacting their own measures to spur the development of electronic healthcare systems. According to a report released in December 2008 by the National Conference of State Legislatures, during an 18-month period between 2007 and 2008, 44 states and the District of Columbia enacted 132 bills containing HIT provisions, three times as many bills as passed in the same period from 2005 to 2006. With this gathering momentum, health lawyers over the next year should continue to see an uptick in work advising healthcare clients on the myriad of issues related to the adoption of electronic health records, e-prescribing, and health information networks and exchanges.

At the same time, additional privacy and security issues for healthcare information arising from the Federal Trade Commission's Red Flag Rules also should figure prominently in health law practices for 2009. The Red Flag Rules impose new obligations on "creditors" to detect, prevent, and mitigate identity theft. The deadline to comply with the identify theft program requirement was initially set for November 1, 2008, but later extended to May 1, 2009 following concerns that many industries, including healthcare providers that extend credit, did not initially realize the rules may apply to them. AHLA has developed a compilation of members' analysis and practical tools designed to expedite integration of best practices regarding detection and prevention of identity theft in healthcare settings. These combined materials can be purchased through the AHLA Bookstore at www.lexisnexis.com/ahla/ProductDetail.aspx?id=1277.

10. RACs and Other Program Integrity Contractors –

Bianca Bishop, AHLA

CMS is intensifying and changing its strategies for curbing fraud, abuse, and waste in federal healthcare programs, CMS Acting Administrator Kerry Weems said at AHLA's fraud and compliance conference in October 2008. As part of this effort, CMS is launching new initiatives using program integrity contractors to conduct audits, identify overpay-

ments, and educate providers. During his remarks, Weems highlighted in particular the national rollout of the Recovery Audit Contractor (RAC) program, which started as a three-year demonstration project and later was made permanent by Congress.

RACs review Medicare Parts A and B claims and are paid a contingency fee for any improper payments they identify, whether over or underpayments. The national RAC program must be in place by January 1, 2010, and CMS recently named four permanent RACs, although contract work was delayed as a result of a bid protest filed by two unsuccessful bidders. According to CMS, the RAC pilot program identified and collected more than $1.03 billion in improper payments, ultimately returning roughly $693.6 million to the Medicare Trust Fund between 2005 and March 2008. Notably, of the overpayments the RACs identified during the demonstration, 85% were collected from inpatient hospitals, 6% from inpatient rehabilitation facilities, and 4% from outpatient hospital payments. CMS said most of the improper payments the RACs identified occurred when healthcare providers failed to comply with Medicare's coverage or coding rules.

With the RAC program expected to move forward in early 2009 in a number of states, Medicare providers and suppliers and their legal counsel should be prepared for increased auditing activities and take steps to identify areas that are likely to trigger review. Health lawyers also will need to be ready to navigate the appeals process and defend against RAC audit determinations if necessary.

End Notes

1 Various authors took responsibility for summarizing different sections, and *Health Lawyers News* would like to thank Bianca Bishop, Cynthia Conner, Jason Christ, Peter Leibold, and William Thompson for their contributions.

2 These procedures are medically necessary in most cases, but patients tend to put them off when they are financially constrained.

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