Fall 2008

With the publication of this issue of The Boston Health Law Reporter (“Reporter”), the Health Law Section (HLS) of the Boston Bar Association (BBA) would like to welcome you to the 2008-2009 Session.

The HLS has several important goals for the year. Through its different committees, the HLS will continue to provide timely and informative continuing legal education programs, “brown bag” lunch presentations, and publications like the Reporter to our members. This will include collaborative efforts with other BBA sections, as demonstrated by our upcoming co-sponsorship of a program on privacy and security law with the Intellectual Property Section.

The HLS also looks forward to further broadening its membership by attracting lawyers from firms and organizations not currently involved in the Section or the BBA. In particular, we hope to attract new lawyers to our Section, as well as lawyers who may not think of themselves as health care attorneys.

Finally, the HLS will work to expand networking opportunities for lawyers through membership events and offerings such the BBA’s Listserv, which appears on the BBA’s web site, in order to promote both professional development and collegial relations with fellow counsel.

The fall issue of The Boston Health Law Reporter advances these goals. This issue contains a wide range of topics for our members. There are two informative articles on the health care plans of the presidential candidates: Democratic nominee Barack Obama’s plan, described by Tad Heuer and Brooke Lierman, and Republican nominee John McCain’s plan, described by Colin Roskey. There is another timely Washington Word article on the Medicare Improvements for Patients and Providers Act of 2008 by regular contributor and former HLS Steering Committee member Tom Barker. Finally, the Reporter provides insights on developments in health law through its regular Health Law Briefs section, authored by Melissa Lopes.

If you are not already active with the HLS, please take the next step by getting yourself or a colleague involved with the Section. We have a variety of committees available to you, including: CLE, Communications, Legislative, Membership, Social Action, and the Ad Hoc Committee on Health Care Reform. Please don’t hesitate to contact us as the HLS co-chairs or the BBA to get involved today with the Section.

We look forward to seeing you at a HLS- event during the year!

Matt Herndon and Dave Szabo

Inside this Issue:

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senator Barack Obama’s Health Care Plan</td>
<td>3</td>
</tr>
<tr>
<td>Senator John McCain’s Health Care Plan</td>
<td>6</td>
</tr>
<tr>
<td>Local Health Law Briefs</td>
<td>13</td>
</tr>
</tbody>
</table>

Section Co-Chairs

Matthew Herndon, Esq.
Harvard Pilgrim Health Care
93 Worcester Street
Wellesley, MA 02481
(617) 509-3077
Matthew_Herndon@harvardpilgrim.org

David S. Szabo, Esq.
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
(617) 439-2000
dszabo@nutter.com
Senator Barack Obama’s Health Care Plan: Providing Affordable, Quality Health Care Coverage For All Americans

By Tad Heuer, Esq. and Brooke Lierman

The Continuing Health Care Crisis

In the United States today, almost 46 million individuals—including eight million children—have no health insurance, despite annual national spending on health care well in excess of $2 trillion. For those fortunate enough to have health insurance through their employers, many are underinsured: coverage is not there when they need it, and for many, premiums have become unaffordable—doubling since 1999. In fact, a new report found that one of every five families had difficulty paying their medical bills last year. And, for those who rely on Medicare, premiums have more than doubled since 2000. These numbers alone demonstrate the need for comprehensive reform of the health care system, yet because a solution to this crisis has eluded experts and politicians alike for so long, many voters could be forgiven for having concluded that the problems facing the American health care system are simply intractable.

This could not be further from the truth. America’s health care problems can be remedied, but doing so will require smart Presidential leadership and a comprehensive strategy that deals with coverage, quality, and cost. In 2006, Massachusetts became the only state to enact legislation designed to achieve universal coverage for all residents. The Massachusetts plan has succeeded beyond expectations, providing hundreds of thousands of uninsured Massachusetts residents with health care coverage. Senator Barack Obama’s health care plan builds on the Massachusetts model of private insurance coverage, combining that approach to expanding coverage with improvements to the health care system, including a renewed emphasis on prevention and public health initiatives to improve quality and better manage costs.

Senator Obama’s plan is designed to build on the existing successes in the health care system - for instance, it would leave in place the existing employer-based system, allowing every American who chooses to do so to keep the health care he or she now has, while providing options for improved, more affordable care for the uninsured and underinsured. Senator Obama’s plan also recognizes the important work of state governments, and encourages state innovation so long as each state meets certain minimum national standards. By combining what already works with a comprehensive approach to reforming what does not work, we believe that Senator Obama has developed a health care plan that can make affordable comprehensive health care a reality for all Americans while improving quality and reducing costs for everyone.

Senator Barack Obama’s Plan

Senator Obama’s plan has three key components. First, delivering quality, affordable, and portable health coverage for all. Second, modernizing the U.S. health care system to improve quality and lower costs. And third, promoting prevention and strengthening public health.

Quality, Affordable and Portable Health Coverage for All. The centerpiece of Senator Obama’s plan is his proposal to provide all Americans with the opportunity to purchase affordable and comprehensive health care. His approach builds on the existing employer-based structure, while strengthening public programs, such as Medicare, Medicaid, and the State Children’s Health Insurance Program (SCHIP).

To cover the uninsured and underinsured, Senator Obama’s plan creates a National Health Insurance Exchange (“Exchange”)...
to assist individuals to purchase a private health insurance plan and to help small employers better afford coverage for their employees. The Exchange will act as both a clearinghouse and a watchdog: creating a pool of Americans in order to strengthen their bargaining position with insurers, providing Americans with one-stop shops for identifying a plan that fits their needs, and creating rules and standards for participating private insurance plans to both ensure fairness and make coverage more affordable and accessible. The Exchange will enable every American to purchase care through an approved and affordable plan, with sliding-scale subsidies provided for those who need them. As noted, Senator Obama’s plan is modeled on the highly successful coverage structure of the Massachusetts plan, as well as on other successful programs such as SCHIP and the Federal Employee Health Benefits Program (FEHBP). The benefit packages for approved plans will be similar to those offered to members of Congress through the FEHBP, a model that could also be made available nationwide to those people still unable to afford private insurance coverage.9

Senator Obama’s plan also seeks to ensure greater employer participation in the provision of health care coverage in several ways. First, small businesses that offer a quality health plan to all of their employees will receive a refundable tax credit of up to 50% on premiums paid by them on behalf of their employees. Second, Senator Obama’s plan would require employers either to offer meaningful coverage to their employees or contribute towards the cost of expanding coverage. Finally, Medicaid and SCHIP eligibility would be expanded, enabling more Americans to take advantage of these successful programs.

**Modernizing the U.S. Health Care System to Improve Quality and Lower Costs.** Senator Obama’s plan recognizes that improving health care quality can reduce costs, and that reforming the health care delivery system is a crucial step in achieving both goals. Senator Obama would start where the greatest opportunity exists—improving care for individuals suffering from chronic disease. Three-quarters of the more than $2 trillion that Americans spend on health care every year goes to treating people with chronic diseases,10 and over 133 million Americans suffer from at least one chronic condition.11 Senator Obama’s plan proposes expanding comprehensive disease management programs for chronic disease sufferers, as such programs have been shown to improve patient health while also controlling costs.12 Other system reforms will include aligning provider payment incentives to achieve excellence and to promote patient safety, tackling disparities, conducting research on comparative effectiveness to better measure the effectiveness of different treatments, rewarding patients for adherence to model treatment regimes, and reforming medical malpractice while preserving patients’ rights.

As an underpinning of the effort to reform the health system, Senator Obama’s plan also proposes investing $50 billion over five years in electronic health information technology systems. These systems, if implemented on a broad scale, should enable hospitals and doctors to review a patient’s medical history thoroughly while still maintaining patient privacy, thus avoiding medical errors and duplicative treatment, and enabling physicians to provide more targeted and more effective care. Health information technology will also help cut administrative costs, allowing hospitals to process claims electronically—at half the cost of traditional paper claims.13

**Promoting Prevention and Strengthening Public Health.** Senator Obama’s plan also seeks to improve health through the prevention of disease in the first place, by tackling underlying causes of chronic disease such as smoking, obesity, and the failure to undergo cancer screening. Indeed, Professor David Cutler, a health care advisor to Senator Obama’s campaign, has observed that less than one dollar in 25 is spent on prevention today, despite the fact that measures like regular screenings and healthy lifestyle information can be effective in reducing prevalence.14 Further, Senator Obama’s plan stresses the importance of encouraging families and individuals to choose health plans that cover preventive services. Preventive services encourage individuals to make routine visits to their doctor and to seek medical assistance before illnesses progress, thus reducing the number of patients who rely upon emergency rooms for primary care, and eventually decreasing the number of Medicare beneficiaries who suffer from chronic diseases.

**Cost**

According to the Economic Policy Institute (EPI) and the Tax Policy Center, both Senator Obama’s and Senator McCain’s plans will cost over a trillion dollars over a ten-year period — $1.3 trillion for the McCain plan and $1.6 trillion for the Obama plan.15 However, for that money, Senator Obama’s plan will cover many more of the projected uninsured population than will Senator McCain’s plan. Thus, EPI concludes that Senator Obama’s plan will be significantly more cost-effective over a decade, “spending far less per capita for its coverage of the uninsured population.”16 Senator Obama also is clear about
how to pay for his plan. Among other cost-saving steps, he will allow the Bush Administration tax cuts on the highest income individuals—those earning more than $250,000 a year—to expire. We believe that Senator Obama’s plan, by expanding coverage and improving the health care system, will lead to reduced costs over time, and thus to more affordable, higher quality health care for all Americans—both in this generation and those to come.

Comparison to Senator John McCain’s Plan

Both Senator McCain and Senator Obama have proposed health insurance reforms that draw upon the existing private insurance markets and use a public insurance program to fill in the gaps. However, that is where the similarities end. Senator McCain’s plan is based upon eliminating the existing tax exclusion for individuals with the contribution to the cost of their health insurance made by their employers. Under Senator McCain’s plan, individuals would be taxed on the employer contribution to their health care. Senator McCain proposes to replace the tax exclusion with a direct, refundable tax credit that would be free to deny coverage due to pre-existing conditions—leaving those Americans who are already sick simply out of luck. And although Senator McCain has proposed a high-risk pool, he has not indicated how it will be funded.

The Bottom Line: Health Care Reform Now

Whether Senator McCain or Senator Obama is sworn into office in January 2009, the prevailing candidate will inherit a health care system that is failing Americans everywhere. Senator McCain’s plan proposes to dismantle the existing health care insurance system, but does little in our view to ensure access to quality and affordable care for all Americans. In contrast, Senator Obama’s plan places the goal of insuring all Americans so that they can receive high quality care, at its core, while also streamlining and reforming the health care system, improving quality, and reducing costs. Health care reform is one of many differences between the candidates, but one that all Americans should be thinking about when they enter the voting booth on November Fourth.
Senator John McCain’s Health Care Plan:
Better Health Care and Lower Costs For Every American

By Colin Roskey, Esq.

Senator John McCain offers an innovative health care plan that will truly transform our health care system. His plan rests on certain common principles: faith in the American people to make the health care decisions that will work best for them, and a belief that the private marketplace, not big government, must continue to play an important role in health care delivery in our country. Senator John McCain and Governor Sarah Palin’s plan represents true change.

By contrast, Senator Barack Obama and Joe Biden’s plan eliminates choices for the American consumer, and increases the power of Washington bureaucrats and the politicization of health care. Their plan would dramatically increase the role of the federal government in health care while dramatically decreasing personal choice and freedom. At the end of the day, their plan would result in more Washington bureaucrats making decisions about your health care, rather than trusting on you to make those decisions with your doctor.

**Senator John McCain’s plan has three principal elements:**

1) Health care should be made more affordable for all Americans. By transforming the health care delivery system, promoting prevention, delivering health care more effectively and efficiently, and focusing on the true drivers of health care costs, we can ensure that every American can afford quality health care coverage of their choice.

2) Health insurance should be portable: Americans should be able to keep their health insurance when they move from job to job or job to home.

3) Health care quality can be strengthened by promoting research and development of new treatment models, promoting wellness, and investing in technology and empowering consumers with better information on health care quality.

**Affordability**

Senator McCain and Governor Palin recognize that the reason that many of the 47 million Americans lack health insurance coverage at any given time is because it is sometimes unaffordable. They will address the affordability issue’s root causes: health care costs too much because much of our current health care system remains locked in the past; because our health care system is not designed to reward prevention; because government mandates artificially drive up the cost of health care; and because the current system incentivizes more costly health care. Their plan will address all four issues.

Second, the American health care system does not encourage prevention. Instead, the drivers of health care reimbursement in this country are chronic diseases such as diabetes and heart failure. The physician who sees a diabetic patient four times a year to check that patient’s blood glucose level, blood pressure, and cholesterol level gets paid more for seeing that patient than for encouraging healthy lifestyles that might have prevented that patient’s diabetes in the first place. Considering initiatives that reward prevention – such as smoking cessation programs – can help to reduce health care costs. Disease management for chronic diseases is also an important component.

Third, insurance companies should compete for American families. This can be accomplished by allowing purchase of insurance across state lines. A 60-year-old woman purchasing health insurance in the non-group market should not have to purchase a health insurance pol-
The American health insurance system needs to change to reflect the realities of the economy of the 21st century. Perpetuating the existing model means that more and more Americans will lose their health insurance coverage.

Senator McCain and Governor Palin support making health insurance portable. They envision a system where American families – not government bureaucrats or insurance companies – choose the coverage that best meets their unique needs, including keeping their current employer-provided coverage. Senator McCain’s plan will allow families to keep their coverage as they move from “job to job” or “job to home” by allowing families to own their health care coverage.

The most important change necessary to make this happen is to end the current discriminatory and unfair tax treatment that only provides a tax benefit for those under the employer-sponsored system. Under the proposal of Senator McCain and Governor Palin, the tax benefit that now is only available to working Americans would be made available to all Americans: to the car mechanic, the hair stylist, and the maintenance worker who are now forced to purchase health insurance on their own or go without, praying that they do not get sick.

This tax benefit would be made available in the form of a refundable tax credit to every American family regardless of their source of coverage. So those in the employer-sponsored system will continue to keep their current coverage, while those who are self-employed or have no coverage at all will have the same tax benefit to purchase coverage of their choice.

Some have suggested that the plan of Senator McCain and Governor Palin will drive everyone into the non-group market and that those with chronic conditions will be priced out of the market and lose the purchasing incentives that are currently available to those in the group market. Those criticisms are false. Under the plan, Senator McCain would work with the nation’s governors to develop a Guaranteed Access Plan (GAP) for everyone seeking to purchase health insurance in the non-group market. One approach might be the establishment of a non-profit corporation that would contract with insurers to cover patients who have been denied insurance and could join with other state plans to enlarge risk pools and lower overhead costs. GAP will also have reasonable premium limits and financial help for low-income families.

Quality

The American health care system should reward quality. That is a far cry from what happens today. Today, physicians and hospitals get paid by the number of procedures they perform. This encourages over-utilization and discourages innovation. Our system should not reward volume; it should reward value. Senator McCain and Governor Palin will build on the steps that have been initiated in the past few years by Medicare, innovative states, and innovative insurers to transition our health care system to one that rewards higher quality. Initiatives such as Medicare’s pay-for-reporting system in the hospital inpatient and outpatient prospective payment systems and the physician quality reporting initiative are good first steps. They need to be expanded so that soon health care payers are actually paying for performance.
In addition to payment reforms, health care payers should work to develop quality standards and best practices for the treatment of medical conditions. These steps are being taken today in the most preliminary of forms. Those efforts must be accelerated. All payers – in the public and private sectors – must work together to improve the quality of American health care.

**Conclusion**

The American health care system is the envy of the world. Our innovation and level of care are second to none. But we also have the costliest system of health care that leaves some of our fellow citizens behind. That is a major problem, and it is one of the most important domestic problems that the next President will face. Because of its importance, it is critical to address it the right way. Expanding the role of government, increasing taxes, and increasing bureaucratic control over decisions that are best left to you and your physician is not the right way. That way will guarantee higher costs, longer lines and waits for health care, and lower quality.

Senator McCain and Governor Palin have offered a truly innovative solution: it would address the root causes of affordability, enhance portability of health care, and improve quality. It is the plan that will best meet the needs of the American people as our health care system transitions to the 21st century.
By Thomas R. Barker, Esq.1

Introduction

At the federal level, the most significant health care legal and policy development of the summer was the enactment, over President Bush’s veto, of the Medicare Improvements for Patients and Providers Act of 2008. Thus MIPPA was born – a bill that rhymes with HIPAA but is instead spelled with two “Ps.” After a brief discussion of the procedural history of the enactment of the legislation, this article will analyze some of the key features of the new law. Aside from being enacted over the President’s veto, MIPPA is notable for being the most substantive piece of health care legislation since the enactment of the Deficit Reduction Act in February of 2006.

Procedural History of the Enactment of the Legislation

MIPPA represents only the third time in the Presidency of George W. Bush that Congress has overridden the President’s veto of legislation, and they did so convincingly.2 Under the Constitution, a two-thirds vote of both the House and the Senate is necessary to override a Presidential veto.3 As will be discussed in this article, the President objected to provisions of the legislation that would have changed the operational rules for Medicare Advantage fee for service plans, and cited those changes as his principal objection to the legislation.4

Massachusetts’ own Senator Ted Kennedy played an important and dramatic role in the veto override vote. The House initially passed MIPPA on June 24 by a veto-proof majority of 355 – 59. It then went to the Senate, where opponents of the legislation successfully filibustered it. A vote to invoke cloture failed by one vote on June 26. Thus, when Congress went home for the Fourth of July recess, it seemed likely that Congress would be unable to pass the legislation with the provisions to which President Bush objected. When Congress returned, however, the Senate Majority Leader had secretly arranged for Senator Kennedy to return to Washington from his medical treatments. Senator Kennedy cast the one vote that permitted the supporters of the legislation to invoke cloture. After his vote, numerous Senators changed their vote, so that cloture was invoked by a veto-proof majority of 69 – 30 on July 9. At that point, the veto and the override were mere formalities. On July 15, President Bush vetoed the legislation. On the same day, the House and Senate voted to override the veto. On that day, pursuant to Article I, section 7 of the Constitution, the bill became law.

Main Provisions of the Legislation

Although the legislation was, in some respects, a routine package of revisions to the Medicare program, it did contain some notable provisions. Out of necessity for brevity, this article will focus on the three most significant: amendments to and extensions of provisions of the fee-for-service Medicare program; revisions to the Medicare Advantage program; and revisions to the Medicare prescription drug benefit codified at Part D of title XVIII of the Social Security Act.5 It is the latter two provisions that provoked the President’s veto of MIPPA.

Fee-for-Service Provisions

The driving force behind enactment of MIPPA was the physician fee schedule formula. Under current law, Medicare payments to physicians are updated every year by the product of medical inflation and the “update adjustment factor.” The statute defines the “update adjustment factor”6 as a measurement of the extent to which actual expenditures for physician services for a year exceed or are below allowed expenditures for physician services for a year.7 To the extent that actual physician expenditures exceed allowed physician expenditures in a year, the physician payment update is negative, since the measurement of medical inflation would, under the statute, be multiplied by a negative number.

In every year since 2001, actual physician expenditures have exceeded allowed physician expenditures; as a result, in each of those eight years, physicians should have, under the statute, received a negative update. However, in seven of those eight years, Congress has legislatively overridden the negative update. MIPPA is now the eighth year that Congress has followed this tradition, and provides a positive update to the physician fee schedule of 1.1% for calendar year 2009.8 Of course, by legislatively specifying higher physician payments for 2009 than would other-
wise be the case, actual physician expenditures for 2009 will, by definition, exceed allowed physician expenditures for that year, necessitating yet another cut in physician payments in 2010 unless Congress intervenes for the ninth year in a row. This endless cycle of a scheduled cut being blocked at the last minute by a beneficent Congress dependent upon campaign contributions from regulated entities (such as the American Medical Association) demonstrates, at least to some people, the folly of having the government attempt to regulate medical prices.

In addition to the 1.1% payment update for physician services, Congress for the first time created an incentive for physicians to adopt and implement electronic prescribing systems. Under the legislation, any physician who is a “successful electronic prescriber” between 2009 – 2013 will receive a bonus in each year they are such a prescriber. Beginning in 2012, any physician who is not a successful electronic prescriber will begin to face a penalty in the form of reduced Medicare payments. Under the statute, a “successful electronic prescriber” is a physician or other eligible professional who meets available electronic prescribing quality measures at least 50% of the time or, if determined appropriate by the Secretary of Health and Human Services (HHS), the eligible professional submitted a “sufficient number” of prescriptions under the Part D prescription drug program in a year.

There were other Medicare fee-for-service provisions of note in MIPPA as well. One is the much-publicized competitive bidding program for durable medical equipment (DME) which began on July 1, 2008. The Medicare Prescription Drug, Improvement and Modernization Act (MMA) required CMS to establish a competitive bidding program for DME that would begin, initially, in ten regions of the United States in the first year of operation. The concept behind DME competitive bidding is that the free marketplace would find a better price for items of DME than a government-imposed fee schedule. Not surprisingly, that is exactly what happened; CMS estimated that in the ten regions of the country where competitive bidding was to occur, the agency would pay 26% less than the government-mandated fee schedule applicable elsewhere in the country. CMS set up the program so that it would begin on July 1, 2008. Section 154 of MIPPA delayed DME competitive bidding at least until 2009; therefore, effective on the day that MIPPA became law (July 15, 2008), the program ceased in those ten regions of the country and the regular fee schedule again became operative in those regions. Anticipating lawsuits from the successful bidders, Congress specified that any damages would be paid from the Medicare Trust Fund.

Another Medicare fee-for-service provision of note is a mental health parity provision included in MIPPA. Since 1965, Medicare has provided far less generous coverage for beneficiaries with mental illness than beneficiaries with physical illness. For example, the 20% co-insurance otherwise applicable in Part B is 50% for beneficiaries with mental illness. MIPPA gradually reduces beneficiary coinsurance for mental illness from 50% to the 20% otherwise applicable in Medicare by 2014.

Revisions to the Medicare Advantage Program

Given that the increase in the physician fee schedule, the delay in DME competitive bidding, the decrease in coinsurance for mental health and the other fee-for-service changes increased Medicare spending, Congress had to find a way to pay for that increased spending. President Bush has, since 2003, objected to any reductions in spending on the Medicare Advantage program as a way to pay for increased spending in the fee-for-service Medicare program. The President has taken that position because Medicare Advantage has been enormously successful in offering additional choices and benefits to Medicare enrollees. In 2008, nearly 20% of Medicare beneficiaries elected to receive their benefits through Medicare Advantage plans and, in doing so, received extra benefits not available in the fee-for-service program such as premium-free prescription drug coverage; a combined Part A and B deductible; and lower coinsurance. The President consistently has warned that reductions in funding for Medicare Advantage would cause plans to reduce those extra benefits, forcing beneficiaries back into a traditional Medicare program that may not work for them.

By contrast, critics of the Medicare Advantage program point to studies that suggest that Medicare Advantage plans are “overpaid” relative to the fee-for-service program. These critics imply – incorrectly – that these extra payments are fattening the profits of private Medicare Advantage plan sponsors. In fact, Medicare Advantage plan sponsors do not receive any extra payments. These plans are paid based upon a bid they submit that reflects their revenue needs to offer the standard Medicare benefit package to their enrollees. In most cases, these bids are less than the government’s cost of pro-
viding those same benefits. Plan sponsors are then paid at that bid amount.\textsuperscript{16} In addition to the bid amount, to the extent that a plan sponsor has a “rebate” (i.e., to the extent that the county-specific “benchmark” applicable to the plan exceeds the bid amount), the sponsor receives that rebate payment as well.\textsuperscript{17} This excess payment, however, does not go to the plans; rather, by statute, 75% of the excess must be returned to Medicare beneficiaries in the form of greater benefits or reduced coinsurance and the remaining 25% is retained by the federal government.\textsuperscript{18}

In MIPPA, Congress chose not to reduce these so-called “extra” payments. The legislation, however, made a major change in the operation of Medicare Advantage private fee-for-service (MA-PFFS) plans. Critics of the Medicare Advantage program focused on MA-PFFS plans as the fastest-growing type of private plan. MA-PFFS plans have been especially popular in rural areas of the United States because traditional Medicare Advantage plans – which include traditional managed care features such as restrictive provider networks – found it difficult to develop robust provider networks to adequately serve all enrollees. MA-PFFS plans are able to meet network access requirements by “deeming” providers not under contract with the plan as members of the plan, permitting enrollee access to those providers, and paying the providers at the Medicare fee-for-service rate.\textsuperscript{19} This deeming provision has made these plans more attractive in rural areas.

MA-PFFS plans have also attracted scrutiny because of their proliferation in urban areas of the country. Because the Medicare Advantage benchmarks generally tend to be higher in urban counties than in rural counties (both because of higher medical costs and because of the way the benchmark rates were initially set), payments to these plans are higher than traditional Medicare Advantage plans. Some argued, however, that it was inappropriate to permit a managed care plan located in an urban county to have essentially unrestricted choice of providers for beneficiaries and, the argument continued, this feature inappropriately drove up the costs of MA-PFFS plans.

In response to these arguments, under MIPPA, beginning in 2011, these “deeming” provisions cannot be used by an MA-PFFS plan in any county where there are at least two “network-based plans” operating in the county.\textsuperscript{20} A “network-based plan” is essentially any Medicare Advantage plan that has a restrictive provider network. So, for example, although under current law, an MA-PFFS plan could operate in Suffolk County (Massachusetts), beginning in 2011, it would not be able to if there are at least two traditional Medicare Advantage plans operating in the county – which there almost surely will be. The Congressional Budget Office (CBO) estimated that this provision of the legislation would reduce enrollment in MA-PFFS plans by 2.3 million enrollees by 2013 relative to the current CBO baseline.\textsuperscript{21} Combined, changes in the Medicare Advantage program under the legislation will reduce federal government spending by $13.6 billion over five years.\textsuperscript{22}

**Modifications to Medicare Part D**

MIPPA also made a significant change to Medicare’s outpatient prescription drug benefit that became effective in 2006. This provision, like the revisions to Medicare Advantage described above, is also likely to have negative consequences for Medicare beneficiaries. The legislation also marks the first time since the enactment of the MMA in December of 2003 that Congress has revised the program in any material way.

CMS has recognized, since the beginning of Part D, that certain Medicare beneficiaries – especially those with mental illness, cancer, or HIV/AIDS – would likely be on complicated medication regimes. Part D plan sponsors were, under CMS guidelines implementing the program, required to cover all or substantially all drugs in six “protected classes” of medications. These six protected classes are: immunosuppressants, anti-retrovirals, cancer medication, anti-depressants, anti-psychotic, and anti-convulsant medication.\textsuperscript{23}

MIPPA contains a provision that effectively would replace or supplement the CMS guidance requiring coverage of the six protected classes with a new standard, codified in statute. Under the MIPPA provision, a Part D plan sponsor would be required to include on its formulary “all covered Part D drugs” identified by the Secretary of HHS as meeting two standards. The first standard is that restricting access to any drug in a class of drugs “would have major or life-threatening clinical consequences” for a Part D enrollee with a medical condition treated by drugs in the class.\textsuperscript{24} The second standard is that there is a “significant clinical need” for such individuals to have access to multiple drugs in the class “due to unique chemical actions and pharmacological effects” of the drugs.\textsuperscript{25} Under the statute, the identification of drugs by the Secretary is a mandatory act.\textsuperscript{26}
Depending on how a future Secretary of HHS interprets such vague terms as “major ... clinical consequences,” “significant clinical need,” and “unique chemical actions and pharmacological effects,” the effect of the provision on Part D could be significant. It is not difficult to imagine a future Secretary being faced with entitlements by pharmaceutical manufacturers to require coverage of particular drugs under the provision, dramatically reducing the leverage that Part D plan sponsors have in negotiating payment rates with manufacturers. The provision could interject a level of politicization into Part D that does not now exist, and could tilt the balance of negotiations dramatically in favor of pharmaceutical manufacturers. Given that the provision is not effective until the 2010 plan year, it remains to be seen whether it will be as pernicious as some observers predict it will be.

**Conclusion**

MIPPA is a significant piece of health care legislation. Unlike every other piece of health care legislation enacted during the past seven years of the Bush Administration, however, this one was enacted with no input by the Administration and with no consultation between Congress and the Administration. Some provisions of the bill – such as the incentives for e-prescribing – will help to further an important priority of the President: increasing adoption of electronic health records. Unfortunately, other provisions of the bill, including many of those discussed in this article, do not reflect the Administration’s priorities, thereby leading to the President’s veto. Time will tell whether the President’s objections will prove correct.
Morales v. Sociedad Espanola de Auxilio Mutuo y Beneficencia, 524 F.3d 54 (1st Cir. 2008)

Morales turns on what it means to “come to” a hospital’s emergency department under the Emergency Medical Treatment and Labor Act (“EMTALA”), 42 U.S.C. §1395dd. Plaintiff Morales’ obstetrician diagnosed her as having a nonviable ectopic pregnancy. Two days later, an ambulance was summoned when the plaintiff experienced severe abdominal pain and vomiting while at work. The ambulance transporting the plaintiff proceeded towards Hospital Espanol Auxilio Mutuo de Puerto Rico (the “Hospital”), where the plaintiff’s obstetrician was affiliated. Neither the ambulance nor the paramedics manning it had any formal affiliation with the Hospital. The paramedics twice called ahead to the Hospital and spoke with the director of the emergency department. Though the director did not state that the Hospital was in diversionary status, he did convey hesitancy to accept the plaintiff as a patient. During the second call, the director terminated the call when he failed to receive assurance that the plaintiff had medical coverage or hospital-related insurance. As a result, the paramedics took the plaintiff to a different facility for treatment.

The plaintiff filed suit, alleging violations of EMTALA and other local law torts.

Upon the defendant Hospital’s motion that the EMTALA statute did not apply, the District Court granted summary judgment on the EMTALA claim and dismissed the local law claims without prejudice. After an unsuccessful motion for reconsideration, the plaintiff appealed. The U.S. Court of Appeals for the First Circuit reversed and remanded, finding that the patient had “come to” the emergency department for the purposes of EMTALA.

In a factually similar case, the Court of Appeals for the Ninth Circuit construed the phrase “comes to the emergency department” as applying to instances where an individual was en route to the hospital. Prior to this First Circuit decision, the Ninth Circuit was the only federal appellate court to have construed this phrase. The Ninth Circuit interpreted the “comes to” language in this way under the rationale that the plain language of the statute compels such an interpretation. The First Circuit concurred with the result, but not the rationale. Agreeing with the initial analysis of the district court, the First Circuit concluded that the district court’s regulatory analysis was ambiguous, and the district court appropriately looked to agency regulations issued by the Secretary of Health and Human Services (“HHS”) pursuant to the statute. However, the First Circuit concluded that the district court’s regulatory analysis was flawed in that its interpretation did not give all language in the regulations operative effect, rendering certain portions of HHS’s regulations “superfluous, void, or insignificant.” Finding that, once read as a whole, the regulations’ overall meaning was obscure, the Court of Appeals determined that an examination of the regulatory framework supporting EMTALA does not end the analysis and that it is necessary to look further into the interpretative guidance issued by the agency. After engaging in such an examination, the First Circuit concluded that there was “an absence of any clear agency interpretation of what the regulation means.”

The First Circuit concluded that where the statutory language is ambiguous, the regulations interpreting it are unenlightening, and a clear agency interpretation of its own regulations is absent, a court must look to the “manifest purpose” of the statute. Where the purpose of EMTALA was to ensure access to emergency services and to deter the “dumping” of financially undesirable patients, the Court found that a reasonable fact-finder could interpret the phrase “comes to the emergency department” as encompassing an individual en route to the hospital’s emergency department under the facts of this case. As a result, the First Circuit reversed and remanded. It reiterated, however, that the authority to interpret EMTALA remains with HHS, the agency charged with implementing the statute. As such, if HHS were to resolve the ambiguity extant in the “comes to the emergency department” language of EMTALA, the HHS interpretation would govern.

In a dissenting opinion, Judge Torruella upheld the majority’s framework for interpreting statutory language, but determined that the majority erred in taking such analysis beyond an examination.
of the statutory language. The dissent argued that the statutory language was plain, and a reasonable interpretation of the “comes to” language would preclude the majority’s holding that such language encompasses the case where an individual merely “moves toward or approaches the emergency department.”


In Matsuyama v. Birnbaum, the Massachusetts Supreme Judicial Court (“SJC”) recognized the doctrine of “loss of chance” under Massachusetts common law for medical negligence actions. As described in this case, the loss of chance doctrine assigns value to a person’s diminished prospects for surviving a serious medical condition due to a physician’s tortious conduct, even when the person’s likelihood of survival is less than 50% absent medical malpractice.

The plaintiff sued Dr. Neil S. Birnbaum and Dedham Medical Associates, Inc. for wrongful death, breach of contract, and negligence in the death of her husband. Defendant Birnbaum became the primary care physician for decedent Matsuyama in July 1995, when the decedent first presented for a routine physical. At the time, the decedent’s medical record was accessible to the defendant. The medical record revealed the decedent’s history of gastric distress complaints and indicated that the decedent’s previous physician had noted the possible need for additional testing, such as an upper gastrointestinal series or small bowel follow-through. Further, the defendant was aware that decedent’s Asian-American ancestry, his time spent living in Korea and Japan, and his history of smoking placed the decedent at greater risk of developing gastric cancer than the general American population.

Despite this collective information, defendant Birnbaum did not order any tests to determine the nature of the decedent’s complaints. Based upon physical examination, the defendant diagnosed gastrointestinal disease and suggested over-the-counter medications. Over three years and several subsequent visits by the decedent complaining of gastric distress and other related symptoms, the defendant failed to order further tests or to diagnose correctly the cause of the distress. Finally in 1999, as the result of an upper gastrointestinal series and abdominal ultrasound, a two-centimeter mass was discovered in the decedent’s stomach, which was later confirmed as a gastric carcinoma. Fewer than six months later, the decedent surrendered to gastric cancer.

The superior court determined that the defendant Birnbaum was negligent and that the negligence was a “substantial and contributing factor” to the decedent’s death. It entered judgment on a jury verdict, awarding loss of chance damages in addition to pain-and-suffering damages. The defendants appealed, asserting that loss of chance was not cognizable under the Massachusetts wrongful death statute, M.G.L. c. 229, §§ 2 and 6, or otherwise. The SJC granted the defendants’ application for direct appellate review.

The SJC found that loss of chance is a “separate, compensable item of damages in an action for medical malpractice.” The SJC determined that allowing loss of chance recovery where a patient’s chances of survival were less than 50% prior to a physician’s tortious conduct is a natural outgrowth of the public policies behind medical malpractice tort law and the common law development of wrongful death. As such, the SJC limited its findings to medical negligence actions. The Court stressed that the “all or nothing” theory of tort recovery—allowing for full wrongful death damages only when a tortious act deprives the patient of a greater than 50% chance of survival—fails to deter negligence when a patient has a less than 50% chance of survival prior to the negligent misdiagnosis or treatment, and immunizes negligence that inflicts injury that is likely but uncertain to shorten a victim’s life. Further, the SJC resolved that the “all or nothing” theory fails to account for the regular use in medical practice of advancements in gauging a patient’s chances of survival to a reasonable degree of medical certainty. Thus, the SJC redefined injury in the loss of chance context, requiring a plaintiff to demonstrate, by a preponderance of the evidence, “a diminished likelihood of achieving a more favorable medical outcome.” Where a defendant’s conduct is the but-for cause of the diminished likelihood of achieving a more favorable medical outcome, the application of loss of chance damages is proper.

In determining appropriate damages, the SJC applied a proportional damages approach. A fact finder must: (1) calculate the total amount of damages allowable for the death under the wrongful death statute, or the full amount of damages for injury that does not result in the patient’s death; (2) calculate the patient’s chance of survival or cure immediately preceding the medical malpractice; (3) calculate the chance of survival or cure the patient has as a result of the medi-
cal malpractice; (4) subtract the amount derived in step 3 from the amount derived in step 2; and (5) multiply the amount determined in step 1 by the percentage calculated in step 4 to determine the damages award. In dicta, the SJC stated that punitive damages are not part of the proportional loss of chance calculus and intimated that a finding of gross negligence and an award of punitive damages may be granted in addition to an award of damages for loss of chance.

The SJC concluded that the superior court had ample evidence from expert testimony to determine that defendant’s negligence caused a diminution in the decedent’s likelihood of achieving a more favorable outcome for his condition. Although the superior court used a “substantial and contributing factor” test rather than a “but-for” test in determining causation, the SJC noted that the judge’s definition of “substantial” adequately instructed the jury that the defendant’s negligence had to be a “but-for” cause of the decedent’s loss of a “fair chance of survival.” Additionally, the SJC held that the superior court judge did not commit reversible error by failing to offer for jury consideration whether, and to what extent, defendant’s negligence left the decedent with any chance of survival in accordance with steps 3 and 4 of the proportional damages approach. The SJC determined that, because the defendants failed to specifically object to the judge’s apportionment formula at trial, their right to offer a more detailed objection on appeal was extinguished. Accordingly, the SJC affirmed the superior court’s award of loss of chance damages, joining the majority of states that have considered and espoused the loss of chance doctrine. The SJC counseled, however, that its decision is limited to cases where the ultimate harm has come to pass, and does not resolve whether a plaintiff may recover loss of chance damages for future harms.
Editors

Catherine L. Annas, Esq.

Catherine L. Annas is the Director of the Eastern Massachusetts Health-care Initiative (EMHI), a group of hospitals, health plans, provider groups and universities working together to create a high performance health care system in Eastern Massachusetts. She oversees projects related to patient safety, quality and cost in health care. Prior to joining EMHI, Ms. Annas served for five years as the Director of Patient Safety at the Department of Public Health and the Betsy Lehman Center for Patient Safety and Medical Error Reduction. Before that, Ms. Annas worked for five years on the House staff of the Massachusetts Legislature’s Joint Committee on Health Care. Ms. Annas received her J.D. from the Columbus School of Law at the Catholic University of America in 1995, and her Bachelor’s Degree in English from the Catholic University of America in 1992.

Mark C. Rogers, Esq.

Mark C. Rogers is an associate at The Rogers Law Firm. He is a member of the Firm’s Corporate and Health Care Practice Groups. Although he has extensive experience representing a variety of clients with regard to regulatory, compliance, employment and corporate matters, Mr. Rogers focuses his practice on health care contractual matters, regulatory compliance, and fraud and abuse investigations. He has published and lectured extensively on legal issues in the health care industry and is an adjunct faculty member at New England School of Law where he teaches Health Law. Mr. Rogers earned his undergraduate degree from the College of the Holy Cross and his law degree (cum laude) from Suffolk University Law School, where he served as the Chief Managing Editor of the Suffolk Transnational Law Review.

Susan J. Stayn, Esq.

Susan J. Stayn is Senior University Counsel at Stanford University and Stanford Medical Center, where she advises on health care regulatory and corporate matters and biomedical research. Ms. Stayn has been an advisor to the Interstate Alliance on Stem Cell Research since its inception in 2007, and developed and taught a stem cell research law and policy course at Berkeley Law School in 2008. She previously worked for many years in the Office of the General Counsel of Partners HealthCare System, Inc. Prior to joining Partners, Ms. Stayn worked in the private and non-profit sectors and clerked for the Honorable Levin H. Campbell on the U.S. Court of Appeals for the First Circuit. She is a graduate of Harvard College, magna cum laude, and Columbia Law School, where she was editor-in-chief of the Columbia Law Review.
Contributors To This Issue

Thomas R. Barker, Esq.

Thomas R. Barker is the Acting General Counsel of the United States Department of Health and Human Services (HHS), serving as the Department’s senior legal advisor. Prior to assuming this role in May of 2008, he served as Counselor to the Secretary of Health and Human Services for Health Policy and, prior to that, as Deputy General Counsel of HHS. From October 2001 until December 2003, Mr. Barker was Health Policy Counselor to the Administrator of CMS. From 1992 to 2001, Mr. Barker was a health policy analyst and regulatory counsel for the Massachusetts Hospital Association.

Tad Heuer, Esq.

Tad Heuer is an associate in the Government Strategies Group at Foley Hoag LLP, where his practice includes advising life sciences and health care clients on legislative and regulatory matters at both the state and federal levels. Previously, Mr. Heuer served as a law clerk to the Honorable Margaret H. Marshall, Chief Justice of the Massachusetts Supreme Judicial Court. Mr. Heuer holds a Ph.D. in social policy from the London School of Economics, as well as a J.D. from Yale Law School, where he was a Notes Editor of the Yale Law Journal and Executive Editor of the Yale Law & Policy Review. Mr. Heuer graduated from Brown University with an A.B. magna cum laude in public policy and an M.A. in political science.

Brooke Lierman

Brooke Lierman is an associate in the Government Strategies Group at Foley Hoag LLP, where she focuses on health care strategy. Ms. Lierman received her J.D. from the University of Texas School of Law, where she was on the Executive Board of the Texas International Law Journal; she holds an A.B. in history from Dartmouth College. Ms. Lierman has interned for the Honorable William W. Justice of the United States District Court for the Eastern District of Texas, and was a policy assistant to State Senator Rodney Ellis (D-Houston) during the 2007 Term. Previously, Ms. Lierman was the Special Assistant in National Security at the Center for American Progress, and has worked on various political campaigns, including the 2002 re-election campaign of Senator Paul Wellstone and the 2004 Howard Dean and Kerry-Edwards presidential campaigns.

Melissa J. Lopes, Esq.

Melissa Lopes is Deputy General Counsel for the Massachusetts Department of Public Health. In the biotechnology arena, Ms. Lopes provides advisory rulings on egg donation in the research context, promulgates regulations under the Massachusetts Stem Cell bill, and works with the Biomedical Research Advisory Council and the Interstate Alliance on Stem Cell Research. Additionally, Ms. Lopes provides legal advice and guidance to the Determination of Need program, the Clinical Laboratories Program and on matters including blood banking and pharmaceutical marketing in the Commonwealth. Prior to joining the Department of Public Health, Ms. Lopes was a Kellogg Fellow with Community Catalyst, a national healthcare advocacy group. In this capacity, Ms. Lopes worked with grassroots community groups across the country to secure and preserve needed healthcare resources. Ms. Lopes also worked as an associate with the law firm Choate, Hall & Stewart in the corporate and healthcare departments. Ms. Lopes is a graduate of Boston College and Boston University School of Law, where she was an editor of the American Journal of Law and Medicine.

Colin Roskey, Esq.

Colin Roskey is a Counsel at Alston & Bird, LLP in Washington, DC, where he focuses on access, coverage and payment issues for a broad range of health care stakeholders. Before joining Alston & Bird, he was the Senate Finance Committee’s lead staff counsel on Medicare ambulatory policy and private insurance issues.

Peer Reviewers:

Julia Hesse, Esq.
Peer Review Coordinator
Mira Burghardt, Esq.
Russell J. Edelstein, Esq.
Michael Lampert, Esq.
Brian Rosman, Esq.
Robert Weber, Esq.
Section Leadership

Section Co-Chairs
Matthew Herndon
Harvard Pilgrim Health Care, Inc.
93 Worcester Street
Wellesley, MA 02481
(617) 509-3077
Matthew_Herndon@harvardpilgrim.org

David Szabo
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
(617) 439-2000
dszabo@nutter.com

Health Law CLE Committee
William Mandell
Pierce & Mandell, P.C.
11 Beacon Street
Suite 800
Boston, MA 02108
(617) 720-2444
bill@piercemandell.com

Alan Einhorn
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 342-4000
aeinhorn@foley.com

Robin Johnson
Johnson & Aceto, LLP
67 Batterymarch Street
Boston, MA 02110
(617) 728-0888
johnson@johnsonaceto.com

Health Law Communications Committee
Susan Stayn
Stanford University, Office of the General Counsel
PO Box 20386
Stanford, CA 94305
(650) 724-3132
sstayn@comcast.net

Mark Rogers
The Rogers Law Firm
100 Cambridge Street
20th Floor, Suite 2000
Boston, MA 02114
(617) 723-1100
mrogers@therogerslawfirm.com

Catherine Annas
Eastern Massachusetts Healthcare Initiative
14 Story Street
2nd Floor
Cambridge, MA 02138
(617) 495-2966
catherine_annas@harvard.edu

Health Law Legislative Committee
Joshua Greenberg
Office of Child Advocacy
300 Longwood Avenue, BK120
Boston, MA 02115
(617) 919-3063
Joshua.Greenberg@tch.harvard.edu

Linda Tomaselli
Epstein Becker & Green, P.C. - DC Office
1227 25th St., NW
Suite 700
Washington, DC 20037
LTomaselli@ebglaw.com

Michael Sroczynski
Massachusetts Hospital Association - Boston
101 Arch Street
Suite 1741
Boston, MA 02110
(617) 367-9667
msroczynski@mhalink.org

Health Law Membership Committee
Eve Horwitz
Archstone Law Group P.C.
245 Winter Street
Suite 400
Waltham, MA 02451
(781) 314-0111
ehorwitz@archstonelaw.com

Dianne McCarthy
Joslin Diabetes Center
One Joslin Place
Boston, MA 02215
(617) 667-1894
dianne.mccarthy@joslin.harvard.edu

Leslie Joseph
Mount Auburn Hospital
330 Mount Auburn Street
Cambridge, MA 02138
(617) 499-5752
ljoyseph@mah.harvard.edu

Social Action Committee
Sarah Anderson
Greater Boston Legal Services
197 Friend Street
Boston, MA 02114
(617) 371-1234
sanderson@gbls.org

Michael Blau
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 342-4040
mblau@foley.com
Barbara Anthony
Health Law Advocates, Inc.
30 Winter Street
Suite 940
Boston, MA 02108
(617) 338-5241
banthony@hla-inc.org

Christie Hager
Office of Speaker Salvatore F.
DiMasi
State House Room 356
Boston, MA 02133
(617) 722-2500
christie.hager@state.ma.us

New Lawyers Liaison

Justin DiBiasio
Appeals Court of Massachusetts
One Pemberton Square
Boston, MA 02108
(774) 254-7413
justin.dibiaskio@gmail.com

Health Law At-Large Committee

Lawrence Vernaglia
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 342-4079
lveraglia@foley.com

Susan Williams
Susan Williams
Associate General Counsel
Massachusetts Eye and Ear Infirmary
243 Charles Street
Boston, MA 02114
(617) 573-3008
Susan_Williams@meei.harvard.edu

Donna Levin
Massachusetts Department of Public Health
250 Washington Street
2nd Floor
Boston, MA 02108
(617) 624-5220
donna.levin@state.ma.us

Lawrence Litwak
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 502-3224
llitwak@foley.com

Clare McGorrian
22 Putnam Avenue
Cambridge, MA 02139
(617) 871-2139
cdmcgcounsel@verizon.net

Diane Moes
Donoghue, Barrett & Singal, P.C.
One Beacon Street
Suite 1320
Boston, MA 02108
(617) 598-6700
dmoes@dbslawfirm.com

Edward Deangelo
Commonwealth Health Insurance
100 City Hall Plaza
Boston, MA 02421
ed.deangelo@state.ma.us

Jesse Caplan
Epstein Becker & Green, P.C.
10 Chestnut Street
9th Floor
Worcester, MA 01608
(508) 368-9571
jcaplan@ebglaw.com

Joel Goloskie
goloskie@comcast.net

Quentin Palfrey
Office of the Attorney General
One Ashburton Place
Boston, MA 02108
(617) 963-2458
quentin.palfrey@state.ma.us

Health Law Education Planning Committee

Sam Senft
Boston Medical Center-Newton-
Medical Legal Partnership for Children
88 East Newton Street, Vose 5
Boston, MA 02118
sam.senft@bmc.org