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Section Co-Chairs' Corner

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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

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In light of the upcoming presidential election, the co-editors of The Boston Health Law Reporter solicited, for educational purposes, articles describing the health care policy proposals of Senator Barack Obama and Senator John McCain. The views expressed represent solely the opinions of the authors; the BBA does not endorse any political candidate or party, and The Boston Health Law Reporter is providing this information for educational purposes only. The authors are not advisors to either campaign, and a coin toss determined the order of the articles.

--Eds.

Senator Barack Obama's Health Care Plan: Providing Affordable, Quality Health Care Coverage For All Americans

By Tad Heuer, Esq. and Brooke Lierman[1]

The Continuing Health Care Crisis

In the United States today, almost 46 million individuals—including eight million children—have no health insurance,[2] despite annual national spending on health care well in excess of $2 trillion.[3] 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.[4] In fact, a new report found that one of every five families had difficulty paying their medical bills last year.[5] And, for those who rely on Medicare, premiums have more than doubled since 2000.[6] 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.[7] 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.[8]

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 employment-based coverage 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 that 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 for 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, he suggests, enable individuals to buy their own health care.

While alluring in its simplicity, the negative consequences of Senator McCain's plan could be enormous. First, because the tax exclusion greatly incentivizes employers to offer health insurance to their employees, ending the tax exclusion may encourage employers to eliminate the quality health care coverage that they offer currently. This may lead many healthy, young employees to drop their coverage, thereby increasing the cost of insurance for those who remain. Second, in order to qualify for the current tax exclusion, employers must provide all employees—regardless of their wages —with similar benefits, pursuant to IRS nondiscrimination regulations. Without the tax exclusion, nondiscrimination rules would not apply, and many low-income wage earners would potentially face the loss of their coverage.

If employers no longer have an incentive to offer health insurance to their workers, more individuals will likely find it necessary to purchase their insurance on the open market. Senator McCain's plan would provide individuals with a tax credit for this purpose, reimbursing them for some of the cost (the credit will be capped at $5,000 for a family). However, health care policies today cost much more than Senator McCain's proposed tax credit would cover. According to the Kaiser Family Foundation, the average annual cost of health insurance premiums is over $12,000 for a family of four with employer coverage.[17] Furthermore, insurers 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.

1 Although the authors support Senator Obama for President, they are not affiliated with the Presidential campaign and were not involved in developing Senator Obama's health care plan.
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5 Center for Studying Health System Change, Problems Paying Medical Bills Increase for U.S. Families Between 2003-2007 (2008), available at http://www.hschange.com/.
6 In 2000, the Medicare Part B premium was $45.50; in 2008, the Medicare Part B premium was $96.40.
7 See Executive Office of Health & Human Services, Div. of Health Care Finance & Policy, Health Care in Massachusetts: Key Indicators (2008) (noting that more than 439,000 new individuals have obtained health insurance in Massachusetts since the inception of health care reform in 2006).
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17 Henry J. Kaiser Family Foundation, supra note 4.

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.

First, the American health care delivery system should move into the 21st century. Too many health care providers still rely on paper records, paper prescriptions, and paper to order tests. All other areas of the American economy have long since moved to the digital age, but not health care. The government has a role to play here; it can oversee the development of health information technology standards. It can reward providers that adopt health IT and incentivize those who do not. It can ensure a smooth transition so that most Americans can have an electronic medical record in five years.

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-

icy that covers in-vitro fertilization, but in some states, that coverage is mandated. The competition that would be engendered by allowing purchase of coverage across state lines would dramatically lower the cost of insurance and according to recent findings reduce the number of uninsured by as much as 12 million individuals.

Finally, hard steps need to be taken to change the cost drivers in our system. Prescription drugs and biologic products are too expensive; this drives up the cost of health insurance. Developing a robust generic marketplace for follow-on biologics will be an important initiative of the next President. Creating systems that encourage coordinated care, such as "medical homes," will eliminate redundancies in the current health care system, especially for those with chronic medical conditions. Fostering the growth of walk-in clinics at retail outlets, such as the recent regulations promulgated here in Massachusetts, will help to limit costs and increase ease and convenience for individuals.

Portability

The American economy has changed dramatically since the end of World War II, when the current employment-based system of health insurance began. A soldier returning from the war who began raising a family in the late 1940s had a job where he would expect to work for the rest of his life. His salary, pension, and health insurance were provided by that employer.

Today, the average American has changed jobs three times by the age of 30. Many of us will work at seven to ten different jobs throughout our lives. But the employment-based health insurance system remains locked in that 1940s model. 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.

Washington Word: The Medicare Improvements for Patients and Providers Act of 2008

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.[9] 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.[10]

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.[11] 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.[12]

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% coinsurance otherwise applicable in Part B is 50% for beneficiaries with mental illness.[13] MIPPA gradually reduces beneficiary coinsurance for mental illness from 50% to the 20% otherwise applicable in Medicare by 2014.[14]

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.[15] 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.[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.[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.[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.[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.[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.[21] Combined, changes in the Medicare Advantage program under the legislation will reduce federal government spending by $13.6 billion over five years.[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: immunosupressants, anti-retrovirals, cancer medication, anti-depressants, anti-psychotic, and anti-convulsant medication.[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.[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.[25] Under the statute, the identification of drugs by the Secretary is a mandatory act.[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 entreaties 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.

1 Thomas Barker is the Acting General Counsel of the U.S. Department of Health and Human Services. The material contained in this article reflect solely Mr. Barker's views, and not necessarily the views of the U.S. Department of Health and Human Services or any other agency of the federal government.
2 An article in the Summer Edition of the Boston Health Law Reporter erroneously stated that the extension of the State Children's Health Insurance Program (SCHIP) enacted last December was accomplished through an override of the President's veto of that legislation. It was not. Congress overwhelmingly approved the Medicare, Medicaid and SCHIP Extension Act of 2007, Pub. L. No. 110-173, last December, and it was signed into law by the President. MIPPA is the only health care legislation enacted during President Bush's presidency over his veto.
3 U.S. Const., Art. I, Sect. 7, Cl. 2.
4 *See* Message to the House of Representatives Returning Without Approval the "Medicare Improvements for Patients and Providers Act of 2008," *reprinted* in 44 Wkly Comp. Pres. Doc 997 (July 15, 2008).
5 Other provisions of the legislation included revisions to the marketing rules for Medicare Advantage and Part D plans. Although significant, they are not discussed in the article because CMS was moving forward to implement many of these provisions on its own initiative in any event. The legislation merely codified the CMS regulations. *See* MIPPA § 103.
6 42 U.S.C. § 1395w-4(d)(4)(A).
7 42 U.S.C. § 1395w-4(d)(4)(B)(i).
8 *See* Pub. L. No. 110-275 (hereinafter, MIPPA) § 131(a)(1)(B) (codifying a 1.1% increase in physician payments at 42 U.S.C. § 1395w-4(d)(9)(A)).
9 42 U.S.C. § 1395w-4(m)(2)(A).
10 42 U.S.C. § 1395w-4(m)(3)(B)(i),(ii), and (iii).
11 *See* "Medicare To Save Average Of 26% For Some Durable Medical Equipment," available at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=2996&intNumPerPage=10&checkDate=&checkKey=2&srchType=2&numDays=0&srchOpt=0&srchData=durable+medical+equipment&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=1&pYear=&year=0&desc=&cboOrder=date (last visited September 14, 2008) (March 21, 2008).
12 *See* 42 U.S.C. § 1395w-3(a)(1)(D)(i)(I) (specifying damages, if applicable, to be paid from the Part B Trust Fund).
13 *See* 42 U.S.C. § 1395l(a)(1)(A) (providing payment for 80% of the expenses for medical and other health services) and 42 U.S.C. § 1395l(a)(3) (recognizing only 62.5% of expenses for "mental, psychoneurotic, and personality disorders"). 62.5% of 80% is 50%, the effective co-insurance rate for mental health services.
14 *See* MIPPA § 102 (revising 42 U.S.C. § 1395l(c)(1))
15 *See, e.g.,* Medicare Payment Advisory Commission, "Report to the Congress: Promoting Greater Efficiency in Medicare" at 58 (June, 2007) (finding that Medicare Advantage benchmarks in 2006 "averaged 116 of ... expected Medicare [fee for service] expenditures.").
16 42 U.S.C. § 1395w-23(a)(1)(B)(i).
17 *See id.* and 42 U.S.C. § 1395w-23(a)(1)(E).
18 42 U.S.C. § 1395w-24(b)(1)(C)(i) and (ii).
19 42 U.S.C. § 1395w-22(j)(6).
20 42 U.S.C. § 1395w-22(d)(5)(B).
21 *See* Congressional Budget Office, letter to Senator Judd Gregg (July 8, 2008), available at http://www.cbo.gov/ftpdocs/95xx/doc9550/hr6331GreggLtr.pdf (last accessed September 14, 2008).
22 *See* Congressional Budget Office, "Cost Estimate of H.R. 6331, Medicare Improvement for Patients and Providers Act of 2008" at 5 (July 23, 2008).
23 *See* Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Chapter 6, § 30.2.5 (listing six medication classes of clinical concern).
24 42 U.S.C. § 1395w-104(b)(3)(G)(i)(I).
25 *See id.* at subclause (II).
26 *See 42* U.S.C. § 1395w-104(b)(3)(G)(i) (noting that the Secretary "shall" identify the classes of drugs).

Local Health Law Briefs

By Melissa Lopes, Esq.

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 found that the statutory meaning of the phrase "comes to the emergency department" 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."

Matsuyama v. Birnbaum, 890 N.E.2d 819 (Mass. 2008)

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 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 reflux 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.

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