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Recent Developments

What a difference a quarter makes. When Ropes & Gray issued its last edition of *Health Reform Matters*, momentum appeared strong for comprehensive reform legislation. Proponents were still flush from two major health care legislative victories—reauthorization of the Children’s Health Insurance Program and enactment of a stimulus package with more than \$100 billion in health care spending—widely touted as a “down payment” on health reform. The House and Senate leadership had outlined orderly, systematic plans for committee and floor consideration of reform bills. The Senate Finance Committee had issued three thoughtful policy papers addressing the major areas of reform ([delivery system](#), [coverage](#) and [financing](#)) and was preparing to poll members and assemble a bipartisan bill for Committee consideration in June. By the August recess, according to these well-laid plans, both Houses would have passed their versions of the bill, leaving August to prepare for House-Senate negotiations in September. Indeed, there was talk in the air of final enactment by the end of the fiscal year—September 30.

While one should not be too surprised that this schedule has slipped, the dramatic turn in momentum during the August recess has taken supporters aback and emboldened opponents. The increasingly strident town hall meetings held across the country by Members of Congress have dominated media coverage of health reform and supplied endless hours of punditry fodder. While the month of July was marked by intensive efforts to find common ground in the Senate among a handful of Democratic and Republican negotiators—and, on the House side, among conservative and liberal Democrats—the prospect that these negotiations will pay dividends has measurably dimmed after the long August recess.

Instead, the talk is whether the Democratic leadership will abandon efforts at bipartisanship and move to pass a bill along straight party lines, using a procedural maneuver known as reconciliation. (We described this maneuver in the last edition of *Health Reform Matters*.) Some are urging splitting the package into two bills—one that contains popular consensus items (such as insurance regulatory reform) passed under the regular process with 60 or more votes to overcome a filibuster, and a separate reconciliation bill with the more controversial provisions (such as a public plan option) that would need only 50 Senate votes (plus the Vice President’s) for passage. This two-step process would require that technical issues be finessed—for instance, reconciliation bills must reduce the deficit within a five-year window rather than the ten-year period under which the current bills are being scored. And the rules would allow any provision deemed

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“not germane” to reconciling the budget to be stripped from the bill unless 60 Senators vote to retain it. Yet as hopes of finding common ground between the parties fade, reconciliation may be the Democratic leadership’s sole remaining option for passing a bill this year.

Before the August break, three committees in the House had each passed versions of H.R. 3200, *America’s Affordable Health Choices Act*. While the markups in the Ways and Means Committee and Education and Labor Committee were relatively smooth and quick, the Energy and Commerce Committee encountered stiff resistance from conservative Democrats concerned about spiraling deficits. After suspending the markup for ten days, Chairman Henry Waxman (D-CA) reconvened the Committee on July 30 having reached a deal to reduce the ten-year cost to less than \$1 trillion and to make the public plan optional. The Committee approved a bill the next day, just as the House adjourned for the August recess. More than 50 amendments, however, were left on the table, each of which the Chairman promised to address in September. The next step is for the three versions of H.R. 3200 to be melded into a single bill (with or without the unaddressed amendments) for floor consideration by the full House.

On the Senate side, the Health, Education, Labor and Pensions (“HELP”) Committee—the committee chaired by the late Senator Kennedy—also approved a bill in July, known as the *Affordable Health Choices Act*. Like the House bills, this legislation includes an individual mandate to obtain coverage with subsidies for low income individuals, the establishment of an insurance exchange through which

standardized coverage can be purchased at affordable rates, insurance regulatory reform, expanded Medicaid coverage and measures intended to hold down costs and reform the health delivery system. (These bills and related information can be found at Ropes & Gray's *Health Reform Resource Center* under "[Comprehensive Health Reform.](#)")

While the three House bills and the HELP bill were each adopted without Republican support, Senate Finance Committee Chairman Max Baucus (D-MT) has been doggedly (and, some would say, quixotically) pursuing bipartisan legislation, a goal that has proven more elusive than anticipated. With the "Gang of Six"—a group of three Republican and three Democratic Committee members—fruitlessly seeking to forge the basis for a compromise throughout July, Chairman Baucus finally had to concede that Finance would not be ready to vote on a bill before the recess. The month of August passed without any apparent breakthrough in the group's negotiations. Over the Labor Day weekend, however, Chairman Baucus released the [outlines](#) of a draft agreement, just days before President Obama is set to deliver what the White House intends as a game-changing nationally televised joint address to Congress on health reform. Given the intensifying partisanship on health reform that has built over the course of August, it is unclear whether any of these efforts will bear fruit. ■

In This Issue

Amidst these uncertainties, Ropes & Gray is releasing its third quarterly edition of *Health Reform Matters*. In this issue, we focus on a few substantive elements of the reform packages under discussion.

- In July, a debate broke out over the wide **geographic variations in health care spending** in different parts of the country, and whether to bend the proverbial cost curve by addressing the underlying causes of such variations. Many believe that Congress lacks the political will to undertake the kind of payment system reform necessary to accomplish this goal and thereby are looking to delegate Congressional authority to various independent bodies to make the tough choices. Please see the [article](#) exploring the competing proposals to tackle this issue.
- Employers, individuals and other taxpayers are likely to be affected by the various tax **provisions** in the legislation. Some are health related—designed either to enforce the individual mandate and employer insurance requirements or to discourage so-called "gold-plated" health plans. Others are pure revenue raisers, intended to offset the burgeoning costs of reform. We provide an [analysis](#) of the differences in

approaches between and within the two chambers, and their impact on our clients.

- Establishing a pathway for expedited regulatory approval of **follow-on biologics** has long been a goal of those seeking to hold down pharmaceutical costs, but safety, comparability and other concerns have made legislation difficult to pass. Now, the two committees with jurisdiction over the FDA have adopted similar provisions in their health reform bills. We describe the areas of controversy in this debate and the measures approved in committee to address them in the article, "[Reform Legislation Includes Regulatory Pathway for Follow-on Biologics.](#)"
- Massachusetts has already proven itself a laboratory for national health reform. Now it is again leading the debate with a sweeping recommendation to establish a common "**global payment**" system for all payers within the Commonwealth. Having successfully expanded coverage, Massachusetts is seeking to contain costs through fundamental payment system restructuring. A Ropes & Gray [analysis](#) of the recommendations was recently published by the Bureau of National Affairs and is previewed [here](#).

As the debate continues to unfold this fall, don't forget that Ropes & Gray's [Health Reform Resource Center](#) is a real-time, "one-stop shopping" source for legislation, amendments, summaries, reports, studies and other materials on the evolving legislation. We also continue to maintain an up-to-date [chart](#) tracking the implementation of funding programs established by the American Recovery and Reinvestment Act. While some of the stimulus money has been allocated, billions in health care funding remain available or are coming on-line for the first time. Our chart, readily available at the *Health Reform Resource Center*, is an excellent way to keep abreast of these developments.

And as always, do not hesitate to pick up the phone and call your regular Ropes & Gray attorney for more information on any aspect of health reform. We have a multi-disciplinary team closely tracking the policy, process and politics of health reform and can help you understand and prepare for its potential impact on your organization. ■

Proposals to Address Geographic Variations in Health Care Spending Gather Momentum, Provoke Controversy

Before the recess, the issue of geographic variations in health care expenditures became a key element in negotiations in both houses to

reach consensus on reform. Concern about such payment disparities has prompted Congress to weigh various proposals to reform Medicare payment policy both to eliminate the disparities and to promote value. At the same time, policymakers have questioned whether Congress has the political will to enact such significant payment changes or whether an independent body should be empowered to make the tough choices. Some view resolving this issue as key to meaningful reform of the health delivery system while others balk at the prospect of shifting authority for fundamental payment decisions to unelected and politically unaccountable officials. As Congress reconvenes, this is one of several controversial issues still to be tackled by negotiators in both Houses.

Geographic disparities in Medicare payments have been a perennial matter of Congressional concern, with “low cost” regions frequently at odds with “high cost” regions that receive higher per capita Medicare payments. However, concern about such disparities has attained new levels as Congress seeks to reform Medicare payments to reduce spending, improve quality and identify scorable savings that can be used to pay for expanded coverage. These efforts have intensified in the wake of a June 2009 *The New Yorker* article, “The Cost Conundrum,” by Atul Gawande, a surgeon and former health policy advisor to President Clinton, which highlighted a February 2009 study conducted by the Dartmouth Atlas Project.

The Dartmouth Atlas study found that the threefold variation in Medicare spending across different regions of the country is explained solely by the volume and intensity of care provided, and is not correlated with the price of discrete services, the distribution of illness, or the quality of the actual care delivered. Gawande’s article profiled health spending in the small border town of McAllen, Texas, where Medicare spending per person exceeds the average resident’s annual salary by \$3,000, while quality and outcomes lag behind lower cost areas, including El Paso, Texas, a demographically similar community a mere 800 miles along the border. The widely-read article is credited with prompting the recent spate of proposals to address Medicare payment variations and to eliminate politics from the Medicare payment process.

The proposals being discussed range from requiring the Institute of Medicine (“IOM”) to study and make recommendations to revise Medicare’s geographic adjustment factors to empowering an independent Medicare payment commission to adopt Medicare payment reforms unilaterally, subject only to the disapproval of Congress. These proposals—described in more detail below—could have a profound impact on provider payments, redistributing payments from high cost to low cost areas and realigning payments to promote quality and value. Depending on how the reforms are

structured, high cost providers—such as academic medical centers—could see a significant drop in funding. Of particular concern to many, the proposals could also dramatically curtail political influence over Medicare payment policies, making it exceptionally difficult for providers disadvantaged by such policies to redress their grievances through the political process.

IOM Recommendations to Revise Medicare Geographic Adjustment Factors.

The bills approved by all three House committees of jurisdiction direct the IOM to issue a report on the accuracy and effect of Medicare’s geographic adjustment factors (for hospital and physician payments) and to recommend modifications. The Secretary of Health and Human Services would then be required to include proposals based on the IOM’s recommendations in the next annual inpatient hospital prospective payment system (“IPPS”) and physician fee schedule rules. The legislation includes a two-year hold harmless provision under which no geographic adjustment factors would be reduced. Thereafter, the changes would need to be budget neutral (with payment reductions in some areas sufficient to offset increases elsewhere). The proposal has, to a large extent, pitted urban representatives against their rural counterparts, as most of any rural increase would likely come at the expense of urban providers and academic medical centers. Indeed, reports indicate that as many as 40 House Democrats are threatening to oppose the bill if it contains this provision.

IOM Recommendations to Adopt Medicare Payment Reforms to Promote Quality Care.

In a separate proposal, the House Ways & Means Committee adopted an amendment during its markup that would require the IOM to develop recommendations to promote “the efficient delivery of high quality, evidence-based, patient-centered care,” including the use of a “value index” based on a composite of measures of quality and cost. Under pressure from a coalition of moderate and conservative Democrats, House leaders reportedly later agreed to strengthen this amendment by requiring that the Secretary of HHS adopt the IOM’s proposals in rulemaking, which would become binding unless Congress adopted a joint resolution of disapproval by a certain date. Although this further provision was not reflected in any of the ensuing committee markups, Energy and Commerce Committee Chairman Henry Waxman (D-CA) stated on the record that he intends to add it before the bill reaches the House floor. More recently, however, rumors have circulated that the deal as reported is still under negotiation.

“IMAC.” In June, President Obama endorsed a proposal to create an Independent Medicare Advisory Council (“IMAC”), which would be granted broad authority to adopt Medicare payment reforms for the full range of providers and services, subject to Congressional disapproval. The President’s IMAC proposal sparked significant provider opposition, as well as resistance by Members of Congress from both parties, who are concerned that the proposal would strip Congress of its ability to influence Medicare payment policy. Support for the proposal has also waned in light of a low score issued by the Congressional Budget Office (“CBO”), which found that the IMAC would result in only \$2 billion in savings over a ten year period.

“Super MedPAC.” Despite the opposition to IMAC, negotiators from the Senate Finance Committee are reportedly interested in pursuing a modified version of the proposal. Although the Senate Finance Committee has yet to release its health reform legislation, Chairman Max Baucus (D-MT) has indicated that the Committee’s package is likely to include a “Super MedPAC” proposal, under which this long-standing advisory panel would be required to recommend changes that would achieve a specified level of annual reduction in the projected growth in program spending. According to press reports, that modification would result in scorable savings of up to \$35 billion, thereby fueling the inevitable concern that it would permit dramatic changes in Medicare payment without the approval of Congress.

If enacted, proposals of this nature could result in significant shifts in Medicare payment with virtually no Congressional oversight. Many in Congress are deeply opposed to such a shift in power, and the provider community likewise aspires to retain its ability to advocate directly to Congress for adequate funding. Yet several key Members of Congress view such a mechanism as essential to controlling costs and restructuring the delivery system, and say that they will not support a bill without it. As one of several pieces of the health reform puzzle still to be assembled, the future of the Medicare payment policy-making process remains up in the air as Congress returns to town. ■

Tax Changes Looming for Employers and Individuals through Health Care Reform

Although few details about a final reform bill are settled, one fact remains certain: if there is a bill, it will have to be paid for. While both chambers of Congress are counting on some form of health care savings to defray the overall cost, it is apparent that the final

bill will contain some changes to the tax code in an effort to forestall increases to the federal deficit and meet Congressional pay-go rules. Employers, among others, are well advised to pay attention to the debate on financing health reform as Congress reconvenes.

Based on the three versions of the bill that each of the three House committees of jurisdiction (Education and Labor, Energy and Commerce, and Ways and Means) reported out before the recess, it is likely that the tax proposals in the final House bill will affect both individual taxpayers and employers. The provisions embraced by these committees would impose an additional tax, not to exceed the average national premium for self-only health care coverage, on individuals who do not have “acceptable health insurance,” as well as an additional tax on individuals whose modified adjusted gross income exceeds a certain threshold (“surtax”). The proposed surtax would apply on a graduated basis starting at 1% and increasing to 5.4% and would be imposed on families and individuals with a modified adjusted gross income in excess of \$350,000 and \$280,000, respectively. Additionally, larger employers (i.e., those with payrolls that exceed a specified payroll threshold) will be required either to satisfy particular “health coverage participation requirements,” the details of which have yet to be finalized, or to pay an excise tax, based on the employer’s wage payments, of up to 8% of the employer’s average wages.

In the Senate, the Health, Education, Labor and Pensions (“HELP”) Committee has passed its version of the bill, but the Finance Committee has yet to do so. The HELP Committee’s version adopts less onerous tax penalties on those not complying with the coverage mandate. It requires individual taxpayers to have a statutorily specified set of benefits (“qualifying coverage”) or, alternatively, to pay a penalty in an amount at least equal to 50% of the average annual premium for a basic health plan. Additionally, the HELP bill requires that employers with more than 25 employees either provide qualifying coverage and pay at least 60% of the monthly premiums for such coverage or, as a penalty for noncompliance, pay \$750 for each full time employee or \$375 for each part time employee—which assessments would be less than the “percentage of wages” tax adopted on the House side.

Given the tenuous state of negotiations among the Finance Committee’s “Gang of Six,” it is impossible to predict what bill, if any, will ultimately emerge from the Committee. In particular, it is uncertain whether the Finance Committee will adopt an employer mandate or penalize employers that do not offer acceptable coverage. One alternative to the approaches adopted by the House committees and HELP is a so-called “free rider” provision.

This condition would require employers to reimburse the government for the cost of government-subsidized health care coverage obtained by their low-income employees under certain circumstances.

Tax-based revenue raisers are still very much the subject of negotiations within the Senate Finance Committee. Serious consideration is being given to levying a tax on insurance companies that offer insurance policies whose value exceeds a certain threshold, on the theory that the tax would both raise revenue and help hold down costs (by discouraging high-end policies that push up demand and prices). Other tax provisions that have been mentioned and may appear in the Finance Committee's final bill include: a limitation on or an elimination of the exclusion from taxable wages for employer-provided health care (e.g., insurance and medical expenses), a further limitation on the itemized deduction for medical expenses, and a ceiling on pre-tax health flexible spending account contributions or a limitation on the items eligible for reimbursement under those accounts.

A number of tax proposals have come and gone over the course of the health care reform debate this summer. The proposals discussed above, while far from certain, appear to reflect the direction that debate is now headed. Stay tuned for further developments once Congress reconvenes after Labor Day. If you would like to discuss the potential tax consequences of the various health proposals, please feel free to contact a member of our Tax & Benefits department or your regular Ropes & Gray advisor. ■

Reform Legislation Includes Regulatory Pathway for Follow-on Biologics

Citing the success of generic drugs in lowering prescription drug costs, health reform advocates have long argued for an abbreviated FDA approval process for “follow-on” or “biosimilar” versions of biologic products. Biologics, which are derived from living materials, involve highly complex molecular structures that are difficult to manufacture and virtually impossible to copy exactly. Thus, unlike generic versions of pioneer chemical drugs, a follow-on version of a biologic will almost certainly not be identical to the pioneer product it imitates. FDA has, therefore, taken the position that the existing abbreviated approval pathway for generic drugs is not appropriate for follow-on biologics. Although lawmakers' past attempts to create a new regulatory approval pathway for biosimilars have not succeeded, it now appears such a measure may be approved as part of comprehensive health care reform legislation.

Earlier this year, several competing bills that would establish a regulatory pathway for follow-on biologics were introduced in Congress. In July, two of them were approved as part of committee-passed reform bills. On July 13, the Senate Health, Education, Labor and Pensions Committee voted 16-7 in favor of adding biosimilars legislation co-sponsored by Sens. Orrin Hatch (R-UT), Michael Enzi (R-WY) and Kay Hagan (D-NC) as an amendment to its health reform bill (“[Hatch Amendment](#)”). Two weeks later, the House Energy and Commerce Committee voted 41-11 to adopt a similar amendment introduced by Rep. Anna Eshoo (D-CA) to its comprehensive health reform package (H.R. 3200) (“[Eshoo Amendment](#)”). Both votes are widely regarded as not only a win for the brand-drug industry, but also a defeat for competing bills proposed by Sen. Sherrod Brown (D-Ohio) (the “[Brown Bill](#)”) and Rep. Henry Waxman (D-CA) (the “[Waxman Bill](#)”), which were more favorable to the manufacturers of follow-on biologics. Below is a summary of the Hatch and Eshoo Amendments' positioning on key issues in the follow-on biologics debate.

- **FDA Approval Requirements.** The Hatch and Eshoo Amendments require makers of follow-on biologics to prove that their products have a sufficient degree of similarity to an approved pioneer biologic product (“reference product”) to obtain FDA approval. Specifically, evidence from analytic studies, animal studies and at least one human clinical study must show that the reference product and the follow-on biologic utilize the same known mechanisms of action, and that the administration, dosage and strength are the same for both products. Following the approval of the Hatch Amendment, Eshoo dropped a provision from her bill requiring FDA to issue product-class specific guidance documents setting forth the criteria it would use to determine biosimilarity prior to accepting applications. As currently drafted, both amendments permit, but do not require, FDA to issue guidance establishing requirements for specific biologic product classes, such as a requirement to withhold all approvals of follow-on biologics in certain product classes until warranted by “science and experience.”
- **Exclusivity for Pioneer Products.** The most hotly-contested issue in the debate over follow-on biologics concerns the duration of “non-patent exclusivity”—i.e., the time period after approval of an innovator biologic during which FDA is barred from approving a follow-on biologic that references the innovator biologic—that should be granted to pioneer biologic drugs. The Obama administration and Federal Trade Commission have suggested that seven years of exclusivity strikes the proper balance between encouraging innovation

and development of pioneer biologics and allowing lower-cost follow-on biologics to enter the market. The defeated Waxman and Brown Bills advocated five and seven years of data exclusivity, respectively. In contrast, the Hatch and Eshoo Amendments would grant pioneer biologics twelve years of non-patent exclusivity. The Eshoo Amendment also offers a six month extension for certain pediatric studies, and an identical provision has been proposed for the Hatch Amendment. Both Amendments would deny exclusivity to a pioneer biologic drug manufacturer seeking to “evergreen” a pioneer drug’s exclusivity period by filing a new application for a minor change to the product. While critics claim that the longer exclusivity period granted by the Eshoo and Hatch Amendments will unnecessarily slow the entry of low-cost alternatives to the biologics market, others see the twelve-year term as necessary to preserve incentives for innovation and development of these complex, cutting-edge products.

- **Exclusivity for “Interchangeable” Products.** The Hatch and Eshoo Amendments also grant limited exclusivity to certain first-to-market follow-on biologics with respect to later-developed follow-on biologics. Specifically, follow-on biologics that FDA first determines are “interchangeable” with a reference product will have an exclusivity period of 12 to 42 months with respect to later-developed biosimilars that are interchangeable with the same reference product. The Eshoo and Hatch Amendments define a product as “interchangeable” with a reference product if:
(1) it is biosimilar to a reference product; (2) the products are expected to produce the “same clinical result” in a patient; and (3) the risk of alternating or switching from the reference product to the interchangeable product is no greater than the risk of continuing to use the reference product. It is still unclear, however, how this “interchangeability” standard would differ in practice from standards for determining biosimilarity.
- **Patent Dispute Resolution.** Both Amendments encourage the resolution of patent disputes between pioneer biologic drug sponsors and follow-on biologic drug sponsors by requiring the parties to exchange written information about their products when a follow-on biologic sponsor applies for FDA approval. Under the Eshoo Amendment, within 30 days of applying for approval of a follow-on biologic, the applicant must provide the pioneer product sponsor with a copy of the application. The pioneer product sponsor must respond with a list of patents in which it holds an interest that may be infringed by the follow-on biologic, and the follow-on product applicant must reply to each listed item either by stating that

it will not commence marketing of the follow-on biologic until the expiration of the patent, or by explaining why the patent is not infringed or is invalid or unenforceable. While similar, the Hatch Amendment provides a more rigorous and comprehensive framework for patent dispute resolution that is more favorable to follow-on product sponsors than the Eshoo Amendment. For example, pioneer product sponsors must provide follow-on product sponsors with information about patents that may be infringed within 60 days after the follow-on product application is filed. Following this initial exchange the parties would continue to exchange detailed statements describing “on a claim by claim basis” why each patent is or is not infringed by the follow-on biologic drug. The parties are also obligated to engage in “good faith negotiations” (or, if negotiations fail, a prearranged dispute resolution process) to agree on which items will be the subject of an infringement suit. Under both Amendments, if the pioneer drug sponsor’s patent infringement suit succeeds, FDA will not approve the follow-on biologic product until the relevant patent expires. ■

Massachusetts Commission Proposes Sweeping Payment Changes

The state whose 2006 adoption of comprehensive health reform legislation helped set the stage for the current national debate is again exploring a major overhaul, this time of the provider payment system. On July 16, the Massachusetts Special Commission on Health Care Payments released its recommendations for reforming the way in which health care in the Commonwealth is paid for, by private and public payers alike. The Commission recommended a system of “global payments with adjustments to reward the provision of high quality and accessible care” as the best solution to contain rising health care costs while ensuring that patients receive the care they need. The Commission issued a harsh criticism of the existing fee-for-service model and explored how risk adjustment and pay-for-performance incentives could be used to maximize the benefits of global payments. The report also called for providers to be reconfigured into accountable care organizations with a focus on providing comprehensive primary care and coordinating services across treatment settings.

Although the Commission’s recommendations were issued pursuant to a legislative mandate, they are, nevertheless, just recommendations, and would need to be adopted by the legislature to be implemented. Even if a regime of global payment were adopted, Massachusetts would face significant implementation challenges, beginning with establishing the “oversight entity” to which the Report leaves many of

the finer details of restructuring. Reform plans would also need to address the complexities of risk adjustment between payers and providers, antitrust constraints on joint price negotiations by providers that are separately organized and would otherwise compete, as well as the need for federal waivers and exemptions from certain Medicare and fraud and abuse restrictions.

Given the significant obstacles to adopting more minor payment reforms on the national level (see, for example, the earlier article, [Proposals to Address Geographic Variations in Health Care Spending Gather Momentum, Provoke Controversy](#) describing efforts to delegate away from Congress the politically thorny task of adopting Medicare payment changes), it is unclear whether this Massachusetts proposal could serve as a model for national reform. Yet five years ago, the idea of mandating individual insurance coverage also seemed unrealistic. At the very least, the Commission's report lays out a vision for what may need to be a longer-term effort to change the payment incentives that drive excess and waste in the delivery of health care services.

Ropes & Gray attorneys have published an in-depth analysis of the Massachusetts proposal, summarizing the Commission's critique of the fee-for-service model, describing in detail how global payments would work under the Commission's proposal and laying out the implementation challenges ahead. Click [here](#) to view a copy of "Is Massachusetts Poised to Leap Ahead of the Curve on Health Care Cost Containment?" by Stephen Warnke, Dan Roble and Jane Willis published in the BNA Health Plan & Provider Report (8/26/09). ■

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