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Tenacity, Creativity and Results are the three words that best describe Shaheen & Gordon's approach to addressing complex legal issues. Our health care team closely monitors the rapidly changing legal environment so that our clients are prepared to meet the challenges of today as well as tomorrow. Relying on a wealth of experience, we offer practical advice and assist in implementing recommendations tailored specifically to meet the needs of both large and small health care clients.

FEDERAL DEVELOPMENTS**Affordable Care Act Implementation*****Health Insurance Marketplace Suffers from Significant Flaws in First Month***

One month after it opened to the public, the federal health insurance marketplace website, healthcare.gov, remains quite difficult to use. While the website's functionality has improved incrementally, fewer than one-third of users have had success in completing an application.

Contractors testifying before Congress have blamed each other and CMS for the failures, and the administration has appointed a team, headed by Jeffrey Zients, to supervise repair of the website. Mr. Zients has been holding weekly update calls with the media, and has promised that healthcare.gov will be running smoothly by the end of November. However, the last week of October saw two periods of time when the site was down for greater than 36 hours, and there remains a lot of work to be done. In light of the website's flaws, initial enrollment numbers, which will be announced soon, are expected to be quite small.

Anthem Will Permit Individual Policyholders to Renew Existing Plans

In October, Anthem sent letters to 22,000 individual plan policyholders notifying them that their current plans would be discontinued because they did not meet the requirements of the Affordable Care Act. On November 1, Anthem sent a second letter to individual policyholders informing them that they can renew their current plan if they act by November 15. These plans will cost more than the comparable marketplace plan, and tend to have higher deductibles, but policyholders will retain access to providers in the existing Anthem network rather than being confined to the "narrow" network offered in the health insurance marketplace. The existing plans may also cover certain prescriptions not covered by the Anthem plan offered in the marketplace. Those who qualify for premium or cost-sharing assistance, however, will need to purchase a plan through the marketplace to get those benefits.

Deadline to Comply with Individual Mandate Extended to March 31

As detailed in our September legal update, the individual mandate goes into effect on January 1, 2014. Under the mandate, those not exempt must purchase insurance or pay a penalty. On October 28, the Department of Health and Human Services announced that uninsured individuals who sign up for care through the marketplace by March 31, 2014, the end of the open enrollment period, will not need to pay a penalty for 2014, despite the fact that such coverage will not go into effect until May 1, 2014.

Small Business Health Insurance Marketplace Expected to Open in Late November

CMS recently announced that the small business health insurance marketplace will open at the end of November. As discussed in more detail in our October update, because the small business marketplace-based plans will use the same “narrow” network as the individual marketplace-based plans, but the price of such plans will be the same as Anthem’s ordinary small group plans purchased outside the marketplace, it appears that the only small businesses for which purchasing coverage through the New Hampshire marketplace will be advantageous are those that want to take advantage of the small employer health insurance tax credit.

Marketplace Plans Are Not Federal Health Programs for Purposes of Anti-Kickback Law

HHS has determined that qualified health plans purchased through the new health insurance marketplaces (as well as other programs related to the federally-facilitated marketplaces) are not considered federal health care programs for purposes of the anti-kickback law, which makes it a criminal offense to knowingly and willingly offer, pay, solicit, or receive any remuneration (including the transfer of anything of value) to induce or reward referrals of items or services reimbursable by a federal health care program. This determination covers plans in both state-based and federally-facilitated marketplaces.

However, substantial federal oversight and consumer-protection measures remain applicable to marketplace plans and programs, including the potential imposition of civil monetary penalties against non-compliant issuers in federally-facilitated marketplaces; Office of Inspector General authority to audit, investigate, and evaluate the programs and “affairs of an exchange”; and the federal False Claims Act, which applies to any “payments made by, through, or in connection with an Exchange if the payments include Federal funds.”

HHS’s determination appeared to open the door for the provision of premium and cost-sharing assistance for qualified health plan members by hospitals, health care providers, or other commercial entities. However, on November 4, 2013, CMS published a “Q&A” in which it stated that it has “significant concerns” regarding this practice, because it could skew the insurance risk pool. HHS subsequently clarified that it “discourages” the provision of premium and cost-sharing assistance by such entities and that it “intends to monitor this practice and to take appropriate action, if necessary.”

Mental Health Parity Rules Announced

On November 8, the U.S. Departments of Treasury, Labor, and Health and Human Services issued final regulations under the Mental Health Parity and Addiction Equity Act of 2008 (“MHPAEA”), defining the meaning of “parity” in benefits and treatment between coverage for mental health/substance use disorder benefits and medical/surgical benefits.

The final regulations follow interim final regulations issued in 2010 and “Frequently Asked Questions” issued in 2011, incorporate most of the guidance provided in those prior documents, and provide new clarifications. MHPAEA provides that financial requirements (including copayments and deductibles) and treatment limitations (including limits on the number of visits or days of coverage) that apply to mental health or substance use disorder benefits cannot be more restrictive than the predominant limitations and requirements that apply to substantially all of the medical/surgical benefits. Under the final regulations, this “substantially all/predominant” test must be separately applied to six classifications of benefits: inpatient in-network; outpatient in-network; inpatient out-of-network; outpatient out-of-network; emergency; and prescription drugs. Plans may use a sub-classification for “office visits” within the outpatient classifications.

The final regulations also contain significant detail on the application of MHPAEA's parity requirement to utilization review processes, such as requirements for concurrent review, step therapy, and prior authorization. (These are known as nonquantitative treatment limitations ("NQTs").) In particular, NQTs applied to mental health or substance use disorder benefits must be comparable to and applied no more stringently than those for medical/surgical benefits, taking into account the processes, strategies, evidentiary standards, and other factors used by the health insurer to determine whether and to what extent a benefit is subject to an NQTL. However, they need not be identical.

The final regulations clarify that geographic, type of facility limitations, and network adequacy must be comparable between medical/surgical benefits and mental health/substance use disorder benefits. In particular, the final regulations provide that parity applies to intermediate levels of care received in residential treatment or intensive outpatient settings.

The final regulations also make clear that the definitions of "benefits" include benefits for items as well as services. They provide, consistent with the ACA, that lifetime and annual dollar limits on employee health benefits are prohibited with respect to mental health or substance use disorder benefits covered by employee health plans. They make clear that group health plans providing mental health or substance use disorder benefits to the extent required by the ACA are not required to provide additional mental health or substance use disorder benefits.

The final regulations apply to small and large group health plans and individual health insurance coverage (with the exception of grandfathered small group plans), including policies available in the health insurance marketplace. The rules do not apply to Medicare and Medicaid, although CMS has previously issued guidance directing states to meet MHPAEA parity requirements in administering Medicaid. The final regulations take effect for plan or policy years beginning on or after July 1, 2014.

Government Reopens

On the evening of October 16, the final day before the government was expected to run out of borrowing authority, the House and Senate agreed to reopen the federal government and extend the debt limit. The short-term agreement funds the government through January 15 and extends the debt limit through February 7. The House and Senate Budget Committee chairpersons agreed to sit down together to negotiate a budget agreement by December 13. Budget negotiations opened on October 30, and are continuing.

Rules Change for Flexible Spending Accounts

In late October, the IRS announced an optional change to the "use it or lose it" rules for health care flexible spending accounts ("FSAs") that will make them more worthy of the moniker "flexible." Plans are now permitted to adopt a "carryover" provision, under which employees can carry over up to \$500 of unused balances remaining at year end to the immediately following plan year, to be used to pay or reimburse medical expenses incurred throughout the entire plan year to which it is carried over. Employees will still be permitted to contribute up to \$2,500 each year, and the carryover of up to \$500 does not affect the maximum contribution amount.

To adopt the carryover, a plan must be amended. Plan amendments must be adopted on or before the last day of the plan year from which amounts may be carried over, and may be effective retroactively to the first day of that plan year. Furthermore, a plan may be amended to adopt the carryover

provision for a plan year that begins in 2013 at any time on or before the last day of the plan year that begins in 2014.

There is a catch, however. Plans wishing to adopt a carryover must eliminate any “grace period” under which the prior plan year’s balance can be used for expenses incurred in the first two months and fifteen days of the subsequent plan year. For example, a plan permitting a carryover to 2015 of unused 2014 health FSA amounts would not be permitted to have a grace period in 2015, but would be permitted to have had a grace period in 2014 (for amounts remaining from 2013). An amendment to eliminate a grace period provision must be enacted by no later than the end of the plan year from which amounts may be carried over. Note, however, that plans with a carryover are still permitted to retain a “run out” period of up to three months during which expenses incurred during the prior plan year can be submitted and paid out of that prior year’s contributions before they are carried over (and before any amounts above the carryover limit are forfeited).

Accordingly, employers without grace periods can modify their plans now to permit, starting with the current plan year, annual carryovers of up to \$500 (or a lesser amount chosen by the employer) to the subsequent plan year. Federal tax law, furthermore, would not prohibit even those employers whose plans have a grace period to make such an amendment for the current plan year, provided that the grace period was eliminated. However, because eliminating a grace period that was previously adopted for the existing plan year (and upon which employees may be relying) could violate other provisions of law and/or employee expectations, employers whose plans currently have a grace period, and who wish to adopt a carryover instead, are advised to adopt amendments that take effect as of the following plan year and to announce these changes during open enrollment so that they are clear to employees before they elect an amount to contribute. That is, an employer with a calendar year plan and grace period feature that wishes to change to a carryover should, no later than December 31, 2013, adopt amendments effective for plan year 2014 that eliminate the grace period for 2015 (with regard to unused 2014 health FSA amounts) and permit a carryover to 2015 of such amounts, up to \$500. Lastly, plans that provide nonelective contributions from the employer should consult with counsel before adopting a carryover feature.

2014 Social Security and Retirement Contribution Thresholds Announced

In late October, the Social Security Administration and Internal Revenue Service issued their annual updates for 2014.

The maximum amount of earnings subject to social security taxes will increase to \$117,000 from \$113,700. Social Security and Medicare tax *rates*, however, are unchanged from 2013.

The maximum amount of salary an employee may contribute annually to a 401(k) or 403(b) plan is unchanged at \$17,500, with those over age 50 being able to contribute an additional \$5,500. The maximum annual contribution to an IRA is similarly unchanged at \$5,500, with those over 50 being able to contribute an additional \$1,000.

The annual gift tax exclusion will remain \$14,000, and the lifetime estate/gift tax exclusion amount will rise to \$5,340,000.

Small Employer Health Insurance Tax Credit

As our September update detailed, for two tax years starting in or after 2014, certain small employers that purchase health insurance in the health insurance marketplace are entitled to a tax credit of up to 50% of the cost of insurance. The IRS has announced that for 2014, the percentage of the credit available to businesses will begin to decrease for businesses with average wages above \$25,400, up from \$25,000.

Physician Fee Schedule

CMS was scheduled to release the final Physician Fee Schedule for 2014 around November 1. However, the timely issuance of the final rule has been delayed while CMS determines the impact of the government shutdown on the schedule. CMS recently announced that it will seek to issue the final Physician Fee Schedule on or before November 27, 2013.

Long-Term Revisions to Medicare Physician Payment System

As discussed in our September Legal Update, the House and Senate are considering legislation that would change how Medicare pays physicians. On October 31, the Chairpersons of the House Ways & Means and Senate Finance Committees released a joint proposal for a new Medicare physician payment reimbursement system. The proposal would replace the existing fee for service system with a "value-based performance system" focused on medical outcomes. Baseline payments to physicians would be frozen for ten years, but would be adjusted based on performance starting in 2017. Quality would be measured using already-existing quality measurement systems, namely the Physician Quality Reporting System, the Value-Based Modifier, and the Electronic Health Record Meaningful Use program. How these metrics would translate into payments has yet to be determined.

Under the proposal, alternative payment models (such as accountable care organizations and "patient-centered medical homes") involving shared risk and quality payments would be encouraged, and physicians would get a 5% bonus payment annually from 2016 through 2021 if they obtained a significant share of revenues through such alternative payment models. The proposal would provide a permanent solution to the need for annual end-of-year legislation to avoid sharp cuts in Medicare payment to physicians, by eliminating the "sustainable growth rate" formula in current law (under which Medicare payments to physicians would be reduced by nearly 25% in 2014). If the proposal becomes law, it will make substantially more certain the determination of physician payments under Medicare going forward.

OIG Advisory Opinions

The U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued two advisory opinions in the past month. These are:

- Advisory Opinion 13-13 (concluding that a non-profit community health services organization that provides free dental services for needy children would not face monetary penalties or anti-kickback law sanctions if it began seeking reimbursement from Medicaid for services provided to Medicaid beneficiaries).
- Advisory Opinion 13-14 (concluding that a county's proposal to waive bona fide county residents' otherwise applicable cost-sharing amounts in connection with emergency ambulance services, and instead to use tax revenues to cover the unpaid amounts, would not result in permissive exclusion from participation in federal health-care programs or sanctions under the anti-kickback law).

NEW HAMPSHIRE DEVELOPMENTS

Medicaid Expansion Commission Recommendations

On October 15, the Medicaid Expansion Commission issued its Final Report on the expansion of Medicaid eligibility. The panel recommends that New Hampshire expand Medicaid through several private and public programs, covering approximately 49,000 adults aged 19-64 and earning up to 138% of the federal poverty level.

Newly eligible adults with access to insurance through their employer would be required to remain on their employer's private insurance plan, and the State would subsidize the employee's premium costs under the State's group coverage premium assistance program, known as the Health Insurance Premium Program (HIPP). Expansion through HIPP would require the New Hampshire Department of Health and Human Services to seek a waiver from CMS. For those newly eligible adults earning between 100% and 138% of the federal poverty level who are not eligible for HIPP, assistance would be provided through the State's Individual Premium Assistance Program. The Commission recommended that the New Hampshire Medicaid Care Management Program be available only to those individuals who are not eligible to participate in HIPP or the Individual Premium Assistance program. They would be required to choose a plan offered by one of the three MCOs currently under contract with the State.

Finally, the Commission recommended that if the federal government reduced its support, it would trigger a requirement that the Legislature reauthorize the New Hampshire Medicaid Expansion Program within six months. Failure to act would result in the automatic discontinuation of the program at the end of that six-month period.

The Commission's proposal still needs the approval of both the House and Senate. The legislature returned to Concord on Thursday, November 7 to begin a two-week special session to resolve the issues. Public hearings will take place the week of November 12, and final votes the next week. Private discussions have also been ongoing between Governor Maggie Hassan, Senate President Chuck Morse, and House Speaker Terie Norelli.

New Hampshire to Receive \$3.8 Million in Johnson & Johnson Settlement

On November 4, 2013, New Hampshire joined with other states and the federal government to settle civil and criminal allegations against Johnson & Johnson and one of its subsidiaries regarding off-label promotion for their second generation antipsychotic drugs, Risperdal and Invega. As part of this settlement, New Hampshire will receive \$3.8 million in restitution and other recovery.

The settlement resolves allegations that from January 1999 through December 2005, the companies made false and misleading statements about the safety and efficacy of Risperdal and paid illegal kickbacks to health care professionals and long-term care pharmacy providers to induce them to promote or prescribe Risperdal to children, adolescents, and the elderly, when the FDA had not approved Risperdal's use in these patient populations. The states had also alleged that from January 2007 through December 2009, the companies promoted Invega for off-label uses and made false and misleading statements about the safety and efficacy of Invega. The alleged unlawful conduct caused false and/or fraudulent claims to be submitted to, or caused purchases to be made by, government funded health care programs, including the state Medicaid program.

Governor Establishes Review Team to Look at Mental Health Crisis

Governor Hassan recently announced that she has set up a team to review “the crisis in our emergency rooms” after two violent incidents involving mentally ill patients being held in hospital emergency departments while waiting for a bed to open at the state’s psychiatric facility. In a letter to Health and Human Services Commissioner Nicholas Toumpas, Governor Hassan explained she asked former Supreme Court Justice Joseph Nadeau to lead a Sentinel Event Review team to look at both of the recent incidents and the broader questions that they raise. Other issues the review team will examine include which resources are being used for varying levels of acuity, how psychiatric emergencies are triaged, what level of training is provided to staff of local hospital emergency departments regarding treatment of acute psychiatric distress, what circumstances are leading to the rise in the number of patients experiencing acute psychiatric distress in the state’s emergency rooms, and what steps are necessary to minimize the risk of harm to patients and staff.

Justice Nadeau will have the support of Dr. Alexander P. de Nesnera, from the Geisel School of Medicine and the Associate Medical Director of the New Hampshire Hospital, and Senior Assistant Attorney General Michael Brown. The team will report its findings to Governor Hassan and Commissioner Toumpas. They have not been given a deadline to complete their work, but have been asked to proceed “as expeditiously as possible.”

Legislative Update

Health, Human Services and Elderly Affairs

HB 597, relative to mandatory drug testing for certain health care workers. At the end of October, the House Health, Human Services and Elderly Affairs Committee unanimously recommended that the state require all hospitals to test employees if there is “reasonable suspicion” that they are under the influence of a controlled drug. As originally written, the bill would have required hospitals and other health care facilities to randomly test every employee for drugs four times each year. While there would not be a monetary penalty for facilities that do not adopt the required testing policy, the policy would be part of the standard that must be met for licensure. The policy covers employees and anyone who provides care to patients, including independent contractors supplied by staffing agencies.

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Cinde Warmington, Clara Dietel, and Benjamin Siracusa Hillman contributed to this month’s Legal Update.

BIOS

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Cinde, a partner at Shaheen & Gordon, leads the Health Care Practice Group and focuses her practice entirely on representing health care clients. Her prior clinical and administrative experience makes her uniquely qualified to assist providers in facing a rapidly changing regulatory environment.

CLARA DIETEL

Clara advises health care providers on a variety of health related regulatory issues, with a focus on HIPAA compliance. She also practices in the area of civil litigation, representing health care providers in state and federal court.

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