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Staying Well Within the Law

A newsletter on the current legal issues facing today's health care industry

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Health Care Reform

Recently signed by President Obama, the Patient Protection and Affordable Care Act (PPACA) and its companion bill, the Health Care and Education Reconciliation Act of 2010 (HCERA), will in some form directly impact virtually all Americans and American employers. At more than 2,500 pages in length, the Act is detailed, complex and contains many provisions with both immediate and long-range changes to how Americans receive health care. Understanding and interpreting these sweeping changes is a top priority for all health care providers.

To help our clients sort through the myriad of issues and changes, we dedicate this issue of "Staying Well Within the Law" to addressing the key elements of reform that are applicable to health care providers and employers. We will cover fraud and abuse changes, reform requirements for charitable hospitals, reform timeline for employers, reform impact on employer-sponsored health plans and the physician payment sunshine provisions.

We encourage you to contact the authors of this issue of "Staying Well Within the Law" or any member of the Health Law Practice with questions you may have regarding the PPACA.

Fraud and Abuse Provisions in the PPACA

by William H. Maruca

The Patient Protection and Affordable Care Act gives the government significant new ammunition to help curb fraud and abuse, including an additional $350 million of fraud enforcement funding over 10 years, a third of which is allocated to the 2011 budget year. The Act may also clear the way for expansion of the False Claims Act and *qui tam* whistle-blower cases to situations where they would not have applied under previous law. Coupled with the Obama administration's statements about a renewed emphasis on curbing fraud, waste and abuse in health care, these changes suggest that enforcement efforts using these powerful tools will be on the increase. Stark Law changes are a mixed bag, requiring a new self-disclosure protocol and permitting some variation in penalties, and also requiring more public disclosures and transparency.

In This Issue:

False Claims Act Changes

Anti-Kickback violations are deemed to be False Claims Act violations. Previously, it was also necessary to show that a false statement was made, i.e., the certification that the provider was in compliance with applicable laws. Hospitals have been required to make such certifications for years, but physicians generally are not required to do so. The Act resolves a contentious issue that has been handled differently in different federal circuits. This change, along with changes to the anti-kickback law's intent standard, may make False Claims and *qui tam* actions more common.

Retention of Overpayments. The PPACA expanded on changes made by the 2009 Fraud Enforcement and Recovery Act (FERA), under which so-called "reverse false claims" are prohibited. FERA imposed penalties on any person who knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government. PPACA requires that an overpayment must be reported and returned under paragraph (1) by the later of 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due, if applicable. Any overpayment retained by a person after the deadline for reporting and returning such an overpayment is defined as an "obligation" subject to FERA.

Public Disclosure Bar. A *qui tam* case may not be brought unless the relator (whistle-blower plaintiff) is the "original source" of the underlying information. This is to prevent so-called "parasitic" cases where a whistle-blower files a suit based on information reported in the media or in administrative actions that reveal fraudulent activities. The PPACA makes it easier for a whistle-blower to qualify as the original source and file suit. Courts are directed to dismiss claims based on allegations or transactions that were publicly disclosed in a federal criminal, civil or administrative hearing in which the government or its agent is a party; in a congressional, Government Accountability Office or other federal report, hearing, audit or investigation; or from the

news media, unless the action is brought by the attorney general or the person bringing the action is an original source of the information. An "original source" is an individual who has voluntarily disclosed to the government the information on which allegations or transactions in a claim are based prior to a public disclosure, or who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the government before filing a *qui tam* action. The Act removes the requirement that the relator have "direct and independent knowledge."

This change will impact situations like those in the recent U.S. Supreme Court decision in *Graham County Soil and Water Conservation District v. U.S. ex re. Wilson*, in which the Court held that the existing False Claims Act prohibits suits based on disclosures made in state and local administrative actions as well as federal actions. The court rejected the whistle-blower's position that the statute's provisions barring actions based on "Congressional, administrative or GAO report, hearing, audit or investigation" should be interpreted as applying only to federal administrative matters. The court also noted that the PPACA changed this provision by limiting the exception to federal sources and removed the vague term "administrative," but only prospectively, so their ruling will apply to all pending cases.

Under the new law, a whistle-blower may bring an FCA suit based on info learned in a state or local administrative proceeding in some circumstances.

Payments Under Exchanges Subject to FCA. PPACA provides that payments made by, through or in connection with the state exchanges to be established under the Act will be subject to the False Claims Act if those payments include any federal funds. This means the FCA, and its *qui tam* enforcement mechanism, will apply to a variety of claims submitted to and reimbursed by payors beyond Medicare and Medicaid.

Anti-Kickback Statue (AKS) Changes

The anti-kickback statute provides criminal penalties for individuals and entities that knowingly offer, pay, solicit or receive bribes or kickbacks or other remuneration in order to induce business reimbursable by federal health care programs. Civil penalties, exclusion from participation in the federal health care programs and civil False Claims Act liability may also result from a violation of the prohibition. To establish a violation, the government must prove the defendant acted "knowingly." The PPACA added a provision that clarifies that with respect to violations of the AKS, "a person need not have actual knowledge of this section or specific intent to commit a violation of this section." This change overturns a series of judicial interpretations that set a higher standard under which prosecutors had to prove the specific intent to disobey the law.

Stark Law Changes

Ownership Disclosure. Referring physicians are required to inform patients in writing that they have ownership or compensation relationships with providers of in-office ancillary services and inform them that they may obtain the specified service elsewhere. Details are murky, and CMS is expected to provide guidance in regulations.

Self-Disclosure Protocol. The Secretary of HHS, in cooperation with the OIG, is required to develop a Stark violation self-disclosure protocol within six months of enactment of the Act. OIG had previously refused to accept such disclosures involving only Stark violations.

Physician-Owned Hospitals. No new physician-owned hospitals will be allowed to participate in Medicare unless they have a provider agreement by December 31, 2010. Those existing physician-owned hospitals grandfathered as of this date will not be permitted to expand their capacity or add more physician owners after this year.

Factors for Reduced Penalties. Finally, some good news: the Secretary is also directed to consider reduced penalties for Stark violations, based on:

1. The nature and extent of the improper or illegal practice;
2. The timeliness of such self-disclosure;
3. The cooperation in providing additional information related to the disclosure; and
4. Such other factors as the Secretary considers appropriate.

That change may mean that purely technical violations where the guilty party comes clean may not be subject to the draconian maximum penalties under current law ($15,000 per claim submitted where a prohibited financial relationship exists). Note that FCA penalties may also apply to Stark violations in many situations.

For more information about this topic, contact William H. Maruca at 412.394.5575 or wmaruca@foxrothschild.com.

Post PPACA Patient Billing: What Does a Nonprofit Hospital Need To Know Now?

by Elizabeth G. Litten

Although portions of the PPACA governing health insurance coverage and rating requirements are familiar to carriers, health care providers and patients in the context of individual health coverage and small employer health benefits plans, and other portions are reminiscent of or similar to laws affecting the provision or payment of health care services, there are key differences that affect nonprofit acute care hospitals.

Section 9007 of the PPACA looks innocuous enough, titled simply "Additional Requirements for Charitable Hospitals." However, this section revokes a charitable hospital's tax-exempt status under Section 501(c)(3) of the Internal Revenue Code of 1986 if the hospital fails to meet any of the following requirements:

- Community health needs assessment requirements;
- Financial assistance policy requirements;
- Limitations on charges requirements; and
- Billing and collection requirements.

Community Health Needs Assessment

Section 9007 does not include a great deal of detail on how these requirements are to be met, but does state that the community

health needs assessment must actually be conducted once every three years (in the taxable year or in either or the two years preceding the taxable year), and the hospital must adopt an "implementation strategy to meet the community health needs identified" by the assessment. The assessment must take into account input from "persons who represent the broad interests of the community served" by the hospital, including those with a knowledge of or expertise in public health, *and must be made widely available to the public.*

Financial Assistance Policy

The hospital's financial assistance policy must be a written policy that includes:

- Eligibility criteria for financial assistance and whether the assistance includes free or discounted care;
- The basis for calculating amounts charged to patients;
- The method for applying for financial assistance;
- If the hospital does not have a separate billing and collections policy, the actions the hospital may take in the event of non-payment, including collections actions and reporting to credit agencies; and
- Measures to *widely publicize the policy within the community to be served by the hospital.*

Limitations on Charges

Hospitals must have a limitation on charges policy that limits amounts charged for emergency or other medically necessary care provided to individuals eligible for assistance under the financial assistance policy to amounts that are not more than those charged to individuals who have insurance covering such care. In addition, hospitals are prohibited from "the use of gross charges." The "Technical Explanation of the Revenue Provisions of the `Reconciliation Act of 2010,' as Amended, in Combination With the `Patient Protection and Affordable Care Act'" prepared by the Staff of the Joint Committee on Taxation dated March 21, 2010 (JCT Report), explains this requirement as follows:

> Each hospital facility is permitted to bill for emergency or other medically necessary care provided to individuals who qualify for financial assistance under the facility's financial assistance policy no more than the amounts generally billed to individuals who have insurance covering such care. A hospital facility may not use gross charges (i.e., "chargemaster" rates) when billing individuals who qualify for financial assistance. It is intended that amounts billed to those who qualify for financial assistance may be based on either the best, or an average of the three best, negotiated commercial rates, or Medicare rates. [JCT Report, p. 82]

Other portions of the PPACA may work to prevent insured patients from facing unexpectedly high (and potentially unaffordable) bills, but it remains to be seen how the various parts of the PPACA will be interpreted by the responsible agencies and how these various parts may ultimately correlate to one another. For example, Section 2719A of PPACA, "Patient Protections," provides that emergency services must be covered by health plans and health insurers in a manner that does not discriminate against a patient having accessed the services at a hospital that is not participating in the carrier's network—the carrier may not require prior authorization or limitations in coverage related to the patient's having received emergency services at a non-network hospital. In addition, the patient's "cost-sharing requirement (expressed as a copayment amount or coinsurance rate) … [must be] the same requirement that would apply if such services were provided in-network." These provisions may be interpreted in a manner that would, at least for emergency services, effectively eliminate the need (or perhaps, ability) for the hospital to bill even insured patients high amounts, regardless of the patient's eligibility under the hospital's financial assistance policy.

Billing and Collection

The requirements related specifically to billing and collection prohibit the hospital from engaging in "extraordinary" collection actions before the hospital has made "reasonable efforts" to determine whether the patient is eligible for assistance under the financial assistance policy.

A charitable hospital might be tempted to roll through these requirements and assume that the hospital's charity care eligibility policy satisfies these new PPACA requirements or that its current financial assistance policy will satisfy these new requirements for continuation of the hospital's tax-exempt status. However, even a hospital with a well-publicized and routinely implemented financial assistance policy may fail to meet the requirement that it cap charges to qualified patients to Medicare rates (or to the best, or an average of the three best, negotiated rate(s)) paid for the service or supply. Worse, a hospital that merely determines whether a patient qualifies for charity care may be overlooking a large portion of its patient population that is underinsured or whose individual financial circumstances warrant a determination of eligibility for financial assistance, despite the existence of in-force health insurance coverage.

If, for example, a hospital finds that an insured patient is liable for a high deductible or coinsurance amount, it must determine whether the patient qualifies for financial assistance before it bills the patient, as eligibility for financial assistance impacts the amount permitted to be billed. The hospital also may not use a collection agency to collect unpaid amounts from a patient until the hospital makes "reasonable efforts" to determine whether the patient qualifies for financial assistance. Regulations adopted by the Internal Revenue Service are likely to provide additional guidance on issues such as whether insured patients who may have high out-of-pocket liability despite their insurance coverage must be screened for financial assistance eligibility or the manner in which the hospital must "widely publicize" its financial assistance policy to its community.

Penalties for Noncompliance

Penalty for noncompliance is high: loss of tax-exempt status, compounded by a penalty (or "excise tax") of $50,000 per year for failure to satisfy the community health needs assessment requirements. As more fully explained in the JTC Report:

> Failure to complete a community health needs assessment in any applicable three-year period results in a penalty on the organization of up to

$50,000. For example, if a facility does not complete a community health needs assessment in taxable years one, two or three, it is subject to the penalty in year three. If it then fails to complete a community health needs assessment in year four, it is subject to another penalty in year four (for failing to satisfy the requirement during the three-year period beginning with taxable year two and ending with taxable year four). An organization that fails to disclose how it is meeting needs identified in the assessment is subject to existing incomplete return penalties…*

PPACA Section 4959 requires a tax-exempt hospital to report to the IRS not only information regarding its community health needs assessment ("a description of how the organization is addressing the needs identified in each community health needs assessment conducted … and a description of any such needs that are not being addressed together with the reasons why such needs are not being addressed") but also to provide the IRS with its audited financial statements or, if applicable, audited consolidated financial statements.

In short, what may appear at first glance to be a relatively innocuous portion of the PPACA is worth a close and careful analysis by nonprofit hospitals seeking to preserve tax-exempt status and avoid costly penalties.

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*[Footnote regarding effective date and imposition of penalties] For example, assume the date of enactment is April 1, 2010. A calendar year taxpayer would test whether it meets the community health needs assessment requirement in the taxable year ending December 31, 2013. To avoid the penalty, the taxpayer must have satisfied the community health needs assessment requirements in 2011, 2012 or 2013.] [JTC Report, p. 81; 83]

Health Care Reform Timeline for Employers

By William H. Maruca

As has been highly publicized, the PPACA will have a major impact on American businesses. Employers of all sizes are scrambling to understand the myriad incentives, restrictions, mandates and penalties to which they will now be subjected.

This article is intended to be an executive summary of the new law's most significant points impacting employers.

While some provisions will have immediate impact, others are being grandfathered such as group health plans or health insurance coverage arrangements for individuals enrolled on the date the law was passed.

To Go Into Effect Right Away:

1. Small employers with fewer than 25 full-time employees with average annual compensation levels not exceeding $50,000 per FTE may claim a tax credit for up to a portion of their employee health care coverage expenses. The credit is phased out based on employer size and employee compensation. This credit is effective for tax years beginning after December 31, 2009. The credit is equal to 35% of the total nonelective contributions made by the employer for payment of premiums for qualified health insurance coverage of its employees, but not more than the average premium for the applicable small group market in the employer's state as determined by the Department of Health and Human Services (HHS). The maximum credit is available to employers with 10 or fewer employees with average compensation of $25,000 or less.
2. As of March 23, 2010, all employers must provide break time and an appropriate location for nursing mothers to express milk for children up to one year of age. Such break time is not required to be paid time.
3. Effective on June 21, 2010, employers are prohibited from encouraging individuals to elect the newly offered high-risk pool coverage instead of employer plans. HHS is also required to create a program to reimburse employer plans for certain medical expenses incurred by early retirees ages 55-64.

To Go Into Effect on or After Sept. 23, 2010:

1. Health plans that offer dependent coverage must offer such coverage though age 26. Grandfathered plans are not required to cover adult children through age 26 if the dependent is eligible for other employer-sponsored coverage. Note that there is no obligation to offer any dependent coverage, nor are there any details about how a plan may classify a subscriber's child as a "dependent," other than to prohibit age caps lower than 26.
2. Lifetime limits on health benefits will no longer be permitted, excepting specific nonessential benefits.
3. Health plans (other than grandfathered plans) must implement an approved internal and external appeals process.
4. The Act extends IRC Section 105(h) nondiscrimination requirements to nongrandfathered insured plans.
5. No pre-existing condition exclusions will be permitted for children under age 19.
6. Nongrandfathered plans must provide preventative care (such as immunizations and preventative screenings) on a first-dollar basis (no co-pays or deductibles).
7. Nongrandfathered plans must cover emergency services without prior authorization and at in-network benefit levels.
8. The controversial practice of "rescission" is limited. Coverage cannot be cancelled except for fraud or intentional misrepresentation. Anecdotally, some insurers were alleged to have engaged in detailed "scrubbing" of applications for minor errors or omissions as the basis for cancelling coverage, particularly for patients who experienced costly claims.
9. All nongrandfathered plans must allow employees to select their own primary care doctor and cannot require that a woman receive permission before seeing an OB/GYN. This is already the law for managed care plans in Pennsylvania under Act 68.

To Go Into Effect in 2011:

1. As of January 1, 2011, over-the-counter medications will no longer be eligible for reimbursements under health flexible spending accounts (FSAs), health savings accounts (HSAs) or medical savings accounts (MSAs) without a prescription.
2. Adults with pre-existing conditions will be eligible to join a temporary high-risk pool, which will be superseded by health care exchanges once they are established in 2014.
3. In 2011, employers with more than 200 full-time employees must automatically enroll eligible employees in their health plans or provide notice of opt-out options. This requirement is subject to the issuance of Department of Labor regulations.

To Go Into Effect in 2012-2013:

1. By March 23, 2012, nongrandfathered health plans must report whether the plan satisfies quality of care measurements to be developed by the Department of Health and Human Services.
2. By March 23, 2012, notices of material modifications must be distributed to plan beneficiaries within 60 days of changes. Plans must provide an HHS-approved summary prior to enrollment.
3. As of January 1, 2013, health FSA contributions will be limited to $2,500. The employee compensation deduction under IRC Section 162(m) is capped at $500,000 for certain health insurance providers. The tax deduction for Medicare Part D plans is eliminated.
4. By March 1, 2013, employers must notify employees of their coverage options, including exchanges and the possibility of subsidy assistance.

To Go Into Effect in 2014:

1. The year 2014 is when the teeth of the Act start to bite. An assessable payment, sometimes called the "Free-Rider Penalty," may apply to employers with at least 50 full-time employees during the preceding calendar year. "Full-time employees" are defined as those working 30 or more hours per week, excluding full-time seasonal employees who work for less than 120 days during the year. The payment will only be assessed if at least one full-time employee obtains coverage through one of the new exchanges and receives a premium credit. Those credits will be made available to individuals who are not offered employer-sponsored coverage and who are not eligible for Medicaid or other programs. To be eligible, the individuals must have income between 138 percent and 400 percent of the federal poverty level. (Employees who are offered employer-based coverage at premiums that exceed 9.5 percent of their household income, or with the employer picking up less than 60 percent of the cost, may also get credits). The credits can be applied toward purchase of coverage through an exchange. The effect is to incentivize, but not require, employers to provide a minimum level of affordable coverage to employees who do not have the opportunity to join other employer-based group plans, such as through a spouse's employer. Employers whose credit-eligible employees get nonexchange-based coverage elsewhere will not be penalized.
2. The monthly penalties start at the number of full-time employees in excess of 30 employees who get premium credits multiplied by 1/12 of $2,000 for any applicable month. A premium adjustment index applies after 2014. Large employers can have up to 30 employees claiming credits without penalty.
3. The penalty may be avoided if the employer offers a "free choice voucher" to qualified employees equal to the amount the employer would have paid for individual or family coverage, as elected by employee.
4. State-based Health Benefit Exchanges will replace the temporary high-risk pool. Qualifying individuals will be eligible for credits that can be used to purchase insurance through the exchanges.
5. No pre-existing condition exclusions may be imposed on any participant.
6. Waiting periods cannot exceed 90 days.
7. The tax credits for certain small employers increase up to 50 percent of the premium costs.
8. No annual claims limits in health plans except for specific covered benefits that are not "essential health benefits."
9. Annual out-of-pocket maximums are limited for HSA-compatible High Deductible Health Plans (HDHPs) to $2,000 single coverage/$4,000 family coverage.
10. Annual reports to the IRS and participants regarding minimum essential coverage including the amount paid by employer will be required.
11. Employers with an average of 100 or fewer employees will be allowed to purchase insurance through the exchanges. States can treat employers with 50 or fewer employees as small for plan years beginning before 2016.

To Go Into Effect in 2017:

Large employers (with at least 101 employees) will be allowed to buy coverage through exchanges.

To Go Into Effect in 2018:

The "Cadillac Tax," a 40 percent excise tax on high-end coverage valued in excess of thresholds to be established, will begin to apply.

Even More Regulations and Policies Ahead

The two laws that comprise the health reform package total 961 pages of small print, but that is just the tip of the iceberg. Administrative agencies including the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, the Department of Labor, the Government Accountability Office and various state agencies will need to implement these changes by issuing regulations and policies. Such regulatory efforts often take years after legislation is passed. In the meantime, midterm elections may shift the balance of power in Congress and further legislative tinkering is possible, although outright repeal is unlikely. Make no mistake: change is coming, and some changes are already here.

For more information about this topic, contact William H. Maruca at 412.394.5575 or wmaruca@foxrothschild.com.

Health Care Reform: Impact on Employee Welfare Benefit Plans

by Keith R. McMurdy

The PPACA lays out a wide variety of changes taking place in the coming years regarding health benefits coverage. Reams of paper will be dedicated to explaining the costs and tax implications as well as the impact on employers and designing implementation. But there are some immediate changes that will impact employers that sponsor employee welfare benefit plans. The purpose of this article is not to explain every detail of the new law or to lay out all of the required changes. Rather, it is intended to explain how employers as plan sponsors will now be obligated to implement changes once the regulations are actually written that explain them.

Before the PPACA, there was no federal program making health care coverage available to all individuals, and the concept of a "qualified health plan" did not exist. We had used the term "qualified" to refer to ERISA health plans, meaning that they qualified for treatment as an employer-sponsored health plan that has preferential status under the tax code. Most people believed (incorrectly) that the term "qualified" meant self-funded. Now, we have a new standard by which health plans will be measured, thereby "qualifying" them as sufficient under the terms of the PPACA.

Generally, it appears that for the most part, the funding status of the plan is of little significance for most of the regulations. So whether it is an insured plan, self-insured or self-funded, it still has to meet these "qualifications." ERISA "qualified" status will still have some significance for the purpose of preemption of state law. But for the remainder of this discussion, the term "qualified" will mean what it does under the PPACA.

Defining a "Qualified Health Plan"

For purposes of the PPACA, a "qualified health plan" is a "health plan" that has in effect a certification that the plan meets certain criteria for certification, issued or recognized by each Exchange (which have yet to be created) through which the plan is offered that provides the "essential health benefits package." The term "essential health benefits package" means a plan that provides for "essential health benefits" and does so at either a bronze, silver, gold or platinum level of coverage (i.e., benefits that are actuarially equivalent to 60 percent, 70 percent, 80 percent or 90 percent (respectively) of the full actuarial benefits provided under the plan). The "essential health benefits" must include at least the following general categories (sometimes referred to as "minimum essential coverage") and the items and services covered within the categories:

- Ambulatory patient services;
- Emergency services;
- Hospitalization;
- Maternity and newborn care;
- Mental health and substance use disorder services, including behavioral health treatment;
- Prescription drugs;
- Rehabilitative and habilitative services and devices;
- Laboratory services;
- Preventive and wellness services and chronic disease management; and
- Pediatric services, including oral and vision care.

What this means is that at some point, we can anticipate that plan sponsors will have to have their plans "certified" as "qualified," demonstrating that they provide "essential health benefits" under an "essential health benefits package."

Defining a "Health Plan"

To the extent ERISA gives us the definition of a "welfare benefit plan," the new law gives us an additional term that differentiates from other welfare benefit packages. The term "health plan" means both "health insurance coverage" and a "group health plan." The funding status is irrelevant. It becomes a function of whether that plan provides the health benefits required to be "qualified."

The term "health insurance coverage" means benefits consisting of medical care (provided directly, through insurance or reimbursement or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract or health maintenance organization contract offered by a health insurance issuer. And the term "health insurance issuer" means an insurance company, insurance service or insurance organization (including a health maintenance organization) licensed to engage in the business of insurance in a state and subject to state law that regulates insurance. However, a health insurance issuer does not include a group health plan.

The term "group health plan" has the same meaning given that term by Section 2791(a) of the Public Health Service Act, which provides that:

> "The term "group health plan" means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. §1002(1)]) to the extent that the plan provides medical care (as defined in paragraph (2)) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise."

So this gives us clarification that the PPACA recognizes that there are ERISA welfare benefit plans that provide health benefits and they are now officially classified as "group health plans." This is important because it should serve as the distinction between whether an employer is offering a "group health plan" and whether an individual has "health insurance coverage." An employer may be offering coverage through a health insurance issuer as the means of funding the benefit, but in fact the employer is sponsoring a "group health plan" and not "health insurance coverage."

Oddly, except to the extent specifically provided by the PPACA, the term "health plan" does not include a group health plan or multiple employer welfare arrangement (MEWA) to the extent the plan or arrangement is not subject to state insurance regulation under Section 514 of ERISA. What this means is that funding IS important for understanding when the new rules apply. Self-funded, self-insured and multiemployer plans are not subject to state insurance regulation. Therefore, in order for the new laws to apply to these plans, the new law

actually has to specify that it applies to them. We will be looking for phrases such as "*as if included in the Code and ERISA*" to tell us when these ERISA benefit plans are impacted. For example:

No Lifetime or Annual Limits

Generally, ERISA plans are not subject to the Public Health Service Act, and insurance companies issuing policies to individuals are not subject to ERISA. The Department of Labor enforces ERISA and not the Public Health Service Act. Those lines are now blurred.

Under the 2010 Health Care Reform Act, the provisions of Part A of Title XXVII of the Public Health Service Act (PHSA)—Sec. 2701 through Sec. 2737, as amended by the Act—apply to (i) "group health plans" and (ii) "health insurance issuers" providing "health insurance coverage" in connection with group health plans, as if included in the Code and ERISA. PHSA Section 2711 is amended to provide that:

> A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish—
>
> (A) lifetime limits on the dollar value of benefits for any participant or beneficiary; or
>
> (B) except as provided in paragraph (2), annual limits on the dollar value of benefits for any participant or beneficiary.

By inserting the reference to ERISA and the Code, PHSA Section 2711 is incorporated into those laws by reference, meaning that self-insured or multiemployer "group health plans" are now subject to this restriction. The DOL can now require plans within its jurisdiction to comply with the PHSA requirement of no lifetime or annual cap.

Extension of Dependent Coverage

The same holds true for extension of dependent coverage until age 26. PHSA Section 2714 provides that any group health plan or a health insurance issuer that offers group or individual health insurance coverage that provides coverage of dependent children, must continue to make dependent coverage available for an adult child (who is not married) until the child turns 26 years of age. This would include ERISA plans by reference.

Some other interesting observations about this new law:

- There is no requirement for a plan or issuer to provide health insurance coverage for anyone, including dependents. But if coverage is provided for dependent children, then the coverage must continue until the children turn 26.
- Presumably, an adult child would have to continue to meet the plan's definition of "dependent"—other than the otherwise applicable age requirement—to remain covered under the group health plan up until age 26. Remember that the tax code has a definition of "qualifying relative" and "qualifying child" that might counteract this definition.
- Nothing in the rule above will require a health plan or a health insurance issuer to make coverage available to a child *of a child* receiving dependent coverage.

Conclusion

These two examples are not the only changes that plans will have to make, either in 2010 or for subsequent plan years. But as a starting point, we can now see how the "health plans" that employers sponsor as ERISA employee benefit plans will be required to comply with the PPACA going forward. Plan sponsors (that is employers sponsoring welfare benefit plans) are encouraged to actively seek out advice and guidance on what changes have to be made to their plans to make sure that they do not run afoul of ERISA or the PPACA.

For more information about this topic, contact Keith R. McMurdy at 212.878.7919 or kmcmurdy@foxrothschild.com.

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Physician Payment Sunshine Provisions: Making Payments to Physicians Publicly Available

by Dean H. Wang

While the PPACA contains numerous provisions addressing many aspects of the health care industry, it also includes certain provisions that were in previous unsigned bills regarding the disclosure of payments to physicians by pharmaceutical and medical device companies—also known as the "physician payment sunshine provisions."

Under Section 6002 of the PPACA, medical device companies, pharmaceutical companies and group purchasing organizations, beginning in 2012, will be required to disclose information concerning payments or other transfers of value that exceed $10 in a single occurrence or $100 in a calendar year that are made to physicians and teaching hospitals. Transfers of value include honoraria, travel expenses, funding, royalties, charitable donations, gifts and other items of value. Companies subject to these disclosure requirements are defined under the PPACA as companies operating in the United States that engage "in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply)." A drug, device, biological or medical supply is considered "covered" when it is subject to payment under a federal health care plan like Medicaid, Medicare or Children's Health Insurance Program (CHIP). When disclosures are made, the Secretary of Health and Human Services will then publish this information on a searchable and downloadable web site, which will be available to the public.

The first deadline for these disclosures will be on March 31, 2013, and companies will

be required to make annual disclosures for each year thereafter. The information required to be disclosed include the following:

1. Identity of the recipient;
2. Recipient's specialty;
3. Business address of the recipient;
4. Amount and date of payment or transfer of value;
5. Form and nature of the payment or transfer of value;
6. Product must also be identified if payment or transfer of value relates to marketing, education or research of a drug, device, biological or medical supply.

In addition, manufacturers and group purchasing organizations will be required to disclose information on whether physicians and/or their immediate family members own any interest in these entities. Such information required to be disclosed includes the dollar amount of the investment, the terms of the investment and whether any payments were made as a result of the ownership interest.

Failure to make annual disclosures could result in civil penalties ranging from $1,000 to $10,000 for each unreported payment, transfer of value or ownership interest. Knowingly failing to report a payment, transfer of value or ownership interest could result in a penalty from between $10,000 to $100,000 for each payment. In addition, the PPACA will preempt state laws requiring similar disclosures unless such states require more information to be disclosed than what is required under the PPACA. Thus, the PPACA will function as a standard for minimum disclosures but states will be permitted to require additional disclosures not required under the PPACA. Furthermore, under the PPACA, additional regulations may be passed that may broaden the scope of the disclosures currently in effect.

When companies begin tracking such disclosures in 2012, many may find that multiple, small payments (or gifts) may become cost-prohibitive due to this new disclosure requirement and may instead choose to make payments in less frequent but larger sums. Due to the increased scrutiny and the accessibility of this information, many physicians may also begin re-evaluating their current relationships with pharmaceutical or medical device companies. While the effects of the PPACA remain to be seen, the PPACA has become law, and pharmaceutical and medical device companies must comply with these provisions or face stiff penalties for inadvertent and knowing violations.

For more information about this topic, contact Dean H. Wang at 609.844.3036 or dwang@foxrothschild.com.

About the Health Law Practice

Fox Rothschild's Health Law Group comprises more than 50 attorneys who counsel clients locally, regionally and nationally. Our multioffice, multidisciplinary approach allows us to offer practical, cost-effective solutions to issues faced by longstanding stakeholders, as well as a variety of industry newcomers.

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