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News for North Carolina Hospitals
from the Health Law Attorneys of Poyner Spruill LLP

Proposed Affordable Care Act Regulations are Designed to Encourage Participation in Wellness Programs

by Laura Russell

With the conclusion of the 2012 elections, federal agencies now are releasing proposed regulations crucial to the implementation of the Patient Protection and Affordable Care Act (the Affordable Care Act). On Tuesday, November 20, 2012, the Department of Labor, the Department of Health and Human Services, and the Treasury Department issued proposed regulations that deal with incentives for nondiscriminatory wellness programs in group health plans. These proposed regulations were published in the November 26, 2012, issue of the Federal Register, which can be found at https://www.federalregister.gov/articles/2012/11/26/2012-28361/incentives-for-nondiscriminatory-wellness-programs-in-group-health-plans.

Wellness programs have been on the rise around the country for quite some time. Mercer, the world's largest human resource consulting firm, reportedly has observed that wellness initiatives currently are employers' top long term strategy for controlling health spending by encouraging employees to maintain better health. Mercer's recent annual survey found a sharp increase in the use of incentives and/or penalties to encourage employee participation in wellness programs. Recognizing that the implementation and expansion of employer wellness programs may offer the opportunity to not only improve the health of Americans but also help control spending, the Obama administration's proposals are designed to further encourage employers to offer such programs to their employees.

The proposed regulations implement changes in the Affordable Care Act that codify the existing HIPAA rules allowing employee wellness programs to offer an incentive for achieving a health standard, the most common incentive being a reduction in the employee's premium contribution. The proposed regulations increase the maximum allowable amount of the incentive from the 20% currently allowed by the HIPAA rules to 30% of the cost of employee-only coverage under the plan, and up to 50% for wellness programs designed to prevent or reduce tobacco use. It is important to emphasize, however, that these increased reward limits do not take effect until plan years beginning on or after January 1, 2014 (which will be even later for a non-calendar-year plan).

The proposed regulations also include other clarifications and enhancements to existing law. They address both recognized categories of wellness programs – "participatory wellness programs" and "health-contingent wellness programs." "Participatory wellness programs," which constitute the majority of wellness programs, generally are available to all employees regardless of their health status, and they either do not provide an award or they do not include any conditions for obtaining the award that are based on an individual satisfying a standard that is related to a health factor. Examples of participatory wellness programs include those where the reward is reimbursement for fitness center memberships, or a participatory award to employees who attend health-related seminars or complete a health risk assessment (without requiring them to take further action). Participatory programs are not required to meet the requirements applicable to health-contingent wellness programs.

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Proposed Rules Implementing Affordable Care Act Rules Prohibit Discrimination by Health Insurers and Set Standards for Essential Health Benefits

by Wilson Hayman

On November 20, 2012, the Department of Health and Human Services (HHS) issued proposed rules under the Patient Protection and Affordable Care Act of 2010, as amended (the Affordable Care Act or the Act), which beginning in 2014 will prohibit health insurance companies from discriminating against individuals because of a pre-existing or chronic condition. The rules were published in the Federal Register on November 26, 2012. The rules also outline standards related to the coverage of essential health benefits and actuarial value while providing significant flexibility to states to determine how these terms will be defined. A set of rules addressing employment-based wellness programs in group health plans published by HHS at the same time are discussed in a separate article in this issue of *Corridors*. This article will summarize the contents of the two other sets of rules implementing the Affordable Care Act. Although not specifically directed toward hospitals, these rules when finalized will affect hospitals as employers and indicate the direction of health care reform.

Market Reforms and Expanded Access to Health Insurance

Under the proposed rule found at https://www.federalregister.gov/articles/2012/11/26/2012-28428/patient-protection-and-affordable-care-act-health-insurance-market-rules-rate-review, health insurance companies offering products in the small group and individual markets may as of 2014 vary premiums within limits, but based only on age, tobacco use, family size and geography. Insurers would be prohibited from denying coverage to any American because of a pre-existing condition or from charging higher premiums to certain enrollees because of their current or past health problems, gender, occupation, and small employer size or industry. However, an individual employer may calculate an employee's contribution for non-grandfathered health insurance coverage (i.e., plans in which consumers were not enrolled as of adoption of the Act) either based on the average, per-employee rate for all its participating employees, as most employers do today, or based on a percentage of the underlying cost of the employee's coverage, which would increase the cost to older employees or smokers.

The proposed rule requires insurers offering individual or group plans to renew or continue coverage at the option of the plan sponsor or individual, with limited exceptions such as termination because of nonpayment of premiums, material breach by the plan sponsor, or the employer has ceased to belong to an association through which it participates in a group plan.

While catastrophic coverage is permitted for individual plans, it is catastrophic coverage with a twist. Consistent with the Affordable Care Act, the proposed rule requires that such policies provide all the essential health benefits (as defined below) once the annual limitation on cost sharing has been met, and provide coverage for at least three primary care visits per year before reaching the deductible. Catastrophic coverage is permitted only for individuals under the age of 30, or those who have received a certificate of exemption because they have no affordable coverage or for reason of hardship pursuant to 42 USC § 18022(e)(2)(B). Such a policy may not impose any cost-sharing requirements (copayment, coinsurance or deductible) for preventive services. This portion of the rule is intended to ensure access to this type of catastrophic coverage for people for whom coverage in the individual market would otherwise be unaffordable.

Standards for Essential Health Benefits

The second proposed rule found at https://www.federalregister.gov/articles/2012/11/26/2012-28362/patient-protection-and-affordable-care-act-standards-related-to-essential-health-benefits-actuarial is designed to promote consistency among plans and thus help consumers compare non-grandfathered private health insurance options in the individual and small group markets. The proposed rule was the result of many thousands of comments received from a wide variety of stakeholders including states, health insurers, small businesses and consumers, as well as studies by the Institute of Medicine and the Department of Labor, and gives states more flexibility in implementing the Affordable Care Act. The rule describes policies and standards for coverage of "essential health benefits" (EHB), which term means a core set of items and services that gives consumers a consistent way to compare health plans in the individual and small group markets. As a part of the Affordable

Care Act's attempt to give Americans access to quality, affordable health insurance, the Act requires that individual and group policies offer EHB in at least the following ten categories: ambulatory patient services, emergency services, hospitalization, maternity and newborn care, treatment of mental health and substance abuse, prescription drugs, rehabilitation and habilitative services and devices, laboratory services, preventive and wellness services and chronic disease management, and pediatric services (including oral and vision care).

Because the Affordable Care Act requires the EHB to be equal in scope to benefits offered by a "typical employer plan," the rule requires states to select a benchmark plan from among several options. All plans that cover EHB must offer benefits that are substantially equal to the benefits offered by the benchmark plan. A state's options for the benchmark plan include the following: (i) the largest plan by enrollment in any of the three largest products in the state's small group market; (ii) any of the three largest state employee health benefit plans by enrollment; (iii) any of the largest three national Federal Employees Health Benefits Program plan options by enrollment; and (iv) the largest insured commercial HMO in the state. If the benchmark plan is missing any of the ten statutory categories for EHB listed in the prior paragraph, then the benchmark plan must be supplemented in that category.

An appendix to the proposed rule provides HHS' list of proposed EHB benchmark plans for each of the fifty states. For North Carolina, HHS proposes the plan from the largest small group product, Blue Cross and Blue Shield of North Carolina's Blue Options PPO, as the benchmark. As a supplemental category for North Carolina, the rule proposes the Federal Employees Dental and Vision Program (FEDVIP) as the benchmark for the categories of pediatric oral and pediatric vision.

Determination of Actuarial Value

The second proposed rule also addresses the calculation of actuarial value (AV), which is the percentage of total average costs for covered benefits that a health plan will cover based on the provision of EHB. As of 2014, health plans in the individual and small group markets that are not grandfathered must meet (within 2 percentage points) the following AVs, or "metal levels," prescribed by the Affordable Care Act: 60 percent for a bronze health plan, 70 percent for a silver plan, 80 percent for a gold plan, and 90 percent for a platinum plan. The intent is that these tiers will allow consumers to compare plans requiring the same level of cost sharing. Health plans may offer catastrophic-only coverage with a lower AV for certain eligible individuals.

HHS has developed a proposed AV calculator, posted on The Center for Consumer Information & Insurance Oversight's (CCIIO) website, http://cciio.cms.gov/resources/files/Files2/02242012/AV-csr-bulletin.pdf, for insurers to use in determining health plan AVs based on a national, standard population. Under the proposed rule, however, insurers may beginning in 2015 use state-specific data sets for the standard population, if the state has submitted alternate data for the calculator that have been approved by HHS.

The initial response from the insurance industry has been not overly critical. The public comment period for both sets of proposed rules ends on December 26, 2012.

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Court Rejects Novant's Challenge to CON Policy AC-3 for Academic Medical Centers

by Pam Scott

The North Carolina Court of Appeals recently affirmed a final agency decision to award a CON for a new ambulatory surgical facility to North Carolina Baptist Hospital (Baptist Hospital), on the basis that the petitioners failed to show that the approval of the project substantially prejudiced their rights. The decision in *Novant Health, Inc. v. N.C. DHHS* underscores prior opinions over the past several years in which the Court of Appeals has held that to successfully challenge approval of a noncompetitive CON application, a petitioner must prove more than competitive impact in order to establish that its rights have been substantially prejudiced. Otherwise, any alleged errors in approval of the health service or facility, such as nonconformity with CON criteria, essentially are harmless as a matter of law.

This case involved an appeal from a decision awarding a CON to Baptist Hospital for a new ambulatory surgery facility under Policy AC-3 of the State Medical Facilities Plan, which establishes special criteria for evaluation of a CON application made by an academic medical center. Novant Health, Inc., challenged the approval of Baptist Hospital's application in large part by contending that it was substantially prejudiced because Policy AC-3 gave Baptist Hospital an unfair competitive advantage by allowing it to develop additional ORs when other providers in Forsyth County could not do so.

This decision illustrates the now well-established law developed by the Court of Appeals that a petitioner challenging approval of another provider's noncompetitive CON application must show substantial prejudice through proof that amounts to something more than existing market conditions and competitive impact. Any petitioner challenging a decision to approve a non-competitive CON application would be well advised to consider this line of cases carefully in developing and presenting evidence in its case. *To read the full version of this article, please visit our website and click on the Winter issue of* **Corridors.**

Is Your Company E-Verify Compliant?

by Jennifer Parser

In June 2011, North Carolina joined the ranks of an increasing number of states requiring the use of E-Verify. E-Verify is a free Internet-based system that allows employers to determine employment authorization by checking an employee's documentation against Department of Homeland Security (DHS) and Social Security Administration (SSA) databases. It applies to certain federal contractors but is also being adopted and required by states, regardless of whether federal contracts are involved.

North Carolina Now Requires Most Private Employers to Enroll in E-Verify

North Carolina counties, cities and public universities have already been required to register and participate in E-Verify since October 1, 2011. Private sector employers' participation in E-Verify is being phased in more slowly, according to the employer's size:

- Employers with 500 or more employees were required to participate by October 1, 2012;
- Employers with 100 or more employees will be required to participate by January 1, 2013; and
- Employers with 25 or more employees will be required to participate by July 1, 2013.

E-Verify Primer for Federal Contractors

Private businesses in North Carolina are required to verify the employment eligibility of current employees, regardless of the above phased-in legislation, if the employer has been awarded a federal contract on or after September 8, 2009, that contains the Federal Acquisition Regulation (FAR) E-Verify clause. Such federal contractors must enroll in E-Verify within 30 days of the contract award date regardless of the business' size. After enrollment, the federal contractor has 90 days to use E-Verify. The federal contractor must then use E-Verify for new hires within three business days of the employee's start date.

E-Verify must also be used for existing employees assigned to work on the federal contract within 90 days of the federal contract being awarded or within 30 days of the employee's assignment to work on the federal contract, whichever is later. For existing employees to be required to be run through E-Verify, the employee must perform substantial work under the federal contract, which does not include administrative or clerical functions. There are a few exceptions to enrolling in E-Verify as a federal contractor, the main one being if the federal contract pertains to commercially available off the shelf items.

Unless the subcontractor is a supplier and not subject to the E-Verify federal contractor rule, a federal contractor is required to ensure that its subcontractors enroll in and use E-Verify if:

- The prime contract includes the FAR E-Verify clause;
- The subcontract is for commercial or noncommercial services or construction;
- The subcontract has a value of more than $3,000; or
- The subcontract includes work performed in the United States.

A Few Important Rules for Every Business Enrolled in E-Verify

- Post the notices that the business is now enrolled in E-Verify alongside antidiscrimination notices by the Office of Special Counsel for Immigration-Related Unfair Employment Practices.
- When completing the I-9 form, the employee's choice of a List B document must contain a photograph in order to be run through E-Verify.
- Do not use E-Verify selectively.
- Do not use E-Verify to prescreen job applicants; it is used post-hiring.
- Do not ask for additional documentation in the event of a "Tentative Nonconfirmation" by E-Verify, but allow the employee time to correct any error by visiting the local SSA office.
- Do not terminate or take adverse action against an employee who receives a tentative nonconfirmation, but allow them time to correct the error.

Penalties, Federal- and State-Imposed

There have been substantial fines levied for immigration-related offenses by Immigration and Customs Enforcement (ICE) against employers enrolled in E-Verify, proving enrollment in E-Verify will not save an employer from potential violations.

Civil penalties for violations of North Carolina's E-Verify law are assessed by the NC Commissioner of Labor and range from $1,000 to $10,000.

E-Verify Link

Unless already enrolled in E-Verify as a federal contractor or subcontractor or having elected to do so on a voluntary basis, private sector North Carolina employers with 25 or more employees should not delay in visiting E-Verify website and enrolling by the mandatory enrollment dates listed above at http://www.uscis.gov/portal/site/uscis/menuitem.

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N.C. Court of Appeals Weighs In on Key CON Litigation Issues

by Pam Scott

Poyner Spruill LLP

The North Carolina Court of Appeals recently made clear that a certificate of need (CON) applicant's submission of additional information after its application has been filed does not constitute a forbidden amendment unless it materially changes the proposal set forth in the application. The CON regulation prohibiting amendments of applications has been around for over 30 years, but it has rarely been interpreted by our appellate courts. The no-amendment rule has often been a basis for attack against CON applicants who submit any supplemental information after their applications have been filed and deemed complete by the CON Section of the Division of Health Service Regulation. In a recent opinion in *WakeMed v. N.C. DHHS* (COA11-1558), the Court of Appeals rejected the notion that the CON Section's consideration of any additional information submitted by an applicant after an application has been deemed complete constitutes a prohibited amendment requiring disapproval of the application. Instead, the Court held that the proper test is whether the additional information materially changed representations made in the application.

At issue in the *WakeMed* appeal were competitive applications for operating rooms (ORs) in Wake County, and the Division of Health Service Regulation's decision to award a CON for three ambulatory ORs to Holly Springs Surgery Center (HSSC), a subsidiary of Novant Health, Inc. Rex Hospital, Inc. d/b/a Rex Healthcare (Rex), whose competing application was denied, argued that HSSC's application should not have been approved because it was impermissibly amended after being filed and deemed complete. Rex based this argument on HSSC's submission of several subsections of the application and a letter of support from an orthopedic physician practice as attachments to its responsive comments during the CON review, approximately two months after the application was deemed complete by the CON Section. Both the subsections and support letter had been inadvertently omitted from HSSC's application when it was originally filed.

The Court of Appeals disagreed with Rex's theory that the test for whether a CON application has been amended should be whether the Agency "considered" information provided after the application was filed. Instead, the Court harkened to the single case in which it previously held that an application had been impermissibly amended. In that 1996 *Presbyterian-Orthopedic Hospital v. N.C. DHHS* case, the Court of Appeals had concluded that the CON applicant made a material amendment to its application when it changed the management company that would oversee the operations of its proposed facility, because all the applicant's logistical and financial data was based upon using the original management company. Consistent with this prior decision, in *WakeMed*, the Court ruled that because the answers to the questions in the missing application subsections were found elsewhere in the HSSC application as originally submitted, and because the physician letter of support was specifically referenced in the original application – including identification of the surgeons who signed the letter – the additional information submitted by HSSC did not materially amend the application. The Court also noted the testimony of the CON Section Chief and project analyst that the approval of the HSSC application was not based upon the additional materials filed.

It is always the best practice to ensure a CON application is complete and contains all necessary information before it is filed with the CON Section. However, inadvertent omissions and other mistakes in the content of applications do happen. The Court of Appeals' recent analysis of this issue sheds new light on the type of additional information that can be submitted regarding a CON application under review, without crossing the amendment line. It should also help CON applicants ward off specious and hypertechnical challenges by opponents based upon the mere submission of supplemental information after an application is filed.

Another noteworthy aspect of the Court of Appeals' decision in the *WakeMed* case is the Court's rejection of the notion that a CON applicant must explain how it derived or calculated its costs, charges and payor mix in order for the proposed project to be found financially feasible. The Court specifically acknowledged that the financial feasibility CON criterion, commonly known as Criterion 5, does not dictate a specific method an applicant must follow to determine payor mix or project revenues and expenses for its proposal. Rather, all that is required by the statute is that the applicant's projections be reasonable. As the Court of Appeals explained: "[N]either the statutory criterion nor the regulations require a particular method of projecting finances and payor mix beyond requiring that they be 'reasonable.' See N.C. Gen. Stat. § 131E-183(a)(5). . . . [R]easonableness is the only requirement that must be met."

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Proposed Affordable Care Act Regulations

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In contrast, "health-contingent wellness programs" provide rewards to employees who meet a specific health-related standard. Examples of health-contingent wellness programs are a program that imposes a premium surcharge based on tobacco use and a program that uses a biometric screening or a health risk assessment to identify employees with specified medical conditions or risk factors (such as high cholesterol, high blood pressure, abnormal body mass index or high glucose level) and provides a reward to employees identified as within a normal or healthy range (or at low risk for certain medical conditions), while requiring employees who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, or complying with a health care provider's plan of care) to obtain the same reward.

The "health-contingent wellness programs" are the more problematic of the two types of programs, as they must offer reasonable alternatives for obtaining the reward to any individual for whom it is either unreasonably difficult due to a medical condition to meet the otherwise applicable standard, or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard. In other words, the same, full reward must be available to individuals who qualify by satisfying a reasonable alternative standard as is provided to individuals who qualify by satisfying the program's otherwise applicable standard.

As discussed in a fact sheet issued by the Department of Health and Human Services on November 20, 2012 (available at http://www.healthcare.gov/news/factsheets/2012/11/wellness11202012a.html), the proposed regulations set forth the following stipulations for health-contingent wellness programs:

- Wellness programs must be reasonably designed to promote health or prevent disease and have a reasonable chance of improving health or preventing disease; further, they must not be overly burdensome for individuals. In addition, a program must offer a different, reasonable means of qualifying for the reward to any individual who does not meet the standard based on the measurement, test or screening.
- Wellness programs must be reasonably designed to be available to all similarly situated individuals. Employers must offer a reasonable alternative means of qualifying for the reward to individuals whose medical conditions make it unreasonably difficult to meet the wellness goal, or for whom attaining the goal would be medically inadvisable.
- Employees must be notified of the alternative means of qualifying for the wellness incentive, and the proposed regulations include sample notice language.

It bears noting that one particularly glaring omission from the proposed regulations is any mention of whether penalties for non-participation in a wellness program are permissible (as opposed to incentives to participate in a wellness program).

Although the Obama administration clearly desires to encourage more employers to offer and more employees to participate in wellness programs, and while the proposed regulations offer *some* clarification and examples of what would constitute a reasonably designed health-contingent wellness program, the regulations do not specify the types of wellness programs an employer may safely offer to its employees and avoid allegations of discrimination. The proposed regulations do seek comment, however, on a number of issues, including (1) possible definitions of "tobacco use," (2) whether additional guidance is needed to help assess a wellness program's reasonable alternative standard and (3) whether additional consumer protections are needed to ensure that wellness programs are reasonably designed to promote health or prevent disease. Comments are due by January 25, 2013, the specifications for which are set forth in the November 26, 2012, issue of the Federal Register (cited above).

Even though the Affordable Care Act encourages the use of wellness programs by employers, strict compliance with the new regulations once issued will be required. Unfortunately, the proposed regulations do not address many of the legal issues that employers have faced with regard to wellness programs, including issues of potential discrimination under the Americans with Disabilities Act, the Age Discrimination in Employment Act, and other federal and state laws, as well as federal benefits issues. Many unanswered questions remain. Given the continued uncertainty and questions that remain with respect to wellness programs, employers would be well served to have even the most seemingly simple program reviewed by legal counsel for compliance.

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