



Healthcare Update

A N.G.A. Member Service Provided by EPSTEIN BECKER & GREEN, P.C.

To: N.G.A.
From: Epstein Becker & Green
Date: July 11, 2011
Re: Status of Health Care Reform – PPACA Updates

Overview

The purpose of this memo is to summarize the current status of the implementation of the Patient Protection and Affordable Care Act (“PPACA”). After a period of relative calm with regards to health care reform, several noteworthy events have recently occurred both with regards to regulatory implementation and legal challenges. Further, we expect several significant regulations to be released in the coming weeks and months. This memorandum provides an update as to recent changes and provides an overview of past implementation.

Legal Challenges

On June 28, 2011, the U.S. Court of Appeals for the Sixth Circuit upheld the constitutionality of the individual mandate on Commerce Clause grounds. Specifically, the court ruled in favor of the Obama Administration (2-1) and held that the individual mandate is a valid exercise of legislative power by Congress under the Commerce Clause.

In general, the Commerce Clause gives Congress the power to regulate commerce “among the several states.” In other words, under the Commerce Clause, Congress has the power to regulate interstate commerce, including activities that substantially affect interstate commerce.¹

In *Thomas More Law Center v. Obama*, the issue, like the issue in many of the challenges to constitutionality of PPACA, rested on whether the Commerce Clause gives Congress the power to regulate economic “inactivity” (i.e., the power to impose a penalty on an individual who does not purchase insurance).

The Administration’s principal argument has been that an individual’s decision not to purchase health insurance is an “economic activity” that substantially affects interstate commerce because at some point all individuals will require medical care. When individuals who do not purchase health insurance become sick and seek medical care, the cost of the uncompensated care delivered to those individuals

¹ *Perez v. United States*, 402 U.S. 146, 150 (1971).

will be shifted to those with health insurance, thereby increasing the cost of coverage overall and substantially affecting interstate commerce. Opponents have argued that an individual's choice not to purchase health insurance is "inactivity" and thus not an activity subject to regulation by Congress under the Commerce Clause.

The court agreed with the Administration's view and stated, "[i]ndividuals must finance the cost of health care by purchasing an insurance policy or by self-insuring, cognizant of the backstop of free services required by law. By requiring individuals to maintain a certain level of coverage, the minimum coverage provision regulates the financing of health care services, and specifically the practice of self-insuring for the cost of care. The activity of foregoing health insurance and attempting to cover the cost of health care needs by self-insuring is no less economic than the activity of purchasing an insurance plan. Thus, the financing of health care services, and specifically the practice of self-insuring, is economic activity."

As of June 2011, at least 26 challenges to the constitutionality of PPACA have been filed in federal court. The law has been overturned in whole or in part in two of those cases. In both of those cases, the individual mandate provision was found to exceed Congress's authority to regulate commerce by virtue of the fact that the individual mandate regulates inactivity. The Virginia Court that struck down the statute found that the unconstitutional individual mandate provision could be invalidated by itself without nullifying the rest of the law. On the other hand, a Florida Court struck down the law in its entirety, because it felt that the individual mandate provision could not be severed from the rest of the law.²

In another six lawsuits, district courts have ruled that the law is constitutional and dismissed the cases. Eight more cases have been dismissed for lack of standing. In one dismissed case the Judge gave the plaintiff the right to re-file. The remaining nine cases in district court have not yet been ruled on. Finally, five cases are pending in various federal circuit courts of appeals.³

The outcome of the cases challenging PPACA is likely to be varied at the Court of Appeals level and action by the U.S. Supreme court is, therefore, probable.

Regulatory Changes

As mentioned above, after the regulatory implementation of Title I of PPACA last Summer and Fall, the regulatory agencies with jurisdiction did not released a significant number of new regulations and guidance implementing PPACA. However, it appears that the agencies are again active in their implementation of PPACA. The following described two recent regulatory releases.

I. "Mini-Med" Waiver Update

² Kaiser Family Foundation, Scoreboard: Tracking Health Law Court Challenges, available at <http://www.kaiserhealthnews.org/Stories/2011/March/02/health-reform-law-court-case-status.aspx> (last visited June 13, 2011).

³ See *Note 1*.

In general, Section 2711 of the Public Health Service Act, as added by PPACA, prohibits lifetime or annual limits on the dollar value of “essential health benefits.” However, prior to 2014, PPACA permits “restricted” annual limits in certain circumstances. Regulations implementing Section 2711 (the “IFR”) provided that these restricted annual limits may be waived by the Secretary of Health and Human Services (“HHS”) if compliance with the annual limit requirements would result in a significant decrease in access to benefits or a significant increase in premiums.

Consequently, the Center for Consumer Information and Insurance Oversight (“CCIIO”) and its predecessor the Office of Consumer Information and Insurance Oversight (“OCIIO”) delineated a process whereby group health plans or health insurance issuers that offered limited benefit, or “mini-med,” plans, could apply for a waiver to the restrictions on annual limits on the dollar value of “essential health benefits” until 2014.

On June 17, 2011, CCIIO released additional guidance (“Guidance”) regarding: the extension of a previously granted waiver; the application process for an initial waiver; notice requirements to beneficiaries or enrollees; and, the sale of policies that have been granted a previous waiver.

Waiver Extension

The Guidance allows an applicant to extend an existing waiver until January 1, 2014. However, such plans or issuers must re-submit certain information described below annually by the end of each calendar year. Specifically, the Guidance requires plans or issuers seeking to extend a previously granted waiver to submit the following information to CCIIO:⁴

- A) Updated contact information, including the name and contact information of the applicant, as well as the name and contact information of the person who prepared the annual update;
- B) Enrollment information for the plan or policy at the time the annual update is sent;
- C) The plan’s or policy’s current annual limit;
- D) A signed attestation certifying:
 - a. The plan or policy was in existence prior to September 23, 2010;
 - b. Compliance with the annual limit requirements would result in a “significant decrease in access to benefits” or a “significant increase in premiums;” and
 - c. The plan or issuer understands and will comply with the requirement to provide an annual notice to consumers.⁵

According to the Guidance, “[t]he deadline for receipt of Waiver Extension forms is September 22, 2011. Elections for a Waiver Extension received after September 22, 2011 will not be accepted. Plans or issuers that do not elect a Waiver Extension will be required to come into compliance with section 2711 of the PHS Act and the IFR.”

New Waivers

The Guidance also clarified that a group health plan or health insurance issuer is eligible to apply for a new waiver from the restricted annual limits until September 22, 2011 if certain conditions are met. Specifically, a plan or issuer must show: A) the plan or policy was offered prior to September 23, 2010; B) the plan or policy has not yet applied for or has not been granted a waiver, and C) the plan or policy

⁴ NOTE: HHS expressly retains the discretion to withdraw a waiver should a condition of the waiver be violated.

⁵ A copy of the attestation is available at <http://cciio.cms.gov/programs/marketreforms/annuallimit/index.html>.

coverage does not meet the enumerated restricted annual limits. Further, the Guidance clarified that applications will be considered in accordance with previously released guidance.

To submit a waiver application⁶ plans or issuers must provide a signed attestation certifying:

- A) The plan or policy was in existence prior to September 23, 2010;
- B) Compliance with the IFR would result in a “significant decrease in access to benefits” or a “significant increase in premiums;” and
- C) The plan or issuer understands and will comply with the annual notice requirements.⁷

According to the Guidance, “[t]he deadline for receipt of new waiver applications is September 22, 2011. Waiver applications received from a New Applicant after September 22, 2011 will not be accepted. Plans or issuers that do not receive a waiver approval will be required to come into compliance with section 2711 of the PHS Act and the IFR.”

Notice

Previously released guidance specified, that as a condition of receiving a waiver from the annual limit requirements, a group health plan or health insurance issuer must provide a notice that informs eligible participants and subscribers that the plan or policy does not meet the minimum annual limits for essential health benefits and has received a waiver from the requirement. The Guidance provides new model notice language that is more expansive than previously released language. Further, the Guidance requires that the updated notice must be provided to eligible participants each year the waiver is in effect.

Sale of New Policy by Insurers Receiving Waivers

The stated purpose of the waiver program was to “minimize, during the period prior to 2014, disruption to existing coverage where the application of restrictions on annual limits would significantly decrease access to benefits, or significantly increase the cost of that coverage.” Consequently, the Guidance clarifies that, “[w]aivers are not intended to permit new, non-compliant insurance coverage to be offered. Accordingly, HHS has granted and will grant waivers of the annual limit requirements solely for the purpose of maintaining coverage that was offered before September 23, 2010.”

Impact on N.G.A. Members

HHS specifically retains the authority to revoke an existing waiver and require immediate compliance with the annual limits provision. Thus, to the extent that N.G.A. members maintain “mini-med” plans currently receiving a waiver or plan on seeking a waiver, it is imperative they follow the new procedures for extending such a waiver and providing notice.

II. Claims and Appeals Update

Section 2719 of PPACA requires group health plans and health insurance issuers to maintain an effective appeals process for coverage determinations and claims. An interim Final Rule (“IFR”) implementing this provision was published in the Federal Register last July.⁸ However, in

⁶ A copy of the application is available at <http://cciio.cms.gov/programs/marketreforms/annuallimit/index.html>.

⁷ A copy of the attestation is available at <http://cciio.cms.gov/programs/marketreforms/annuallimit/index.html>.

⁸ 75 Fed. Reg. 43330.

response to public comments received in connection with the IFR the Department of Labor (“DOL”), the Department of Health and Human Services (“HHS”) and the Treasury Department (“Treasury”) published an amendment to the IFR on June 22, 2011 (“Amendment”) making several significant changes to the appeals process. The following summarizes those changes.

Internal Claims and Appeals Changes

Urgent Care Claims: The IFR provided that a plan or issuer must notify a claimant of a benefit determination (whether adverse or not) involving urgent care as soon as possible, but not later than 24 hours after receipt of the claim.

In response to concerns raised in connection with the IFR, the Amendment, reverts to the previous DOL claims procedure standard, and requires the plan or issuer notify claimant as soon as possible but no later than 72 hours after receipt of the claim, provided that the plan defer to the attending provider for a decision as to whether the claim involves urgent care.

Notification: The IFR required that any notice of adverse benefit determination include information sufficient to identify the claim involved including automatically providing the diagnosis code (such as ICD-9, ICD-10, or DSM-IV) and treatment code (such as CPT) and their respective meanings.

In response to concerns raised during the rule making process, the Amendment eliminates the automatic provision of such codes in connection with an adverse benefit determination. Instead a plan, in connection with an adverse benefit determination, must provide notice of a claimant's right to request such codes. The Amendment further clarifies that a plan must not consider a request for diagnosis or treatment codes in itself, to be a triggering event beginning an internal appeal or external review process.

Strict Adherence: The IFR permitted claimants to immediately seek external review or available legal remedies if a plan or issuer failed to strictly adhere to all procedural requirements for internal claims and appeals. In such circumstances, the reviewing tribunal was not permitted to give deference to the plan's or issuer's decision, but rather the reviewing tribunal was to resolve the dispute de novo.

The Amendment provides an exception to the “strict adherence” standard for errors that are minor and meet certain other specified conditions. Under the Amendment, any violation of the procedural rules of the IFR pertaining to internal claims and appeals would permit a claimant to seek immediate external review or court action as applicable, unless the violation was: a) de minimis; b) non-prejudicial; c) attributable to good cause or matters beyond the plan's or issuer's control; d) in the context of an ongoing good-faith exchange of information; e) not reflective of a pattern or practice of non-compliance.

Further, the Amendment provides that a claimant would be entitled, upon request, to an explanation of the plan's or issuer's basis for asserting that it meets the exception, so that claimant could make an informed judgment about whether to seek immediate review. If the claimant's request for immediate review is denied on this basis, the claimant has the right to resubmit and pursue internal appeal of the claim.

Culturally and Linguistically Appropriate (“CALA”): The IFR required that notices be provided in a non-English language if certain threshold numbers of people were literate only in the same non-English language. In the group market, the threshold differed depending of the number of enrollees in a plan.⁹ In the individual market, the threshold was 10 percent of the population residing in the county being literate only in the same non-English language. Under the IFR, if an applicable threshold was met with respect to a non-English language the plan or issuer was required to provide the notice, upon request, in the non-English language, in addition to providing a statement in all English versions of all notices, prominently displayed in the non-English language, that informs the participant of their right to receive all future notices in the non-English language. Further, the IFR required that if a plan or issuer provides a telephone hotline or other customer assistance, that service must be available in the non-English language.

The Amendment removes the threshold distinctions in the individual and group markets, and establishes a single threshold with respect to the percentage of people who are literate only in the same non-English language. Specifically, group health plans and health insurance issuers offering group or individual health insurance coverage must provide notices in a non-English language if 10 percent of the population residing in the claimant’s county is literate only in the same non-English language. Further the Amendment requires that each notice sent by a plan or issuer to an address in a county that meets this threshold include a one sentence statement in the relevant non-English language regarding the availability of language services.¹⁰

In addition, the Amendment places an affirmative obligation on plans and issuers, in areas meeting the thresholds, to provide a customer assistance process such as a hotline, with oral language services in the non-English language and provide written notices in the non-English language upon request. Significantly however, the notices are only required upon request, removing the requirement that once a notice is requested in a non-English language all further notices must be provided in such non-English language.

External Review

Scope: The IFR provided that any adverse benefit determination was eligible for external review unless it related to a participant’s failure to meet the requirements for eligibility under the terms of the plan.

The Amendment temporarily narrows the scope of the Federal external review process to apply to claims that involve: a) medical judgment (excluding those that involve only contractual or legal interpretation without any use of medical judgment) as determined by the external reviewer;¹¹ or b) a rescission of coverage. According to the Amendment, the Departments with jurisdiction expect the temporary reduction in scope will be lifted by January 1, 2014.

Clarification Regarding Requirement that External Review Decision be Binding:

⁹ For a plan with fewer than 100 participants the threshold is 25 percent of all plan participants being literate only in the same non-English language. For a plan that covers more than 100 participants, the threshold is the lesser of 500 participants, or 10 percent of all plan participants, being literate only in the same non-English language.

¹⁰ NOTE: The Amendment provides a list of counties in which 10 percent or more of the population is literate only in the same non-English language triggering the CALA requirements. This list will be updated on a yearly basis.

¹¹ NOTE: The Amendment contains a list of claims that involve “medical judgment.”

The IFR provided that an external review decision by an Independent Review Organization (“IRO”) be binding on the plan or issuer as well as, the claimant, except to the extent that other remedies are available under Federal or State law.

The Amendment clarifies that the plan or issuer must provide benefits (including making a payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review.

Timelines

State External Review Processes: Under the IFR and previously released Technical Guidance, group health plans and insurance issuers offering group and individual health care coverage that were already complying with existing State external appeals process, were provided with a transition period before full compliance with the IFR was required. Prior to July 1, 2011, HHS pledged to work with States to assist them in making any necessary changes so that their external review process provide at a minimum the consumer protections under the NAIC Uniform Model Act. During the transition period, an enforcement safe harbor was instituted whereby no enforcement would be taken against a health insurance issuer or plan in compliance with the Technical Guidance. However, under the IFR and previously released Technical Guidance for plan and policy years after July 1, 2011, the State external review process was required to meet the minimum Federal standards set forth by HHS.

DOL Technical Release 2011-02 (published in conjunction with the Amendment) extends the transition period for States to implement external review processes to January 1, 2012.

External Review IRO Requirement Delay: Under the IFR, a group health plan must assign an IRO accredited by URAC or another similar organization to conduct the external review. To protect against bias and to ensure the independence of the IRO’s decision the plan was required to contract with three IRO’s and rotate assignments among them.

Technical Release 2011-02 modified the DOL/IRS enforcement policy with respect to IROs. Under the Technical Release 2011-02, plans must now contract with at least two IROs by January 1, 2012 and with at least three IROs by July 1, 2012.

Impact on N.G.A. Members

The Amendment represents a significant victory for employers subject to the claims and appeals provision of PPACA. Many of the more unworkable provisions were corrected to relieve some of the burden on employers. However, to the extent N.G.A. members have instituted policies and procedures to comply with the IFR, those procedures should be amended to reflect the Amendment.

III. Exchange Regulations Imminent

On June 17, 2011, the Centers for Medicare and Medicaid Services (“CMS”) submitted to the Office of Information and Regulatory Affairs (“OIRA”), for review, a proposed regulation titled, “Requirements To Implement American Health Benefit Exchanges and Other Provisions of the Affordable Care Act.” Further, on June 20, 2011 CMS submitted an additional proposed regulation to OIRA titled, “State

Requirements for Exchange--Reinsurance and Risk Adjustments.” Both sets of regulations were released by CMS on July 11, 2011. We are in the process of reviewing these regulations and will prepare a separate update addressing issues of concern in the near future.

Impact on N.G.A. Members

The scope and impact of these rules are not yet known. As such, we will provide an update outlining the requirements of these provisions as they relate to N.G.A. members after publication.

Implementation Chart

PPACA contains several provisions that will significantly affect employer sponsored health-care plans. The chart below lists several provisions that will go into effect in the coming years.

<i>Implementation Date</i>	<i>Description of PPACA Provision</i>
Currently in Effect	Plans that provide for coverage of dependents of their employees must extend that coverage to age 26
Currently in Effect	Plans must eliminate lifetime benefit restrictions on “essential benefits”
Currently in Effect	Plans must not impose pre-existing conditions or exclusions on children under age 19
Currently in Effect	No retaliation against an employee who challenges employer’s implementation of law; whistleblower protections
Currently in Effect	Breaks must be provided for nursing mothers for the purpose of expressing breast milk
Currently in Effect	Small employers may adopt a simple cafeteria plan
2011	Exclusion of costs for OTC drugs for reimbursement from HRAs, HSAs, FSAs, and MSAs
2011	Tax on HSA and MSA distributions not used for qualified expenses increased from 10 to 20% of disbursed amount
2011	Value for premium payments (Medical Loss Ratio (MLR) of 80% in individual and small group market; 85% in large group market)
2011	Tax credit for small businesses (fewer than 25 employees)
2011	Wellness grants for small employers (fewer than 100 employees)
2012	60-Day notice must be provided for material changes to the plan
2012	Explanation of benefits and coverage for group health plans
2013	Elimination of tax deduction for Medicare part D drug subsidy payments
2013	Deferrals to an FSA limited to \$2500 per year
2013	Notice to new and current employees of: (1) existence of Exchange, (2) Eligibility for premium tax credit (3) Possibility of loss of employer contribution if insurance purchased through Exchange
2014	No pre-existing conditions or exclusion for any employees
2014	No waiting periods longer than 90 days for coverage
2014	No discrimination in eligibility based on health-related status factors
2014	New cost and coverage reporting requirements (to be announced)
2018	40% nondeductible excise tax on insurance companies and plan administrators of self-insured plans if plan costs exceed certain thresholds