June 23, 2010

TO: Trion

RE: PPACA Provisions on Annual and Lifetime Limits, Pre-Existing Condition Exclusions, Rescissions, and Access to Providers – Interim Final Rules

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On June 22, the U.S. Department of Health and Human Services, U.S. Department of Labor, and U.S. Department of the Treasury (collectively, the "Departments") issued interim final regulations" ("IFR") that provide more details on the implementation of the Patient Protection and Affordable Care Act ("PPACA")'s prohibitions on annual and lifetime limits, pre-existing condition exclusions, rescissions, and the statute's requirements for allowing access to certain providers. To facilitate an understanding of the impact of these rules – dubbed the "Patient's Bill of Rights" – on plan design, this memorandum provides an overview of the new rules and additional details on the types practices that will be prohibited.

Overview

The market reform provisions in PPACA, as interpreted by the IFR, prohibit or limit a number of practices by plans,[1] including (as explained in detail in the Analysis below):

Restricted Annual Limits. Rather than immediately eliminating annual limits, which the Departments arguably had the discretion to do under PPACA, the Departments have opted to phase out annual limits starting with plan years that begin on or after September 23, 2010, as follows –

- For plan years beginning on or after September 23, 2010 but before September 23, 2011, the minimum annual limit is $750,000;
- For plan years beginning on or after September 23, 2011 but before September 23, 2012, the minimum annual limit is $1.25 million; and,
- For plan years beginning on or after September 23, 2012 but before January 1, 2014, the minimum annual limit is $2 million.

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[1] The word "plans" will be used in this memorandum as a short-hand reference to indicate both self-insured and insured employer-sponsored "group health plans." Recognizing that "health plan" has a particular meaning under various statutes that may exclude self-insured plans, use of the word "plan" here is not intended as a means of distinguishing between self-insured or insured arrangements. The rules discussed here apply to self-insured as well as insured plans. Also note that in some respects, the rules in the IFR for group health plans and group coverage differ from those applicable in the individual market. This memorandum generally does not discuss the differing rules that apply to the individual market.

As required by PPACA, annual limits will be completely banned for plan years starting January 1, 2014.

The IFR explicitly addresses concerns about the effect that annual limit restrictions would have on mini-med plans by providing for a "waiver" that such plans can seek to avoid application of the annual limits in the IFR, if compliance with those limits "would result in a significant decrease in access to benefits or a significant increase in premiums." This waiver program would be administered by the Department of Health and Human Services ("HHS") but has not yet been established. The IFR advises that HHS will issue guidance on the waiver program "in the near future." Note that it appears that the waiver would only apply until the complete ban on annual limits goes into effect in 2014, leaving mini-med plans to an uncertain fate after that point.

The annual limit rules apply to "essential benefits," which for the moment, the IFR defines as those categories of essential benefits described in PPACA.[2]

Ban on Lifetime Limits. Lifetime limits on essential benefits are prohibited beginning with plan years starting on or after September 23, 2010. Individuals who reach a lifetime limit prior to the ban becoming effective (i.e., plan years beginning before September 23, 2010) and who are otherwise still eligible under the plan must be provided with a notice that the lifetime limit no longer applies, and if the individual is no longer enrolled, must be given a special enrollment opportunity that continues for at least 30 days. The notices and special enrollment opportunity must be provided no later than the first day of the first plan year beginning on or after September 23, 2010, and coverage must be effective no later than the first day of the first plan year beginning on or after September 23, 2010. Significantly, those enrolled through this special enrollment opportunity cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit.

The rules on annual and lifetime limits apply to both grandfathered and non-grandfathered plans. The IFR contains additional detailed guidance for grandfathered plans on the types of actions with respect to annual and lifetime limits that would cause loss of grandfathered status. But consistent with the rules already released by the Departments on grandfathering, any changes would essentially cause loss of grandfathered status with the exception of plans that had lifetime but no annual limits, which may adopt new annual limits greater than or equal to the lifetime limit – an exception that appears to afford little flexibility as a practical matter.

Ban on Pre-Existing Condition Exclusions. Starting with plan years beginning on or after September 23, 2010, all pre-existing condition exclusions are prohibited for those under 19 years of age. Pre-existing condition exclusions are prohibited for all others for plan years beginning on or after January 1, 2014. The IFR advises that the restrictions on pre-existing condition exclusions that apply to group plans in the Health Insurance Portability and Accountability Act ("HIPAA") – which did

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[2] The categories of "essential benefits" listed in Section 1302(b) of PPACA are: 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.

allow exclusions in limited circumstances – will continue to apply until the PPACA provision goes into effect (i.e., the first plan year beginning on or after September 23, 2010 or January 1, 2014 as the case may be). The pre-existing condition rules apply to grandfathered as well as non-grandfathered plans.

Unlike the rules for lifetime limits and coverage of adult dependents, the IFR provides no special enrollment period for persons previously denied coverage by an employer-based plan due to a pre-existing condition. This is likely because of the creation of the state high-risk pools for those with pre-existing conditions, which are reportedly set to begin enrolling individuals on July 1.

To finally close the door on an interpretive dispute that arose immediately after PPACA's enactment regarding the applicability of this provision to individuals not currently enrolled, the IFR specifies that the ban on pre-existing condition exclusions applies to current enrollees as well as those who apply for enrollment, meaning plans cannot deny enrollment, and they cannot deny specific benefits, based on pre-existing conditions.

Ban on Rescissions Except in Cases of Fraud or Intentional Material Misrepresentation. PPACA prohibits rescissions except in cases of fraud or intentional material misrepresentation, which may go beyond existing state laws or federal common law that may have allowed rescission in cases of unintentional misrepresentation, such as where an enrollee makes a mistake in filling out a pre-enrollment medical questionnaire.

Importantly, the IFR states that the protections afforded by the statute also extend to representations made by "a person seeking coverage on behalf of an individual." Thus, the IFR states for example, if a plan sponsor makes representations about prior group claims experience, the group is protected from rescission based on unintentional mistakes in the sponsor's representations. While the IFR does not explicitly provide that the rescission rules protect against mistakes made by brokers, a reasonable argument can be made that it does where a broker is relaying information received from a sponsor.

The rescission rules apply to both grandfathered and non-grandfathered plans.

Access to Certain Providers. Section 2719A added to the Public Health Service Act by Section 1001 of PPACA imposes new requirements relating to the choice of health care provider and requirements related to emergency services. These requirements, as implemented in the IFR, will generally allow participants to select the primary care provider or pediatrician of their choice so long as the provider participates in the plan's network and will require plans to provide enrollees with notice of these rights; will prohibit plans from requiring a referral or prior authorization for a female to see a specialist in obstetrics or gynecology; and will prevent plans from requiring pre-authorization before seeking emergency care from an out-of-network provider, in addition to prohibiting plans from imposing more burdensome administrative requirements and higher cost-sharing amounts on out-of-network emergency care.

Note that these provider access requirements do not apply to grandfathered plans, although other state and federal requirements concerning these matters will continue to apply.

Generally, plans and their advisors are urged to carefully study this IFR as part of the plan design process to ensure that plans will be in compliance with the applicable rules at the applicable times. Plans should also be aware that in many cases (e.g., rescissions, access to providers), the

requirements in PPACA set a federal "floor" and do not supersede stricter state requirements, so state requirements in these areas continue to be relevant.

Because the Departments sought to issue regulations on these market reforms in a relatively short time frame, the agency is issuing these regulations as "interim final" ones while providing an opportunity for public comment on the rules. Comments will be due 60 days from Federal Register publication of the IFR, i.e., the deadline will be on or about August 21, 2010 (the IFR has not yet been published in the Federal Register). The IFR is currently available at: http://www.federalregister.gov/OFRUpload/OFRData/2010-15278_PI.pdf.

Additional details regarding the IFR are discussed below.

Analysis

Annual and Lifetime Limits

A. Rules on Annual Limits

Although the Departments arguably had the discretion under PPACA to immediately eliminate annual limits, the Departments opted to phase out annual limits starting with plan years that begin on or after September 23, 2010, as follows –

- For plan years beginning on or after September 23, 2010 but before September 23, 2011, the minimum annual limit is $750,000;
- For plan years beginning on or after September 23, 2011 but before September 23, 2012, the minimum annual limit is $1.25 million; and,
- For plan years beginning on or after September 23, 2012 but before January 1, 2014, the minimum annual limit is $2 million.[3]

As required by PPACA, annual limits will be completely banned for plan years starting January 1, 2014.

The IFR explicitly addresses concerns about the effect that annual limit restrictions would have on mini-med plans by providing for a "waiver" that such plans could seek to avoid application of the annual limits in the IFR, if compliance with those limits "would result in a significant decrease in access to benefits or a significant increase in premiums." This waiver program would be administered by HHS but has not yet been established. The IFR advises that HHS will issue guidance on the waiver program "in the near future." Note that while the establishment of the waiver program seems to signal a victory for those seeking to preserve mini-med plans, it appears that the waiver would only apply

[3] The IFR notes that plans with plan years that begin between September 23 and December 31 have more than one plan year under which the $2 million annual limit is available, but generally may not impose an annual limit for a plan year beginning after December 31, 2013. Note that the restrictions on annual limits before January 1, 2014 do not apply to policies in the individual markets.

until the complete ban on annual limits goes into effect in 2014, leaving mini-med plans to an uncertain fate thereafter.

With respect to tax-advantaged accounts, the IFR advises that the annual limits do not apply to health Flexible Spending Accounts ("FSAs") (these will be subject to the separate $2500 limit imposed by Section 9005 of PPACA), Medical Savings Accounts ("MSAs"), and Health Savings Accounts ("HSAs"). Annual limits also would not apply to Health Reimbursement Accounts ("HRAs") that are integrated with other coverage as part of a plan that complies with the annual limits, and retiree-only HRA plans, but left open the question of whether the annual limit rules should apply to stand-alone HRAs.

B. Rules on Lifetime Limits

Lifetime limits on essential benefits are prohibited beginning with plan years starting on or after September 23, 2010. Individuals who reach a lifetime limit prior to the ban becoming effective (i.e., plan years beginning before September 23, 2010) and who are otherwise still eligible under the plan must be provided with individual written notice that the lifetime limit no longer applies, and if the individual is no longer enrolled, must be given a special enrollment opportunity that continues for at least 30 days. The notices and special enrollment opportunity must be provided no later than the first day of the first plan year beginning on or after September 23, 2010, and the notice may be provided with other enrollment material a plan distributes to employees provided that the notice is "prominent," a term that is not defined in the IFR. Coverage must be effective no later than the first day of the first plan year beginning on or after September 23, 2010.

Anyone enrolled under this special enrollment period must be treated as a special enrollee, meaning they must be given the right to enroll in all of the benefit packages available to similarly situated individuals upon initial enrollment. Those enrolled under this special enrollment opportunity cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit.

C. Rules Applicable to Both Annual and Lifetime Limits

The annual and lifetime limit rules apply to "essential benefits," which for the moment, the IFR defines as those categories of essential benefits described in Section 1302(b) of PPACA: 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.

The IFR advises that this definition is temporary and will be in place until the Departments complete a rulemaking to define "essential benefits." In the meantime, the Departments will take into account "good faith efforts" to comply with a reasonable interpretation of essential benefits, but warns that plans must apply their definitions consistently, and not define a benefit as essential for one purpose but not essential for another.

The rules do not prohibit the imposition of a per-individual limit on specific covered benefits that are not classified as essential benefits.

The IFR further clarifies that in applying annual limits for plan years before January 1, 2014, the plan may take into account only the amounts spent on essential benefits.

Note that as discussed in the grandfathering rules, the market reforms in PPACA, including the restrictions on annual and lifetime limits, do not apply to retiree-only plans or to excepted benefits such as dental-only or vision-only plans.[4] But given that the definition of "essential benefits" includes "pediatric services, including oral and vision care," and the IFR does not harmonize this apparent disconnect, additional regulatory guidance will be necessary to determine precisely what pediatric dental and vision services would be subject to the rules on annual and lifetime limits. In the meantime, plans should use their best judgment to develop a reasonable interpretation of the rules in order to rely on the safe harbor provided in the IFR for "good faith efforts" to comply.

The annual and lifetime limits apply on an individual-by-individual basis. This means, for example, that an overall annual limit applied to families cannot operate to deny a covered individual the minimum annual benefits for the plan year. The IFR further advises that the annual and lifetime limit prohibitions do not prevent a plan from excluding all benefits for a condition – a complete exclusion will not be treated as an annual or lifetime "limit." But if any benefits are provided for the condition, the rules in the IFR apply.

The restrictions on annual and lifetime benefits apply to grandfathered as well as non-grandfathered group plans, and . The IFR provides additional guidelines for grandfathered plans with respect to annual and lifetime limits. More specifically, if on March 23, 2010, a plan –

- did not impose an overall annual or lifetime limit, it ceases to be grandfathered if it now imposes an overall annual limit;
- imposed an overall lifetime limit but no overall annual limit, it ceases to be grandfathered if it now adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010;
- imposed an overall annual limit, it ceases to be grandfathered if it now decreases the dollar value of the annual limit (regardless of whether the plan also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

Ban on Pre-Existing Condition Exclusions

Starting with plan years beginning on or after September 23, 2010, all pre-existing condition exclusions are prohibited for those under 19 years of age. Pre-existing condition exclusions are prohibited for all others for plan years beginning on or after January 1, 2014. The IFR advises that the restrictions on pre-existing condition exclusions that HIPAA presently applies to group plans – which did allow exclusions in limited circumstances – will continue to apply until the PPACA provision goes into effect (i.e., the first plan year beginning on or after September 23, 2010 or January 1, 2014 as the

[4] *See* Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act; Interim Final Rule and Proposed Rule, 75 Fed. Reg. 34537, 34540 (June 17, 2010).

case may be). The pre-existing condition rules apply to grandfathered as well as non-grandfathered group plans.

Unlike the rules for lifetime limits and coverage of adult dependents, the IFR provides no special enrollment period for persons previously denied coverage by an employer-based plan due to a pre-existing condition. This is likely because PPACA mandated the creation of the state high-risk pools for those with pre-existing conditions, and coverage under these pools, known as the Pre-Existing Condition Insurance Plan, is reportedly set to become available on July 1.

A "pre-existing condition exclusion" will continue to be defined as it is in HIPAA: "a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date." Therefore, an exclusion of coverage of specific benefits associated with a pre-existing condition will be prohibited, as well as a complete exclusion from the plan if that exclusion is based on a pre-existing condition.

The IFR further provides that, as is the case under HIPAA, exclusions that apply regardless of when the condition arose are allowed. Accordingly, in an example cited by the IFR, if a plan excludes all coverage for the treatment of cleft palate, such an exclusion will not run afoul of the law because it applies regardless of when the condition arose relative to the effective date of the coverage. But grandfathered plans should be mindful that any new exclusions of this nature implemented after June 17, 2010 (the public release of the grandfather rules) will cause the plan to lose grandfathered status.

Finally, the ban on pre-existing condition exclusions applies to current enrollees as well as those who apply for enrollment, meaning plans cannot deny enrollment, and they cannot deny specific benefits, based on pre-existing conditions.

Rescissions

PPACA prohibits rescissions except in cases of fraud or intentional material misrepresentation, which goes beyond existing state laws or federal common law that may have allowed rescission in cases of unintentional misrepresentation, such as where an enrollee makes a mistake in filling out a pre-enrollment medical questionnaire. The IFR clarifies that fraud and intentional misrepresentations covered by the rules include can include omissions.

The IFR advises that this prohibition applies to all rescissions in the group market, whether related to self-insured or insured arrangements (as well as to the individual market). The prohibition is in addition to, and does not affect, existing federal law governing guaranteed issue and renewal. The provision also does not pre-empt state laws on rescission that are stricter than what PPACA provides.

Importantly, the IFR states that the protections afforded by the statute also extend to representations made by "a person seeking coverage on behalf of an individual." Thus, the IFR states for example, if a plan sponsor makes representations about prior group claims experience, the group is protected from rescission based on unintentional mistakes in the sponsor's representations. While the IFR does not explicitly provide that the rescission rules protect against mistakes made by brokers, a reasonable argument can be made that it does where a broker is relaying information received from a sponsor.

A “rescission” is defined in the IFR as a cancellation or discontinuance of coverage that has retroactive effect. It follows that a cancellation or discontinuance with only prospective effect, or that has a retroactive effect limited only to the extent it is attributable to a failure to timely pay premiums or contributions toward coverage, is not prohibited by these rules.

The IFR includes a new notice provision requiring plans to provide at least thirty calendar days prior notice before coverage may be rescinded, which must be provided regardless of whether the rescission is of insured or self-insured group coverage, and regardless of whether the rescission applies to an entire group or to only one individual within a group. The Departments specifically warn that further regulations or guidance may be issued concerning rescission if the Departments become aware of attempts to “subvert” the rescission rules.

The rescission rules apply to both grandfathered and non-grandfathered plans.

Access to Certain Providers

Section 2719A added to the Public Health Service Act by Section 1001 of PPACA imposes new requirements on non-grandfathered plans relating to the choice of health care provider and requirements related to emergency services.[5] These requirements, as implemented in the IFR, are as follows:

- Primary Care Providers and Pediatricians –
  - if a plan requires or provides for designation of a primary care provider[6], the plan must permit each participant or beneficiary to designate any participating primary care provider who is available to accept the participant or beneficiary; and,
  - if a primary care provider can be designated for a child, the plan must allow the designation of any participating pediatrician who is available to accept the child. The general terms of the plan regarding pediatric coverage are otherwise unaffected.

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[5] Although these provider access provisions do not apply to grandfathered plans, the IFR notes that other applicable state and federal requirements concerning these matters remain in effect for such plans.

[6] The IFR advises that the provider choice rules do not apply to plans that have not negotiated with any provider for the delivery of health care, but that merely reimburse covered individuals for their receipt of health care.

- In both cases, the plan must provide notice to participants of the terms of the plan regarding designation of a primary care provider or pediatrician, and the IFR provides model language for such notices.[7]

- Obstetrical and Gynecological Care – a plan may not require an authorization or a referral from either the plan or a primary care provider for a female participant or beneficiary who seeks obstetrical or gynecological care to see a participating specialist in obstetrics or gynecology, and the plan must provide notice of this fact to participants and beneficiaries (the IFR provides model language for such notices).[8] The rules, however, do not preclude the plan from requiring the specialist to adhere to policies and procedures regarding referrals, prior authorization for treatment, and the provision of services pursuant to a treatment plan approved by the plan, although the plan must treat the provision of OB/GYN care and ordering of related items and services as the authorization of a primary care provider. The general terms of plan coverage regarding OB/GYN coverage are otherwise unaffected. And,

- Emergency Services – if a plan provides any benefits with respect to emergency services, it must:

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[7] Following is the IFR's model language to satisfy the notice requirements:

> [Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

For plans that require or allow for the designation of a primary care provider for a child, the IFR recommends adding to the above model language: "For children, you may designate a pediatrician as the primary care provider."

[8] For plans that cover OB/GYN care and require the designation by a participant or beneficiary of a primary care provider, the IFR recommends adding to the model language reproduced in Note 6 above:

> You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

- provide coverage of such services without the need for prior authorization and without regard to whether the provider furnishing the emergency services is in-network;

- if emergency services are provided out-of-network, the plan cannot impose any administrative burden that is more restrictive than that applied to in-network emergency services, and,

- the co-payment or co-insurance amount imposed for out-of-network emergency services cannot exceed the amounts that would be imposed if the providers were in-network. While providers are allowed to balance-bill patients for the difference, the IFR includes an "anti-abuse" formula that requires plans to pay a minimum amount to the out-of-network provider based on factors such as what the plan has negotiated to pay in-network providers, what would typically be paid to out-of-network providers (but reduced only by the in-network cost-sharing amount), and what would be paid by Medicare. There is also a limit on applying any special deductible or out-of-pocket maximum on out-of-network emergency care – any such amounts must be ones that apply generally to out-of-network services.

"Emergency services," "emergency medical condition," and "stabilize" are generally defined in the IFR by reference to the current definition in the Emergency Medical Treatment and Labor Act ("EMTLA") (42 U.S.C. sec. 1395dd(e)(1)(A)), except that they may be judged by what "a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in such consequences," rather than a standard that requires application of judgment of "qualified hospital medical personnel."

Under EMTLA as incorporated by the IFR, an emergency medical condition is one "manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part."

Comment Period

It should be kept in mind that the Departments seek comment on all aspects of the IFR. To the extent there is a view that the new rules are uninformed or problematic, there is an opportunity to offer such views to the agencies. Comments on the IFR will be due 60 days after publication of the IFR in the Federal Register, i.e., on or about August 21, 2010.

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