Interim Final Rules Released on Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Patient Protections, and Preventive Care

July 23, 2010

The federal agencies responsible for Healthcare Reform regulations have recently issued significant guidance, including several model notices, applicable to some of the provisions under the Patient Protection and Affordable Care Act (PPACA) as amended by the Health Care and Education Reconciliation Act of 2010 (the Reconciliation Act; together, the Healthcare Reform Law).

On June 23 and July 14, 2010, the federal agencies responsible for Healthcare Reform regulations issued interim final rules addressing preexisting condition exclusions, lifetime and annual limits, rescissions, patient protections, and preventive care applicable to group health plans (the Rules) under the Healthcare Reform Law.

On July 2, the Department of Labor (DOL) published model language to satisfy notice requirements contained in several of the Healthcare Reform Law’s provisions, including lifetime limits, patient protections, grandfathered plan status and coverage of adult children.¹

The Tri-Agency Group (the IRS, the Department of Labor, and the Department of Health and Human Services) that published the Rules will release additional nonregulatory administrative guidance as they deem necessary to clarify or interpret the Rules.

Background

Under the Law, group health plans are subject to new requirements related to coverage offered under such plans, including a prohibition on the application of preexisting conditions for individuals under age 19, no lifetime or annual limits, restrictions on rescissions, mandatory patient protections, and coverage of preventive care services. Grandfathered plans, however, are not subject to the mandatory patient protections and coverage of preventive care services requirements. The new requirements are effective for plan years beginning on or after September 23, 2010, unless otherwise noted below.

Prohibition on Preexisting Condition Exclusions

Under the Healthcare Reform Law, group health plans (including grandfathered plans) may not impose a preexisting condition exclusion for any individual under age 19. Beginning with plan years on or after January 1, 2014, the age limit no longer applies and plans may not apply a preexisting condition exclusion to any individual regardless of age.

The Rules apply the same definition of “preexisting condition” as the Health Insurance Portability and Accountability Act (HIPAA). Generally, a preexisting condition is any health condition or illness that was present before the coverage effective date, regardless of whether medical advice or treatment was actually received or recommended.

The Rules provide several examples of what constitutes a prohibited preexisting condition exclusion and clarify that denial of coverage based on a preexisting condition (rather than excluding from coverage benefits related to the condition) is also prohibited.

The Rules also clarify that any preexisting condition exclusion running at the time the prohibition takes effect is cut short and coverage must be offered immediately. For example, if a dependent child with asthma is covered under a calendar-year plan beginning October 1, 2010 and subject to a 12-month preexisting condition exclusion for all benefits related to asthma, that exclusion ends on January 1, 2011 when the prohibition goes into effect, and the plan must cover asthma-related claims for the child.

The Healthcare Reform Law and related Rules will eventually replace the HIPAA portability rules with respect to preexisting condition exclusions, and make obsolete the tracking of periods of prior health coverage and the issuance of certificates of creditable coverage for this purpose.

No Lifetime or Annual Limits

No Lifetime Limits

Under the Healthcare Reform Law, group health plans (including grandfathered plans) may no longer impose a lifetime limit on the dollar amount of essential health benefits under the plan.

The Rules do not limit the ability of a plan sponsor to exclude all benefits for a condition (though such exclusion may be limited by other state or federal laws) but provide that if a condition is covered there may be no lifetime limit. The Rules also do not restrict the plan sponsor’s ability to impose lifetime limits on nonessential health benefits.

The definition of “essential health benefits” includes services in the following categories and is subject to further guidance:

- Ambulatory patient services
- Emergency services
- Hospitalization
- Maternity and newborn care
- Mental health and substance use disorder services
- Behavioral health treatment
- Rehabilitative and habilitative services and devices
- Laboratory services
- Preventive and wellness services
Notice Requirement. The Rules provide that a notice must be given to group health plan participants that lifetime limits no longer apply, and that an individual who has reached the lifetime limit is once again eligible for benefits under the plan. In addition, if an individual is no longer enrolled in the plan, the plan must provide a notice and special enrollment opportunity to the individual. The notice must be provided no later than the first day of the first plan year beginning on or after September 23, 2010 and the individual must be allowed a 30-day special enrollment opportunity. The notice may be included with other enrollment materials that a plan distributes to employees provided the notice is prominent. The DOL model language satisfying the notice requirement is available on its website at www.dol.gov/ebsa/lifetimelimitsmodelnotice.doc.

Restriction on Annual Limits

Beginning January 1, 2014, group health plans (including grandfathered plans) may no longer impose an annual limit on the dollar amount of essential health benefits. For plan years beginning prior to January 1, 2014, the plan may impose an annual limit on the dollar amount of essential health benefits subject to certain restrictions.

The Rules provide a gradual implementation opportunity for plan sponsors to impose an annual limit prior to 2014 which increases each year. A group health plan may establish an annual limit on the dollar amount of essential health benefits provided it is not less than the following limits:

<table>
<thead>
<tr>
<th>Annual Limit</th>
<th>For Plan Years</th>
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<tbody>
<tr>
<td>$750,000</td>
<td>On or after 9/23/2010 and before 9/23/2011</td>
</tr>
<tr>
<td>$1,250,000</td>
<td>On or after 9/23/2011 and before 9/23/2012</td>
</tr>
<tr>
<td>$2,000,000</td>
<td>On or after 9/23/2012 and before 9/23/2013</td>
</tr>
</tbody>
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Caution: Keep in mind that if a plan does not have an annual limit or its current annual limit is higher than the restricted amounts above, imposing a new annual limit or lowering the annual limit to take advantage of this incremental restriction will cause a plan to lose grandfathered status.²

Annual Limit Waiver Program. Some plan sponsors have expressed concern that imposing this annual limit on a limited benefit plan (a “mini-med” plan) will significantly increase the cost of the plan to employees. In response to these concerns, the Rules open the door for a waiver program to be implemented by the Department of Health and Human Services (HHS). For plan years beginning before January 1, 2014, the program will provide an opportunity to request waiver of the application of the annual limit prohibition for certain limited benefit group health plans if imposing the annual limit will cause a significant decrease in access to coverage or a significant increase in premiums. Additional guidance from HHS is expected soon.

Restriction on Rescission

Under the Healthcare Reform Law, group health plans (including grandfathered plans) may not rescind coverage (i.e., terminate coverage retroactively) except in the case of an act, practice, or omission constituting fraud or an intentional misrepresentation of material fact as prohibited by the terms of the plan. If a rescission is warranted, the Rules also state that a 30-day advance written notice must be provided to each affected participant before coverage may be rescinded.

*Tip:* Note that the Rules reference the terms of the plan. Plan documents and SPDs should be reviewed and updated, if necessary, to mirror the rescission language in the Rules.

Making a case to show “fraud or intentional misrepresentation of material fact” is a high standard to meet and plan sponsors may find it challenging to prove intent on the part of participants who simply fail to disclose information. In addition, the Rules will disrupt many common administrative practices and essentially end the retroactive termination of coverage due to employer or carrier mistakes.

The Rules do not prohibit retroactive termination of coverage due to failure to pay premiums or prospective termination of coverage.

Patient Protections

Under the Healthcare Reform Law, group health plans must provide certain protections related to an individual’s choice of healthcare provider and access to emergency services. Grandfathered plans are not subject to this requirement.

Choice of Primary Care Provider

The Rules clarify two patient protections with respect to a participant’s right to choose a primary care provider:

- **Primary Care Provider or Pediatrician.** If the group health plan requires the designation of a primary care provider, the participant must be permitted to designate any participating primary care provider accepting new patients. With respect to a child, the participant may designate any participating physician who specializes in pediatrics as the child’s primary care provider.

- **OB/GYN.** A group health plan may not require authorization or referral for obstetrical or gynecological care. A participant may receive such services from any participating OB/GYN specialist.

Notice Requirement. The Rules require group health plans to provide notice to participants of the right to (1) choose a primary care provider or a pediatrician when a plan requires designation of a primary care physician, and (2) obtain obstetrical or gynecological care without prior authorization. The notice must be provided with the summary plan description or other similar description of benefits under the plan no later than the first day of the first plan year beginning or after September 23, 2010. The DOL model language satisfying the notice requirement is available on its website at [http://www.dol.gov/ebsa/patientprotectionmodelnotice.doc](http://www.dol.gov/ebsa/patientprotectionmodelnotice.doc).

If proper notice is provided and the participant fails to designate a provider, the plan may designate a provider until one has been designated by the participant.
**Emergency Services**

The Rules also outline new mandates with respect to coverage for emergency services and cost-sharing for out-of-network emergency services. If a group health plan provides coverage for emergency services, it may not require prior authorization for emergency care or require higher cost-sharing amounts for out-of-network services. While co-pays or coinsurance must be the same for in-network and out-of-network emergency services, the Rules do permit out-of-network providers to bill participants for the balance of the out-of-network provider rate over the amount the plan pays. This “balance bill” provision only applies, however, if the plan pays an amount equal to the greatest of the three following amounts:

- The median of all negotiated rates with network providers for the emergency services furnished, excluding amounts attributable to participant cost-sharing
- The amount the plan pays for out-of-network benefits (the usual, customary, and reasonable amount, or UCR) less the in-network co-pay or coinsurance that the participant would be responsible for if the emergency services had been provided in-network
- The amount that would be paid under Medicare for the emergency services, excluding any in-network co-pay or coinsurance imposed with respect to the participant

The Rules walk through several examples of the emergency services coverage requirement and calculation of the amounts above.

**Coverage and Cost-Sharing for Preventive Care Services**

Under the Healthcare Reform Law, group health plans must provide certain in-network preventive care services without cost-sharing. Plans must cover and can no longer require a co-pay, co-insurance, or deductible for “recommended” preventive care services when delivered by an in-network provider. The plan may, however, continue to apply a co-pay, coinsurance, or deductible to preventive care services provided by an out-of-network provider. Grandfathered plans are not subject to this requirement.

Recommended preventive services required to be covered with no cost-sharing generally fall under one of four categories under the Rules:

- Evidence-based services with a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPTF)
  
  **Examples:**
  - Breast and colon cancer screenings
  - Screening for vitamin deficiencies during pregnancy
  - Diabetes screening
  - High cholesterol and high blood pressure screening
  - Tobacco cessation counseling

- Routine immunizations currently recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (ACIPCDC)
  
  **Examples:**
  - Tetanus shots for adults
  - Routine childhood immunizations

- Evidence-informed preventive care and screenings for infants, children, and adolescents in guidelines currently supported by the Health Resources and Services Administration (HRSA)
Examples:
  o Regular pediatrician visits
  o Vision and hearing screening
  o Developmental assessments
  o Obesity screening and counseling

- Evidence-informed preventive care and screenings for women in guidelines currently supported by the HRSA. Guidelines for this category are expected to be issued by August 2011

A noteworthy exception in the Rules is that mammogram breast cancer screening will continue to be recommended under prior rules (annually) rather than the new less frequent USPTF recommendation that was issued in November 2009.

A complete list of current recommended preventive care services that must be provided with no cost-sharing under the Rules can be found at: http://www.HealthCare.gov/center/regulations/prevention.html. The Rules specify that the USPTF, HRSA, and ACIPCDC are required to review recommendations and guidelines each year and only current recommendations and guidelines are subject to the prohibition on cost-sharing. If the list is updated to add a new recommended preventive care service, plan sponsors will have one year to update plan coverage. If a recommended preventive care service is dropped from the list, the plan is no longer required to provide that service subject to other state or federal requirements or notice obligations.

The Rules also outline permissible cost-sharing when preventive care services are provided as part of an office visit together with other services. Whether a co-pay, coinsurance, or deductible may be applied depends on whether the services are tracked and billed separately. The Rules provide examples illustrating the following three possible outcomes:

- The plan **may** impose cost-sharing with respect to the cost of the office visit if the preventive care service is billed or tracked separately from the office visit.
- The plan **may not** impose cost-sharing with respect to the cost of the office visit if the preventive care service not billed or tracked separately and the primary purpose of the office visit was to receive the preventive care service.
- The plan **may** impose cost-sharing with respect to the cost of the office visit if the preventive care service is not billed or tracked separately and the primary purpose of the office visit was not the preventive care service.

The Rules also clarify that if a required preventive care service has no recommended frequency, method, treatment, or setting for the service, the group health plan may use reasonable medical management techniques to determine coverage limitations related to the service.

**Plan Sponsor Action**

Plan sponsors should assess current group health plan design to identify changes that will be required to comply with the Healthcare Reform Law, consider whether any contemplated plan design changes may conflict with preservation of grandfathered plan status, if applicable, assimilate the notice requirements with enrollment materials and summary plan descriptions and consult with its third-party insurer or stop loss carrier to determine the cost impact of the changes.
Morgan Lewis will continue to monitor developments as final guidance is released regarding Healthcare Reform and its implications. For more information, or if you have questions regarding the issues discussed in this LawFlash, please contact Andy R. Anderson (312.324.1177; aanderson@morganlewis.com) or Kimberly J. Boggs (312.324.1758; kboggs@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

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