

July 22, 2010

MEMORANDUM TO CLIENTS

RE: Preventive Care Requirements under PPACA—Interim Final Rule

On July 19, 2010, the Departments of Health and Human Services ("HHS"), Labor ("DOL"), and Treasury jointly published "Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act" (the "Rule"). 75 Fed. Reg. 41726 (July 19, 2010). The Rule requires group health plans and health insurers to *cover certain preventive health services* and to *eliminate cost-sharing requirements* for such services. The Rule does not apply to grandfathered plans.

Among other things, the Rule describes the limited circumstances under which coverage limitations or cost-sharing (which, according to the Rule, includes a copayment, coinsurance, or deductible) may be permitted with respect to preventive services. Notably, the Rule provides that cost-sharing is permitted in the case of a participant receiving preventive care from an out-of-network provider. The Rule is effective on September 17, 2010, and generally applies for plan years beginning on or after September 23, 2010. Comments on the Rule are due by September 17, 2010.

I. Background

Section 2713 of the Public Health Service Act ("PHSA"), as added by the Patient Protection and Affordable Care Act ("PPACA" or the "Act"), generally requires that group health plans and insurers offering group or individual health insurance: (1) provide coverage for certain preventive health services, and (2) not impose cost-sharing requirements with respect to such services. In general, these requirements apply with respect to the following types of recommendations and guidelines:

- Evidence-based items or services rated A or B in the current recommendations of the United States Preventive Services Task Force ("USPSTF");
- Immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention ("ACIP");
- Preventive care and screenings for infants, children, and adolescents, provided for in the comprehensive guidelines supported by the Health Resources and Services Administration ("HRSA");
- Additional preventive care and screenings for women as provided for in the comprehensive guidelines supported by the HRSA; and

- Recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention, excluding the recommendations issued in or around November 2009.

The Act generally requires HHS, DOL, and Treasury to establish a minimum interval (not shorter than one year) between the date a recommendation or guideline is issued and the plan year in which the recommendation must be covered by group health plans and insurers. The Act also provides the agencies with discretion to develop guidelines to permit a group health plan or health insurer to utilize "value-based insurance designs."

II. Interim Final Rule

A. General Rules

1. Definition of Preventive Health Services

The Rule generally tracks the statutory language regarding the definition of preventive health services subject to the coverage and no cost-sharing requirements (referred to in the Preamble to the Rule and this memorandum as "recommended preventive services"). The Preamble includes a chart with the list of recommended preventive services subject to the new rules as of July 13, 2010. The Preamble also includes a link to the complete list of recommended preventive services on the Federal government's healthcare.gov website:

<http://www.healthcare.gov/center/regulations/prevention/recommendations.html>. This link contains the current list of Grade A and Grade B recommendations for preventative services made by the USPSTF. That list is identical to the list of Grade A and Grade B recommendations found on the USPSTF website itself as of July 20, 2010. One difficulty with the list is that there is no explanation concerning the scope or frequency of items that are required to be covered. It is unclear at this time whether the agencies will issue further guidance to address questions concerning listed services.

The Rule clarifies that the covered immunizations are those "for routine use in children, adolescents, and adults" that have "in effect" a recommendation of the ACIP, and that such a recommendation is considered to be "in effect" after it has been adopted by the Director of the Centers for Disease Control and Prevention.

The Rule also provides that the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered current. The Preamble clarifies that this means the recommendations regarding these matters issued by the USPSTF before those issued in or around November 2009 will be considered current until new recommendations in this area are issued by the USPSTF or appear in comprehensive guidelines supported by the HRSA.

2. Timing of Recommendations and Required Coverage

The Rule provides that a plan or insurer must provide required coverage for recommended preventive services without cost-sharing for plan (or policy) years beginning on or after September 23, 2010, or, if later, for plan (or policy) years beginning on or after the date that

is one year after the applicable recommendation or guideline is issued. For calendar year plans, this means that for the 2011 plan year, coverage must be provided for recommended preventive services addressed in recommendations or guidelines issued prior to January 1, 2010.

The Preamble clarifies when a recommendation or guideline is considered to be issued for purposes of this one-year timing rule:

- A recommendation or guideline of the Task Force is considered to be issued on the last day of the month on which the Task Force publishes or otherwise releases the recommendation;
- A recommendation or guideline of the Advisory Committee is considered to be issued on the date on which it is adopted by the Director of the Centers for Disease Control and Prevention; and
- A recommendation or guideline in the comprehensive guidelines supported by the HRSA is considered to be issued on the date on which it is accepted by the Administrator of the HRSA or, if applicable, adopted by the Secretary of HHS.

The Preamble also notes that the list of recommended preventive services on the Federal government's Healthcare.gov website will be updated on an ongoing basis, and will include the date on which the recommendation or guideline was adopted or accepted.

B. Coverage and Cost-Sharing Rules

1. Out-of-Network Providers

The Rule provides helpful guidance with respect to the application of these rules to recommended preventive services provided by out-of-network providers. The Act did not specify whether plan sponsors and insurers are required to cover recommended preventive services provided by out-of-network providers, or whether plan sponsors and insurers could impose cost-sharing requirements on any such out-of-network services. The Rule clarifies that in the case of a plan or insurer that has a network of providers, the plan or insurer (i) is not required to provide coverage for recommended preventive services delivered by an out-of-network provider, and (ii) may impose cost-sharing requirements for recommended preventive services delivered by an out-of-network provider.

2. Cost-Sharing for Office Visits

The Rule also clarifies how the cost-sharing rules apply in the case of a recommended preventive service provided during an office visit. Generally, the Rule provides as follows:

- If a recommended preventive service is billed separately (or is tracked as "individual encounter data" separately) from an office visit, then cost-sharing requirements may be imposed with respect to the office visit;
- If a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose

of the office visit is the delivery of the recommended preventive service, then cost-sharing requirements may not be imposed with respect to the office visit;

- If a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of the recommended preventive service, then cost-sharing requirements may be imposed with respect to the office visit.

According to the Preamble, the reference to tracking "individual encounter data" was included to provide guidance with respect to plans and insurers that use capitation or similar payment arrangements that do not bill individually for items and services.

In addition, the Rule includes four examples illustrating the following:

- In the case of an individual receiving a cholesterol test (a recommended preventive service) during a routine, in-network office visit, the plan or insurer may impose cost-sharing requirements for the office visit because the cholesterol test is billed separately.
- A treatment resulting from a preventive care screening can be subject to cost-sharing requirements if the treatment itself is not a recommended preventive service.
- Where an individual receives a blood pressure screening (a recommended preventive service) that is not billed separately during an in-network office visit to discuss recurring abdominal pain, the plan may impose a cost-sharing requirement for the office visit charge because the primary reason for the visit was not the delivery of the recommended preventive service.
- Where a child receives an annual physical exam (a recommended preventive service) that is not billed separately during an in-network office visit to receive the exam, and also receives services that are not recommended preventive services during the visit, the plan may not impose a cost-sharing requirement for the office visit charge because the primary reason for the visit was the delivery of the recommended preventive service

3. Treatment of Non-Preventive Services

The Rule clarifies that nothing in the new regulations prevents a plan or insurer from covering additional items and services that are not recommended preventive services, or from denying coverage for such additional items and services. It also clarifies that a plan or insurer may impose cost-sharing requirements for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.

4. Use of Medical Management Techniques

The Rule provides that a plan or insurer may use "reasonable medical management techniques" to determine the frequency, method, treatment, or setting for a recommended preventive service to the extent such information is not specified in the applicable recommendation or guideline. The Preamble notes that a plan or insurer may use reasonable medical management techniques in those circumstances to determine any coverage limitations, and to adapt the relevant recommendations and guidelines to the coverage of specific items and services for which cost-sharing is not permitted.

III. Other Guidance in the Rule

A. Value-Based Designs

PPACA provides the agencies with authority to develop guidelines to permit a plan or insurer to utilize "value-based insurance designs." The Preamble provides that value-based insurance designs "include the provision of information and incentives for consumers that promote access to and use of higher value providers, treatments and services." It then cites the fact that the Rule permits plans and issuers to implement designs with cost-sharing for recommended preventive services delivered out-of-network as an example of the agencies' recognition of the important role that value-based insurance designs can play in promoting the use of appropriate preventive services. The Preamble also states that the agencies are developing additional guidelines regarding the utilization of value-based designs, and requests comments related to the development of the guidelines.

B. Services Ceasing to be Recommended Preventive Services

The Rule provides that plans and issuers are not required to provide coverage for items and services that cease to be a recommended preventive service. The Rule, however, then provides that other Federal or State law requirements may apply in connection with a plan or insurer ceasing to provide coverage (or changing cost-sharing requirements) for any such items or services, and cites PPACA's 60-day advance notice requirement (found in new PHSA § 2715(d)(4)) as an example of such a requirement. This provision requires a group health plan or insurer to provide 60 days advance notice to an enrollee before any "material modification" becomes effective. The Rule and Preamble do not expressly state that this 60-day advance notice requirement is effective currently – and we do not think that is the best reading of the PPACA statutory language – but do state that PHSA § 2715(d)(4) "requires" the notice (using the present tense). Because the effective date is not specifically addressed in the statutory language, this reference in the Rule has generated some concern that the regulators may take the position in future guidance that the requirement is currently effective.

IV. Conclusion

Plan sponsors and insurers should examine their plans and policies to ensure that: (1) all recommended preventive services are covered, and (2) no cost-sharing is imposed on recommended preventive services that are provided in-network. While the Rule lists those recommended preventive services that must be covered without cost-sharing for the upcoming

plan year, plan sponsors and insurers will need to monitor the recommended preventive services list to track future updates for plan years that begin after July 19, 2011. In addition, in the absence of further guidance, plan sponsors and insurers will need to develop their own interpretations of the specific requirements associated with providing a listed service.

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