ERIC

The
ERISA
Industry
Committee

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Room 5205
Internal Revenue Service
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

Attention: REG-120391-10

Ladies and Gentlemen:

The ERISA Industry Committee ("ERIC") is pleased to submit these comments on the interim final regulations for group health plans and health insurance issuers relating to coverage of preventive services under the Patient Protection and Affordable Care Act ("ACA"). The interim final regulations were published by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the Departments) in the *Federal Register* on July 19, 2010.

ACA amends the Public Health Service Act to include new section 2713. Section 2713 requires non-grandfathered group health plans to provide benefits for (1) evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (the "Task Force"); (2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention; and (3) evidence-informed preventive care and screenings for infants, children, adolescents, and women supported by the Health Resources and Services Administration ("HRSA") (collectively, "recommended preventive services"). Section 2713 prohibits group health plans from imposing any in-network cost-sharing requirements, such as copayments, coinsurance, or deductibles, on the recommended preventive services.

ERIC's Interest in the Interim Final Regulations

ERIC is a nonprofit association committed to the advancement of the employee retirement, health, incentive, and welfare benefit plans of America's largest employers. ERIC's members sponsor some of the largest private group health plans in the country. These plans provide comprehensive health benefits to tens of millions of workers and their families.

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ERIC's members are committed to, and known for, providing high-quality, affordable health care. They expend considerable resources to maintain plans of this caliber. It has become increasingly difficult for companies to maintain comprehensive group health plans, however, as medical costs continue to grow at unsustainable rates.

Many ERIC members offer extensive coverage for preventive services under their plans. The interim final regulations, however, appear to require plans to provide services that significantly exceed those that our members currently provide. Moreover, ERIC is concerned that the new preventive care regulations impose mandates that are based on recommendations for an audience of health care providers and, as such, are often ambiguous or unclear with respect to their application to health plans.

Depending on the scope of these mandates, plans could be forced to expand their coverage for preventive services beyond the level required by the statute, adding significant new cost burdens at a time when increasing costs are already driving many employers to question the extent of the coverage they offer. ERIC offers a number of recommendations below to resolve some of this ambiguity, helping employers understand the parameters of the regulation and comply with the new preventive care mandate.

ERIC welcomes and strongly supports the provisions in the interim final regulations that permit employers to apply reasonable medical management techniques to preventive care. We offer several recommendations that will clarify and strengthen this key concept. ERIC also strongly supports the provisions that promote value-based insurance designs by permitting plans to impose cost-sharing requirements on out-of-network services. We are concerned, however, that the regulations do not provide sufficient guidance to plan sponsors and administrators in several important areas, including:

(1) distinguishing between preventive care and treatment, and making clear that plans are not required to cover the cost of treatment;

(2) confirming that plans are not required to cover taxable benefits (such as over-the-counter drugs);

(3) confirming that a plan will not become subject to the parity requirements of MHPAEA merely because it provides a mental health or substance use disorder benefit in compliance with the regulations' recommended preventive services (such as counseling for alcohol misuse); and

(4) explaining technical terms related to counseling and interventions in a way that will help plan sponsors and administrators to understand the scope of the recommendations and the preventive services that must be offered. ERIC provides specific recommendations in each of these areas.

ERIC offers specific recommendations in each of these areas and urges that the Departments establish an advisory task force that will give employer plan representatives a voice in the process used to identify preventive services in the future.

Comments on the Regulations

1. The regulations should clarify and illustrate the scope of a plan's discretion to use reasonable medical management techniques.

Group health plans are required to cover items and services identified in recommendations and guidelines included in section 2713 of the Public Health Service Act. In many cases, these guidelines are quite general: they recommend a preventive service, but do not specify where, how, or how often the service must be provided.

The interim final regulations state that plan administrators may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for a recommended preventive service to the extent not specified in the recommendations or guidelines.[1] The Departments state that plans may use this authority "to adapt the recommendations and guidelines to coverage of specific items and services where cost-sharing must be waived."[2] Accordingly, although the interim final regulations identify the recommended preventive services that plans must cover, they give plans the authority to identify the specific items and services they must cover and to limit the scope of their coverage using reasonable medical management techniques.

We agree strongly that such decisions should be left to plan administrators and plan sponsors. We note, however, that employers face an excise tax of up to $100 per day per individual for each failure to comply with section 2713. In addition, plan administrators potentially must conduct a burdensome and exacting appeals process to resolve any dispute with participants concerning the preventive services the plan must cover without cost-sharing. Therefore, it is critically important that the Departments clarify and illustrate the extent of a plan's discretion to define the scope of coverage for recommended preventive services.

The Departments also should make clear that a plan may limit its coverage to the preventive services that are appropriate for the general population defined by the recommendations and guidelines (for example, men aged 35 and older): the plan is not required to cover more frequent screenings or other additional services

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[1] 26 C.F.R. § 54.9815-2713T(a)(4); 29 C.F.R. § 2590.715-2713(a)(1); 45 C.F.R. § 147.130(a)(1).

[2] 75 *Fed. Reg.* 41726, 41729 (July 19, 2010).

for specific individuals within that population who might be at higher risk for a particular condition (for example, a man with a family history of cardiovascular disease).

ERIC recommends that the Departments add examples to the interim final regulations that will, at a minimum, illustrate the following points:

- **Frequency of Service:** A plan may use reasonable medical management techniques to determine how often a participant may receive a recommended preventive service without cost-sharing, unless the recommendation includes a specific statement regarding frequency. For example, the Task Force recommends that women aged 65 and older be screened "routinely" for osteoporosis. Because the recommendation is silent as to the frequency of the screenings, a plan may cover a screening for osteoporosis only once every five years if it determines, using reasonable medical techniques, that this frequency is appropriate. The plan is not required to cover more frequent screenings even if they are recommended by a physician for an employee who has a family history of osteoporosis.

- **Recommended Range of Frequencies:** If the recommendation covers a range of possible frequencies for a particular service, the plan is required to cover only the low end of the range. For example, the Task Force recommends screening mammographies "every 1–2 years for women aged 40 and older." The plan may cover a mammography every other year for a woman aged 40 or older, even if a patient's doctor recommends that she receive a mammogram every year.

- **Setting:** If a recommended preventive service may be provided in more than one setting (for example, in a doctor's office, on an outpatient basis, or on an inpatient basis), a plan may use reasonable medical management techniques to determine what setting or settings it will cover for the service. For example, the Task Force recommends screening adults for depression. If the plan determines that the screening can be conducted effectively in a doctor's office, the plan is not required to cover a patient's 48-hour stay in a mental health clinic that offers depression screening on an inpatient basis.

- **Method:** Some preventive services may be provided in more than one way. If a recommendation or guideline identifies more than one item or service for preventing a particular condition, the plan is required to cover only one of the recommended items or services and may use reasonable medical management techniques to determine which item or service to cover. For example, the Task Force recommends screening for colorectal cancer between age 50 and age 75 using fecal occult blood testing, sigmoidoscopy, or colonoscopy. The Task Force observes that "[t]he risks and benefits of these screening methods vary." A plan may cover a colorectal screening using only

fecal occult blood testing if the plan sponsor determines, using reasonable medical management techniques, that this screening is effective for the majority of participants in the covered age group. Similarly, if a plan sponsor chooses to cover colonoscopy, the plan may specify that it will cover actual colonoscopy but not virtual colonoscopy.

- **Scope:** It often is not clear what elements are included in a recommended preventive service. A plan may rely on reasonable medical management techniques to determine what items or procedures are a necessary part of the service. For example, if the plan covers colonoscopy as a preventive service to screen for colorectal cancer, the plan might conclude that this service includes the cost of preparation for the colonoscopy procedure, the procedure itself, sedatives and anesthesia provided in connection with the colonoscopy, related lab work, radiology, and a follow-up office visit to interpret the results of the procedure, but does not include the treatment of complications resulting from the colonoscopy.

2. The regulations should make clear that plans are not required to cover the treatment of conditions identified through recommended preventive care.

The treatment of a condition that has become clinically apparent is not preventive care.[3] Section 2713 of ACA requires plans to cover recommended preventive services without cost-sharing, but it does not require plans to cover recommended treatments for particular conditions. In many cases, however, the recommendations and guidelines incorporated in the statute do not clearly state where prevention stops and treatment begins. The Departments should revise the regulations to make clear that the mandate to cover recommended preventive services does not require a group health plan to cover the cost of treating a particular condition, even if the treatment is mentioned in the recommendations and guidelines. The regulations should also make clear that a plan administrator may make reasonable judgments concerning the point at which prevention ends and treatment begins.

For example, the Task Force recommends screening adolescents age 12–18 for major depressive disorder "when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up." The plan is required to cover the cost of the initial screening as a recommended preventive service, but it is not required to cover the cost of the psychotherapy or follow-up that would be used to treat an actual depressive disorder identified in the screening.

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[3] *See* I.R.S. Notice 2004-50, 2004-2 C.B. 196, Q&A-27 ([T]he preventive care safe harbor under section 223(c)(2)(C) does not include any service or benefit intended to treat an existing illness, injury, or condition, including drugs or medications used to treat an existing illness, injury or condition.")

Similarly, if a physician detects and removes polyps during a routine colonoscopy covered by the Task Force recommendations, the plan is required to cover the cost of the colonoscopy as a recommended preventive service, but is not required to cover the cost of the polyp removal as a recommended preventive service.

As we explain below, the distinction between preventive care and treatment is especially important as it relates to the various types of counseling included in the Task Force's recommendations. The interim final regulations should make clear that a plan is not required to cover counseling when the purpose of the counseling is to treat an existing condition. For example, a group health plan would be required to cover counseling to prevent sexually transmitted infections in patients at increased risk. If a patient contracted a sexually transmitted infection, however, the plan would not be required to cover the treatment of the infection, including any counseling provided in connection with the treatment.

3. The regulations should make clear that plans are not required to cover interventions identified in the guidelines that are not part of the recommended preventive services.

The purpose of some recommended preventive services is to make the patient aware of possible interventions. Although the interventions might, in some cases, be viewed as prevention rather than as treatment, they are not included in the recommendation. In these cases, the interim final regulations should make clear that the plan must cover only the cost of the recommended counseling: the plan is not required to cover the cost of any intervention the patient elects to pursue as a result of the counseling.

For example, the Task Force recommends that clinicians discuss the benefits and harms of chemoprevention for women at high risk of breast cancer. Accordingly, a plan is required to cover the cost of an office visit whose primary purpose is to convey information about chemoprevention. In contrast, however, if a woman elects to receive chemoprevention, the plan is not required to cover the cost of the chemoprevention itself. The Task Force does not recommend that every woman at high risk of breast cancer actually receive chemoprevention, but only that she receive counseling concerning the risks and benefits of this intervention. Accordingly, chemoprevention is not a recommended preventive care service.

Similarly, screening for obesity and referral for counseling are recommended preventive services that a plan must cover without cost-sharing. In contrast, if an obese patient elects to receive counseling or other forms of intervention, the counseling or intervention is not a recommended preventive service that the plan must cover. The Task Force's recommendations concerning obesity are as follows (with emphasis added):

> "The [Task Force] recommends that clinicians screen all adult for obesity and *offer* intensive counseling and

> behavioral interventions to promote sustained weight loss for obese adults."
>
> "The [Task Force] recommends that clinicians screen children aged 6 years and older for obesity and *offer them or refer them* to comprehensive, intensive behavioral interventions to promote improvement in weight status."

Accordingly, we urge the Departments to clarify that once the clinician has screened the patient and made the offer or referral, the recommended preventive service is at an end. Thus, any actual counseling or intervention should be considered a separate service that is not included in the Task Force's recommendation.

4. The regulations should not require a group health plan to cover a preventive item or service that is not exempt from taxation as a medical expense.

When employers provide compensation to their employees under a group health plan, the group health benefits are excludable from the employees' gross income for federal income tax purposes. Group health plans generally do not cover items that are, or might be, taxable to the employee.

Several of the recommended preventive items and services are taxable under the Internal Revenue Code. For example:

- The Task Force recommends the use of aspirin to reduce the likelihood of certain forms of cardiovascular disease. Effective January 1, 2011, ACA has amended the Internal Revenue Code to provide that reimbursements for over-the-counter drugs such as aspirin will not be excludable from gross income.[4]

- The Task Force recommends a daily supplement of folic acid for women who are planning or capable of pregnancy. Reimbursements by group health plans for dietary supplements generally are not excludable from gross income unless they are prescribed by a physician for treatment of a diagnosed condition.[5]

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[4] I.R.C. § 106(f) as added by ACA § 9003.

[5] Rev. Rul. 2003-102 (Sept. 3, 2003) (explaining that expenditures for nutritional supplements that are merely beneficial to the participant's general health are not excludible under Code § 105(b) because they are not an expense for medical care within the meaning of Code § 213.); I.R.S. Pub. No. 502 at p. 16 (Nov. 10, 2009)(explaining that nutritional supplements may be deducted under Code § 213 if they are recommended by a physician for the treatment of a diagnosed condition).

- The Task Force recommends intensive behavioral dietary counseling by a dietician or nutritionist for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. The cost of medical nutrition therapy is not a medical care expense.[6]

We do not think Congress intended to force group health plans to cover taxable items—particularly over-the-counter drugs, which Congress was at pains to exclude from group health plan coverage in the same legislation.[7] Benefit payments under large group health plans often are made by a third-party claims administrator that is different from the employer's payroll administrator: the claims administrator does not have the capability to track taxable reimbursements or to issue Forms W-2 or 1099 to participants who receive taxable payments.

The administrative burdens and risks associated with taxable payments are especially great in the case of health reimbursement accounts and health flexible spending accounts, since the Internal Revenue Service has ruled that these accounts will lose their tax-advantaged status if they permit participants to receive any reimbursement for taxable items or services.[8] These accounts must follow detailed substantiation procedures in order to ensure that participants do not inadvertently receive reimbursement for the cost of taxable items such as aspirin.[9] Even assuming that the Internal Revenue Service creates an exception for taxable preventive services, it will be exceptionally difficult for employers and third-party administrators to develop, and to explain to covered employees, a system that allows reimbursement of some taxable items and not others.

The cost of building administrative systems and processes to allow taxable reimbursements under a group health plan would be many times greater than the cost to the participant of purchasing aspirin or similar items with the participant's own funds. To the extent possible, ERIC's members favor a solution under which the Internal Revenue Service would make clear that recommended preventive services are not includable in a participant's gross income. Where the statute precludes the Internal Revenue Service from treating preventive services as tax-free benefits, however, the Departments should revise the regulations to make clear that a group health plan is not required to cover any preventive item or service that would be included in an employee's gross income under the Internal Revenue Code.

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[6] IRS Information Letter 2000-0276 (Dec. 29, 2000).

[7] ACA § 9003 excludes over-the-counter drugs other than insulin from reimbursement as medical expenses.

[8] *See, e.g.,* Rev. Rul. 2006-36, 2006-2 C.B. 353; Rev. Rul. 2005-24, 2005-1 C.B. 892; I.R.S. Notice 2002-45, 2002-2 C.B. 93; Prop. Treas. Reg. § 1.125-5(k)(1).

[9] *See, e.g.,* IRS Notice 2006-69, 2006-2 C.B. 107; Rev. Rul. 2003-43, 2003-1 C.B. 935.

5. The Department of Treasury should make clear that high deductible health plans may cover recommended preventive services.

High deductible health plans described in section 223(c)(2) of the Internal Revenue Code generally must impose an annual deductible on participants' medical expenses. Although these plans are permitted to cover preventive care without imposing a deductible, the items that the Internal Revenue Service recognizes as preventive care for this purpose do not always match the recommended preventive services that the plans must cover under ACA. For example, the interim final regulations require plans to cover screenings for obesity in children aged six years and older. In contrast, the safe harbor list of preventive screenings for high deductible health plans includes obesity screenings only for adults.[10] The safe harbor list of preventive care for high deductible health plans does not mention interventions, such as interventions to support or promote breast feeding. In addition, it is not clear to what extent counseling can be treated as a form of preventive care under high deductible health plans, although the Task Force recommendations identify various forms of counseling as mandated preventive services.

A high deductible health plan will not meet the requirements of Internal Revenue Code section 223(c)(2) if it covers medical expenses before a participant has met the annual deductible and if the expenses do not qualify as "preventive care" under section 223(c)(2)(C). Accordingly, we request that the Department of Treasury issue guidance making clear that any item or service identified as "preventive care" for purposes of the ACA mandate will automatically qualify as "preventive care" for purposes of the rules governing high deductible health plans.

6. A plan that does not otherwise cover mental health and substance use disorder benefits should not become subject to the MHPAEA merely because it complies with a Task Force recommendation requiring the provision of mental health or substance use disorder benefits.

Many of the Task Force recommendations require plans to provide counseling for various conditions, including alcohol misuse, tobacco use, obesity, and sexually transmitted diseases. We assume that some of these counseling services would be considered mental health or substance use disorder benefits under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (the "MHPAEA").[11] For example, alcohol abuse is considered a substance use disorder under the current version of the International Classification of Diseases, with the

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[10] I.R.S. Notice 2004-23, 2004-15 I.R.B. 725.

[11] Pub. L. No. 110-343 (2008).

result that counseling for alcohol misuse is a substance use disorder benefit subject to the parity requirements of the MHPAEA.[12]

The statutory provisions amended by MHPAEA specifically provide that they do not require group health plans to offer mental health or substance use disorder benefits.[13] If a plan sponsor chooses to offer these benefits, however, then the plan must ensure that any limitations imposed on the mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitation applied to substantially all medical and surgical benefits in the same classification. Compliance with these parity requirements is a significant and costly administrative burden and often entails a substantial redesign of the plan itself.

Nothing in ACA suggests that Congress intended to overturn the provision of the MHPAEA that gives employers the freedom to choose whether to offer mental health or substance use disorder benefits and, thus, whether they will be subject to the parity restrictions of MHPAEA. If the preventive care provisions of ACA require plans to provide coverage for any mental health or substance use disorders, however, plan sponsors will no longer be able to choose whether they wish to subject their plans to the parity requirements. Instead, the plan sponsors will be forced not merely to cover substance use disorder benefits that are classified as preventive but also to provide these benefits on a basis that is in parity with the plan's medical and surgical benefits.

We request that the Departments issue guidance to provide that a plan will not become subject to the parity requirements of MHPAEA merely because it provides a mental health or substance use disorder benefit in compliance with the regulations' recommended preventive services. This exclusion would preserve the MHPAEA's intent not to force employers to provide benefits that will be subject to the parity requirements.

7. The Departments should clarify the scope of the recommendations requiring counseling.

The Task Force recommendations are written for an audience of health care providers rather than plan sponsors. The recommendations often use technical or clinical terms that do not convey any clear meaning to plan sponsors; thus, it is difficult for plan sponsors to understand the parameters of the recommendations and the exact scope of the services that must be covered. Plan sponsors need guidance from the Departments to assist them in understanding exactly what preventive services they must provide.

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[12] 26 C.F.R. § 54.9812(a); 29 C.F.R. § 2590.712(a); 45 C.F.R. § 146.136(a).

[13] Code § 9812(b); ERISA § 712(b); PHSA § 2726 (after renumbering of PHSA by ACA).

The recommendations and guidelines include the following similar phrases relating to counseling:

1. Task Force recommendation regarding counseling for alcohol misuse: Recommends *behavioral counseling interventions* to reduce alcohol misuse.

2. Task Force recommendation regarding counseling for BRCA screening: Recommends referrals for *genetic counseling and evaluation* for BRCA testing.

3. Task Force recommendation regarding counseling for breast feeding: Recommends *interventions* to support breast feeding.

4. Task Force recommendation regarding counseling for diet: Recommends *intensive behavioral dietary counseling*, which may be provided by nutritionists and dieticians.

5. Task Force recommendations regarding screening and counseling for obesity in adults and children: Recommends that providers offer *intensive counseling and behavioral interventions*.

6. Task Force recommendation regarding counseling for STIs: Recommends *high-intensity behavioral counseling* to prevent STIs.

7. Task Force recommendation regarding counseling for tobacco use in adults: Recommends *tobacco cessation interventions*.

8. Task Force recommendation regarding counseling for tobacco use in pregnant women: Recommends *pregnancy-tailored counseling*.

Plan sponsors need clarification regarding the meaning of these terms and other similar terms that may be used in other recommendations and guidelines and how the terms should be translated into required preventive services. For example, we request that the Departments explain the following:

- The differences, if any, between treatment and intervention and between intervention and counseling; for example, what is the difference between tobacco cessation interventions and treatment?

- The significance, if any, of the term "behavioral" in terms of the service provided; and

- Definitions of "intensive counseling", and "high-intensity behavioral counseling" and how they are to be measured as well as the difference, if any, between intensive and high-intensity counseling.

To the extent that the recommendations and guidelines require group health plans to cover any type of counseling or behavior modification, the Departments should clarify that counseling is required solely as a preventive measure to identify a possible risk or to reduce the possibility that the risk will lead to an adverse health condition, and not to treat an adverse condition that already exists. Moreover, the Departments should make clear that the plan may use reasonable medical management techniques to limit the types of providers and the number of sessions the plan will cover. It should be clear, for example, that a plan is not required to cover counseling services by an unlicensed provider.

8. The Departments should create an advisory task force that will give group health plans a voice in delineating the recommended preventive care mandates.

When the Task Force, the Centers for Disease Control and Prevention, or HRSA adopts a new recommendation or guideline for preventive care, the new item or service will be added automatically (after a one-year interval) to the list of items and services that group health plans must cover without cost-sharing. Similarly, when an item or service is downgraded or removed from the recommendations and guidelines, plans will no longer be required to cover the item or service.

The groups that develop recommendations and guidelines for preventive care consist mainly of health care providers and other professionals concerned with the delivery of health care. These groups do not include representatives of the employer group health plans that must cover these services. It would be extremely helpful if representatives of group health plans could have a voice in the process that will identify new items and services that must be covered as "recommended preventive services," and that will determine when items and services should be removed from the mandated coverage list. These representatives could help translate the provider recommendations into terms that plan sponsors can understand with respect to the precise benefits that must be offered. In addition, the employer plan representatives might have insights into participant behavior and plan administrative issues that would be helpful to the providers as they develop the preventive care recommendations.

Accordingly, we urge the Departments to create an advisory task force or other forum through which group health plan representatives can participate in the process of identifying and delineating the items and services that will be included in the recommendations for preventive care.

ERIC appreciates the opportunity to provide comments on the interim final regulations. If the Departments have any questions concerning our comments, or if we can be of further assistance, please let us know.

Sincerely,

Mark J. Ugoretz
President & CEO