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The Hewitt logo consists of the word "Hewitt" in a white, serif font, centered within a dark blue square.

September 16, 2010

Submitted electronically via the Federal Rulemaking portal @ www.regulations.gov

Attention: RIN 1210–AB44
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N–5653
U.S. Department of Labor
200 Constitution Avenue, NW.
Washington, DC 20210

Dear Sir or Madam:

Subject: 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 Affordable Care Act) (RIN 1210–AB44)

Hewitt Associates (Hewitt) welcomes the opportunity to submit for consideration by the Departments of Labor, Treasury, and Health and Human Services (the agencies) our comments relating to the interim final rules pertaining to preventive services published in the *Federal Register* on July 19, 2010.

Who We Are

Hewitt Associates (NYSE: HEW) provides leading organizations around the world with expert human resources consulting and outsourcing solutions to help them anticipate and solve their most complex benefits, talent, and related financial challenges. Hewitt works with companies to design, implement, communicate, and administer a wide range of human resources, retirement, investment management, health care, compensation, and talent management strategies. With a history of exceptional client service since 1940, Hewitt has offices in more than 30 countries and employs approximately 23,000 associates who are helping make the world a better place to work. For more information, please visit www.hewitt.com.

Hewitt is submitting comments on the following topics: value-based insurance design and covered preventive services.

Value-Based Insurance Design

The Affordable Care Act gives the agencies authority to develop guidelines for group health plans and health insurance issuers offering group or individual health insurance coverage to utilize value-based insurance designs (VBIDs) as part of their offering of preventive health services. In the preamble, the agencies ask for comments related to the development of such guidelines for VBID that promote consumer choice of providers or services that offer the best value and quality, while ensuring access to critical, evidence-based preventive services.

Defining Value-Based Insurance Design

From Hewitt's perspective, VBID can be defined as follows:

VBID is a benefit design that identifies clinically beneficial preventive screenings, lifestyle interventions, medications, immunizations, diagnostic tests and procedures, and efficacious treatments for which copayments or coinsurance may be adjusted due to their high value and effectiveness when prescribed for particular clinical conditions.

To be more specific, VBID is the use of incentives or disincentives to accomplish the following:

- Encourage the appropriate use of high-value services, including preventive services and prescription drugs;
- Discourage the overutilization of low-value, non-evidence-based services;
- Increase utilization of high-quality, low-cost providers and facilities that adhere to evidence-based treatment guidelines;
- Decrease utilization of low-quality, high-cost providers and facilities; and
- Adopt healthy lifestyles, such as smoking cessation, healthy eating habits, and increased physical activity.

The incentives and disincentives may include such initiatives as premiums or employee payroll contributions differentiated by behavior, plan design provisions (e.g., deductibles, copayments) differentiated by behavior or value of service, funding of health savings accounts (HSAs) or health reimbursement arrangements (HRAs) differentiated by behavior, or behavior-based cash or non-cash rewards.

VBID Use in the Group Health Plan Market

In today's economic environment, VBID is one of many solutions employers are implementing to improve health risk and mitigate cost. Value—clinical benefit achieved relative to cost expended—is largely absent from the current health care environment. Instead, disconnected conversations about cost and quality lead to mixed messages for plan participants. The goal of VBID is to get more value out of an employer's health care dollars by reducing financial barriers to essential care while improving patient compliance in efforts to reduce overall direct costs (e.g., hospital and emergency room charges) and indirect costs (e.g., productivity and absences) to payers.

A wide spectrum of VBID plans exists today, but the fundamental principles are based on two general approaches: clinically valuable services and select clinical diagnoses.

Clinically Valuable Services

The first approach simply targets clinically valuable services (or classes of medications) for copayment/cost-sharing reduction. This concept suggests that prescriptions for drugs treating chronic medical conditions such as hypertension, lipid disorder, or diabetes should cost nothing or very little to the patient compared to the expenses for non-chronic medical conditions. The philosophy suggests that if people do not have barriers (such as cost) to accessing necessary medications and services, they are more

likely to utilize them appropriately. Additionally, through appropriate medication utilization, the patient is more likely to prevent the major complications known to accompany these disease states, thus reducing total medical spend and increasing overall productivity.

Although this approach may provide substantial benefit for some users (e.g., covering a class of drugs called beta blockers for patients with heart failure or after a heart attack), it provides less value for other patients (people who use beta blockers for performance anxiety). This approach does not attempt to differentiate between these types of patients.

Select Clinical Diagnoses

The second approach targets patients with select clinical diagnoses (e.g., heart failure) and lowers copayments for specific high-value services (e.g., beta blockers and angiotensin converting enzyme (ACE) inhibitors). Designs cover what is considered to be “gold standard” medication therapy classes and services based on clinical practice guidelines for the disease being targeted. Only medications or medical services used to treat the targeted chronic condition are covered under the incentive-based plan. Medical services or medications for other indications (chronic or acute) have the non-incentive-based copayment or coinsurance applied. Although it requires a bit more technological sophistication with integrated medical and pharmacy data, this approach creates a differential copayment based on the patients’ own characteristics. Programs designed in this manner target the disease states that provide the greatest return on investment to lower direct and indirect medical cost. Ultimately, the long-term result should be an overall reduction in total health care spending.

Although this approach targeting patients is less common, two well-known programs, designed by the municipality of Asheville, North Carolina, and the University of Michigan, are implemented in this manner. Both of these organizations successfully created programs that reduced the copayments for selected medications for patients with diabetes along with education and marketing campaigns and coaching support for patients.

Other Areas Where Guidance Is Requested

In order to utilize VBID programs in the most effective way, Hewitt has identified some questions that we hope the agencies will consider providing guidance on in the final regulations or in other sub-regulatory guidance, as the agencies deem appropriate.

High-Value Medicines

A prevalent VBID design among employers is to cover high-value medications (e.g., beta blockers for a post-myocardial infarction patient) at no or reduced cost sharing. Medications in other therapeutic classes follow the standard plan design. Hewitt believes that such incentives encourage compliance with these recommended treatments that have been proven to be beneficial to the patient. Hewitt requests guidance on whether employers will be able to continue to vary cost sharing for other preventive or maintenance therapeutic classes of drugs.

Pharmacogenomics

Forward-thinking employers have recently explored a new area called pharmacogenomics, which is defined as the science concerned with ways to compensate for genetic differences in patients that cause varied

responses to a single drug. In other words, pharmacogenomics uses information about a person's genetic make-up to choose the drugs and doses that might work best for that individual. This new scientific approach may:

- Eliminate the “one-size-fits-all” approach to drug therapy; and
- Lead to a tailor-made approach based on a patient's unique genetic profile.

For example, in determining whether to cover the drug *Herceptin*® (trastuzumab) to treat breast cancer, the lab test would measure HER2 (overexpression) and answer the question, “Does tumor overexpress HER2, making it sensitive to *Herceptin*?” If the answer is yes, the plan would cover the drug at a higher percentage (e.g., 90%). If the answer is no, there would be no coverage for the medication. In a VBID plan design, this addresses both clinical and cost concerns. As medical technology in genetics advances, more of these types of drugs are expected to enter the marketplace. Hewitt suggests that the agencies consider allowing a plan to require the lab test at a minimal or no cost and then to allow coverage of the specific drug based on the results of the test.

Maximum Allowable Reimbursement

In any given market, there are potentially significant price and quality variations for the same service. One way to ensure quality yet control for costs is to set a maximum allowable reimbursement for a specific procedure in a given market. Therefore, Hewitt recommends that the agencies allow a plan or insurer to cover services up to a certain dollar threshold in a geographic market.

For example, if a given geographic market has ten providers that are “in network,” yet the charge for a routine mammogram ranges from \$500–\$1,500, the plan or insurer should be able to cover a mammogram provided in-network at 100% up to \$1,000.

Centers of Excellence

While the interim final regulations allow the imposition of cost sharing for preventive services received at out-of-network providers, it is unclear if the final regulations will allow employers to create coverage distinctions for preventive care delivered at centers of excellence. Hewitt suggests that the agencies allow plans and insurers to make such coverage distinctions.

For example, based on cost and quality outcomes, a plan or insurer may provide richer coverage if a patient seeks care at a specific center or facility for a certain set of procedures and standard coverage if the patient does not utilize the “preferred center,” even though both facilities are in-network.

Covered Preventive Services

The Affordable Care Act and these implementing regulations require non-grandfathered group health plans and health insurance issuers to cover an enumerated list of preventive health services with no cost sharing. Part of this list of covered preventive health services includes 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 (USPSTF) with respect to the individual involved.

Number of Similar Screening Tests That Must Be Covered

While Hewitt believes that this list of tests is fair and appropriate, there is ambiguity in what must be covered with no cost sharing when there are multiple tests that could be used for screening. For example, with respect to breast cancer screening, there are numerous current procedural terminology (CPT) codes covering mammography, some of which are screening and some of which are diagnostic in nature. It is unclear whether all or only some of these CPT codes must be covered in order to comply with the law.

Hewitt requests that the agencies specify which CPT codes must be covered in order to reduce the ambiguity that exists and to prevent a plan from having to cover numerous repeated tests that do not add value to a patient's diagnosis.

Similarly, there are CPT codes for screening for cholesterol, LDL, HDL, and a lipid panel. However, it is unclear if a plan would also need to cover screening for VLDL, microparticles, or apolipoproteins.

Determination of High-Risk Patients

Some of the screening tests are recommended only for individuals who are at increased risk, such as BRCA screening for breast cancer. Neither the interim final regulations nor the Affordable Care Act explains how the plan or payer will be able to know whether the individual is at increased risk and therefore whether the screening is appropriate. Hewitt is concerned that physicians may decide that everyone should be screened regardless of whether the individual is at increased risk for the disease leading to false positives, overdiagnosis, overtreatment, and ultimately harm to public health.

Coverage of Professional Services

The interim final regulations provide guidance on when cost sharing can be imposed on the patient when a recommended preventive service is provided during an office visit. However, it remains unclear what professional services the provider can or must include for reimbursement by the plan or insurer. Should only the preventive service codes be mandated? Or must the plan also cover office evaluation and management (E & M) services codes 99201-99215 for visits and consultations furnished by physicians when used for a preventive exam without other significant services? In addition, it is unclear which counseling codes must be covered—individual counseling only or both individual and group counseling codes. Hewitt recommends that the final regulations address this issue to provide clarification to plans, issuers, and providers.

Frequency of Preventive and Professional Services

The interim final regulations provide that if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations. Hewitt understands this statement in the interim final regulations to allow a plan to limit the frequency of certain services, such as colorectal cancer screening. However, it would be helpful if the final regulations include an example of this use of medical management techniques. In addition, Hewitt requests that the agencies clarify whether frequency limits can be placed on professional services where cost-sharing requirements may not be imposed.

Coverage of Prescription and Over-the-Counter Medicines

Many, if not all, health plans and insurers do not currently provide coverage for over-the-counter (OTC) medicines.

The USPSTF guidelines recommend the use of aspirin for specified individuals at risk for myocardial infarction or ischemic strokes. It is unclear whether or not a plan must cover the cost of the aspirin even though the plan does not otherwise cover OTC medicines. The same ambiguity exists for the coverage of folic acid for women planning or capable of pregnancy and for iron supplements for children age 6–12 months at risk for iron deficiency anemia. Hewitt suggests that plans and insurers should not be required to cover OTC medicines that do not require a prescription and that in addition, if a health plan or insurer does choose to cover OTC medicines, such as aspirin, that the plan be permitted to require a prescription for such coverage.

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With respect to counseling for tobacco use and the provision of tobacco cessation interventions, it is unclear what interventions plans and insurers are required to cover under these rules. It is unclear whether a plan or insurer must cover all pharmaceutical interventions for tobacco cessation, both prescription and OTC, or whether a plan or insurer can choose to cover only certain types of these interventions. Hewitt recommends that the agencies allow plans and insurers to choose to cover only certain types of these interventions and to not require coverage of OTC tobacco cessation products.

Closing

If you have any questions or comments, please contact the undersigned at the telephone number or e-mail address provided below.

Sincerely,

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