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**Docket:** IRS-2010-0017

Requirement for Group Health Plans and Health Insurance Issuers to Provide Coverage of Preventive Services under the Patient Protection and Affordable Care Act

**Comment On:** IRS-2010-0017-0001

Requirement for Group Health Plans and Health Insurance Issuers to Provide Coverage of Preventive Services under the Patient Protection and Affordable Care Act

**Document:** IRS-2010-0017-0005

Comment on FR Doc # 2010-17243

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## Submitter Information

**Name:** Raymond Frost

**Address:**

Woodcliff Lake, NJ,

**Organization:** Eisai Inc.

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## General Comment

Please find the attached comments from Eisai Inc. related to Document ID IRS-2010-0017-0001, Interim Final Regulation: Requirement for Group Health Plans and Health Insurance Issuers to Provide Coverage of Preventive Services under the Patient Protection and Affordable Care Act.

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## Attachments

**IRS-2010-0017-0005.1:** Comment on FR Doc # 2010-17243



Elsai Inc.  
100 Tice Blvd.  
Woodcliff Lake, NJ 07677  
Telephone: 201-692-1100

*hhc*  
human health care

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September 9, 2010

**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**

Elsai is pleased to submit comments to the Departments of the Treasury, Labor, and Health and Human Services on the interim final rule on coverage of preventive services for health plans to help ensure patient access to needed healthcare.<sup>1</sup> We support the Departments' efforts to clearly elucidate the preventive services provisions in the Affordable Care Act (ACA) in a timely and cohesive manner.

Elsai Inc. is the U.S. pharmaceutical operation of Eisai Co., Ltd., a research-based human healthcare company that discovers, develops, and markets products throughout the world. We strive to meet the diverse healthcare needs of patients and their families and caregivers, and with extensive clinical expertise in preventive care, we believe primary and secondary preventive health measures are critical to improving population health. We are encouraged by the focus on preventive services in healthcare reform efforts and the commitment to expanding access to these vital services.

ACA includes a number of provisions that seek to expand coverage and reduce financial barriers for "recommended preventive services." These recommended services consist of select recommendations of the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), and the Health Resources and Services Administration (HRSA)—three organizations highly regarded for their commitment to evidence-based decision making.

**Flexibility in individual plan decision making should not come at the cost of clear evidentiary guidance:** We have concerns about the flexibility the regulation provides plans in interpreting recommendations. The regulation notes that if a recommendation does not specify the frequency, method, treatment, or setting for the provision of the recommended service, the plan or issuer may use "reasonable medical management techniques"<sup>2</sup> to determine these parameters. To avoid discrepancies in the interpretations of evidence and therefore patient

<sup>1</sup> *Federal Register*. Vol. 75, No. 137. July 19, 2010. Rules and Regulations. Department of the Treasury, Department of Labor, Department of Health and Human Services.

<sup>2</sup> *Federal Register*. Vol. 75, No. 137. July 19, 2010. Rules and Regulations. Department of the Treasury, Department of Labor, Department of Health and Human Services. p. 41757.

access to preventive services by that application of restrictive management techniques, we urge the Departments to clarify “reasonable” techniques.

*Eisai recommends that the final rule define reasonable medical management techniques, and that, as in the public sector, private plans communicate the techniques they use to all stakeholders in an open and transparent decision-making process*

**Plan decision making should primarily be driven by evidence; USPSTF evidence reports and other evidence-based sources provide that evidence:** In addition to offering plans discretion to use established management techniques, the regulation allows plans to rely on the “relevant evidence base”<sup>3</sup> to determine coverage specifications. We encourage the Departments to provide detail on what “relevant” evidence entails and to offer plans direction in ensuring that evidence evaluated is both high quality and current. As the USPSTF recommendations are based on comprehensive evidence reports conducted by an AHRQ Evidence-based Practice Center (EPC), these evidence reviews should be consulted for additional levels of detail that the actual recommendation document may not include. In addition to AHRQ USPSTF evidence reports, evidence-based guidelines, systematic reviews, and peer-reviewed literature are the types of information that should be consulted.

*Eisai recommends that the final rule provide directions to plans on the evidence sources that may be used to define coverage specifications*

**Obesity screening recommendation is well-defined, and is an example where interpretation by plans should not be ambiguous:** Basic guiding principles are needed for plans to appropriately determine recommendation parameters, though this need is superseded by the need for plans to appropriately interpret issued recommendations. We are concerned by the possibility that recommendation statements could be mistakenly thought to lack specificity. The USPSTF disseminates its recommendations through guidance documents, which are distilled into graded recommendation statements. Using obesity screening as an example, the USPSTF summary statement says “the USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults. B Recommendation.”<sup>4</sup> Furthermore, the recommendation document goes on to clarify type of screening (Body Mass Index) and to define intensive counseling (more than one person-to-person session per month for at least the first three months of intervention) and what constitutes a counseling and behavioral intervention (a variety of approaches aimed at promoting change in diet and/or physical activity, including lifestyle change, pharmacotherapy, and surgery).<sup>5</sup> Additionally, the full guidance document clarifies that for moderate-or low-intensity counseling, the evidence is insufficient to recommend for or against the service (and is therefore graded I). Despite the fact that these parameters are

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<sup>3</sup>*Federal Register*. Vol. 75, No. 137. July 19, 2010. Rules and Regulations. Department of the Treasury, Department of Labor, Department of Health and Human Services. p. 41729.

<sup>4</sup> U.S. Preventive Services Task Force. Screening for Obesity in Adults. <http://www.uspreventiveservicestaskforce.org/uspstf/uspsobes.htm>.

<sup>5</sup> U.S. Preventive Services Task Force, Screening for Obesity in Adults. Recommendations and Rationale. pp. 2-4. <http://www.uspreventiveservicestaskforce.org/3rduspstf/obesity/obesrr.pdf>.

clearly stated in the recommendation document, and that the recommendations of the Task Force are accordingly stratified, we are concerned that these specifications may be overlooked or lost in the dissemination of the recommendation summary statement alone.

*Eisai recommends that the final rule direct plans to reference the full guidance documents that accompany USPSTF recommendations*

In conclusion, Eisai notes the U.S. federal government's commitment to promoting evidence-based coverage for preventive services, and urges the Departments to hold plans accountable to these evidence-based decision-making standards. Eisai is committed to working in partnership with the Departments and health plans on this important human healthcare issue. We look forward to further collaboration on ensuring beneficiary access to preventive healthcare services.

Sincerely,



Raymond Frost  
Executive Director  
Government Affairs & Public Policy