



September 16, 2010

By Mail

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

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
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Internal Revenue Service
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Washington DC 20004

To whom it may concern:

The American Cancer Society Cancer Action Network (“ACS CAN”) is the advocacy affiliate of the American Cancer Society (the “Society”). The Society is a nationwide, community-based, voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer, through research, education, advocacy, and service. The American Cancer Society, operating through its national office and 12 chartered, geographic division affiliates throughout the United States is the largest voluntary health organization in the United States.

ACS CAN appreciates the opportunity to provide comments to the U.S. Department of Labor, the Department of Health and Human Services and the Internal Revenue Service (the “Departments”) on the Interim Final Rules (the “Interim Rules”) published in the Federal Register on July 19, 2010. These rules implement provisions of the Patient Protection and Affordable Care Act (the “PPACA”) relating to coverage of preventive care services.

Increasing the role of prevention in the health care system is vital to improving the nation’s health, and more specifically, increasing access to proven screening and prevention services is essential in the fight against cancer. The Interim Rule is consistent with the statute’s intent for these provision, and from a policy perspective, it reflects an important first step in improving access to effective prevention services. However, in the context of the essential benefit package, a broader perspective and understanding of the role of prevention will be necessary if we are to realize the full potential of prevention in improving our nation’s health.

ACS CAN offers the following specific comments for your consideration. References to “plan” in our comments are intended to refer to both health care plans and insured health coverage.

Reliance on Independent Standards for Delivery of Preventive Care. The provision of no-cost preventive services is a key component of health care reform, providing access to a common core of no-cost health care services for millions of Americans. While the Interim Rules closely track the PPACA mandate in defining the scope of covered preventive services, the regulations are silent on the applicable standards for determining the frequency, method, treatment or setting for the provision of a preventive service “to the extent not specified in a recommendation or guideline”. Specifically, in the absence of a specific recommendation or guideline, the Interim Rules defer to a plan’s interpretation of “reasonable medical management techniques” to determine specific coverage limitations on no-cost preventive care. However, this approach tends to ignore the fact that the applicable recommendations or guidelines for preventive care, and particularly the U.S. Preventive Services Task Force recommendations, more often than not fail to specify a frequency, method, treatment or setting for the implementation of the guideline. Thus, in most instances, it will be left to the plan to establish these criteria on the basis of “reasonable medical management techniques”, a criterion which, ACS CAN believes, will create significant variation in the delivery of no-cost preventive services to the detriment of consumers. In addition, under this approach, it is inevitable that disputes between plans and consumers, and plans and physicians, over what constitutes “reasonable medical management techniques” will proliferate, thereby, undermining what was intended to be a relatively simple set of rules, which should be susceptible to straightforward application based on accepted medical management techniques. Accordingly, ACS CAN recommends that the Interim Rules be revised to require plans to follow independent clinical guidelines for preventive services management on matters relating to the frequency, method,

treatment or setting for the delivery of preventive services. For example, the U.S. Public Health Service guidelines for tobacco cessation or the Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology for Colorectal Cancer Screening and Surveillance are all appropriate independent clinical guidelines. Without a clear and independent reference point for the appropriate medical management of preventive services, it is possible that consumers will either be denied the full benefit of adequate no-cost preventive services by plans that adopt a narrow interpretation of how such services are delivered or find themselves mired in disputes over the delivery of such services.

Enhanced Transparency and Disclosure. ACS CAN recommends that the Interim Rules be revised to require plans to provide comprehensive, periodic disclosure to consumers and physicians on preventive care services in a format and style that clearly distinguishes those services from services that are subject to the plan's cost-sharing requirements. Such disclosure should occur at minimum once every 12 months. Absent such disclosure, it may prove very difficult for participants to identify specific services as preventive and evaluate how such services relate to other services provided at the same time as the preventive services. This disclosure should also provide consumers with specific information on the frequency, method, treatment or setting for the delivery of such services.

In addition, ACS CAN recommends that plans be required to provide specific, detailed disclosure on the application of the no-cost sharing rule to situations where the primary purpose of an office visit is, or is not, the delivery of a preventive service or situations where such services are, or are not, separately billed or tracked. Without such disclosure, the application of these rules is likely to be very confusing to consumers and physicians who must first ascertain whether a service is "preventive" in nature and then determine whether the delivery of the service occurred in a context where cost sharing is, or is not, permitted. The disclosure should include specific, detailed examples of common situations with an analysis of how the no-cost sharing rule applies in each situation. For instance, if a 40 year-old woman visits her OB-GYN for her regular Pap smear but other services are also provided, is the visit a covered service?

Clarification of Exclusion for Out-of-Network Preventive Care. Although the Interim Rules clearly limit the obligation of a network plan to provide no-cost preventive services through an out-of-network provider, the Interim Rules fail to address the consequences of the situation where the plan is unable to provide such services in-network due to (i) gaps in the roster of in-network medical specialties or (ii) the unavailability of specific services or providers in a part of the plan's geographic coverage area. ACS CAN recommends that, if, as a result of such factors, the plan is unable to provide an in-network preventive care service to a material segment of the plan's population, the plan should be obligated to provide such services without cost-sharing on an out-of-network basis.

The Interim Rules are also silent on the status on the application of the cost-sharing rules to preventive services that are obtained from a network provider with the assistance of medical professionals who are out-of-network providers. By way of example, a physician who is performing a colonoscopy may be in-network but the anesthesiologist who assists in the procedure may be out-of-network and bill separately (this appears to be a fairly common occurrence; specialties like anesthesiology and radiology are often not in networks). In this situation, ACS CAN recommends that the regulations provide that all of the services be treated as no-cost preventive services regardless of whether they are in-network or out-of-network since the ancillary services provided out-of-network are integral to the delivery of the in-network preventive services.

Chronic Disease Monitoring and Prevention in High Risk Populations.

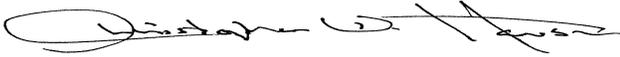
There are a number of medical conditions that require periodic monitoring of high-risk individuals through procedures or tests designed to identify the onset or progress of the condition, including breast and colon cancer. For example, Lynch syndrome, also called hereditary nonpolyposis colorectal cancer syndrome (HNPCC), is an inherited tendency to develop colorectal, endometrial (uterine) and other cancers. It is recommended that men and women with this inherited condition receive colonoscopy screening every year starting at age 20 to 25. Similar considerations apply to high-risk populations, including racial and ethnic minorities, where earlier or more frequent screening for conditions with a high incidence in the population is the essential first step to the proper medical management of the condition. While these tests or procedures are reasonably classified as “preventive” with regard to the management of the specific condition, ACS CAN is concerned that, under the highly subjective “reasonable medical management standard” (see above), the Interim Rules may allow plans to draw narrow and unwarranted distinctions between preventive services and chronic disease monitoring services, thereby, shifting the cost burden of periodic monitoring to the consumer following an initial diagnosis. Accordingly, ACS CAN recommends that the Interim Rules be clarified to provide that a plan may not impose cost sharing requirements on requirements for high-risk populations who may need enhanced coverage or need access to different prevention modalities or chronic disease monitoring services that are preventive in nature insofar as such services relate to the monitoring of a specific chronic disease.

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The delivery of no-cost preventive services under the PPACA reforms is critical, not only to the consumer, but also to the economic success of health care reform as a means of restraining the spiraling cost of care. While ACS CAN appreciates the limited statutory basis under the PPACA for the authorization of no-cost preventive services, we believe the changes proposed in our comments are

consistent with the intent of the PPACA and, if adopted, would provide necessary clarifications to this important advance in our system of health care delivery.

Sincerely,

A handwritten signature in black ink, appearing to read "Christopher W. Hansen". The signature is fluid and cursive, with a large initial "C" and "H".

Christopher W. Hansen
President