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MEMORANDUM

October 13, 2015

FROM: Seth Perretta

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RE: Inclusion of Services Related to Managing Chronic Conditions in High Deductible

Health Plans

Introduction

This memorandum addresses the question of whether the U.S. Department of the Treasury ("Treasury") and the Internal Revenue Service ("IRS") have the authority to broaden the scope of the preventive care safe harbor for High Deductible Health Plans ("HDHP"s) in order to provide such plans with increased flexibility in permitting participants to most effectively manage their chronic health conditions. Specifically, the memorandum discusses whether Treasury and the IRS may permit HDHPs to include pre-deductible coverage for services related to managing chronic conditions and preventing the exacerbation of those conditions and resulting medical complications. After summarizing relevant statutes, regulations, and other guidance, the memorandum concludes that (1) Treasury and the IRS do have the necessary authority to permit this type of coverage, and (2) an expansion of preventive care services available under HDHPs would be in keeping with prevailing public health policy practices and goals. The memorandum ends with a recommendation that Treasury and the IRS issue guidance expanding the preventive care safe harbor for HDHPs.

Statutory and Regulatory Background

An HDHP, as defined in Internal Revenue Code ("Code") section 223(c), is a health plan that satisfies certain requirements regarding minimum deductibles and maximum out-of-pocket expenses. HDHPs that meet the regulatory requirements may be paired with Health Savings Accounts ("HSA"s) that allow consumers and employers to save pre-tax dollars to pay for eligible health care services both in the year in which contributions are made to the HSA, and in subsequent years.

Generally, HDHPs may not provide benefits for any year until the minimum deductible for that year has been satisfied. The Code, however, has an exception for certain preventive care services. Under this exception, often referred to as the preventive care safe harbor, HDHPs may voluntarily provide coverage for preventive services prior to the deductible being met. The preventive services that may be covered on a pre-deductible basis include "preventive care

¹ Code sec. 223(c)(2)(C).

(within the meaning of section 1871 of the Social Security Act, except as otherwise provided by the Secretary)."²

In subregulatory guidance issued in 2004, Treasury and the IRS stated that the preventive service safe harbor does not apply to benefits or services meant to treat "an existing illness, injury, or condition." This guidance can most easily be read as suggesting that management of chronic medical problems is not "preventive" within the meaning of the safe harbor because it relates to an "existing" condition. Such a reading, however, severely restricts HDHPs from implementing benefit designs that encourage the use of evidence-based, high-value services recommended by an increasing number of public health organizations.

Treasury and IRS Have the Legal Authority to Expand the Safe Harbor

The Code explicitly grants the Secretary of the Treasury flexibility in defining the scope of preventive care for purposes of the safe harbor. In relevant part, the Code refers to "preventive care (within the meaning of section 1871 of the Social Security Act, *except as otherwise provided by the Secretary*)." The phrase "except as otherwise provided by the Secretary" is an explicit delegation of authority to Treasury and the IRS, acting on the Secretary's behalf, to define the scope of "preventive care" for purposes of Code section 223. While the Social Security Act's definition is a starting point, it is not the end of the inquiry *if the Secretary so provides*.

The authority granted to the Secretary in Code section 223 is in addition to the Secretary's general authority to prescribe rules and regulations as necessary to enforce the Internal Revenue Code. Code section 7805(a) states that "...the Secretary shall prescribe all needful rules and regulations for the enforcement of this title..." Since the preventive care safe harbor is part of the enforcement of Code section 223, any expansion of that safe harbor is governed by the general regulatory authority of section 7805.

It thus appears clear as a matter of law that the Secretary has the authority to expand the definition of preventive services for purposes of the safe harbor.

Broadening the Scope of the Safe Harbor is Consistent with Current Understandings of the Vital Role of Preventive Care and Chronic Condition Management

One reason that Congress may have delegated authority to the Secretary in Code section 223 is to enable the Secretary to ensure that the scope of the rule is consistent with the everchanging health care landscape. Agencies are generally more agile and able to act in a time

² Note that the reference to section 1871 may be a scrivener's error. That section describes the Department of Health and Human Services' procedures for promulgating regulations and does not reference preventive services. The statute likely intended to refer to section 1861 of the Social Security Act, which describes the scope of preventive services for Medicare purposes.

³ IRS Notice 2004-23.

⁴ Code sec. 223(c)(2)(C) (emphasis added).

sensitive manner than is Congress, and health care in particular is an area where Congress has increasingly looked to Treasury and the IRS to issue rules in keeping with current best practices.

There is recognition throughout the public health community that chronic care management cannot be separated from "preventive care." This is especially true when the management of chronic conditions assists in preventing complications, exacerbation, or acute flare-ups related to the condition. In a 2009 paper, the Centers for Disease Control ("CDC") — one of the government's most important players in disease prevention and management — noted that "[p]revention encompasses health promotion activities that encourage healthy living and limit the initial onset of chronic diseases." The paper then goes on to explain that "[p]revention also embraces early detection efforts, such as screening at-risk populations, as well as strategies for appropriate management of existing diseases and related complications" (emphasis added). 6

Numerous governmental agencies have recognized the importance of managing chronic conditions, especially when an individual has multiple chronic conditions. These agencies have begun to recognize the importance of preventive services in improving standards of care. The U.S. Department of Health and Human Services ("HHS"), for example, has stated that "[a] cornerstone of our nation's approach to chronic diseases must be to prevent their occurrence. An enhanced focus on prevention and public health is essential to ensuring optimum health and quality of life for all people. In addition, however, prevention is an important consideration for persons who already have one or more chronic conditions." HHS administers a large number of federal programs directed toward the prevention and management of chronic conditions, including an initiative to improve health outcomes in individuals with multiple chronic conditions.

Broadening the Scope of the Safe Harbor is Consistent with the Policy of Encouraging Access to High-Value Services

There is increasing interest in health insurance benefit design models that align cost sharing with the value of services. Indeed, enabling greater access to high-value services and decreasing wasteful health care spending was one of the fundamental purposes of the HDHP/HSA design at its inception, and was most likely a key factor in establishing the preventive care safe harbor as well.

Quite significantly, on several occasions since the enactment of Code section 223, the Secretary has utilized its authority under Code section 223(c)(2)(C) to deem certain services "preventive services" for purposes of Code section 223(c)(2)(C). See IRS Notice 2004-23 (setting out a enumerated list of qualifying preventive services); IRS Notice 2004-50 (clarifying that if it would be unreasonable or impracticable to perform another procedure to treat the condition, any treatment that is incidental or ancillary to a preventive care service or screening under IRS Notice 2004-23 also falls within the preventive care safe harbor); IRS Notice 2013-57

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⁵ http://www.cdc.gov/chronicdisease/pdf/2009-Power-of-Prevention.pdf.

⁶ Id.

⁷ HHS U.S. Department of Health and Human Services, Multiple Chronic Conditions—A Strategic Framework: Optimum Health and Quality of Life for Individuals with Multiple Chronic Conditions. Washington, DC. December 2010.

(stating that "preventive services" for purposes of Code section 223 includes any preventive services required by the market reform rules of the Affordable Care Act).

Enhancing consumer access to services that help them manage chronic conditions can be a particularly important part of quality improvement and cost saving efforts, as chronic conditions represent a growing concern both in terms of health outcomes and costs. Chronic disease management post-diagnosis has been a critical component in both improving the public's health and in reducing health care costs. Recent studies reflect a growing body of evidence that helping patients manage chronic illnesses can reduce utilization of high-cost services, resulting in significant savings, while substantially improving patient health.⁸

Permitting coverage of chronic medical conditions on a pre-deductible basis also complements existing alternative payment models and related initiatives on the provider side that encourage physicians and other clinicians to help patients access certain evidence-based services. If the safe harbor were expanded, it would promote better alignment of these "demand and supply side efforts" consistent with both the goals of the safe harbor and a broad range of efforts in both the public and private sectors.

Definition of "Chronic" Medical Condition

There already exist various definitions of chronic medical condition, disease, and illness. If Treasury and the IRS wish to expand the preventive care safe harbor to include services that help manage chronic conditions they can look to existing definitions of "chronic medical conditions" for guidance.

HHS defines chronic illnesses as "conditions that last a year or more and require ongoing medical attention and/or limit activities of daily living." In addition to physical conditions, chronic conditions include problems such as substance abuse and addiction disorders, mental illnesses, dementia and other cognitive impairment disorders, and developmental disabilities. HHS lists arthritis, asthma, chronic respiratory conditions, diabetes, heart disease, human immunodeficiency virus infection, and hypertension as examples of chronic illnesses.

The CDC defines a chronic condition as one that lasts more than three months. Additionally, certain conditions such as arthritis, diabetes, cancer, and heart conditions are considered chronic regardless of their duration. The US National Center for Health Statistics also defines a chronic disease as one that lasts three months or more.

Treasury and IRS Should Issue Guidance Expanding the Preventive Care Safe Harbor

⁸ See, e.g., Laurence C. Baker et al., Integrated Telehealth And Care Management Program For Medicare Beneficiaries With Chronic Disease Linked To Savings, Health Affairs (2011); C. Sack et al., A chronic care model significantly decreases costs and healthcare utilisation in patients with inflammatory bowel disease, J. of Crohn's & Colitis (2012). See also Goetzel RZ, et al. Return on investment in disease management: a review. Health Care Finance Rev. 2005.

⁹ CDC Summary Health Statistics for the U.S. Population: National Health Interview Survey, 2012.

Allowing the millions of Americans covered under HDHPs to have better access to preventive services targeted at managing their chronic conditions would be in keeping with the public health policy goals of many in the public health community, including HHS and the CDC. Treasury and IRS should use their authority to issue guidance expanding the preventive care safe harbor to encompass the management of chronic medical conditions, thus allowing tax-favored dollars to be spent more efficiently and in keeping with current public health goals. In particular, Treasury and IRS should consider the following issues:

- In promulgating rules, Treasury and the IRS may wish to look to other organizations' definitions of chronic diseases, conditions, and illnesses for purposes of the safe harbor. Rather than issuing a list of diseases or conditions that qualify as chronic for purposes of the safe harbor, an effort which may be outdated as soon as it is published, one approach might be for the guidance to contain a definition of the term along with an illustrative, but not exhaustive, list of qualifying conditions.
- Treasury and the IRS could indicate that the expanded set of services covered by the safe harbor should be expected to aid in the management of a chronic disease or condition.
- The definition of chronic disease or condition could also include one or more of the following requirements as a limiting principle:
 - o The condition requires ongoing medical attention.
 - The condition limits, or would limit if left untreated, one or more activities of daily living

If Treasury and the IRS feel they need an additional limiting principle they could require that the condition last, or is expected to last, longer than six months or has occurred three or more times in the past 12 months and is expected to reoccur.

Numerous studies support the proposition that management of chronic conditions results in cost savings. Accordingly, it seems that sound public policy would support leaving unrestricted the value or amount of preventive services that could be covered on a pre-deductible basis under the safe harbor. If, however, Treasury and the IRS feel that a limit must be placed on the value of services that could be provided, there appear to be several avenues for achieving such a result. For example, one approach could look to limit the increase in the underlying plan's actuarial value as a result of the additional pre-deductible covered services by more than a specified percentage (*e.g.*, three percent). Such an approach, while providing a limit on the value of additional covered services that could be provided, would preserve important plan flexibility in designing benefits and would seem to not require undue additional administrative work on the part of plans or plan sponsors.

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We hope this memorandum is helpful. Please let us know if you have any questions.