UHY LLP
Certified Public Accountants

HEALTH CARE INSIDER

VOLUME 4 :: ISSUE 3

In This Issue:

Will Wellness and Prevention Initiatives Reduce Your Health Care Cost Over Time?

The media has spent a great deal of time discussing penalties, taxes, mandates and whether employers will "Play or Pay". For example, the employer mandate, which was to go into effect January 2014, has been delayed to January 2015. However, one aspect of the ACA that has not been discussed is the wellness and prevention provision.

In 2007 a section was added to the Health Insurance Portability and Accountability Act (HIPAA) which permitted employers to use 20% of the plans cost as either an incentive or penalty for employees who were willing to participate in a wellness and prevention program. The purpose of adding this to the law was to deal with increasing amounts of illnesses such as obesity, diabetes, metabolic syndrome and heart disease. Over the past 20 years, it has become evident that the population under-30 years of age has become increasingly unhealthy, and for many reasons. Our technologically advanced society has created a sedentary lifestyle. The under-30 population lack physical activity in addition to improper dieting. This combined with smoking, alcohol consumption and drug abuse creates very serious medical conditions. With this in mind, adding the wellness provision to the law provides employers with the ability to put into place wellness programs that would deal with these issues.

Prior to 2007, wellness and prevention programs did not have a great deal of momentum. Insurance companies and employers felt it was the responsibility of their employees to keep themselves healthy. This philosophy was fostered from earlier years when infectious diseases were the leading cause of death. The chart below illustrates the death rates in the US from 1900 to 2009. The major causes of death in 1900 were from infectious diseases. The average life span was age 47.

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"It is apparent that the delivery systems we had in the past will be changing."

The next level of service

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Death Rates for Leading Causes of Death in the United States (1900 – 2009)

U. S. Causes of Death in 1900	Crude Death Rate Per 100,000 Population per Year	U. S. Causes of Death in 2009	Crude Death Rate Per 100,000 Population per Year
All Causes	1719	All Causes	793.8
Pneumonia and Influenza	202.2	Disease of the Heart	195.2
Tuberculosis	194.4	Malignant neoplasms (cancer)	184.9
Diarrhea, inflammatory intestine ulceration	142.7	Chronic lower respiratory diseases	44.7
Diseases of the Heart	137.4	Cerebrovascular Diseases (strokes)	42
Senility or ill defined	117.5	Accidents (unintentional injuries)	38.4
Intracranial lesions of vascular origin	106.9	Alzheimer's Disease	25.7
Nephritis (kidney failure)	88.6	Diabetes mellitus	22.4
All Accidents	72.3	Influenza and Pneumonia	17.5
Cancer and other malignant tumors	64	Nephritis (kidney failure)	15.9
Diphtheria (respiratory infection)	40.3	Suicide (intentional self-harm)	12

Source: Centers for Disease Control and Prevention

The data for 2009 illustrates the complete opposite of 1900 when the leading causes of death were cancer, heart disease and stroke, which are chronic diseases. The death rate has decreased by more than 50% and the average life span increased to age 78. This data illustrates that the key driver of our health care cost is chronic disease. When wellness and prevention are applied, it can have a significant effect in reducing costs and maintaining a healthy lifestyle.

The first four diseases illustrated in the 2009 chart are brought on by inflammation in the body. As a matter of fact, 85% of disease is brought on by such inflammation and more importantly, wellness and prevention programs can mitigate this type of a problem.

During the debate on healthcare reform, both Democrats and Republicans favored wellness and prevention initiatives. For this reason, the ACA included enhanced incentives and increased penalties from 20% to 30% of the healthcare cost. This permits an employer to have employees put more of their "own skin in the game". Additionally, an incentive or penalty can be assessed to any employee that is a smoker (50% in 2014).These enhanced provisions give employers greater latitude in how they structure their programs.

There are many different types of wellness programs. These programs are identified as passive and compliant. Some examples of passive programs would be to offer employees on a voluntary basis (gym membership, smoking cessation programs, weight loss and nutritional education, etc.) Such programs are a good start; however, because they are on a voluntary basis, they don't necessarily attract the people who need these types of programs the most. The other issue with this type of a program is that it is impossible to identify any return on the employer's investment. Clearly, it is better to have this type of program than none at all, but it will not bring the desired results that most employers seek.

The second type of wellness program is one that is known as compliant or value-based. Compliant programs drive employees by utilizing incentives or penalties to participate in a wellness program. An example of would be if an employer offers a physical exam and blood test (biometric screening) and health risk assessment program. If the employee and insured spouse participate they may have a reduction in the employee insurance contribution amount or receive a company contribution to

their Health Savings Account (HSA) or a gift card. The results of these programs are measured and an ROI can be identified to satisfy senior management. If this program cannot be measured, then it will be ineffective in determining the amount of ROI that may have been gained.

Wellness and prevention programs are not without criticism. Over the past few years, studies have been published which claim exorbitant amounts of ROI. As an example, for every dollar spent some claim a $10 return, and in another case, for every dollar spent a $20 return. Employers should typically expect a $3 to $4 return for every $1 spent on these types of programs and should discount any information that indicates returns above this level.

When one looks at the changes that the ACA will have on health care, it is apparent that the delivery systems we had in the past will be changing. Accountable Care Organizations and Patient-Centered Medical Homes will begin to dominate over the next few years. HMOs (Health Maintenance Organizations), PPOs (Preferred Provider Organizations) and POS (Point of Service) plans will slowly disappear over time. The best thing an employer can do to control the cost of such programs is to identify the overall health of the population and help them improve their conditions. The companies that have taken this approach have reduced the magnitude of their cost increases for health care.

A good case in point is an employer who undertook physical exams, health risk assessments and coaching for their employees and spouses. Two and a half years ago, 94% of this group had some type of a health risk. These risks included such things as obesity, high blood pressure, diabetes, cholesterol, etc. The employees recognized their health risks through discussions with their doctors/coaches and significantly improved their health so much that the results of their most recent exams indicated that the health risk dropped to 72% of the population and their ROI was $3.73 for every $1 spent on wellness. This is encouraging news and it is recommended that employers that have 50 or more employees and are either fully insured or self-funded should consider initiating such programs for their employees. Additional factors such as employee turnover, amount of incentives/ penalties, buy-in from senior management, and age of population also apply for such programs.

Article written by John DePalma
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The Latest on Medical Device Excise Taxes

Effective January 1, 2013, a 2.3% medical device excise tax was imposed on manufacturers, producers, and importers of applicable medical devices. A "taxable medical device" is any device defined in Section 201(h) of the Federal Food, Drug & Cosmetic Act (FFDCA) that is intended for humans. While the definition appears relatively clear, the IRS and Department of Treasury received numerous requests to further elaborate on what actually constituted a "taxable medical device".

In response to these requests, the IRS and Department of Treasury issued T.D. 9604 to provide interim guidance on specific areas. These areas include medical and non-medical uses, veterinary devices which are also used on humans, biologic devices, humanitarian use devices, software upgrades, and devices sold for use within the health care industry.

The IRS and Department of Treasury clarified whether the sale of devices that meet the criteria described in section 201(h) of the FFDCA that is listed as a device with the FDA under 21 CFR part 807 but that is used for a non-medical purpose should not be subject to the medical device excise tax. They determined that the definition of a taxable medical device in section 4191 is not limited to a device that is intended exclusively for medical purposes. While section 4191 offers several exemptions, the statute does not provide an exemption based on whether the intended use of a device is for medical or non-medical purposes.

Manufacturers and importers selling devices used for both human use and veterinary use strictly in the veterinary industry requested a special exemption if the product was labeled "not for human use" or "veterinary use only". While section 4191 limits a taxable medical device to devices intended for humans, the IRS and Department of Treasury clarify a taxable medical device is not limited to devices intended exclusively for humans. However, devices used exclusively in veterinary medicine are not listed as devices under section 510(j) of the FFDCA and 21 CFR part 807 and are not taxable medical devices.

The IRS and Department of Treasury received requests to clarify whether biologic devices are taxable medical devices. Biologics are licensed with the Center for Biologics and Research (CBER) and listed with the FDA under either 21 CFR part 607 or 21 CFR part 807. Devices listed under 21 CFR part 607 such as in vitro diagnostic tests for blood donor screening are not taxable medical devices. However, biologics listed under 21 CFR part 807 are considered taxable medical devices.

Manufacturers of Humanitarian Use Devices (HUDs) requested clarification on devices for which the FDA

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approved as a Humanitarian Device Exemption. HUDs are intended to benefit patients with a condition that manifested in fewer than 4,000

individuals in the United States per year. The IRS and Department of Treasury stated that "there is no statutory basis for excluding HUDs from the definition of a taxable medical device". Therefore, unless a HUD is included with a statutory exemption in section 4191(b)(2), it is considered a taxable medical device.

Software providers inquired about sales of software upgrades and whether they are considered to be taxable medical devices. It was determined that software and software upgrades that are not required to be listed separately with the FDA are not considered to be a taxable medical device.

The IRS and Department of Treasury received a request to verify the sole fact that a device is sold for utilization in health care offices is not a factor in determining whether a device meets the retail exemption. The IRS and Department of Treasury have taken a facts and circumstances approach to identifying whether a device meets the criteria of a retail exemption. Therefore, all of the facts and circumstances should be reviewed to determine whether a device meets the retail exemption criteria; the sole fact that a device is sold for use in health care offices is not a determining factor of whether a device is disqualified from the retail exemption.

The IRS and Department of Treasury recognize the challenges of adhering to the medical device excise tax. Many manufacturers and importers in the medical device industry were not previously required to file Form 720, Quarterly Federal Excise Tax Return and will require additional time to comply with these requirements. Therefore, the IRS and Department of Treasury will not impose failure to pay penalties until September 2013, unless nonpayment is due to willful neglect.

Legislatures continue the push to repeal the medical device excise tax. Congress wasted little time introducing proposals to repeal the tax in both the House of Representatives and the Senate. The Senate voted 79-20 to repeal the tax, but until legislatures produce an alternative plan to generate $10 billion in tax revenue over the next 10 years, the medical device excise tax is here to stay.

Article written by Ryan Burns
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PROVIDING VALUE TO THE HEALTH CARE INDUSTRY

Today's growing and advanced health care industry is a fast-paced environment where regulatory issues, competition, and rapidly changing consumer expectations converge. Managing risks and realizing opportunities becomes a more important focus as health care organizations decide how they will adapt and evolve their business models for long-term survival.

Ensuring today's actions will lead to achieving long-term goals can be a major challenge for anyone. Many health care organizations are unable to address the issues at hand and consider the "big picture" because they are overwhelmed with urgent matters and patient care. UHY LLP's National Health Care Practice brings an understanding of the industry together with innovative solutions that have a positive impact on bottom line. We understand the challenges facing health care providers and facilities.

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