New Focus: Comparative Effectiveness Research

The new Patient Protection and Affordable Care Act (PPACA) creates a national program to conduct comparative effectiveness research. In the United States, our health care services are more expensive than comparable services in any other developed country while our health outcomes are just average. Most patients do not realize that physicians can recommend a wide variety of treatment options without a lot of empirical data showing which treatments are most effective. While some treatments may be more effective, others may even be harmful.

PPACA established the Patient-Centered Outcomes Research Institute (PCORI), a non-government institute with a government-appointed board of directors. The PCORI will offer government funds to sponsor studies of treatments for many conditions; a key focus will be on cancer treatments. The simple concept is that these studies should provide a reasonably good idea on how different interventions work and how they compare to other treatments for the same condition.

It all sounds like a great idea. More effective treatments will improve the quality and decrease the cost of health care in the long run. However, this issue was debated fiercely during the construction of the health care reform acts. Would a database on treatment effectiveness for various services cause the rationing of health care in the United States? Last summer that argument misled people into believing the government would create “death panels.” Physicians do, however, have concerns about this type of database being established without accounting for all the variables involved in responsible care decisions. Despite strong opinions on both sides of the issue, the PPACA includes comparative effectiveness research funding and the government recently appointed the Board of Directors for PCORI.

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About the ViewsLetter

We welcome you to the fourth quarterly issue in Volume Thirteen of the McGraw Wentworth ViewsLetter. It is our mission to be the leader in the employee group benefits brokerage and consulting industry to mid-sized organizations.

We have established theViewsLetter as an integral part of our commitment to keep you informed of benefit trends, legislative and marketplace developments that may affect your group benefit programs.

We welcome your comments and suggestions regarding the ViewsLetter. You can pass your comments directly to your McGraw Wentworth Account Director or Account Manager, or you can reach us at www.mcgrawwentworth.com.
PPACA defines comparative effectiveness research as "research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of two or more medical treatments, services or items." Services and items can include health care interventions, protocols for treatment, care management and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals, integrative health practices, and any other strategies or items used to treat, manage, diagnose or prevent illness or injury. The potential scope of federally funded comparative research studies is very broad.

Comparative effectiveness research is aimed at providing evidence to help patients and physicians make reasonable decisions about health care and health systems. Research studies may include the following issues:

- Differences in health care delivery systems and their impact on treatment effectiveness.
- Differences in worksite wellness programs and the impact these programs have on reducing and managing chronic conditions.

Anyone granted PCORI research funds will be required to publish the findings on a publicly available website. Unfortunately, simply posting the results of research studies will not likely have the necessary widespread impact on treatment decisions. The government must determine the best way to publicize this information and to make the findings clear not only for medical professionals, but also for patients. This information should become an easily accessed decision support tool that patients and providers can use together. However, the government, health plans, employers and other public health organizations will need to take the time to inform plan participants that this information is available and that it can be a useful tool to help them evaluate treatment options.

Comparative effectiveness research studies have been conducted for many years and most areas of health care services can benefit from this research. Dartmouth studies show that treatments vary across the country and the only real reason for these differences seems to be prevalent practice pattern in the area. As different, but similar, medications are approved for many different ailments, physicians and patients need to decide which one is better. In many cases, the decision has been based on a physician’s recommendation and whether or not the health plan covers the drug.

Americans do support using comparative effective research in a number of ways. In 2010 YouGov/Polimetrix conducted an Internet survey asking Americans how strongly they would support or oppose using comparative research for various purposes. Following are the results:

- 63% of respondents support providing information about whether a given treatment works better than another (only 8% opposed).
- 62% of respondents support creating warning labels for treatments not supported by strong scientific evidence (only 10% oppose).
- 51% of respondents support using comparative research to determine whether Medicare or private insurers will cover new treatments that have just been made available (21% oppose).
- 45% of respondents support using comparative research to determine whether Medicare and private insurers will cover treatments that have been used historically (24% oppose).

DID YOU KNOW?

The troubling economy may have positive health effects:

- 47% of workers report they pack a lunch more often to save money and eat healthier.
- 44% of workers who smoke report that they are more likely to quit smoking because of the economic downturn.
- 21% of smokers report they have cut down on the number of smoke breaks they take during the work day:
  - 70% report they take up to three smoke breaks in a work day.
  - 12% report they take more than five smoke breaks in a work day.
  - 78% of smokers say they take up to ten minutes a day for each smoke break.

Source: CareerBuilder.com, June 2010

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Q. One of our employees has requested FMLA leave starting on November 1 for a serious health condition. The employee is expected to be out of the office until March 1. How long will FMLA protect his job and how long are we required to offer health coverage at the employee’s contribution rate? The employee has worked for our organization full-time for the last five years and has never taken an FMLA leave during this employment. We define our leave year as the calendar year.

A. It depends. Since you have defined your leave year as a calendar year, your employee may be able to “stack” FMLA leave time. Your employee has already met the first requirement for FMLA leave; he has worked for your organization for at least 12 months. Your employee is eligible for 12 weeks of FMLA leave during the 2010 calendar year and also for 12 weeks during 2011 so long as he continues to meet the FMLA requirements. It is best to split this leave request in two parts - leave for 2010 and leave for 2011:

2010

• The proposed time off for 2010 is November 1 until December 31 (which is roughly 9 weeks, when 12 weeks are allowed).
• Since the employee has worked 1,250 hours in the 12 months preceding the leave (October 2009-October 2010) he is eligible. Leave for 2010 should be granted.

2011

• The proposed time off for 2011 is January 1 until February 28 (which is just over 8 weeks, when 12 are allowed).
• To be eligible, the employee must have worked 1,250 hours in the 12 months preceding the leave (December 2009-December 2010). The employer does not have to count time when the employee was off on the FMLA leave. No time would be allotted from November 1 on. If the employee still meets the 1,250 hour requirement, the employee is eligible for the FMLA leave in 2011. If the employee does not meet the 1,250 hour requirement in 2011, the employer does not have to allow the leave.

If your organization is concerned about employees stacking leave time, you can choose a different way to calculate the leave year. If you use a “rolling forward” or a “rolling lookback” option, an employee would not be able to stack leave. In any case, you need to define your FMLA leave year policy and consistently administer the designated leave year.
The Family Medical Leave Act (FMLA) challenges many employers. The FMLA allows 12 weeks of unpaid job protected leave if an employee or immediate family member has a serious health condition or is having or adopting a child.

Most employers struggle with administering FMLA because it can be difficult to determine whether a given medical condition qualifies as a serious health issue. Employers also struggle with managing intermittent leave requests. If the condition warrants it, an employee may be allowed to take intermittent FMLA leave.

The latest round of FMLA guidance went into effect in January 2009 and clarified only a few key issues. The details of these FMLA changes can be found in our first Benefit Advisor of 2009 at http://mcgrawwentworth.com/Benefit_Advisor/2009/BA_Issue_1.pdf.

The Department of Labor (DOL) just recently clarified the FMLA definition of son and daughter. Initially, the FMLA defined a son or daughter as a “biological, adopted, or foster child, a stepchild, a legal ward, or a child of a person standing in loco parentis, who is—(A) under 18 years of age; or (B) 18 years of age or older and incapable of self-care because of a mental or physical disability.”

The DOL clarified the issue to ensure that an employee who assumes the role of caring for a child receives family leave rights regardless of the employee’s legal or biological relationship with the child.

The FMLA originally included leave rights for employees who are not technically the parent of a child, but operate in the parental role. However, a number of employers have had questions on how to determine whether an FMLA leave is appropriate in these situations.

Congress intended the revised definition of son or daughter to reflect “the reality that many children in the United States today do not live in traditional ‘nuclear’ families with a biological father and mother. Increasingly, those who find themselves in need of workplace accommodation for their child care responsibilities are not the biological parent of the children they care for, but their adoptive, step, or foster parents, their guardians, or sometimes simply their grandparents or other relatives or adults.” Congress stated that the definition of son or daughter in the FMLA was intended to be “construed to ensure that an employee who actually has day-to-day responsibility for caring for a child is entitled to leave even if the employee does not have a biological or legal relationship to that child.”

Courts use the following factors in these situations:

- The age of the child.
- The degree to which the child is dependent on the person claiming parental status.
- The amount of support provided.
- The extent to which the employee acts as a parent.

The FMLA regulations define in loco parentis to include employees with day-to-day responsibilities to care for and financially support a child.
Future Focus on FMLA, cont.

The DOL has simply clarified when an employee is acting *in loco parentis*. The DOL does not require an employee who intends to assume the responsibilities of a parent to officially establish that he or she provides both day-to-day care and financial support in order to stand *in loco parentis*. For example, when an unmarried employee provides day-to-day care for a partner’s child (with whom there is no legal or biological relationship) but does not financially support the child, the employee could still be considered to stand *in loco parentis* to the child and therefore be entitled to FMLA leave to care for the child if the child had a serious health condition.

The same principles apply to leave for the first 12 weeks after a child is born or adopted. For instance, an employee rearing a child along with the child’s biological parent would be entitled to FMLA when the child is born because the employee will stand *in loco parentis*. Similarly, even though they have no legal relationship with the child, employees who share equally in rearing an adopted child with a same sex partner would still be entitled to FMLA in order to bond with the child or to care for the child if the child has a serious health condition, because the employees stand *in loco parentis*.

The fact that a child has a biological parent in the home, or has both a mother and a father, does not prevent a finding that the child is the son or daughter of both the biological parents and the stepparents and all four adults would have equal rights to take FMLA leave to care for the child if a serious health condition exists. Employers with questions about whether an employee’s relationship to a child is covered under FMLA may require the employee to provide reasonable proof or a statement of the family relationship. A simple statement asserting that the requisite family relationship exists is all that is needed in situations such as *in loco parentis* where there is no legal or biological relationship.

The DOL did include examples of situations in which an *in loco parentis* relationship may be found in the clarification, including:

- If a grandparent takes in a grandchild and assumes ongoing responsibility for raising the child because the parents are incapable of providing care.
- If an aunt assumes responsibility for raising a child after the death of the child’s parents.

Such situations may or may not ultimately lead to a legal relationship with the child (adoption or legal ward), but no such relationship is required to meet *in loco parentis* requirements.

This latest clarification will help employers who have struggled with determining whether an employee is a parent under the FMLA and is thus eligible for leave when a child is born, adopted or develops a serious health condition.

The DOL has also announced that it intends to conduct a Family Medical Leave Act survey in 2011. The DOL is interested in collecting baseline data of current family workplace policies and practices as well as information on regulatory changes. The DOL is placing a priority on workplace flexibility in an effort to help parents and other caregivers keep their jobs while they balance their responsibilities at home. MW

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During the thick of open enrollment season keeping employees informed takes center stage. This year the wide range of changes involved has made it even more difficult to keep employees up-to-date. If your organization has not yet moved to electronic communication, discuss this issue for 2011.

To reach all employees, employers must use the media their employees use. If your organization wants employees to pay attention to the message, the message must be readily available and understood. As employee benefits become more complicated and technology becomes more embedded in our culture, deciding how to keep employees informed of the changes becomes an important step in the process.

Your method of communication depends largely on your employees. Manufacturing organizations typically use print communications or employee meetings. It makes sense since many of these employees do not have access to computers during their work day. However, times are changing quickly and many employees now have Internet access at home. You may want to survey your employees to see whether they would agree to electronic communication. Their responses may surprise you. Your employees may prefer this method.

Be careful when a required process for delivering the material electronically exists, for example, delivering Summary Plan Descriptions. When employees do not have access to computers at work, employers must meet additional requirements to deliver these materials electronically. Please see our 2005 Benefit Advisor, Issue 10 at http://mcgrawwentworth.com/Benefit_Advisor/2005/BA_Issue10.pdf for more details. Once you switch to electronic delivery, you may want to include messages or notices along with payroll informing employees that you have sent information regarding their benefits by e-mail and that they can contact HR if they have any problems accessing the information.

If your employees do have access to a computer as part of their regular work, your organization has likely already begun communicating electronically. If your employees are geographically spread out or difficult to gather for a meeting, you may want to investigate doing employee meetings electronically. Your organization could conduct the meeting using a teleweb. Teleweb meetings are live over the Internet and participants can ask questions during the session. For some employees, the teleweb may not be the best choice because it may be difficult to participate at a specific time. In these cases, you can send them a recorded copy of the teleweb or presentation. That way the employee can view the program when time allows.

If your organization has not discussed using electronic technology to keep employees informed, you may want to consider the issue in 2011. Technological advances and Internet access have made electronic communications a cost-effective, flexible option. MW