HEALTH LAW

CASES, MATERIALS AND PROBLEMS
Seventh Edition

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benefit? What effect do these provisions have on the cost of coverage? To the extent that they increase costs, what effect might this have on access? Which of the provisions addressing UR issues are likely to be most strongly supported by plan members? Which are most likely in fact to be of use to them? Which provisions also benefit providers? Which providers benefit from these provisions? Which provisions are likely to be opposed most strongly by managed care trade associations? How enforceable are limitations on plan incentive structures? How useful are they to plan members? Are provisions aimed at improving quality of care likely to be effective? Considering only the interest of the public, which provisions will you recommend keeping and which repealing? Finally, after studying the next section, consider which provisions are redundant with requirements of the Affordable Care Act, and which, if any, might be preempted as preventing its application?

VI. INSURANCE REGULATION UNDER THE AFFORDABLE CARE ACT

The regulation of health insurance is revolutionized by the Affordable Care Act. This does not mean that pre-existing state and federal law is entirely repealed or replaced. Much of the law covered in the earlier sections of this chapter will remain unchanged. Aggrieved members of health insurance plans that are not protected by ERISA can still sue their insurers in contract and tort. Much of pre-existing federal law remains unchanged as well. The ACA neither expands nor contracts the scope of ERISA preemption of state law. Under 29 U.S.C. § 1144, state law that "relates to" employee benefit plans will still be preempted except insofar as it "regulates insurance," and self-insured plans will continue to be completely exempt from state regulation. ERISA remedies provided under 29 U.S.C. § 1132 will continue to be available to ERISA participants and beneficiaries and will continue to preempt all state remedies and permit removal of litigation by ERISA plans to federal court. The ADA and other antidiscrimination laws will continue to apply to health insurance to the extent they do now.

Nevertheless, the ACA dramatically changes the scope of federal insurance regulation. The ACA extends federal regulation over the nongroup (individual) market to an unprecedented extent. Previously, the nongroup market was largely untouched by federal law. The ACA also applies a much larger body of federal requirements to group health insurance plans, including self-insured plans. Section 1563(e) and (f) of the statute create a new section 715 of ERISA and 9815 of the Internal Revenue Code purporting to apply all but two of the insurance regulation provisions of Title A of title XXVII of the Public Health Services Act (PHSA), as amended by the ACA, to ERISA plans. In fact, however, each of the insurance reform provisions in the statute has its own scope. Some extend to all nongroup and group plans, some only to insured plans, and some only to nongroup and small group insured plans. In the end, however,

federal regulation of health insurance will be much more extensive after the legislation is fully implemented than before.

Title I of the health reform legislation adopts a comprehensive strategy to expand health insurance coverage. Chapter 7 examines the three major elements of this strategy: 1) premium and cost-sharing subsidies, 2) a minimum coverage requirement that requires individuals to purchase health insurance, and 3) taxes imposed on employers who fail to provide adequate coverage for their employees and whose employees end up benefiting from public subsidies, as well as interim assistance programs. Title I of the ACA also, however, dramatically expands insurance regulation as part of this comprehensive strategy.

The regulatory provisions of Title I have several objectives. These include:

1) Ending insurance underwriting and premiums based on health status,

2) Requiring plans to cover essential health benefits in the nongroup (individual) and small group market,

3) Eliminating unreasonable or unfair restriction on coverage and coverage exclusions,

4) Requiring insurers to spend a minimum proportion of premiums on medical claims and on programs to enhance quality of care and limiting "unreasonable" increases in premiums,

5) Expanding and making more accessible the information available to consumers on health insurance options, and

6) Enhancing competition among insurers through the creation of "exchanges" in the nongroup and small group markets.

A few of the reforms took effect upon enactment or for the first plan year beginning more than six months after enactment. Most, however, do not go into effect until 2014. This delay was necessary for several reasons. The primary reason is that implementation of the reforms takes time. Time had to be allowed for the federal government to draft implementing regulations (and final regulations are still not out on many of the reforms), for state legislatures to adopt implementing legislation (and most have not yet done so as of 2013), and for the states to actually implement the reforms. Four years is not, therefore, overly generous, and as we go to press in 2013, it seems like too little time. Moreover, the reforms are highly interdependent; insurers cannot be expected to forego health status underwriting or pre-existing condition exclusions in the nongroup and small group market until they are assured of a substantial pool of healthy enrollees, and thus underwriting reforms must await the implementation of the mandates. The mandates cannot be implemented, however, until the premium affordability subsidies are available to ensure that those who are required to purchase insurance can afford it. But the availability

of the premium subsidies must await the implementation of the exchanges, through which they will be offered. And the exchanges are to be established by the states, and again must await federal regulatory and state legislative action (still in progress in 2013 as we go to press). Finally, the premium subsidies will cost the federal government $88 billion a year when fully implemented and delayed implementation was necessary to meet ten year budget targets. Both immediate and 2014 reforms are discussed below by category.

The exchanges will play a key role in organizing, regulating, and financing insurance once they are in place in 2014. Briefly, exchanges are organized markets for nongroup and small group health insurance plans. They will market qualified health plans (QHPs) and administer the premium affordability tax credits and cost-sharing reduction subsidies, but will also play a regulatory role. Because they will not become operational until 2014, when many of the other provisions of the legislation are already in force, they are not discussed until later. Keep in mind, however, that once they come online, exchanges will play a key role in administering the other health care reforms.

As you work through the materials that follow, keep in mind that the ACA recognizes a number of categories of private health plans, and to some extent regulates them differently. The main categories are individual QHPs within the exchange, individual plans outside of the exchange, small group QHPs within the exchange, small group health plans outside of the exchange, large group plans, self-insured plans, grandfathered plans, and plans not subject to the ACA (such as early retiree plans, fixed-dollar indemnity plans, or Medicare Supplement plans). While some requirements apply to all categories of plans regulated under the ACA, some requirements only apply to a subset of regulated plans. See, Timothy Stoltzfus Jost, Loopholes in the Affordable Care Act: Regulatory Gaps and Border Crossing Techniques and How to Address Them, 5 St. Louis U. J. Health L. & Pol'y 27 (2011).

A. UNDERWRITING REFORMS

As noted earlier, a fundamental characteristic of modern health care is that a very high percent of health care costs are incurred in any given year by a very small proportion of the population, while the vast majority of the population accounts for a very small proportion of health care costs. The most rational strategy for an insurer, therefore, is to match premiums as closely as possible to the predicted costs of any particular enrollee (or group of enrollees) based on health status, to refuse to cover preexisting conditions, and to reject applicants who can be predicted to present essentially uninsurable risks because of their health status. This strategy, however, means that those most in need of health care will not be well served by a normally functioning health private health insurance

market. This is one of the reasons why most developed countries have instituted social insurance systems or public health care delivery systems to assure universal access to health care.

As noted later in this chapter, the Health Insurance Portability and Accountability Act of 1986 prohibited group health insurance plans from taking into account health status in determining eligibility or premium rates for group coverage and limited the use of pre-existing conditions exclusions by group plans. The ACA goes further and, effective January 1, 2014, outlaws all health status underwriting in the nongroup market and prohibits all pre-existing conditions clauses.

Section 2701 of the PHSA, added by Section 1201 of the ACA, provides:

SECTION 2701. FAIR HEALTH INSURANCE PREMIUMS.

(a) Prohibiting Discriminatory Premium Rates—

(1) With respect to the premium rate charged by a health insurance issuer for health insurance coverage offered in the individual or small group market—

(A) such rate shall vary with respect to the particular plan or coverage involved only by—

(i) whether such plan or coverage covers an individual or family;

(ii) rating area, * * *

(iii) age, except that such rate shall not vary by more than 3 to 1 for adults * * *; and

(iv) tobacco use, except that such rate shall not vary by more than 1.5 to 1; and

(B) such rate shall not vary with respect to the particular plan or coverage involved by any other factor not described in subparagraph (A).

Section 2705 of the statute provides:

PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(a) In General—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

(1) Health status.

(2) Medical condition (including both physical and mental illnesses).

(3) Claims experience.

(4) Receipt of health care.

(5) Medical history.

(6) Genetic information.

(7) Evidence of insurability (including conditions arising out of acts of domestic violence).

(8) Disability.

(9) Any other health status-related factor determined appropriate by the Secretary.

* * *

Section 2705, however, contains a general exception allowing plans to permit premium discounts or rebates, or reduced cost sharing, for participation in "Programs of Health Promotion or Disease Prevention," also called "wellness programs." The ACA provides:

(j) Programs of Health Promotion or Disease Prevention.—

(1) GENERAL PROVISIONS.—

(A) GENERAL RULE.—* * * a program of health promotion or disease prevention * * * shall be a program offered by an employer that is designed to promote health or prevent disease that meets the applicable requirements of this subsection.

(B) NO CONDITIONS BASED ON HEALTH STATUS FACTOR.—If none of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals and the requirements of paragraph (2) are complied with.

(C) CONDITIONS BASED ON HEALTH STATUS FACTOR.—If any of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if the requirements of paragraph (3) are complied with.

(2) WELLNESS PROGRAMS NOT SUBJECT TO REQUIREMENTS.—If none of the conditions for obtaining a premium discount or rebate or other reward under a wellness program as described in paragraph (1)(B) are based on an individual satisfying a standard that is related to a health status factor (or if such a wellness program does not provide such a reward), the wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals. The following programs shall not have to comply with the requirements of paragraph (3) if participa-

tion in the program is made available to all similarly situated individuals:

(A) A program that reimburses all or part of the cost for memberships in a fitness center.

(B) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

(C) A program that encourages preventive care related to a health condition through the waiver of the copayment or deductible requirement under group health plan for the costs of certain items or services related to a health condition (such as prenatal care or well-baby visits).

(D) A program that reimburses individuals for the costs of smoking cessation programs without regard to whether the individual quits smoking.

(E) A program that provides a reward to individuals for attending a periodic health education seminar.

(3) WELLNESS PROGRAMS SUBJECT TO REQUIREMENTS.—If any of the conditions for obtaining a premium discount, rebate, or reward under a wellness program as described in paragraph (1)(C) is based on an individual satisfying a standard that is related to a health status factor, the wellness program shall not violate this section if the following requirements are complied with:

(A) The reward for the wellness program, together with the reward for other wellness programs with respect to the plan that requires satisfaction of a standard related to a health status factor, shall not exceed 30 percent of the cost of employee-only coverage under the plan. * * * A reward may be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan. The Secretaries of Labor, Health and Human Services, and the Treasury may increase the reward available under this subparagraph to up to 50 percent of the cost of coverage if the Secretaries determine that such an increase is appropriate.

(B) The wellness program shall be reasonably designed to promote health or prevent disease. A program complies with the preceding sentence if the program has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health status factor, and is not highly suspect in the method chosen to promote health or prevent disease.

(C) The plan shall give individuals eligible for the program the opportunity to qualify for the reward under the program at least once each year.

(D) The full reward under the wellness program shall be made available to all similarly situated individuals. For such purpose, among other things:

(i) The reward is not available to all similarly situated individuals for a period unless the wellness program allows—

(I) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(II) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(ii) If reasonable under the circumstances, the plan or issuer may seek verification, such as a statement from an individual's physician, that a health status factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.

(E) The plan or issuer involved shall disclose in all plan materials describing the terms of the wellness program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under subparagraph (D). If plan materials disclose that such a program is available, without describing its terms, the disclosure under this subparagraph shall not be required.

* * *

The ACA also requires insurers to guarantee issue and renewability of coverage to all applicants, prohibits all pre-existing condition exclusions, and bans waiting periods for coverage in excess of 90 days.

Finally, the ACA introduces risk adjustment programs to ensure that insurers who are successful in gaming the system and disproportionately attracting good risks and repelling bad risks are not rewarded for it. Indeed, the ACA institutes three risk accommodation programs, two interim for the three years following the 2014 implementation date and one permanent.

First, Section 1341 creates a reinsurance program for the years 2014, 2015, and 2016 that will collect about $25 million from health insurers and third party administrators of self-insured health plans and distribute these funds equitably to reinsure insurers who insure high risk individuals in the individual market. Second, Section 1342 establishes a risk corridor program for the same time period to move funds from insurers in the exchange whose claims costs come in under a "target amount" to those

whose claims costs come in over that amount. Third, Section 1343 establishes a permanent program under which states assess a charge against health plans and health insurers in the individual and small group market (other than self-insured group health plans or grandfathered plans) whose enrollees' average actuarial risk is below average and make payments to plans and insurers (other than self-insured group health plans or grandfathered plans) whose enrollees' average actuarial risk is above average. See Mark A. Hall, Risk Adjustment Under the Affordable Care Act: Issues and Options, 20 Kan. J. L. & Pub. Pol'y 222 (2011); Mark Hall, The Three Types of Reinsurance Created by Federal Health Reform, 29 Health Aff. 1168 (2010); Tom Baker, Health Insurance, Risk, and Responsibility after the Patient Protection and Affordable Care Act, U of Penn, Inst for Law & Econ Research Paper No. 11–03. Final regulations implementing this program are found at 77 Fed. Reg. 17220 (2012).

Only one ACA underwriting reform went into effect before 2014. The ACA banned the application of pre-existing conditions exclusions to minors effective for plan years beginning six months after the effective date of the law. HHS interpreted the legislation to ban not only pre-existing condition clauses, but also the exclusion of minors with pre-existing conditions. The enforcement of this provision caused serious disruption in the availability of child-only insurance coverage as insurers dropped or limited child-only coverage or raised premiums to avoid adverse selection by families with sick children. The states and administration responded by expanding child coverage in the pre-existing conditions high risk pool, authorizing open enrollment periods, or requiring insurers to sell child-only policies, but the child-only market remains problematic in many states. The experience dramatically demonstrates why a mandate is necessary to preserve insurance markets once pre-existing conditions exclusions are eliminated.

NOTES AND QUESTIONS

1. Is the 3 to 1 ratio in rate variation based on age in fact a surrogate for health status underwriting, as health status tends to deteriorate with age? Is it otherwise justified? Is the fact that the ACA also eliminates gender discrimination in the individual and small group market. In fact, 60 year old males have claims costs about 5 times those of 25 year old males, while 60 year old females have claims costs twice those of 25 year old females. See William F. Bluhm, Individual Health Insurance (2007) at 121.

2. Wellness programs are touted as improving the health of individuals who participate in them while saving employers money. They are very popular with those who believe that ill health (and accompanying health care costs) are largely the fault of individuals with poor health habits and that individuals who do not take care of themselves should bear their own health care's costs rather than be allowed to impose them on society. Much was made during the health care reform debate of the success of the Safeway

Company in particular in saving money through employee wellness programs. An investigation of these claims, however, found them largely unfounded. David Hilzenrath, Misleading Claims About Safeway Wellness Incentives Shape Health Care Bill, Washington Post, Jan. 17, 2010.

Although it would seem to be intuitive that enrollees would respond to financial incentives by improving health habits, the extent to which these programs really improve health or save money is not clearly established, except perhaps for smoking cessation programs. A recent meta-analysis of the literature on workplace wellness programs claimed that they save about $3.27 in medical costs and $2.73 in reduced absenteeism for every dollars spent. Katherine Baicker, David Cutler, & Zirui Song, Workplace Wellness Programs Can Generate Savings, 29 Health Aff. 304 (February 2010). It is not at all clear, however, that published reports are representative of experience generally or that they could be reproduced more broadly. See also Kevin Volpp et al., P4P4P: An Agenda for Research on Pay-for-Performance for Patients, 28 Health Aff. 206 (Jan./Feb. 2009); Jill Horwitz, Brenna Kelly, John DiNardo, Wellness Incentives in the Workplace: Cost Savings by Cost Shifting to Unhealthy Workers, 32 Health Aff. 468 (2013).

Consumer groups are particularly concerned that wellness programs based on biometric measurements (blood glucose or cholesterol levels or body mass index (BMI) measurements) will penalize enrollees who have health conditions about which they can do little, and that provisions for reasonable alternative standards may be burdensome and inadequate, particularly if they are based on premium surcharges rather than discounts. Programs based on biometric measurements are permissible under the current federal regulations if certain safeguards are observed. 29 C.F.R. § 2590.702(f). How are wellness premium surcharges based on biometric measures different from premiums based on health status?

Under regulations proposed late in 2012, health-contingent wellness programs, which condition the receipt of a reward on meeting a health status standard, such as a BMI or blood pressure measure or not smoking, must meet five requirements to fall within the exception to the health status underwriting prohibition. First, all persons eligible for the program must be given an opportunity at least once a year to qualify. Second, the size of the reward cannot exceed 30 percent of the total cost of coverage, including both the employer and employee's contribution. The proposed rule would allow a 20 percent additional reward (for a 50 percent of cost of coverage total) for smoking cessation to counterbalance the permissible 1.5 to 1 tobacco use surcharge in the individual and small group market.

A third critical standard that health-contingent wellness programs must meet is that they must provide a "reasonable alternative standard" or waiver of the health-contingent standard for individuals who find it unreasonably difficult to meet the otherwise applicable standard because of their medical condition, or for whom it is medically inadvisable to attempt to satisfy the standard. Such an alternative must be provided on request and cannot be refused simply because the individual has not been successful in prior at-

tempts to address an issue. A reasonable alternative standard cannot be one that requires the participant to pay for the cost of the program or for a membership or participation fee. If an alternative is proposed by a medical professional who is an employee or agent of the plan, but the individual's personal physician states that the proposal is not medically appropriate, the treating physician's judgment must prevail. A plan or insurer can require verification of a claim that it is unreasonably difficult for an individual to comply with a health standard, but only if such a request is reasonable under the circumstances. A request would be unreasonable if the plan or insurer is already aware of the individual's medical condition.

Fourth, health-contingent wellness programs must also be reasonably designed to promote health or prevent disease, not be overly burdensome, not be a subterfuge for health status discrimination, and not use a highly suspect approach. Fifth, the program must require plans and insurers to disclose the availability of other means of qualifying for a reward or the possibility of waiver of a standard.

To what extent will the wellness incentive provisions of the legislation continue to in fact allow health status underwriting? Are the protections built into the legislation and regulations to keep wellness programs from becoming a substitute for health status underwriting likely to be effective? Are they realistic? See, discussing these issues, Scott D. Halpern, Kristin M. Madison, & Kevin G. Volpp, Patients as Mercenaries? 2 Circulation: Cardiovascular Quality & Outcomes 514 (2009). See also, on the appropriateness of using health insurance to encourage wellness, Wendy Mariner, The Affordable Care Act and Health Promotion: The Role of Insurance in Defining Responsibility for Health Risks and Costs, 50 Duq.L.Rev. 271 (2012).

3. Wellness programs must also comply with the Americans with Disabilities Act. Although health conditions are not necessarily disabilities under the ADA, some may be, particularly given the broader definition of disability that became law in 2009 under the ADA Amendments Act and that was meant to reverse Supreme Court decisions limiting the definition of disability. The ADA prohibits mandatory medical examinations or workplace health inquiries unless the examination or inquiry is job-related and consistent with business necessity. 42 U.S.C. § 12112(d)(4). Employers may conduct voluntary medical examinations or inquiries as part of an employee health program. An employer that does so must keep the wellness program records confidential and separate from personnel records. Equal Employment Opportunity Commission Guidance also provides that "a wellness program is 'voluntary' as long as an employer neither requires participation nor penalizes employees who do not participate." The EEOC has offered the opinion that a wellness program could be considered voluntary if inducements to participate did not exceed 20 percent of program cost, which was all that was allowed by HIPAA before the ACA was adopted, but has not offered an opinion with respect to whether larger incentives are allowable.

Wellness incentives may have other legal consequences as well. The Genetic Information Nondiscrimination Act includes a provision allowing em-

ployers to permit wellness programs that provide health or genetic services to ask employees to voluntarily provide genetic information, as long as the information is not disclosed in identifiable form to the employer. 42 U.S.C. § 2000ff–1(b)(2). The Age Discrimination in Employment Act and Title VII would also prohibit wellness programs that had a disparate effect based on age or race. Wellness incentives provided to employees that are not health benefits (such as gym memberships) may be taxable income. Finally, state laws—such as those prohibiting employers from discriminating against smokers or obese persons—might further limit wellness programs.

See Nancy Lee Jones, et al., Wellness Programs: Selected Legal Issues (Congressional Research Service 2010); Anita K. Chancey, Getting Healthy: Issues to Consider before Implementing a Wellness Program, 2 J. Health & Life Sci. L. 73 (2009); Lucinda Jesson, Weighing the Wellness Programs: The Legal Implications of Imposing Personal Responsibility Obligations, 15 Va. J. Soc. Pol'y & L. 217 (2008).

4. In one of the more bizarre twists of the often bizarre health care reform debate, the claim was spread among gun rights advocates that the wellness provisions of the legislation were a veiled attempt to attack gun ownership. In response, the manager's amendment added a lengthy provision prohibiting wellness and health promotion programs from requiring disclosure of information about the lawful use, possession, or storage of firearms or ammunition and barring insurers from basing premium rates or health insurance eligibility on the lawful, use, ownership or storage of ammunition or possession of firearms or ammunition and from collecting data regarding firearms or ammunition. The implementing agencies have clarified that this provision does not prohibit physicians from discussing firearm issues with their patients.

5. Might ACA regulation of insurance underwriting raise constitutional questions? Might rate regulation result in a taking, prohibited by the Fifth Amendment? See Richard Epstein and Paula Stannard, Constitutional Ratemaking and the Affordable Care Act: A New Source of Vulnerability, 38 Am. J. L. & Med. 243 (2012).

6. Title IV of the reform legislation contains a number of other prevention and wellness programs, some of which are discussed in Chapter 1. Section 4303 of the ACA provides technical assistance for employee wellness programs while § 10408 authorizes grants for workplace wellness programs for small employers.

PROBLEM: DESIGNING A CORPORATE WELLNESS PROGRAM

As legal counsel for a corporation that expects to purchase health insurance for its employees, you have been asked to review the design of a proposed wellness program for legal issues. The corporate human resources manager would like to give employees a substantial discount on their portion of their health insurance premium if they participate in the program. In particular, the human resources manager has proposed giving each employee

who participates a 10% discount on that employee's health insurance premium for each one of the following "wellness opportunities" that employee undertakes during the initial pilot year:

(1) a smoking cessation program, with the discount available to anyone who does not smoke, or who successfully completes this program,

(2) a "maintaining appropriate body weight" program, with the discount available to anyone who maintains a proper body weight, or who makes substantial progress toward maintaining a proper body weight, during the program,

(3) an immunization program, with the discount available to any employee who has received every medically recommended immunization,

(4) a basic care program, with the discount available to anyone who visits a primary care provider at least once during the year, and, finally,

(5) a basic safety program, with the discount available to anyone who agrees not to own or ride on a motorcycle, bicycle, skidoo, or seadoo, or engage in a dangerous sport (like skiing and diving).

In addition, the human resources manager wants to give another 5% discount on the premium to an employee if for six months neither the employee or a family member uses medical care covered by the health plan.

Several of the employees have complained about the contours of the proposed program. An overweight employee has a letter from a website from which he purchased a genetic test, which says that his obesity is a consequence, at least in great part, of genetic factors. A few employees object to the immunization program because they have decided to forgo immunization (for themselves and their children) either for medical, philosophical, or religious reasons. A Christian Scientist objects to the requirement that he see a primary care provider regularly to partake in the discounts. An employee who just bought a time share in a ski resort argues that it would be unfair to create the basic safety program. A pregnant employee argues that she will be excluded from some because of her pregnancy.

Can the employer institute these wellness programs and give premium discounts if it does? How would you structure these programs to make them consistent with the limitations of ACA?

B. MINIMUM ESSENTIAL BENEFIT AND COST-SHARING REQUIRMENTS

1. Requirements Effective in 2014: Section 1302

Never before has federal law attempted to specify the benefits that private insurance plans must cover, beyond a handful of specific mandates. Indeed, although many states require insurers to cover specific

services, providers, or insureds, states do not generally specify comprehensively the bundle of items and services that health insurance must cover.

The ACA requires that, effective January 1, 2014, insurers that offer coverage in the individual and small group market (groups of 100 or fewer employees except that, for 2014 and 2015, a state can defined "small group" as 50 or fewer) must cover an "essential benefits package" specified by the law. The requirement does not apply to large group or self-insured plans, nor does it apply to "grandfathered" plans, that is plans that existed as of the date of enactment of the ACA. It does apply, however, to all nongrandfathered nongroup and small group plans. It applies whether or not plans are sold through the exchange.

Section 1302 requires HHS to define "essential health benefits." The statute lists categories of benefits that must be included in this category, including:

- ambulatory patient services,
- emergency services,
- hospitalization,
- maternity and newborn care,
- mental health and substance use disorder services,
- prescription drugs,
- rehabilitation and habilitation services,
- laboratory services,
- preventive and wellness services including chronic disease management, and
- pediatric services, including oral and vision care.

The ACA-defined essential benefits must be equal in scope to those offered under a typical employer plan. HHS must, as it defines essential health benefits, also make sure that benefits:

- are "not unduly weighted toward any category;"
- do not discriminate based on age, disability, or expected length of life;
- do take into account the needs of diverse segments of the population;
- ensure that essential benefits are not denied individuals against their wishes based on age, expected length of life, present or predicted disability, dependency, or quality of life;
- provide access to emergency care without prior approval, limitation to in-network providers, or higher cost-sharing for using out-of-network providers; and
- are periodically reviewed and updated.

HHS has decided to implement this provision initially by asking each state to designate a "benchmark" plan, the benefits of which will become the standard against whose benefits other plans will be measured. The state may either choose the largest plan of one of the three largest small group products in the state, one of the three largest state employee plans in the state, any of the largest three national Federal Employee Health Benefits plans, or the state's largest commercial non-Medicaid HMO plan. If the plan chosen does not cover any of the ten required benefit categories, the state must add benefits from another plan. Under HHS rules, plans must offer the greater of one drug in every United States Pharmacopeia (USP) category or class or the number of drugs in each category and class as the EHB-benchmark plans. Plans need not cover the same drugs as are covered by the benchmark plan as long as they cover the minimum number of drugs. Insurers will have some flexibility in substituting benefits within categories as long as they are equivalent in value and none of the other requirements are violated.

The ACA also itself contains a few additional explicit benefit mandates. Beginning in 2014, group health plans and health insurance issuers must cover the routine patient costs of enrollees participating in approved clinical trials for cancer or other life-threatening conditions. If in-network providers are participating in the trial, the plan can require an enrollee to participate through the in-network provider, but if the trial is conducted out of the state in which the individual resides, the care can be provided by an out-of-network provider if out-of-network benefits are otherwise provided under the plan. Additional mandates that take effect immediately are discussed below.

Plans may offer benefits in excess of the essential benefits. States may also require benefits in addition to the essential benefits mandated by federal law, but states must pay the additional cost of those benefits for individuals and families enrolled in QHPs. Current small group plans are likely to cover state-mandated benefits (unless state mandates apply only in the nongroup market) and so by choosing a small group plan as its benchmark a state can probably ensure that it will not have to pay for mandated benefits, at least until 2016, when HHS has indicated it might change the essential health benefit rules. If a state does have to pay, it is unclear how exactly the costs of state mandates will be calculated, as some mandates arguably save money by helping to prevent costly future care and others are for services almost universally covered in any event. This requirement is unlikely to lead to the immediate repeal of existing state benefit mandates, which are numerous in some states, but will discourage the adoption of mandates in the future.

Although all exchange plans must offer all essential benefits, most will probably not offer significant additional benefits since additional benefits will not be eligible for federal subsidies. Plans will vary signifi-

cantly in the amount of cost-sharing that they require. The statute does set some cost-sharing limits. For 2014, cost-sharing may not exceed the limits imposed on high-deductible insurance plans that are coupled with health savings accounts (set at $6,250 for an individual and $12,500 for a family for 2013). Health plan deductibles in the small group market may not exceed $2,000 for an individual or $4,000 for a family (except in situations where this deductible limit would make it impossible for insurers to offer plans that comply with metal level actuarial value requirements). After 2014, the out-of-pocket limit and small group plan deductible limits will be adjusted upward annually based on the amount that the average per capita premium for health coverage exceeds the average per capita premium in 2013. Cost-sharing is defined to include deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts for out-of-network providers, or spending for non-covered services.

The ACA further requires that health plans offered in the individual and small group markets cover specific percentages of actuarial value specified in the statute. As noted in Chapter 7, these are arrayed in "precious metal" categories. "Bronze" plans must cover 60 percent of actuarial value; silver, 70 percent of actuarial value; gold, 80 percent of actuarial value; and platinum, 90 percent of actuarial value. The actuarial value of services is to be determined on the basis of the cost of providing the essential benefits to a standard population, not the actual population of the plan. Employer contributions to a health reimbursement or health savings account are taken into account in determining actuarial value. Insurers may also offer a catastrophic plan, with a deductible equal to the out-of-pocket limit for high deductible plans plus coverage for at least three primary care visits, but the catastrophic plan can only be offered to individuals in the individual market who are under age 30 or who are exempted from the individual mandate because they cannot afford coverage or because of hardship.

Actuarial value is a concept that is unfamiliar to most Americans, who typically think about coverage and cost-sharing in terms of deductibles ($500 which must be paid by the enrollee before insurance coverage begins), copayments ($20 per doctors visit, $10 for each generic drug prescription, $30 for each name-brand prescription), coinsurance (20% of the hospital bill), or out-of-pocket limits ($5,000 per year). Because medical costs vary dramatically from insured to insured while actuarial value is defined in terms of average costs, the actual cost-sharing experienced by individuals will vary significantly regardless of the actuarial value of a plan. For purposes of comparison, the average actuarial value of employment-based plans is estimated to be about 80 percent, the Federal Employee Health Benefits Program Blue Cross Blue Shield standard option has an actuarial value of about 84 percent to 87 percent, while Medicare Parts A and B alone have an actuarial value of about 64 percent and Med-

icare Parts A, B and D with a Medigap policy would have a value of about 90 percent. The concept of actuarial value is explored further in the discussion of cost-sharing reduction payments in Chapter 7.

2. Benefit Requirements in Effect Prior to 2014: Section 1001

Although the essential benefit and cost-sharing requirements do not go into effect until 2014, several benefit mandates have already gone into effect for plan years beginning after September of 2010. First, non-grandfathered (see below) group health plans and health insurers must cover preventive services without cost-sharing. These services include at least the evidence-based items and services rated A or B by the United States Preventive Services Task Force, immunizations recommended by the Advisory Committee on Immunization of the CDC, and preventive care and screening for women and children recommended by the guidelines of the Health Resources and Services Administration (including the pre–2009 breast cancer recommendations). Plans may alternatively use value-based insurance designs permitted by guidelines provided by HHS. See John Aloysius Cogan, The Affordable Care Act's Preventive Services Mandate: Breaking Down the Barriers to Nationwide Access to Preventive Services, 39 J. L. Med. & Ethics 355 (2011).

Second, the ACA requires group health plans and insurers that cover children as dependents to offer such coverage for adult children until the child turns 26 (but not to the children's children), regardless of whether the adult child is in fact a dependent or even lives with the parent. This Section also covers grandfathered plans, but prior to 2014 group plans need not cover adult dependents if they can be covered under any other employment-related group plan that is not grandfathered coverage. Plans may not charge more for adult dependents than they would charge for other family members. This has been one of the most popular provisions of the legislation, and was implemented by many insurers and group plans even before its actual effective date. As of 2012, 2.5 million young adults have been covered under this provision. See Joel Cantor, et al., Expanding Dependent Coverage for Young Adults: Lessons from State Initiatives, 37 J. Health Pol., Pol'y & L. 99 (2012).

Third, the ACA requires group health plans or health insurers that obligate enrollees to designate a primary care provider to permit enrollees to designate any available participating primary care provider. Group health plans or health insurers that cover emergency department services must cover emergency medical conditions without prior authorization and whether or not an emergency care provider is in-network. Plans are also prohibited from charging higher cost sharing for out-of-network than for in-network emergency services. The HHS regulation implementing this Section interprets it to mean that plans must pay out-of-network emergency care providers the greater of the amount they pay in-network pro-

viders, out-of-network emergency care providers without regard to out-of-network cost sharing, or the Medicare rate. Group health plans and health insurers that require designation of a primary care provider must permit designation of a pediatric specialist for children. Group health plans and health insurers must also provide direct access without authorization or referral of women to gynecologists or obstetricians for obstetrical or gynecological care.

NOTES AND QUESTIONS

1. Many of the requirements of the ACA do not apply to "grandfathered" plans. One of the promises made by President Obama was that "if you like the insurance you have, you can keep it." Group and nongroup insurance plans that existed on the effective date of the statute can continue in force indefinitely and be renewed without having to comply with many of the requirements of the statute. New family members and employees can be added to these plans. At some point, however, plans may change sufficiently that they lose their grandfathered status. Regulations implementing this provision stipulate that a plan loses its grandfathered status if any of the following changes take place:

- Elimination of all or substantially all of any benefit necessary to diagnose or treat a particular condition;
- Any increase in coinsurance percentages;
- An increase in a deductible, out-of-pocket limit, or other fixed dollar cost-sharing requirement or limit other than a copayment by more than the increase in the medical component of the CPI since March 2010 plus a total of 15 percentage points;
- An increase in a copayment in excess of the greater of 1) medical inflation plus $5.00 or 2) medical inflation plus a total of 15 percentage points;
- A decrease of the employer contribution, whether based on the cost of coverage or on a formula, by more than 5 percentage points below the contribution rate in place on March 23, 2010; and
- A reduction in the dollar value of existing annual limits, the imposition of an annual limit on coverage by plans that did not impose any limits before, or the adoption of annual limits less than any lifetime limits a plan imposed before if it only imposed lifetime limits before the effective date.

Even grandfathered plans must comply with a number of the requirements of the ACA, including:

- Coverage disclosure and transparency provisions;

- The minimum medical loss ratio provision requiring plans to pay out a minimum of 80 or 85 percent of their premiums to cover health care claims or quality improvement activities;
- The prohibition against waiting periods in excess of 90 days;
- The provision prohibiting lifetime limits;
- The ban on rescissions except in the case of fraud; and
- The requirement that plans cover adult children up to age 26.

In addition, the provisions relating to annual limits and prohibiting exclusion of pre-existing conditions (initially only for children) apply to grandfathered group plans, although grandfathered group plans need not cover adult children if other non-grandfathered coverage is available. Elizabeth Weeks Leonard, Can you Really Keep Your Health Plan? The Limits of Grandfathering Under the Affordable Care Act, 36 J. Corp. L. 753 (2011).

2. Section 1303 of the ACA prohibits the use of federal subsidies to finance abortion coverage beyond coverage for rape, incest, or to protect the mother from physical life endangerment. The pre-existing condition, high-risk pool is also prohibited from paying for abortions. Several cases have been brought challenging the preventive service regulation's requirement that group health plans and insurers cover post-intercourse contraceptives, thought by some to be abortifacients. These provisions are discussed further in connection with Chapter 15.

3. HHS has defined contraception as a preventive service for women that insurers must cover without cost-sharing. This ruling was met with strong resistance from Catholic organizations. HHS exempted religious employers from covering contraception, and gave nonprofit organizations sponsored by religious organizations (such as universities, hospitals, and charities) until August of 2013 to comply. HHS has further proposed a compromise under which religious organizations do not need to cover contraception, but their insurers or self-insured plan administrators must offer contraception coverage to employees of the religious organizations. The agencies have not proposed any accommodation for for-profit employers with objections to contraceptive coverage. This issue is currently being litigated in dozens of cases, which are being brought under the First Amendment and Religious Freedom Restoration Act. See Chapter 15.

C. INSURANCE REFORMS: SECTIONS 1001, 1003, 10101

Several provisions of the ACA respond to insurance industry practices that have been regarded as unfair or unreasonable. Other provisions require plans to offer procedural protections to their members. Most of these provisions are already in effect, having become effective for the first plan year following the six-month anniversary of enactment.

Lifetime and Annual Limits. The ACA prohibits group health plans and health insurers, including grandfathered plans, from imposing lifetime limits on the dollar value of benefits. The ACA also prohibits annual limits on the dollar value of benefits after 2014. Prior to 2014, group health plans and insurers were only allowed to impose "restricted annual limits" on essential health services that would make needed services available while having only "a minimal impact on premiums," as determined by HHS guidance. HHS regulations prohibited annual limits below $750,000 for 2010, $1.25 million for 2011, and $2 million for 2012 and 2013. HHS also, however, set up a waiver process in 2010 for group health plans and insurers that could not meet these requirements, so-called "limited benefit" or "mini-med" plans. Over 1200 waiver requests were granted, covering almost 3.4 million enrollees before HHS ceased accepting waiver applications in 2011. Special rules also applied to annual limits found in university student health plans. But as of 2014, the vast majority of Americans will be covered by plans meeting the annual limit requirements. Group health plans and insurers may also impose limits on benefits that are not essential benefits as permitted by federal and state law. The prohibition against annual limits does not apply to grandfathered individual plans, but does apply to grandfathered group plans that do not qualify for a waiver.

Rescissions. The ACA prohibits rescission of coverage except for fraud or intentional misrepresentation of material fact. This provision also applies to grandfathered plans. It addresses the problem of "post-claims underwriting," under which insurers have insured individuals with minimal investigation and then gone back carefully over their application forms once expensive medical problems have developed to find grounds for rescission for "misrepresentation."

Medical Loss Ratios. Section 10101 adds Section 2718 of the Public Health Service Act, which requires insurers to spend a minimum proportion of their premium revenues on health care services and activities that improve health care quality, the so-called "minimum medical loss ratio" requirement. Since 2011, health insurers (including grandfathered plans but not self-insured plans) have been required to report to HHS the ratio that their loss adjustment expenses bear to earned premiums. An insurer must also report the percentage of premium revenue that it spends on clinical services, activities that improve health care quality, and on all other non-claim (administrative) costs. Premium revenues are adjusted for payments to or collections for risk adjustment, risk corridor, and reinsurance programs (see below) and reduced by taxes, licensing, or regulatory fees.

Since January 1, 2011, health insurers have had to provide annual rebates to their enrollees if their medical loss ratios (the ratio of amounts incurred for claims and paid for activities that improve health care quali-

ty to adjusted premium revenue) are less than 85 percent of premium revenue in the large group market or 80 percent in the small group or individual market. The rebates must equal the product of the percentage by which a company's MLR falls short of the allowed percentage for its state and market and the total amount of premium revenue (excluding federal and state taxes and licensing or regulatory fees and payments or receipts for risk adjustment, risk corridor, and reinsurance costs). In other words, if an insurer in the nongroup market pays 75 percent of its adjusted premiums for clinical services and 2 percent for health care quality improvement activities (such as disease management or patient education programs), it would owe a rebate of 3 percent for the year. These rebates will be paid on August 1 of the following year, usually through reductions in premiums. After January 1, 2014, the rebate must be based on the average MLRs of the preceding three years and will not be paid until the end of September HHS and the states must consider insurance market conditions in setting and adjusting the required MLRs.

As directed by the statute, the National Association of Insurance Commissioners developed definitions and methodologies for implementing this provision during an exhaustive months-long process. HHS in turn adopted a regulation based on these recommendations. The regulation allows insurers to apply the costs of a wide range of quality improvement activities against the MLR, including activities that reduce medical errors and protect patient safety, improve outcomes of care, encourage prevention and wellness, and prevent rehospitalizations, as well as a range of health IT costs. All but the largest insurers receive "credibility adjustments" to account for the fact that they do not have enough enrollees in the state to produce a statistically credible medical loss ratio in any one year, given the fluctuation of claims from year to year. Some types of plans, including mini-med plans, international and expatriate plans, student health plans, and new plans are also given special treatment because of their unusual characteristics. Finally, states that believed that immediate application of the federal minimum MLRs would destabilize their markets were allowed to apply for an "adjustment." Seventeen states applied for such adjustments, but only seven were granted. In 2012, insurers returned $1.1 billion to their enrollees under the MLR requirement.

Unreasonable Premium Increases. Section 1003 of the bill adds Section 2794 to the Public Health Services Act, establishing immediately a process for annual review by HHS and the states of "unreasonable" increases in health insurance premiums. Health insurers must submit to HHS and to all relevant states justifications for unreasonable premium increases and prominently post this information on their websites. Under regulations adopted by HHS, insurers had to justify any annual increases in excess of 10 percent during 2011 and in excess of 10 percent or a state-specific standard thereafter. If a state has an "effective" rate review pro-

gram, premium increases above this level are evaluated by the state. If the state does not have such a program, HHS reviews the rate increase. HHS does not have authority, however, to disapprove proposed rate increases.

Beginning in 2014, HHS and the states must monitor premium increases inside and outside of the exchanges. A state must "take into account" excess premium growth outside of the exchange in determining whether to open the exchange to larger groups. The ACA authorizes $250 million for the five-year period between 2010 and 2014 to assist the states in conducing premium reviews and for funding medical reimbursement data centers at academic and other nonprofit institutions to collect, analyze, and make available information to the public on provider fee schedules and costs. It does not, however, give the states authority to actually deny unreasonable premium increases. Some states have this authority under state law, others do not, but the ACA does not expand their authority. The ACA does, however, require exchanges to consider whether there is a pattern or practice of excessive or unjustified premium increases in determining whether or not to make a particular health plan available.

Discrimination. A new section 2706 of the PHSA prohibits group health plans and insurers from discriminating against providers acting within the scope of their license or certification under state law. This section also prohibits group health plans and insurers from discriminating against an individual who benefits from a premium tax credit or cost-sharing reduction payment. Section 2716 prohibits employers from discriminating in favor of highly-compensated employees in insured coverage. A similar non-discrimination provision already applies to self-insured and cafeteria plans.

Internal and External Reviews. The ACA requires group health plans and insurers to offer plan members both internal and external review procedures for coverage and claims determinations. Plans and insurers must provide notices to enrollees in a culturally and linguistically appropriate manner of available internal and external appeal procedures and of the availability of a state office of health insurance consumer assistance or ombudsman for assistance with appeals. They must allow enrollees to review their files and to present evidence and testimony. Group health plan internal appeals processes must comply with the ERISA regulations discussed below and individual insurance internal review procedures must comply with state law and with standards promulgated by HHS.

The internal appeals rule issued by HHS and the Departments of Labor and Treasury require all plans and insurers to comply with the Department of Labor ERISA claims and appeals regulations, and imposes several additional requirements on group plans. The additional requirements are that plans must:

- Allow appeals of rescissions as well as adverse benefit determinations;
- Notify members of determinations in urgent care claims within 72 hours;
- Provide claimants, without charge, with any new or additional information relied upon or generated by the plan as soon as possible and far enough in advance of a determination to allow an opportunity to respond;
- Ensure that internal reviewers do not have a conflict of interest;
- Provide culturally and linguistically appropriate notices.

If plans or insurers fail to adhere to the requirements of the process, the claimant may proceed to an external appeal or judicial review. Individual plans, which are often offered by insurers, must comply with the same rules.

Group health plans and insurers must comply with either their state or the federal external review requirements. If a state has in place an external review process offering at least as much protection as the NAIC Model Act, an insurer must comply with the state law. Plans and insurers not subject to state law (self-insured employee benefit plans) or located in states without external review laws as protective as the NAIC Model Act, must comply with a federal external review process.

State external review processes must comply with a number of requirements. Specifically they must:

- Provide external review of adverse determinations based on medical necessity, appropriateness, health care setting, level of care, or effectiveness requirements, as well as of determinations involving coverage of experimental or investigational treatments;
- Ensure that it is unnecessary to pursue an internal review first if the insurer fails to comply with regulatory requirements or if the claimant is pursuing internal and external review at the same time for urgent claims;
- Require the insurer to pay the cost of external review, although the claimant can be charged $25 for an appeal (up to $75 per plan year) if it would not impose a hardship and if the fee is refunded if the claimant wins;
- Not impose a minimum dollar amount requirement for appeals;
- Assign claims to independent review organizations (IROs) that are accredited and qualified to review the type of claim involved on a random basis;
- Use only Independent Review Organizations (IROs) that have no conflicts of interest;
- Provide that the decision of the IRO is binding on the insurer;

- Require an external review decision to be made within 45 days; and
- Provide for an expedited process in urgent circumstances.

Existing state external review requirements that do not contain these essential elements but that meet lower standards contained in the rule will govern plans and insurers for a transitional period through 2015. The Department has established an external review process similar to the state process to govern self-insured plans and insured plans not governed by state law. See, discussing IROs, Marc A. Rodwin, New Standards for Medical Review Organizations: Holding Them and Health Plans Accountable for their Decisions, 30:3 Health Aff. 519 (2011); Dustin Berger, The Management of Health Care Costs: Independent Medical Review After "Obamacare," 42 U. Mem. L. Rev. 255 (2011).

PROBLEMS: INSURANCE REFORMS

1. Joan Hart purchased a nongroup health insurance policy early in 2012. She filled out a detailed questionnaire asking about her health history. She neglected to mention that she had received medication for depression a year earlier following the death of her brother, even though the form asked for all medications she had taken in the past two years. Late in 2012, she was diagnosed with cancer. Her health insurer reviewed her medical history, discovered the earlier medication, and rescinded her policy under a contract provision that permits rescission for material misrepresentations retroactive to the date the policy was issued. Was the rescission legal? What are Joan's remedies? If the same thing had happened in 2014, would it be legal?

2. George McNamara purchased an insurance policy in 2014. The policy covers pharmaceuticals but does not cover a particular drug that he is taking for his asthma. Must the plan do so? It also does not cover physical therapy, which he has been prescribed because of a recent injury. Must the plan cover physical therapy, and can it limit the number of visits to which George is entitled?

3. Valley Products has covered all of its employees with health insurance since the year 2000. Since 2010 it has increased its deductibles three times, but each time the increase did not exceed the percentage in growth in the medical care component of the Consumer Price Index since the last increase. Must the plan comply with the ACA's internal and external review requirements?

NOTES

1. Whether and to what extent external review will be subject to judicial review is an open question. Section 2719(b)(1) provides that the external review must be binding on the health plan. The federal guidance further provides, "Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final internal adverse benefit determi-

nation, the plan immediately must provide coverage or payment (including immediately authorizing or immediately paying benefits) for the claim." It would seem, therefore, that the external review decision is effectively a final decision. The federal regulation implementing the provision, however, states that the decision of an external reviewer "is binding on the plan or issuer, as well as the claimant, except to the extent other remedies are available under State or Federal law." Moreover, the ACA does not amend Section 502 of ERISA (29 U.S.C. § 1332), which allows ERISA plan beneficiaries a federal cause of action for benefits due to them under an ERISA plan. The scope of review of federal courts reviewing decisions of health plans (or of external reviewers) is not, therefore, wholly clear.

A number of states have adopted external review laws that make the decisions of an external reviewer binding on the insurer or both the insurer and enrollee. See William Pitsenberger, "SezWho?" State Constitutional Concerns with External Review Laws and the Resulting Conundrum Posed by Ruth Prudential HMO v. Moran, 15 Conn. Ins. L. J. 85, 94–99 (2008). There are few reported cases addressing the question of whether "binding" external review decisions are reviewable. A series of New York cases, interpreting the New York statute, which provides that the external review decision shall "be binding on the plan and the insured," but also provides that the decision "shall be admissible in any court proceeding," have held this to mean that the external review is the final step of the administrative process but is also reviewable by a court. Schulman v. Group Health Inc., 833 N.Y.S.2d 62 (N.Y. App. Div. 2007); Vellios v. IPRO, 765 N.Y.S.2d 222 (N.Y. Sup. Ct. 2003).

No reported case has simply held an external review decision to be final, binding, and unreviewable. In *Rush Prudential HMO v. Moran*, 536 U.S. 355 (2002), (see below) the Supreme Court characterized external review as a "second opinion." In his dissent, however, Justice Thomas correctly characterized external review as essentially compulsory arbitration. The ACA does not set out the parameters of judicial review of external review decisions, unlike other laws that require or permit arbitration. Judicial review of statutory-based arbitration is usually limited to very narrow grounds, such as whether the award was in "manifest disregard of the law" or "exceeded the power of the arbitrator." See Peter Hoffman & Lindsee Gendro, Judicial Review of Arbitration Awards after Cable Connection: Towards a Due Process Model, 17 UCLA Ent. L. Rev. 1, 16 (2010). This could be the approach courts will take in reviewing ACA administrative decisions, but they may review decisions more broadly. Serious constitutional questions would be raised, however, if an external review decision were in fact totally unreviewable. See Pitsenberger, *supra*, at 103–112; Jean R. Sternlight, Rethinking the Constitutionality of the Supreme Court's Preference for Binding Arbitration: A Fresh Assessment of Jury Trial, Separation of Powers, and Due Process Concerns, 72 Tul. L. Rev. 1 (1997). It seems most likely that courts will review external review decisions applying the deferential "arbitrary and capricious" standard commonly applied currently in ERISA cases (see below). Federal courts will review ERISA plan decisions under 29 U.S.C. § 1132, state courts will review

non-ERISA plan decisions under special state statutes, state administrative procedure laws, or possibly the common law. In the vast majority of cases, however, the external review decisions will not be appealed and will, as a practical matter, have the final say; external review will in fact be binding.

2. In early 2011, HHS issued a regulation recognizing a new category of health insurance plans: student health plans. Student health plans are health insurance plans that are only available to college and university students. They are regulated like individual insurance coverage except that they are not subject to some of the regulatory provisions of the ACA. Student health plans, for example, do not need to admit all applicants, only students. They also can have annual limits as low as $500,000 for policy years beginning before 2014, can charge an administrative fee for the use of the student health services, and are only subject to a medical loss ratio of 70% for 2013. Finally, student health plans at religious universities are subject to the same rules regarding contraception coverage that apply to employees at those institutions. See Final Rule on Student Health Insurance Coverage. Otherwise, however, they must comply with the ACA.

D. DISCLOSURE REQUIREMENTS: SECTIONS 1001, 1002, 1311

The ACA imposes a number of requirements on health plans to increase the information available to plan enrollees or prospective enrollees. Disclosure enhances consumer control by allowing consumers to identify and choose plans with the features that they desire and avoid plans with characteristics they wish to avoid. Disclosure increases competition—reducing price and improving quality—by identifying differences in price and quality and focusing consumer choice on these differences. It also can improve performance by making poor performance more visible and thus more costly.

The ACA provides both for channels through which information must be made available and for specific types of information that must be disclosed. HHS has established a website, healthcare.gov, through which the residents of any state can identify health insurance coverage options that are available to them, including private insurance, Medicaid, CHIP, a state high-risk pool, or the pre-existing condition risk pool established by the statute. The website also identifies sources of employer coverage, including the reinsurance for early retiree and small business tax credit programs. HHS has developed a standard format for presenting information on this website, including information on eligibility, availability, premium rates, cost-sharing, and medical loss ratios.

HHS has also, pursuant to Section 2715 of the PHSA, added by Section 1001 of the ACA, developed standards for disclosure of benefits and coverage to applicants, enrollees, and policy or certificate-holders by insurers and self-insured plans. These were developed in conjunction with a

stakeholder committee appointed by the NAIC. The HHS standards preempt state laws that allow plans to provide less information. The HHS standards provide a uniform format for plans to use that is no longer than 4 pages (double-sided, in fact 8 pages) and with type no smaller than 12–point. The form is intended to use culturally and linguistically appropriate, readily understandable language. HHS has also developed uniform definitions of insurance and medical terms to use in the forms. All plans must use these forms for plan years beginning after September 23, 2012.

The forms include a description of coverage for all categories of health benefits, including a description of exceptions, reductions and limitations on coverage; cost-sharing provisions; and renewability provisions. The coverage descriptions also must include "coverage facts labels" which illustrate coverage and cost sharing requirements for common benefits scenarios, including initially a normal delivery and type II diabetes. For example, a coverage fact label could say that if you have diabetes, you can expect coverage for the following listed products and services with cost-sharing obligations as described. The form also sets forth an amount the insurer is likely to pay and an amount the patient is likely to pay. Plans are required to disclose whether they cover at least 60 percent of allowed costs. This is important because if any employer plan fails to do so, the employee may be able to get a premium tax credit and purchase insurance through the exchange. Finally, a plan must provide a contact number for consumers to call with additional questions and a web address where a copy of the actual policy or certificate can be found. Notice of any modifications in benefits must be provided 60 days prior to the effective date.

The exchange provisions of the Act, described in the next section, require QHPs to disclose in plain language information on claims payment policies, financial data, enrollment and disenrollment data, data on claims denials and rating practices, information on cost-sharing relevant to out-of-network coverage, and information on enrollee and participant rights. QHPs must also provide information on cost-sharing for specific services in a timely manner on request through an internet website and otherwise for individuals without internet access. Non-exchange plans, including self-insured plans, must provide this same information to HHS and to state insurance commissioners, who shall in turn disclose the information to the public. Plans must also, as noted above, provide to insurance commissioners and to the public justification for unreasonable premium increases.

HHS is required to develop reporting requirements for use by group health plans and health insurers to report information related to improving health outcomes, preventing hospital readmissions, improving patient safety, and promoting wellness but has not yet done so. Group health plans and health insurance issuers must report annually information re-

garding their conformity with these requirements to HHS, their enrollees, and the public.

Section 1002 authorizes federal grants to the states to establish and support independent offices of health insurance consumer assistance or health insurance ombudsman programs. These offices are supposed to assist consumers in filing complaints and appeals; collect, track, and quantify information on consumer problems and inquiries; educate insurance consumers on their rights and responsibilities; assist consumers in enrolling in health plans; and resolve problems with obtaining premium tax credits. The consumer assistance offices are supposed to collect and report data on consumer problems to HHS. Thirty-five states received the first round of grants in 2010, totaling $30 million..

Finally, although most of the disclosure provisions of the ACA apply to health plans, Section 2718 requires hospitals to establish, update, and publish their standard charges for items and services. To a considerable degree, insurers merely pass on costs that they incur to health care providers, so if transparency is to play a role in bringing down costs, we will need provider cost transparency as well.

NOTES AND QUESTIONS

1. What is the legal effect of the disclosure document created by Section 2715? The document is supposed to use language that "accurately describes the benefits and coverage under the applicable plan or coverage" but also must also include "a statement that the outline is a summary of the policy or certificate and that the coverage document itself should be consulted to determine the governing contractual provisions." The disclosure document is intended for comparison-shopping and it would be of little value for this purpose if it has no binding legal effect. On the other hand, it is likely that there will be provisions found in insurance contracts that are not in the four-page disclosure document.

2. Another question that has arisen with respect to the Section 2715 document is who is entitled to see it. Section 2715 provides that the information should be provided to "applicants, enrollees, and policyholders or certificate holders," but the document will be useless for comparison-shopping purposes unless it is also available to prospective applicants as well. The HHS rule requires insurers to provide the 2715 information to "shoppers," but they may do so through the healthcare.gov website rather than mailing individual copies. Insurers are permitted to disclose the 2715 document electronically as long as consumers have notice that this is how it is being provided.

E. CONSUMER CHOICES AND INSURANCE COMPETITION THROUGH HEALTH BENEFIT EXCHANGES: SECTIONS 1301, 1311, 1312, 1313, 1321

At the heart of the health care reforms is the concept of the health insurance exchange. An exchange is a consumer-friendly market for health insurance, resembling a farmer's market, stock market, or online travel service. It will be a place where consumers can go, browse through the range of available insurance options, and choose the insurance plan that is best for themselves and their families. Small business health options (SHOP) exchanges will offer the same opportunities to small businesses. Given the range of understandable and transparent information that consumers will have available under the provisions just examined, they should be able to make intelligent choices.

But exchanges will also play a regulatory role, as described below. The extent to which exchanges become, on the one hand, passive markets for displaying the wares of insurers, or, on the other, take responsibility for ensuring that their customers actually receive quality health insurance products, remains to be seen.

Under Section 1311, states are responsible for establishing an exchange for the nongroup market and a SHOP exchange by January 1, 2014. A state can choose to combine the two exchanges. Exchanges may operate regionally if all participating states and HHS approve of a regional approach. States may also operate subsidiary exchanges that serve geographically distinct areas. Exchanges may be governmental or nonprofit entities. One of the most contentious issues that has arisen as states establish exchanges is who should have a seat on the exchange governing board, and in particular whether insurers or agents and brokers or others with a conflict of interest can serve on the governing board. HHS has determined that boards must contain at least one consumer representative and a majority of members must not have a conflict of interest, but insurers, agents and brokers, and others with conflicted interests are allowed to serve on the board and participate in board business where they are not conflicted.

Exchanges may contract with the state Medicaid agency or with "eligible entities" that have relevant experience but are not health insurers to carry out certain exchange functions. The federal government is providing the states with grants and technical assistance between 2011 and 2015 to establish the exchanges. After January 1, 2015, exchanges must be self-sustaining through charging assessments or user fees to health insurers or consumers, or though raising revenue in some other way.

The exchanges may only offer QHPs (and dental plans that offer pediatric benefits). Exchanges are responsible for:

- certifying, recertifying, and decertifying health plans;
- operating a toll-free consumer hotline;
- maintaining an internet website providing standardized comparative information on QHPs;
- providing for annual open enrollment periods and for special enrolment periods under certain circumstances;
- rating plans, using a standardized format for providing health benefit information;
- assisting individuals in applying for Medicaid, CHIP, or other government programs;
- making available a calculator to assist individuals to determine the cost of coverage after the application of premium and cost-sharing subsidies;
- certifying individuals as exempt from the individual mandate;
- providing the IRS with a list of persons who are exempt from the mandate and of employers whose employees are receiving premium tax credits and of employers who have failed to provide affordable minimum essential coverage; and
- establishing a Navigator program.

Navigators will be trade, industry, professional, consumer, employer, or labor organizations with which exchanges contract to conduct public education, distribute information, and help individuals to enroll in QHPs and to apply for premium credits and cost-sharing reduction payments. They can also refer enrollees to resources for the processing of grievances, complaints, and inquires. Navigators cannot be insurers or receive consideration from insurers for enrollment.

The extent to which navigators must or should be licensed brokers or agents has become one of the most contentious issues at the state level, as agents and brokers have tried to protect their traditional role in selling insurance while consumer advocacy groups have pushed for the creation of navigator programs that would reach out to currently underserved groups to provide education and information about insurance and public programs. It is likely that agents and brokers will serve as navigators in many states, but the exchange final rules provide that exchanges must provide at least two kinds of navigators, and one must be a consumer organization. States cannot require navigators to have agent or broker licenses.

Under Section 1321, HHS has issued regulations establishing standards for the establishment and operation of exchanges, including SHOP exchanges, and for the offering of QHPs through the exchanges. As noted above, each state that chooses to set up an exchange itself and apply these standards must have in place not later than January 1, 2014 either the federal standards or a state law that HHS determines will implement the

federal standards. If a state elects not to implement the standards or HHS determines, on or before January 1, 2013, that an electing state will not have an operating exchange in place by January 1, 2014 or will not implement the ACA and standards promulgated under it, then HHS must on its own establish an exchange within that state or do so through a nonprofit organization. As of this writing, it appears that no more than 17 states and the District of Columbia could be ready to run an exchange by 2014. The federal government is planning, therefore, to establish "federally facilitated" exchanges in all other states. The federal government is planning to partner with states that wish to work with it, with the federal government performing some functions and the state government others in "partnership exchanges."

The exchanges may only offer QHPs. The standards that QHPs must meet are established in the exchange final rule. QHPs will not be permitted to employ marketing practices or benefit designs that discourage enrollment by persons with significant health needs. They will be required to:

- ensure network adequacy and information;
- include essential community providers, where available, to serve low income, medically underserved individuals;
- be accredited by an entity recognized by HHS;
- implement a quality improvement strategy;
- utilize a uniform enrollment form and the standard format developed for presenting health benefits options;
- provide information on cost-sharing for specific services in a timely manner on request through an internet website and otherwise for individuals without internet access;
- provide information in plain language; and
- provide information on health plan quality performance.

Quality improvement strategies include activities to improve health outcomes and prevent hospital readmissions, patient safety and error reduction activities, prevention and wellness activities, and activities to reduce health and health care disparities. After January 1, 2015, QHPs may only contract with 1) hospitals with more than 50 beds if those hospitals have patient safety evaluation programs and mechanisms to assure appropriate discharge planning, and 2) with providers that have implemented required quality improvement programs.

The ACA requires HHS to develop a system for rating plans based on quality and price. Exchanges must rate plans using this system. HHS is also required to develop an enrollee satisfaction survey system. The exchanges must post information that will allow enrollees to compare satisfaction levels among plans. The mental health parity law applies to QHPs.

One of the major debates surrounding exchanges involves whether they should become "active purchasers," trying to influence the insurance market through selective purchasing or negotiating with insurers, or whether they should simply accept any insurer willing to meet minimum standards. An exchange may only certify a qualified health plan (QHP) for participation in the exchange if the QHP meets certification requirements and if "the Exchange determines that making available such health plan through such Exchange is in the interests of qualified individuals and qualified employers in the State or States in which such Exchange operates," so to that extent they cannot be completely passive. On the other hand, an exchange may not exclude a QHP because it is a fee-for-service plan or because the plan provides treatments for preventing patients' deaths that the exchange deems too costly. HHS has announced that the federally facilitated exchange will not be an active purchaser, at least not for the first year.

Exchanges are prohibited from imposing premium price controls. The exchange must require plans to justify premium increases before implementing them and must take information regarding premium increases into account before certifying a plan. Health plans seeking certification must disclose information on claims payment policies, financial data, enrollment and disenrollment data, data on claim denials and rating practices, information on cost-sharing relevant to out-of-network coverage, and information on enrollee and participant rights.

One potentially valuable role of an exchange is to standardize the plans available in the exchange to simplify consumer choice. See, on standardization, Troy Oechsner and Magda Schaler–Haynes, Keeping it Simple: Health Plan Benefit Standardization and Regulatory Choice Under the Affordable Care Act, 74 Albany L. Rev. 241 (2010–2011). See on how exchanges can assist people without web access, Brendan S. Maher, Some Thoughts on Health Care Exchanges: Choice, Defaults, and the Unconnected, 44 Conn. L. Rev. 1099 (2012).

F. CONSUMER CHOICE: SECTIONS 1312, 1322, 1334

Section 1312 specifies that qualified individuals may enroll through the exchange in any QHP. A qualified individual is a resident of a state who is not otherwise insured through employment or a public program and who is neither incarcerated (other than pending the disposition of charges) nor an alien who is illegally in the United States. Qualified employers may offer their employees insurance through the exchange and may specify the level of coverage to be made available to their employees. A qualified employer is a small employer that covers all of its full-time employees through the exchange, or, beginning in 2017 at a state's option, larger employers. Although the ACA defines small employer as having

100 or fewer employees, states can elect to limit small employers to those with 50 or fewer employees until 2016, and most probably will.

Under the statute, employees may choose any QHP offered through the exchange within the tier specified by their employer. The final rules also allow employers to pick a particular plan for their employees or to allow employees wider choice, among plans in multiple tiers for example. Exchanges must aggregate premiums for employers and present the employer with a single bill, so that employers will not have to pay multiple bills to multiple insurers. For 2014, federally facilitated exchanges will not provide employee choice or premium aggregation. Employers will only be able to pick a single plan for their employees. The FFE is expected to offer employee choice in future years.

One strategy that employers who purchase insurance for their employees through the SHOP exchange are likely to pursue is a "defined contribution" approach—the employer will pay an amount sufficient to cover a share of the cost of a lower-cost plan and the employee must pay extra if the employee wants a higher cost plan. How this will work legally depends on how premiums are set for health plans in a SHOP exchange. The Age Discrimination in Employment Act regulations prohibit employers with 20 or more employees from paying a lower proportion of the cost of health benefits for older employees (aged 40 or older) than for younger employees. 29 C.F.R. § 1625.10(d)(4)(ii). An employer subject to the ADEA could not, therefore, pay a flat dollar amount if it meant older employees would need to pay a higher proportion of their premiums. An employer could, however, pay a fixed percentage of premiums, or pick a particular plan and require employees to pay the additional cost of a more expensive plan.

Insurers can offer policies outside of the exchange and individuals and employers may purchase insurance policies outside of the exchange. The only people in the United States who must enroll in QHPs through the exchange are members of Congress and their staffs. QHPs may not penalize enrollees who cancel their enrollment because they have become eligible for coverage through their employer or a public program. States must allow agents and brokers to assist individuals and employers to enroll in plans and apply for premium tax credits and cost-sharing reductions. The exchange final rules specify that web-based brokers can assist in the exchange enrollment process, although they are not permitted to determine eligibility for premium tax credits or actually enroll exchange participants in plans.

Although insurers may sell policies both through the exchange and outside of the exchange, they must consider all enrollees in all health plans (except grandfathered plans) in the individual market, in and outside of the exchange, to be a single risk pool. The same is true with respect to the small group market. A state may require the merger of the

individual and small group risk pools. Policies sold outside of the exchange to individuals and small groups must offer the essential benefits package. They also must charge the same premium for QHPs purchased in and outside of the exchange. State benefit requirements continue to apply outside of the exchange. Insurers will undoubtedly find ways to steer good risks outside of the exchange, but the legislation is intended to minimize this. One way in which insurers may risk select is through offering stop-loss insurance to self-insured plans outside of the exchange. Many of the requirements of the ACA, including the essential health benefits package, metal tiers, the risk pooling and risk adjustment programs, medical loss ratio requirements, unreasonable premium increase justification requirement, and premium tax do not apply to self-insured plans. Self-insured plans are now common in the large group market, but are becoming more common in the small group market. Small employers can rarely bear the risk of catastrophic medical costs, but insurers are increasingly selling "stop-loss" insurance to small employers, effectively insuring them for significant medical costs but allowing the employer to claim to be self-insured. This strategy could destabilize the small group market both in and outside of the exchange. Mark A. Hall, Regulating Stop–Loss Coverage May be Needed to Deter Self–Insuring Small Employers from Undermining Market Reforms, 31 Health Aff. 316 (2012); Timothy Stoltzfus Jost, Loopholes in the Affordable Care Act: Regulatory Gaps and Border Crossing Techniques and How to Address Them, 5 St. Louis U. J. Health L. & Pol'y 27 (2011). See, also on self-insured plan, Robert W. Miller, The Effects of the Health Reform of Self–Insured Employer Plans, 4 J. Health & Life Sci L. 59 (2010).

The ACA provides several other options to increase consumer choice and competition, although most of the insurance plans sold within the exchange are expected to be offered by private insurers that otherwise operate within the state of the exchange. First, Section 1322 provides federal grants and loans to encourage the creation of nonprofit, member-owned consumer insurance cooperatives governed by majority vote. These entities cannot be government entities or pre-existing insurance companies. They will be tax-exempt, but are also subject to a number of requirements to make sure that they do not compete unfairly with private insurers. A number of cooperative plans have received federal funding and are now in the planning stage. Second, states may, under Section 1333, after January 1, 2016, enter into interstate compacts under which insurance plans may be offered in one state subject to the laws and regulations of another. Although the interstate insurer will basically be regulated by its home state, it will remain subject to the market conduct, unfair trade practices, network adequacy, consumer protection, and dispute resolution standards of any state in which the insurance was sold. It will also have to be licensed in each state, and notify consumers that it was

not otherwise subject to the laws of the selling state. HHS will have to approve interstate insurance compacts.

Finally, Section 1334 of the law authorizes the Office of Personnel Management to enter into contracts with multi-state insurance plans for insurers to offer individual or small group coverage through the exchanges. Plans that have contracts with OPM will be deemed to be certified to participate in the exchanges. At least two plans must be available in each state, at least one of which must be a non-profit. OPM may negotiate with the plans a medical loss ratio, profit margin, premium levels, and other terms and conditions that are in the interests of the enrollees. Multi-state plans must be licensed and comply with the requirements of each state in which they do business and with all standards that apply to the Federal Employees Health Benefit Plan that are not inconsistent with the reform law. Although multi-state plans are administered by the OPM, which also administers the FEHBP, FEHBP plans are not required to participate in the multi-state insurance program and the two programs will be administered separately. See, on multi-state plans, Sidney Watson, Yolanda Campbell, Timothy McBride, Creating Multi–State Qualified Health Plans in Health Insurance Exchanges: Lessons for Rural and Urban America From the Federal Employees Health Benefit Program, 6 St. Louis U. J. Health L. and Pol'y 103 (2011).

G. STATE FLEXIBILITY: SECTIONS 1331, 1332

Finally, two provisions of the ACA give states additional flexibility in implementing health reform. First, Section 1331 allows states to establish a basic health care program under which the state can offer one or more standard health plans that cover the essential health benefits to individuals who have (1) household incomes between 133 percent and 200 percent of poverty (or up to 133 percent for legal aliens), (2) are not eligible for Medicaid or affordable employment-related coverage, and (3) are under age 65. Standard plans are private insurance plans that contract with the state and meet a number of requirements. Individuals eligible for the program must not be required to pay a premium higher than they would have paid if enrolled in the second-lowest-cost silver plan in the exchange after the application of premium tax credits and cost-sharing reductions, or to pay cost-sharing in excess of what they would have had to pay for a platinum plan through the exchange if the individual has a household income of less than 133 percent of poverty and for a gold plan otherwise. HHS is required to pay a state that operates a basic health program 95 percent of the amount of the premium tax credits and cost-sharing reductions that enrolled individuals would have been eligible for if they had received health insurance through the exchange. A person eligible for coverage under the basic health program will not be able to purchase insurance through the exchange. HHS has indicated that it is delaying implementation of the Basic Health Plan until 2015. In the interim, it will

work with states to find ways to address the needs of households with incomes between 133 percent and 200 percent of poverty, who are expected to move frequently between the Medicaid and premium tax credit population.

Second, under Section 1332 a state may, effective January 1, 2017, apply to HHS for a waiver of the requirements in the ACA for

- exchanges,
- qualified health plans,
- premium affordability credits,
- cost-sharing reduction payments,
- small employer tax credits, and
- individual and employer responsibility,

if the state comes up with a proposal that HHS determines would provide coverage at least as comprehensive as the coverage that would be offered by QHPs through the exchange with at least as affordable premiums and cost-sharing to at least a comparable number of the state's residents and without increasing the federal deficit. Waiver requests are subject to a number of procedural requirements to ensure public input and may last for a period of up to five years. HHS is required to pay to the state an amount equivalent to what the residents of the state would have received through premium tax credits, cost sharing reductions, and small business tax credits.

This provision would presumably allow a state to establish a single payer or consumer-driven system if it could otherwise meet the requirements. Vermont has adopted legislation to allow it to establish a "single payer" system in 2017. The effective date of this provision was delayed to give time to determine how much the federal government spent per state in tax credits before allocating these credits to the states, but imposes on the states the burden of first complying with the ACA by 2014, and then implementing a completely different program in 2017. Legislation has been introduced into Congress that would accelerate the effective date of this provision to 2014 so that states do not have to implement the exchange system first and then change to a state-specific system. As of this writing it is not moving, though.

VII. THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974: ERISA

Although regulation of health insurance has traditionally been the responsibility of the states, the ACA is not the first foray of Congress into regulating private health insurance. Since the 1970s, a series of federal laws have been enacted regulating private health insurance. The most important of these is the Employee Retirement Income Security Act of