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Section Co-Chairs' Corner

Greetings to all in the Health Law Section. We hope you are having a wonderful, invigorating summer and that you will hit the month of September with renewed energy, and, of course, a renewed commitment to making the Health Law Section even better than it was during the year that ended in June.

As we all know, last year was an exciting one for those of us who have chosen health care as our field of concentration. After many twists and turns, Congress finally did pass a federal health care reform bill. Closer to home, Massachusetts grappled mightily (in the legislature, several state agencies, and even the courts) with the complicated and contentious issues surrounding payment and insurance reform. Those issues will continue to be at the forefront of our (and the legislature's and various state agencies') consciousness in the days (and years) to come.

Sadly, last year also marked the passing of one of the great champions of health care reform—and our own senior Senator—Ted Kennedy.

As we have done in the past, the Health Law Section worked hard and successfully to keep our constituents abreast of the many changes in our industry as they occurred. We sponsored numerous CLE programs, including one on Federal Health Care Reform and one on Massachusetts Payment Reform; we held Brown Bag Programs, we hosted special membership events, and, of course, we published our Health Law Reporter.

We are excited and pleased to kick off this new “Bar Association Year” with our “2010 summer edition” of the Health Law Reporter. The focus of this issue is two-fold: Federal Health Care Reform, and Senator Kennedy. Chris Hager has written a tribute to our senior Senator; and Clare McGorrian (Consumer Protections), Tom Barker and Maia Larsson (Pharmaceuticals and Biologics), Josh Greenburg (Children's Health), Sara Hanson (Controversy Surrounding Abortion Coverage Issues), and Ari Gottlieb (Constitutional Challenges) have all contributed articles that will address the new federal health reform law.

We want to thank our authors for their wonderful and selfless contributions to this issue; we want to thank our peer reviewers; and we want to thank Mark Rogers, who will continue in his role this year as Co-Chair of the Health Law Section's Communications Committee (which oversees the production of the newsletter), Katie Annas, our out-going Committee Co-Chair, and Julia Hesse, our incoming Committee Co-Chair.

As we start this new year, we invite all of you to participate in one or more of the Health Law Section's committees (CLE, Communications, Membership, Legislative Update, Social Action), to volunteer as a speaker at one of our CLE programs or Brown Bags, and/or to contribute ideas for new programs, events or approaches to making our Section better.

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Inside this Issue

The Cause of a Life and the Character of a Country

Page 4

Key Impacts on Individuals of the Federal Health Reforms of 2010

Page 5

Implementing Health Care Reform: Key Provisions Affecting the
Pharmaceutical Industry

Page 9

Children's Health and the Patient Protection and Affordable Care Act

Page 13

"A Fair Compromise": Abortion Policy under the Patient Protection and
Affordable Care Act

Page 16

Constitutional Challenges to the Patient Protection and Affordable Care Act

Page 20

Editors

Page 25

Contributors

Page 26

Section Leadership

Page 28

The Cause of a Life and the Character of a Country

by Christie L. Hager, Esq.

In a letter to President Barack Obama, dated May 12, 2009, three months before his death and nearly one year before the enactment of health reform as law of the land, Senator Ted Kennedy referred to health reform as “the cause of [his] life.”¹

When the Patient Protection and Affordable Care Act (PPACA) was signed into law by President Obama nearly one year later, we who had been inspired by Senator Kennedy inherited this cause from him. Health reform for all Americans, designed to ensure that health insurance is available to protect you when you’re in need of care, to make health care more affordable, and to make health insurers more accountable in a sustainable health care system is law of the land. It is no longer “the great unfinished business of our society” that it was during Senator Kennedy’s lifetime, but rather a great and positive change for the lives of all Americans.

In 2006, as the Massachusetts Legislature struggled with the challenge of expanding access to health coverage for nearly all of its residents, Senator Kennedy addressed the General Court in Full Formal Session. On March 22, 2006, in the Chamber of the House of Representatives, he called health reform a “defining issue for our time.” His presence and passion reflected the gravitas of the votes before them. He spoke before a strikingly silent chamber, filled with an audience of House

members and staffers who grew up in his tradition of public service and social justice. As he recalled his personal trials with specialty medical care during the illnesses of his children, and the blessings of his parents who lived to old age, his powerful prose and solemn tone summoned the members to the courage needed at that moment in history, for the residents of the Commonwealth that had meant so much to him and to his family. After months of negotiating with the Centers for Medicare and Medicaid Services (CMS) to secure the necessary funding and foundation for expansive and innovative reform in the Commonwealth, he was at the State House that day to encourage Legislative leaders to strike the compromise needed to bring the health reform bill to a floor vote. His visit that day was portentous of his upcoming role in the development of health reform in Congress.

He was a treasure of Massachusetts, and a treasure of the nation, as it sought to provide health and human service benefits to its most vulnerable residents. He was, for generations, the champion of the fundamental principles of social justice. For, after all, making affordable health insurance available to all Americans relies upon the “character of our country” as reflected in the political will of our elected officials and the commitment of those who work every day to ensure that individuals who now have access to health coverage actually will be able to use it.

As he worked with individuals and groups to secure health and human services for them, regardless of ability to pay, Senator Kennedy inspired generations of professionals, and particularly public servants, committed to a government that provides for the basic support of its people. Just a piece of his legacy that is woven throughout health reform includes alumni of his staff, now working to implement this historic agenda, at the U.S. Department of Health and Human Services. Those former staffers include Dr. David Blumenthal, National Coordinator for Health Information Technology; Mark Childress, Principal Deputy General Counsel; Paul Dioguardi, Director of Intergovernmental Affairs; Dora Hughes, Counselor to the Secretary for Public Health and Science; Caya Lewis, Chief of Staff to the Administrator of CMS; and, Keith Maley, Press Secretary.

While the “details of policy,” to which Senator Kennedy referred in his letter, are the focus as PPACA takes shape, the fundamental principles of social justice that guided Senator Kennedy’s work now will guide ours.

The views expressed herein are the author’s, and not necessarily those of the U.S. Department of Health and Human Services.

Endnote

¹ Except where otherwise noted, all quotes in this article are from the text of the letter from Sen. Kennedy to President Obama, dated May 12, 2009, available at http://www.whitehouse.gov/the_press_office/Text-of-letter-to-the-President-from-Senator-Edward-M-Kennedy/.

Key Impacts on Individuals of the Federal Health Reforms of 2010

by **Clare D. McGorrian, Esq.**

The Patient Protection and Affordable Care Act¹ as amended by the Health Care and Education Reconciliation Act of 2010² - together, the “Federal Health Reform Act” - will have a direct and significant impact on individual health care consumers. Among the most notable consumer-directed aspects of the law are a requirement that everyone have health coverage, financial assistance to lower-income Americans for the purchase of health insurance and significant changes in permissible insurance practices. Because Massachusetts’ health reform experiment has been underway since 2006, the impact may be felt less acutely in the Commonwealth than elsewhere. This article aims to give an overview of *select* key aspects of the law that affect individual health care consumers.

The individual insurance mandate

Perhaps the most controversial provision of the Federal Health Reform Act is the requirement that every American have health insurance coverage. Twenty state attorneys general have sued the Department of Health and Human Services (HHS) on the grounds that the requirement is unconstitutional.³ The following are specifics of the mandate, which is codified in new Internal Revenue Code section § 5000A.

The insurance requirement takes effect in tax year 2014 and requires that citizens and legal residents obtain and maintain “minimum essential” health coverage.⁴ During 2014, individuals who do not have qualifying coverage and are not exempt from the requirement will pay an excise tax.⁵ Individuals with income below the tax filing threshold and those for whom available coverage would cost more than 8% of their income will be exempt from the tax.⁶ A religious conscience exemption is also available.⁷

The tax will be phased in over three years, for adults (over 18 years) starting at \$95 annually in 2014 and rising to \$695 annually in 2016.⁸ The penalty amount will be indexed for inflation after 2016.⁹ If the resulting tax is greater than the flat dollar amounts noted, the tax will be pegged to income, rising from 1.0% in 2014 to 2.5% for 2016 and thereafter.¹⁰ The total household penalty may not exceed three times the single adult penalty, regardless of household size.¹¹

State health insurance exchanges

The Federal Health Reform Act provides funds to the states to establish “health benefit exchanges” (“Exchanges”) through which individuals and employers with up to 100 employees may

purchase health insurance beginning in 2014.¹² An Exchange shall be a governmental agency or nonprofit entity that is established by a State.¹³ A qualified health plan offered by a state Exchange must cover the following “essential” benefits: ambulatory services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services, chronic disease management and pediatric services, including oral and vision care.¹⁴ The Exchanges will also offer catastrophic coverage plans to adults up to 30 years old and those exempt from the insurance mandate.¹⁵ All Exchange plans must be guaranteed issue and guaranteed renewable.¹⁶ Premiums for Exchange plans may be based only on age, family size, benefit level and tobacco use.¹⁷

As a result of the state health reform law, Massachusetts has already established a health benefit Exchange, the Commonwealth Health Insurance Connector Authority (“Connector”).¹⁸ The Exchange plans described in the Federal Health Reform Act are similar to the Commonwealth Choice plans offered by the Connector. The Connector is expected to operate as the federally recognized Exchange in Massachusetts.

Financial assistance with health coverage costs

Effective in 2014, under new Internal Revenue Code section § 36B, individuals “lawfully present” in the United States who purchase a plan through a state Exchange may qualify for financial assistance in the form of premium tax credits and cost-sharing subsidies.¹⁹ To be eligible, household income must be less than or equal to 400% of the Federal Poverty Level (FPL).²⁰

The premium credit amount is determined by the percentage of income premium costs may represent at different income levels, from 2% of income for individuals at 100% of FPL to 9.5% of income for individuals at 400% of FPL.²¹ An individual whose employer (or whose spouse’s employer) offers insurance is not eligible for financial help unless the employer plan subsidizes less than 60% of the total allowed cost of benefits or if the employee portion of the premium equals more than 9.5% of household income.²² Cost-sharing reductions are achieved primarily by lowering the permissible out-of-pocket limit: by two-thirds for individuals with income 100-200% of FPL; by one-half for individuals with income 200-300% of FPL; and by one-third for individuals with income 300-400% of FPL.²³

Changes in permissible insurance practices

As a result of the Federal Health Reform Act, group health plans and health insurance issuers offering group and individual insurance coverage must make significant changes in the way they do business. Massachu-

setts insurance carriers may feel the changes less acutely due to a longstanding requirement of guaranteed issue coverage in the individual market and the impact of the 2006 state health reform law.²⁴

Major changes to be implemented by September 23, 2010 (January 1, 2011 for calendar-year plans), include: 1) elimination of pre-existing condition exclusions for children under 19 years of age; 2) elimination of *lifetime* limits on the dollar value of “essential” health benefits; 3) prohibition of rescission of coverage for enrolled individuals, except in the case of fraud; 4) group health plan eligibility for adult children until age 26; and 5) prohibition of waiting periods longer than 90 days.²⁵ Significant changes to take effect in 2014 include, but are not limited to, the elimination of pre-existing condition exclusions for adults and prohibition of *annual* limits on the dollar value of “essential” health benefits.²⁶ Interim final regulations were recently issued by HHS, the Department of Labor and the Internal Revenue Service, addressing some of these consumer protections.²⁷

The foregoing provisions apply to “grandfathered” plans, with minor differences.²⁸ Grandfathered health insurance coverage means coverage provided by a group health plan or health insurance issuer in which an individual was enrolled on March 23, 2010.²⁹ However, grandfathered plans are exempt from many provisions of federal health reform, including but not limited to coverage of preventive services without cost-sharing, limits on cost sharing and

mandated coverage of clinical trials.³⁰

Below are additional details about important changes to health plan practices made by the Federal Health Reform Act, including the elimination of pre-existing condition exclusions, extension of coverage for adult children, and consumer-directed changes to the federal tax code.

Elimination of pre-existing condition exclusions

Group health plans and health insurance issuers may not impose any pre-existing condition exclusion on children beginning September 23, 2010 (January 1, 2011 for calendar year plans), and for adults as of January 1, 2014.³¹ The Act authorizes funding for the establishment and operation of state temporary high risk pools for uninsured adults with pre-existing conditions.³² To qualify a person must have been without insurance (creditable coverage) for at least six months before enrolling in the pool plan.³³ The high risk pools will be phased out December 31, 2013 when the prohibition of pre-existing condition exclusions for adults takes effect.³⁴ Because of state health insurance reform, Massachusetts does not have a high risk pool and will create and administer other programs with federal funding.³⁵

Extension of coverage to adult children until age 26

The Act requires plans and issuers that offer dependent coverage to make such coverage available until an adult child reaches the age of 26.³⁶ This requirement applies to individual plans, new employer group plans

and grandfathered plans.³⁷ Massachusetts requires coverage of young adults on their parents' policies until *the earlier of* age 26 or two years after the child ceases to be a dependent pursuant to section 106 of the Internal Revenue Code.³⁸ Since federal law is more protective of the individual, the federal provision supersedes existing state law.³⁹ Regulations and guidance have been issued interpreting the dependent coverage provisions.⁴⁰

Plans and issuers must give eligible children a 30-day window to enroll.⁴¹ In addition, group health plans must provide children who had not previously enrolled because of ineligibility based on age an opportunity to enroll as of the first day of the first plan year beginning on or after September 23, 2010.⁴² Children under 26 who qualify for this special enrollment opportunity and are covered under COBRA must be provided the opportunity to enroll under the new law instead.⁴³

Under the Federal Health Reform Act, beginning in April 2010 the value of the child's coverage is not treated as taxable income as long as the child has not reached 27 during the calendar year.⁴⁴ To be eligible, the child does not have to be considered a dependent for exemption purposes on the parents' federal income tax return.⁴⁵

Consumer-directed changes to the federal tax code

The Federal Health Reform Act contains many provisions that revise the Internal Revenue Code, of which several have a particularly direct impact on individuals. These include: 1) limits on

contributions to health flexible spending accounts (FSAs) and health reimbursement accounts (HRAs); 2) an increase in the threshold for itemized deduction of health-related costs not covered by insurance; 3) an excise tax on high-cost employer-sponsored coverage; and 4) an increase in the hospital insurance (Medicare) tax for high-income individuals.

Changes affecting flexible spending accounts

Under current tax law, there is no limit on permissible pre-tax contributions to a health FSA or HRA. The Federal Health Reform Act imposes a \$2,500 annual cap per account (indexed for inflation) on such contributions beginning in tax year 2013.⁴⁶ In addition, beginning January 1, 2011, health FSAs and HRAs may no longer reimburse for over-the-counter medicines (other than insulin) without a doctor's prescription.⁴⁷ These changes may adversely impact people with chronic illness, who frequently have high out-of-pocket medical costs.⁴⁸

Increase in itemized health deduction threshold

The Federal Health Reform Act raises the threshold for an individual to claim itemized deductions for medical expenses.⁴⁹ The current threshold is 7.5% of Adjusted Gross Income (AGI).⁵⁰ Effective in tax year 2013 the threshold will increase to 10% of AGI.⁵¹ For tax years 2013 through 2016, however, if a taxpayer (or his or her spouse) turns 65 before the end of the tax year he or she may continue to use the existing 7.5% threshold.⁵²

Excise tax on high-cost employer-sponsored plans

The Act creates Internal Revenue Code § 4980I, which imposes an excise tax on high cost (a.k.a. "Cadillac") employer-sponsored health plans beginning in 2018.⁵³ For that year, if the aggregate cost of employer-sponsored health coverage exceeds \$10,200 for employee-only or \$27,500 for family coverage, an excise tax of 40% of the "excess benefit" will be imposed on the coverage provider.⁵⁴ While the covered provider (i.e., the employer or plan administrator) is responsible for paying the tax, it seems likely that such costs will be passed on, at least in part, to covered employees.

Additional hospital insurance tax on high-income taxpayers

Beginning with the 2013 tax year, the employee portion of the hospital insurance tax required by the Federal Insurance Contributions Act (FICA) will increase by 0.9% on wages that exceed a specified threshold.⁵⁵ The applicable thresholds for covered wages will be: \$250,000 for married couples filing jointly, \$125,000 for a married individual filing separately, and \$200,000 for everyone else.⁵⁶ For self-employed individuals, the additional tax applies to the hospital insurance portion of the Self-Employment Contributions Act (SECA) on self-employment income in excess of the threshold amount.⁵⁷

Conclusion

Any attempt to exhaustively cover *all* of the consumer-related impacts of the Federal Health Reform Act would nec-

essarily fall short. Therefore, many provisions of the Act are not addressed here. Instead, this article has endeavored to provide a broad introduction to certain important aspects of the new law as they affect individuals. For an excellent and detailed summary of the Federal Health Reform Act, including consumer-directed provisions, see <http://www.kff.org/healthreform/upload/8061.pdf> (Kaiser Family Foundation). Further and up-to-date details on consumer elements of the new law may be found at implementing agency websites, including the Department of Health and Human Services (<http://www.healthreform.gov>), the Department of Labor (<http://www.dol.gov/ebsa/healthreform>) and the Internal Revenue Service (<http://www.irs.gov>), select “Affordable Care Act Provisions”).

Endnotes

- 1 Pub. L. No. 111-148, 124 Stat. 119 (March 23, 2010) (hereafter “Affordable Care Act”).
- 2 Pub. L. No. 111-152, 124 Stat. 1029 (Mar. 30, 2010) (hereafter “Reconciliation Act”).
- 3 See Kevin Sack, Florida Suit Poses a Challenge to Health Care Law, N.Y. TIMES (May 10, 2010), available at <http://www.nytimes.com/2010/05/11/health/policy/11lawsuit.html>.
- 4 See Affordable Care Act §§ 1501(b), 10106; Reconciliation Act § 1002.
- 5 *Id.*
- 6 *Id.*
- 7 *Id.*
- 8 *Id.*
- 9 *Id.*
- 10 See Affordable Care Act §10106; Reconciliation Act § 1002.
- 11 *Id.*
- 12 See Affordable Care Act § 1311(b).
- 13 Affordable Care Act § 1311(d).
- 14 Affordable Care Act §§ 1302(a), (b).
- 15 Affordable Care Act § 1302(e).
- 16 Affordable Care Act § 1201(2)(A).
- 17 *Id.*
- 18 See chapter 58 of the Acts of 2006, *as amended*.
- 19 Affordable Care Act §§ 1401(a), 1402. An individual is *lawfully present* if she or he is, and is reasonably expected to be for the entire period of enrollment for which a credit or cost-sharing reduction is claimed, a citizen or national of the United States or an alien lawfully present in the United States. *Id.* at §§ 1401(a), 1402(c)(2).
- 20 Affordable Care Act §§ 1401(a), 1402(b).
- 21 Affordable Care Act § 1401(a); Reconciliation Act § 1001.
- 22 *Id.*
- 23 Affordable Care Act § 1402(c); Reconciliation Act § 1001(b).

- 24 See Mass. Gen. Laws c. 176M, § 2 (guaranteed issue non-group coverage effective August 15, 1996); chapter 58 of the Acts of 2006, *as amended*.
- 25 See Affordable Care Act §§ 1001, 1201, 10101; Reconciliation Act, § 2301. Some of the other changes to take effect by 2011 are: required coverage of certain preventive health services; uniformity in explanation of coverage documents; and rebates to consumers for insufficient plan spending on medical care. See Affordable Care Act § 1001.
- 26 *Id.* Before 2014, plans may impose annual limits on the dollar value of essential health benefits subject to maximums specified in interim final regulations. See 75 Fed. Reg. 37188 (June 28, 2010).
- 27 See 75 Fed. Reg. 37188 (June 28, 2010).
- 28 See Affordable Care Act §1251; Reconciliation Act § 2301.
- 29 Affordable Care Act §1251(e); 75 Fed. Reg. 34538 (June 17, 2010) (interim final rule). For changes that cause cessation of grandfathered plan status, see 75 Fed. Reg. 34538 (e.g., 26 C.F.R. 54.9815-1251T(g)).
- 30 See 75 Fed. Reg. 34538 (June 17, 2010). Other provisions from which grandfathered plans are exempt include group health plan nondiscrimination rules and claims appeals and review process. *Id.*
- 31 Affordable Care Act § 1201; see also 75 Fed. Reg. 37188 (June 28, 2010).
- 32 *Id.*
- 33 *Id.*
- 34 *Id.*
- 35 Robert Pear, Insurance Pools Readied in Some States: Health Coverage for High-Risk Patients Could Start by August, N.Y. TIMES, June 27, 2010, at 12.
- 36 Affordable Care Act § 1001.
- 37 *Id.*; see also Reconciliation Act § 2301. Before 2014, a grandfathered plan need not extend coverage to an adult child if she or he has other employer-sponsored coverage. See 75 Fed. Reg. 34538 (June 17, 2010). Where Massachusetts’ law provides greater consumer protections (see chapter 324 of the Acts of 2006, §§ 33, 34, 36, 38, 40, *as amended*), it should prevail over the new federal provisions with respect to fully insured plans.
- 38 See Massachusetts Division of Insurance, Bulletin 2008-01, Amendments Created by Chapter 205 of the Acts of 2007 Related to Eligibility as a Dependent in an Insured Health Plan (January 15, 2008).
- 39 See Commonwealth Health Insurance Connector Authority, National Health Insurance Reform and Massachusetts: Frequently Asked Questions, available at <http://www.mahealthconnector.org> (select “Health Care Reform,” then “Read frequently asked questions on national reform”).
- 40 See 75 Fed. Reg. 27122 (May 13, 2010); IRS Notice 2010-38.
- 41 Affordable Care Act § 1001; 75 Fed. Reg. 27122 (May 13, 2010).
- 42 *Id.*
- 43 *Id.*
- 44 Affordable Care Act §1001; IRS Notice 2010-38. Thus, while coverage is *required* only until the child turns 26, Internal Revenue rules provide for tax exemption of the benefit for the entire year in which the child’s 26th birthday occurs.
- 45 *Id.*
- 46 Affordable Care Act § 9003; Reconciliation Act § 1403.
- 47 Affordable Care Act § 9005.
- 48 See Walecia Conrad, Flexible Spending: A Little Less So, N.Y. TIMES (April 16, 2010), available at <http://www.nytimes.com/2010/04/17/health/17patient.html>.
- 49 Affordable Care Act § 9013.
- 50 See 2009 Instructions for Schedule A, Form 1040, Itemized Deductions, at 2, available at <http://www.irs.gov/pub/irs-pdf/i1040sca.pdf>.
- 51 *Id.*
- 52 *Id.*
- 53 Affordable Care Act § 9001; Reconciliation Act §1401.
- 54 *Id.* Higher thresholds apply to retirees and to employees

- in high risk professions, such as police, firefighters and emergency response personnel.
- 55 See Affordable Care Act § 9015(a); Reconciliation Act §1402(b). The current assessment is 1.45% of covered wages.
- 56 *Id.*
- 57 Affordable Care Act § 9015(b); Reconciliation Act §1402(b).

Implementing Health Care Reform: Key Provisions Affecting the Pharmaceutical Industry

By Thomas Barker, Esq. and Maia Larsson, Esq.

The Affordable Care Act (also referred to as the “ACA”) was enacted earlier this year culminating over a year of intense political negotiations, legislative drafting, and numerous Congressional hearings over whether, and how, to comprehensively reform the U.S. health care system. The ACA is made up of two pieces of legislation – the Patient Protection and Affordable Care Act, or “PPACA,” Pub. L. No. 111-148, which President Obama signed on March 23, 2010, and the Health Care and Education Reconciliation Act, or “HCERA,” Pub. L. 111-152, which President Obama signed on March 30, 2010.

This issue of the Health Law Reporter describes some of the sweeping changes the ACA makes to the way in which health care will be accessed, delivered, and paid for in the United States. The ACA has a broad reach, which will affect most Americans, as well as many, if not all, sectors of the U.S. health care system including health care providers, health insurers, and biomedical companies such as pharmaceutical and device manufacturers. While the law has been written, many details are yet to be decided upon as the departments and agencies—in particular, the Department of Health and Human Services (“HHS”), the Centers for Medicare & Medicaid Services (“CMS”, or “Agency”) and the Food and Drug Administration (FDA)—begin their work of implementing the law.

This article will focus on four aspects of the ACA that will significantly impact the biomedical and pharmaceutical industries. The sections below address, in turn, the issues of: closing the Part D coverage gap, expanding Medicaid drug rebates, expanding the Public Health Service Act Section 340B program, and creating an approval pathway for follow-on biologics.

The Part D Coverage Gap

The standard Part D benefit design contains a “gap” in coverage during which a Medicare beneficiary enrolled in Part D is fully liable for her prescription drug costs. Social Security Act § 1860D-2(b)(3)(A), 42 U.S.C. § 1395w-102(b)(3)(A). In plan year 2010, the coverage gap, or “donut hole,” occurs for a beneficiary after she has incurred \$2,830 in Part D prescription drug spending (split between the enrollee and the plan) and until the beneficiary incurs an additional \$4,550 in true out-of-pocket (TrOOP) Part D spending (for a total generally equivalent to \$6,440 in covered spending for covered Part D drugs under the plan).¹ Once the beneficiary has incurred the requisite amount of TrOOP costs, the beneficiary’s “catastrophic coverage” begins wherein Medicare pays 95% of the cost and the beneficiary is responsible for the other 5%.²

Under the new law, which establishes the Medicare Coverage Gap Discount Program (“Coverage Gap

Program”), in order for a pharmaceutical manufacturer’s brand name drug, and in some cases, authorized generic drug, to be covered under Part D, the manufacturer must enter into an agreement with CMS stating that it will provide beneficiaries a 50% discount off of the negotiated price of the drug at the point of sale. Social Security Act § 1860D-14A(b)(1)(B). The 50% discount is treated as TrOOP spending for purposes of determining the level of the beneficiary’s incurred costs.³ *Id.* at § 1860D-2(b)(4)(E). The pharmacy will charge a Part D plan 50% of the negotiated price and the beneficiary the remaining 50%. The manufacturer will then be required to reimburse the Part D plan, generally within 38 days of receiving the invoice.⁴

In addition, beginning in 2011, the ACA gradually reduces the remaining 50% beneficiary coinsurance while the beneficiary is in the coverage gap. Thus, between the Coverage Gap Program described above and the reduction in coinsurance, the beneficiary’s share for an applicable Part D drug while in the coverage gap will phase down to 25% by 2021.⁵ At that point, the beneficiary’s Part D coinsurance between the initial coverage limit and the catastrophic limit will be the same as it was before the initial coverage limit was reached under the standard Part D benefit design.

As with many aspects of the ACA, the Coverage Gap Program provi-

sions must be implemented by CMS. CMS began this process with initial guidance issued on April 30, 2010 explaining how the Agency plans to implement the new program.⁶ The Agency received and considered public comments submitted to its initial guidance, and then issued a revised guidance on May 21, 2010 that included a draft Model Agreement which drug manufacturers will be required to enter into beginning January 1, 2011 for their applicable Part D drug to be covered by the Medicare Part D program.⁷ On August 2, 2010 CMS issued the finalized model Manufacturer Agreement that prescription drug manufacturers must enter into by September 2010.⁸ The CMS guidance and Model Agreement include key dates and requirements for manufacturers and Part D Plans, and describe critical aspects of the Coverage Gap Program such as how prescription drug event (PDE) data will be used to generate an invoice to be sent to the manufacturer from the CMS third party administrator (TPA) administering the Coverage Gap Program.

Changes to the Medicaid Drug Rebate

Under current law, pharmaceutical manufacturers of “covered outpatient drugs” are required to enter into and have in effect an agreement with the Secretary of HHS (“Secretary”) to provide a rebate as a condition of coverage of those drugs under a State Medicaid program or under Medicare Part B. Social Security Act § 1927(a)(1), 42 U.S.C. § 1395r-8(a)(1). Prior to the ACA, the “basic” rebate for innovator pharmaceutical products was calculated as the greater of: (1) 15.1% of the average manufacturer price (AMP) of the drug (also referred to as the “minimum rebate percentage”), or (2) the difference

between the AMP for the drug, and the “best price” of the drug. *Id.* at subsection (c)(1). In addition to this basic rebate, a manufacturer must also provide an “additional” rebate to the extent that the price of its drug exceeds the increase in the consumer price index for urban consumers. *Id.* at subsection (c)(2)(A). Manufacturers must provide information about the AMP and best price to CMS.

The ACA makes several changes to the Medicaid drug rebate program. First, with respect to the basic rebate, the ACA increases the minimum rebate percentage for most branded pharmaceuticals from 15.1% to 23.1% of AMP.⁹ Social Security Act § 1927(c)(1)(B). Further, the ACA provides that any increases in rebates attributable to the changes in minimum rebate percentage described above, taking into account the rebate extension to Medicaid managed care organizations (MCOs) and with respect to new formulations described below, are payable entirely to the federal government and not shared with the States under the usual FMAP principles that apply in Medicaid. *Id.* at subsection (b)(1)(C). The ACA provides, and CMS’ guidance issued to State Medicaid Directors on April 22, 2010 further explains, that the federal government will apply this policy by offsetting Federal Medical Assistance Program (FMAP) payments to States by the increases in the amount of rebates the States receive as a result of the new policy.¹⁰ *Id.* at clause (ii).

Second, the ACA applies the rebate requirement to “line extensions” of an existing single source drug or an innovator multiple source drug that is an oral solid dosage form. Social Security Act § 1927(c)(2)(C). The ACA provides that a drug is a “line extension” if it is a new formulation

of the drug, such as an extended release formulation.¹¹ *Id.* Under the ACA, a drug that is a “line extension” of an innovator drug that is an oral solid dosage form is now subject to a rebate, which is calculated as the greater of: (1) the amount calculated under section 1927 of the Social Security Act for the new drug, or (2) the product of: (i) the AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, (ii) the highest additional rebate (calculated as a percentage of AMP) for any strength of the reference brand name drug, and (iii) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).¹² *Id.*

Third, the ACA applies the rebate to drugs dispensed to enrollees in Medicaid MCOs. Social Security Act § 1903(m)(2)(A)(xiii). Prior to the enactment of the ACA, rebates were only paid with respect to prescription drugs dispensed to enrollees in fee-for-service (FFS) Medicaid. The ACA mandates that State contracts with MCOs require that covered outpatient drugs dispensed to managed care enrollees are “subject to the same rebate required by the agreement entered into” with the manufacturer for prescription drugs dispensed to enrollees in FFS Medicaid. *Id.* Thus, regardless of whether the manufacturer is paying the rebate based upon the minimum rebate percentage or the difference between AMP and best price, that rebate must also be paid by the manufacturer to the State under the Medicaid drug rebate program for drugs dispensed to enrollees in Medicaid MCOs. It is notable that, since the legislation does not specify an effective date for extending the drug rebate

to Medicaid MCOs, this provision is effective upon enactment, March 23, 2010. This appears to require pharmaceutical manufacturers to re-negotiate their contracts with Medicaid MCOs in order to meet the new statutory requirement.

Further, many pharmaceutical manufacturers currently have private contracts with Medicaid MCOs whereby the manufacturer provides a rebate to the Medicaid MCO with respect to both the Medicaid and commercial lives enrolled in the plan, and which has been privately negotiated between the parties. The ACA does not address these private contracts. Rather, whether a manufacturer will have to continue to pay such a rebate to the Medicaid MCO – in addition to the new rebate required under the ACA – under a privately negotiated contract will depend on the contract and negotiations between the pharmaceutical manufacturer and Medicaid MCO. Thus, regardless of the result of these private negotiations, a pharmaceutical manufacturer will be liable to the State for the full Medicaid drug rebate, as expanded in the ACA. CMS is expected to issue further guidance on the MCO provision.

Fourth, the ACA revises the definition of “average manufacturer price” (AMP).¹³ Social Security Act § 1927(k)(1). It is important to note that since the enactment of the ACA in March 2010, Congress has again made changes to the calculation of AMP.¹⁴ Specifically, in legislation that was signed into law by the President on August 10, 2010, Congress amended the ACA to require that Medicaid rebates will be collected from prescription drug manufacturers of inhalation, infusion, instilled, implanted, or injectable drugs that are not generally sold at retail pharmacies.¹⁵ The AMP definition affects the Medicaid

drug rebate requirement because a rebate, as stated above, is determined by either one of the following two calculations: (1) 23.1% of AMP, or (2) AMP minus “best price” – whichever is larger. The new definition of AMP – because it will tend to raise the AMP of a pharmaceutical product – will result in increased rebates paid by manufacturers.

Expansion of 340B Program

The 340B Drug Pricing Program (“340B program”), provides that “covered entities” that purchase “covered outpatient drugs” (any drug used in the outpatient setting, excluding vaccines) receive discounted prices for such covered outpatient drugs.”¹⁶ Public Health Service Act § 340B, 42 U.S.C. § 256b.

The ACA makes two main changes to the 340B program: (1) it expands the definition of a “covered entity,” and (2) it adds new program integrity requirements for pharmaceutical manufacturers and 340B covered entities. Notably, the ACA does not include an expansion of the 340B program to covered drugs provided to inpatients. An earlier version of PPACA proposed to expand the 340B program to inpatients, but this provision was deleted in HCERA. That said, Congress may make further changes to the 340B program through future legislation.¹⁷

With respect to the definition of a “covered entity,” which currently refers to certain socially favored health care providers, such as community health centers, disproportionate share hospitals, and AIDS drug assistance programs,¹⁸ the ACA adds the following new “covered entities”: pediatric hospitals that are excluded from the Medicare inpatient prospective payment system (IPPS) and that would have

had a disproportionate share adjustment percentage of greater than 11.75% (“DSH threshold”) if they were subject to the IPPS, cancer hospitals that are excluded from the Medicare IPPS and that meet the 11.75% DSH threshold, rural referral centers that have a disproportionate share adjustment percentage equal to or greater than 8%, critical access hospitals that treat Medicaid patients, and sole community hospitals that have a disproportionate share adjustment percentage equal to or greater than 8%. Public Health Service Act § 340B(a)(4).

With respect to program integrity, the ACA added requirements for both pharmaceutical manufacturers and covered entities aimed to strengthen the 340B program by increasing the Secretary’s oversight of manufacturers and covered entities. *Id.* at paragraph (d). The ACA also establishes a dispute resolution process for administratively handling disputed claims. *Id.*

Follow-On Biologics

Prior to the enactment of health care reform, there was no FDA approval pathway for “follow-on” biologics (FOBs) as there is for generic small molecule drugs. The ACA amends the Public Health Service Act to create a new regulatory pathway for FDA approval of FOBs – products that are “biosimilar” to a reference product that is approved by the FDA under a biological license application (BLA).¹⁹ Public Health Service Act § 351(k). To do so, the ACA creates a new abbreviated biological product application (aBPA) for “biosimilar” biological products, and requires the Secretary to grant an aBPA if she determines that the product is “biosimilar” to the reference product and that the FOB

has made the requisite clinical and safety showings. *Id.*

Further, the ACA provides for 12 years of data exclusivity for the innovator product. *Id.* at subsection (k)(7). Thus, under the ACA, the FDA cannot approve a biosimilar product until 12 years after the BLA for the reference product was approved. Regarding the first approved interchangeable FOB for a reference product, the ACA provides one year of exclusivity. *Id.* at subsection (k)(6).

The ACA includes a number of other provisions related to the follow-on biologics approval pathway, for example, applying the risk evaluation and mitigation strategies (REMS) requirement to FOBs. *Id.* at subsection (k)(5)(C). It also leaves open issues that must be worked out in the implementation phase, such as the handling of the application and information that could have implications in patent infringement cases. *Id.* at subsection (l). Another issue to be addressed in implementation is the development of user fees for biosimilar biologic products. The ACA provides for a public process with all stakeholders, including industry, scientific and academic experts, Congress, patient representatives and health care professionals, to develop appropriate user fees and FDA performance and safety goals for FOBs, to be implemented October 1, 2012. See ACA, § 7002(f). The public process must be started no later than October 1, 2010. The statute also provides for data collection on the cost of reviewing aBPA applications from the date of enactment through October 1, 2010. *Id.*

In addition to creating the approval pathway for FOBs, the ACA provides for a separate billing code for Part B biosimilar products, and mandates

that reimbursement for biosimilar products covered under Medicare Part B is 100% ASP of the biosimilar product plus 6% of the ASP for the reference product. Social Security Act § 1847A(b)(1).

Conclusion

The ACA includes numerous provisions that must be implemented through regulatory or subregulatory guidance by federal departments and agencies, in particular HHS and CMS. The implementation process for some provisions has already begun and for all provisions the process will unfold and expand over the next several years. Stakeholders should pay close attention to the statutory deadlines as well as departmental and agency actions for developments that will impact their industries.

Endnotes

- 1 Under the statute, only spending incurred by the beneficiary “or by any other person, such as a family member, on behalf of the individual” counts as incurred costs. Social Security Act § 1860D-2(b)(4)(C)(ii). CMS regulations interpret the phrase “any other person” as including a family member, a bona-fide charity, and a State pharmacy assistance program. See definition of “incurred costs” at 42 C.F.R. § 423.100. See also discussion at 70 Fed. Reg. 4193, 4239 (Jan. 28, 2005).
- 2 These dollar amounts are indexed each year for inflation. Social Security Act § 1860D-2(b)(3)(A)(ii).
- 3 Spending by AIDS drug assistance programs and by the Indian Health Service are also treated as incurred costs. Social Security Act § 1860D-2(b)(4)(C)(iii)(III) and (IV).
- 4 CMS Medicare Coverage Gap Discount Program Manufacturer’s Agreement, available at <http://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/ManuAgreement.pdf>; see also, CMS, Center for Medicare, Memorandum to All Part D Sponsors, “Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance” (May 21, 2010), available at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_Revised%20Guidance%20052110.pdf.
- 5 See Social Security Act, § 1860D-14A (implementing 50% discount in PPACA) and § 1860D-43 (phasing out the coverage gap).
- 6 CMS, Center for Medicare, Memorandum to All Part D Sponsors, “Medicare Coverage Gap Discount Program beginning in 2011” (April 30, 2010), available at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_043010.pdf.
- 7 CMS, Center for Medicare, Memorandum to All Part D Sponsors, “Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance” (May 21, 2010), available at [- \[www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_Revised%20Guidance%20052110.pdf\]\(http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_Revised%20Guidance%20052110.pdf\); Medicare Program; Medicare Coverage Gap Discount Program Model Manufacturer Agreement and Announcement of the June 1, 2010 Public Meeting, 75 Fed. Reg. 29555 \(May 26, 2010\), available at <http://edocket.access.gpo.gov/2010/pdf/2010-12559.pdf>.
 - 8 CMS Medicare Coverage Gap Discount Program Manufacturer’s Agreement, available at <http://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/ManuAgreement.pdf>.
 - 9 The minimum rebate percentage for clotting factors and outpatient drugs approved by the Food and Drug Administration \(FDA\) exclusively for pediatric indications only increases to 17.1% of AMP. CMS will issue further guidance on the process it will use to identify clotting factors and drugs with pediatric indications. See CMS, Center for Medicaid, CHIP, and Survey & Certification, Memorandum to State Medicaid Directors \(April 22, 2010\), available at <https://www.cms.gov/smdl/downloads/SMD10006.pdf>.
 - 10 CMS, Center for Medicaid, CHIP, and Survey & Certification, Memorandum to State Medicaid Directors \(April 22, 2010\), available at <https://www.cms.gov/smdl/downloads/SMD10006.pdf>.
 - 11 CMS is expected to issue further guidance on the process that will be used to identify “line extensions” of existing drugs.
 - 12 See also CMS, Center for Medicaid, CHIP, and Survey & Certification, Letter to State Medicaid Directors, Re: Medicaid Prescription Drug Rebates \(April 22, 2010\), available at \[http://www.cms.gov/Reimbursement/08_MedicaidPrescriptionDrugsundertheAffordableCareAct.asp#TopOfPage\]\(http://www.cms.gov/Reimbursement/08_MedicaidPrescriptionDrugsundertheAffordableCareAct.asp#TopOfPage\).
 - 13 The new definition of AMP enacted in the ACA includes in the calculation of AMP the average price paid by wholesalers to manufacturers of the drug with respect to drugs distributed to retail pharmacies, which in effect, removes mail order sales from the calculation of AMP. In addition, the legislation includes in the calculation of AMP the average price paid by retail pharmacies that purchase covered outpatient drugs directly from the manufacturer; and excludes from the calculation of AMP prompt pay discounts extended to wholesalers, bona fide service fees paid by manufacturers to wholesalers or community pharmacies, reimbursement to wholesalers or community pharmacies, reimbursement or other charges for damaged drugs, and payments or rebates to non-retail pharmacies, including HMOs, PBMs, mail order pharmacies, and other entities.
 - 14 The Aviation Safety and Investment Act of 2010 \(also referred to as the “Education Jobs and Medicaid Funding bill”\), H.R. 1586, enacted on August 10, 2010 as Pub. L. 111-226.
 - 15 See Colloquy on Medicaid Pharmacy Reimbursement, H.R. 1586, § 202, between Senate Majority Leader Reid, Senator Lincoln and Senator Murray \(Aug. 4, 2010\), Enacted in the Veterans Health Care Act of 1992, Pub. L. 102-585.
 - 16 The American Jobs and Closing Tax Loopholes Act of 2010, H.R. 4213, 111th Cong. \(2010\), includes an expansion of the 340B program to include drugs dispensed to hospital inpatients who do not have insurance. The House of Representatives passed H.R. 4213 on May 28, 2010 with a vote of 245 – 171. At the time of this article’s writing, the Senate had not yet voted on this legislation.
 - 17 See Public Health Service Act § 340B\(a\)\(4\) \(describing “covered entities.”\).
 - 18 The statute defines a “biosimilar” product as a product that is “highly similar” to the reference product “notwithstanding minor difference in clinically inactive components,” and for which there are “no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product.” Public Health Service Act § 351 \(k\)\(2\)\(i\).](http://www.

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Children's Health and the Patient Protection and Affordable Care Act

by Joshua Greenberg, Esq.

This article takes a “big picture” overview of major issues affecting children and pediatric care providers in the Patient Protection and Affordable Care Act (PPACA). As a general matter, federal health reform did not primarily focus on children’s health care. Most of the newly insured are adults, and many of the policy changes assume health care delivery models in adult care settings. This result is due in part to the belief of some legislators that they “had done kids health” when the Children’s Health Insurance Program (CHIP) was finally reauthorized in 2009. Nevertheless, there were several provisions included in the legislation that create opportunities for expanded coverage and system redesign efforts. As a consequence, the new legislation raises a number of opportunities and challenges for the child health community and pediatric providers.

The child health community is closely monitoring at least four broad issue categories:

Medicaid and CHIP

Medicaid and the companion CHIP program are the largest national payors of health care services for children, providing coverage for 31% of all children nationally. It plays a particular role in assuring coverage for significantly vulnerable pediatric populations including low income children, children with

special health care needs, and children in state protective custody. There is no question that Medicaid has improved access to care nationally for children and adolescents. However, the program generally pays providers significantly below the cost of care delivered. These payment policies have arguably lead to more concentrated use of “safety net” providers including health centers and hospital-based providers.

Clearly, PPACA’s emphasis on expanded health coverage and enrollment will benefit children. Of the estimated 8.1 million uninsured children nationally, approximately 5 million are eligible for Medicaid or CHIP coverage. The Department of Health and Human Services has prioritized signing up these “eligible but unenrolled” children through a multi-pronged outreach initiative.

At the same time, the general economic downturn and resulting state fiscal crises have led state Medicaid programs to institute significant provider rate cuts, increased use of enrollment and utilization controls, and internal administrative staff reductions.¹ Most states have responded to fiscal pressures by further reducing provider reimbursement rates. Intermittent media reports show that providers are dropping out of Medicaid as a result.² As of this writing, Congress’ repeated failure to

extend supplemental federal matching assistance funding to help states handle the recession-induced double-whammy of increased enrollment and declining tax revenue does not bode well for future political or fiscal support for state Medicaid programs.

Federal health reform may exacerbate these trends in a number of ways because more people will be covered and more resources will be required to manage the Medicaid program at the state level. Approximately 50% of the newly insured (16 million individuals, mostly single adults), will be enrolled in the Medicaid program. While the Federal Government will pick up the full cost of these individuals in the short term, there is concern that state Medicaid budgets will be further stretched, and that the focus of attention will be on finding, enrolling, and providing care to newly insured adults.³ Child advocates rightly worry that an already-stressed Medicaid program may quickly unravel.

For pediatric providers, the situation can be more complicated as children frequently travel across state lines for subspecialty care given the shortage of pediatric subspecialists nationally and their tendency to concentrate in larger (urban) academic medical centers. As a consequence, providers are often dealing with multiple state Medicaid pro-

grams on a regular basis, many of whom attempt to (or do) pay out-of-state providers even less than their in-state counterparts.

One of the opportunities to address some of these concerns is the Medicaid and CHIP Payment and Access Commission (MACPAC) established as part of the CHIP reauthorization legislation and charged with advising the Federal Government on pediatric care delivery and payment policies. Modeled on the Medicare Payment Advisory Commission (MedPAC), the relationship to federal health reform implementation is yet to be determined, but may include recommendations about standardizing payment and coverage policies across state boundaries.

Private Coverage

There are a number of changes being made to private insurance coverage that have the potential to “soften the blow.” Federal reform eliminates pre-existing conditions exclusions, and annual and lifetime caps in coverage. It also enables children to stay on their parent’s private insurance plans through age 26. Children will be some of the earliest beneficiaries of these changes, although there has been some limited pushback from the payors about the scope and timing of the pre-existing conditions exclusion.

It will be interesting to see how state Medicaid programs adapt to these changes, as Medicaid often serves as wraparound coverage for very sick children who have reached coverage limits with their private payors. In Massachusetts, for example, the Medicaid program has had

the longstanding ability through its third party liability program to pay for private coverage when it is more affordable than paying claims through Medicaid directly. The state should have an improved opportunity to better coordinate benefits and wrap-around coverage with private payors as a result of the law’s changes, leading to better continuity of coverage for children and families and less strain on state budgets.

With respect to the creation of new, subsidized plans and health exchanges, Congress decided in the short term to preserve the CHIP program rather than to put low-moderate income children into the newly established exchange plans. This is consistent with the Massachusetts approach (low income children are enrolled in MassHealth, not Connector plans). Similarly, the law did not make any fundamental changes in the nature of benefits offered to children. It does require that all public and private plans offer a standard preventive pediatric benefits package modeled on the American Academy of Pediatrics “Bright Futures” recommendations (a relatively comprehensive set of benefits).

Innovation Opportunities

There are number of places in federal health reform where funding is authorized for innovation in care delivery. For children, these funds will likely flow primarily through state Medicaid programs. The legislation establishes an innovation center at the Centers for Medicare and Medicaid Services (CMS) to “test the feasibility, cost effectiveness and quality outcomes of new

healthcare delivery models.” It also allows CMS to fund demonstration projects in the development of pediatric accountable care organizations.

Children with special health care needs are an especially important community in this regard. Much of the spending in pediatric care, and much of the opportunity for improved quality and care coordination, is for children with more complicated conditions. These children will often become long-term, frequent users of the health care system. Their care often depends upon strong integration with community-based resources (indeed the concept of the “medical home” was developed by the special health care needs community). The ability to develop new care delivery models for this population of children offers exciting possibilities to better integrate community-based resources, enable self-management, and measurably impact short and long-term health outcomes.

There is no question that states have theoretically possessed waiver authority to redesign care for this population under pre-existing law. However, to date many of the care delivery innovations have focused on adults (for example, programs to better manage care for individuals dually-eligible under the Medicare and Medicaid programs). The specific directive to develop pediatric approaches combined with the increased emphasis on cost-effective quality improvement strategies is likely to result in more “bottom up” approaches rooted in collaborations between providers, community-based organizations and patient groups.

Prevention and Wellness

Lastly, there is no better place to embed prevention and wellness activities than in the pediatric community because they engender a lifetime of benefit. There are both funding and policy initiatives underway to tackle the childhood obesity crisis, with strong involvement from First Lady Michelle Obama. There is an obvious association of obesity with serious, expensive health conditions, and growing recognition that overweight and obese children are at seriously heightened risk of becoming obese adults. The strategy for confronting this crisis must involve health providers, but must also tackle food and nutrition policy, conditions in the built environment (e.g. the availability and accessibility of safe recreational areas), and school policies on nutrition and exercise.

A similar focus on children with developmental and mental health concerns makes a great deal of sense. Conditions like autism and depression are prevalent, they are correlated with other negative health outcomes, and if identified in a timely fashion, there are treatments that can significantly reduce their impact. For example, in the case of autism, early identification and appropriate treatment has been shown to improve IQ scores and the socialization and self-care abilities of children. The need to develop multi-disciplinary approaches (for example, involving both healthcare providers and school systems), and financing mechanisms (the appropriate balance of public and private support) is essential. One of the most challenging and long-standing problems in the area

of behavioral health services is “who pays.” There has been an increasing trend towards clarifying the obligations of the private payor community through state and federal mental health parity laws, as well as specific legislative initiatives around autism treatment.

Conclusion

In theory, federal health reform creates a number of opportunities to begin to “take the long view” with respect to pediatric health care expenditures and services. However, the significant impact of short-term funding challenges at the state and federal levels should not be underestimated. Absent an explicit, coherent approach that prioritizes child health needs there is a real danger of doing significant damage to the pediatric delivery system and to child health.

Endnotes

- 1 Vernon Smith, Stan Rosenstein and Robin Rudowitz, *Medicaid's Continuing Crunch In a Recession: A Mid-Year Update for State FY 2010 and Preview for FY 2011*, Kaiser Commission on the Future of Medicaid, February 2010.
- 2 See e.g. Kevin Sack, *As Medicaid Payments Shrink, Patients Are Abandoned*, N.Y. TIMES, March 16, 2010 at A1. In 2008, over 28% of physicians refused to accept ANY new Medicaid patients (vs. 13% for Medicare and 4% for private insurance), only 40% accepted ALL new Medicaid patients (vs 58% for Medicare and private coverage); Elynn Boukus, Alwyn Cassil, Ann S. O'Malley, *A Snapshot of U.S. Physicians: Key Findings from the 2008 Health Tracking Study Physician Survey*, Data Bulletin No. 35, Center for Health Systems Change, September 2009.
- 3 January Angeles and Matt Broaddus, *Federal Government Will Pick Up Nearly All Costs of Health Reform's Medicaid Expansion*, Center on Budget and Policy Priorities, Revised June 18, 2010; but see, Pat Wechsler, *States Sue Over Overhaul That Will Bust State Budgets (Update2)*, Bloomberg News, March 23, 2010.

“A Fair Compromise”: Abortion Policy under the Patient Protection and Affordable Care Act

by Sara Hanson, Esq.

“When you have both extremes saying they’re unhappy, I think it’s a fair compromise.”

-Senator Barbara Boxer¹

Introduction

When President Obama signed the Patient Protection and Affordable Care Act into law on March 23, 2010, it marked a monumental achievement in domestic policymaking. There was a time, however, when controversy over a single issue nearly brought the whole of health reform debate to a screeching halt. The issue in question was not potential tax increases, or even the possibility of a public insurance option, but rather an issue that itself makes up only a tiny fraction of the bill’s language and content: federal funding of abortion coverage.

Abortion, which has arguably polarized American social politics more than any other issue over the past half century, became a lightning-rod of the health care reform debate, pitting members of the same party against one another and all but eclipsing debate over any other substantive provisions of the various congressional health care reform proposals for several months.

This article will endeavor to trace the history of abortion policy’s influence on federal health care reform debate, as well as delineate the abortion-related provisions included in the Patient Protection and Affordable Care Act. Finally, it will briefly

discuss more recent developments in abortion policy around the country in response to the federal health care reform.

Abortion Financing in the Debate over Health Care Reform

As a result of the Hyde Amendment², federal money has been prohibited from funding elective abortions, except in cases of rape, incest, or danger to the life of the pregnant woman, since the mid-1970s. President Obama’s administration had consistently pledged that health care reform would not allow for federal funding of abortion procedures beyond the scope of the Hyde Amendment³. However, both Obama administration officials and legislators initially had “difficulty translating that principle into enforceable legislative language.”⁴

In late September, as concern over abortion coverage in health care reform began to grow in earnest, both the Senate and House health care bills purported to comply with the technical requirements of the Hyde Amendment by requiring health insurers to segregate any monies provided by federal subsidies from monies collected as premiums and co-payments; insurers would be allowed to cover abortion only out of funds collected from private sources.⁵ This model, however, did not satisfy the concerns of anti-abortion Democrats and Republicans, who likened the plan to a mere accounting trick rather than a consistent

principle against taxpayer funding of abortion.⁶ These legislators’ reluctance to support a bill without stronger abortion funding restrictions – particularly Democratic legislators – threatened to derail health care reform completely.

After an intense round of negotiating within her own party, Speaker of the House Nancy Pelosi allowed anti-abortion Democratic representatives to propose an amendment to the House bill barring any government monies from subsidizing the purchase of a health care plan that offered abortion coverage.⁷ Effectively, the amendment dictated specific coverage options that insurance companies would be barred from offering beneficiaries in order to accept federal subsidies. This amendment, now widely known as the Stupak Amendment after its primary sponsor, Representative Bart Stupak (D – Mich.), was ultimately included in the House’s health care reform package, H.R. 3962, the Affordable Health Care for America Act, passed on November 7, 2009.⁸ The legislation, including the Stupak Amendment, received significant backing from the United States Conference of Catholic Bishops, an organization firmly devoted to both the goal of national health care reform and staunch anti-abortion views.⁹

Abortion rights advocates promptly and loudly decried the inclusion of the Stupak Amendment in

the House bill. Under the reform package, anyone earning up to 400% of the federal poverty level – approximately \$88,000 for a family of four – would be eligible for federal subsidies to purchase insurance coverage.¹⁰ Opponents of the Stupak Amendment argued that, given the sheer size of the marketplace eligible for subsidies under the reform package, private insurers would eliminate abortion coverage from their plans in order to take advantage of this burgeoning new marketplace, thus leaving millions of women without access to coverage for abortion services.¹¹ In fact, opponents of the amendment asserted that countless women who received abortion coverage under their current plans would likely lose that coverage as a result of the House plan’s new restrictions.¹² Despite this criticism, Congressman Stupak stood firm in support of his amendment, insisting that it upheld established precedent under the Hyde Amendment and left women the option to purchase insurance coverage for abortion care with their own money on the open market.¹³

Soon after the abortion controversy blighted the House’s health reform debates, the issue made its way to the Senate chamber. In late December, leading Senate Democrats were scrambling to secure the necessary 60 votes to avoid a Republican filibuster of the legislation. Senator Ben Nelson (D – Neb.), an adamant abortion opponent and former insurance industry executive, became the focal point of Senate negotiations.¹⁴ Initially, Senator Nelson pushed for an amendment to the Senate version of the health care reform bill that mirrored the Stupak Amendment’s restrictions on the use of federal subsidies.¹⁵ However, the Senate eventually reached a compromise and passed a health care reform package with abortion-

related provisions that more closely resembled the House’s original plan of segregated funding mechanisms.¹⁶ Under the Senate bill, individual states would have discretion to prohibit the use of federal subsidy funds to pay for health plans that include abortion coverage; in the alternative, insurers in states that allow health plans to include abortion coverage would be obliged to separate subsidy funds from private monies, and ensure that abortion care is only financed by income from private sources.¹⁷ In effect, the Senate plan would require that beneficiaries who receive subsidies and choose a health plan that provides abortion coverage write two separate premium checks.¹⁸ While still more restrictive of abortion coverage than abortion rights supporters would prefer, the Senate bill’s provisions were significantly less restrictive than the House’s Stupak Amendment.

Throughout the early months of 2010, Democratic leadership in both the House and Senate worked diligently to reconcile the differences between the two chambers’ differing reform legislation. In late February, President Obama unveiled his own proposal at a health summit at Blair House, at which he encouraged legislators to seek out common ground and compromise as diligently as possible.¹⁹ Congressional Democrats continued to spar over the specific language of the bill; the House’s Democratic leadership, particularly Speaker Nancy Pelosi faced the unsavory challenge of persuading key socially conservative Democratic legislators to support the Senate’s version of health care reform in an election year.²⁰ As negotiating continued, however, the more conservative Democratic contingent began losing ground, as more and more anti-abortion Democrats expressed satisfaction with

the restrictive language included in the Senate bill.²¹ On March 21, 2010, the House voted to pass the Senate version of the bill, and the Patient Protection and Affordable Care Act (PPACA) was signed into law by President Obama on March 23, 2010.²² To pacify concerned anti-abortion legislators, President Obama also issued an Executive Order on March 24, 2010, pledging dutiful monitoring and enforcement of the legislation’s restrictions relating to abortion funding, consistent with the Hyde Amendment.²³

PPACA was soon modified by the Health Care and Education Reconciliation Act of 2010 (HCERA).²⁴ The HCERA implements several changes to provisions of the PPACA, though none substantively impact the law’s abortion-related restrictions.²⁵

Health Care Reform and Abortion Coverage – PPACA’s Provisions

Simply put, the PPACA preserves the Hyde Amendment’s mandate that federal taxpayer dollars not be used to pay for abortion services. The law accomplishes this through a number of mechanisms.

No qualified health plan is required to include abortion services as an “essential health benefit” - health insurers maintain discretion over whether to include abortion services as a covered benefit in the coverage plans they offer.²⁶ Federal funding may not be used to fund elective abortions under a community health insurance option.²⁷ The Secretary of Health and Human Services (“Secretary”) may determine that a community health insurance option shall provide coverage for abortion services, or an individual state may require insurance coverage for abortion services under a community health insurance option offered in that state.²⁸ In either of these

cases, adequate procedural steps must be taken to ensure that no federal funding goes toward paying the costs for abortion procedures that are prohibited from coverage by federal taxpayer dollars.²⁹ Exceptions to this policy exist for abortion procedures for which federal funding is permitted, *i.e.*, in the case of rape, incest, etc.³⁰

The Secretary must ensure that within each Health Plan Exchange there is at least one plan that covers all abortion procedures (both those eligible for federal funding and those excluded from federal funding), as well as at least one plan that does not include coverage for abortion services that are not eligible for federal funding.³¹ Any insurer that offers a qualified health plan that includes coverage for abortion services ineligible for federal funding must not use any monies from federal taxpayer sources, including specific tax monies and federal statutory cost-sharing programs, to defray the costs of such abortion procedures.³² Furthermore, in the case of such a plan, the segregation of funds is mandated.³³ The Secretary must produce actuarial calculations representing the cost of including abortion coverage in health plans for those abortion services whose costs are prohibited from federal funding; such an estimate may not be less than \$1 per month, per enrollee.³⁴ This amount must be compiled from private sources and isolated from all public monies.³⁵ A state may opt to prohibit abortion coverage in qualified health plans offered through an Exchange in that state, through the enactment of legislation to that effect.³⁶ The state also has the power to repeal any such law.³⁷

Additionally, PPACA includes anti-discrimination language that preserves conscience protections for individual providers or entities that refuse to

“provide, pay for, provide coverage of, or refer for abortions.”³⁸ PPACA also specifically disclaims preemption of any state laws regarding abortion coverage, funding, or procedural requirements, such as parental notification laws.³⁹ Finally, the text of the PPACA specifically disclaims any interpretation of its provisions that would relieve health care providers of their obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA).⁴⁰

Moving Forward: What Does PPACA Mean for the Future of Abortion Policy?

Since the passage of the PPACA, numerous states have taken action to prohibit abortion coverage by health plans that will be offered through state Exchanges. The so-called “Nelson Amendment” specifically allows states to ban private insurers from providing abortion coverage, and state legislatures have wasted no time passing such legislation – long before the state-based exchanges themselves are set to go into effect.⁴¹

Arizona passed legislation on April 24, 2010, banning abortion coverage in the state’s employee benefit plan and Medicaid plans.⁴² The legislation also forbids insurers offering plans through the state’s exchange from covering abortion services unless such coverage is contained in a separate and distinct abortion policy rider that is paid for through a second premium payment.⁴³ In early May, Tennessee passed similar legislation, prohibiting all insurers participating in the state health insurance exchange from including abortion coverage in their benefits packages.⁴⁴ By the end of May, Mississippi had also enacted a bill prohibiting the inclusion of abortion coverage in plans offered through the state’s health exchange.⁴⁵

On June 11, 2010, newly-Independent Florida Governor Charlie Crist vetoed legislation that would have barred private insurers from including abortion coverage in plans offered through state exchanges.⁴⁶ Interestingly, another provision of the vetoed legislation allegedly would have reinforced Florida’s pending lawsuit against the federal health care reform legislation.⁴⁷ Florida’s Attorney General, Bill McCollum, is currently leading a group of 20 state Attorneys General in a legal challenge against the reform in federal district court in Pensacola, Florida.⁴⁸ Finally, Democratic Missouri Governor Jeremiah (Jay) Nixon allowed pending anti-abortion legislation to become law in mid-July.⁴⁹ Existing Missouri law already prohibited abortion coverage in private insurance policies, instead requiring that women wanting such coverage pay an additional premium; the newly passed legislation will prohibit insurance plans offered through any state exchanges from covering abortion services, even if women are willing to pay an additional premium.⁵⁰ More comprehensive information on state policies concerning insurance coverage of abortion services is available online from the Guttmacher Institute.⁵¹

While Massachusetts now has the authority from the Federal Government to prohibit abortion coverage in plans available through the Commonwealth Connector, it seems unlikely that such a measure is on the State Legislature’s immediate horizon. It remains to be seen how Massachusetts legislators will rework the Commonwealth’s revolutionary health care reform plan to comply with new federal restrictions. In the case of abortion policy in particular, however, these new measures appearing across the country evidence a dynamic shift in the ongoing political struggle over

abortion. While more traditional anti-abortion measures – which typically erect barriers to women’s access in the form of increased cost and time impositions, e.g., mandatory ultrasounds, waiting periods, parental consent, etc. – will remain a salient part of abortion opponents’ arsenal, lawmakers and advocates on both sides of this ever-controversial issue should expect to continue seeing state-sponsored bans of private insurance coverage for abortion services.

Endnotes

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2 An Act Making further continuing appropriations for the fiscal year 1978, and for other purposes, Pub. L. No. 95-205, 1977 H.J. Res 662 (1977) (“Provided, That none of the funds provided for in this paragraph shall be used to perform abortions except where the life of the mother would be endangered if the fetus were carried to term; or except for such medical procedures necessary for the victims of rape or incest, when such rape or incest has been reported promptly to a law enforcement agency or public health service; or except in those instances where severe and long-lasting physical health damage to the mother would result if the pregnancy were carried to term when so determined by two physicians.”). Hyde Amendment

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7 David M. Herszenhorn & Jackie Calmes, *Abortion Was at Heart of Wrangling*, N.Y. TIMES, Nov. 8, 2009, available at <http://www.nytimes.com/2009/11/08/health/policy/08scene.html>.

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17 *Id.*

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19 Sheryl Gay Stolberg & Robert Pear, *President Urges Focus on Common Ground*, N.Y. TIMES, Feb. 26, 2010, available at <http://www.nytimes.com/2010/02/26/health/policy/26health.html>; see also the Kaiser Family Foundation website for the full text of President Obama’s health care proposal, available at <http://www.kaiserhealthnews.org/Stories/2010/February/22/Obama-Health-Care-Proposal.aspx>.

20 Sheryl Gay Stolberg & Robert Pear, *Wary Centrists Posing Challenges in Health Care Vote*, N.Y. TIMES, Feb. 27, 2010, available at <http://www.nytimes.com/2010/02/28/us/politics/28health.html>.

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22 Sheryl Gay Stolberg & Robert Pear, *Obama Signs Health Care Overhaul Bill, With a Flourish*, N.Y. TIMES, Mar. 23, 2010, available at <http://www.nytimes.com/2010/03/24/health/policy/24health.html>.

23 Exec. Order No. 13535, 75 Fed. Reg. 15599, 2010 WL 1169592 (March 24, 2010), available at <http://www.whitehouse.gov/the-press-office/2010/03/24/20100324-executive-order-patient-protection-and-affordable-care-acts-consistency-with-longst>.

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25 David Herszenhorn & Robert Pear, *Health Vote is Done, but Partisan Debate Rages On*, N.Y. TIMES, Mar. 22, 2010.

26 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1303, 124 Stat 119, 168-171 (2010).

27 *Id.*

28 *Id.*

29 *Id.*

30 Only abortion procedures resulting from rape, incest, or to save the life of the pregnant woman are eligible for federal funding, as per the Hyde Amendment. See Summary of New Health Care Reform Law from the Kaiser Family Foundation, available at <http://www.kff.org/healthreform/upload/8061.pdf>.

31 Patient Protection and Affordable Care Act, *supra* note 25.

32 *Id.*

33 *Id.*

34 *Id.*

35 *Id.*

36 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10104, 124 Stat 119, 896-900 (2010).

37 *Id.*

38 Patient Protection and Affordable Care Act, *supra* note 25.

39 *Id.*

40 *Id.*

41 Small Business Health Option Program Exchanges, or SHOP Exchanges, are not required to be up and running in the states until 2017. See Summary of New Health Care Reform Law from the Kaiser Family Foundation, available at <http://www.kff.org/healthreform/upload/8061.pdf>.

42 John Leland, *Abortion Foes Advance Case at State Level*, N.Y. TIMES, June 2, 2010, available at <http://www.nytimes.com/2010/06/03/health/policy/03abortion.html>.

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46 John Frank and Lee Logan, *Gov. Charlie Crist Vetoes Abortion Bill*, ST. PETERSBURG TIMES, June 12, 2010, available at <http://www.tampabay.com/news/health/gov-charlie-crist-vetoes-abortion-bill/1101696>.

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50 *Id.*

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Constitutional Challenges to the Patient Protection and Affordable Care Act

by Ari Gottlieb, Esq.

On March 23, 2010, President Barack Obama signed the Patient Protection and Affordable Care Act (PPACA) into law.¹ Less than one hour later, a lawsuit was filed by attorneys general from 13 states in the U.S. District Court for the Northern District of Florida challenging the constitutionality of the law.²

The suit makes a number of constitutional claims that center on four specific issues. First, the lawsuit alleges that by mandating all Americans maintain qualifying health care coverage or pay a tax, the federal law exceeds Congress's powers under the Commerce Clause.³ Second, the suit alleges that forcing citizens to procure qualifying health coverage violates Fifth Amendment due process rights.⁴ Third, the suit alleges that PPACA violates Tenth Amendment state sovereignty by "commandeering" the states to enforce a federal program.⁵ Lastly, the suit alleges that the tax levied against those who do not procure proper health coverage is a direct tax that exceeds Congress's power under the taxing and spending clause.⁶

While the Florida suit is the most comprehensive in its constitutional claims, there have been numerous other legal challenges to the PPACA.⁷ Some states have even taken

to filing legislation exempting their citizens from certain aspects of the PPACA.⁸ While none of the lawsuits levied against the PPACA are identical, the Florida suit serves as the best illustration of the major constitutional issues surrounding the new law. This article will examine each of these issues in turn and the Constitutional precedents that they invoke.

The Personal Mandate and The Commerce Clause

The Florida lawsuit alleges that Congress has exceeded its authority under the Commerce Clause by mandating that all American citizens take an affirmative act to procure health insurance⁹. Section 5000A of PPACA requires individuals to maintain health care coverage or pay a gradually increasing percentage of their income in the form of a tax.¹⁰ The argument is that the PPACA is looking to regulate *inactivity*, namely taxing individuals for not doing something, i.e. not buying health insurance.¹¹ This inactivity, the states argue, cannot be considered "commerce" and is therefore outside the scope of the Commerce Power.

Article I, Section 8, Clause 3 of the United States Constitution gives Congress the power to "regulate Commerce with foreign Nations, among the several

States, and with the Indian Tribes".¹² The Commerce Power is the chief mechanism by which Congress regulates the economy, and it is extremely broad. The United States Supreme Court has articulated three areas of permissible congressional regulation: *channels* of interstate commerce, *instrumentalities* of interstate commerce, and activities having a *substantial effect* on interstate commerce.¹³ Health insurance would fall in the category of regulation having a *substantial effect* on interstate commerce, and there are several cases that limit Congresses power under the Commerce Clause to activity that is fundamentally economic in nature.¹⁴ In *United States v Lopez*, the Court held that the Federal Gun Free School Zones Act was unconstitutional because its connection to commerce was far too attenuated.¹⁵ Similarly, in *United States v. Morrison*, the Court overturned the civil remedy provision of the Violence Against Women Act because it determined that gender related violence, when seen in the aggregate, could not be considered substantially related to commerce.¹⁶ In *Gonzales v Raich*, however, the Court held that Congress could regulate medical marijuana grown strictly for personal use in California under the Federal Controlled Substances Act.¹⁷ The Court used a "rational basis" test and held that Congress had properly

concluded that although the marijuana on Angel Raich’s windowsill was not itself in the stream of commerce, its regulation was an important part of the larger federal regulatory scheme pertaining to controlled substances, and therefore, was deemed to have a substantial effect on interstate commerce.¹⁸

The question then becomes whether a mandate to purchase health insurance can be considered economic in nature and if so, does it have a substantial effect on interstate commerce.

Purchasing health insurance is certainly a commercial transaction. Proponents of the law would argue that the purchase of health insurance is economic in nature because it makes citizens health care consumers.¹⁹ The Florida case takes issue with the idea that PPACA forces individuals to enter the market for health insurance and uses that forced participation in that market as evidence that they are engaging in commerce.²⁰ The government may reason in response that a requirement to purchase health insurance would have a tremendous impact on the insurance industry and health care system.²¹ Those who have insurance will no longer be forced to shoulder the economic burden of those who utilize emergency care as their primary means of medical treatment.²² Premiums would theoretically go down since providers no longer have to shift the cost of the uninsured onto the insured population.²³ In addition, mandated health insurance increases the insured population which could result in better

overall health and increased productivity among American workers. The decreased productivity due to poor health and higher mortality among the uninsured population that costs \$102-204 billion annually provides the “rational basis” on which Congress relied in passing the PPACA.²⁴

If the mandate to purchase health insurance were not considered economic in nature, then the government would argue that the mandate is an important part of a larger regulatory scheme for the health insurance industry.²⁵ The Federal Government is deeply involved in health regulation evidenced by such laws as the Employee Retirement Income Security Act (ERISA) and the Health Insurance Portability and Accountability Act (HIPAA). Furthermore, the McCarran-Ferguson Act allows Congress to enact laws that pertain to the business of insurance.²⁶ Applying the analysis on which the Court relied in *Raich* to these facts may lead to the conclusion that the mandate is acceptable as part of a comprehensive health care overhaul.

The Personal Mandate and Fifth Amendment Due Process

The Florida complaint alleges that mandate provision of PPACA violates the Fifth Amendment Due Process rights of individuals by forcing them to spend money on a health insurance plan.²⁷ The plaintiffs argue that PPACA “deprives them of their right to be free of unwarranted and unlawful federal government compulsion.”²⁸ In order to qualify for the strictest standard of review by the Court, this alleged economic

right to be free from having to pay for health insurance would have to be considered “fundamental.”²⁹ The Court has repeatedly refused to accord regulation of economic rights such consideration and held that Congress needs only act rationally and reasonably in regard to economic legislation.³⁰ PPACA would therefore be subject to the minimum standard of review and need only serve a legitimate purpose.³¹ PPACA serves, in part, to protect the public health. The Court has held in numerous cases that this is a legitimate purpose.³² The importance of having health insurance and the economic burden the uninsured place on the healthcare system also supports the argument that Congress acted rationally and reasonably in passing the PPACA.

Health Benefit Exchanges and the Tenth Amendment

Section 1311 of PPACA mandates the creation of Health Benefit Exchanges (“Exchanges”) to enable individuals to purchase qualifying health plans.³³ In addition, Section 1321 gives the states flexibility to either establish and run the Exchange themselves or cede control of the Exchange to the Federal Government.³⁴ The Florida complaint alleges that these sections violate Tenth Amendment state sovereignty by “commandeering” the states into implementing a federal program.³⁵

The Tenth Amendment states that all powers “not delegated to the United States by the Constitution...are reserved to the States.”³⁶ Historically, the

Tenth Amendment was treated as a “truism” and understood to mean that Congress could not exceed its power enumerated in the Constitution.³⁷ The Supreme Court has in recent years come to embrace a form of “new federalism” and seen the Amendment as a legitimate protector of state sovereignty.³⁸ Under current Tenth Amendment jurisprudence, Congress cannot force state executives to administer a federal program.³⁹ In *Printz v. United States*, the Supreme Court struck down the Brady Handgun Violence Prevention Act on the grounds that it “commandeered” state officials to conduct background checks on handgun purchasers.⁴⁰ Similarly, in *New York v. United States*, the Supreme Court invalidated the “take title” provision of the Low-Level Radioactive Waste Policy Amendments Act requiring non-conforming states to be held civilly liable for any radioactive waste within their borders.⁴¹ Non-conforming states would have to pay damages to injured individuals. The Court did state that Congress could offer the states monetary incentives for their participation in the federal program (under the Spending Power) or allow the states the option to independently regulate the activity according to federal standards.⁴²

The drafters of PPACA have heeded the advice of the Supreme Court in *New York v. United States* and drafted the law to provide the states with such a choice. States are permitted to set up insurance exchanges themselves and run them in compliance with the federal law.⁴³ If they choose not to, the Federal Government

will step in and establish an Exchange for them.⁴⁴ The Supreme Court opposed the “take title” provision in *New York v. United States* because the “choice” offered in the statute was so severe that the Court felt it was coercive and “commandeered” states into complying with a federal regulatory program. If they chose not to comply, they were then forced to take ownership of radioactive waste and be liable in tort for any injury resulting from that waste. It is not enough that a provision of a law be optional - it cannot be crafted in such a way that leaves states with no true choice but to comply. It is difficult to see how this situation is analogous to *New York v. United States*. PPACA imposes no harsh penalty on the states. If they chose not to create an Exchange, the Federal Government simply does it for them. The states have the option of independently regulating the activity according to federal standards, and this would appear to be constitutionally permissible.⁴⁵

Some have suggested that PPACA’s application to state employee’s health plans could be a viable challenge.⁴⁶ For example, the bill allows state employees to enroll certain dependants in the Children’s Health Insurance Program (CHIP).⁴⁷ The Supreme Court has rejected the argument that some areas of government are integrally and traditionally within the states’ control, preferring to defer to the political process to protect against federal abuses.⁴⁸ While this principle is still good law, it was a narrow decision and given the present makeup of the court it is unclear how a

challenge, if accepted, would be decided.⁴⁹

Expanding Medicaid and the Taxing and Spending Power

The Plaintiffs in the Florida case also argue that Congress has exceeded their powers under the Spending Clause by grossly expanding their responsibilities under Medicaid to a level not financially feasible.⁵⁰ PPACA improves access to Medicaid in a number of ways, most notably by creating a new mandatory eligibility category for individuals at or below 133% of the Federal Poverty Level.⁵¹ The Plaintiffs’ claim that their population is so dependent on Medicaid that withdrawal from the program would leave millions of uninsured Floridians. Participation in Medicaid is optional, but federal funds for it are conditioned upon administration of the program to federal standards.

The Supreme Court has held that placing conditions on federal funds is a valid exercise of the spending power so long as they are clearly stated and bear some relationship to the purpose of the program.⁵² In *South Dakota v. Dole*, the Court held that Congress could create a 21-year-old drinking age by withholding 5% of federal highway funds to those states that failed to comply. One of the purposes for the federal highway grants was to create safe interstate travel, and a 21-year-old drinking age bore a direct relationship to that goal. Similarly, PPACA seeks to expand access to health care to millions of Americans who are without it. Expanding Medicaid bears a clear relationship to that goal.

The court acknowledged in *Dole* that financial inducement could reach a level where “pressure turns into compulsion” and left open the possibility that these decisions may have to be taken on a case by case basis.⁵³

Budgetary issues aside, this expansion of Medicaid appears constitutionally permissible because states have this choice – participate in Medicaid and receive federal money or opt out and receive no funding. Providing a means to induce states to act – i.e., a financial incentive - is not presently unconstitutional.⁵⁴

The Plaintiffs also argue that the tax imposed on individuals not buying health insurance is a direct tax and unconstitutional.⁵⁵ Congress’s power to “lay and collect taxes and provide for the general welfare” is extremely broad and one which the Court gives great deference.⁵⁶ A tax that is revenue-generating on its face but regulatory in nature is not considered unconstitutional so long as the funds generated are used to promote the general welfare.⁵⁷ A challenge to the PPACA tax is unlikely to succeed because, as Jack Balkin, writes, “Promoting a healthy populace, expanding access to health insurance, and preventing members of the public from being driven into poverty by medical costs surely count as contributions to the general welfare.”⁵⁸

Conclusion

The scope of health reform under PPACA is massive, and the mandate that all citizens purchase qualifying health insurance is unprecedented.

While no one can state with certainty how the Supreme Court would rule on a constitutional challenge to the law, an examination of past decisions gives some guidance. Congress appears to have the authority to enact PPACA under current Commerce Clause jurisprudence. The court’s stance on Tenth Amendment state’s rights, Fifth Amendment Due Process, and the Taxing and Spending power also seem to favor the law. On July 1, 2010, a federal judge in Virginia heard arguments on the Federal Government’s motion to dismiss the Virginia based challenge to PPACA, in part, on the grounds that Congress had the constitutional authority to enact PPACA. A ruling is expected in late July. The Virginia lawsuit does not present all of the same arguments as the Florida suit, but the result of this ruling will certainly have a substantial impact on all legal challenges to the bill moving forward. The legal community will no doubt anxiously await this decision.

Endnotes

- 1 See Sheryl Gay Stolberg & Robert Pear, *Obama Signs Health Care Overhaul Bill, With a Flourish*, N.Y. TIMES, March 23, 2010, available at <http://www.nytimes.com/2010/03/24/health/policy/24health.html>.
- 2 See *Florida v. U.S. Department of Health and Human Services*, 3:10-cv-00091-RV-EMT, U.S. District Court for the Northern District of Florida, available at <http://www.healthcarelawsuit.us/>. The complaint was later amended to include seven more states as well as the National Federation of Independent Businesses (NFIB) and two individuals.
- 3 *Id.*
- 4 *Id.*
- 5 *Id.*
- 6 *Id.*
- 7 On March 23, 2010, the Attorney General of Virginia filed suit in federal court. The suit argued that PPACA was invalid on grounds that Congress exceeded its powers under the commerce clause. It also argued that a Virginia “anti-mandate” law shielding citizens from federal health insurance mandates was valid despite the supremacy clause because the PPACA was unconstitutional. On July 1, 2010, a federal judge in Virginia heard arguments on the federal government’s motion to dismiss the suit. A decision is expected by the end of July, 2010. The Virginia complaint is available at <http://jurist.org/paperchase/2010/06/virginia-ag-responds-to-motion-to-dismiss-health-care-lawsuit.php>.

Another lawsuit was filed on March 23, 2010, by the Thomas More Law Center, a public interest law firm based in Michigan. The Thomas More Law Center is described on their website as a “not-for-profit public interest law firm dedicated to the defense and promotion of the religious freedom of Christians, time-honored family values, and the sanctity of human life”. The lawsuit echoed the arguments put forth in the Florida and Virginia lawsuits (violations of the commerce clause, Tenth Amendment state sovereignty, Fifth Amendment due process, the taxing power) but added a First Amendment element to its challenge. They alleged that the PPACA violates their right of free exercise of religion by forcing the plaintiffs, as Christians, to fund abortions with their tax dollars. The Thomas More complaint is available at http://www.thomasmore.org/downloads/sb_thomasmore/TMLCFilesCourtChallengeMomentsAfterObamaHealth.pdf. The Thomas More Law Center’s website is located at <http://www.thomasmore.org>.

There are several other lawsuits in various stages of litigation pertaining to PPACA. See *Sollars v. Reid, et al.*, 1:09-cv-00361-TLS-RBC, U.S. District Court for the Northern District of Indiana, complaint available at <http://governwisely.org/ppaca/innd1-2009-cv-00361/zzqpmain>; *Judicial Watch, Inc., v. U.S. Dept. of HHS*, 1:10-cv-00443-ESH, U.S. District Court for the District of Columbia, complaint available at <http://governwisely.org/ppaca/dcdc1-2010-cv-00443/zzqpmain>; *Liberty University, Inc. et al. v. Geithner et al.*, 6:10-cv-00015-nkm, U.S. District Court for the Western District of Virginia, complaint available at <http://governwisely.org/ppaca/vawd6-2010-cv-00015/zzqpmain>; *Association of American Physicians & Surgeons v. Sebelius et al.*, 1:10-cv-00499-RMC, U.S. District Court for the District of Columbia, complaint available at <http://governwisely.org/ppaca/dcdc1-2010-cv-00499/zzqpmain>; *Walters et al. v. Holder et al.*, 2:10-cv-00076-KS-MTP, U.S. District Court for the Southern District of Mississippi, complaint available at <http://governwisely.org/ppaca/mssd2-2010-cv-00076/zzqpmain>; *Calvey et al. v. Obama et al.*, 5:10-cv-00353-R, U.S. District Court for the Western District of Oklahoma, complaint available at <http://governwisely.org/ppaca/okwd5-2010-cv-00353/zzqpmain>; *Shreeve v. Obama et al.*, 1:10-cv-00071, U.S. District Court for the Eastern District of Tennessee, complaint available at <http://governwisely.org/ppaca/tmed1-2010-cv-00071/zzqpmain>; *U.S. Citizens Association et al. v. Obama et al.*, 5:10-cv-01065-DDD, U.S. District Court for the Northern District of Ohio, complaint available at <http://governwisely.org/ppaca/ohnd5-2010-cv-01065/zzqpmain>.

8 Some states have chosen to enact “anti-mandate” laws shielding residents from federal mandates for health insurance. As of June 28, 2010, Virginia, Idaho, Utah, and Georgia had enacted statutes prohibiting or limiting the implementation of PPACA. Constitutional amendments will appear on the ballots in Arizona, Florida, and Oklahoma in November 2010 and in Missouri in August 2010. Twenty-four states have rejected such legislation and resolutions, including Alabama, Alaska, Arkansas, Colorado, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Nebraska, New Hampshire, New Mexico, North Dakota, Rhode Island, South Dakota, Tennessee, Washington, West Virginia, Wisconsin, and Wyoming. See the National Conference of State Legislatures website, located at <http://www.ncsl.org/?tabid=18906>.

All of these states used model legislation provided by the American Legislative Exchange Council (ALEC). The ALEC is an association of conservative policy advocates. Their model legislation for health reform is entitled the *Freedom of Choice in Healthcare Act* and can be accessed at http://www.alec.org/AM/Template.cfm?Section=Meet_our_Staff&CONTENTID=13652&TEMPLATE=/CM/ContentDisplay.cfm. (The proposed law protects the rights of individuals to purchase their medical care directly and to not be subject to a tax for

refusing to participate in a health insurance plan. This is the model legislation that recently passed in Virginia, leading to the federal lawsuit.)

9 See *Florida v. U.S. Department of Health and Human Services*, *supra* note 2.

10 See Pub. L. No. 111-148, § 1501. See also *Summary of the Health Care and Education Reconciliation Act*, Democratic Policy Committee Website, available at http://dpc.senate.gov/dpdod-sen_health_care_bill.cfm (“Specifically, the PPACA mandates that the tax increases gradually, from the greater of \$95 or 1% of income in 2014, \$325 or 2% of income in 2015, or \$695 or 2.5% of income in 2016 with a cap placed on the value of the national average cost of a bronze plan premium.”).

11 *Id.* See also *Florida v. U.S. Department of Health and Human Services* *supra* note 2.

12 See U.S. Const. Art. 1 Sec. 8 Clause 3.

13 See *United States v. Lopez*, 514 U.S. 549, 558-59 (1995).

14 *Id.* See also *United States v. Morrison*, 529 U.S. 598 (2000).

15 See *Lopez* *supra* note 9.

16 See *Morrison* *supra* note 20, at 613.

17 See *Gonzales v. Raich*, 545 U.S. 1, 18 (2005).

18 *Id.*

19 See Mark A. Hall, *The Constitutionality of Mandates to Purchase Health Insurance, Legal Solutions in Health Care Reform*, at 6, available at <http://www.law.georgetown.edu/oneillinstitute/national-health-law/legal-solutions-in-health-reform/1-eight-legal-issues.html>. (arguing that health insurance is often purchased through multi-state companies, and that “most medical supplies, drugs, and equipment are shipped in interstate commerce.”).

20 See *Florida v. U.S. Department of Health and Human Services* *supra* note 2.

21 See Hall *supra* note 19 (arguing that a mandate addresses free-rider and adverse selection problems reduces the cost of insurance); see also Jennifer Staman & Cynthia Brougher, *Requiring Individuals to Obtain Health Insurance: A Constitutional Analysis* (July 24, 2009) at 7, available at www.ncsl.org/documents/health/Constitutionality.pdf. (“...because one of the motivating factors for a requirement to obtain health insurance is to get healthy individuals who do not have health insurance to purchase it (so as to offset the cost of the individuals who need greater, more expensive care), this would also contribute to the proper functioning of the healthcare system.”).

22 *Id.*

23 *Id.*

24 See Staman & Brougher *supra* note 21.

25 *Id.* See also Hall *supra* note 19.

26 See Staman & Brougher *supra* note 21.

27 See *Florida v. U.S. Department of Health and Human Services* *supra* note 2. See also Pub. L. No. 111-148, § 1501.

28 *Id.*

29 See Edwin Cherminsky, *Constitutional Law: Principles and Policies* (New York: Aspen Law & Business, 3rd ed. 2006), at 675.

30 See Staman & Brougher *supra* note 21. See also *Nebbia v. New York*, 291 U.S. 502, 537 (1934) (“a state is free to adopt whatever economic policy may reasonably be deemed to promote public welfare, and to enforce that policy by legislation adapted to its purpose.”).

31 *Id.*

32 See *Williamson v. Lee Optical Co.*, 343 U.S. 483 (1955). (statute restricting the activity of optometrists by requiring those who needed eyeglasses to have a prescription upheld on a public health basis) See also *Nebbia v. New York* 291 U.S. 502 (1934) (where commission formed to fix milk process seen as a reasonable public health measure.).

33 See Pub. L. No. 111-148, § 1311.

34 See Pub. L. No. 111-148, § 1321.

35 See *Florida v. U.S. Department of Health and Human Services*, *supra* note 2.

36 See U.S. Const. Amend. X.

37 See *United States v. Darby*, 312, U.S. 100, 124 (1941) (“the amendment states but a truism that all is retained which has not been surrendered”).

38 See *New York v. United States*, 505 U.S. 144, 173 (1992); (“take title” provision of Low-Level Radioactive Waste Policy Amendments Act forcing non-compliant states to take ownership of radioactive waste in their borders seen as impermissible “commandeering” of state government to implement a federal program); *Reno v. Condon*, 528 U.S. 141, 151 (2000) (Challenge to Drivers Privacy Protection Act, which prohibited state departments of motor vehicles to disclose personal information rejected because the law prohibited *conduct* - i.e., the selling of private information to vendors - and did not require affirmative action by the state);

Printz v. United States, 521 U.S. 898, 922 (1997). (Court applied *New York v. United States* and struck down Brady Handgun Violence Prevention Act because it commandeered local and state law officials to implement background checks on handgun purchasers).

39 *Id.*

40 See *Printz*, 521 U.S. at 922.

41 See *New York*, 505 U.S. at 173.

42 *Id.* at 171-173.

43 See Pub. L. No. 111-148, § 1321.

44 *Id.*

45 See Hall *supra* note 19 (arguing the holding from *New York v. United States* that if the regulation is permissible under the Commerce Clause, Congress may offer states the choice of regulating according to federal standards or pre-empting state regulation and doing it themselves).

46 See Center for Children and Families, Georgetown University Health Policy Institute, *Early Wins for Children and Families in Health Care Reform*. Available at <http://ccf.georgetown.edu/index/early-wins>.

47 See Pub. L. No. 111-148, § 2101.

48 See *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528, 545-547 (1985). (“We...reject, as unsound in principle and unworkable in practice, a rule of state immunity from federal regulation that turns on a judicial appraisal of whether a particular government function is ‘traditional’ or ‘integral’”).

49 See Hall *supra* note 19 at 9.

50 See *Florida v. U.S. Department of Health and Human Services* *supra* note 2.

51 See Pub. L. No. 111-148, § 2001.

52 See Cherminsky, *supra* note 29 at 279. See also *Oklahoma v. Civil Service Commission*, 320 U.S. 127, 143 (1947) (holding that the conditioning of federal funds on states implementing civil service systems was a permissible exercise of spending power); *South Dakota v. Dole*, 483 U.S. 203, 206 (1987) (“Incident to the [spending clause] power, Congress may attach conditions on the receipt of federal funds.”).

53 *Id.*

54 See *Dole*, 483 U.S. at 212.

55 See *Florida v. U.S. Department of Health and Human Services* *supra* note 2.

56 See *Helvering v. Davis*, 301 U.S. 619, 640 (1937). (The discretion belongs to Congress, unless the choice is clearly wrong, a display of arbitrary power, not an exercise of judgment.”)

57 See David B. Rivkin, Jr., Lee A. Casey, Jack Balkin, Debate, *A Healthy Debate: The Constitutionality of an Individual Mandate for Health Insurance*, 158 U. Pa. L. Rev. PENNunbra 93 (2010), <http://www.pennunbra.com/debates/debate.php?did=23>.

58 *Id.*

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