Extracting the Financial Incentives of Health Care Reform for the Life Sciences Industry

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What is the Health Reform Law?

- Patient Protection and Affordable Care Act
  - Signed March 23, 2010
- Health Care and Education Reconciliation Act
  - Signed March 30, 2010

Conclusion of a Wild Year

- Health Reform Bills (House and Senate)
- January 2010, Scott Brown won, Democrats lost 60-senator supermajority that could break a filibuster.
- Health Reform on Life Support
- Sunday, March 21, 2010, House passed two bills
- On March 23, 2010, President Obama signed comprehensive health reform, the Patient Protection and Affordable Care Act, (PPACA) into law.
- Senate Bill (H.R. 3590)
- Sidecare Bill (H.R. 4872), various compromises between the two chambers.
  - Sidecar Bill "reconciliation" requires only a simple majority of 51 votes in the Senate, after the election of Sen. Scott Brown in January 2010 and Democrats lost 60-senator supermajority that could break a filibuster.
- Executive Order to Address Funding for Abortion Services (to address concerns of Rep. Bart Stupak (D-Mich.) that no federal funds will be spent under the legislation to cover abortion.)

Associated Costs and Estimated Impact

- CBO est.
  - $940 billion over the first 10 years
  - Reduce the deficit by $148 billion during the same period.
  - From 2020 – 2029, the legislation is projected to reduce the deficit by $1.2 trillion.
- The legislation will cover 32 million Americans (one million more than the Senate-passed bill), or 95 percent of the legal population.

Changes for Individuals

- Requires individuals to carry insurance or pay a tax penalty of $695 (Max of 2.5% of household income.)
- Expands Medicaid eligibility to those 133 % of FPL
  - Increased FMAP assistance for MA up from 50% to 90% in 2020 (additional $1.8b to MA from 2014-2019 and $347m each year thereafter).
- Establishes federal subsidies for up to 400% of FPL
  - MA covers up to 300%; change will cover add'l 75,000 people.
- Provides $4.1b in premium & cost-sharing tax credits for MA residents to purchase private health insurance.

Changes for Individuals (cont.)

- Eliminates co-pays and deductibles for preventive care.
  - MA currently requires at least 3 preventive visits pre-deductible.
- Requires Health insurance "exchanges" (MA Connector)
- Closes Medicare Part D "doughnut hole."
- Establishes a high-risk insurance pool for uninsured until the exchanges are operational in 2014.
- Provides for voluntary public long-term care insurance program (CLASS Act).
- Provides federal subsidies for legal immigrants.

Changes for Employers

- Employers not *required* to cover, but penalized $750 to $3,000 for each employee who qualifies for a federal subsidy.
- Offers tax credits to small employers.
  - Up to 35% of premium to small businesses who offer coverage in 2010 and up to 50% tax credit beginning in 2014.
- Creates a reinsurance program to incentivize employers to continue health coverage for their retirees aged 55-64, until the insurance exchanges are created.

Private Insurance Market Reforms

- Insurance companies prohibited from:
  - Denying coverage for pre-existing conditions;
  - Rescinding coverage when a patient falls ill;
  - Setting annual and lifetime limits on benefits;
  - Designing plans with exorbitant out-of-pocket expenses; &
  - Charging more based on gender.
  - MA already prohibits these practices.

- Young adults allowed to remain on parents' insurance plans through age 26.

Private Insurance Market Reforms (cont.)

- Insurance companies will be required to:
  - Have a Medical Loss Ratio (MLR) of 85% for group plans and 80% for individual plans by 2011; and
  - Submit justification for premium increases to the federal and state governments before they take effect which will be reviewed for reasonableness.
  - Provide standard benefits packages with options for varying levels of cost-sharing.

- MA Senate passed on 5/18/10 a small business health care cost relief bill that requires the commissioner of insurance to presumptively disapprove rate increases that are greater than 150% of medical inflation unless the carrier's MLR is at least 88% and profit or surplus is no more than 1%.

Payment Changes

- Increase Medicaid reimbursement for PCPs
- Medicare bonus payments for some PC services and general surgeons providing care in HPSAs
- Many Medicare and Medicaid demonstration programs/pilots
- Accountable Care Organizations (ACOs)
- Bundled payments Pilot Programs
- Independent payment advisory board to create binding proposals for Congress to slow the growth of Medicare costs.
- Prohibits federal payments for hospital acquired conditions.
- Promotes value-based purchasing for physicians and hospitals.

Fraud, Waste, and Abuse

- Increased funding
  - $250 million over six years to fund enforcement
  - Additional $95 million for FY 2011
  - FY 2010 all agency enforcement budget of over $311 million
- “Transparency” provisions
- “Compliance and ethics programs” required
- Harsher enrollment (particularly DME and HHA)
- Stark Changes and self-disclosure protocol
- Expands Recovery Audit Contractor (RAC) “bounty hunter” program will be expanded to cover Medicaid and Medicare C & D

How do we pay for it?

- TAXING:
  - Increasing Medicare payroll tax to 3.8% on individuals earning more than $200,000 annually ($250,000/couple) and expanding it to apply to investment income.
  - 2.3% tax on medical device makers.
  - Taxing pharmaceutical and health insurance industries
  - 40% excise tax on “Cadillac” plans ($10,200/individual; $27,500/family)
- CUTTING COSTS:
  - Lowers Medicare provider payments to hospitals, hospice, and home health agencies.
  - Cuts federal funds to MA plans through competitive bidding program
- FRAUD BUSTING:
  - Obama: “We've estimated that most of this [health care reform] plan can be paid for by finding savings within the existing health care system, a system that is currently full of waste and abuse.”

Tax Credit for New Therapies

- A credit for 50% of the "qualified investment" costs in 2009 and 2010 for a certified "qualifying therapeutic discovery project."
- Once certified, the credit applies to costs incurred in 2009 and 2010 regardless of when the project is completed (i.e., you get the credit even if the project is completed years later).
- Complex limitations on "doubling up" of benefits under other available tax credits or deductions.

Qualifying Therapeutic Discovery Project

- A "qualifying therapeutic discovery project" is a project that is designed —
  - To treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research protocols, for the purpose of securing approval of a product under Federal Food, Drug and Cosmetic Act §505(b) (21 USC 355(b)) or Public Health Service Act §351(a) (42 USC 262(a));

Qualifying Therapeutic Discovery Project (cont.)

- To diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics, molecular drugs and companion drugs and diagnostics to guide therapeutic decisions; or
- To develop a product, process, or technology to further the delivery or administration of therapeutics.

Qualified Investment Costs

- "Qualified investment" costs include those costs paid or incurred in the tax year for expenses necessary for and directly related to the conduct of a qualifying therapeutic discovery project.
- Specifically excluded are:
  - Remuneration of CEO and in the case of public companies, certain other highly compensated individuals.
  - Interest expense.
  - Facility maintenance expenses.
  - Certain indirect costs.
  - Other costs identified by the IRS (which it has not yet done).

Who Can Claim the Credit?

- Credit can be claimed by taxpayers that employ no more than 250 employees at the time of the submission of the application (for certification).
  - Not limited to full-time employees.
  - Does not include independent contractors or leased employees.
- Special "controlled group" rules apply for determining the number of employees.

The Grant Alternative

- In lieu of (but not in addition to) the credit, an eligible taxpayer can receive a grant equal to 50% of the qualified investment costs.
- The same qualification rules apply except that the following persons cannot apply for a grant:
  - Tax-exempt 501(c) organizations.
  - Governmental entities.
  - Certain issuers of qualified clean energy bonds.
  - Any pass-through entity that has one of the above as an equity participant.

How to Get it Certified

- The total amount of credits that can be allocated under the program can't exceed $1 billion for the 2-year period beginning with 2009.
- Each applicant for certification must submit a separate application for each project containing the information set forth in Notice 2010-45.
  - No guidance on how you determine what projects are separate.

How to Get it Certified (cont.)

- Applications due July 21, 2010 (postmark rule applies).
- IRS, in consultation with HHS, will take action to approve or deny any application before October 29, 2010.
- The application can include a request for an allocation of credits for both 2009 and 2010. If any credits still available after 10/29, a second round will be held but no guarantee that any credits will be available.

Notice 2010-45

- The review process must determine that:
  - The taxpayer's project is a qualifying therapeutic discovery project;
  - The taxpayer's project shows reasonable potential (a) to result in new therapies (i) to treat areas of unmet medical need, or (ii) to prevent, detect, or treat chronic or acute diseases and conditions, (b) to reduce long-term health care costs in the United States, or (c) to significantly advance the goal of curing cancer within the 30-year period beginning on May 21, 2010; and

Notice 2010-45 (cont.)

- The taxpayer's project is among those projects that have the greatest potential (a) to create and sustain (directly or indirectly) high quality, high-paying jobs in the United States, and (b) to advance United States competitiveness in the fields of life, biological, and medical sciences.

Application Form

- Applications for certification will be made on Form 8942, "Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program" and is available on www.irs.gov.
- The Form has to have a Project Memorandum attached.

Application Form (cont.)

- Appendix A of Notice 2010-45 elaborates on the information that will be required on Form 8942 and in the Project memorandum. Don't forget to read the Form instructions carefully.
- No appeal right in the event that the application is denied or the amount allocated is less than desired.

Effect of Certification

- Once certified, the credit is based on actual costs up to the amount certified.
- If total qualifying costs are less than the certified amount, the excess amount of credit cannot be utilized.
- If total qualifying costs are more than the certified amount, the taxpayer can allocate except that if costs incurred in both 2009 and 2010, have to allocate the certified amount first to all qualifying costs in 2009 and then the remainder to 2010.

Grant Application

- Can apply for a grant rather than a tax credit for a "qualifying therapeutic discovery project."
- Election to take grant made on Form 8942.
- Applicants for a grant must also register with the Central Contractor Registration (CCR) at www.ccr.gov/startregistration.aspx and a Dun & Bradsteet number is required.
- For 2009 tax year, grant paid no later than October 29, 2010.
- For 2010 tax year, grant paid during the 30-day period beginning on the day after the last day of the 2010 taxable year.

Excise Tax on Branded Prescription Drug Sales

- Beginning in 2011, an annual excise tax (nondeductible) will be payable by any manufacturers or importers on their sales of branded prescription drugs to certain government programs (e.g., Medicare, Medicaid, etc.).

Excise Tax on Branded Prescription Drug Sales (cont.)

- Branded prescription drugs are any prescription drug:
  - The application for which was submitted under §505(b) of the Federal Food, Drug, and Cosmetic Act (new drug applications, 21 U.S.C. §355(b)).
  - Any drug that is subject to §503(b) of the Federal Food, Drug, and Cosmetic Act (drugs that must be prescribed by a physician, 21 U.S.C. §353(b)).
  - Any biological product the license for which was submitted under §351(a) of the Public Health Service Act (PHSA) (license to introduce biologic products into interstate commerce, 42 U.S.C. §262(a)).

Specified Government Programs

- The following are the specified government programs to which the sales of branded prescription drugs are subject to the excise tax:
  - Medicare Part D Program under part D of title XVIII of the SSA (prescription drug insurance for Medicare recipients);
  - Medicare Part B Program under Part B of title XVIII of the SSA (provides supplemental insurance to cover medical costs not covered by Medicare Part A);

Specified Government Programs (cont.)

- Medicaid Program under title XIX of the SSA (state-funded with federal matching funds medical insurance for the indigent);
- Any program under which branded prescription drugs are procured by the Department of Veterans Affairs;
- Any program under which branded prescription drugs are procured by the Department of Defense programs; or
- TRICARE retail pharmacy program under §1074g of title 10 USC.

Calculation of the Excise Tax

- The tax is based on a fixed aggregate annual amount (e.g., $2.5b in 2011 and increasing to $4.1b in 2018) divided pro rata among all of the covered sales with a sliding scale of applicability for smaller manufacturers and importers.

Calculation of the Excise Tax (cont.)

- The fee will be calculated by the IRS for each taxpayer by determining all of the covered sales by all manufacturers and importers for the prior year, calculating the relative percentage of each manufacturer and importer's covered sales (reduced by a sliding scale for less than $400M of branded sales) to all such sales and then multiplying that percentage to the fixed annual amount.

Excise Tax on Sales of Medical Devices

- After Dec. 31, 2012, the sale of a taxable medical device by the manufacturer, producer, or importer will be subject to a tax equal to 2.3% of the sales price.
- A taxable medical device is any device (as defined in Sec. 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans, except:
  - Eyeglasses;
  - Contact lenses;
  - Hearing aids; and
  - Any other medical device determined by IRS to be of a type that is generally purchased by the general public at retail for individual use.

Exclusions

- The excise tax will not apply to the following exports or uses so long as such exportation or use is to occur before any other use:
  - For use by the purchaser for further manufacture, or for resale by the purchaser to a second purchaser for use by such second purchaser in further manufacture;
  - For export, or for resale by the purchaser to a second purchaser for export;
  - For use by the purchaser as supplies for vessels or aircraft;

Exclusions (cont.)

- To a State or local government for the exclusive use of a State or local government;
- To a nonprofit educational organization for its exclusive use; or
- To a qualified blood collector organization for such organization's exclusive use in the collection, storage, or transportation of blood.

Cures Acceleration Network

- Mission:
  - Acceleration “high needs cures”
  - Commercial incentives inadequate
  - Translation
  - Innovation
  - Safety and efficacy
  - Reduce barriers between discovery & FDA trials

Cures Acceleration Network (cont.)

- Board Memberships:
  - 12 industry representatives
  - 4 VCs
  - 8 advocacy groups
- Requirements:
  - Any size entity
  - Up to $15m per project
  - 1:3 match (waiver)
- Bridge across “valley of death”

Patient-centered Outcomes Research Institute

- NGO
- Mission:
  - Research focusing on sub-populations
  - Informed health decisions
  - Toward personalized medicine
  - Comparative clinical effectiveness
  - Cost containment

Physician Payment Sunshine Act

- Manufacturers
- Annual electronic reports
- Not gift ban
- Minimal exceptions
- Disclose physician and family ownership of manufacturers and GPOs
- State laws mostly survive

Clinical Trial Costs

- 2014: health insurance must cover “routine patient costs”
- Excludes:
  - Investigational items
  - Data collection

Expansion of Public Health Service Program

- PHS section 340B – lower prices for public service health care centers, clinics, hospitals
- Entity definition expanded to certain hospitals
  - Children's
  - Cancer
  - Critical access
  - Rural
- Excludes orphan drugs

Research Grants

- Emergency Medicine Basic Science Grants
  - NIH grants to study basic ER service
  - Meds for children in ER
- Women's Health Condition Grants
  - Research grants (office w/in HHS and CDC)
  - Office w/in FDA
- Tooth Decay Disease Management
  - Focus on children

Research Grants (cont.)

- Infectious Disease Surveillance Grants
  - $190M per year
  - State & local health department
  - Academic centers
- Causes & Treatments of Pain Research
  - Research
  - Educational programs
- Congenital Heart Disease
  - Causation

Research Grants (cont.)

- New Breast Cancer Screening
  - Young women (14 – 44)
- Postpartum Depression
  - $3m annually
  - Public or non-private entities
- Medicare Payments for Companion Diagnostics
  - 2 year demo project for direct payment to laboratories
  - Complex diagnostic lab tests
- Bone Density Tests
  - Restores payments to 70% of 2006 Medicare rate

Miscellaneous

- Physician subsidies in Medicaid
  - 10% incentive payment for primary care physicians
  - 10% incentive payment for general surgeons in shortage areas
  - 5% incentive payment for mental health services
- Administrative simplification of claims
- Preventive and screening benefit expansion

Thank You & Questions

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