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HEALTH CARE LAWYERS

THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2010

SUMMARY OF SELECT PROVISIONS AFFECTING PROVIDERS AND SUPPLIERS

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THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2010 "PPACA"

Introduction

By John R. Hellow

With a single stroke of his pen on July 30, 1965, Lyndon Johnson enacted the Medicare and Medicaid programs, a process begun by President Harry S. Truman in 1945. That very same day former President Truman became the first Medicare beneficiary with all the rights to those services immediately available. While the path to the passage of the Patient Protection and Affordable Care Act of 2010 ("PPACA" or "Act") on March 23, 2010 did not take quite so long, President Obama had to use his pen more than once to finish that legislative puzzle. Unlike the programs' initial creation, which became effective at a turn of a switch, the PPACA will take over five years to achieve its primary goal of dramatically expanding available health insurance coverage to the uninsured, and many of its ancillary goals including system redesign, cost controls and quality improvement will become effective over an equally long period. Indeed, many changes that become effective over the next year principally concern cuts to health care revenues to pay for the benefits of the Act that occur well into the future.

The legislative contortions necessary to the Act's passage created a maze of amendments and amendments to amendments.[1] Below, in an effort to provide a map to this maze, we set forth our synopsis of those sections of the Act affecting institutional providers and suppliers, including all relevant amendments to each such section. We do not purport to address all of the Act's many provisions, but we do endeavor to address those of significance to institutional providers. Consequently, while we review the Act in section order, there are gaps in that order for sections or entire Titles we do not address. In the coming months, we will address select topics from the Reform Legislation in more comprehensive white papers.

Finally, as you review the information below, please be aware that we identify each section of the PPACA as the primary reference and then we have inserted the pertinent section of the Senate managers' amendment (a number in the 10000 range) if any, and finally the HCEARA amendment (a number in the range of 1001 – 2303) if such amendment applies to that PPACA section.

1 In addition to the PPACA, several days later President Obama signed the budget reconciliation package, the Health Care and Education Affordability Reconciliation Act of 2010 ("HCEARA") that reconciled differences between the PPACA and certain corrections and enhancements emanating from the House of Representatives. The HCEARA also contains a set of managers' amendments set forth in the Section 10000 et seq. provisions of that Act. Finally, the House managers inserted a set of amendments ("HMAs") that were approved by both chambers and enacted by the President. The sections generally first referenced in this document are first to the PPACA and fall in the range of 1000-6000. Occasionally, a PPACA amendment section at 10000 et seq. is referenced after the PPACA section 1000-6000 that it amends. Additionally, some provisions of the PPACA are amended by the HCEARA and such amendment is referenced after the corresponding PPACA section. Finally, the HMA added some provisions as if they were part of the HCEARA and those are also addressed when relevant.

TITLE I – QUALITY AFFORDABLE HEALTH CARE FOR ALL AMERICANS

Title 1 sets forth the insurance reforms. Key elements include prohibiting pre-existing conditions or other health factors from being considered with respect to eligibility or pricing, limiting the ability to rescind policies, and creating insurance exchanges to enhance the availability of coverage in the individual and small group markets.

Subtitle A -- Immediate Improvements in Health Care Coverage for All Americans

Section 1001 (Section 10101) – Amendments to the Public Health Service Act ("PHSA")

1. Lifetime and Annual Limits (PHSA Section 2711)

Prior to 2014, insurers in the group or individual markets may not impose any lifetime coverage limits on the value of essential health benefits. However, such plans ("plans" and "insurers in the group or individual markets" are used interchangeably) may impose "restricted annual limits," as will be defined by the Secretary of Health and Human Services (the "Secretary"), on the value of "essential health benefits." After 2014, plans may not establish lifetime limits or annual limits on the dollar value of essential health benefits. However, for benefits that are <u>not</u> "essential health benefits," plans may place annual and lifetime per beneficiary limits.

2. Rescission of Coverage (PHSA Section 2712)

Insurers in the group or individual markets may not rescind an enrollee's coverage unless the enrollee obtained coverage through fraud or intentional misrepresentation of material fact as prohibited by the plan or coverage. If coverage is rescinded due to an enrollee's fraud or intentional misrepresentation, then the plan must still give prior notice of rescission to the enrollee.

3. Preventative Health Services (PHSA Section 2713)

The Act requires insurers in the group or individual markets to provide coverage, without any cost sharing requirements, for certain preventative health services, such as certain immunizations and screening tests.

4. Dependent Coverage (PHSA Section 2714)

Plans offered in the group or individual market that include dependent coverage must extend dependent coverage to adult children up to age 26, regardless of the adult child's marital status. However, the Act does not require that the child of an adult child receive coverage, and coverage does not need to be extended to the adult child if the adult child dependent is eligible to enroll in another employer-sponsored health plan.

5. Standardized Consumer Communications (PHSA Sections 2715 and 2715A)

Within 12 months after enactment of the Act, the Secretary must develop standards for plans to use in providing summaries of benefits and coverage information to enrollees, applicants, and certificate holders. The Act establishes certain minimum standards such as page limits, formatting rules, and language requirements. It also defines specific content pertaining to coverage limitations, share of cost requirements, and renewability provisions, among other things. Insurers will have to provide the information as defined by the Secretary and the Act by March 2012. Plans that must provide the information and fail to do so may be subject to fines for such failure. Plans will also have to provide the information that is provided by other health plans available on the Insurance Exchange. (*See* Subtitle C, *Part II for discussion of Exchanges.)*

6. Discrimination Based on Salary (PHSA Section 2716)

The Act prohibits group plans from instituting eligibility requirements that have the effect of discriminating in favor of higher wage employees. Plans are also not permitted to use lawful gun ownership as a basis for premium setting.

7. Premium Ratios (PHSA Section 2718)

The Act attempts to ensure plans will spend the vast majority of premiums on patient care as opposed to administration. The Act will require plans in the group and individual markets, (including grandfathered plans, but not self-insured plans) to report to the Secretary the amount of premium revenues spent on patient care, actions to improve quality, and all other non-claims costs. Starting in 2011, large group plans that spend less than 85 percent of premium revenue on reimbursement for clinical services and activities that improve health care, must pay an annual rebate to each enrollee. Thus, if more than 15 percent of a large group plan's premium revenue is expended on non-claims costs, the plan will be penalized. Plans in the small group market may not permit non-claims costs to exceed 20 percent of total premium revenue.

All hospitals in the United States must establish and update each year a list of the hospital's standard charges for items and services provided by the hospital, including charges for Medicare DRGs. The information must also be made available to the public.

8. Appeals Process (PHSA Section 2719)

The Act requires all insurers in the group and individual markets to implement an effective appeals process for coverage determinations and claims appeals. For group plans, the Secretary of Labor may require certain appeal rights and requirements. For plans in the individual market, the Secretary of HHS may establish certain standards. All appeals processes must include an external review procedure.

9. Patient Protections (PHSA Section 2719A)

The Act gives enrollees of plans the right to select any participating primary care provider or pediatrician who is available to accept the enrollee. The Act prohibits plans from requiring pre-

authorization for emergency services, regardless of whether the emergency provider is in network or out of network. The plan is also not permitted to force an increased share of cost when an enrollee seeks emergency services at an out of network provider. Female enrollees may not be required to seek pre-authorization or referral for obstetrical or gynecological care by a specialist who participates with the plan, i.e., is in the plan's network.

Section 1003 -- Monitoring of Health Plans and Providers

The Act provides $250 million in funding for the Secretary to award grants to the states for fiscal years 2010 through 2014 for monitoring health plans, premium practices and rate increases. The Secretary must establish a process with the states, whereby the states beginning in 2010 will monitor rate increases by health plans. For certain large increases in rates, plans will be required to provide necessary justification for certain large rate increases and make information about the request available to the public prior to a state giving approval for the request. For lesser rate increases, the state is charged with tracking changes to determine if the cumulative changes are reasonable. Based on a state's analysis, the state may recommend that the Secretary take action against an insurer to preclude participation in the Exchange (see Subtitle C, *Part II* for discussion of Exchanges). The states will also establish "medical reimbursement data centers" at academic or nonprofit institutions that will collect information on health care reimbursement. They will develop fee schedules and other data summary tools to reflect the market rates for medical services in a geographic area. Such health care cost information will be made available to the public through the internet so that the public may understand what health care providers are charging for medical services.

Section 1004 -- Unless otherwise specified, the insurance reforms described in Subtitle A take effect for group health plan years and individual health insurance coverage years beginning 6 months after the date of enactment.

Subtitle B -- Immediate Actions to Preserve and Expand Coverage

Unless otherwise specified, the reforms in Subtitle B take effect immediately, upon enactment, March 23, 2010.

Section 1101 -- Immediate Access to Insurance for Uninsured Individuals with a Pre-Existing Condition

Within 90 days of enactment, the Secretary shall establish a temporary high risk insurance pool program. Five billion dollars is currently allotted for the program that will expire January 1, 2014. It will provide access to health care coverage for those who are particularly costly to insurers or cannot secure coverage from insurers due to pre-existing conditions. People with pre-existing conditions who have not had insurance for at least six months will receive access to coverage that exposes them to no more than 35 percent of the allowable costs of treatment with out-of-pocket caps at $5,950 a year for an individual or $11,900 for a family.

Section 1102 (Section 10102)-- Subsidies for Employers Providing Coverage to Retirees

Within 90 days of enactment, the Secretary must create a program that provides reimbursement to employers whose group health plans cover individuals who retire, do not currently qualify for Medicare, and are between the age of 55 and the age they are on the date they become eligible for Medicare, up to age 65. Employers providing such coverage may qualify for reimbursement of up to 80 percent of the costs of providing the coverage to such individuals, when the costs exceed $15,000, but do not exceed $90,000. The reimbursement payments are to be used to lower the employer's plan expenses. Five billion dollars in funding is provided for the temporary program, which expires on January 1, 2014.

Section 1103 -- Consumer Access to Information to Identify Affordable Coverage Options

The Act requires the creation of an internet portal whereby consumers may compare health insurance options, including those under federally funded programs such as Medicare and Medicaid. The Secretary may contract with certain entities to perform this service.

Section 1104 – Administrative Simplification

This provision supplements the purpose of Section 261 of HIPAA by inserting into the purpose statement the clause "to reduce the clerical burden on patients, health care providers, and health plans." Section 1104(a)(2). The inserted phrase establishes Congress' intent to revise the HIPAA administrative simplification provisions to ease the administrative burden on health care participants through the use of HIT.

The Secretary is directed to adopt standards and operating rules to "enable determination of an individual's eligibility and financial responsibility for specific services prior to or at the point of care." In addition, the Secretary must "seek to reduce the number and complexity of forms, including paper and electronic forms, and data entry required by patients and providers. The Secretary is further required to consider the recommendations developed by a "qualified nonprofit entity." Those rules, adopted by regulation, must specify the requirements of such a nonprofit entity: dedicated to administrative simplification, multi-stakeholder and consensus-based, transparent governance and open to public review.

Health plans must certify to the Secretary by December 31, 2013, that their data and information systems are in compliance with Section 1104's standards and operating rules for electronic funds transfers, eligibility for a health plan, health claim status, and health care payment and remittance advice. By December 31, 2015, plans must certify that their data and information systems comply with Section 1104's standards and operating rules for health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, health claims attachments, and referral certification and authorization.

The Secretary must conduct periodic audits to ensure the health plans comply with these standards and operating rules by April 1, 2014. The Secretary must assess a penalty fee against a health plan for noncompliance with certification and documentation requirements of $1 per member per day of noncompliance up to $30 per member per day of noncompliance if there is misrepresentation involved.

The penalties will be increased annually based on the annual percentage increase in total national health expenditures, as determined by the Secretary.

Section 1104 requires the Secretary to issue an interim final rule to establish a unique health plan identifier (as described by 42 U.S.C. § 1320d-2(b)) effective by October 1, 2012. The Secretary must also issue an interim final rule to establish a standard for electronic funds transfers by January 1, 2012, effective by January 1, 2014. Finally, the Secretary must issue a final rule to establish a transaction standard and a single set of associated operating rules for health claims attachments (as described in 42 U.S.C. § 1320d-2(a)(2)(B)) that is consistent with the X12 Version 5010 transaction standards. The transaction standards and operating rules must be adopted via interim final rule by January 1, 2014, effective by January 1, 2016.

Subtitle C -- Quality Health Insurance Coverage for All Americans

Parts I and II—Health Insurance Market Reforms

Insurance Reforms – Expanding the Risk Pool and Reining in Prices

One of the fundamental tenets underlying the Act is the notion that in order to rein in the rising costs of health care, it is critical to expand the risk pool of insured Americans as broadly as possible. The Act strives to expand the current insured risk pool through several mechanisms, including improving access to insurance, ensuring that health insurance meets certain minimum benefits requirements, and imposing price controls to ensure that insurance remains affordable. Unless otherwise noted, the insurance reforms contained in the Act generally take effect for plan years beginning on or after January 1, 2014.

Section 1201 (Section 10103)

1. Access to Insurance (PHSA Sections 2702-2705, 2708)

The Act prohibits insurers in the group or individual markets from denying insurance coverage due to any pre-existing condition. For enrollees under 19 years old, this prohibition takes effect for plan years beginning on or after the date that is 6 months after enactment, although some insurers now dispute this view of the Act's effective date for this provision. The Act also prohibits insurers from discriminating against individuals or participants based on health status, and prohibits group plans from imposing waiting periods greater than 90 days. In addition, the Act requires guaranteed issue (subject to annual and special open enrollment periods) and guaranteed renewability (for plans other than self-insured plans). The Act also promotes improved coverage of clinical trials by requiring group and individual plans to cover routine patient costs for items and services furnished in connection with participation in certain clinical trials by qualified individuals.

2. Employer Wellness Programs (PHSA Section 2705)

The Act imposes new requirements on employer wellness programs by permitting premium differentiation and other rewards only for programs that meet various requirements under the Act. The Act grandfathers existing wellness programs that comply with applicable regulations as of March 23,

2010. The Act authorizes a 10 State demonstration for wellness programs in the individual market, to begin not later than July 1, 2014, with the potential for expansion in July 2017 if the Secretaries of Treasury and Labor determine that the demonstration project is effective. The Act establishes criteria for State participation in the demonstration.

3. Discrimination Against Providers (PHSA Section 2706)

The Act prohibits insurers from discriminating against any health care provider acting within the scope of the provider's professional license and applicable State laws, although the Act does not require insurers to contract with providers and insurers remain permitted to vary provider rates based on "quality or performance."

4. Benefit Structure (PHSA Section 2707)

Health insurance issuers in the small group and individual markets must provide coverage for the "essential health benefits package" (described in more detail below). The Act requires group plans to meet certain cost-sharing requirements, and requires offering of child-only plans in certain circumstances. The benefit structure requirements do not apply to dental-only plans.

Sections 1201 and 1252 -- Pricing of Insurance (PHSA Section 2701)

The Act imposes several pricing controls on health insurance. It limits insurers' ability to vary premiums in the individual and small group markets and the Exchange to four underwriting criteria: (1) number of family members; (2) geography ("rating areas"); (3) age (limited to 3:1 ratio); and (4) tobacco use (limited to 1.5:1 ratio). The Act requires each State to establish 1 or more rating areas, subject to Secretarial review (if rating areas are not "adequate," Secretary can establish rating areas); and requires the Secretary, in consultation with National Association of Insurance Commissioners ("NAIC"), to establish permissible age bands. The standards and requirements adopted by States must be applied uniformly to all plans in each relevant insurance market in a State.

Section 1251 – Grandfathering Existing Plans

In addition to creating ways for insurance consumers to "get in the door" and stay in a plan, the Act preserves the ability of consumers to maintain their existing coverage by "grandfathering" existing plans, including the ability to add family members and new employees to existing plans. Grandfathered plans include coverage maintained pursuant to a collective bargaining agreement. When the insurance reforms become applicable to other plans, grandfathered individual and group plans must be required to meet requirements related to excessive waiting periods, lifetime limits, rescissions, and extension of dependent coverage. Grandfathered group plans will also be required to meet annual limit and pre-existing condition requirements when applicable to other plans, but will be required to cover dependent children up to age 26, starting in 2014, only if the adult child is not otherwise eligible for an employer-sponsored plan.

Subtitle D -- Available Coverage Choices for All Americans

Part I -- Establishment of Qualified Health Plans

Section 1301 -- Qualified Health Plans

Several of the Act's provisions require or relate to a "qualified health benefit plan," which the Act defines as a plan that meets criteria for certification by Exchanges where it is offered; provides the "essential health benefits package" (defined below); and is offered by a licensed insurer that agrees to (1) offer at least one "silver" and one "gold" plan in each Exchange through which the plan is offered (*see Section 1303 for a discussion of plan levels*); (2) agrees to charge the same premium rate for each qualified health plan whether offered inside or outside of the Exchange; and (3) complies with federal regulations. "Qualified health benefit plan" includes a CO-OP plan or a multi-State plan (*see Section 1322 for a discussion of CO-OP plans*). The Act permits a qualified health benefit plan to provide coverage through a qualified direct primary care medical home plan, and permits such a plan to vary premiums by rating area.

Section 1302(b) -- Essential Health Benefits Package

The Act creates an Essential Health Benefits Package that: (1) provides coverage for "essential health benefits" as defined in the Act; (2) limits annual cost-sharing to the current law Health Savings Account (HSA) limits ($5,590/individual and $11,900/family in 2010); and (3) provides one of the four benefit categories defined in the Act (discussed below). The Act requires the HHS Secretary to define and annually update the essential health benefits package through a transparent and public process. The Act requires the essential benefits package to be equal to the scope of typical employer plan benefits, and requires the Secretary to consider certain factors and to use notice and comment rulemaking to establish the package. The Act limits cost-sharing within a self-only plan beginning in 2014 and other coverage starting in 2015, and imposes an annual limit on deductibles in the small group market ($2,000/individuals, $4,000 for other plans) (indexed based on premium adjustments). The Act prohibits abortion coverage from being required as part of the essential health benefits package.

Section 1302(d) -- Levels of Coverage

The Act creates four benefit categories of plans (bronze, silver, gold, platinum) plus a catastrophic plan to be offered through the Exchange, and in the individual and small group markets. All four plan benefit categories must provide essential health benefits and limit out-of-pocket costs to the HSA current law limits. The four basic plans differ in the percent of plan benefit costs they cover – Bronze represents minimum creditable coverage and covers 60 percent of plan benefit costs; Silver covers 70 percent; Gold covers 80 percent; and Platinum covers 90 percent. The level of coverage of a plan would be determined on the basis that the essential benefits are provided to a standard population. The Act requires the Secretary to issue regulations whereby the employer contribution would be taken into account in determining the level of a plan offered by an employer. In addition to the four basic benefit categories, the Act allows catastrophic-only policies for people 30 years or younger who are exempt from the individual responsibility requirement because coverage is unaffordable to them or they have a hardship. Regardless of the benefit category, the Act requires qualified health plans to pay for services rendered at FQHCs at the same rate that would have been paid to the FQHC under federal law.

Section 1303 (Section 10104j) — Special Rules

Less than a year after the civil False Claims Act ("FCA") was significantly changed by the Fraud Enforcement and Recovery Act of 2009, the statute has again been changed by the recent health care reform legislation. This time, the change lowers the FCA's long-standing bar to certain whistleblower lawsuits based on the prior "public disclosure" of the allegations unless the relator is the "original source" of such allegations. While the bar remains structurally intact, Congress has modified application of this statutory provision in the following respects:

Under the prior "public disclosure/original source" bar, public disclosure sources included (a) a criminal, civil, or administrative hearing, (b) a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or (c) the news media. As interpreted by certain courts, these disclosure sources included both federal and state proceedings. The revised provision now specifies that it only applies to federal hearings and a federal administrative report, hearing, audit, or investigation, while retaining the other congressional, Government Accounting Office, and new media sources.

As a practical matter, this means that a whistleblower may now file a federal FCA lawsuit without being the original source even if the allegations have already been publicly disclosed in a state proceeding, including a wrongful termination lawsuit, an action brought under a state false claims statute, or a published state Medicaid program audit report. Note, however, that allegations in many state proceedings – including criminal prosecutions, civil lawsuits, and agency reports – are routinely published on the Internet and may still trigger the public disclosure bar because most courts interpret "news media" to include information disseminated on the Internet to the general public.

If the FCA lawsuit's allegations have been previously disclosed, the prior definition of an "original source" required the lawsuit to be dismissed unless the relator had "direct and independent knowledge of the information on which the allegations are based . . ." The new provision expands this exception to the public disclosure bar by eliminating the "direct" knowledge requirement, while still requiring a relator to have "knowledge that is independent of and materially adds to the publicly disclosed allegations" to qualify as an original source. Since the meaning of "materially adds" is undefined, courts will have to decide what level of independent knowledge is sufficient to add something of value to allegations that have already been publicly disclosed. Nevertheless, standing alone, the revised "original source" exception still appears to prevent a relator without any first hand knowledge from bringing an FCA action based entirely on information acquired secondhand from public sources.

If the "public disclosure/original source" bar applies, a district court was previously required to dismiss the whistleblower's lawsuit for lack of "jurisdiction." Under the new provision, however, the district court's dismissal is only mandatory if government does not oppose application of the bar. Put another way, without explanation, it appears the government may trump the "public disclosure/original source" bar and permit a whistleblower to bring an FCA action based entirely on information acquired secondhand from public sources, but without any insider knowledge of the allegations.

While the government presumably will not want to share an FCA recovery with every whistleblower without original knowledge, the new provision appears to authorize the government to reward whistleblowers who identify false claims based on information entirely in the public domain,

but which may not yet have come to the government's attention. In addition, since the Supreme Court previously held that the prior "public disclosure/original source" bar was jurisdictional and applied even if the government intervened, the new provision eliminates the word "jurisdiction" to reflect Congress's apparent belief that the government – rather than the district court – should ultimately decide whether the bar should apply to a particular relator.

Section 1304 -- Definitions Applicable to Qualified Health Plans

The Act largely adopts existing definitions from the Public Health Service Act in establishing qualified health plans. The Act also adds definitions of "large employer" (employed average of 101 or more employees on business days during the preceding calendar year) and "small employer" (same definition as large employer but for 1-100 employees). The Act allows States to cap small employers at 50 employees for years prior to 2016, and allows small businesses participating in the Exchange to continue to be treated as eligible even if more employees are hired. The Act also defines "educated health care consumers," who are required to be consulted by the Exchanges for input on various issues under Section 1311(d)(6).

Part II -- Consumer Choices and Insurance Competition Through Health Benefit Exchanges

Section 1311 -- Affordable Choices of Health Benefit Plans

The Act requires each State to establish an American Health Benefit Exchange ("Exchange") by 2014. The Exchanges facilitate the purchase of qualified health plans and include a Small Business Health Options Program ("SHOP") Exchange for small businesses. The Act requires the Secretary to award grants to States for the planning and establishment of Exchanges, which will be available until 2015. The Act requires the Secretary to:

- Establish certification criteria for qualified health plans. This criteria must require plans to meet marketing requirements, ensure a sufficient choice of providers, include essential community providers in their networks that serve predominantly low-income individuals, be accredited on quality, implement a quality improvement strategy, utilize a uniform enrollment form, utilize a standard format for presenting plan information in a standard format, and provide data on quality measures. However, a qualified health plan is not required to include in its network a provider that does not accept its generally applicable payment rates.

- Develop a rating system that would rate qualified health plans offered through an Exchange, as well as provide a model template for an Exchange's Internet portal.

- Determine an initial and annual open enrollment period, as well as special enrollment periods for certain circumstances.

Under the Act, Exchanges must certify "qualified health plans." Exchanges may certify a health plan if it meets the certification criteria developed by the Secretary and offering it is in the interests of individuals and employers. Plans seeking certification by Exchanges must publicly disclose, in plain language, information on claims payment policies, enrollment, denials, rating practices, out-of-network cost-sharing for a specific item or service, and enrollee rights. (The Act requires the Secretary of Labor

to update the rules for group health plans to also conform to these disclosure standards.) Exchanges must operate a toll-free hotline and Internet portal, rate qualified health plans, present plan options in a standard format, inform individuals of eligibility for Medicaid and CHIP, provide an electronic calculator to calculate plan costs, and grant certifications of exemption from the individual responsibility requirement. Beginning in 2015, Exchanges must be self-sustaining and will be allowed to charge assessments or user fees.

Under the Act, States may require additional health benefits beyond the "essential health benefits," but States must defray the cost of such additional benefits directly to individuals or plans. The Act allows States the flexibility to create regional or interstate Exchanges if the Secretary approves of such Exchanges.

The Act requires the Secretary to develop guidelines regarding improving health outcomes, preventing hospital readmissions, improving patient safety, promoting health and wellness, and reducing health disparities. Qualified health plans must implement these guidelines through strategic payment structures such as increased reimbursement or other incentives.

Exchanges must award grants to "Navigators" – entities including but not limited to trade and professional associations, community and consumer non-profit groups, unions, or insurance agents or brokers – that educate the public about qualified health plans, distribute impartial information on enrollment and tax credits, facilitate enrollment, and provide referrals on grievances, complaints, or questions.

Section 1312 -- Consumer Choice

The Act allows "qualified individuals," defined as individuals who are not incarcerated and who are lawfully residing in a State, to enroll in qualified health plans through that State's Exchange. The Act allows qualified employers to offer a choice of qualified health plans at a specified level of coverage which the employee may choose. Initially, only small employers may be deemed "qualified." States may allow large employers to qualify beginning in 2017. Insurers must pool the risk of all enrollees in all plans (except grandfathered plans) in each market, regardless of whether plans are offered through Exchanges. The Act requires the Secretary to establish procedures under which States may allow agents or brokers to enroll individuals and employers in qualified health plans and assist individuals in applying for tax credits and cost-sharing reductions.

Section 1313 -- Financial Integrity

The Act requires Exchanges to keep an accurate accounting of all activities, receipts and expenditures, and to submit annual accounting reports to the Secretary. The Secretary may investigate an Exchange, and Exchanges must cooperate with Secretarial investigations. The Secretary will also conduct annual audits of the Exchanges. If the Secretary finds serious misconduct in a State, the Secretary may rescind up to 1 percent of Federal payments to the State. Federal payments related to Exchanges are subject to the False Claims Act. The GAO will conduct an ongoing study of Exchange activities and the enrollees in qualified health plans offered.

Part III – State Flexibility Relating to Exchanges

Section 1321 – Exchange Standards

The Secretary must set standards for: (1) establishing and operating Exchanges; (2) offering of qualified health plans through Exchanges, and (3) establishing reinsurance and risk adjustment programs for each State for implementation by no later than 2014. Such standards will be developed in "consultation" with the National Association of Insurance Commissioners, consumer organizations, and other individuals the Secretary selects to ensure "balanced representation." If the Secretary determines before 2013 that a State will not have an Exchange operational by 2014, or will not implement the standards, the Secretary must establish and operate an Exchange in the State, either directly or through agreement with a nonprofit entity. States operating an Exchange before January 1, 2010 are presumptively in compliance with the standards.

Section 1322 – Loan and Grant "CO-OP"

To encourage the creation of qualified nonprofit health insurance issuers to offer qualified health plans in the individual and small group markets, the Secretary will award loans and grants through the Consumer Operated and Oriented Plan ("CO-OP") program to help meet start up costs and State solvency requirements. If no health insurance issuer applies to be a qualified nonprofit health insurance issuer within a State, the Secretary may use appropriations to establish qualified nonprofit health insurance issuers within the State, or to expand a qualified nonprofit health insurance issuer from another State to the State.

Section 1323 – Private Purchasing Council

Qualified nonprofit health insurance issuers participating in the CO–OP program may establish a private purchasing council. The purchasing council may enter into collective purchasing arrangements for items and services, but may not set payment rates. The Comptroller General of the General Accountability Office must conduct an ongoing study on competition and market concentration in the health insurance market after the implementation of the Act. The sum of $6 billion will be appropriated for the CO-OP program. CO-OP program participants will be exempt from taxation under amendments to Section 501(c) of the Internal Revenue Code.

Section 1324 -- Level Playing Field for CO-OP Plans

A "level playing field" will be created by making private health insurers subject to all Federal and State laws applicable to CO-OP program qualified health plans and multi-State qualified health plans, with respect to laws concerning guaranteed renewal, rating, pre-existing conditions, non-discrimination, quality improvement and reporting, fraud and abuse, solvency and financial requirements, market conduct, prompt payment, appeals and grievances, privacy/ confidentiality, licensure, and benefit plan material or information.

Part IV—State Flexibility to Establish Alternative Programs

Section 1331 – State Contracting for Individual Coverage

States may contract through a competitive process with standard health plans for individuals: (1) who are not eligible for Medicaid or other affordable coverage; (2) less than 65 years of age; and (3) have income between 133 and 200 percent of the Federal Poverty Level (FPL). In such case, the Secretary must certify that participating individuals do not have to pay more in premiums and cost-sharing than they would have paid under qualified health plans, and that the plans cover essential health benefits. The Secretary must transfer to participating States 95 percent of the tax credits and cost-sharing reductions that would have been provided to individuals enrolled in standard health plans if they were enrolled in qualified health plans.

Section 1332 -- State Application for Waiver of Requirements

Starting January 1, 2017, States may apply for a waiver of requirements relating to qualified health plans, Exchanges, cost-sharing reductions, tax credits, the individual responsibility requirement, and shared responsibility for employers, for a period of up to 5 years, with an option to extend the waiver upon request to the Secretary. The Secretary must provide to a State the aggregate amount of tax credits and cost-sharing reductions that would have been paid to residents of the State in the absence of a waiver. The Secretary must determine that the State plan for a waiver will provide coverage that is at least as comprehensive and affordable, to at least a comparable number of residents, as the Act would provide; and that it will not increase the Federal deficit.

Section 1333 -- Interstate Health Care Choice Compacts

By July 1, 2013, the Secretary, in consultation with the National Association of Insurance Commissioners, must issue regulations for interstate health care choice compacts, which can be entered into beginning in 2016. Under such compacts, qualified health plans could be offered in all participating States, but insurers would still be subject to unfair trade practices, network adequacy, and consumer protection laws of the purchaser's State. Insurers would be required to be licensed in all participating States (or comply as if they were licensed). States must enact a law to enter into compacts and Secretarial approval, but only if the Secretary determines that the compact will provide coverage that is at least as comprehensive and affordable, to at least a comparable number of residents, as the Act would provide; and that it will not increase the Federal deficit or weaken enforcement of State consumer protection laws.

Section 1334 – Multi-State Qualified Health Plan Contracts

The Director of the Office of Personnel Management ("Director") must enter into contracts with health insurance issuers without regard to competitive bidding, to offer at least two multi-State qualified health plans (at least one of which must be a nonprofit) through each Exchange in each State to provide individual and group coverage. The Director must implement such contracting provisions consistent with Federal Employees Health Benefit Program ("FEHBP") medical loss ratios, profit margins, and the premiums to be charged. Multi-State qualified health plans contracting with the Director must meet minimum benefits requirements and other standards applicable to qualified health plans, and must offer

the plan in all geographic regions and in all States that have adopted adjusted community rating before the Act's enactment. Enrollees in the multi-State qualified health plans shall be treated as a separate risk pool from enrollees in the FEHBP.

Part V -- Reinsurance and Risk Adjustment

Section 1341 -- Transitional Reinsurance Program For Individual Market In Each State

The Act requires States to establish a non-profit reinsurance entity that collects payments from insurers in the individual market and makes payments to such insurers that cover high-risk individuals. The Secretary must establish Federal standards for the determination of high-risk individuals. The Secretary must also develop a formula for payment amounts, as well as contributions required of insurers, which will total $25 billion over 2014, 2015 and 2016.

Section 1342 -- Establishment of Risk Corridors for Plans in Individual and Small Group Markets

The Act requires the Secretary to establish and administer "risk corridors" for qualified health plans in 2014, 2015, and 2016. If a plan's "allowable costs" (total costs other than administrative costs) exceed 103 percent of total premiums, the Secretary will make payments to the plan to defray the excess. If a plan's allowable costs are less than 97 percent of total premiums, the plan must make payments to the Secretary.

Section 1343 -- Risk Adjustment

The Secretary, in consultation with the States, will establish criteria and methods for carrying out risk adjustment activities. These guidelines will require States to provide payments to health plans with enrollees of higher-than-average risk, and assess charges on health plans with enrollees of lower-than-average risk. Risk adjustment applies to plans in the individual and small group markets, but not to grandfathered health plans.

Subtitle F -- Shared Responsibility for Health Care

Overall Summary -- In order to effectively expand the risk pool of insureds, the Act requires individuals to obtain minimum creditable coverage, requires employers to ensure that their employees obtain such coverage, and imposes penalties on both individuals and employers for failing to do so.

Section 1501-02 -- Individual Mandate

All individuals will be required to have health insurance, with limited exceptions, beginning in 2014. Those who fail to obtain minimum essential coverage will be required to a pay a yearly financial penalty of the greater of $695/person (up to a maximum of $2,085/family), or 2.5 percent of household income, which penalties will be phased in from 2014-2016. After 2016, the penalty amounts will be increased by an annual cost of living adjustment. Minimum coverage includes a government plan (Medicare, Medicaid, CHIP, TRICARE, VA, etc.), an employer-sponsored plan, plans in the individual market, grandfathered health plans, or other coverage recognized by the Secretary. Exceptions will be given for financial hardship and religious objections; to American Indians; to people who have been

uninsured for less than three months; to those for whom the lowest cost health plan exceeds 8 percent of income; and if the individual has income below the tax filing threshold ($9,350/individual and $18,700/married couple in 2009). The Act requires reporting of coverage by individuals, employers, and governmental units under the Internal Revenue Code, and requires the IRS to notify individuals of non-enrollment.

Section 1511-14 (Section 10108) -- Employer Requirements

The Act does not contain an employer mandate, but does impose several requirements on employers with respect to ensuring that employees obtain minimum essential coverage. Employers with more than 50 employees will be assessed a fee of $2,000 per full-time employee (in excess of 30 employees) if they do not offer coverage and if they have at least one employee who receives a premium credit through an Exchange. Employers that do offer coverage but nevertheless have at least one employee who receives a premium credit through the Exchange are required to pay the lesser of $3,000 for each employee that receives a premium credit, or $2,000 for each of the employer's full-time employees. Employers must notify their employees of the existence of the Exchange, and if the employer plan's share of the employer plan's benefit costs is less than 60 percent, must notify employees that they may be eligible for a premium credit through the Exchange. Employers with more than 200 employees will be required to automatically enroll employees into the employer's lowest-cost premium plan if the employee does not sign up for employer coverage or fails to opt out of coverage.

In addition, employers that offer coverage will be required to provide a "free choice voucher" to employees with incomes below 400 percent of the poverty level if their share of the premium cost is between 8.0-9.8 percent of income (indexed based on the rate of premium growth starting in 2014) to enable them to enroll in a plan in an Exchange. The free choice voucher must be equal to the contribution that the employer would have made to its own plan. Employers that offer a free choice voucher will not be subject to the penalties above.

Finally, large employers will be required to report to the IRS whether they offer full-time employees and their dependents the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan, the length of any applicable waiting period, the lowest cost option in each of the enrollment categories under the plan, and the employer's share of the total allowed costs of benefits provided under the plan. Large employers will be required to also report the number and names of full-time employees receiving coverage and to furnish statements to employees about whom information is reported.

Subtitle G -- Miscellaneous Provisions

Section 1552 -- New HHS Secretary Powers

By April 22, 2010, the Secretary shall publish on the HHS website a list of all of the authorities provided to the Secretary under this Act.

Section 1554 -- Limits on HHS Secretary Powers

The Act prevents the Secretary from promulgating regulations that create unreasonable barriers to individuals obtaining medical care; impede timely access to health care services; interfere with communications regarding a full range of treatment options between patient and provider; restrict

the ability of providers to provide full disclosure of all relevant information for making health care decisions; violate the principles of informed consent and ethical standards of health care professionals; or limit the availability of treatment for the full duration of a patient's medical needs.

Section 1555 --Freedom Not to Participate in Federal Health Insurance Programs

The Act clarifies that no individual, company, business, nonprofit entity, or health insurance issuer shall be required to participate in any Federal health insurance program created under this Act.

Section 1558 -- Protections for Employees

Amends the Fair Labor Standards Act to ensure that no employer shall discharge or in any manner discriminate against any employee with respect to his or her compensation, terms, conditions, or other privileges of employment because the employee has received a premium tax credit; has provided or caused to be provided information relating to a violation of Title I; has testified or is about to testify about such violation; has assisted or is about to assist in such a proceeding; or has objected to or refused to participate in an activity the employee reasonably believes to be in violation of Title I.

Section 1559 -- Oversight by OIG.

The Inspector General of the Department of HHS shall have oversight authority with respect to the administration and implementation of Title I related to quality affordable health care for all Americans.

Section 1561 – Health Information Technology Enrollment Standards and Protocols

Section 1561 requires the Secretary, no later than 180 days after enactment, and in consultation with the HIT Policy Committee and the HIT Standards Committee of the Office of the National Coordinator for Health Information Technology (ONCHIT) to develop interoperable and secure standards and protocols that facilitate the enrollment of patients in federal and state health programs. The means for doing so will include standards and protocols for electronic matching of existing federal and state vital records, employment history, enrollment systems, tax records and other data; reuse of stored eligibility information, online application, recertification and eligibility processes and information and communication via email and cellular phones, among other means. The Secretary can also require that states or other entities incorporate any such standards and protocols approved by the HIT Policy Committee and the HIT Standards Committee as a condition of receiving Federal funds for HIT investments.

Finally, the Secretary will also be authorized to award grants to entities to develop technology systems to implement these HIT enrollment standards and protocols. To be eligible, an entity must be a state, political subdivision of a state, or local government entity and submit an application containing information determined by the Secretary.

TITLE II – ROLE OF PUBLIC PROGRAMS

Subtitle A -- Improved Access to Medicaid

Section 2001 & Section 1201 of the Reconciliation Act – Medicaid coverage for the Lowest Income Populations

Section 2001 makes substantial changes to Medicaid eligibility, benefits, and the Federal Matching Assistance Percentage ("FMAP"), and imposes a maintenance of effort requirement on the states.

1. Medicaid Eligibility Expansion

Section 2001 expands mandatory Medicaid coverage as of January 1, 2014, to individuals under 65 years of age, not pregnant, not entitled to or enrolled in Medicare Part A and whose income does not exceed 133 percent of FPL for the applicable family size, that are not currently eligible for benchmark coverage or an equivalent under a state plan or waiver. These individuals will become eligible for benchmark coverage or an equivalent. (These individuals, who are not already eligible for Medicaid, are referred to as "newly eligible" individuals.")

Medicaid eligibility for children ages 6 to 19 also increases to 133 percent of the FPL as of January 1, 2014.

States have the option to provide this expanded coverage on or after April 1, 2010 and may also extend coverage to these non-elderly, non-pregnant individuals above 133 percent of FPL through a State plan amendment. States may provide for a presumptive eligibility period. States may phase in by income, but only if granting assistance to those with lower income first. Also, section 2001 provides that if such a newly eligible individual has a child under 19 years (or such higher age as a state may have elected) who is eligible for Medicaid or under a waiver, the newly eligible individual may not be enrolled unless his/her child is.

Section 2001 also adds an optional coverage group under Medicaid, beginning January 2014, for individuals who are under 65 and otherwise ineligible for Medicaid, do not fall into any other optional category and whose income is between 133 percent FPL and the limit as may be established by a State.

2. FMAP

The reconciliation bill increases FMAP for medical assistance to newly eligible individuals, namely individuals under 65 years of age, not pregnant, not entitled to or enrolled in Medicare Part A and whose income does not exceed 133 percent of FPL for the applicable family size, that are not currently eligible for benchmark coverage or an equivalent under a state plan or waiver. The FMAP for services to these beneficiaries shall be: 100 percent for calendar quarters in 2014, 2015, and 2016; 95 percent for calendar quarters in 2017; 94 percent for calendar quarters in 2018; 93 percent for calendar quarters in 2019; and 90 percent for calendar quarters in 2020 and each year thereafter.

From January 1, 2014 through December 31, 2015, the FMAP otherwise determined shall be increased by 2.2 percent for medical assistance to individuals other than the "newly eligible" for states that have already expanded adult eligibility to 100 percent of the poverty level, i.e., "expansion states," that will not receive increased FMAP for the "newly eligible" and for which the Secretary has not approved the diversion of DSH to the costs of providing medical assistance under a waiver in effect on July 2009.

For calendar quarters in 2014 and thereafter, expansion states will receive a phased-in increase in the FMAP for non-pregnant childless adults. The FMAP for expansion states for medical assistance to newly eligible individuals who are nonpregnant childless adults with respect to whom the State may require enrollment in benchmark coverage shall be equal to the FMAP plus the "transition percentage" of the number of percentage points by which the FMAP for the State is less than the State's FMAP for newly eligible individuals (i.e., 100 percent for calendar quarters in 2014, 2015, and 2016; 95 percent for calendar quarters in 2017; 94 percent for calendar quarters in 2018; 93 percent for calendar quarters in 2019; and 90 percent for calendar quarters in 2020 and each year thereafter). The "transition percentage" for 2014 is 50 percent, for 2015 is 60 percent, for 2016 is 70 percent, for 2017 is 80 percent, for 2018 is 90 percent and for 2019 and each subsequent year is 100 percent. Thus, beginning in 2019, expansion states would bear the same state share of the costs of covering nonpregnant childless adults as non-expansion state.

3. Maintenance of Effort

Section 2001 requires that state plans include provisions for maintenance of effort. Starting from the date of enactment until the date on which the Secretary determines that an exchange in the State is fully operational, as a condition of federal payment, a state shall not have eligibility standards, methodologies, or procedures under the State Plan or any waiver that are more restrictive than what was in effect on the date of enactment. This requirement shall apply for determining eligibility for any child under 19 years of age (or other age as the State may have elected) through 2019. This requirement does not apply from January 1, 2011 to December 31, 2013, with respect to nonpregnant, non-disabled adults who are eligible for medical assistance and whose income exceeds 133 percent of FPL, if, on or after December 31, 2010, the State certifies that it has a budget deficit with respect to the fiscal year when the certification is made, or that the State is projected to have a budget deficit in the subsequent state fiscal year. This requirement does not apply to the change to using modified adjusted gross income to determine eligibility. This requirement also does not apply to the implementation of less restrictive eligibility criteria or moving beneficiaries from a waiver into the state plan.

4. Expansion of Benchmark Coverage

Benchmark coverage must consist of coverage for the essential health benefits, prescription drugs, and mental health services.

5. Reporting

Section 2001 requires that states submit annual reports starting with January 2015 enrollment, outreach, and other data. Beginning April 2015 and annually thereafter, Secretary must make reports to Congress on enrollment and recommendations for administrative and legislative improvements.

Subtitle B – Enhanced Support for The Children's Health Insurance Program

Ensuring Health Care Coverage for Children

The Act devotes particular attention to ensuring and enhancing health care coverage for children by expanding the existing Children's Health Insurance Program ("CHIP"). Among other things, the Act includes certain mandates for states regarding CHIP eligibility standards and also offers enhanced FMAP for CHIP populations. The Act also seeks to ensure that children who do not qualify for coverage under the CHIP program have coverage available through the Insurance Exchanges that will be created under the Act.

Section 2101 – Additional Federal Financial Participation for CHIP

The Act enhances the FMAP available to states for the CHIP program by 23 percentage points, with a maximum for any state of 100 percent. This enhanced FMAP becomes available on October 1, 2013 and ends on September 20, 2019.

Beginning March 23, 2010 through October 1, 2019, States are not permitted to further restrict CHIP eligibility standards, methodologies or procedures. The Act, however, does not prohibit states from making CHIP eligibility standards less restrictive than the standards currently in place in a particular state.

The Act provides that, if the enhanced FMAP is not sufficient to allow a state to provide health care coverage to all low-income children under CHIP, a state shall establish procedures "to ensure" that children that are otherwise excluded from CHIP can receive coverage through an insurance exchange created under the Act.

With respect to eligibility determinations, the provisions of the Act concerning CHIP are consistent with the Medicaid provisions in that they require states to use modified gross income for the purposes of assessing financial eligibility criteria. Children who are determined to be ineligible for medical assistance under Medicaid on the basis of an income disregard mandated under the Act shall be provided coverage under CHIP.

Subtitle C – Medicaid and CHIP Enrollment Simplification

The overriding purpose of this subtitle of the Act is to simplify the procedures through which individuals can apply for and receive benefits under either Medicaid or CHIP. The Act also includes provisions designed to allow states to integrate the Medicaid/CHIP enrollment process with newly created insurance exchanges. The Act also requires States, as a condition of Medicaid participation, to utilize certain technologies in the beneficiary enrollment process.

Section 2201 -- Enrollment Simplification and Coordination with State Insurance Exchanges

Under the Act, states are mandated to make several modifications to current Medicaid/CHIP enrollment procedures in order continue to participate in those federal health care programs. For all calendar quarters beginning after January 1, 2014, states must maintain a public website that allows individuals to apply for enrollment in the Medicaid program or renew enrollment. This internet-based

enrollment process must be available to individuals who are determined to be eligible for Medicaid or CHIP by an insurance exchange established under the Act. The internet enrollment process must have the capacity to ensure that individuals who apply for Medicaid or CHIP, but are found to be ineligible, be screened for coverage under qualified health plans offered by insurance exchanges. In addition, the internet enrollment process called for under the Act must utilize a "secure" electronic interface.

The Act also places additional requirements on states to coordinate benefits for individuals who have coverage through Medicaid or CHIP and a health care plan offered through an Insurance Exchange. States are required to conduct outreach to underserved populations that may include individuals potentially eligible for Medicaid or CHIP for the purposes of seeking to get such individuals enrolled in these programs.

Finally, the Act authorizes states to enter into contracts with Insurance Exchanges under which the state can determine whether an individual is eligible for premium assistance with respect to a health plan offered by an Exchange, so long as the agreement meets minimum standards the Secretary of the Treasury may establish.

Section 2202 -- Permitting Hospitals to Make Presumptive Eligibility Determinations for All Medicaid Eligible Populations

This section allows a Medicaid participating hospital to elect to be a "qualified entity" for the purpose of determining, on the basis of preliminary information, whether an individual is eligible for Medicaid coverage during a presumptive eligibility period, subject to guidelines the Secretary of HHS may establish.

Subtitle D – Improvements to Medicaid Services

Section 2303 (Section 1202)– Payments to Primary Care Physicians

With respect to services rendered in 2013 and 2014, this provision increases the Medicaid payments for physicians with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine. Such services must be reimbursed at not less than 100 percent of payment rates available for the same services under Medicare. Further, payments for primary care services furnished under a Medicaid managed care plan must be consistent with these payment rate increases. The increases in a state's Medicaid rates required by this section will be entirely paid for with federal funding.

Subtitle E – New Options for States to Provide Long-Term Care Services and Supports

This subtitle encourages states to shift the setting for long-term care services from institutional to community based and in-home settings. The Act authorizes states to amend their state plans to allow for the provision of home and community based services to individuals who are otherwise Medicaid eligible and who would require the level of care provided in an institutional setting, but only if the individual chooses to receive home and/or community based services and the state meets certain other requirements, as discussed below.

Section 2401 -- Community First Choice Option

The Act mandates that states choosing to provide home and community based services shall make them available to assist with activities of daily living, instrumental activities of daily living and health related tasks under a plan of care agreed upon by the individual and his/her representative. The Act then goes on to specify the models of delivery through which such services may be available and also enumerates the types of services that may be covered under this component of the program, as well as those services that may not be covered. For states that elect to make coverage of home and community based services available as specified by the Act, FMAP is increased by six percentage points.

States must comply with a number of very specific mandates in order to have a state plan amendment regarding home and community based services approved. Among other things, a state must develop the state plan amendment in collaboration with a "Development and Implementation Council" established by the state, which includes a majority of members with disabilities, elderly members or their representatives. Any services provided in this regard must occur in the most integrated setting appropriate to individual needs, but without regard to an individual's age, type or nature of disability. Further, the Act mandates that states develop a comprehensive and continuous quality assurance program with respect to community based and in-home support services, and establishes various standards by which such a quality assurance program must operate. Related to this obligation, the Act requires states to collect and report information regarding community based and in-home services to the Secretary of HHS. Finally, the Act establishes specific definitions relevant to the other provisions concerning community and in-home services.

Section 2402 -- Removal of Barriers to Providing Home and Community Based Services

This Section includes additional measures related to the expansion of community and home based services. It requires the Secretary to adopt regulations that will ensure that states will develop systems that allow beneficiaries to obtain, as well as maintain, non-institutional services, and have a say in the design of their treatment.

This Section authorizes states to expand coverage of community and home based services to individuals who would not otherwise be eligible for them and also allows states to offer such services "to specific populations and to differ the type, amount, duration and scope of such specific populations." To the extent a state elects to experiment with the provision of these services in this manner, the program will be approved by the Secretary for a period of 5 years and then renewed for another five year team if the Secretary determines the state has complied with applicable requirements of the Act.

Subtitle G -- Medicaid Disproportionate Share Hospital ("DSH")

Section 2551 – Disproportionate Share Hospital Payments

As enacted, the Act significantly replaced the original proposal regarding Medicaid DSH payments. The new provision provides for $18.1 billion in aggregate reductions to Medicaid DSH payments through 2020, beginning in 2014, with relatively small reductions at first and the most significant reductions not beginning until fiscal year 2018. Congress left it to the Secretary to develop a "DSH Health Reform methodology" to determine how to distribute the reductions among states.

This methodology must meet the following requirements: (1) It must impose the largest percentage reductions in States that have the lowest percentage of uninsured individuals based on the most recent data available and that do not target their DSH payments on hospitals with high volumes of Medicaid inpatients and uncompensated care; (2) It must impose a smaller percentage reduction on low DSH states (as defined in 42 U.S.C. §1395r-4(5)(A)); and (3) It must take into account the extent to which the DSH allotment for a state was included in the budget neutrality calculation for a Section 1115 coverage expansion. The Act also provides for a Medicaid DSH allotment for states that would have had $0 allotments in 2012 and 2013.

Subtitle I – Improving the Quality of Medicaid for Patients and Providers

Section 2703 -- State Option to Provide Health Homes for Enrollees with Chronic Conditions

Under Section 2703(a) a state, at its option, as a state Medicaid plan amendment, may provide for medical assistance for Medicaid beneficiaries with chronic conditions who select a designated provider, a team of health care professionals operating with such a provider, or a health team at the individual's health home for purposes of providing the individual with health home services.

Section 2703(f) requires a state to include in such a state Medicaid plan amendment "a proposal for use of health information technology in providing health home services . . . including the use of wireless patient technology to improve coordination and management of care and patient adherence to recommendations made by their provider." In reporting to the Secretary under this program, the State is also required to use HIT when appropriate and feasible.

Section 2704 -- Medicaid Bundled Payments Demonstration Project

A Medicaid Bundled Payment Demonstration Project is to be established in eight states, beginning on January 1, 2012 through December 31, 2014. The services included would encompass acute care hospital, concurrent physician and post acute services, and that hospitals would receive a singled bundled payment from Medicaid for such services.

Title III -- IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE

Subtitle A – Transforming the Health Care Delivery System

Part I – Linking Payment to Quality Outcomes Under the Medicare Program

Section 3001 – Hospital Value-Based Purchasing Program

The Act establishes a value-based purchasing program for hospital services, by adding 42 U.S.C. §1395ww(o), designed to provide some hospitals with incentive based payments that meet certain objectives commencing in federal fiscal 2013 and paying for those incentives with reductions to DRG base payment amounts from all hospitals. The program will apply to payments for discharges occurring on and after October 1, 2012 for hospitals subject to acute care inpatient PPS ("IPPS"). Thus, this program will not apply to psychiatric, rehabilitation, children's, certain cancer hospitals and long-term care hospitals. But even some IPPS hospitals will be ineligible for incentives, including those: (1) subject to reductions beginning in FY 2015 because they are not a meaningful EHR user, (2) cited for deficiencies that pose immediate jeopardy to patient health or safety, (3) for which a minimum number of measures for quality do not apply, or (4) for which a minimum number of cases are not available to apply such measures.

Beginning in FY 2013, the measures used for incentive payments must include at least the following conditions: acute myocardial infarction, heart failure, pneumonia, surgeries under the Surgical Care Improvement Project and health care associated infections. Beginning in FY 2014, the Secretary must include efficiency measures including Medicare spending per beneficiary. Any measures selected must be included in the process provided by statute, section 1395ww(b)(3)(B)(VIII) and included on the Hospital Compare Internet website for at least 1 year prior to the beginning of a performance period. Performance standards for a measure must be announced at least 60 days prior to the beginning of a performance period.

Incentive payments must be distributed based on performance scores of the hospitals receiving such payments and must vary based on relative scores. Such incentives will be paid through increases in the base operating DRG amount. Reducing base operating DRG payments for all hospitals by 1 percent in 2013, 1.25 percent in 2014, 1.5 percent in 2015, 1.75 percent in 2016 and 2 percent thereafter funds incentives payments. Medicare dependant small rural hospitals and sole community hospitals are subject to special rules.

Each fiscal year of the program is handled independently, that is, no incentive or payment reduction in one year affects the subsequent year. Hospital may appeal their assessment under performance standards and their score for incentive payments under the process provided by the Secretary. There is no other administrative or judicial review of the establishment of standards or methodology used to determine amounts or measures.

Sections 3004 – 05 (Section 10322) – Quality Reporting for Long-Term Care Hospitals, Inpatient Rehabilitation Hospitals, Hospice Programs, PPS-Exempt Cancer Hospitals and Psychiatric Facilities

For several years, hospitals paid under IPPS have been required to report quarterly to CMS on a series of "quality indicators" that relate to treatment of various more commonly occurring conditions. The Act now begins to extend several features of the current IPPS hospital quality measure reporting requirements to several other types of providers that are paid under different PPS and other payment systems including long-term care hospitals, inpatient rehabilitation facilities, hospice programs, PPS-exempt cancer hospitals and inpatient psychiatric hospitals (and distinct part psychiatric units), to commence during providers' rate year 2014.

The Secretary of HHS is required to select and publish by October 1, 2012, the quality measures that must be reported by each separate type of facility. The Act requires the Secretary to choose only those quality measures for each type of provider that have been endorsed by a consensus-based performance measurement contractor (such as the National Quality Forum), or for unendorsed measures, the Secretary must assure that due consideration has been given to measures adopted by a consensus-based contractor.

Beginning in Rate Year 2014, long-term care hospitals, inpatient rehabilitation facilities, hospice programs and psychiatric hospitals and units will receive their full annual updates to their applicable type of provider's standard Federal rate for the discharge amount only if their reporting obligations have been met. Providers who fail to comply with the applicable quality measure reporting requirements will have their standard Federal rates reduced by two (2) percent, which may result in such annual update being negative in any specific rate year. Any such reduction will not be cumulative from year to year. PPS-exempt cancer hospitals are not subject to this reduction, but only to the reporting requirements.

The Secretary is further required by the Act to establish procedures for making data submitted pursuant to the quality measure reporting requirement available to the public, provided the submitting facility has the opportunity to review the data that is to be made public.

Section 3006 (Section 10301) -- Plans for a Value-Based Purchasing Program for Skilled Nursing Facilities, Home Health Agencies and ASCs

By October 1, 2011, the Secretary is required to submit to Congress a Medicare value-based purchasing implementation plan for SNFs. The plan must consider: (1) the development, selection, and modification process of measures, to the extent feasible and practical, of all dimensions of quality and efficiency; (2) the reporting, collection and validation of quality data; (3) the structure of proposed value-based payment adjustments, including the determination of thresholds or improvements in quality that will substantiate a payment adjustment, the size of such payments, and the source of the funding for the value-based bonus payments; (4) methods of publicly disclosing performance information; and (5) the other issues as determined by the Secretary. Similar requirements apply to home health agencies with the same report date. As amended the section also requires similar considerations for ASCs, with a report deadline of January 1, 2011.

Section 3008 – Payment Adjustment for Hospital Acquired Conditions

The Act establishes an adverse payment adjustment for hospital acquired conditions by adding 42 U.S.C. §1395ww(p). The new adjustment applies to discharges occurring on and after October 1, 2014. Under this program, IPPS hospitals in the top quartile of hospitals relative to a national average

with hospital-acquired conditions will only receive 99 percent of the total IPPS payments they would otherwise have received. The measure of such hospitals must be risk adjusted, as determined by the Secretary. Prior to FY 2015 and in any subsequent year, the Secretary must provide a confidential report to an applicable hospital with respect to hospital-acquired conditions.

The Secretary is also required to make information available to the pubic regarding the hospital-acquired conditions in such hospitals. However, the Secretary must make such information available to hospitals, with an opportunity to correct such information, before it is made available to the public.

These provisions generally, and the disclosure of information to the public specifically, are not subject to administrative or judicial review.

The section also calls for a study and report by January 1, 2012 of the extension of health care facility acquired conditions to other provider types.

Part II—National Strategy To Improve Health Care Quality

Section 3011 (Section 10302) – National Strategy to Improve Health Care Quality

The Secretary is directed to create a national quality improvement strategy addressing the following priorities: delivery of health care services, patient health outcomes and population health. Under Section 3011, the Secretary is responsible for identifying national priorities that address, among other things: the high-cost chronic diseases; patient safety improvements and medical errors; preventable hospital admissions and readmissions; health care-associated infections; reduce health disparities across health disparity populations and geographic areas; and other areas as determined appropriate by the Secretary. Once the priorities are established, a strategic plan must be created taking into account the following: coordination among agencies to minimize duplication and utilization of common quality measures; agency-specific strategic plans; a regular status reporting process; establishment of annual benchmarks for each participating agency; strategies to align incentives among public and private payors for quality and patient safety efforts; incorporating quality improvement; and measures for health information technology. The Secretary is required to submit the national quality improvement strategy to Congress for review by January 1, 2011. In addition, a website must be created so that the public may access the details of the strategy.

Section 3012 -- Interagency Working Group on Health Care Quality

The President is directed to convene a working group to be known as the Interagency Working Group on Health Care Quality (the "Working Group") that shall have the following goals:

- Collaboration, cooperation and consultation between Federal departments and agencies with respect to developing and disseminating strategies, goals, models and timetables consistent with the national priorities under the Public Health Service Act.
- Avoidance of inefficient duplication of quality improvement efforts and resources, where practicable, and a streamlined process for quality reporting and compliance requirements.
- Assess alignment of quality efforts in the public sector with private sector initiatives.

The Working Group is to be composed of senior level representatives from HHS, CMS, NIH, CDC, FDA, HRSA, AHRQ, ONCHIT and fifteen other enumerated federal agencies, as well as any others that the President determines have activities relating to improving health care quality and safety. The group shall be chaired by the Secretary of HHS. Not later than December 31, 2010, and annually thereafter, the Working Group must submit to the relevant Committees of Congress, and post on a public website, a report describing the progress and recommendations of the Working Group in meeting its goals.

Section 3013 – (Section 10303) --Quality Measure Development

The Secretary receives $75 million dollars for each of fiscal years 2010 through 2014 to award grants, contracts or intergovernmental agreements to eligible entities for developing, improving or expanding quality measures. The quality measures shall be developed after consultation with the Director of the Agency for Healthcare Research and Quality ("AHRQ). The measure must take into account factors enumerated in the legislation, including for example acquisition of data from electronic health records. The agency is required to identify, at least triennially, gaps where no measures exist or existing measures that need improvement, updating or expansion. The identification of any such gaps is required to be reported on an appropriate website.

The Secretary is required to update at least every three years outcome measures for hospitals and physicians. Measures must include, to the extent feasible, outcome measures for the 5 most prevalent resource intensive acute and chronic conditions and must, not later than 24 months after enactment, develop not less than ten measures. Within 36 months of enactment, the Secretary must develop not less than ten measures for primary and preventive care that cover distinct patient populations.

The Secretary must publicly report measures that are used by CMS to adjust payments for hospital acquired infections. The amendment also contemplates the development of clinical practice guidelines.

Section 3014 (Section 10304) -- Quality and Efficiency Measurement

The section amends 42 U.S.C. 1395aaa(b), which requires HHS to have a contract with a consensus-based entity such as the National Quality Forum. The amendment requires that entity to convene multi-stakeholder groups to provide input on the selection of quality and efficiency measures and the development of national improvements in population health. The Secretary receives $20 million dollars to support quality and efficiency measures and for use in reporting performance information to the public, and for use in health care programs. The amendment also sets forth requirements for an open and transparent process for these activities.

Part III – Encouraging Development of New Patient Care Models

Section 3021 (Section 10306) - Establishment of Center for Medicare and Medicaid Innovation within CMS

This section creates an Innovation Center within CMS effective January 1, 2011 to test, evaluate, and expand different payment structures and methodologies to reduce program expenditures while maintaining or improving quality of care. Phase I provides for a testing of models and $5 million for the

design, implementation and evaluation of models for fiscal year 2010. Phase II provides for possible expansion of models being tested under demonstration projects and allocates $10 billion for expansion of models for fiscal years 2011 through 2019.

The Secretary may limit testing of a model to certain geographic areas and will select the models to be tested where there is evidence of deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs while preserving or enhancing the quality of care. This section suggests a number of models to be potentially tested, such as models that transition primary care practices away from fee-for-services based reimbursement and toward comprehensive payment or salary-based payment, and establishing comprehensive payments to Healthcare Innovation Zones consisting of groups of providers that deliver a full spectrum of integrated and comprehensive health services while incorporating innovative methods for clinical training of future health care professionals.

Section 3022 (Section 10307) -- Medicare Shared Savings Program

Another provision of the Act, the "*Shared Savings Program,"* may have a significant impact on how the health care delivery system is structured. The provision encourages the formation of Accountable Care Organizations ("ACOs"). ACOs are groups of providers and suppliers that work together to manage and coordinate care for Medicare fee-for-service beneficiaries. ACOs that meet certain quality and performance standards established by the Secretary will be eligible to receive bonus payments based on reductions in Medicare costs for patients under their care.

The following providers are entitled to participate as ACOs: (i) physicians in group practice, (ii) networks of individual practitioners, *e.g,* IPAs, (iii) partnerships or joint ventures between hospitals and physicians, (iv) hospitals employing physicians, and (v) other groups as determined by the Secretary. In order to participate in the Shared Savings Program, an ACO must have, among other things, an agreement with the Secretary for at least a three year term, a formal legal structure which allows it to receive and distribute payments for shared savings to its participating providers, at least 5,000 Medicare beneficiaries assigned to it, and a defined process to promote evidence-based medicine and to report on quality and cost measures.

Providers who participate in an ACO would continue to be paid for their services under the Medicare fee-for-service program. In addition, however, they would be eligible for bonuses if the ACO meets the quality and performance standards, and reduces costs to the Medicare program for the patients assigned to it below a benchmark threshold. The benchmark would be based on the most recent available three years of per beneficiary expenses for Medicare beneficiaries assigned to the ACO, subject to certain adjustments.

Medical groups that have a large base of primary care patients and sophisticated utilization/quality control systems, such as capitated medical groups and IPAs, will be well positioned to become ACOs. Hospitals, however, will either have to employ physicians, which may not be possible in states which prohibit the corporate practice of medicine, or enter into partnership or joint venture arrangements with physicians, if they desire to participate as ACOs. Because the ACO program is to be implemented by no later than January 1, 2012, hospitals will need to accelerate their plans for physician integration to meet this deadline.

Section 3023 (Section 10308) – National Pilot Program on Payment Bundling

The Secretary must implement a national, voluntary pilot program to coordinate care during an entire episode of care provided to Medicare beneficiaries not covered under Part C who have been hospitalized, in order to improve the coordination, quality and efficiency of health care services. The Secretary shall establish such a pilot program by no later than January 1, 2013. The Secretary shall specify ten conditions for which the pilot program shall apply, taking the following into account: whether the specified conditions include both chronic and acute conditions; whether there is a mix of surgical and medical conditions; whether a condition allows providers and suppliers to improve the quality of care while reducing total expenditures; whether there is significant variation in the number of readmissions, the amount of expenditures for post-acute care; whether a condition "has high volume and high post acute care expenditures; and which conditions the Secretary decides are most "amenable to bundling across the spectrum of care given practice patterns."

Services to be included in the bundle are: acute care inpatient hospital services; physician services delivered inside and outside of the acute care hospital setting; outpatient hospital services, including emergency department visits; services associated with acute care hospital readmissions; post acute care services including home health, skilled nursing, inpatient rehabilitation and long term care hospital; and other services that the Secretary determines appropriate. If a pilot program improves patient outcomes, reduces costs (as certified by the CMS actuary) and improves efficiency, the Secretary may expand such pilot program after January 1, 2016. Section 3023 also directs the Secretary to test bundled payment arrangements involving continuing care hospitals within the bundling pilot program. The pilot program may also include vertically integrated hospitals, those that provide under single management acute, rehabilitation, long term care and SNF services, referred to as "continuing care hospitals."

Section 3024 – Independence at Home Demonstration Program

The Secretary is required to develop a demonstration program to begin no later than January 1, 2012, to test payment incentives and delivery models that use physicians and nurse practitioners to manage home based primary care teams for the Medicare population that is chronically and significantly ill and currently account for about 80 percent of medical expenditures, while comprising only about 20 percent of Medicare beneficiaries. The overall design of the demonstration program is required to reduce expenditures while improving patient outcomes. The demonstration is limited to a sufficient number of practices to accommodate 10,000 eligible Medicare beneficiaries.

The goals of the demonstration are to reduce preventable emergency room visits, hospitalizations and readmissions, improve outcomes commensurate with a patient's chronic conditions, improve patient and family satisfaction with caregivers and reduce service duplication and costs.

A Independence at Home Medical Practice is a legal entity that includes a physician or nurse practitioner, or combinations of the same, that provides care as part of team that includes, as appropriate, physicians, nurses, physician assistants, pharmacists and other health or social services staff through home based primary care. The team must be available all hours of every day. Each practice must be organized to provide physicians' services, have documented experience in providing primary care to high cost chronically ill beneficiaries, furnish services to at least 200 eligible beneficiaries each year of the demonstration, enter in to an agreement with the Secretary, be an EHR, mobile monitor and mobile

diagnostic user, and meet other criteria as determined by the Secretary. A team can be led by a nurse practitioner or physicians' assistant. Physicians or providers can be affiliates and share in savings. Preference in the demonstration must be provided to practices in high cost areas.

The Secretary is directed to develop a per capita spending target for the amount that would have been spent per beneficiary under parts A and B in the absence of the demonstration. Incentive payments are based on actual spending below the target based on a formula. The Secretary is authorized to waive requirements of Title XI and XVIII.

Applicable beneficiaries cannot be enrolled under part C or PACE, must have 2 or more chronic illnesses as described in the statute or as provided by the Secretary, have had a non-elective hospital admission in the last year and have two or more functional dependencies requiring assistance.

Section 3025 (Section 10309) – Hospital Readmissions Reduction Program

Beginning with discharges occurring in a fiscal year commencing on and after October 1, 2012, hospitals subject to IPPS will be penalized for excess readmissions through a payment which is the product of the base operating DRG payment and an adjustment factor for that fiscal year. The base operating DRG amount subject to adjustment for excess readmissions is determined without regard to reductions for the value based purchasing program, but subject to reductions for outlier, IME, DSH and low volume hospitals. Special rules apply for sole community and small rural hospitals.

The adjustment factor is the greater of: (a) 1 minus the ratio of payments for excess aggregate readmissions and aggregate payments for all discharges, or (b) a floor adjustment of .99 for FY 2013, .98 for 2014, or .97 for FY 2015 and thereafter. The aggregate payment for excess readmissions is, for an applicable year, the sum for applicable conditions, of the product for each condition of the base operating amount for the condition, the number of admissions for that condition and the excess admissions ratio for the hospital minus 1.

Conditions subject to this excess readmission calculation include certain conditions or procedures that are high volume or high expenditure under the criteria in the section. Beginning in FY 2015, the Secretary may expand the conditions beyond the three currently endorsed to the additional 4 identified in MedPAC's June 2007 report to Congress. Readmission as used in the section includes a condition subject to this section for which an individual is discharged from an IPPS hospital to the same or another IPPS hospital within a time period specified by the Secretary from the date of the initial discharge.

Just as with hospital-acquired conditions in section 3008, there is a similar public disclosure process and an opportunity to correct errors in such reports by the agency. Administrative and judicial review is similarly limited.

Section 3026 – Community-Based Care Transitions Program

The program provides funding to eligible entities that provide improved transition services to high-risk Medicare beneficiaries. The eligible entities include IPPS hospitals identified under section 3025 and an "appropriate community-based organization that provides care transition services" through

an arrangement with an IPPS hospital. Such organizations must include a governing body with representation of multiple health care stakeholders (including consumers).

A high risk Medicare beneficiary is defined as such using a hierarchical condition category score using multiple chronic conditions or other risk factors associated with readmission including cognitive impairment, depression, a history of readmissions and other risk factors as the Secretary may determine. Part C beneficiaries are not included.

The program will begin January 1, 2011 and continue for 5 years. The Secretary has authority to expand both the duration and scope of the program. A hospital that seeks to participate in the program must enter in to a partnership with a community-based organization. Funding for the program is set at $500 million for the five years. Payment will be made for care transition intervention services described in subsection (c)(2)(B) as determined by the Secretary.

Section 3027 – Extension of Gainsharing Demonstration

Medicare's gainsharing demonstration project is extended through FY 2014 or until additional funding is expended.

Subtitle B – Improving Medicare for Patients and Providers

Part I – Ensuring Beneficiary Access to Physician Care and Other Services

Section 3103 - Therapy Caps

While the expiration of the current exception process for therapy caps under Medicare Part B was recently reinstated retroactively to January 1, 2010, the exception process is extended through December 31, 2010.

Section 3108 - Ability of Physician Assistants to Certify Need for Post Acute Care

Effective for services furnished on and after January 1, 2011, the section establishes authority for nurse practitioners, physician assistants and clinical nurse specialists to certify the need for post-hospital extended care.

Part II – Rural Protections

Section 3121 - Extension of Outpatient Hold Harmless Provision

The Act extends the currently existing "hold harmless" provision applicable to outpatient services payments to rural hospitals with under 100 beds and sole community hospitals, for one additional year, to January 1, 2011. This provision will continue to protect such rural and sole community providers when the outpatient PPS payment amount is determined to be lower than the pre-BBA payment amounts for covered outpatient services.

Section 3122 – Extension of Reasonable Cost Payments For Certain Clinical Diagnostic Tests Furnished to Hospital Patients in Certain Rural Areas

The Act extends Medicare reasonable costs payments for specified clinical diagnostic laboratory tests furnished to hospital patients in previously identified and qualifying rural areas. These protections will now extend until July 1, 2011.

Section 3123 (Section 10313) – Extension of Rural Hospital Demonstration Program

The Act extends the "Rural Community Hospital Demonstration Program" for an additional five (5) year term. During the extension, the number of states eligible under the program is expanded to 20, but the total number of hospitals under the expansion is capped at 30 community hospitals.

Section 3124 – Extension of the Medicare-Dependent Hospital (MPH) Program

The Act extends the Medicare-Dependent Hospital Program for one additional year, through October 1, 2012.

Section 3125 (Section 10314) - Temporary Improvements to the Medicare Inpatient Hospital Payment Adjustment for Low-Volume Hospitals

Qualifying low volume hospitals for FYs 2011 and 2012 are redefined to include hospitals that are more than 15 miles (instead of 25 miles) from the nearest facility, and that have less than 1600 (instead of less than 800) discharges. Further, the Act instructs the Secretary to determine an applicable percentage increase ranging from 25 percent for hospitals with fewer than 200 discharges in the fiscal year, to zero for low volume hospitals with greater than 1600 discharges in the applicable fiscal year.

Section 3126 – Improvements to the Demonstration Project on Community Health Integration

The Act eliminates the existing limitation on eligible counties that will be permitted to participate in the demonstration project on community health integration models. Previously, this program had been limited to no more than six counties. The demonstration project also has been modified to include physicians' services, while eliminating references to rural health clinics.

Section 3127 – MedPAC Study on Adequacy of Medicare Payments to Rural Providers

MedPAC must conduct a study on the adequacy of payments for items and services furnished by providers and suppliers in rural areas. This study is required to review adjustments to payments to rural providers and suppliers, access by Medicare beneficiaries to health services in rural areas, and the adequacy of payments to rural providers and suppliers. The report must be completed by January 1, 2011.

Section 3128 – Technical Correction Related to Critical Access Hospital Services

Effective as if adopted in Section 405(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the facility fee costs of critical access hospitals and ambulance services furnished to critical access hospitals shall be paid at 101 percent of reasonable costs.

Section 3129 – Extension and Revisions to Rural Hospital Flexibility Program

The program is modified and extended to assist rural hospitals in participating in reforms that are included in the Patient Protection and Affordable Care Act, including but not limited to, value-based purchasing programs, accountable care organizations, payment bundling programs and other delivery systems. These revisions apply effective with grants made on or after January 1, 2010.

Part III – Improving Payment Accuracy

Section 3131 (Section 10315) - Payment Adjustments for Home Health Care

The Secretary is directed to rebase home health payments starting in 2014 based on an analysis of the current mix of services and intensity of care provided by home health services. Additionally, a 10 percent cap is imposed on the amount of reimbursement a home health provider can receive from outlier payments, and an add-on payment for rural home health providers is reinstated from April 1, 2010 through 2015.

Section 3133 (Sections 10316 and 1104) – Improvements to Medicare Disproportionate Share Hospital Payments

The Act provides for a significant decrease in Medicare disproportionate share payments, effective in federal fiscal year 2014. DSH payments are to be reduced to *25 percent of the amounts that would otherwise have been paid* under current law, *plus* an additional amount that is to be calculated pursuant to a very complex formula relating to the amount of uncompensated care being provided. The *additional amount* is to be calculated based on the product of three factors:

(1) The aggregate amount of payments by which total DSH payments have been reduced (i.e., 75 percent of what would otherwise have been paid);

(2) For fiscal years 2014 through 2017, a factor of 1 minus the percentage change from 2013 in the number of uninsured individuals under age 65 minus 0.1 percentage points (for 2014) and minus 0.2 percentage points (for 2015, 2016 and 2017); and for fiscal years 2018 and 2019, a factor of 1 minus the percentage change of uninsured individuals minus 0.2 percentage points;

(3) A factor equal to the percent, for each hospital, that represents the quotient of (i) the amount of uncompensated care for such hospital, as estimated by the Secretary for a period chosen by the Secretary, and (ii) the aggregate amount of uncompensated care for all Medicare DSH hospitals.

The Act also provides that there will be no administrative or judicial review of any estimates of the Secretary for determining the above factors or any period selected by the Secretary for such purposes.

Section 3135 (Section 1107) – Modification of Equipment Utilization Factor for Advanced Imaging Services

This provision reduces Medicare payments for advanced imaging services. As modified, the section increases the current assumed utilization rate from 62.5 to 75 percent for the practice expense

portion of advanced diagnostic imaging services, which includes imaging involving equipment costing $1 million or more as determined by CMS. This provision supersedes a CMS rule increasing assumed utilization rate to 90 percent in 2013. Excluded services from the effect of the provision include radiation therapy and low-tech imaging, such as ultrasound, x-rays and EKGs. The section also increases the technical component discount on single session imaging studies on contiguous body parts from 25 percent to 50 percent.

Section 3137 (Section 10324) -- Hospital Wage Index Improvement

The Act sets forth a "plan for reforming the Medicare hospital wage index system," but provides no specifics for this reform. It requires the Secretary to submit a plan for wage index reform by December 31, 2011. It sets forth various considerations that should be taken into account, all of which have previously been on the table in discussions of wage index reform (e.g., using Bureau of Labor Statistics data, minimizing volatility, addressing occupational mix, providing for a transition, etc.).

In addition to this requirement for a report by the end of 2011, there are a few changes that take effect prior to any major revision of the wage index system. Three current changes include:

(1) Section 508 reclassifications are extended to September 30, 2010, using the wage index currently in effect;

(2) Recent changes to the criteria for geographic reclassifications are reversed. Instead, the criteria used to determine geographic reclassifications must revert to the criteria that were in effect as of September 30, 2008, until the fiscal year beginning on or after the date that is 1 year after the Secretary submits the report to Congress on the plan for reforming wage index; and

(3) Effective for discharges occurring on or after October 1, 2010, the wage index for hospitals located in "frontier states" shall not be lower than 1. Frontier states are defined as those states where at least 50 percent of the counties are "frontier counties." Frontier counties are defined as counties in which the population per square mile is less than six. This provision shall <u>not</u> apply to either Alaska or Hawaii, and it shall <u>not</u> be applied in a budget neutral manner. According to the CBO, states that will meet the criteria are: Wyoming, Montana, North Dakota, South Dakota and Utah.

Section 3141 – Application of Budget Neutrality on a National Basis in the Calculation of the Medicare Hospital Wage Index Floor

The Secretary is required to apply budget neutrality to the calculation of the wage index floor for discharges occurring on and after October 1, 2010, as was applied by the Secretary in the same calculation for FY 2008, under 42. C.F.R. § 412.64(e), through a uniform national adjustment to the area wage index.

Section 3142 – HHS Study on Urban Medicare-Dependent Hospitals

The Secretary is obliged to conduct a study on the need for an additional payment to such hospitals through an analysis of their inpatient margins as compared to other hospitals that receive additional payments under IPPS and whether payments to small rural Medicare dependent hospitals

should be applied to these urban hospitals. These hospitals are defined to include hospitals that did not receive IPPS add-on payments under most provisions under section 1395ww(d)(5) and had Medicare utilization in excess of 60 percent based on days or discharges during two of the three most recently audited cost reporting periods. The report is due nine months after enactment.

Manager's Amendment to H.R. 4872 Adding Section 1109 – Payment for Qualifying Hospitals

The Manager's amendment originating in the House added section 1109 to the Reconciliation Bill to provide an additional payment for "qualifying hospitals," that is hospitals in counties that, demographically adjusted, are in the lowest quartile of expenditures under Medicare parts A and B per enrollee. A qualifying hospital is entitled to receive a portion of the available funding equal to the ratio of its total payments under IPPS to the aggregate total payments for all other qualifying hospitals. The funds are being made available for such additional payments for FYs 2011 and 2012. The provision makes $400 million available from the Medicare Trust Fund for this purpose, but it is unclear from the provision whether that sum is the total expenditure for both years under the program, or per year under the program.

Subtitle E – Ensuring Medicare Sustainability

Section 3401 (Sections 10319 and 1105) – Market Basket Update

As amended, the market basket and productivity amendments would save the Medicare program approximately $156.6 billion over 10 years and are the largest single savings associated with the reform legislation. These adjustments reduce the market basket update for inpatient services beginning April 1, 2010 by .25 percent for each of FYs 2010 and 2011, by .1 percent for each of FYs 2012 and 2013, in FY 2014 by .3 percent, by .2 percent in FYs 2015 and 2016 and by .75 percent in FYs 2017 through 2019. Similar if not identical market basket adjustments apply beginning in FY 2012 and thereafter for long term care hospitals, inpatient rehabilitation facilities, psychiatric hospitals and outpatient hospital services. There is no cut to the overall SNF market basket.

Beginning in 2012, the market basket percentage increase is subject to a productivity adjustment for all of the provider types noted above and others. The adjustment equals the 10-year moving average of changes in the annual non-farm productivity, as determined by the Secretary. Application of the productivity adjustment can result in a market basket increase of less than zero, that is, payments in a current year may be less than the prior year once the adjustment applies.

Section 10324 - Protections for Frontier States

The Manager's amendment establishes a floor on the wage index for inpatient hospital services in Frontier States of not less than 1.0 for discharges on and after October 1, 2010. A Frontier State is a state where at least 50 percent of the counties are frontier counties. A frontier county is a county where the population is less than 6 per square mile. The provision does not apply to any hospital in a state that receives a non-labor related share adjustment section 1395ww(d)(5)(H). Budget neutrality is waived for this provision.

Similarly, for outpatient services, the same floor and limitations are set for services provided on and after January 1, 2011.

Section 10325 -- Revisions to the SNF Prospective Payment System.

Through a Manager's amendment, the RUGs-IV payment system changes are delayed until October 1, 2011. The implementation of the concurrent therapy adjustment, the look-back period change and the introduction of MDS 3.0 will go into effect in October 2010. The expected adverse financial impact is estimated to be approximately $2 billion.

Subtitle F – Health Care Quality Improvements

Section 3501 – Health Care Delivery System Research, Quality Improvement Technical Assistance

Section 3501 contains several initiatives to identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices in health care quality, safety, and value; and implement a model to pursue such research. One of those initiatives requires the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality to "(G) expand demonstration projects for improving the quality of children's health care and the use of health information technology, such as through Pediatric Quality Improvement Collaboratives and Learning Networks." Section 3501(c)(2)(G).

Section 3502 – Establishment of Community Health Teams to Support the Patient-Centered Medical Home

Under Section 3502(a) the Secretary must establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams (referred to in this section as "health teams") to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities. Grants or contracts shall be used to: (1) establish health teams to provide support services to primary care providers; and (2) provide capitated payments to primary care providers as determined by the Secretary.

Under Section 3502(c) a health team established pursuant to a grant under Section 3502(a) must support patient-centered medical homes, defined as a mode of care that includes, in part, the "appropriate use of HIT."

Section 3509 – Improving Women's Health

Section 3509(a) establishes within HHS an Office of Women's Health. Under Section 3509(b) the Secretary must establish a National Women's Health Information Center to facilitate the exchange of information regarding matter related to women's health.

Selected Other Provisions

Section 3301 (Section 1101) – Closing the Medicare Prescription Drug Donut Hole

This provision addresses the donut hole in prescription drug coverage under Medicare Part D. A $250 rebate is provided for all Medicare Part D enrollees who enter the donut hole in 2010. The donut hole is phased out and completely closed by 2020 through increasing discounts on brand name and generic drugs, culminating in a 75 percent discount by 2020.

Section 3403 (Section 10320) -- Independent Payment Advisory Board

This provision creates an independent, 15-member Payment Advisory Board. The Board is responsible for making annual recommendations to the President, Congress, and private entities on actions to improve quality and constrain cost growth in the private sector. The Board must also make non-binding recommendations to Congress in years in which the Medicare per capita cost growth is below targets. The Board may not make proposals that would reduce premium supports for low-income Medicare beneficiaries. Beginning in 2020, the Board must make biennial recommendations to Congress if the growth in overall health spending exceeds the growth in Medicare spending. Such recommendations are to focus on slowing overall health spending while maintaining or enhancing beneficiary access to quality care under Medicare.

Title IV—PREVENTION OF CHRONIC DISEASE & IMPROVING PUBLIC HEALTH

Section 4103 -- Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan

Under Section 4103, the annual wellness visit afforded Medicare beneficiaries now has a requirement that to the extent practicable, the Secretary encourage the use of, integration with and coordination of HIT, including HIT compatible with electronic medical records and personal health records and experimentation with the use of personalized technology to aid in the develop of self-management skills and adherence to provider recommendations. Section 4103(b)(3)(F).

TITLE V – HEALTH CARE WORK FORCE

Subtitle D – Enhancing Health Care Workforce Education and Training

Section 5301 – Training in Family Medicine, General Internal Medicine, General Pediatrics and Physician Assistantship

Under Section 5301(a) the Secretary may award grants to or enter into contracts with, an accredited public or nonprofit private hospital, school of medicine or osteopathic medicine, academically affiliated physician assistant training program, or a public or private nonprofit entity to train practitioners in family medicine, general internal medicine, or general pediatrics for medical students, interns and residents. In making grants under Section 5301(a), the Secretary must give preference to applicants who can say that they will provide training in HIT.

Subtitle F – Strengthening Primary Care and Other Workforce Improvements

Section 5501 (Section 10501) - Expanding Access to Primary Care Services and General Surgery Services

This section provides a 10 percent bonus payment to be paid on a monthly or quarterly basis to primary care practitioners (including family medicine, internal medicine, geriatric medicine, and pediatric medicine physicians, as well as nurse practitioners, clinical nurse specialists, and physician assistants for whom primary care services account for at least 60 percent of the allowed charges for such practitioner) and for major surgical procedures furnished by general surgeons in health professional shortage areas from January 1, 2011 through December 31, 2015.

Section 5502 (Section 10501) -- Medicare Federally Qualified Health Center Improvements

The Secretary shall develop and implement a prospective payment system (PPS) for payment for Federally qualified health services furnished by Federally Qualified Health Centers (FQHCs) so that the estimated amount of expenditures for federally qualified health center services in the first year the PPS is implemented is equal to 100 percent of the estimated amount of reasonable costs that would have occurred for such services if the system had not been implemented. The payment rate in the first year after implementation shall be the payment rate of the previous year increased by the percentage increase in the Medicare Economic Index (MEI) for the year involved, and in subsequent years by the percentage increase in a market basket of FQHC goods and services as promulgated through regulations. The PPS for FQHCs shall apply for cost reporting periods beginning on or after October 1, 2014.

This section also expands the term federally qualified health center services to include preventive services furnished on or after January 1, 2011.

Section 5503 - Distribution of Additional Residency Positions

This section distributes 65 percent of a hospital's unused Medicare-funded resident slots to hospitals committing to use 75 percent of the additional slots for primary care or general surgery training. It is effective for portions of cost reporting periods occurring on or after July 1, 2011.

Section 5504 – Counting Resident Time in Nonprovider Settings

This section relaxes the requirements associated with hospitals claiming intern and resident full time equivalents ("FTEs") for rotations at nonprovider sites. Hospitals can claim nonprovider rotation time for Medicare direct graduate medical education ("GME") and indirect medical education ("IME") purposes so long as they incur the costs of the stipends and fringe benefits for the residents during the nonprovider rotations. It is effective for cost reporting periods beginning on or after July 1, 2010.

Section 5505 - Counting Resident Time for Scholarly Activities

This allows hospitals to claim non-patient care didactic time (i.e., classroom or other purely educational activities) in non-provider settings for GME purposes and in the hospital for IME purposes. However, this section expressly excludes research time not associated with the treatment or diagnosis of a particular patient from the allowance of non-patient care didactic time. This section also allows hospitals to claim residents' vacation and sick time as part of the IME and GME FTE count. Effective dates: cost reporting periods beginning on or after July 1, 2009 (GME didactic time in non-provider settings); cost reporting periods beginning on or after October 1, 2001 (inability to claim time associated with non-patient care research for IME purposes); and January 1, 1983 (all other provisions, including ability to count didactic time for IME purposes in the hospital setting and ability to claim vacation and sick time for IME and GME purposes).

Section 5506 - Preservation of Resident Cap Positions from Closed Hospitals

This allows the distribution of FTE slots from hospitals that close on or after March 23, 2008. The highest priority for receiving FTE slots from closed hospitals goes to hospitals in the same core-based statistical area that were also in a shared rotational affiliation agreement with the closed hospital.

Section 5507 - Demonstration Projects to Address Health Professions' Workforce Needs; Extension of Family-to-Family Health Information Centers.

This section establishes various demonstration projects to address health professions' workforce needs and to extend family-to-family health information centers.

Section 5508 - Increasing Teaching Capacity

The section amends the Public Health Service Act to provide grants (up to three years for an aggregate of up to $500,000) to federally qualified health centers, rural health clinics, community mental health centers, and Indian Health Service centers (among other similar community based, ambulatory patient care centers) that expand or establish primary care residency programs. This section also amends the Public Health Service Act to provide $230,000,000 from 2011 to 2015 for direct and indirect medical education payments to the same types of community based, ambulatory patient care centers discussed immediately above for sponsoring the training of residents in expanded or new residency programs above and beyond the number of primary care residents already trained in a to-be-determined base period.

Section 5509 - Graduate Nurse Education Demonstration

The section provides a demonstration project for up to 5 hospitals to receive reasonable cost reimbursement for the provision of training to that number of advance practice nurses ("APN") which is above and beyond the average number of APNs who graduated from an affiliated school of nursing in each year from January 1, 2006 through December 31, 2010.

Title VI – TRANSPARENCY AND PROGRAM INTEGRITY

Subtitle A—Physician Ownership and Other Transparency

Section 6001 – Limitation on Medicare Exception to the Prohibition on Certain Physician Referrals for Hospitals

The Act makes sweeping changes to the Stark law's "whole hospital" exception, effectively blocking new physician-owned hospitals after December 31, 2010 and limiting the capacity and amount of physician ownership in existing physician-owned hospitals. As revised, the Stark law now prohibits physicians from referring Medicare patients to a hospital in which they have an ownership or investment interest unless the hospital has physician ownership and a Medicare provider agreement as of December 31, 2010. Even a physician-owned hospital that meets these requirements will be subject to significant restrictions that cap the hospital's aggregate physician ownership and, with certain narrow exceptions for high Medicaid hospitals, prohibit expansion of the number of operating rooms, procedure rooms or beds. The Act also subjects a physician-owned hospital to reporting requirements and extensive disclosure requirements, to its patients, on the hospital's website and in any public advertisements.

Section 6002 – Transparency Reports and Reporting of Physician Ownership or Investment Interests

Beginning March 31, 2013, and annually thereafter, drug, device, biological and medical supply manufacturers are required to report transfers of value made to a physician, physician medical practice, a physician group practice, and/or a teaching hospital. The information would be made available to the public. Substantial penalties are imposed for non-compliance.

Section 6003 – Disclosure Requirements for In-Office Ancillary Services Exception to the Prohibition on Physician Self-Referral

The Act imposes certain disclosure requirements on the referring physician to satisfy the in-office ancillary services exception from the Stark self-referral prohibition. The disclosures include a written list of suppliers who furnish the service in the area in which the patient resides. The requirements apply to MRI, CT, and PET and any other designated health services that the Secretary determines are appropriate. Section 6003 states that it is effective for services furnished on or after January 1, 2010. We recognize that this appears to impose a retroactive disclosure requirement, and would anticipate guidance from the Secretary.

Subtitle B—Nursing Home Transparency and Improvement

Section 6101 -- Nursing Home Transparency and Required Disclosures

SNFs will be required to disclose information regarding organizational structures as well as information on officers, directors, trustees, or managing employees, including names, titles and start dates of services. The Act requires disclosure of owners with a whole or part interest in any mortgage, deed, or other obligation exceeding five percent of a facility's total property/assets. Additional disclosable parties include entities establishing policies or procedures for any of the operations of the facility, providing financial or cash management services, or providing management or administrative services, clinical consulting services, or accounting or financial services to the facility. The Act also requires disclosure of limited liability company information and any limited partners or limited partnerships who/that have an ownership interest in the limited partnership, which is equal to or exceeds 10 percent. Facilities will be required to make all disclosable parties' information available to the public upon request and update the information as necessary to reflect any changes. Facilities are required to certify to the Secretary and the Inspector General ("OIG") that the information submitted upon request is, to the best of the facility's knowledge, accurate and current. The Secretary must develop a standardized format for the information no later than two years after enactment.

Section 6102 -- Compliance Programs

SNFs must have a compliance and ethics program in operation within 36 months of enactment. This program must be effective in preventing and detecting criminal, civil and administrative violations and in promoting quality of care. The secretary must have regulations for compliance and ethics programs in place within two years of enactment.

Section 6103 -- Nursing Home Compare Medicare Website and Comparable Websites

The Secretary must ensure that information provided on the Nursing Home Compare Website be displayed in a prominent, easily accessible, and timely basis. The website will also include summary information on the number, type, severity and outcome of adjudicated instances of criminal violations by a facility or the employees of a facility that were committed inside the facility. It must also reflect the number of civil money penalties levied against the facility, employees, contractors, or other agents. Additional information on the Special Focus Facility ("SFF") program must be posted on the website. States are also mandated to maintain a consumer-oriented website providing information on SNFs within the state, including state inspection reports, facilities' plans of correction, and any other information that the state or the Secretary considers useful to the general public.

Section 6104 -- Reporting of Certain Expenditures

SNFs will be required to report expenditures separately for direct care services, indirect care services, capital assets and administrative costs. This will be done through cost reports for cost reporting periods beginning on or after the date that is two years after enactment.

Section 6105 -- Standardized Complaint Form

The Secretary is required to develop a standardized complaint form for use by a resident (or a person acting on the resident's behalf) in filing a complaint with a state survey and certification agency and/or the state's long term care ombudsman program.

Section 6106 -- Reporting Staffing Information

The Secretary is required to develop a program for facilities to report staffing information in a uniform format based upon payroll data, including information on agency or contract staff. The Secretary is to do so within two years of enactment.

Section 6107 -- Analysis of the Five-Star Quality Rating System

The GAO is required to conduct a study of the CMS Five-Star System that will evaluate how the system is being implemented and problems associated with that system, as well as how the system may be improved. The GAO is required to issue a report of the findings of the study to Congress within two years of enactment.

Section 6111 -- Changes to Civil Money Penalties Under the Federal Enforcement System

The Secretary is authorized to reduce civil money penalties ("CMPs") as much as 50 percent in cases where a facility self reports and promptly corrects the deficiency within 10 days. Reductions would not be made for self reported deficiencies which are cited at the levels of either immediate jeopardy or actual harm. Similarly, the Secretary will not reduce penalties for repeat deficiencies if there had been a previous reduction in the preceding year.

In addition, SNFs will have an opportunity to participate in an informal dispute resolution process 30 days after imposition of any CMP. The Secretary will have the authority to collect and place CMPs imposed for deficiencies citing immediate jeopardy or actual harm violations in an escrow account following completion of the dispute resolution process or a date that is 90 days after the imposition of the CMP, whichever is earlier. Successful appeals will result in a repayment of the amount collected plus some amount of interest. Finally, the Secretary is authorized to use a portion of collected CMPs to fund activities to benefit residents or initiatives to improve the facility.

Section 6112 -- Independent Monitoring Demonstration Project

The Secretary, along with the OIG, is required to establish a demonstration project to develop, test and implement use of an independent monitoring program to oversee interstate and large intrastate chains of SNFs. The chains will be responsible for a portion of the costs associated with the appointment of independent monitors. The Secretary and the OIG will evaluate the demonstration project after a two year period.

Section 6113 -- Facility Closures

Establishes written notification requirements in advance of the closure of SNFs by at least 60 days prior to closure. Requires the submission of a closure plan that must be approved by the State. Sanctions for a SNF's failure to comply with facility closure notification requirements will include CMPs of $100,000 as well as possible exclusion from other related facilities participating in federal health care programs. These provisions are effective a year from enactment.

Section 6114 Culture Change and the Use of Information Technology

The Secretary is required to conduct administration projects on the development of those practices in SNFs that are involved in the "Culture Change" movement and other demonstration projects for best practices in the use of information technology to improve resident care. The demonstration projects are to be implemented no less than one year after the enactment of the health care reform legislation.

Section 6121 -- Dementia and Abuse Prevention Training

SNFs are required to include dementia management and abuse prevention training as part of pre-employment initial training for permanent and contract agency staff and, if the Secretary deems appropriate, as part of ongoing in service training. These provisions are effective a year from enactment.

Subtitle C -- Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long Term Care Facilities and Providers

Section 6201 -- Background Checks

The Secretary is required to establish a national program for background checks on "direct patient access" employees of certain long term care facilities, including SNFs, and provide federal matching funds to states to conduct these activities. SNFs, along with any assisted living/residential care facilities that participate in either the Medicare or Medicaid programs will be required to obtain state and national criminal history and other background checks on their prospective employees through such means as the Secretary requires. There will be a 60-day grace period during which newly hired staff may be given provisional employment, pending completion of the background check.

Subtitle D – Patient-Centered Outcomes Research

Sections 6301, 6302 (Section10602) -- Patient-Centered Outcomes Research, Federal Coordinating Council for Comparative Effectiveness Research, and Clarifications to Patient-Centered Outcomes Research

Establishes a non-profit Patient-Centered Outcomes Research Institute to identify research priorities and conduct research that compares the clinical effectiveness of medical treatments to advance the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed. The Institute shall ensure that research findings do not include practice guidelines, coverage recommendations, payment or policy recommendations.

The Institute will be overseen by a multi-stakeholder Board of Governors (including patients, physicians, private payors, pharmaceutical, device, and diagnostic manufacturers or developers, quality improvement researchers, and members of the Federal Government or States) and will be assisted by expert advisory panels. The Institute replaces the Federal Coordinating Council for Comparative Effectiveness Research established by the American Recovery and Reinvestment Act. Funding is available beginning fiscal year 2010.

Subtitle E—Medicare, Medicaid, and CHIP Program Integrity Provisions

Section 6401 (Section 1305) -- Provider Screening and Other Enrollment Requirements Under Medicare, Medicaid, and CHIP

This provision requires the Secretary to establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and CHIP. The level of screening applied to each category of provider or supplier will be determined in accordance with the risk of fraud, waste, and abuse as determined by the Secretary. Providers and suppliers may be required to pay a fee for this

enhanced screening. Moreover, one year after the enactment of the Act, providers and suppliers applying for enrollment or revalidation of enrollment in Medicare, Medicaid, or CHIP are required to disclose current or previous affiliations with any provider or supplier that: (1) has uncollected debt; (2) has had its payments suspended; (3) has been excluded from participating in a federal health care program; or (4) has had billing privileges revoked. Based upon these disclosures, providers and suppliers may be denied enrollment in the programs if the affiliations pose an undue risk. Furthermore, pursuant to this section, as a condition of enrollment, providers and suppliers will be required to establish a compliance program containing core elements that are to be established by the Secretary.

This section provides, effective January 1, 2011, if the Secretary determines there is a significant risk of fraudulent activity among suppliers of DME, the Secretary shall withhold payment with respect to the DME furnished by such supplier during the 90-day period beginning on the date of the first submission of a claim for DME furnished by the supplier.

Section 6402 -- Enhanced Medicare and Medicaid Program Integrity Provisions

This section makes numerous significant changes to the integrity provisions affecting Medicare and Medicaid. Selected aspects of this section are discussed below.

This section strengthens enforcement tools for anti-kickback statute violations, by stating that a claim that includes items or services "resulting from" a violation of the anti-kickback statute constitutes a false or fraudulent claim. This provision may end up being highly litigated, as it is debatable as to whether services provided in any particular situation were the "result" of a kickback being paid, or the result of other factors, such as the need for patient care.

The section also attempts to repeal one holding of the Ninth Circuit *Hanlester* case, which interpreted the "knowing and willful" intent element of the anti-kickback statute as requiring a party to specifically believe its conduct was illegal under the anti-kickback statute before a violation would result. The law revises the statute by adding that "with respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." The effect of this change is that a person no longer needs to believe their conduct specifically violates the anti-kickback statute ***itself*** for a violation to exist. However, it appears the person still must believe his or her conduct is illegal in order for there to be a violation of the anti-kickback statute.

This provision requires providers and suppliers to report and return Medicare and Medicaid overpayments within 60 days from the date the overpayment was "identified" or by the date a corresponding cost report was due, whichever is later, and that the failure to comply with this deadline subjects the provider to potential liability under FCA for a reverse false claim and to civil monetary penalties. However, since the term "identified" is not defined, providers are left in the dark about when the 60-day deadline for reporting and returning overpayments will actually begin to run. At a recent conference, OIG officials indicated that regulations would likely be needed to effectively implement this new provision.

This section also authorizes the Secretary to: (1) exclude providers' and suppliers' participation in any federal health care program for providing false information on any application to enroll or participate; and (2) suspend payments to a provider or supplier "pending an investigation of a credible

allegation of fraud against the provider of services or supplier." However, the term "credible allegation of fraud" is undefined and will be addressed by the Secretary through implementing regulations.

Additionally, this section requires the Secretary to take into account the volume of billing for a durable medical equipment (DME) supplier or home health agency when determining the size of the supplier's and agency's surety bond and authorizes the Secretary to require other providers and suppliers to post a surety bond if the Secretary considers them to be at risk.

This section further requires disclosure of payments or transfers of value between physicians and teaching hospitals and manufacturers and distributors of covered drugs, devices, biologics, and medical supplies. It exempts transfers of value less than $10/transfer or $100/calendar year (adjusted by the consumer price index (CPI) after 2012), product samples not intended to be sold, educational materials that directly benefit patients or are intended for patient use, loans of covered devices for short-term trial periods, items and services under contractual warranty, discounts and rebates, in-kind items for the provision of charity care, dividends or other profit distributions, as well as other specifically defined payments or transfers.

Applicable manufacturers will be required to submit detailed reports to the Secretary of payments or other transfers of value to covered recipients on an annual basis beginning March 31, 2013. Applicable manufacturers will be subject to civil monetary penalties for failure to report each payment, transfer of value, or ownership or investment interest ($1,000-$10,000/transfer and $150,000 total for unknowingly failing to report; $10,000-$100,000/transfer and $1 million total for knowingly failing to report).

This section also amends the definition of remuneration for purposes of civil monetary penalties for anti-kickback violations to exclude any remuneration that promotes access to care and possesses a low risk of harm to patients and federal health care programs, the offer or transfer by a retailer of coupons, rebates, or other awards if certain conditions are met, or the offer or transfer of items or services for free or less than fair market value by a person to an individual in financial need if certain conditions are satisfied.

This section provides that a person excluded from participation in federal health care programs will be subject to a civil monetary penalty for ordering or prescribing a medical or other item for which payment may be made under a federal health care program if the person knows or should know that a claim for such medical or other item or service will be made.

Section 6404 – Maximum Period for Submission of Medicare Claims Reduced to Not More Than 12 months

This section reduces the maximum period for submission of Medicare claims to one year after the date of service, though it does allow the Secretary to specify exceptions to the one year period of time. This provision is applicable to services furnished after January 1, 2010.

Section 6405 -- Physicians Who Order Items or Services Required to be Medicare Enrolled Physicians or Eligible Professionals

Section 6405 provides that DME or home health services can only be ordered by an enrolled Medicare eligible professional or physician. This provision applies to written orders and certifications

made on or after July 1, 2010. Moreover, this section authorizes the Secretary to extend these requirements to other Medicare items and services to reduce fraud, waste, and abuse.

Section 6406 -- Requirement for Physicians to Provide Documentation on Referrals to Programs at High Risk of Waste and Abuse

Section 6406 authorizes the Secretary to disenroll, for up to one year, a Medicare enrolled physician or supplier that fails to maintain and provide access to written orders or requests for payment for DME, certification for home health services, or referrals for other items and services. Additionally, this section authorizes the Secretary to exclude from participation in any federal health care program any individual or entity ordering, referring for furnishing, or certifying the need for an item or service that fails to provide adequate documentation to verify payment.

Section 6407 -- Face to Face Encounter with Patient Required Before Physicians May Certify Eligibility for Home Health Services or DME under Medicare

The Secretary shall require that an order be written documenting that a physician, physician assistant, nurse practitioner, or clinical nurse specialist has had a face-to-face encounter with the patient (including through use of telehealth) during the 6-month period preceding a written order for DME as a condition of payment for DME.

Section 6408 -- Enhanced Penalties

Imposes a civil monetary penalty for knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim for payment under a federal health care program of up to $50,000 for each false record or statement. Imposes a civil monetary penalty for failing to grant timely access, upon reasonable request to the HHS Inspector General for the purpose of audits, investigations, evaluations, or other statutory function of the Inspector General of up to $15,000 per day.

Section 6409 -- Medicare Self-Referral Disclosure Protocol

A very welcome change to the Stark law is a mandate that CMS develop and implement a voluntary self-disclosure protocol for actual and potential Stark law violations, within six months of enactment. The absence of a mechanism for resolving such issues had been a long-standing problem, aggravated last year when the OIG announced it would no longer accept "Stark only" self-disclosures. Of critical importance, the legislation expressly permits compromising payment and penalty amounts for violations. Previously, CMS had taken the position that it could not reduce or compromise amounts owed under the Stark Law, which meant minor, technical violations (such as failure to obtain signatures on a contract) could potentially result in enormous settlement amounts.

Section 6410 -- Adjustments to the Medicare DME, Prosthetics, Orthotics, and Supplies Competitive Acquisition Program

This section expands Round 2 of the DME Competitive Bidding Program to include the next 21 largest metropolitan statistical areas by total population and requires competitive bid areas or use of competitive bid prices by January 1, 2016.

Section 6411 -- Recovery Audit Contractors

Requires that by December 31, 2010 Medicare Parts C and D, as well as Medicaid programs, will be folded into the Recovery Audit Contractor program ("RAC"), which currently identifies and collects overpayments for Medicare Parts A and B. It is unclear how this requirement will interact with the current development of the Medicaid Integrity Program and the use of Medicaid Integrity Contractors ("MICs"), the funding of which was increased due to the inclusion of a CPI adjustment.

Subtitle F -- Additional Medicaid Program Integrity Provisions

Section 6501 -- Termination of Provider Participation Under Medicaid if Terminated Under Medicare or Other State Plan

The Act adds several provisions requiring Medicaid exclusion of certain individuals and entities. Under this section, a state must terminate a person's participation in Medicaid if the person is terminated from participation in Medicare or in any other state's Medicaid program.

Section 6502 -- Medicaid Exclusion From Participation Relating to Certain Ownership, Control, and Management Affiliations

Medicaid agencies must exclude from Medicaid participation any entity or individual which owns, controls, or manages an entity that has failed to repay overpayments during such period as will be determined by the Secretary; is suspended, excluded, or terminated from participation in any Medicaid program; or is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.

Section 6507 -- Mandatory State Use of National Correct Coding Initiative

Effective for claims submitted on and after October 1, 2010, the states are required to incorporate the national correct coding initiative into their Medicaid claims processing systems.

Subtitle H -- Elder Justice Act

Section 6703 -- Elder Justice

Appropriates $5 million for FY 2011, $7.5 million for FY 2012, and $10 million for each of FYs 2013 and 2014 for grants to eligible entities to support the long term care ombudsman program. Appropriates $10 million for each of FYs 2011 through 2014 for the Secretary to establish programs to provide and improve ombudsman training related to elder abuse.

Establishes an Elder Justice Program providing significant grant funding as well as the establishment of Elder Justice Coordinating Counsel within the Secretary's office. Grants are authorized to be provided to entities that will establish forensic centers, SNFs that offer training and benefits to employees as well as for various state-based activities investigating reports of elder abuse, neglect and exploitation.

Authorizes the Secretary to make grants to long term care facilities for the purpose of assisting such entities in offsetting the costs related to purchasing, leasing, developing, and implementing certified EHR technology. Grant funds may be used for: (a) purchasing, leasing, and installing computer software and hardware, including handheld computer technologies; (b) making improvements to existing computer software and hardware; (c) making upgrades and other improvements to existing computer software and hardware to enable e-prescribing; and (d) providing education and training to eligible long term care facility staff on the use of such technology to implement the electronic transmission of prescription and patient information.

To be eligible to receive a grant, a long term care facility shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require (which may include evidence of consultation with the State in which the long term care facility is located with respect to carrying out activities funded under the grant). A grant recipient must, where available, participate in its state's electronic health information exchange program. Finally, pursuant to regulation, the Secretary must adopt electronic standards for the exchange of clinical data by long term care facilities, including, where available, standards for messaging and nomenclature.

Title VII – IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES

Subtitle A -- Biologics Price Competition and Innovation

Sections 7001 -7003 -- Biologics Price Competition and Innovation Act of 2009, Approval Pathway for Biosimilar Biological Products, Savings

These sections authorizes the Food and Drug Administration (FDA) to approve generic versions of biologic drugs and grants biologics manufacturers 12 years of exclusive use before applications for biosimilars can be approved. Applications for biosimilar approval may not be submitted until 4 years after the date on which the referenced product was first licensed. Any savings to the Federal Government generated as a result of the enactment of this section shall be used for deficit reduction.

Subtitle B -- More Affordable Medicines for Children and Underserved Communities

Sections 7101-7103 (Section 2302)

This subtitle makes changes to the federal 340B Drug Pricing Program, which requires pharmaceutical manufacturers to sign pricing agreements with the Secretary of Health & Human Services stipulating that they will sell outpatient drugs to certain "covered entities" at or below specified maximum ceiling prices. Current covered entities, listed in 42 USC 256b(a)(4), include federal grantees, federally qualified health centers, qualified disproportionate share hospitals, family planning providers, black lung clinics, AIDS drug purchasing assistance programs, Native Hawaiian Health Centers, and urban Indian organizations.

Section 7101 of the Act extends covered entity status to certain free-standing cancer hospitals excluded from the Prospective Payment System, certain critical access hospitals, and rural referral centers and sole community hospitals with qualifying disproportionate share adjustment percentages.

The Act also amends 42 U.S.C. 256b to include children's hospitals, which previously were included in the 340B program under section 6004 the Deficit Reduction Act of 2005 (codified at 42 U.S.C. 1396r-8(a)(5)(B)) but had not been formally added to the list of covered entities in 42 U.S.C. 256b(a)(4).

Section 7101 initially extended the 340B program to inpatient drugs. However, this provision was removed by Section 2302 of the Reconciliation bill. The Reconciliation bill also exempted orphan drugs (drugs designated by the Secretary under Section 526 of the Federal Food Drug and Cosmetic Act for rare diseases and conditions) from the required discounts for the new 340B entities added by the Act.

Section 7102 also establishes new auditing, reporting, and compliance requirements for the Secretary, pharmaceutical manufacturers, and 340B covered entities, and orders the Secretary to establish procedures to improve compliance with the rules of the 340B program. The Act sets forth sanctions for covered entities that violate the 340B program, including monetary penalties and removal from the 340B program. These provisions are effective as of January 1, 2010. The Act also requires the federal GAO to make recommendations on improving the 340B program to Congress within 18 months.

TITLE VIII – "CLASS" ACT

Section 8002 -- Establishment of National Voluntary Insurance Program for Purchasing Community Living Assistance Services & Support

Establishes the Community Living Assistance Services and Support ("CLASS") program, a voluntary, public long term care insurance program that is designed to allow individuals the ability to contribute through payroll deduction contributions for community living and institutional benefits. The Secretary is directed to ensure that the plan is actuarially sound and that it ensures solvency for 75 years. In addition, the plan allows for a five-year vesting period for eligibility of benefits and establishes benefit triggers that permit for the determination of functional limitations in order to obtain benefits. The cash benefit to be provided under the CLASS program is not to be less than an average of $50 per day.

TITLE IX – REVENUE PROVISIONS

Revenue Measures – Paying for Reform by "Spreading the Pain" The substantial costs associated with implementing health care reform required the Congress to get both diverse and creative in devising methods to pay for it. In addition to cost savings from reimbursement changes and additional revenues from increased enforcement recoveries, Title IX of the Act contains a number of "revenue measures" to offset the costs of reform by imposing new financial obligations across many different stakeholders in healthcare, including insurers, healthcare providers, drug and device manufacturers, employers, and consumers. These measures include excise taxes, annual fees, and changes in tax treatment for certain activities or businesses.

Subtitle A – Revenue Offset Provisions

Section 9001 (Section 10901 and Section 1401)
Section 9010 (Section 10905)
Section 1406; Section 9014, 9016.
For Insurers

The Act imposes new tax restrictions on health insurers. For example, beginning in 2010, the Act requires non-profit Blue Cross Blue Shield plans to have a medical loss ratio of 85 percent or greater in order to receive the special tax benefits currently provided to them under the Internal Revenue Code. Beginning in 2013, the Act limits the deductibility of executive and employee compensation to $500,000 per applicable individual for health insurers. The Act also imposes new taxes and fees on health insurers. Beginning in 2014, the Act imposes an aggregate annual fee on health insurers, based on their market share, starting at $8.0 billion in 2014 and ramping up over four years to $14.3 billion for 2018, after which the fee amount will be adjusted based on premium growth rates. Certain non-profit insurers and voluntary employee benefit associations are exempt.

Finally, beginning in 2018, the Act imposes a 40 percent excise tax (the "Cadillac tax") on the aggregate value of employer-sponsored health coverage that exceeds a "threshold amount." For 2018, this amount is $10,200 for individual and $27,500 for group coverage, and the threshold amount may be increased for employees engaged in high-risk professions or for employers with higher healthcare costs because of the age and gender of their workers. The threshold amount will be indexed to the consumer price index (CPI-U). "Aggregate value" includes both employer and employee plan contributions, but excludes dental and vision coverage. The insurer or the plan administrator (which may be the employer) will pay the tax, depending on whether the plan is fully-funded or self-funded.

Section 9007 (Section 10903) -- Additional Requirements for Charitable Hospitals

Provider-based financing of the Act is generally addressed in sections relating to provider reimbursement and fraud and abuse. However, one major revenue-related provision affecting providers in the Act contains four new requirements to qualify as a section 501(c)(3) charitable hospital organization, including (1) conducting community health needs assessments; (2) meeting financial assistance policy requirements; (3) limiting the amount a charitable hospital can charge for emergency or medically necessary services to individuals qualifying under the financial assistance policy outlined above to the amount generally charged to insured patients for the same services, and prohibiting the use of gross charges; and (4) not engaging in extraordinary collection actions before the organization has made reasonable efforts to determine whether the individual is eligible for assistance under the financial assistance policy described above.

In addition, the Act imposes an excise tax of $50,000 on a hospital organization that fails to meet the requirements of section 501(r)(3) for any taxable year. Further, the Act directs the Treasury Secretary to review the community benefit activities of each hospital organization to which 501(r) applies at least once every 3 years. Moreover, the Act imposes additional reporting requirements on charitable hospitals by requiring in each applicable taxable year, (1) a description of how the organization is addressing the needs identified in each community health needs assessment, and a description of any such needs that are not being addressed along with the reasons why such needs

are not being addressed; and (2) the audited financial statements of such organization. Finally, the Act requires an annual report to Congress from the Treasury Secretary, in consultation with the HHS Secretary, regarding various charity care and bad debt expenses for different classes of hospitals. These provisions are effective for taxable years beginning after March 23, 2010, except with respect to the community health needs assessment, which will apply starting March 23, 2012.

Section 9008 (Section 1404)
Section 9009 (Section 10904 and Section 1405
For Drug and Device Manufacturers

Beginning in 2011, the Act imposes an aggregate annual fee on all brand-name prescription drug manufacturers and importers to fund Medicare Part B. The fee will be $2.5 billion for 2011, $2.8 billion for 2012-2013; $3.0 billion for 2014-2016, $4.0 billion for 2017, $4.1 billion for 2018, and $2.8 billion for 2019 and following. The amount of each company's fee will be based on market share of prescription drug sales, and the fee would not apply to companies with $5M or less in sales, and orphan drugs would be excluded. The fees will be deposited in the Medicare Part B Trust Fund. In addition, starting in 2013, the Act imposes a 2.3 percent excise tax on the sale of any medical device. The Act exempts from the tax eyeglasses, contact lenses, hearing aids, and any other medical device determined by the HHS Secretary to be of a type that is generally purchased by the general public at retail for individual use.

Section 9002; Section 9012 (Section 1407) -- For Employers

The Act's revenue measures generally do not focus on employers, likely due to other provisions elsewhere in the Act that impose penalties on employers that fail to make affordable, minimum creditable coverage available to their employees. However, beginning in 2011, the Act requires an employer to disclose the value of employer-sponsored health insurance for each of its employees on the employee's W-2. In addition, beginning in 2013, the Act eliminates employer tax deductions for the Medicare Part D subsidy provided by employers who maintain prescription drug plans for their Medicare Part D-eligible retirees.

Section 9003-9004
Section 9005 (Section 10902 and Section 1403)
Section 9013;
Section 9015 (Section 10906),
Section 1402, Managers' Amendment
H.R. 4872, Section 1402
Section 9017 (Section 10907)
For Consumers

The Act imposes several new taxes on consumers. For example, beginning in 2013, the Act increases Medicare Part A payroll taxes (FICA/SECA) from 1.45 percent to 2.35 percent for earnings over $200,000 for individuals, $250,000 for joint filers, or $125,000 for a married taxpayer filing separately, and also imposes a 3.8 percent Medicare tax on the lesser of a taxpayer's net investment income or the excess (if any) of the modified adjusted gross income in that taxable year over the "threshold amount" ($250,000 for joint filers or a surviving spouse; $125,000 for a married taxpayer filing separately; $200,000 for anyone else). The threshold amounts are not indexed.

On a lighter note, in lieu of the "Botax" on elective cosmetic procedures, beginning July 1, 2010 the Act imposes a 10 percent excise tax on indoor tanning services, whether paid by insurance or otherwise, on the individual for whom the services are performed. In addition to some new taxes, the Act makes a number of tweaks to tax treatment of healthcare-related expenses. For example, the Act limits the inclusion of medicines or drugs that constitute "qualified medical expenses" under various nontaxable health expense accounts (FSAs, HRAs, or HSAs) to a medicine or drug that is prescribed or is insulin; increases to 20 percent the additional tax for unqualified HSA and Archer MSA withdrawals (effective starting in 2011); limits to $2,500 the amount of salary contributions to Health FSAs under a cafeteria plan (starting in 2013, indexed to CPI-U); and increases to 10 percent of adjusted gross income the threshold for itemized deduction of medical expenses (also starting in 2013), with exemptions for individuals age 65 and older for taxable years 2013-2016 (who would be subject to the prior 7.5 percent threshold).

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