



***Patient Protection and Affordable Care Act  
H.R. 3590***

**DXA Reimbursement**

- Restores payments for dual-energy x-ray absorptiometry (DXA) services furnished during 2010 and 2011 to 70 percent of the Medicare rate paid in 2006. These payments are retroactive to January 1, 2010.

**Pediatric Loan Repayment Program for Pediatric Subspecialists**

- Authorizes the establishment of a loan repayment program for pediatric subspecialists and mental and behavioral health service providers who agree to work in medically underserved areas.

**Physician Quality Reporting Initiative**

- Ensures a timely feedback requirement and informal appeals process by 2011.
- Requires in 2012, the Secretary develops a plan to integrate quality measure reporting with EHR meaningful use reporting requirements.

*PQRI Bonuses*

- 1 percent for 2011 and 0.5 percent 2012-2014, totaling 4 years of PQRI bonuses

*PQRI penalties*

- Penalties for unsuccessful participation will begin to apply in 2015 (1.5 percent) and thereafter (2 percent)
- Includes a new PQRI option beginning in 2011 where physicians can qualify for maintenance of certification (MOC) or equivalent program and complete MOC practice assessment. Participating physicians will receive an additional 0.5 percent incentive payment.

**Biosimilars**

*New FDA Authority:*

- Confers the FDA with the authority to establish an abbreviated pathway to approve biosimilars for market.

*Medicare Part B Payment:*

- Reimburses biosimilars and biologicals at the same rate. Sets the add-on payment rate for biosimilar product reimbursement at 6% of the average sales price of the brand biological product.

*Exclusivity:*

- Provides 12 years of market exclusivity protection for licensed product.

*REMS:*

- Applies rigorous regulatory provisions for approval of biosimilars.
- Applies the Risk Evaluation and Mitigation Strategy requirement to biosimilars in the same manner it is applied to innovators.

*Approval Pathway:*

- Requires the FDA to issue guidance documents for approval of biosimilars.
- Require immunogenicity studies which may be waived after FDA guidance issued that the current state of scientific evidence allows for a determination of immunogenicity safety.

**Comparative Effectiveness Research**

*Patient-Centered Outcomes Research Institute.*

- Establishes an independent non-profit CER institute tasked with supporting research on comparative clinical effectiveness.

*Governance.*

- Establishes an Independent Board of Governors appointed by U.S. Comptroller to be responsible for all activities and would include physician representation.

*Use of CER Findings:*

- Allows the institute to issue recommendations concerning practice guidelines, coverage recommendations, or policy, but prohibits construing recommendations as mandates.

*Personalized Medicine:*

- Includes provisions to ensure CER supports the advancement of personalized medicine.

**Creation of Independent Payment Advisory Board**

- Authorizes the creation of an Independent Payment Advisory Board which is responsible for making payment recommendations to curb the growth in national health expenditures.

**Medical Liability Reform**

- Contains Sense of the Senate language saying States should develop and test alternate methods and Congress should consider establishing a State demonstration program.
- Contains \$50 million in demonstration grant money to states for the development, implementation, and evaluation of alternatives to current tort litigation.

**Closing the Part D “Donut Hole”**

- Requires immediate one year reduction in coverage gap for 2010 by providing a \$250 rebate. Over the next ten years, the coverage gap will shrink to 25 percent.

### **Eliminates Pre-Existing Condition Exclusion**

- Prohibits all plans from establishing lifetime or unreasonable annual limits on benefits.
- Prohibits insurers from excluding based on pre-existing conditions or discriminating against those who have been sick in the past, beginning in 2014.
- Enacts a temporary insurance program for those who have been uninsured for several months or have a pre-existing condition.
- Ensures premium rate limits for the newly insured population.

### **Access to Care**

- Requires that any health insurance issuer that offers health insurance coverage in the individual or small group market must include the “Essential Health Benefits Package”, which is to be defined by HHS Secretary, but **must** include terms and services in prescription drug coverage and preventative and wellness services and chronic disease management.

### **Imaging Provisions**

#### *Self-Referral Exception:*

- Requires referring physicians to notify patients in writing that in-office ancillary services for specified imaging services may be obtained from a person other than the referring physician.

### **Administrative Simplification**

- Requires the Secretary to adopt a single set of operating rules, recommended by a qualifying non-profit entity, for electronic transactions like eligibility verification, claims status, claims remittance/payment, claims attachments, as well as a rule to establish an electronic funds transfers (EFT) standard, within specified periods of time.
- Requires the Secretary to adopt the development of a unique health plan identifier and the mandated use of EFT under Medicare by January 1, 2014.
- Requires health plans to certify compliance with standards and operating rules and would be subject to penalties for noncompliance.