A NEED FOR EDUCATION IN HEALTHCARE POLITICS FOR

MEDICAL PROFESSIONALS

APPROVED BY SUPERVISORY COMMITTEE

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A NEED FOR EDUCATION IN HEALTHCARE POLITICS FOR MEDICAL PROFESSIONALS

By

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The University of Texas Southwestern Medical Center at Dallas

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Program Description

The Congressional Fellowship program offered through the office of Congressman Michael Burgess, M.D., in partnership with the University of Texas Southwestern Medical School, is an opportunity for health science graduate students to work in a congressional office as a legislative assistant. My fellowship began in May 2007 and ended in May 2008. My duties were to advise and assist the Congressman and his legislative assistants in areas of healthcare policy by meeting with lobbyists and advocacy groups, attending briefings and seminars, preparing public statements, answering constituent correspondence, collaborating on the drafting of legislation, and preparing the Congressman for legislative hearings and floor debates.

The Role of the Physician in Health Policy

There are few doctors in Congress. While many physicians complain about the intrusion of the government into their domain, few have placed themselves in the position to understand and influence the government's role in modern medicine. During the years between 1960 and 2004, 25 out of 2196 members of Congress were physicians.

Table 1. Congressional Representation by Occupational Category and Years of Service

Occupation	No. of Legislators (%)	Years of Service, Mean
All	2196 (100)	12.3 (11.9-12.7)
Attorney	979 (44.6)	13.3 (12.7-13.9)
Business	298 (13.6)	11.2 (10.2-12.2)
Public service	217 (9.9)	10.6 (9.6-11.6)
Education (all levels)	162 (7.4)	12.3 (10.9-13.7)
Military	111 (5.1)	13.5 (11.6-15.8)
Media/entertainment	92 (4.2)	13.4 (11.2-15.5)
Agriculture	82 (3.7)	12.6 (10.8-14.5)
Banking and insurance	82 (3.7)	10.9 (9.2-12.8)
Other/miscellaneous	80 (3.6)	9.4 (7.9-10.9)
Health care (non-physician)	25 (1.1)	8.8 (6.1-11.6)
Physician	25 (1.1)	9.2 (6.2-12.3)
Law enforcement	24 (1.1)	13.0 (9.3-16.9)
Minister/clergy	15 (0.7)	9.0 (6.2-11.8)
Unknown	4 (0.2)	5.3 (0.0-14.1)*

*97.5% confidence interval reported

Kraus, C., and Suarez, T. "Is There a Doctor in the House?...Or the Senate?" JAMA 292.17: 2125-2129 (November 3, 2004).

Table 2 111th Congress Medical Doctors

Representative	Party/State	Specialty
Boustany, Charles	Republican/Florida 07	Cardiovascular Surgeon
Broun, Paul	Republican/Georgia 10	Family Practice
Burgess, Michael	Republican/Texas 26	OB/GYN
Cassidy, Bill	Republican/Louisiana 06	
Christensen, Donna	Democrat/ Virgin Islands	Family Practice
Fleming, John	Republican/ Louisiana 04	
Gingrey, Phil	Republican/ Georgia 11	OB/GYN
Griffith, Parker	Democrat/ Alabama 05	Oncology
Kagen, Steve	Democrat/ Wisconsin 08	Immunology
Paul, Ron	Republican/Texas 14	OB/GYN
Price, Tom	Republican/Georgia 06	Orthopedic Surgeon
Roe, David	Republican/Tennessee 13	OB/GYN
Snyder, Vic	Democrat/ Arkansas 02	Family Practice
Barrasso, John	Republican/ Wyoming	Orthopedic Surgeon
Coburn, Tom	Republican/ Oklahoma	OB/GYN

http://clerk.house.gov/library/reference-files/RFD_111_MedicalDoctors.pdf

With healthcare expenses becoming an ever-pressing problem for the nation, there is a clear need for more physicians in Congress to help steer the discussion and to give practical advice to the lawyers and other professionals who are legislating healthcare more and more.

Legislation

While in Congress, I worked on many pieces of legislation. A complete list is included in the appendix. The topics varied, but Medicare, Medicaid, FDA, NIH, and private insurance regulations were my main areas of concern.

The frustrations of the Congressional system of legislating were very discouraging to me. Many quality bills died without ever having a hearing. Others were dismissed after a hard fought committee debate. The most difficult part of my job was listening to the heartfelt pleas of lobbyists, especially those with incurable diseases, and telling them we could not support their legislation.

I spent a majority of my time on two bills: the CHAMP bill and the FDA Amendments Bill of 2007. Both of these bills required many briefings by many different governmental agencies, advocacy groups, lobbyists, and other staffers as well as research into complex history and current issues.

CHAMP Bill

The State Children's Health Insurance Program (SCHIP) was created in 1997 with the purpose of providing health insurance for those children whose families made too much money for Medicaid but could not afford to pay the premiums for private insurance. Prior to SCHIP, approximately 19 million Medicaid beneficiaries were children, and combined federal and state expenditures on their behalf totaled $32 billion. However, there remained an estimated 9 million to 11.6 million children who were uninsured at some time during 1997. The legal mandate expired on September 30, 2007. One of the biggest healthcare bills of that year was the renewal of SCHIP.

HR 3162, the Children's Health and Medicare Protection Act of 2007 (CHAMP), was a huge bill introduced by the Democrats in an effort to renew SCHIP as well as partially reform Medicare. The press and interest groups focused mostly on the SCHIP portion. However, there were several controversial aspects of this bill that were debated in committee and on the floor of the House.

The first controversy was physician ownership of hospitals. CHAMP, Section 651, was a provision to eliminate the whole hospital exception to the Stark law (prohibiting physicians from self-referral) so physicians would no longer be allowed to refer Medicare patients to hospitals in which they have an ownership interest. Existing facilities would have 18 months to limit physician ownership to less than 40% and no more than 2%

individually. The Democrats were in favor of this provision due to the idea that physician ownership increased Medicare expenditures from overutilization and lack of competition. The Republicans argued that in 2003, the Center for Medicare and Medicaid Services did a study showing no problems from physician-owned hospitals.

Another contentious issue in the CHAMP bill was how the Sustainable Growth Rate (SGR) would once again be pushed back another year instead of being dealt with now. Every year the SGR is postponed, the amount of payment reductions for physicians increases. CHAMP would not stop the problem. One of the ways to pay for the SGR delay was to eliminate the higher payments to Medicare Advantage plans, which the Republicans were convinced would hurt seniors' access to better healthcare.

One of the biggest arguments the Republicans had against CHAMP was the crowd-out effect of SCHIP. SCHIP is a grant program like Medicaid but is matched at a higher rate by the federal government than Medicaid, and states had a lot of room to develop the program as they wanted. There were three ways to administer SCHIP: a separate children's program, expanded Medicaid services, or both. Some states had allowed adults to be covered by SCHIP allocated money in the belief that by simplifying the process and allowing adults to apply with their children, they would expand the number of children enrolled. SCHIP was designed for families with income up to 200% of poverty, but some states expanded that to 400% of poverty due to the high cost of living in these states. The states that covered adults and had a higher income level for approval often ran out of funds early and required increased Federal assistance to keep their SCHIP programs running. One of the problems with this expanded coverage is that newly enrolled children sometimes formerly carried private insurance. SCHIP only pays

a percentage of what private insurance pays for the same services. Some pediatricians lobbied against CHAMP on the basis of reduced income for children's clinics already barely able to stay open.

Finally, CHAMP proposed to pay for these changes to SCHIP and Medicare by increasing taxes on cigarettes to almost double the then current tax. The Democrats position was that smokers should contribute to healthcare due to their documented higher healthcare needs, and it is a tax on an optional item many families can do without. Their deduction was that making smoking more expensive, will result in fewer smokers that the taxpayers will have to support in the future. The Republicans argued that taxing a segment of the population that may not benefit from the service is morally wrong, and also that making smoking too expensive will eventually deplete the number of smokers to pay the tax. CHAMP was vetoed by the President and not overridden, but SCHIP was extended in a separate bill.

FDA Amendments Bill of 2007

The Food and Drug Administration is an agency of the United States Department of Health and Human Services that is responsible for protecting and promoting public health through regulating and supervising many consumer products. In 2007, the FDA came under increased scrutiny due to revelation that it was unable to adequately inspect medical device and drug manufacturing plants, prevent infiltration of counterfeit drugs into the country, or regulate tobacco products. While I attended hearings on all of these issues, I worked mostly on the FDA Amendments Bill of 2007.

The FDA Amendments Bill of 2007 was a mega-bill that consisted of the Prescription Drug User Fee Amendments of 2007, Medical Device User Fee Amendments of 2007, Pediatric Medical Device Safety and Improvement Act, Pediatric Research Equity Act of 2007, Best Pharmaceuticals for Children Act of 2007, Reagan Udall Foundation, and several smaller segments on food safety, conflicts of interest, and clinical trial databases. This bill renewed ways to pay for the FDA's role in new drugs and medical devices, so that the advances in science made their way to the public quickly without compromising safety. The manufacturers pay the FDA for expedited review. This bill also established the Reagan Udall Foundation as a private-public partnership to figure out ways to expedite medical product advancement. The pediatric sections of the bill outlined ways to encourage manufacturers and researchers to investigate their products for children's use.

The majority of the discussion on this bill was spent debating the propriety of manufacturers paying the FDA for their approval. The Republicans argued that the FDA was able to keep conflicts of interest at a minimum. The Democrats were concerned that the FDA could be persuaded to allow some devices and drugs to pass without complete evaluation in the interest of maintaining its budget.

Another contention between the Democrats and Republicans was the direct-to-consumer advertising that the drug companies were beginning to embrace. The Democrats wanted to stifle the ads and require the FDA to approve these ads before they could be shown to the public due to concern that the ads were intentionally misleading as to the side effects and indications. The Republicans believed this would violate free speech.

Eventually, this bill was passed with the FDA able to approve ads that the manufacturers volunteered for preview, but no mandates on FDA approval were made. A section on conflict of interest spelled out instruction to FDA committee members on how to handle their income from drug companies and their positions on panels. As 2007 progressed, many scares on tainted foods and dangerous overseas products would generate several hearings on the FDA, its powers, and its role in consumer safety.

Recommendations for Physician Education in Health Policy

The government continues to intrude on healthcare. Recently, the government passed a bill that reforms the way insurance is regulated, and the full impact of that bill has not yet been felt. By controlling the largest insurance company in the country, Medicare, the government is able to dictate policies to doctors and hospitals with the power of the purse. Many briefings I attended in Congress were on the ever rising costs of healthcare and how they were unsustainable for much longer. As healthcare costs continue to rise, the government will continue to look for ways to control it. Eventually, the way healthcare is bought and sold in this country will have to fundamentally change.

Only by learning how the policies are developed, passed, and challenged can physicians hope to have a hand in guiding healthcare. I frequently saw ineffectual lobbying by physician groups that did not focus on the big picture but instead gave ammunition to their enemies by attacking other specialties, showing ignorance of the bills, and quitting far short of their goals. Rather than building political capital, these groups supported the consensus that physicians are not powerful enough to stop anyone from taking over medicine.

Since healthcare is now so tightly regulated by those in politics, it only makes sense that physicians become educated about the political process that will govern their professional lives. Medical doctors can learn to influence Congress, the President, and local governments in order to protect their patients and their livelihoods from unnecessary government interference. In my experience, the House of Representatives wants physicians to be involved because as lawyers and other professionals, they feel overwhelmed by medical issues and healthcare reforms. We can and should assist them with proper, focused lobbying and by holding political office after years of clinical practice.

Resources

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Appendix A

Healthcare Bills of Fellow's Time in Office

H.R. 976 Children's Health Insurance Program Reauthorization Act of 2007

10/18/2007 Failed of passage in House over veto

H.R. 20 Melanie Blocker-Stokes Postpartum Depression Research and Care Act

10/15/2007--Passed House amended. Failed in the Senate.

H.R. 410 United States Physician Shortage Elimination Act of 2007

H.R. 427 Legal Immigrant Health Restoration Act of 2007

H.R. 493 Genetic Information Nondiscrimination Act of 2008

Became Public Law No: 110-233

H.R. 552 Pulmonary and Cardiac Rehabilitation Act of 2007

H.R. 562 Medicare Long-Term Care Hospital Improvement Act of 2007

H.R. 583 Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2007

H.R. 677 Nursing School Capacity Act of 2007

H.R. 741 Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2007

H.R. 748 Medicare Access to Rehabilitation Services Act of 2007

H.R.758 Breast Cancer Patient Protection Act of 2008

9/25/2008--Passed House amended. Failed in the Senate.

H.R. 772 Nurse Education, Expansion, and Development Act of 2007

H.R. 780 Counterfeit Drug Prevention Act of 2007

H.R. 853 Wellness and Prevention Act of 2007

H.R. 962 Preservation of Antibiotics for Medical Treatment Act of 2007

H.R. 992 Cloned Food Labeling Act

H.R. 1013 To amend title XXI of the Social Security Act to prohibit the approval or continuation of section 1115 waivers insofar as they provide coverage of nonpregnant adults under the State Children's Health Insurance Program (SCHIP).

H.R. 1014 Heart Disease Education, Analysis Research, and Treatment for Women Act

9/25/2008--Passed House amended. Failed in the Senate.

H.R. 1017 Protecting Children's Health in Schools Act of 2007

H.R. 1032 Alzheimer's Treatment and Caregiver Support Act

H.R. 1038 To amend the Public Health Service Act to provide for the licensing of comparable and interchangeable biological products, and for other purposes

H.R. 1046 Medicare Quality Improvement Organization Modernization Act of 2007

H.R. 1076 HIPAA Recreational Injury Technical Correction Act

H.R. 1093 Resident Physician Shortage Reduction Act of 2007

H.R. 1113 Inflammatory Bowel Disease Research Enhancement Act

H.R. 1134 Physical Therapist Student Loan Repayment Eligibility Act of 2007

H.R. 1154 To award a Congressional Gold Medal to Michael Ellis DeBakey, M.D.

Became Public Law 110-95

H.R. 1157 Breast Cancer and Environmental Research Act of 2008

Became Public Law No: 110-354

H.R. 1165 SAFE Drug Act

H.R. 1174 Healthy Hospitals Act of 2007

H.R. 1237 Cytology Proficiency Improvement Act of 2008

H.R. 1245 Kidney Disease Educational Benefits Act of 2007

H.R. 1247 9/11 Comprehensive Health Benefits Act of 2007

H.R. 1310 Relief and Elimination of the Medicare Enrollment Deadline Penalty (REMEDY) Act of 2007

H.R. 1368 Personalized Health Information Act of 2007

H.R. 1414 9/11 Heroes Health Improvement Act of 2007

H.R. 1418 Traumatic Brain Injury Act of 2008

Became Public Law 110-206

H.R. 1424 Paul Wellstone Mental Health and Addiction Equity Act of 2007

Became Public Law No: 110-343

H.R. 1440 Men's Health Act of 2007

H.R. 1457 Post-Abortion Depression Research and Care Act of 2007

H.R. 1494 Pediatric Medical Device Safety and Improvement Act of 2007

H.R. 1553 Caroline Pryce Walker Conquer Childhood Cancer Act of 2008

Became Public Law No: 110-285

H.R. 1560 Alzheimer's Breakthrough Act of 2007

H.R. 1624 Colorectal Cancer Mortality Prevention Act of 2007

H.R. 1634 Newborn Screening Saves Lives Act of 2007

H.R. 1665 Medicare Hearing Health Care Enhancement Act of 2007

H.R. 1666 Health Care Price Transparency Promotion Act of 2007

H.R. 1727 Christopher and Dana Reeve Paralysis Act

10/15/2007--Passed House amended**.** Failed in the Senate.

H.R. 1845 Medicare Durable Medical Equipment Access Act of 2007

H.R. 1884 National Health Service Corps Improvement Act of 2007

H.R. 1983 Optometric Equity in Medicaid Act of 2007

H.R. 2066 Medicaid Advanced Practice Nurses and Physician Assistants Access Act of 2007

H.R. 2101 Mercury in Dental Fillings Disclosure and Prohibition Act

H.R. 2236 Breastfeeding Promotion Act of 2007

H.R. 2241 Diabetes Treatment and Prevention Act of 2007

H.R. 2295 ALS Registry Act

Became Public Law 110-373

H.R. 2340 Medicare Osteoporosis Measurement Act of 2007

H.R. 2502 Geriatricians Loan Forgiveness Act of 2007

H.R. 2503 FDA Scientific Fairness for Women Act

H.R. 2560 Human Cloning Prohibition Act of 2007

H.R. 2567 Medicare Home Infusion Therapy Coverage Act of 2007

H.R. 2583 Physician Workforce Enhancement Act of 2008

9/23/2008--Passed House amended. Failed in the Senate.

H.R. 2584 High-Need Physician Workforce Incentives Act of 2007

H.R. 2585 Ensuring the Future Physician Workforce Act of 2007

H.R. 2677 IMPACT Act

H.R. 2731 Safe Tissue Act

H.R. 2820 Reconstructive Surgery Act of 2007

H.R. 2900 Food and Drug Administration Amendments Act of 2007

Became Public Law 110-85

H.R. 2915 National Health Service Corps Scholarship and Loan Repayment Programs Reauthorization Act of 2007

H.R.3014 Health Equity and Accountability Act of 2007

H.R. 3115 Carbon Monoxide Treated Meat, Poultry, and Seafood Safe Handling, Labeling, and Consumer Protection Act

H.R. 3162 Children's Health and Medicare Protection Act of 2007

Passed House 8/1/2007. Failed in the Senate.

H.R. 3186 Meth Mouth Prevention and Community Recovery Act

H.R. 3334 SMA Treatment Acceleration Act

H.R. 3536 Paget's Cancer Awareness Act

H.R. 3610 Food and Drug Import Safety Act of 2007

H.R. 3701 Safety of Seniors Act of 2008

Became Public Law 110-202

H.R. 3800 Promoting Health Information Technology Act

H.R. 3825 Newborn Screening Saves Lives Act of 2008

Became Public Law 110-204

H.R. 3865 Home Health Care Access Protection Act of 2007

H.R. 3967 Imported Food Safety Improvement Act of 2007

H.R. 4001 Nursing Education Opportunities Act

H.R. 4077 To authorize the interstate traffic of unpasteurized milk and milk products in final package form for human consumption when the milk or milk product originates in a State that allows the sale of unpasteurized milk and milk products in final package form and is destined for another State that allows the sale of unpasteurized milk and milk products in final package form.

H.R. 4116 To provide for the issuance of a veterans health care stamp.

H.R. 4205 National Health Services Corps and Loan Repayment Programs Renewal Act of 2007

H.R. 4206 Medicare Fracture Prevention and Osteoporosis Testing Act of 2007

H.R. 4230 School-Based Health Clinic Act of 2007

H.R. 4460 Health Care Choice Act of 2007

H.R. 4736 To amend part B of title XVIII of the Social Security Act to repeal limiting charges under the Medicare Program for non-participating physicians and to preempt State laws that prohibit balance billing.

H.R. 4778 Medicare Wound Therapy Patient Protection Act of 2007

H.R. 4790 Accountability and Transparency in Medicare Marketing Act of 2007

H.R. 4848 To extend for one year parity in the application of certain limits to mental health benefits, and for other purposes.

H.R. 4879 Virtual Screening for Cancer Act of 2007

H.R. 4911 Human Growth Hormone Restriction Act of 2007

H.R. 5032 Ultrasound Informed Consent Act

H.R. 5033 Hospital Price Reporting and Disclosure Act of 2007

H.R. 5265 Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2008

Became Public Law No: 110-361

H.R. 5317 Medicare Prescription Drug Affordability Act of 2008

H.R. 5426 To amend title XVIII of the Social Security Act to increase the per resident payment floor for direct graduate medical education payments under the Medicare Program.

H.R. 5445 To amend part B of title XVIII of the Social Security Act to increase Medicare payments for physicians' services through December 31, 2009.

H.R. 5544 Patients and Public Health Partnership Act of 2008

H.R. 5545 Ensuring the Future Physician Workforce Act of 2008

H.R. 5549 Deamonte Driver Dental Care Access Improvement Act of 2008

H.R. 5613 Protecting the Medicaid Safety Net Act of 2008

Became Public Law 110-252

H.R. 5669 Poison Center Support, Enhancement, and Awareness Act of 2008

Became Public Law 110-377

H.R. 5702 Advance Directive Promotion Act of 2008

H.R. 5757 Medicaid Fraud Reduction Act of 2008

H.R. 5842 Medical Marijuana Patient Protection Act

H.R. 5874 National MS Disease Registry Act

H.R. 5885 Health Information Technology Promotion Act of 2008

H.R. 5979 Stillbirth Awareness and Research Act of 2008

H.R. 1108 Family Smoking Prevention and Tobacco Control Act

7/30/2008--Passed House amended. Failed in the Senate.

H.R. 6151 Responsibility in Drug and Device Advertising Act of 2008

Appendix B
Summary of HR 2900 from THOMAS

SUMMARY AS OF:
7/11/2007--Passed House amended.

Food and Drug Administration Amendments Act of 2007 - **Title I: Prescription Drug User Fee Amendments of 2007** - (Sec. 101) Prescription Drug User Fee Amendments of 2007 - (Sec. 102) Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to include postmarket safety activities within the process for the review of human drug applications or supplements, including: (1) developing and using improved adverse event data collection systems and improved analytical tools to assess potential safety problems; (2) implementing and enforcing provisions relating to postapproval studies, clinical trials, labeling changes, and risk evaluation and mitigation strategies; (3) preparing and making publicly available a summary analysis of the adverse drug reaction reports received for recently approved drugs; (4) conducting screenings of the Adverse Event Reporting System database and reporting on new safety concerns; and (5) developing postmarket safety performance measures. Repeals provisions limiting postmarket safety activities to the three years after approval of a new drug.

(Sec. 103) Reauthorizes prescription drug user fees beginning in FY2008.

Requires the Secretary of Health and Human Services to provide a partial refund of an applicant's user fees if the application is withdrawn without a waiver before filing.

Sets forth special rules for positron emission tomography drugs, including subjecting an applicant in an approved human drug application for a positron emission tomography drug to one-sixth of the annual prescription drug establishment fee.

Establishes the amount of revenue that fees are to generate for FY2008-FY2012. Requires that such fees be derived equally from fees related to human drug applications and supplements, prescription drug establishments, and prescription drug products. Sets forth provisions regarding adjustments to such fees.

Authorizes appropriations for FY2008-FY2012.

Exempts approved prescription drugs or licensed biological products designated for a rare disease or condition (orphan drugs) from product and facility fees if certain requirements are met, including having U.S. drug sales that fall below a certain amount.

(Sec. 104) Requires the Secretary to assess and collect fees for advisory review of proposed direct-to-consumer television advertisements of prescription drug products. Sets forth procedures for such review.

Subjects each person that is assessed an advisory review fee to an operating reserve fee. Establishes the amount of revenue that may be generated from such fees. Requires the Secretary to annually set the advisory review fee. Sets forth fee limits.

Terminates the advisory review program if revenue falls below a certain threshold.

Authorizes appropriations for FY2008-FY2012.

(Sec. 105) Requires the Secretary to report on the progress of the Food and Drug Administration (FDA) toward achieving goals related to expediting the drug development process and the process for the review of human drug applications.

(Sec. 106) Terminates provisions related to prescription drug users fees and advisory review fees on October 1, 2012.

Title II: Medical Device User Fee Amendments of 2007 - (Sec. 201) Medical Device User Fee Amendments of 2007 **- Subtitle A: Fees Related to Medical Devices** - (Sec. 211) Defines terms relating to fees for medical devices, including defining "30-day notice" as a supplement to an approved premarket application or premarket report that is limited to a request to make modifications to manufacturing procedures or methods affecting the safety and effectiveness of the device.

(Sec. 212) Makes changes to medical device fees, including establishing a fee for: (1) a 30-day notice; (2) a request for classification information; and (3) periodic reporting for a class III device.

Subjects each medical device establishment to a fee for each initial or annual registration beginning with its registration for FY2008, except for establishments operated by a state or federal governmental entity or an Indian tribe.

Establishes the amount of revenue that may be generated from medical device fees.

Makes changes to provisions related to qualifications for fee waivers for small businesses.

Authorizes appropriations for FY2008-FY2012.

(Sec. 213) Sets forth reporting requirements, including requiring the Secretary to report to the relevant congressional committees on the FDA's progress in achieving medical device review goals.

(Sec. 214) Requires the Secretary to consult with the relevant organizations, individuals, and industry in developing recommendations for meeting goals for the process for the review of medical devices applications for fiscal years after FY2012 and for the reauthorization of provisions relating to device fees.

(Sec. 215) Authorizes additional appropriations for FY2008-FY2012 to collect, develop, review, and evaluate postmarket safety information on medical devices.

(Sec. 216) Makes amendments made by this title effective on the date of enactment of this title, except that fees shall be assessed for all premarket applications, premarket reports, supplements, and premarket notifications submissions received on or after October 1, 2007, regardless of such enactment date.

(Sec. 217) Terminates amendments made by this title on October 1, 2012.

Subtitle B: Amendments Regarding Regulation of Medical Devices - (Sec. 221) Extends the authority of accredited persons to review premarket reports for devices and make recommendations to the Secretary regarding the initial classification of devices.

(Sec. 222) Requires any establishment within a foreign country engaged in the manufacturing, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States to annually register with the Secretary.

(Sec. 223) Requires registered device producers to annually report to the Secretary with a list of new devices introduced by the registrant for commercial distribution, devices discontinued, a notice of resumption of processing of a device, and any material change in information previously submitted.

(Sec. 224) Requires registrations and listings to be submitted to the Secretary electronically unless the Secretary grants a waiver of such requirement.

(Sec. 225) Directs the Comptroller General to study the appropriate use of the process requiring registrants to report to the Secretary before introduction of a device into interstate commerce on the classification of the device.

(Sec. 226) Requires the Secretary to promulgate regulations establishing a unique identification system for medical devices.

(Sec. 227) Makes changes to reporting requirements for devices that have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(Sec. 228) Requires a person accredited to conduct inspections of device establishments to notify the Secretary within 30 days of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems for any inspected establishment. Sets forth conditions that a device establishment must meet to be eligible for inspections by accredited persons.

(Sec. 229) Directs the Comptroller General to study and report on nosocomial infections attributed to new and reused medical devices and the causes of such infections.

Title III: Pediatric Medical Device Safety and Improvement Act of 2007- (Sec. 301) Pediatric Medical Device Safety and Improvement Act of 2007 - (Sec. 302) Requires applications for a humanitarian device exemption, an application for premarket approval of a medical device, or a product development protocol for a medical device to include, if readily available: (1) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and (2) the number of affected pediatric patients.

Requires the Secretary to submit to the relevant congressional committees an annual report that includes: (1) the number of devices approved in the preceding year for which there is a pediatric subpopulation that suffers from the disease; (2) the number of approved devices labeled for use in pediatric patients; (3) the number of fee-exempt devices approved; and (4) the review time for each approved device.

Authorizes the Secretary to conclude that adult data on medical devices may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations if the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients.

(Sec. 303) Excludes a person granted a humanitarian device exemption from the prohibition against selling such a medical device for an amount that exceeds its research and development, fabrication, and distribution costs if: (1) the device is intended to treat or diagnose a disease or condition that occurs in pediatric patients; (2) the device was not approved for pediatric patients prior to enactment of this Act; (3) the number of devices distributed does not exceed an annual distribution number specified by the Secretary; and (4) the request for exemption is submitted on or before October 1, 2013.

Requires the Secretary to: (1) refer any adverse event report related to a device to the Office of Pediatric Therapeutics for review; and (2) provide for an annual review by the Pediatric Advisory Committee of all devices subject to the humanitarian device exemption to ensure that such exemption remains appropriate for the pediatric population for which it is granted.

Directs the Comptroller General to report on the impact of allowing persons granted a humanitarian device exemption to profit from such a device.

(Sec. 304) Requires the Director of National Institutes of Health (NIH) to designate a contact point to help innovators and physicians access funding for pediatric medical device development.

Requires the Commissioner of Food and Drugs to report to the relevant congressional committees a plan for expanding pediatric medical device research and development.

(Sec. 305) Requires the Secretary to award grants or contracts for demonstration projects to promote pediatric device development.

Authorizes appropriations for FY2008-FY2012.

(Sec. 306) Includes as a duty of the Office of Pediatric Therapeutics increasing pediatric access to medical devices.

Expands the duties of the advisory committee on pediatric therapeutics to include providing advice and recommendations on matters relating to medical devices.

(Sec. 307) Allows the Secretary to require: (1) postmarket surveillance as a condition to approval or clearance of certain medical devices; (2) postmarket surveillance on class II or class III medical devices that are indicated for, or have significant use in, pediatric populations; and (3) a prospective surveillance period of more than 36 months for a device that is expected to have significant use in pediatric populations.

Title IV: Pediatric Research Equity Act of 2007 - (Sec. 401) Pediatric Research Equity Act of 2007 - (Sec. 402) Requires an applicant seeking to defer submission of some or all pediatric assessments of the safety and effectiveness of a new drug or biological product to submit to the Secretary a timeline for the completion of pediatric studies. Sets forth annual reporting requirements for an applicant following the approval of such a deferral.

Requires an applicant seeking a full or partial waiver of pediatric assessment submission requirements to submit to the Secretary documentation detailing why a pediatric formulation cannot be developed.

Authorizes the Secretary to require submission of a pediatric assessment if the Secretary finds that: (1) adequate pediatric labeling could confer a benefit on pediatric patients; or (2) the absence of adequate pediatric labeling could pose a risk (currently, significant risk) to pediatric patients.

Directs the Secretary to utilize an internal committee to consult with reviewing divisions on: (1) all pediatric plans and assessments prior to approval of an application or supplement for which a pediatric assessment is required; and (2) all deferral and waiver requests granted.

Requires the Secretary to track and make publicly available information related to pediatric assessments, including: (1) the number of assessments conducted; (2) the specific drugs and biological products and uses assessed; (3) the number of deferrals requested and granted; and (4) the labeling changes made as a result of such assessments.

Considers a supplement to any new drug or biological license application proposing a labeling change as a result of any pediatric assessments to be a priority application or supplement. Sets forth dispute resolution procedures if the Commissioner and the sponsor are unable to reach agreement on appropriate labeling changes for such drug.

Requires the Secretary to: (1) order the label of a product to include information about the results of the assessment and a statement that a pediatric assessment does or does not

demonstrate that the drug is safe and effective in pediatric populations; (2) make publicly available the pharmacology reviews of pediatric assessments; (3) require the sponsors of the assessments that result in labeling changes to distribute such information to physicians and other heath care providers; and (4) ensure that all adverse event reports that have been received for a drug are referred to the Office of Pediatric Therapeutic for review.

Requires the Secretary to contract with the Institute of Medicine to study and report to Congress regarding the pediatric studies and the labeling changes made as a result of such studies.

(Sec. 403) Requires the Comptroller General to submit a report to Congress that addresses the effectiveness of FFDCA pediatric research provisions in ensuring that medicines used by children are tested and properly labeled.

Title V: Best Pharmaceuticals for Children Act of 2007 - (Sec. 501) Best Pharmaceuticals for Children Act of 2007 - (Sec. 502) Amends the Federal Food, Drug, and Cosmetic Act to revise provisions regarding market exclusivity for pediatric drug studies on new or already approved drugs, including to: (1) change the definition of "pediatric studies" to authorize the Secretary to include preclinical studies; (2) require that the studies are completed using appropriate formulations for each age group for which such a study is requested; (3) require that appropriate labeling changes are made within a time frame requested by the Secretary; and (4) prohibit the Secretary from extending the period of market exclusivity later than one year prior to the expiration of the period.

Requires an applicant or holder that does not agree to the request for a pediatric study to submit to the Secretary the reasons such pediatric formulations cannot be developed. Requires an applicant or holder that agrees to such a request to provide the Secretary with all postmarket adverse event reports regarding the drug.

Extends to 180 days (currently, 90 days) the period the Secretary has to accept or reject reports on pediatric studies and notify the sponsor or holder.

Directs the Secretary to: (1) publish a notice identifying any drug for which a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population if the pediatric formulation is not introduced onto the market within one year after the determination regarding market exclusivity; (2) establish an internal committee to review all written requests for pediatric studies issued; (3) track and make publicly available information on the pediatric studies conducted; (4) order the labeling of a product to include information about the results of the study and a statement that a pediatric study does or does not demonstrate that the drug is safe and effective in pediatric populations; and (5) ensure that all adverse event reports that have been received for a drug are referred to the Office of Pediatric Therapeutics.

Sets forth actions for the Secretary to take if pediatric studies have not been completed and there is a continuing need for information relating to the use of the drug in the pediatric population.

Requires the Secretary to contract with the Institute of Medicine to study and report to Congress regarding written requests for pediatric studies made and the studies conducted.

Requires the Secretary, acting through the Director of NIH, to: (1) develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that need study; and (2) study and report to Congress on the feasibility of establishing a compilation of information on pediatric drug use.

Authorizes appropriations.

Includes activities relating to the support of studies of drugs on pediatric populations within the process for the review of human drug applications.

Authorizes the Foundation for the National Institutes of Health to solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of activities relating to studies on the Secretary's priority list of needs in pediatric therapeutics.

Amends the Best Pharmaceuticals for Children Act to require the advisory committee on pediatric therapeutics to continue to operate for five years after enactment of this Act. Requires the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee to: (1) provide recommendations to the internal committee that reviews pediatric research requests with respect to the treatment of pediatric cancer; and (2) continue to operate for five years after enactment of this Act. Sets forth reporting requirements.

Directs that the proposed rule issued by the Commissioner entitled "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products" take effect on January 1, 2008, unless the final rule is issued before such date.

Title VI: Reagan-Udall Foundation - (Sec. 601) Establishes the Reagan-Udall Foundation for the Food and Drug Administration as a nonprofit corporation to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety. Requires the Foundation to: (1) identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness of such products; (2) establish goals and priorities; (3) identify federal research and development programs and minimize duplication; (4) award grants to scientists and entities to efficiently and effectively advance such goals and priorities; and (5) provide objective clinical and scientific information to the FDA and other federal agencies.

(Sec. 602) Requires the Secretary to establish an Office of the Chief Scientist to: (1) oversee, coordinate, and ensure quality and regulatory focus of FDA intramural research

programs; (2) track and coordinate intramural research awards made by each FDA center or science-based office; (3) develop and advocate for a budget to support intramural research; (4) develop a peer review process by which intramural research can be evaluated; and (5) identify and solicit intramural research proposals from across the FDA.

(Sec. 603) Requires the Secretary, acting through the Commissioner, to enter into Critical Path Public-Private Partnerships with eligible entities to implement the Critical Path Initiative of FDA by developing research, education, and outreach projects to foster medical product innovation, accelerate medical product development, and enhance medical product safety.

Authorizes appropriations for FY2008-FY2012.

Title VII: Conflicts of Interest - (Sec. 701) Directs the Secretary, through the Office of Women's Health, the Office of Orphan Product Development, the Office of Pediatric Therapeutics, and other relevant offices within FDA, to develop and implement strategies on effective outreach to potential members of advisory committees. Requires the Secretary to review the expertise and financial disclosure report of an individual when considering an appointment to an advisory committee.

Prohibits any member of an advisory committee from voting on any matter in which the member has a financial interest without a waiver by the Secretary.

Title VIII: Clinical Trials Databases - (Sec. 801) Amends the Public Health Service Act to require the Secretary, acting through the Director of NIH, to establish and administer a clinical trials registry database and a clinical trials results database. Requires the responsible party for an applicable clinical trial to submit the relevant information and periodic updates to the Director of NIH for inclusion in the databases. Sets forth penalties for failure to submit the required clinical trial information and for the submission of false or misleading information.

Authorizes appropriations.

Prohibits a state or political subdivision from establishing any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

(Sec. 802) Requires the Comptroller General to study whether information on the trials registry and database is considered promotional and to evaluate the implementation of the database.

Title IX: Enhanced Authorities Regarding Postmarket Safety of Drugs - (Sec. 901) Prohibits a responsible person from introducing into interstate commerce a new drug if the person is in violation of a requirement related to postapproval clinical trials or labeling changes.

Authorizes the Secretary to: (1) require a responsible person for a drug to conduct a postapproval study or clinical trial of the drug to assess a known serious risk or signals of serious risk or to identify such a risk; (2) require a postapproval study or trial for an already approved drug only if the Secretary becomes aware of new safety information; and (3) issue an order directing a responsible person to make a labeling change to address new safety information. Sets forth procedures for dispute resolution.

Prohibits a person from introducing into interstate commerce a new drug or biological product for which a risk evaluation and mitigation strategy is required if: (1) the person fails to maintain compliance with the requirements of such strategy; or (2) does not cooperate in developing such a strategy.

Prohibits the Secretary from approving the application for a new drug or a biological products license unless the person involved has submitted a statement as to whether a risk evaluation and mitigation strategy and a postmarket study or clinical trial should be required.

Requires a person to submit a risk evaluation and mitigation strategy as part of the application if determined necessary to ensure that the benefits of the drug involved outweigh the risks. Sets forth factors the Secretary must consider in making such a determination.

Requires a proposed risk evaluation and management strategy to include a timetable for assessment of the strategy. Allows the Secretary to require such a strategy to include additional elements, including: (1) distribution to each patient of a Medication Guide and a patient package insert; (2) a communication plan to health care providers; and (3) restrictions on distribution.

Requires the elements of a risk evaluation and mitigation strategy to be commensurate with a specific serious risk listed in the labeling of the drug.

Establishes the Drug Safety Oversight Board.

Authorizes the Secretary to: (1) require the submission of any television advertisement for a drug for review before dissemination; (2) recommend but not require changes in such advertisements; and (3) require inclusion in advertisements of certain disclosures about a serious risk listed in the labeling of the drug.

Requires the Secretary to establish a permanent advisory committee to advise the Secretary on a report to Congress on direct-to-consumer advertising and its ability to communicate to subsets of the general population.

(Sec. 902) Deems to be misbranded a drug: (1) subject to an approved risk evaluation and mitigation strategy if the responsible person fails to comply with the strategy's requirements; or (2) if the responsible person is in violation of a requirement relating to postmarket studies and clinical trials or labeling.

(Sec. 903) Authorizes the Secretary to withdraw or suspend the approval of a new drug application without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy.

(Sec. 904) Directs the Commissioner to report to Congress on how best to communicate to the public the risks and benefits of new drugs and the role of the risk evaluation and mitigation strategy in assessing such risks and benefits.

(Sec. 905) Requires the Secretary to establish public-private partnerships to develop tools and methods to enable the Secretary and others to use available electronic databases to create a robust surveillance system that will support active surveillance on important drug safety questions.

Authorizes appropriations for FY2008-FY2012.

Requires the Comptroller General to evaluate data confidentiality and security issues relating to collection, transmission, and maintenance of data for the surveillance system under this Act and make recommendations to relevant congressional committees regarding the need for any additional legislative or regulatory actions to ensure confidentiality and security.

(Sec. 907) Deems a drug or device to be misbranded if a direct-to-consumer advertisement does not include a specified statement related to reporting adverse effects.

(Sec. 908) Requires the Secretary, acting through the Commissioner, to issue guidance for the conduct of clinical trials with respect to antibiotic drugs.

(Sec. 909) Prohibits the introduction into interstate commerce of any food to which has been added an approved drug, a licensed biological product, or certain other drugs or biological products unless: (1) such drug or biological product was marketed in food prior to approval, licensure, or clinical investigation; or (2) the Secretary has issued a regulation approving the addition of such drug or biological product to food.

(Sec. 910) Requires the Secretary to: (1) develop standards to secure the prescription drug distribution system against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs; (2) prioritize and develop standards for the identification, validation, authentication, and tracking of prescription drugs; and (3) expand the Office of Regulatory Affairs of the FDA to protect the prescription drug distribution system.

(Sec. 911) Directs the Commissioner to convene a public meeting regarding which serious and life threatening infectious diseases potentially qualify for available grants and contracts under the Orphan Drug Act or other incentives for development.

Amends the Orphan Drug Act to reauthorize appropriations for grants and contracts to defray the costs of: (1) qualified testing expenses incurred in connection with the development of drugs for rare diseases and conditions, (2) developing medical devices

for rare diseases or conditions, and (3) developing medical foods for rare diseases or conditions.

Authorizes appropriations for FY2008-FY2012 for grants under the Orphan Drug Act.

(Sec. 912) Prohibits the Secretary from delaying approval of an application on the basis of a citizen petition unless the Secretary determines that a delay is necessary to protect the public health and provides the applicant with a written explanation of the reasons for the delay.

(Sec. 913) Authorizes additional appropriations for FY2008-FY2012 for carrying out this title.

(Sec. 914) Makes this title effective 180 days after enactment. Deems already approved drugs to have an approved risk evaluation and mitigation strategy if specified restrictions on distribution or use are in effect, but requires the holder of such an approved drug application to submit a proposed risk evaluation and mitigation strategy within 180 days.

Appendix C

Summary of HR 3162 from THOMAS

SUMMARY AS OF:
8/1/2007--Reported to House amended

Children's Health and Medicare Protection (CHAMP) Act of 2007 - **Title I: Children's Health Insurance Program** - (Sec. 100) States that it is the purpose of this title to provide dependable and stable funding for children's health insurance under titles XXI (Children's Health Insurance Program) (CHIP) (also known as SCHIP) and XIX (Medicaid) of the Social Security Act (SSA) in order to enroll all six million uninsured children who are eligible, but not enrolled, for coverage today.

Subtitle A: Funding - (Sec. 101) Prescribes formulae for new base CHIP allotments for states and territories beginning with FY2008.

(Sec. 102) Makes CHIP allotments for FY2008 and each following fiscal year available for two years only (currently three years).

(Sec. 103) Provides for redistribution of unused allotments to address state funding shortfalls.

(Sec. 104) Increases from 20% to 30% the percentage of any CHIP allotment that a state may use for Medicaid payments after FY2007.

Subtitle B: Improving Enrollment and Retention of Eligible Children - (Sec. 111) Directs the Secretary of Health and Human Services (HHS) to make performance bonus payments to states to offset the additional Medicaid and CHIP child enrollment costs resulting from enrollment and retention efforts.

(Sec. 112) Gives states the option to provide that, in determining a child's Medicaid eligibility, it may rely on a finding made within a reasonable period from an Express Lane agency. Requires the state to use its regular procedures to determine Medicaid eligibility, however, if the Express Lane finding is negative.

Authorizes a federal or state agency or private entity possessing sources of data potentially pertinent to Medicaid eligibility determinations to convey such data to the state agency administering the state Medicaid plan, subject to specified requirements.

(Sec. 113)Applies Medicaid outreach procedures to all children and pregnant women.

(Sec. 114) Requires payments to states to cover translation or interpretation services in connection with the enrollment and retention under Medicaid of children of families for whom English is not the primary language.

Provides for the use of community health workers for outreach activities.

Subtitle C: Coverage - (Sec. 121) Requires the child health assistance provided to a targeted low-income child to cover dental services, federally-qualified health center (FQHC) services, and rural health clinic (RHC) services.

(Sec. 122) Revises the definition of both CHIP and Medicaid: (1) Secretary-approved coverage, relating to child health assistance to a targeted low-income child, to require the health benefits coverage to be at least equivalent to the coverage in a benchmark benefit package; and (2) state employee benchmark coverage to

be that selected most frequently by employees seeking dependent coverage in either of the previous two plan years.

(Sec. 123) Establishes a 30-day premium grace period for state child health plans.

Subtitle D: Populations - (Sec. 131) Provides for optional coverage of older children, up to age 25, under Medicaid and CHIP.

(Sec. 132) Provides for optional coverage of legal immigrants under Medicaid and CHIP.

(Sec. 133) Gives states the option to expand or add coverage of targeted low-income pregnant women under CHIP.

(Sec. 134) Prohibits the Secretary, through exercise of waiver authority, from providing for federal financial participation to a state for CHIP health care services for individuals who are not targeted low-income children or pregnant women, unless the Secretary determines that no eligible targeted low-income child in the state would be denied such coverage because of such eligibility.

Subtitle E: Access - (Sec. 141) Amends SSA title XIX (Medicaid) to establish as an agency of Congress the Children's Access, Payment, and Equality Commission to review federal and state payment policies of the Medicaid and CHIP programs and make pertinent recommendations to Congress.

(Sec. 142) Directs the Comptroller General to develop, and report to Congress on, a model process for the coordination of Medicaid and CHIP enrollment, retention, and coverage of children who, because of migration of families, emergency evacuations, educational needs, or otherwise, frequently change their state of residency or otherwise are temporarily located outside of the state of their residency.

(Sec. 143) Gives states the option to require children to present satisfactory documentary evidence of proof of U.S. citizenship or nationality for Medicaid eligibility purposes.

(Sec. 144) Directs the Secretary to develop a program to deliver oral health educational materials that inform new parents about risks for, and prevention of, early childhood caries and the need for a dental visit within their newborn's first year of life.

Prohibits a state from preventing an FQHC from contracting with private practice dental providers in the provision of FQHC services.

(Sec. 145) Prohibits the Secretary from approving any new health opportunity account demonstration programs.

Subtitle F: Quality and Program Integrity - (Sec. 151) Requires the Secretary to establish a child health care quality measurement program to develop and implement pediatric quality measures for children's health care, as well as overall program performance measures, that may be used by public and private health care purchasers.

(Sec. 152) Requires any state child health plan to apply to CHIP coverage, state agencies, enrollment brokers, and managed care entities and organizations certain managed care quality safeguards that apply to such coverage and entities under Medicaid.

(Sec. 153) Directs the Secretary to conduct an independent subsequent evaluation of 10 states with approved child health plans.

(Sec. 154) Grants access to CHIP records for Inspector General and General Accounting Office audits and evaluation.

Title II: Medicare Beneficiary Improvements - Subtitle A: Improvements in Benefits - (Sec. 202) Amends SSA title XVIII (Medicare) to provide coverage of, and waiver of cost-sharing for, specified preventive services. Eliminates coinsurance in outpatient hospital settings and waives application of any deductible for all preventive services, as well as medical nutrition therapy services.

(Sec. 202) Revises requirements for payments from the Federal Supplementary Medical Insurance Trust Fund. Waives the deductible for colorectal cancer screening tests regardless of coding, subsequent diagnosis, or ancillary tissue removal.

(Sec. 203) Eliminates the 62 1/2% limitation on payments for outpatient treatment of mental disorders (thus requiring parity of payments for mental health coinsurance).

Subtitle B: Improving, Clarifying, and Simplifying Financial Assistance for Low Income Medicare Beneficiaries - (Sec. 211) Provides that, beginning in 2009, the maximum resources level shall be the same for both part D low-income subsidy (LIS) groups. Sets such level in 2009 at $17,000 for an individual and $34,000 for a couple, and in subsequent years at the previous year's level increased by $1,000 for an individual and $2,000 for a couple. Applies such maximum resource levels also to eligibility determination for Medicare Savings programs.

(Sec. 212) Revises requirements for the program under which individuals qualifying for Medicare (QIs) also qualify for Medicaid. Repeals the termination date for the QI program to make the program permanent. Eliminates the funding limitation, thereby expanding eligibility to all persons meeting the income and resource criteria. Provides a 100% federal medical assistance percentage (FMAP) for payments under the QI program. Sets the resources standard for the QI program at 150% of the federal poverty level.

(Sec. 213) Requires that persons applying for the part D LIS program be permitted to qualify on the basis of self-certification of income and resources without the need to provide additional documentation.

Requires that a subsidy eligible individual (or particular class, such as a full or partial subsidy individual) be deemed to continue to be eligible without the need for any annual or periodic application (automatic reenrollment), unless and until the individual notifies a responsible federal or state official that the eligibility conditions have changed so that the individual is no longer subsidy eligible.

Requires the Secretary to take all reasonable steps to encourage states to provide, under the Medicare Savings Program (MSP), for such administrative verification of income and automatic reenrollment.

Directs the Commissioner of Social Security to provide Medicare part A benefit applicants information describing the MSP and the LIS program (LISP), applications for LISP for medical assistance for Medicare cost-sharing, as well as information on how to obtain assistance in completing such applications.

Requires the Commissioner to: (1) make such application forms available at local Social Security Administration (SS Admin) offices; and (2) provide training to SS Admin employees in assisting applicants in completing an MSP application.

Requires the state Medicaid agency to accept MSP applications and act on them in the same manner, and subject to the same deadlines, as if they had been submitted directly by the applicant.

Requires the Secretary to translate the Model Form used for MSP applications into at least 10 languages that are most often used by persons applying for Social Security or Medicare part A benefits.

Amends the Internal Revenue Code to provide for the disclosure of tax return information to SS Admin officers and employees for purposes of providing low-income subsidies under Medicare.

(Sec. 214) Prohibits any estate recovery of Medicaid correctly paid for Medicare cost-sharing or related benefits on behalf of an individual who was 55 years of age or older when the individual received such medical assistance.

(Sec. 215) Eliminates part D cost-sharing for certain non-institutionalized full-benefit dual eligible mentally retarded individuals.

(Sec. 216) Excludes from calculation of income and resources for LIS eligibility the value of any life insurance policy or any balance in a pension or retirement plan.

(Sec. 217) Limits the aggregate cost-sharing per year for LIS-eligible individuals to 2.5% of income.

(Sec. 218) Prohibits the automatic enrollment of a part D eligible individual in a prescription drug plan unless the plan meets specified formulary, pharmacy network, quality, and low cost requirements.

Subtitle C: Part D Beneficiary Improvements - (Sec. 221) Revises requirements for the annual out-of-pocket threshold that part D beneficiaries must meet for any costs incurred by AIDS drug assistance programs and the Indian Health Service.

(Sec. 222) Permits a special enrollment period in the case of an individual enrolled in a prescription drug plan (PDP) or Medicare Advantage-Prescription Drug (MA-PD) plan who has been prescribed a covered part D drug while so enrolled, if the formulary of the plan is materially changed (in midyear, and other than because of a Food and Drug Administration recall or withdrawal) in a way to reduce the drug coverage (or increase the cost-sharing).

(Sec. 223) Repeals the exclusion of benzodiazepines from required part D drug coverage (thus extending coverage to such drugs).

(Sec. 224) Authorizes the Secretary to apply to part D the same process for updating drug compendia as used under Medicare part B.

(Sec. 225) Requires PDP formularies to include all or substantially all covered part D drugs in the therapeutic classes: (1) anticonvulsants; (2) antineoplastics; (3) antiretrovirals; (4) antidepressants; (5) antipsychotics; and (6) immunosuppressants.

(Sec. 226) Eliminates part D late enrollment penalties for LIS-eligible individuals.

(Sec. 227) Creates a special enrollment period for LIS-eligible individuals, together with automatic enrollment for those who fail to enroll in a PDP or MA-PD plan during such period.

Subtitle D: Reducing Health Disparities - (Sec. 231) Directs the Secretary to: (1) collect data on the race, ethnicity, and primary language of each Medicare benefits applicant and recipient; (2) analyze and report on such data annually to the Director of the Office for Civil Rights and specified congressional committees; and (3) ensure that the provision of assistance to an applicant or recipient of assistance is not denied or otherwise adversely affected because of the failure of the applicant or recipient to provide race, ethnicity, and primary language data.

(Sec. 232) Directs the Secretary to study and report to the appropriate congressional committees on ways that Medicare should develop payment systems for language services using the results of Sec. 233

demonstration programs to improve effective communication between Medicare service providers and Medicare beneficiaries who are limited English proficient.

(Sec. 233) Directs the Secretary, acting through the Centers for Medicare & Medicaid Services, to award 24 three-year grants to eligible Medicare service providers to conduct such demonstration programs.

(Sec. 234) Directs the Secretary to establish a demonstration project to determine the greatest needs and most effective methods of outreach to Medicare beneficiaries who were previously uninsured.

(Sec. 235) Directs the Inspector General of the Department of Health and Human Services to report on: (1) the extent to which Medicare providers and plans are complying with the Office for Civil Rights' Guidance to Federal Financial Assistance Recipients Regarding the Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, and the Office of Minority Health's Culturally and Linguistically Appropriate Service Standards in health care; and (2) a description of the costs associated with or savings related to the provision of language services. Directs the Department of Health and Human Services to implement changes responsive to any deficiencies identified in the report.

(Sec. 236) Requires the Secretary to seek to arrange with the Institute of Medicine to report on the impact of language access services on the health and health care of limited English proficient populations.

Title III: Physicians' Service Payment Reform - (Sec. 301) Amends SSA title XVIII (Medicare) to require establishment of: (1) separate target growth rates for service categories; (2) separate conversion factors for each service category; and (3) updates for such conversion factors.

(Sec. 302) Directs the Secretary to: (1) establish an expert panel to identify misvalued physicians' services; and (2) conduct a five-year review of physicians' services in conjunction with the five-year review by the American Medical Association/Specialty Society Relative Value Update Committee (RUC), particularly for services that have experienced substantial changes in length of stay, site of service, volume, practice expense, or other factors that may indicate changes in physician work.

Gives the Secretary the authority to reduce the work component for services with accelerated growth without using the RUC process.

(Sec. 303) Requires the Secretary to develop a mechanism to measure resource use on a per capita and an episode basis in order to provide confidential feedback to physicians in the Medicare program on how their practice patterns compare to physicians generally, both in the same locality as well as nationally.

(Sec. 304) Creates incentive payments under the Medicare program for participating physicians practicing in an efficient area.

(Sec. 305) Directs the Comptroller General to analyze and report to Congress on: (1) codes paid under the Medicare physician fee schedule to determine whether the codes for procedures that are commonly furnished together should be combined; and (2) those procedures under the same schedule for which no global payment methodology is applied but for which a "bundled" payment methodology would be appropriate.

(Sec. 306) Directs the Secretary to establish: (1) an expanded medical home demonstration project; and (2) a process for selection of a qualified standard setting and certification organization to establish standards for medical practices to qualify as medical homes or as HIT-enhanced medical homes.

Requires the Secretary to provide for payment to the personal physician of each participating beneficiary of a monthly medical home care management fee.

(Sec. 307) Repeals the Physician Assistance and Quality Initiative Fund.

(Sec. 308) Requires the Secretary to revise the fee schedule areas for California for services furnished on or after January 1, 2008 using a specified proposed county-based geographic adjustment factor.

(Sec. 309) Requires diagnostic imaging services to be furnished at an accredited facility in order to be covered by the part B physicians' services fee schedule.

Provides for the adjustment in practice expenses to reflect a higher presumed utilization of such imaging services. Requires the Secretary to adjust the number of practice expense relative value units for imaging services to reflect a 75%, rather than a 50%, presumed rate of utilization.

Directs the Secretary to increase from 25% to 50% the reduction in expenditures ("discount") attributable to the multiple procedure payment reduction applicable to the technical component for single-session imaging involving consecutive body parts under a specified final rule published by the Secretary in the Federal Register.

Directs the Secretary, in computing the practice expense component for imaging services, to change the interest rate assumption for capital purchases of imaging devices to reflect the prevailing rate in the market, but in no case higher than 11%.

Prohibits the Secretary from accepting or paying a claim for imaging unless it is made separately for each component of such services. (Thus disallows global billing.)

(Sec. 310) Reduces the frequency of meetings of the Practicing Physicians Advisory Council from once each quarter to once a year.

Title IV: Medicare Advantage Reforms - Subtitle A: Payment Reform - (Sec. 401) Revises requirements for Medicare Advantage (MA) rates for monthly capitation payments to the MA plans, currently set by a process based on county level benchmarks and MA plan bids.

Requires phase-out of payments to MA plans in excess of 100% of the average Fee-for-Service (FFS) costs in each county over four years to 100% of the FFS cost in the county in 2011. Prescribes a formula for blended county benchmarks and FFS to accomplish this goal. Excludes indirect medical education (IME) costs from the calculation of the 100% FFS for an MA plan in a county area.

Provides that, if a MA plan bid exceeds 106% of the county FFS amount for 2009 or 103% of the FFS amount in 2010, then that MA plan may not enroll any new enrollees for that year during the annual, coordinated election period or during the year (if the enrollment becomes effective during the year).

Requires FFS rates to be rebased annually beginning in 2009.

Repeals the regional Preferred Provider Organization (PPO) stabilization fund.

Subtitle B: Beneficiary Protections - (Sec. 411) Requests the National Association of Insurance Commissioners (NAIC) to develop and submit to the Secretary model regulations regarding Medicare plan marketing, enrollment, broker and agent training and certification, agent and broker commissions, and market conduct by plans, agents and brokers. Prescribes general guidelines for such regulations.

Declares that any contract with an MA organization shall require it to meet all marketing and enrollment standards adopted pursuant to such NAIC model regulations, subject to specified sanctions.

Doubles the civil monetary penalties that may be imposed on an MA organization that violates its contract.

Requires the Secretary to: (1) disclose on the HHS public website all market and advertising contract violations and imposed sanctions; and (2) develop standard definitions of benefits and formats for use in marketing materials.

Specifies funding to support Medicare part C and part D (Voluntary Prescription Drug Benefit Program) counseling and assistance provided by State Health Insurance Assistance Programs (SHIPs).

(Sec. 412) Requires Medicare part C (private) plans to offer benefits under the original Medicare FFS program option with cost-sharing requirements no greater than those imposed under the traditional Medicare program. States that nothing shall be construed as prohibiting Medicare part C plans from using flat co-payments or per diem rates in lieu of part A or part B cost-sharing amounts, as long as they do not exceed the level of cost-sharing under traditional Medicare.

Prohibits Medicare part C plans from imposing cost-sharing for dual-eligible individuals or qualified Medicare beneficiaries enrolled in a Medicare part C plan that exceeds the cost-sharing amounts permitted under the Medicare and Medicaid statutes.

(Sec. 413) Authorizes continuous open enrollment in Medicare part C plans for full benefit dual-eligible individuals and qualified Medicare beneficiaries (QMBs). Changes the continuous open enrollment period to allow institutionalized, dual-eligible individuals and QMBs to disenroll from MA plans and return to traditional Medicare at any time.

Authorizes special election periods for specified low-income Medicare beneficiaries and beneficiaries enrolled in Medicare part C plans in which enrollment has been suspended for not meeting the terms of their contracts.

Requires the Secretary to take into account the health or well-being of the individual when determining the exceptional conditions in which individuals may be allowed to take advantage of a special election period.

Increases from one year to two years the length of time certain categories of individuals who leave Medicare part C plans have to enroll in a Medigap plan.

Prohibits the Secretary from enrolling Medicaid-eligible individuals (automatically) as dual-eligibles or QMBs in a Medicare part C plan without the individual's affirmative enrollment application.

(Sec. 414) Directs the Secretary to publish for each Medicare part C plan: (1) its medical loss ratio in the previous year: (2) the per enrollee payment to the plan, as adjusted to reflect a risk score of 1.0; and (3) the average risk score (as so based).

Prescribes requirements for preparation of the data necessary for such information, including standardized data elements and definitions.

Requires a contract with a Medicare part C organization to provide the Secretary with the right to audit and inspect any pertinent book or record.

Provides that, beginning in 2010, if an MA plan fails to have a medical loss ratio of at least .85, it will be subject to the following sanctions: (1) reduction of the blended benchmark amount; (2) no new enrollees for a specified period of time; and (3) termination of the plan contract if the plan fails to have such a medical loss for five consecutive contract years.

Directs the Secretary to publish monthly the actual enrollment in each Medicare part C plan by contract and county.

Requires the Medicare Payment Advisory Commission (MEDPAC) to study and report to Congress on the need and feasibility of providing for different minimum medical loss ratios for different types of Medicare part C plans.

Subtitle C: Quality and Other Provisions - (Sec. 421) Requires any Medicare Advantage organization offering a private fee-for-service plan or an MSA plan for contract year 2009 to submit to the Secretary the same information on the same performance measures for which such information must be submitted for Medicare part C plans that are PPO plans for that year. Requires any such Medicare Advantage organization for contract year 2010 to submit to the Secretary the same performance measure information for which such information must be submitted for coordinated Medicare part C plans for that year.

Requires employer-sponsored Medicare part C plans to have 90% of the Medicare beneficiaries enrolled in the plan reside in a county in which the organization offers a Medicare part C local plan.

(Sec. 422) Requires the Secretary to develop quality measures for Medicare part C plans that measure disparities in the amount and quality of health services provided to racial and ethnic minorities.

Requires the Secretary to provide for Medicare part C organizations to submit data that permits analysis of such disparities, together with biennial reports to Congress on how quality assurance programs measure and report on them.

(Sec. 423) Requires Medicare Advantage plan audits to cover plan information submitted for risk adjustment purposes.

Authorizes the Secretary to take actions, including pursuit of financial recoveries, necessary to address deficiencies identified in an audit or other activities.

Applies such authority of the Secretary to PDPs under Medicare part D.

(Sec. 424) Directs the Secretary to report to Congress on the adequacy of the Medicare Advantage risk adjustment system.

(Sec. 425) Eliminates the providers' ability to bill enrollees in private fee-for-service plans more than the Medicare fee schedule amount.

Repeals the exemption of private FFA plans from the Secretary's authority to review and negotiate Medicare Advantage plan bid amounts. (Thus authorizes the Secretary to review and negotiate the bid amounts for private FFS plans in the same manner as with other Medicare part C plans.)

(Sec. 426) Renames the Medicare Advantage program as the Medicare part C program.

Subtitle D: Extension of Authorities - (Sec. 431) Extends the authority to limit enrollment in special needs plans to only special needs beneficiaries for periods before January 1, 2012.

Redefines a special needs plan to require that it to meet either of the following conditions: (1) at least 90% of enrollees are institutionalized as determined under regulation in effect as of July 1, 2007; or (2) at least 90% of enrollees are also entitled to Medicaid and are full-benefit dual eligible individuals for Medicare and Medicaid or qualified Medicare beneficiaries. Requires special needs plans to meet additional requirements for enrollment.

Requires special needs plans for institutionalized individuals to: (1) have an agreement with the state regarding cooperation on the coordination of care for such individuals; (2) have contracts with long-term

care facilities and other area providers sufficient to provide proper care; and (3) report to the Secretary on additional quality measures.

Requires special needs plans for dual eligible individuals to have agreements with the state Medicaid agency regarding cooperation on the coordination of the financing of care for such individuals, certain payment requirements, and capitation payments. Limits out-of-pocket costs for part A and part B services charged to enrollees to maximum Medicaid out-of-pocket costs.

Requires the Secretary to develop new quality measures appropriate to meeting the needs of special needs plan beneficiaries who are institutionalized or are dually eligible individuals.

(Sec. 432) Extends for three additional years the length of time a cost-based plan may continue operating in an area where either two local or two regional Medicare Advantage plans had entered.

Applies certain Medicare Advantage requirements to reasonable cost contract extended or renewed after enactment of this Act.

Title V: Provisions Relating to Medicare Part A - (Sec. 501) Amends SSA title XVIII (Medicare part A (Hospital Insurance Benefits for Aged and Disabled)) to set the following inpatient hospital payment updates for acute hospitals and for other hospitals: (1) for acute hospitals, for FY2007, the market basket percentage increase for hospitals in all areas, and for FY2008, the market basket percentage increase minus .25 percentage points for hospitals in all areas; and (2) for other hospitals, for FY2003-FY2007, the market basket percentage increase, and for FY2008, the market basket percentage increase minus .25 percentage point.

(Sec. 502) Sets the payment update factor for FY2008 at 1% for payments for inpatient rehabilitation facility (IRF) services.

Amends the Deficit Reduction Act of 2005 to require the IRF compliance rate to remain at a maximum of 60% for cost reporting periods beginning on or after July 1, 2006. Requires the Secretary to continue to consider comorbidities as qualifying conditions.

Creates a special payment rule for patients in IRFs admitted for three applicable medical conditions: (1) unilateral knee replacement; (2) unilateral hip replacement; and (3) unilateral hip fracture.

Directs the Secretary to examine and report to Congress on: (1) Medicare beneficiaries' access to medically necessary rehabilitation services; (2) alternatives or refinements to the 75% rule policy for determining exclusion criteria for IRF designation; and (3) any condition for which individuals are commonly admitted to IRFs to determine the appropriate setting of care, and any variation in patient outcomes and costs, across settings of care, for treatment of such conditions.

(Sec. 503) Creates cross-references to the Medicare, Medicaid, and CHIP Balanced Budget Refinement Act of 1999 and the Medicare, Medicaid and CHIP Benefits Improvement and Protection Act of 2000 for the prospective payment of long-term care hospitals (LTCHs). Makes the LTCH base rate for rate year 2008 the same as the one used for discharges in the previous rate year.

Defines LTCH and establishes new patient criteria for prospective payment to LTCHs.

Requires the Secretary to approve distinct part rehabilitation units in certain LTCHs if rehabilitation services are not included within one of the major diagnostic categories.

Directs the Secretary to contract with one or more appropriate fiscal intermediaries or Medicare administrative contractors to review the medical necessity of long term care admissions and continued stays for individuals entitled to benefits under Medicare part A.

Directs the Secretary to impose a four-year moratorium, with certain exceptions, on certification of new LTCHs (and satellite facilities) and new LTCH and satellite facility beds.

Creates a separate classification for a certain long-stay cancer hospital.

(Sec. 504) Raises the disproportionate share hospital (DSH) adjustment cap for small urban hospitals and rural hospitals to 16% for discharges occurring in FY2008 and to 18% for discharges in FY2009. Makes the adjustment cap for discharges on or after October 1, 2009, revert to 12%.

(Sec. 505) Authorizes the Secretary to compute the target amount for the hospital's 12-month cost reporting period beginning during FY2008 in the case of certain cancer hospitals exempt from the inpatient prospective payment system (IPPS) that: (1) received payment for inpatient hospital services furnished during cost reporting periods beginning before October 1, 1999; and (2) request a rebasing.

Establishes three additional IPPS-exempt cancer hospitals for cost reporting periods beginning after January 1, 2006.

Directs MEDPAC to evaluate and report to the Secretary and Congress on: (1) measures of payment adequacy and Medicare margins for PPS-exempt cancer hospitals; (2) the margins of a PPS-exempt cancer hospital and another hospital with which it was previously affiliated as separate entities, as well as their margins when affiliated; and (3) payment adequacy for cancer discharges under the Medicare IPPS.

(Sec. 506) Eliminates the skilled nursing facility market basket update for FY2008.

(Sec. 507) Revokes the deeming authority granted to the Joint Commission of Healthcare Organizations to accredit hospitals for participation in Medicare.

(Sec. 508) Amends the Medicare Improvements and Extension Act of 2006 (MIEA) and Section 508 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MPDIMA) to extend through FY2009 the geographic reclassification of certain hospitals otherwise unable to qualify for administrative reclassification to areas with higher wage index values.

(Sec. 509) Amends MPDIMA to enable Minnesota to designate one hospital in Cass County as a necessary provider of health care on or after January 1, 2006.

Designates a hospital located in Butler County, Alabama, as a critical access hospital.

Title VI: Other Provisions Relating to Medicare part B - Subtitle A: Payment and Coverage Improvements - (Sec. 601) Amends SSA title XVIII (Medicare part B (Supplementary Medical Insurance Benefits for Aged and Disabled)), as amended by MIEA, to extend through calendar 2009 the process for exceptions from beneficiary payment limits for Medicare part B outpatient physical therapy services.

Directs the Secretary to study and report to Congress on refined and alternative payment systems to the Medicare payment cap for physical therapy, speech-language pathology, and occupational therapy services.

(Sec. 602) Establishes a separate definition for outpatient speech language pathology services to permit speech language pathologists practicing independently to bill part B, subject to the same conditions applicable to physical and occupational therapists in independent practice.

(Sec. 603) Removes the limitation on the fee schedule amount for a service furnished by a certified nurse midwife to 65% of the fee amount for a physician.

(Sec. 604) Sets the outpatient hospital fee schedule increase factor for services furnished in 2008 as the market basket increase reduced by .25 percentage points.

(Sec. 605) Creates an exception to the 60-day limit on Medicare reciprocal billing arrangements in the case of physicians ordered to active duty in the armed forces.

(Sec. 606) Excludes clinical social worker services from the skilled nursing facility PPS.

(Sec. 607) Includes marriage and family therapist services and mental health counselor services within the definition of medical and other heath services covered under Medicare part B. Excludes such services, however, from the skilled nursing facility PPS.

(Sec. 608) Eliminates the option to purchase a power-driven wheelchair with a lump sum payment at the time a purchase agreement has been entered into. (Does not, however, eliminate the lump-sum purchase option for a replacement wheelchair.)

(Sec. 609) Decreases from 36 continuous months to 18 continuous months the length of time Medicare will make rental payments for oxygen equipment before transferring title to the beneficiary. Maintains the 36-month rule, however, for oxygen generating portable equipment (concentrators or transfilling systems).

Directs the Secretary to study and report to Congress on the service component and equipment component of the provision of oxygen to Medicare beneficiaries.

(Sec. 610) Increases by 5% the part B payment for applicable mental health services.

(Sec. 611) Extends cost reimbursement for brachytherapy services until January 1, 2009.

(Sec. 612) Requires the Secretary to use a specified formula to assure consistent volume-weighting in the computation of the average sales price (ASP) payable for drugs and biologicals furnished on or after July 1, 2008.

Modifies the Competitive Acquisition Program (CAP), permitting continuous open enrollment and vendor delivery of drugs to the site of administration.

Requires the Secretary to: (1) conduct an outreach and education program on the CAP; and (2) provide for the rebidding of CAP contracts only for periods on or after the expiration of the contract in effect on the date of enactment of this Act.

Establishes a special rule for the payment calculation for inhalation drugs furnished through items of DME.

Subtitle B: Extension of Medicare Rural Access Protections - (Sec. 621) Extends the floor on Medicare work geographic adjustment through December 31, 2009.

(Sec. 622) Amends the Medicare, Medicaid, and CHIP Benefits Improvement and Protection Act of 2000, as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and other specified law, to extend through December 31, 2009, the special treatment of certain physician pathology services under Medicare.

(Sec. 623) Extends until July 1, 2009, reasonable cost reimbursement for certain clinical diagnostic laboratory services provided by qualified rural hospitals.

(Sec. 624) Extends through December 31, 2009, the Medicare incentive payment program for physician scarcity areas.

(Sec. 625) Reinstates the ground ambulance bonus payments for rural areas for the period beginning on January 1, 2008, and ending on December 31, 2009.

(Sec. 626) Extends a specified hold harmless for small rural hospitals under the hospital outpatient department PPS, by maintaining through calendar year 2009 the calendar year 2007 payment of 90% of the difference between PPS payments and payments that would have been made under the prior reimbursement system.

Subtitle C: End Stage Renal Disease Program - (Sec. 631) Directs the Secretary, acting through the Director of the National Institutes of Health, to establish demonstration projects to: (1) increase public and medical community awareness about the factors that lead to chronic kidney disease, how to prevent it, how to diagnose it, and how to treat it; (2) increase screening and use of prevention techniques for chronic kidney disease for Medicare beneficiaries and the general public; and (3) enhance surveillance systems and expand research to better assess the prevalence and incidence of chronic kidney disease.

(Sec. 632) Extends Medicare coverage to kidney disease patient education services.

Requires the Comptroller General to report to Congress on the chronic kidney disease Medicare program.

(Sec. 633) Requires training for patient care dialysis technicians.

(Sec. 634) Requires MEDPAC to report to the Secretary and Congress on the barriers that exist to increasing the number of individuals with end-stage renal disease who elect to receive home dialysis services under Medicare.

(Sec. 635) Sets the payment amounts for erythropoietin and darbepoetin alfa furnished during 2008 or 2009 to an individual with end stage renal disease (ESRD) by a large dialysis facility.

(Sec. 636) Makes the payment for providers of dialysis services furnished by hospital-based facilities the same as the rate for services furnished by renal dialysis facilities that are not hospital-based (site neutral composite rate), with an exception for the application of the labor share of the geographic index to hospital-based facilitates.

(Sec. 637) Requires the Secretary to implement a bundled ESRD payment system under which a single payment is made for Medicare renal dialysis services.

Requires quality incentive payments for ESRD services meeting certain performance standards that are furnished during specified periods during 2008 through 2011.

(Sec. 638) Directs MEDPAC to report to Congress on the implementation of the ESRD bundling payment system.

(Sec. 639) Requires the Inspector General of the Department of Health and Human Services to study and report to Congress on dosing guidelines, standards, protocols, and alogorithims for erythropoietin stimulating agents (ESAS) recommended or used by providers of services and renal dialysis facilities.

Subtitle D: Miscellaneous - (Sec. 651) Prescribes new requirements for hospitals to qualify for the hospital exception to the general prohibition against physician referral (self-referral) of Medicare patients for certain services to facilities in which they (or their immediate family members) have financial interests.

Title VII: Provisions Relating to Medicare Parts A and B - (Sec. 701) Eliminates the market basket update for home health payments for 2008.

(Sec. 702) Amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as amended by the Deficit Reduction Act of 2005, to extend through calendar 2009 the temporary Medicare payment increase for home health services furnished in a rural area.

(Sec. 703) Amends SSA title XVIII to extend from 30 to 42 months the coordination period for ESRD Medicare Secondary Payer requirements under which any third-party group health plan coverage beneficiaries receive through their employer or their spouse's employer is the primary payer.

Applies this extended coordination period, however, only to those individuals who receive group coverage through a large group health plan (one offered by an employer that normally employed at least 100 employees on a typical business day during the preceding calendar year)

(Sec. 704) Directs the Secretary to develop a plan to implement, beginning in FY2010, a policy to reduce or eliminate payments under Medicare for never events.

Defines "never event" as an event involving the delivery of (or failure to deliver) physicians' services, inpatient or outpatient hospital services, or facility services furnished in an ambulatory surgical facility in which there is an error in medical care that: (1) is clearly identifiable, usually preventable, and serious in consequences to patients; and (2) indicates a deficiency in the safety and process controls of the services furnished with respect to the physician, hospital, or ambulatory surgical center involved.

(Sec. 705) Provides for redistribution of residency slots (including those for osteopaths and allopaths) if one or more hospitals with approved medical residency training programs, located within the same metropolitan division of the core-based statistical area as of January 1, 2001, closes.

Requires the Secretary, in the event of such a closure, to increase by no more than 10 the otherwise applicable resident limit for each hospital within the same metropolitan division that meets specified criteria.

Prescribes an adjustment for any hospital with a dual accredited osteopathic and allopathic family practice program that had its resident limit reduced under certain residency redistribution requirements using a cost report subsequently revised between September 1 and 15, 2006.

Title VIII: Medicaid - Subtitle A: Protecting Existing Coverage - (Sec. 801) Amends SSA title XIX (Medicaid) to extend through FY2009 certain requirements for state provision of transitional medical assistance to recipient families who lose their Medicaid eligibility for certain reasons.

Authorizes a state to opt to: (1) substitute a 12-month, in lieu of the current six-month, initial eligibility period for extended transitional Medicaid; and (2) waive the minimum three-month receipt of medical assistance requirement for eligibility for transitional Medicaid.

Requires each state to collect and submit to the Secretary information on: (1) average monthly enrollment and average monthly transitional Medicaid participation rates for adults and children; and (2) the number and percentage of children who become ineligible for transitional Medicaid whose medical assistance is continued under another eligibility category or who are enrolled under the state's child health plan under title XXI (State Children's Health Insurance Program) (SCHIP).

(Sec. 802) Authorizes state Medicaid plans to: (1) cover a specified categorically needy group, whose medical assistance shall be limited to family planning services and supplies, including medical diagnosis or treatment services; and (2) provide for such assistance during a presumptive eligibility period.

(Sec. 803) Prohibits the Secretary, between November 3, 2005, and March 1, 2009, from denying federal financial participation in any adult day health services approved under a state Medicaid plan.

(Sec. 804) Revises requirements for treatment of the income and resources of certain institutionalized spouses by redefining "institutionalized spouse" to specify one who is receiving medical assistance for home and community-based services.

(Sec. 805) Amends the Consolidated Omnibus Budget Reconciliation Act of 1959 to exempt Medicaid health insuring organizations operated by public entities in Ventura and Merced Counties, California, from the requirement that they be Medicaid managed care organizations meeting certain criteria.

Declares that such exemption shall not apply with respect to any period for which the number of Medicaid beneficiaries enrolled with such health insuring organizations exceeds 16% (currently 14%) of the number of such beneficiaries in California.

Subtitle B: Payments - (Sec. 811) Increases Medicaid payments to Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY2009-FY2012.

Removes the federal matching payments for improving data reporting systems from the over-all limit on payments to such territories for any territory.

(Sec. 812) Increases from 15.1% to 20.1% after December 31, 2007, the minimum Medicaid drug rebate percentage drug manufacturers must agree to for covered outpatient drugs.

Revises the definition of "best price," for the calculation of a rebate, to include cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (as under current law), plus discounts and other price concessions to pharmaceutical benefit managers (PBMs).

(Sec. 813) Requires the disregard of any significantly disproportionate employer pension contribution (whose aggregate allocation exceeds 25% of the total increase in personal income in the state) in calculating the state's per capita income for purposes of computing its federal medical assistance percentage (FMAP) for a fiscal year.

(Sec. 814) Places a one-year moratorium on any federal action, policy, or practice to restrict Medicaid coverage or payment for rehabilitation services, or school-based administration, transportation, or medical services, if such restrictions are more restrictive in any aspect than those applied to such coverage or payment as of July 1, 2007.

(Sec. 815) Deems the DSH allotments for Tennessee for each fiscal year beginning with FY2008 to be $30,000. Permits the Secretary to impose a limitation on the total amount of payments made to hospitals under the TennCare Section 1115 waiver only to the extent that it is necessary to ensure that a hospital does not receive payment in excess of certain amounts or as necessary to ensure that the waiver remains budget neutral.

(Sec. 816) Addresses construction of certain requirements for reduction in state medical assistance expenditures for federal Medicaid payment purposes by the amount of specified donations and taxes.

States that nothing in such requirements shall be construed as prohibiting a state's use of funds as the nonfederal share of Medicaid expenditures where they are transferred from or certified by a publicly-owned

regional medical center located in another state, as long as the Secretary determines that the use of funds is proper and in the interest of the Medicaid program.

Subtitle C: Miscellaneous - (Sec. 821) Amends SSA title XXI (SCHIP) to direct the Secretary to establish a demonstration project under which up to 10 states may provide under the state child health plan for a five-year period for child health assistance in relation to family coverage for children who would be targeted low-income children but for coverage as beneficiaries under a group health plan as the children of participants by virtue of a qualifying employer's contributions.

(Sec. 822) Requires a transfer of certain FY2009 SCHIP funds for diabetes grants.

Title IX: Miscellaneous - (Sec. 901) Establishes MEDPAC as an agency of Congress.

(Sec. 902) Repeals subtitle A of title XVIII of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MPDIMA), which requires the board of trustees of the Hospital Insurance and Supplemental Medical Insurance trust funds to determine annually for Congress whether or not general revenue financing will exceed 45% of total Medicare outlays within the next seven years.

(Sec. 903) Repeals the Comparative Cost Adjustment (CCA) program, as added by the Medicare Prescription, Drug, Improvement, and Modernization Act of 2003.

(Sec. 904) Directs the Secretary to establish within the Agency of Health Care Research and Quality a Center for Comparative Effectiveness Research.

Requires the Center to conduct, support, and synthesize research with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which disease, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.

Directs the Secretary to establish: (1) an independent Comparative Effectiveness Research Commission to oversee and evaluate the Center's activities; and (2) a Coordinating Council for Health Services Research.

Amends the Internal Revenue Code to establish in the Treasury a Health Care Comparative Effectiveness Research Trust Fund, to be financed in part by fair share per capita fees.

Imposes on each specified health insurance policy for each policy year a fee, payable by the policy issuer, which shall be equal to the fair share per capita amount multiplied by the average number of lives covered under the policy.

Imposes a similar fee on self-insured plans.

(Sec. 905) Directs the Secretary to report to Congress: (1) a plan to develop and implement a health information technology (health IT system) for all health care providers under Medicare; and (2) an analysis of the impact, feasibility, and costs associated with the use of health information technology in medically undeserved communities

(Sec. 906) Directs the Secretary to designate and arrange with a single organization meeting specified requirements (such as the National Quality Forum) for advice and recommendations to the Secretary on \the key elements and priorities of a national system for establishing health care measures.

(Sec. 907) Directs the Secretary to provide for implementation of the changes in the NAIC model law and regulations (for improvements to the Medigap program) recommended by the National Association of

Insurance Commissioners (NAIC) in its Model #651 on March 11, 2007, as modified to reflect the changes made under this Act.

Requires issuers of Medicare supplemental (Medigap) policies to offer, in addition to the core package, at least benefit packages classified as "C" or "F."

(Sec. 908) Directs the Secretary, in order to implement the first nine titles of this Act, to provide for the transfer of $40 million from the Federal Supplementary Health and Human Services Trust Fund to the Centers for Medicare & Medicaid Services Program Management Account for FY2008.

Title X: Revenues - (Sec. 1001) Amends the Internal Revenue Code to increase the excise taxes on: (1) cigars; (2) cigarettes; (3) cigarette papers; (4) cigarette tubes; (5) smokeless tobacco; (6) pipe tobacco; and (7) roll-your-own tobacco.

Imposes a floor stocks tax on certain domestic or imported cigarettes, including those located in a foreign trade zone, except cigarettes in vending machines. Allows a credit of $500 against such increased excise taxes.

(Sec. 1002) Exempts from federal excise tax any liquid fuel sold for use in any ambulances providing transportation for emergency medical services.

Entitles the ultimate purchaser of such fuel to a rebate of any excise taxes paid.