ARNOLD & PORTER LLP

Memorandum

From: The FDA and Healthcare Practice Group

Date: June 18, 2009

Re: Health Reform Takes Shape—A Side-by-Side Comparison

This side-by-side chart presents a brief summary of key issues in the healthcare reform proposals under consideration by the authorizing committees in Congress. It reflects information made available as of June 17, 2009.

The Affordable Health Choices Act was made available on June 6, 2009 on behalf of the Chairman of the Senate Committee on Health, Education, Labor and Pensions (HELP), Edward Kennedy (D-MA). The Committee will begin marking up this draft legislation the week of June 15, 2009. This bill is ultimately expected to be combined in some manner with a bill forthcoming from the Senate Finance Committee to form the Senate health reform proposal.

Although the Finance Committee has published options papers, it has not yet released proposed legislative text. However, we have included the Patient-Centered Outcomes Research Act, as introduced by Finance Committee Chairman Baucus (D-MT) on June 6, 2009, under "comparative effectiveness" in the Senate Finance Committee column below, and because we anticipate that Senator Baucus' bill, or something close to it, will appear in the Senate Finance Committee's larger health reform bill.

An outline of the health reform proposals of the House of Representatives' three authorizing committees, Ways & Means, Energy and Commerce, and Education and Labor, were published in the form of a "Tri-Committee" summary paper on June 8, 2009. The House Committees have not yet provided further detail.

Below, Arnold & Porter briefly summarizes certain key provisions in the documents aforementioned in the following seven major categories: Healthcare Coverage; Comparative Effectiveness; Quality and Delivery System Reform; Prevention and Wellness; Workforce; Fraud and Abuse; and 340B.

Senate HELP		Senate Finance		House Tri-Committee	
Brief Description	**Page**	**Brief Description**	**Page**	**Brief Description**	**Page**
I. Healthcare Coverage					
A. Exchange					
Authorizes "American Health Benefit Gateways," which may be established by states or the Secretary of Health and Human Services (HHS), and would facilitate the purchase of health plans by individuals and employers.	43-44			"Establishes a new Health Insurance Exchange to create a transparent marketplace for individuals and small employers to comparison shop among private insurers and a new public health insurance option."	2
A state may establish a Gateway and become an “establishing” state, or a state may request that HHS establish a Gateway. If, four years after enactment, a state has done neither, HHS shall establish a Gateway in that state. A state in which HHS establishes a Gateway is a “participating” state. A state must at least make certain minimum changes to incorporate health insurance reform principles, or HHS will not establish a Gateway in the state and its residents will not be eligible for federal credits to purchase health insurance.	71-75			"Creates a new national health Exchange that permits States the option of developing a State or regional exchange in lieu of the national Exchange."	1
Provides grants to states to establish Gateways.	40-44				
A Gateway may operate in more than one state, and a state may create one or more subsidiary Gateways that serve geographically distinct areas.	53				
A Gateway may assess a surcharge on insurers, not to exceed 3% of the premiums collected by that insurer.	46				

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Individuals eligible for Children's Health Insurance Program (CHIP) may elect to enroll in CHIP or a health plan under the Gateway.	49				
HHS must establish three different cost-sharing tiers with different cost-sharing percentages and out-of-pocket limits, allowing for limited variability of these two factors.	79-81				
Allows public and private entities to serve as "navigators" that contract with states to raise public awareness of the health insurance program, distribute information, and assist with enrollment.	76-79				
Provides payments to small business for each insured employee and additional payments to encourage small businesses to cover a larger share of premium payments.	94-103				
"Non-discrimination in Healthcare": "Policy under discussion"	103				
B. Qualifying Plan					
A health plan must be certified by a Gateway as a "qualified health plan" in order to be offered by the Gateway to individuals or employers.	52				
"Qualified health plans" may only contract with hospitals that implement a patient safety evaluation system and a program for patient-centered education and counseling at discharge and with providers that implement mechanisms specified by HHS to improve quality.	59-60				

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To be certified, a plan must: ▪ not employ marketing practices that have the effect of discouraging the enrollment of individuals with significant health needs; ▪ employ methods to ensure that insurance products are simple, comparable, and structured for ease of consumer choice; ▪ ensure a wide choice of providers; ▪ make available a detailed description of the benefits offered, service area premiums, cost-sharing, access to providers, and the plan's grievance and appeals procedure; ▪ provide coverage for at least the essential healthcare benefits (as established by the Medical Advisory Council); ▪ be accredited (or receive accreditation within a given period) by the National Committee for Quality Assurance or another accrediting entity recognized by HHS; ▪ implement a quality improvement strategy that meets specified requirements; ▪ have adequate procedures for appeals of coverage determinations; and ▪ not establish a benefit design that likely would substantially discourage enrollment by certain qualified individuals in such plan.	56-57			▪ "Independent public/private advisory committee recommends benefit packages based on standards set in statute; ▪ Guarantees choice and fair, transparent competition by creating various levels of standardized benefits and cost-sharing arrangements, with additional benefits available in higher-cost plans; and ▪ Phases-in requirements relating to benefit and quality standards for employer plans."	3

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C. Insurance Reform					
Group health plans (GHPs) and health insurers offering group or individual health insurance coverage may not deny coverage based on preexisting conditions.	7-8			"Ensures availability of coverage by prohibiting insurers from excluding pre-existing conditions or engaging in other discriminatory practices."	2
GHPs and health insurers offering group or individual coverage may not vary premium rates based on health status-related factors, gender, class of business, claims experience, or any factor other than family structure, community rating area, actuarial value of the benefit, or age (for age, the rate may not vary by more than 2 to 1).	8-9			"Prohibits rating based on gender, health status, or occupation and strictly limits premium variation based on age."	2
Any insurer that offers healthcare coverage in a state must offer coverage to every employer and individual in the state that applies for coverage.	9				
Insurers that offer health insurance in the individual or group market must offer renewal of coverage.	10				
Insurers may not establish eligibility rules based on an individual's health status, medical condition (physical or mental), claims experience, medical history, genetic information, evidence of insurability, disability, or "[a]ny other health status-related factor determined appropriate by the Secretary."	12-13				

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Insurers offering group or individual health insurance coverage must submit cost accounting reports to HHS, and provide annual rebates to enrollees based on the percentage of total premium revenue spent on non-claim costs.	10; 11-12				
GHPs and insurers offering group or individual health insurance coverage must have a “reimbursement structure” that gives incentives for various measures to improve quality; among other things, the incentives must “substantially reflect[] the payment policy of [Medicare and CHIP] with respect to any generally implemented incentive policy to promote high quality healthcare.”	13-15				
GHPs and health insurers offering group or individual health insurance coverage must cover preventive health services and may not impose cost-sharing requirements on preventive services.	15-17			"Waives cost-sharing for preventive services in benefit packages."	2
GHPs and health insurers offering group or individual health insurance coverage may not impose lifetime or annual limits on benefits.	17				
GHPs and health insurers offering group health insurance coverage may not discriminate based on salary.	18-19				

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Allows individuals to keep their current health insurance without changes, and allows family members to join health plans in which an individual was enrolled prior to the passage of this bill (i.e., otherwise-required insurance reforms will not apply to a GHP or issuer in connection with coverage of an individual enrolled before enactment of the bill, or such insurance in which a covered individual's family members wish to enroll).	19			"Maintains the ability for people to keep what they have and minimizes disruption."	1
				"Caps total out-of-pocket spending in all new policies to prevent bankruptcies from medical expenses."	2
D. Public Plan					
Each Gateway must include a "public health insurance option." Definition of "Public Health Insurance Option": "Policy under discussion"	43; 110			▪ Would create "a new public health insurance option within the Exchange to offer choice and ensure competition;" ▪ The public option is "self-sustaining and competes on 'level field' with private insurers in the Exchange;" ▪ "When individuals 'enter' the Exchange, whether on their own or as employees of a business that is purchasing in the Exchange," they could choose between public and private options.	3

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E. Mandates					
Penalty for individuals uninsured for an entire calendar year, set by HHS as "the minimum practicable amount that can accomplish the goal of enhancing participation in qualifying coverage."	103-107			"Once market reforms and affordability credits are in effect to ensure access and affordability, individuals are responsible for having health insurance with an exception in cases of hardship."	3
"Shared Responsibility of Employers" (i.e., penalties: "Policy under discussion").	110			"Employers choose between providing coverage for their workers or contributing funds on behalf of their uncovered workers."	3
				Government must make insurance affordable via “affordability credits, insurance market and delivery system reforms and oversight of insurance companies."	3
				"Protects small businesses by exempting small low-wage firms and providing a new small business tax credit for firms providing health coverage."	3
F. Subsidies					
HHS will pay "credits" to qualified insurers through the Gateways on behalf of low-income individuals. Credits are not available to low-income individuals in states that are not “participating” states or “establishing” states in the Gateway system.	81-94			"Includes sliding scale affordability credits in the Exchange to support individuals and families with incomes between Medicaid eligibility levels and 400% of the federal poverty level (FPL); (NOTE: The average cost of family coverage today is 14% of a family’s income at 400% of poverty.)"	

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The credits would be calculated to ensure that an individual with income up to 500% of FPL is not required to pay an amount that exceeds 10% of income. Individuals with incomes up to 150% should not be required to pay more than 1% of income.	82				
Credits are calculated to subsidize premiums only to the extent that a plan covers “essential healthcare benefits,” as defined by the Medical Advisory Council.	85				
Establishes a Medical Advisory Council to make recommendations to HHS on the "essential healthcare benefits" eligible to receive credits.	62-71				
G. Medicaid Expansion					
"Assumes that the provisions of [this Act] will be considered by the Senate as part of legislation that amends Title XIX of the Social Security Act” to make Medicaid changes, such as: ▪ eligibility up to 150% of FPL ▪ improvements to facilitate enrollment ▪ requiring states to maintain current eligibility levels for current Medicaid enrollees ▪ temporary adjustments to state Federal Medical Assistance Percentages (FMAP) payments.				"Expands Medicaid for the most vulnerable, low-income populations and improves payment rates to enhance access to primary care under Medicaid."	

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H. Other Access Measures					
Increases funding for Federally Qualified Health Centers (FQHCs).	118-119				
Provides more flexibility on location of FQHCs.	119-121				
HHS may establish and administer projects to reduce FQHCs' costs of supplies and services, including collaborative purchasing and other collaborative efforts HHS deems "appropriate."	123-124			"Expands Community Health Centers…Creates community-based programs to deliver prevention and wellness services; targets community-based programs and new date collection efforts to better identify and address racial, ethnic, and other health disparities; and strengthens state, local, tribal and territorial public health departments and programs."	2
Increases funding for the National Health Service Corps.	125				
Mandates negotiated rulemaking to develop methodology and criteria for designating medically underserved populations and health professions shortage areas.	126-129				
Reauthorizes the Emergency Medical Services for Children Program through 2014.	130-131				
Provides reimbursement to employers that provide health coverage to retirees between ages 55 and 64, subject to specified requirements. HHS reimburses 80% of costs for certain claims, net of "negotiated price concessions." Program is temporary; only applies in a state until it becomes a "participating" or "establishing" state.	131-137				

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I. Health IT					
Authorizes studies and reports and appropriates additional funding.	137-153				
J. CLASS Act					
Improves community living assistance services.	153-208				
Comparative Effectiveness					
A. General Description					
Establishes a Center within the Agency for Healthcare Research and Quality (AHRQ) to collect, conduct, support, and synthesize research on comparative health outcomes and effectiveness of the full spectrum of healthcare treatments, including drugs, devices, procedures, diagnostics and other interventions.	314-316	Establishes a nonprofit corporation that is not an agency or establishment of the federal government, to prioritize, conduct, and synthesize comparative clinical effectiveness research with respect to medical treatments, services, and items, including drugs, devices, procedures, and other treatments or protocols.	2-4		
B. Body Supporting Comparative Effectiveness Research (CER)					
Creates the Center for Health Outcomes Research and Evaluation (CHORE) within AHRQ.	314	Establishes an independent nonprofit body called the Patient-Centered Outcomes Research Institute (PCORI).	3		
C. Bodies Carrying Out CER					
CHORE may either conduct its own research or award grants or contracts for others to conduct original research.	317	PCORI will contract out research to government agencies that have CER experience or to appropriate private organizations with such experience; within five years, PCORI will issue a report detailing the feasibility of conducting CER in-house.	8; 11-12		

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D. Governing Body and Advisory Panels					
"To ensure transparency," the HHS Secretary or designee appoints an advisory council of 21 members appointed for 4 years. The Council includes: the AHRQ Director, the CMS Chief Medical Officer, and 19 others from "a broad range of perspectives."	317-319	PCORI has a governing board that consists of 21 members appointed for six years. The Board consists of: the HHS Secretary, the Agency for Healthcare Research and Quality (AHRQ) Director, the National Institutes of Health (NIH) Director, and 18 others appointed by Comptroller General (including: three patient and consumer representatives; three physician representatives; one person from Centers for Medicare & Medicaid Services (CMS); one representing state healthcare administrators; one from another government agency administering federal healthcare programs (e.g., the Department of Defense or Veteran's Affairs); three private payer representatives, three representatives of pharmaceutical, device, and diagnostic manufacturers; one representing nonprofit health research organizations; one representing quality measurement organizations; and one representing independent health services researchers); PCORI also must appoint an external expert advisory panel to assist with technical research questions such as study designs or protocols.	30-32; 13		
E. Who Determines Research Priorities					
The HHS Secretary determines research priorities, subject to requirements for transparency.	213; 321	PCORI determines research priorities, subject to requirements for transparency.	5; 25; 41		

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F. Methodologies Considered					
CHORE shall "use a broad range" of methodologies, including observational studies, randomized controlled studies, "and other approaches."	315	Any methodology may be adopted by the PCORI board upon recommendation by the methodology committee (17-member body appointed by Comptroller General).	7; 16		
G. Source of Data					
CHORE may use any data from "any [US government] department or agency" and may use any published or unpublished data obtained either via CHORE-funded research or directly from the public.	316-317	PCORI may collect any existing CMS data or contract with AHRQ and any other government or private entity that has appropriate experience.	8		
H. Review of Data					
CHORE is subject to periodic audits by the Comptroller General.	317	PCORI research will be peer-reviewed.	21		
I. Dissemination of Data and Transparency					
Data must be available to public via a database and other "informational tools" for patients and providers; priority setting "shall be transparent," methods and standards "shall be publically documented," and stakeholders must be able to "review and provide comment" on methods and findings.	315; 321	PCORI must consult with stakeholders as to dissemination methods "that will be most useful to end users;" PCORI must allow 45-60 day public comment periods for determinations of (1) priorities, (2) data standards, (3) methodologies, (4) individual study designs, and (5) initial findings.	24; 41-42		

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J. Effect of CER on Coverage Policies					
Findings cannot be construed as mandates for payment, coverage, or treatment.	323	Findings and reports cannot be construed as mandates, recommendations, or guidelines for payment, coverage, or treatment; CMS may use findings for coverage decisions if the process for such use is "iterative and transparent," which requires that (1) stakeholders and individuals have input and opportunity to review draft proposals of decisions; (2) CMS consider all other data in addition to CER results; and (3) CMS consider benefits of coverage for subpopulations, even if CER demonstrates that, “on average, with respect to the general population, the benefits of coverage do not exceed the harm.”	24; 46-48	Commitment to "protect[] current coverage and preserve[] choice of doctors, hospitals and health plans" (this is a general commitment not specifically related to CER, which is not addressed in the Tri-Committee outline).	1
K. Cost Effectiveness Research					
CHORE is to develop minimum standards for conducting “studies of comparative health outcomes and value.”	316	The methodology committee is to contract with the Institute of Medicine (IOM) for a report, due within three years of appointment of the methodology committee, examining methods “by which efficiency and value (including the full range of harms and benefits, such as quality of life) could be assessed in a scientifically valid and standardized way” (the methodology committee, within the same timeframe, must also contract with IOM for a report that will examine methods by which benefit design and performance research could also be conducted in a scientifically valid and standardized way).	19-21		

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L. Funding					
	212-213	US$210M in appropriations FY2010–2013 and US$150M in each of FY2014 and 2015; US$10M from HHS discretionary funds from the American Recovery and Reinvestment Act of 2009 (ARRA); funds from Medicare Trust Funds plus fees for public and private insurers; PCORI sunsets on September 30, 2019.	50; 50-51; 48-49, 54-64; 53		
III. Quality and Delivery System Reform					
A. National Strategy to Improve Healthcare Quality					
Requires HHS to establish a national strategy for improving healthcare quality and to develop the infrastructure necessary to support such a strategy, using a collaborative and transparent process. HHS must identify priorities (e.g., high-cost, chronic disease). Plan must be updated every three years.	211-212				
Requires development of an Interagency Working Group on Healthcare Quality to improve coordination across Federal agencies and reduce duplication of efforts.	218-220				
B. Public Reporting					
Annual national healthcare quality report card, beginning on or before January 31, 2011.	216				

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C. Quality Measurement					
Requires identification of gaps where no quality measures exist, or where measures need improvement or updating; publication of such information on an Internet website.	220-221				
Funds grants or contracts for quality measure development to eligible entities.	222-224				
D. Quality Measure Endorsement, Public Reporting, and Data Collection					
Qualified consensus-based entities may make recommendations to HHS regarding national priorities, gaps in endorsed quality measures, and updating of endorsed quality measures.	225-230				
Requires public reporting on quality measures within five years of enactment, using rulemaking process. Public reporting must include outcomes, assessment of care coordination and care transitions, and assessment of the patient experience, and must be risk-adjusted. Information must be made available on a public website.	236				
Requires HHS to establish a process for collecting and aggregating data on quality measures from providers receiving funds under this Act.	242				

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E. Healthcare Delivery System Research					
Requires AHRQ to identify, develop, and evaluate innovative methodologies for improving the delivery of healthcare services. Establishes a Patient Safety Research Center to coordinate research and support activities, and to translate research into practice recommendations.	245-251			Requires adoption of "innovative payment approaches," and promotion of better care coordination "through programs such as accountable care organizations."	4
Provides grants to establish community-based multidisciplinary teams to support primary care services in a Medical Home model.	259				
Provides grants to implement medication management services in the treatment of chronic diseases.	265				
Requires hospitals to report preventable readmission rates and to work with patient safety organizations to improve practices, reduce inefficiency, and improve coordination of care. Requires information gathering beginning in 2010, and a procedure for reporting readmission rates beginning in 2011. The Secretary shall determine what is an "applicable readmission," in consultation with CMS and AHRQ.	295-301			Requires reforms that address the high rate of growth in spending and generate savings, including a "program in Medicare to reduce preventable hospital readmissions."	4

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Requires HHS to determine whether standardized, quantitative information regarding the benefits and risks of drugs (tabular or fact box, or other format) would improve healthcare decision making. Requires a report to the Congress not later than one year after enactment. If alternative format would improve decision making, HHS must issue regulations "as necessary" to implement alternative format.	312-313				
Provides for grants for demonstration programs to integrate quality improvement and patient safety training into the academic curricula of health professionals.	325				
Establishes an Office of Women's Health within the Office of the Secretary and other agencies within HHS, including Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), the US Food and Drug Administration (FDA) and AHRQ.	327-342				
IV. Prevention and Wellness					
A. Insurance					
				"Waives cost-sharing for preventive services in benefit packages."	2
Sets up a council of federal agency heads to coordinate prevention and wellness efforts and to develop a national prevention, health promotion, and public health strategy.	346-351				

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Creates Prevention and Public Health Investment Fund to provide investment in prevention, wellness, and public health activities authorized by Public Health Service Act. Appropriates to the fund US$10B per year for 2010–2019 and at least that amount in following years.	351				
Establishes a new Preventative Services Task Force, charged with developing recommendations and providing technical assistance to providers, and the Community Preventive Services Task Force, with similar duties related to population-level interventions.	353-359				
Requires the Secretary of HHS to guide a national public-private prevention campaign to raise awareness, encourage healthy behaviors, and promote use of preventive services.	359-361				
B. Access					
Subtitle B. Increasing Access to Clinical Preventive Services.	361-382				
Sets up annual grants to each state to conduct outreach and provide to underserved populations certain services including referral and treatment.	361-366				
Authorizes grants for school-based health clinics to provide preventive and primary healthcare to medically underserved children and adolescents.	366-375				

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Establishes certain Oral Healthcare Prevention Activities. Focus is on women and children; creates demonstration project on oral health delivery.	376-378				
Sets up cooperative agreements with states to promote oral health. Requires the Secretary of HHS to improve surveillance of oral health.	378-382				
Requires grants to state and local governments and community-based organizations for community preventive health activities in order to reduce chronic disease rates, address health disparities, and develop a stronger evidence base of effective prevention programming.	382-387			"Expands Community Health Centers… Creates community-based programs to deliver prevention and wellness services; targets community-based programs and new date collection efforts to better identify and address racial, ethnic, and other health disparities; and Strengthens state, local, tribal, and territorial public health departments and programs."	2
C. Healthcare in a Community Setting					
Provides for grants to state or local health departments for five-year pilot programs to provide public health community interventions, screenings, and, where necessary, clinical referrals for individuals aged between 55 and 64.	387-393				
D. Disabled Populations					
Amends the Americans with Disabilities Act to establish standards for accessibility of medical diagnostic equipment by individuals with disabilities.	393-394				

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E. Immunizations and Vaccinations					
HHS may negotiate with manufacturers for purchase vaccines for certain adults; permits states to purchase vaccines at the price negotiated by the Secretary. Creates a demonstration program to award grants to states to improve provision of vaccines.	394-398				
F. Nutritional Labeling					
Restaurants in chains with 20 or more locations must post calorie counts (and other nutritional information specified by HHS through regulations) on menu boards.	399-408				
G. Public Health Research					
Provides for funding of research on public health services and systems.	408-409				
H. Data Collection					
Requires that any federal health program, activity, or survey report data on race, ethnicity, geographic location, socioeconomic status, health literacy, primary language, and other indicators of disparity.	410-414				
Facilitates the use of health impact assessments to measure the impact of the "built environment" (e.g., buildings schools, transportation systems) on health outcomes.	414-417				

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Directs CDC to evaluate the best employer-based wellness practices; to conduct educational campaigns that raise awareness of such programs; to provide employers with technical assistance; and to institute workplace demonstration projects.	417-420				
V. Workforce					
A. Gather Data on Workforce					
Forms National Healthcare Workforce Commission to track the supply and demand of healthcare workforce and disseminate best practices in recruitment and retention of workforce. The commission will consist of health professionals, employers, third-party payers, economists, consumers, labor unions, state and local government, and educational institutions.	430-459				
Establishes the National Center for Health Workforce Analysis to coordinate State and Regional Centers for Health Workforce Analysis. Regional Centers will study regional and national workforce issues and provide technical assistance to local and regional entities. Special grants will be awarded to regional centers for longitudinal studies that evaluate participation in the National Health Service Corps. and quality performance measures in primary care medicine and dentistry.	459-470				

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B. Increase Supply of Health Professionals					
Support for Education: ▪ Adjusts interest rates for federally supported student loans for medical students who go into primary care. ▪ Increases loan amounts for nursing workforce development. ▪ Establishes a loan repayment program for students who receive training in pediatric medical subspecialties, pediatric surgical specialties, or child and adolescent mental and behavioral healthcare. These specialists can receive up to US$35,000 per year if that they agree to practice for at least two years. ▪ Establishes a Public Health Workforce Loan Repayment program for students in public health or health professions programs who agree to work for a federal, state, local, or tribal public health agency for at least three years. These students can receive up to US$35,000 per year. ▪ Establishes loan forgiveness for allied health professionals. ▪ Establishes scholarships for current public health and allied health professionals to receive additional training.	470-485				

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Enhancing Existing Programs: ▪ Increases funding for the National Health Service Corps. scholarship and loan repayment programs. ▪ Establishes a grant program to support operation of nurse-managed Health Clinics. ▪ Defines school of nursing.	485-492			Expands the National Health Service Corps. /expands scholarships and loans for individuals in needed profession and shortage areas.	1
C. Enhancing Healthcare Workforce Education and Training					
▪ Provides grants to for training programs (including financial assistance for trainees and faculty) in primary care and physician assistant programs. Priority is given to programs that educate students in team-based approaches to care, including the patient-centered medical home.	493-500			Boosts training of primary care doctors and expands pipeline of individuals going into health professions, including primary care, nursing, and public health.	
▪ Grants funds to geriatric education. ▪ Establishes centers to support training in geriatrics, chronic care management, and long-term care for faculty in health professions schools and family caregivers; develops curricula and best practices in geriatrics; expands the geriatric career awards to advanced practice nurses, clinical social workers, pharmacists, and psychologists; and establishes traineeships for individuals who are preparing for advanced education nursing degrees in geriatric nursing.	512; 500-502				

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▪ Creates grants for schools to develop or enhance training programs in social work, graduate psychology, professional training in child and adolescent mental health, and pre-service or in-service training to paraprofessionals in child and adolescent mental health. ▪ Nurse Midwifery programs to receive advanced nurse education grants in Title VIII. ▪ Awards grants to nursing schools to strengthen nurse education and training programs and to improve nurse retention. ▪ Adds faculty at nursing schools as eligible individuals for loan repayment and scholarship programs. ▪ Establishes a federally-funded student loan repayment program for nurses with outstanding debt who pursue careers in nurse education. Creates grants to states, public health departments, FQHCs, and other nonprofits to promote positive health behaviors for populations in medically underserved areas through the use of community health workers.	502 530-536				

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C. Enhancing Healthcare Workforce Education and Training					
▪ Establishes a youth public health program to expose and recruit high school students into public health careers. ▪ Authorizes the Secretary to address workforce shortages in state and local health departments in applied public health epidemiology and public health laboratory science and informatics.	540				

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D. Support Existing Health Professionals					
▪ Reauthorizes the Centers of Excellence program which enhances recruitment, training, academic performance and other supports for minorities. ▪ Provides scholarships for disadvantaged students who commit to work in medically underserved areas as primary care providers. ▪ Establishes community-based training and education grants for Area Health Education Centers (AHECs) and programs. ▪ Expands the allowable uses of diversity grants to include completion of associate degrees, bridge or degree completion program, or advanced degrees in nursing, as well as pre-entry preparation, advanced education preparation, and retention activities. ▪ Creates a Primary Care Extension Program to educate and provide technical assistance to primary care providers about evidence-based therapies, preventive medicine, health promotion, chronic disease management, and mental health. ▪ The Center for Primary Care, Prevention, and Clinical Partnerships at the AHRQ will award planning and program grants to state entities including state health department, state-level entities administering Medicare and Medicaid, and at least one health professions school.	549-580				

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E. Other					
Defines the following within the health professions section of the Public Health Service Act: Area Health Education Center, Area Health Education Center Program, Clinical Social Worker, Cultural Competency, Graduate Psychology, Health Disparity Population, Health Literacy, Mental Health Service Professional, One-stop Delivery System Center, Paraprofessional Child and Adolescent Mental Health Worker, Racial, and Ethnic Minority Group/Population, Rural Health Clinic.	425-429				
VI. Fraud and Abuse					
Establishes a new senior level position within HHS: Senior Advisor for Healthcare Fraud, responsible for the coordination of efforts relating to the detection and prevention of fraud and abuse involving public and private health insurance coverage; and a new Senior level position at US Department of Justice: Senior Counsel for Healthcare Fraud Enforcement, responsible for coordination of efforts relating to the investigation and prosecution of fraud and abuse involving public and private health insurance coverage.	581-583			Creates new Consumer Protections for Medicare Advantage beneficiaries.	3

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Establishes Healthcare Program Integrity Coordinating Council (PICC), charged with developing a strategic plan to improve the coordination and sharing of information among federal and state agencies and private insurers.	583-587				
Amends the Employee Retirement Income Security Act (ERISA) to prohibit false statements and representations in connection with the marketing of Multiple Employer Welfare Arrangements (MEWAs), including, but not limited to representations regarding the financial solvency of a plan or benefits provided.	587-589				
Adds three new MEWA related crimes to list of Federal healthcare offenses (resulting in expanded government investigation, civil & enforcement action powers)	589				
National Association of Insurance Commissioners (NAIC) to develop model private healthcare fraud reporting form for private health plans to refer suspected fraud and abuse to state agencies for investigation.	589-590				
Department of Labor (DOL) may issue regulatory standards related to removing barrier of federal preemption for state MEWA related fraud claims.	590-591				
Gives DOL authority to issue cease and desist and seizure orders against MEWAs whose conduct is fraudulent or is a threat to public health and safety.	592-594				

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Requires MEWA registration (must verify registration before enrolling members).	594-595				
DOL may promulgate regulations to allow confidential communication among public officials and NAIC relating to fraud and abuse investigations.	595-596				
VII. 340B					
A. Expanding the List of Covered Entities					
▪ Expands the list of entities eligible to qualify as 340B covered entities (and thus receive drug price discounts) to include: (a) A children's hospital that is not a disproportionate share hospital (DSH) because its inpatients are predominantly under 18 years old, if it satisfies the other requirements for a DSH to participate in 340B; (b) critical access hospitals, as defined at Social Security Act (SSA) § 1820(c)(2), which satisfy the current DSH hospital 340B eligibility requirements on ownership or operation; and (c) a "sole community hospital," as defined at SSA § 1886(d)(5)(C)(iii), or a "rural referral center," as defined at SSA § 1886(d)(5)(C)(i), if either type of entity also both satisfies the current DSH 340B requirement on ownership or operation and has at least a disproportionate share adjustment percentage of 8%.	597-598				

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B. Expanding 340B to Inpatient Setting					
▪ Expands the 340B program to require discounts on drugs used "in connection with" inpatient services by covered entity hospitals.	597-598				
C. Exceptions to Group Purchasing Organization (GPO) Exclusion					
▪ 340B covered entity hospitals could continue to purchase inpatient drugs through GPOs ▪ HHS must develop "reasonable exceptions" to the current prohibition against covered entity hospitals purchasing outpatient drugs through GPOs: – In cases of drug shortages, manufacturer non-compliance, or any other circumstance beyond the hospital's control; – To facilitate generic substitution when a generic covered outpatient drug is available at a lower price; and – To reduce the administrative burden of managing two drug inventories—drugs obtained under 340B and drugs purchased outside 340B—so long as the exception does not create a duplicate discount diversion problem.	599-601				

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D. Medicaid Credit					
Covered entity hospitals would be required to issue a credit (as determined by HHS) to Medicaid (within 90 days of filing their Medicare cost reports) for 340B inpatient drugs provided to Medicaid beneficiaries.	601				
E. Average Manufacturer Price (AMP) and Best Price					
Amends Medicaid rebate statute to provide that if a covered drug is not distributed to the "retail pharmacy class of trade," then the AMP for the drug equals "the average price paid to the manufacturer for the drug in the US by wholesalers for drugs distributed to the acute care class of trade, after deducting customary prompt pay discounts." Amends the Medicaid rebate statute to exclude from Best Price "any prices charged for a covered drug as defined in section 340B(b)(2) of the Public Health Service Act." "Covered drug" would be defined as either "a drug used in connection with an inpatient or outpatient service provided by" a 340B covered entity hospital or a covered outpatient drug.	603				

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F. 340B Requirement					
The bill would require that manufacturers submit 340B ceiling prices to HHS every quarter.	614				
G. Program Integrity					
Manufacturer: HHS develops a system to verify the accuracy of 340B ceiling prices; procedures for manufacturers to issue refunds to covered entities; and a secure website to provide ceiling prices to covered entities. Civil money penalties may be assessed on manufacturers that knowingly and intentionally overcharge a covered entity (which would not exceed US$5,000 for each instance of overcharging).	603-611				
Covered Entity: HHS must develop procedures for the covered entity to update information on the HRSA web site. HHS must develop guidance on avoiding "duplicate discounts" and a standardized system by which manufacturers could verify the status of covered entities. Covered entities that knowingly and intentionally sell drugs to non-patients would be subject to sanctions in the form of interest on the sums for which the covered entity is found liable. A covered entity that diverts drugs to non-patients in a manner that is systematic and egregious, as well as knowing and intentional, could be expelled from the 340B program.					

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H. Dispute Resolution					
HHS must develop regulations establishing a dispute resolution process to handle claims by covered entities that they have been overcharged for covered drugs and claims by manufacturers of drug diversion or duplicate discounts. ▪ Creates HHS decision-making body to review and resolve these claims. ▪ This body could, at manufacturer's request, consolidate claims against the manufacturer. Multiple covered entities could jointly assert claims against a manufacturer. HHS would establish procedures for a covered entity to obtain information from manufacturers and third parties related to its claim ▪ Manufacturer must audit a covered entity prior to initiating administrative dispute resolution proceedings. ▪ Administrative resolutions are final and binding unless invalidated by court of competent jurisdiction.	611-615				