RSC Republican Study Committee
REP. TOM PRICE, M.D. (R-GA), CHAIRMAN
PAUL TELLER, EXECUTIVE DIRECTOR
424 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
rsc.price.house.gov
ph (202) 226-9717 / fax (202) 226-1633

RSC Outlook: Health Care

February 2009

In light of the many health care issues that could be considered early in the 111th Congress, the RSC has prepared the following RSC outlook paper.

SCHIP and "Stimulus" Package:

Many of the health care items on the liberal agenda have already become law as part of the SCHIP reauthorization (H.R. 2) and the "Stimulus" (H.R. 1) including:

- **Funding for Universal Health Care:** Nearly $39 billion in the "stimulus" was aimed at laying the groundwork for universal healthcare. According to the House Appropriation's report language, the "stimulus" provides funding to "prepare our country for universal healthcare" by paying for training and school expenses of primary care providers, as well as funding for a Prevention and Wellness fund, Health IT and the establishment of a Federal Coordinating Council for Comparative Effectiveness Research (CER).
- **Government Controlled Rationing Board:** The House Democrats' insistence that the Senate's insertion of the word "clinical" be removed from the final Comparative Effectiveness Research provision shows that their true intent is ultimately to create a board that makes decisions in place of patients and doctors and rations care based on "cost".
- **Expanded Entitlements and Federal Funding:** The expansion of SCHIP, Medicaid and government subsidies will eat away at private insurance and individual choice, and shift more Americans to middle-class entitlement programs.
    - The expansion of SCHIP will shift 2.4 million children out of private coverage, allow income disregards, and permit states to continue to cover families up to 400% of FPL, which encompasses 75% of all families ($84,800 for a family of 4 in 2008).
    - The "stimulus" provides nearly $27 billion to extend public programs and provide new government subsidies to an estimated 6.5 million unemployed individuals through COBRA, leaving an ever shrinking portion of the population with truly private health care coverage**.**
    - In addition to subsidizing higher income unemployed workers, the "stimulus" bill extends the Transitional Medical Assistance (TMA) program that allows individuals to remain on Medicaid despite transitioning from welfare to work.

Although some provisions did not make it into the conference report which was enacted into law, some conservatives may be concerned that the following House passed proposals will make their way back into legislation later this year:

- The true intent of the CER board can be seen in the report language accompanying the House Appropriations' bill: "By knowing what works best and presenting this information more broadly to patients and healthcare professionals, those items, procedures, and interventions that are most effective to prevent, control, and treat health conditions will be utilized, while those that are found to be less effective and in some cases, more expensive, will no longer be prescribed."
- The "Medicaid for millionaires" portion of the "stimulus" bill would have forced the American taxpayer to subsidize insurance for unemployed wealthy individuals at 100% FMAP; the bill explicitly stated that "no income or resources test shall be applied with respect to" any of the newly eligible groups.
- The House Democrats' "stimulus" package would have establish a brand a new public program in which employers are mandated to continue COBRA coverage for workers to "buy-into" until they qualify for Medicare, even though it could significantly increase their health costs. The federal government's "temporary" extension and expansion of COBRA would create a major new health spending program that can easily be replaced with early access to Medicare as proposed by liberals such as Stark, Rockefeller and Baucus.

Some Conservatives may be concerned that the above provisions mark the first skirmish in a longer-term campaign by liberals to demolish independent private-sector health care in America. Below are highlights of other legislation Democrats may tackle in the early part of the 111th Congress.

Medicare: The Democrats have proposed many alterations to Medicare including restructuring payments for participating physicians, allowing the government to negotiate drug prices, vast program expansions, and making Medicare the model for health care reform.

Medicare Reimbursement Rate: Sustainable Growth Rate (SGR): The physician reimbursement rate for Medicare is scheduled for a staggering estimated 21% cut in 2010. This leaves the Congressional Democrats with the challenging task of coming up with approximately $318 billion to $556 billion over 10 years, depending on the method, in order to create a permanent fix. A one year freeze, even using a budget gimmick (which would result in an estimated 27% cut in 2011), would cost $10 billion.

While many believe that the SGR formula is fundamentally flawed and should be replaced, there are various approaches for how to do so. Some Members are pushing to retroactively remove the cost of physician-administered drugs from the SGR formula calculation in order to keep it from triggering more payment cuts. Others like Baucus, believe that Congress may need to replace SGR with an alternative expenditure target

approach based on categories of services, which they hope will reallocate resources from high-growth areas – specialists such as heart surgeons, who they believe are overpaid – to primary care and prevention. While greater incentives may be needed to encourage entrance into primary care, conservatives may disagree with politicians deciding what services are more valuable or with penalizing specialists who already have greater financial burdens placed on them because of higher education and liability insurance costs.

Some conservatives may be concerned with government bureaucrats making market decisions that will disincentivize entry into specialty fields, which could result in a reduction in cutting edge innovation and quality of care. Other suggested payment reforms put forth by Democrats include bundled payments for defined medical episodes, and "capitated" payment – a fixed amount for all services that a patient receives over a specified period. Many doctors are opposed to giving control over a large portion of their incomes to hospitals, which in many cases would be responsible for coordinating distribution of bundled payments. Others are concerned that those with higher risk patients will not be compensated accordingly, and that doctors and hospitals may cherry pick the healthiest patients.

Medicare Part D / Prescription Drugs: Congressional Democrats have stated that they would like to open up Medicare Part D and have the government negotiate drug prices by eliminating the noninterference clause in the Medicare Modernization Act. Conservatives may be concerned with the government's unnecessary intrusion into an already competitive market that is costing about one-third less – about $50 billion – than originally estimated since it started in January 2006.

Democrats recently introduced HR 684, which allows the government not only to "negotiate" drug pricing but also to create a Medicare prescription drug plan to "compete' with private plans. The bill's sponsor, Rep. Berry, claimed: "If they like (Medicare beneficiaries) the coverage they have, they can keep it." But he later contradicted himself by stating the true intent of the bill: "If this works as we think it will, most of the private plans would drop out."

Conservatives may be concerned that this will result in a system that places cost before quality as the government - through price mandates - will push companies out of the program reducing competition and seniors' access to a wide range of options. Those companies that may be able to comply with the price setting may have to sacrifice quality and investment in future innovation. According to a CBO report, allowing HHS to negotiate prices "would have a negligible effect on federal spending."

Other cost containment options that Congressional Democrats may propose include the extension of the 340 B Drug Pricing program currently utilized by the VA or through allowing drug reimportation.

Killing the Medicare Trigger: The Democrats' rules package for the 111th Congress turned off the "Medicare Trigger," a funding warning mechanism put in place by

conservatives in the Medicare Modernization Act of 2003 (MMA) as a means to force consideration of spending reform if for two consecutive years, 45% or more of Medicare's funding comes from general tax revenues. Liberals may introduce legislation, as they did in the 110th Congress, that will overturn the law, which currently still requires the president to submit legislation (which due to the rules package Congress no longer has to debate) to slow excess spending over and restore fiscal stability.

CBO projects that Medicare spending will increase by $435 billion or 96% over 10 years. Conservatives may be concerned that eliminating this Medicare cost containment provision will make it less likely that the 111th Congress will take a critical look at unsustainable entitlement spending. The new rules package which not only turned off the Medicare trigger, but also allows Congressional Democrats to ignore PAYGO with an "emergency" designation, may be setting the stage for massive spending on health care reform without having to actually "pay" for it.

Medicaid/Medicare Buy In: Congressional Democrats may try to pass legislation that will slowly eat away at private health care by continuing to expand Medicaid to higher incomes and Medicare to younger populations. The first step in nationalizing health care could be seen in the House version of the "stimulus", which allowed for "temporary" federal funding of provisions expanding Medicaid to unemployed individuals with higher incomes without a sunset on the expansion, TMA coverage of employed individuals, and a government subsidy to all unemployed individuals to purchase for COBRA coverage while allowing individuals 55 and older to remain on COBRA until they reach Medicare eligibility.

Although the House provision allowing individuals to remain on COBRA after age 55 was removed in the final bill, conservatives may be concerned that the intent of the government funded COBRA extension was meant to pave the way for an early Medicare buy-in or subsidy once an individual no longer receive the COBRA government subsidy and cannot afford to maintain coverage under this expensive plan. Liberals in Congress have been proposing a Medicare-buy option in for years; most recently in Baucus' health reform white paper and the "Medicare Early Access Act of 2008", introduced by Rockefeller in the Senate and previously in the House by Stark. Specifically, this bill would provide a 75% advanceable, refundable credit to allow early retirees to enroll under this new government program while keeping their federal or state COBRA continuation coverage. The bill would drive employers to modify their private retirement coverage and pay instead for supplemental insurance and a portion of the premium for the new public plan.

Health Saving Account (HSA) Substantiation: Last Congress the House passed H.R. 5719, the Taxpayer Assistance and Simplification Act of 2008, with provisions placing additional restrictions on Health Savings Accounts (HSAs). Section 17 of H.R. 5719 required point-of-sale "substantiation" of all HSA transactions from an independent third party, to ensure that money withdrawn from an HSA pays for qualified medical expenses. Specifically, it would make the income tax deduction associated with HSA contributions contingent on substantiation of all withdrawals. The oversight of every single account

transaction would make HSAs similar to Flexible Spending Arrangements (FSAs). The bill ultimately stalled in the Senate, but may find its way into the agenda again.

Currently, non-qualified withdrawals from an HSA are subject to individual income taxes, as well as a 10% penalty. HSA account activity is already subject to audits from the Internal Revenue Service, and account holders are advised to retain their receipts documenting qualified medical expenses in the event of an audit. Furthermore, some banks that administer HSAs have electronic debit cards that can "read" the merchant code where the transaction is taking place (e.g. a doctor's office). If a request for a transaction is occurring at a location not normally associated with qualified medical expenses, the debit card can decline the transaction. Studies related to the percentage of withdrawals for non-qualified are unclear and range from 2.7% - 12% as withdrawals from vendors not normally associated with qualified medical expenses (e.g. a grocery store), does not does not mean that the transaction itself is not a qualified medical expense (e.g. cough syrup)

Some Conservatives may be concerned that this is an attempt by liberals to increase tax revenues by making HSAs less attractive to consumers thus reducing uptake/lower contribution levels in addition to fines collected by non-compliance. In addition to increased inconvenience for users, introducing a new step of independent "substantiation" may well increase costs for banks and account administrators, who are likely to pass these costs on to employers and/or consumers. Some conservatives may also be concerned that should this proposal pass, an HSA mechanism created to reduce the growth of health care costs – which has achieved some noteworthy successes in enrolling over 10 million people since its introduction in 2003 – would lead to increased costs for businesses and individuals.

Food and Drug Administration (FDA): The Democrats have proposed numerous modifications to the FDA including a vast expansion of oversight and policing powers, provisions allowing state tort lawsuits to preempt the Federal Food, Drug, and Cosmetic Act, and controversial follow-on biologics legislation.

FDA Tobacco Bill: One of the highest priorities for Rep. Waxman will be a House-passed bill, from the 110th Congress, H.R. 1108, the Family Smoking Prevention and Tobacco Control Act which gave the FDA the authority to regulate tobacco. This bill will have dire consequences on competition in the market and the purpose and function of the FDA. Despite the title, the bill does little to protect children specifically; rather it makes the government a policing agency over products that are already widely known to be harmful.

The new tax or "user fees" imposed on companies may end up being passed on to consumers. Still some argue that the FTC, which already regulates tobacco advertising, would be better suited than the FDA which is already overwhelmed and under-resourced. The Commissioner of the FDA himself did not want jurisdiction over tobacco as it requires the Agency to approve tobacco products without reducing the dangerous contents to zero, thus undermining its core mission of promoting public health. The US

Bureau of Alcohol, Tobacco and Firearms has also expressed concerns about this over-regulation which they predict will increase crime funded through the sale of cigarettes on the black market. Some may be concerned that the bill enacts numerous barriers to market entry, driving down competition and potentially impeding the introduction of reduced-risk tobacco products. Finally, the bill eliminates federal preemption while simultaneously creating overly burdensome advertising restrictions that may be seen as a violation of companies' freedom of speech under the First Amendment.

Expanded and Increased Authority of FDA: Representatives Dingell, Stupak, and Pallone have introduced H.R. 759, The Food and Drug Administration Globalization Act of 2009 that will negatively affect food, drug, device and cosmetic companies due to expanded taxes or "user-fees" and a provision that appears to unilaterally eliminate FDA's Federal preemptive authority. Without federal preemption the FDA approval process becomes near meaningless as a local jury's decision will supersede scientists at the FDA. Some conservatives may believe that this benefits trial lawyers at the cost of the FDA approval process. The globalization bill, which beefs up the FDA's power to police, had remained in draft form since last Congress due in part to Republican and industry opposition.

The bill states, "This Act and the amendments made by this Act may not be construed as modifying or otherwise affecting any action or the liability of any person (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) under the law of any State." Conservatives may be concerned that this language takes away the backstop and opens up all companies to civil law suits such as strict liability, breach of implied warranty, and negligence in design, testing, labeling, manufacturing, labeling, distribution, sale, inspection, or marketing of the device for any product despite FDA premarket approval. Conservatives may be concerned that juries in 50 different states, not the FDA will be deciding what is acceptable despite the companies' compliance with federal regulations. Ultimately, this attempt to pay back tort lawyers will drive up health care costs and hurt future growth and innovation while placing burdensome requirements on companies who now must adhere to not 1 but 50 different state regulations.

While the bill does not include specific provisions that attempt to resolve the GAO report which faulted the FDA for its inability to oversee medical product safety, Democrats plan on addressing it early this Congress. Waxman is already working to garner support for the Medical Device Safety Act of 2009, which is similar to a bill Pallone introduced in the 110th Congress (H.R 6381) that may be introduced as early as next week. The bill will seek to overturn the Supreme Court's decision that FDA approval adequately protects patients from unsafe medical devices and "correct the Court's flawed interpretation of the medical device statute by explicitly clarifying that an injured patient's ability to seek compensation is preserved." Other FDA topics Congress may consider include IVD regulation, importation, and advertising restrictions.

Follow-On Biologics: Several proposals in the 110th Congress would have amended the Public Health Service Act in order to provide an expedited marketing approval pathway for biologics that are "comparable" to previously approved brand-name products. However, Democrats, Republicans, and the Bush Administration were at odds on the best way to move forward. The main issues at stake include the approval process of follow-on

biologics (clinical data), the appropriate length of exclusivity for brand biologic drugs and stipulations on follow-on biologics' interchangeability with brand biologic drugs.

The discussion is generally between supporters of brand name and generic products. Three different pieces of legislation were introduced in the House in the 110th Congress, with Rep. Waxman's being the least industry-friendly. The Bush Administration did not support interchangeability (without physician consent), which would allow pharmacists to substitute follow-on biologics for brand prescriptions, without FDA developed guidance due to their complex structure and difficulty in proving the follow-on biologics are the same as their brand counterparts. The Administration also believed that a follow-on biologic should have a different nonproprietary name than the brand name product.

Waxman and Pallone are looking to move a more generic-friendly bill, similar to one introduced by Waxman in the 110th Congress, HR 1038, the Access to Life-Saving Medicine Act which, among other things, does not give brand biologic makers an exclusivity period. Due to opposing views with the Bush Administration, Pallone has decided to get a second opinion from the FDA now that Obama is President.

Conservatives may be concerned about allowing an adequate amount of time for exclusivity for brand biologic companies to recoup the investment cost of research and development before allowing generics to be sold.

Other Issues of Note: This year Democrats will consider legislation to reauthorize and expand countless government programs (such as the Ryan White CARE Act) and introduce a steady influx of legislation to overturn the Bush Administration's regulations and Executive Orders. Some early highlights will include repealing (not just moratorium) Medicaid outpatient services regulations**,** repealing conscience clause provisions, and a removal of the ban on new destructive embryonic stem cell research.

Pay-Fors: Without the threat of a Presidential veto, Democrats will no longer be forced to find bipartisan non-controversial "pay-fors" and instead can use "pay-fors" that many House Republicans have repeatedly objected to such as:

- Cuts to the Medicare Advantage plan or overly burdensome restrictions to drive private plans out of the market;
- A ban on physician owned hospitals; and
- Medicaid rebates for beneficiaries in Medicare Part D.

Health Care Reform: At this point it appears that health care reform, at least in the House, will either be led by the Administration (as with the CER in the "stimulus" bill) or by liberal leaders in Congress such as Stark or Waxman. It may be less likely that a health care reform proposal will come from the Administration due to the void left by the withdrawal of the Daschle nomination as Secretary of Health and Human Services (HHS). In the Senate it appears that Baucus will lead the way in coordination with Kennedy and his appointed HELP task force.

Democrats will try to avoid repeating the mistakes made during 1993-1994 with "HillaryCare". In order to try and avoid the charge of being too secretive, the Obama Administration has requested "public" input by giving people the chance to highlight their concerns and experiences with health care. Many Democrats realize that some of their ideas may not be popular with the public, and they have several options to get around this problem. The first strategy would be to pass comprehensive legislation early in the first year of President Obama's first term, when he is most popular and is least likely to be resisted by Congress and the public. The second option is to put in place holders (for example within the "stimulus") which can be filled in later, that slowly and quietly chip away at the private market. The Democrats appear to be following Daschle's advice to leave the nasty details out of any health reform bill – as he believes one of Clinton's mistakes was putting too many details into her reform package, alerting those who disagreed to mount an opposition. According to Tom Daschle one component of a comprehensive health care reform bill would be "a Federal Health Board should be charged with establishing the system's framework and filling in most of the details. This independent board would be insulated from political pressure." The final option would be to introduce a bill, hold hearings on it all year, and try to gain public buy-in.

RSC will provide an overview of specific health care proposals and conservative concerns in the coming weeks.

Note: This is not meant to be an exhaustive list of all the health issues that will come up during the 111th Congress.

RSC Staff Contact: Emily Henehan, emily.henehan@mail.house.gov, (202) 225-9286