

# Implementation of Federal Health Reform: A Primer for Anesthesiologists

## Introduction

In light of recent passage of the Senate-passed health reform bill, and pending Senate consideration of the reconciliation “sidecar”, this memorandum provides a high-level overview of the key components of health reform implementation that will occur over the coming months and years. The document focuses on the key changes to federal health policy that will unfold as these bills are implemented, specifically: health insurance market reforms (section III); health insurance exchanges (section IV); public program expansions (section V); delivery system reforms (section VI); prevention and wellness programs (section VII); healthcare workforce (section VIII); fraud and abuse (section IX); and revenues (section X).

Our analysis of the foreseeable regulatory and administrative actions necessary to effectuate these proposals is based on the provisions included in the Senate-passed health reform bill – the Patient Protection and Affordable Care Act (H.R. 3590) – and the sidecar bill – the Reconciliation Act of 2010 (H.R. 4872).

Furthermore, absent explicit (or inferred) statutory direction provided by Congress to the Department of Health & Human Services (HHS) and other Executive agencies to effectuate such provisions, we have offered some prospective commentary as to how the regulatory process might unfold, including interactions with other federal agencies, states, and stakeholders on those efforts. Given the sheer number and foreseeable impact of the reforms put forward by Congress through this legislation, it is possible that HHS may seek to request direct-hire staffing authority from the Office of Management & Budget, as it did when tasked with the implementation of the Medicare Modernization Act of 2003 (MMA), to ensure that the Department and its agency counterparts are equipped to respond to the new regulatory and enforcement responsibilities. In particular, we note that many of the new regulatory and enforcement responsibilities will be directed toward the Centers for Medicare & Medicaid Services (CMS), where such responsibilities would, of course, be *in addition to* the Agency’s existing regulatory responsibilities associated with the customary annual Medicare rule-making processes.

We would also note that while the expanded federal role in regulating the health care sector cannot be disputed, this legislation still delegates a substantial degree of authority to the states and territories. Additional tracking and analysis of trends in state implementation will be required, especially with regard to state-based insurance exchanges and the rigor (or lack thereof) with which states choose to regulate them.

**Finally, we believe it would be a mistake to assume that federal legislative action on health care is going to come to a halt after consideration of this round of health care reform ends.**

Quite to the contrary, we expect Congress will be compelled to address several health care matters in the months and years ahead, including:

- A long-term or additional shorter-term fixes to the still-broken Medicare physician payment formula (SGR), with this debate potentially continuing through the fall of this year and, if a permanent fix is not enacted, in the years to come;
- Other extensions and changes to components of the Medicare program (several other “Medicare extenders” in the health reform bill expire by the end of 2011);
- A response to the Entitlements Commission’s report that is required per Executive Order by December 1, 2010 (with the annual April 15 Medicare Trustees Report coming soon, we believe additional action on the deficit is very likely to come in the 112th (2011-2012) Congress);
- Mandatory congressional responses to the Independent Payment Advisory Board (IPAB) established in the health reform bill;
- A primarily Republican-driven effort to repeal at least some significant components of the health reform package; and
- Other attempts to correct, improve, weaken, or expand the statutory provisions contained in this year’s health reform package, with at least one “fixer” package virtually guaranteed before the exchanges and other major reforms “go live” in 2014.

### **Health Insurance Market Reforms**

Title I of the Senate-passed health reform bill outlines a number of private health insurance market reforms, many of which are largely established via amendments to existing statutes – namely, the Public Health Service Act of 1944 (PHSA) (primarily individual and group health plans, as well as some governmental plans); the Employee Retirement Income Security Act of 1974 (ERISA) (primarily pension and health plans in the private industry); the Internal Revenue Code of 1986 (IRC) (primarily group health plans); and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (broadly applicable to healthcare providers, plans, and clearinghouses).

A number of the health insurance market provisions are slated to take effect immediately (i.e., upon enactment of the legislation or shortly thereafter), whereas most of the broader, more systemic reforms are not set to begin until 2014. As opposed to the House-passed health reform bill – which establishes a “Health Choices Administration,” a newly-formed independent executive branch agency to coordinate with HHS, the Department of Labor (DOL) and state insurance regulators to oversee the Exchange and to provide oversight to plans – the Senate-passed health reform bill provides a federal pathway to effectuate such requirements and to provide ongoing oversight but, in general, largely defers to the states to implement them.

Initial health insurance reforms – or, those deemed “early deliverables” – include provisions, which are applicable to plan years beginning on or after 6 months of the bill’s enactment, that would, among other things: (1) prohibit plans from establishing lifetime or unreasonable limits on the dollar value of benefits; (2) require plans to provide coverage of preventive health services and immunizations without cost-sharing; and (3) require plans offering dependent coverage to allow certain individuals up to age 26 to remain on their parents’ health insurance. Furthermore, certain provisions provide up-front relief (effective upon enactment) to states to comply with the new federal mandates, including provisions that support state health insurance consumer assistance or health insurance ombudsman programs and assist states in reviewing annual increases in premiums for health insurance coverage.

Several of the more immediate reforms, particularly those that take effect upon enactment but for which implementation will be ongoing, would require the Secretary of HHS to work with states, federal advisory committees, and other key stakeholders to issue federal standards or to promulgate regulations to effectuate such provisions. For example, under the Senate-passed health reform bill, the Secretary is required to, within 12 months of the bill’s enactment, consult with the National Association of Insurance Commissioners (NAIC) and other key stakeholders to develop standards for use by health insurers in compiling and providing to enrollees a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage. Under such provision, health insurers must in turn, within 24 months of the bill’s enactment, provide to the Secretary a summary of benefits and coverage explanation pursuant to the standards prescribed by the Secretary prior to any new enrollment restrictions.

As noted above, more fundamental health insurance market reforms do not take effect until 2014, including those that would: (1) prohibit individual and group health plans from imposing any pre-existing condition exclusion or using medical underwriting; (2) prohibit individual and group health plans from discriminating (via coverage denials or rate-setting) against individual participants and beneficiaries based on health status or other factors; (3) prohibit “discriminating” against certain health care providers and (4) require health insurers in small group and individual markets to provide comprehensive health insurance coverage meeting federally-defined standards. Similar to some of the more immediate health insurance market reforms, many of the longer-term reforms are accompanied by both reporting and rule-making requirements. On the latter, a handful of such provisions call for the Secretary’s close consultation with the DOL and Treasury on regulatory matters of common jurisdiction.

### **Health Insurance Exchanges**

Effective January 1, 2014, the Senate-passed health reform bill requires states to establish American Health Benefit Exchanges, administered by a governmental agency or nonprofit entity, to serve as a new health insurance marketplace through which tax credits and premium and cost-sharing subsidies would be available to individuals and families meeting specified income thresholds (i.e., up to 400% of the federal poverty level (FPL)) to purchase an Exchange-certified “qualified health benefit plan.” Under the state-based Exchanges, the Senate-passed

health reform bill would require states to provide for the establishment of a Small Business Health Options Program (SHOP) Exchange to assist qualified small businesses in facilitating the enrollment of their employees in qualified health plans offered in the small group market. Pending Secretarial approval, states may also form regional or interstate Exchanges, in addition to asserting other means of flexibility in the operation and enforcement of the Exchanges, as evidenced through the provision to deploy alternative coverage initiatives, including a provision to allow states to establish non-Medicaid basic health plan programs for certain low-income individuals.

There are a number of key differences between the Senate-passed health reform Exchange provisions and those included in the House. For example, unlike the House-passed health reform bill, which would create a federally-administered National Health Insurance Exchange with the HHS Secretary serving as the chief rate negotiator, the Senate-passed health reform bill defers largely to the states for the overall administration of the Exchanges and does not require Exchanges to offer a new public health insurance option. Moreover, should a state fail to establish an Exchange by January 1, 2014 or implement the federal requirements, the Senate-passed health reform bill contains a “fall-back” provision that would require the Secretary to establish and operate an Exchange in the state and to implement the standards.

Despite the inherent deference to states in the administration of the Exchanges under the Senate-passed health reform bill, there are a number of both implicit and explicit deliverables – regulatory or otherwise – imposed upon the Secretary of HHS prior to and throughout the implementation of the Exchanges to ensure that states are well-equipped to do so, both in terms of overall financial support as well as through receipt of federal guidance and technical assistance. To begin with, the Senate-passed health reform bill requires the Secretary to, not later than 1 year upon the bill’s enactment, award grants to states for activities (including planning activities) related to establishing an Exchange. The amount of the awards to each state under such provision is at Secretarial determination, so while there are some broad legislative parameters around the amount (albeit subject to the limitations on the amounts appropriated by Treasury) and use of such grants, there appears to be some administrative latitude or discretion in the overall process. In addition, the Senate-passed health reform bill requires the Secretary to make available technical assistance to states in the implementation of the SHOP Exchanges, so presumably more informal and formal guidance will be issued by HHS to states in this regard.

Finally, the Senate-passed health reform bill also makes clear the role that the federal government will play in outlining federal standards and providing ongoing oversight to states. For example, the Senate-passed bill requires the Secretary of HHS to promulgate regulations that address a number of key Exchange-related issues, including rules that address the certification criteria for qualified health plans (e.g., marketing requirements, choice of providers, quality accreditation requirements). The Senate-passed health reform bill also calls for the Secretary to issue regulations “as soon as practicable after the date of enactment” regarding the standards under which states would operate when administering and enforcing Exchanges, qualified health plans, and reinsurance and risk adjustment programs – regulations

to be issued only upon close consultation with the NAIC and health insurance issuers, consumer organizations, and others.

### **Public Program Expansions**

Effective January 1, 2014, the Senate-passed health reform bill would expand coverage under Medicaid and the Children's Health Insurance Program (CHIP), while providing federal support to states via increases in the state's regular Medicaid or CHIP federal medical assistance percentage (FMAP) rates. The Senate-passed health reform bill establishes a federal mandatory Medicaid threshold of 133% of federal poverty level (FPL) – as opposed to the House-passed health reform bill, which raises the threshold to 150% of FPL – and (with changes included in the sidecar) provides full Medicaid financing to states to offset the cost of covering the “newly-eligible” over the first 3 expansion years (2014-2016); 95% in 2017; 94% in 2016; 93% in 2019; and 90% thereafter. For states that have already (as of December 1, 2009) expanded eligibility for adults with incomes up to 100% of FPL – i.e., “expansion states” – the “side car” bill provides for a phased-in reduction of the states' share of the responsibility for the newly eligible population (50% in 2014; 60% in 2015; 70% in 2016; 80% in 2017; and 90% in 2018) such that by 2019, expansion states would receive the same federal Medicaid financing as non-expansion states. In addition, under the Senate-passed health reform bill, states would have the option (via a state plan amendment (SPA)) to extend Medicaid coverage to all non-elderly individuals at or below 133% FPL beginning April 1, 2010.

Unlike the House-passed health reform bill – which would allow CHIP to sunset upon expiration of its current reauthorization window (September 30, 2014) and provide for the enrollment of such children in the Exchange, provided certain conditions are met – the Senate-passed health reform bill extends the current CHIP reauthorization window through September 30, 2015, with the assumption that Congress would again reauthorize the program at that time. From October 1, 2015 through September 30, 2019, the Senate-passed health reform bill provides for a 23% increase in states' regular CHIP match rate (not to exceed 100%).

With respect to the administrative implementation of the above-referenced public program coverage provisions, although some of the provisions may go through the formal notice of public rule-making process (including the likely publication of the enhanced FMAP rates in the *Federal Register*, among other things), many of these provisions, because they are largely self-implementing, are likely to be effectuated by CMS via lower-level, but detailed, guidance to the states, including through State Medicaid Director (SMD) and/or State Health Official (SHO) letters, as well as through more informal channels, including regular CMS calls with state Medicaid agency staff and stakeholders.

### **Delivery System Reforms**

The Senate-passed health reform bill contains a number of provisions aimed at improving the overall quality and efficiency of care in both the Medicare and Medicaid programs, including via the creation of new patient care models such as Accountable Care Organizations (ACOs) and

medical homes, as well as other payment reforms intended to link Medicare payment with quality outcomes, including value-based purchasing for hospitals, expansion of the Physician Quality Reporting Initiative (PQRI) and inclusion of a punitive component for non-compliant providers, improvements to the overall programs' quality infrastructure, payment refinements including authorizing the Secretary of Health & Human Services to review "mis-valued" codes, and initiatives aimed at incenting health care quality improvements.

Furthermore, the Senate-passed health reform bill includes a provision to establish a Center for Medicare and Medicaid Innovation (CMI) within CMS. The purpose of the CMI is to test innovative payment and service delivery models with the goal of reducing program expenditures and enhancing quality. In accordance with the Senate language, CMS must establish the CMI no later than January 1, 2011. We believe CMS has already taken steps in this direction by realigning the Office of Research, Development, and Information (ORDI) and the Office of Policy (OP) under the newly-established Center for Strategic Planning.

Importantly, the CMI has the authority to implement the models it tests more broadly, if they prove successful in reducing cost or improving quality, *without* additional congressional authorization. As is the case with several of the other delivery system reforms, including the newly-enacted or expanded pilot programs and demonstration projects, the CMI must consult with relevant federal agencies and other stakeholders in the implementation of the projects it decides to pursue. We believe it possible that CMS may opt to begin the formal process to establish the CMI via the publication of a notice in the *Federal Register* updating the Agency's "statement of organization, function, and delegations of authority."

In addition, some of the delivery system reforms – particularly those that are broadly applicable to a given provider sector and that impact the customary annual Medicare provider payment system regulations – may be effectuated via the typical annual notice-and-comment rule-making process. For a number of the new patient care models, however, including those pertaining to either new or expanded Medicare demonstration authority, CMS may instead opt to leverage its administrative flexibility to implement these provisions via less formal regulatory routes, though the Agency would likely allow for public input in the ongoing development of such initiatives via open door forums (ODFs) and other meetings with stakeholders.

The bill also establishes an Independent Payment Advisory Board (IPAB) to make recommendations on reducing Medicare spending. Beginning in January 2015 and annually thereafter, IPAB is required to submit a proposal to the President and Congress for reducing Medicare spending to a target amount when program spending is projected to exceed the Consumer Price Index (through 2017) or Gross Domestic Product (after 2017). The 15-member board will be comprised of health policy experts, but may not include a majority of providers. It will be appointed by the President in consultation with Congress. The Secretary of HHS, the Administrator of CMS, and the Administrator of the Health Resources and Services Administration (HRSA) will serve as ex officio members.

IPAB is charged with recommending spending reductions in all areas of Medicare, including payments to Medicare Advantage plans and Part D drug plans, but is not permitted to suggest changes that will ration care, raise beneficiary premiums and cost-sharing, or restrict benefits and eligibility in the program. IPAB will submit its proposals to the President and Congress by January 15 annually, with the Senate Finance Committee, and the House Energy and Commerce Committee and Ways and Means Committee reporting any related legislation by April 1. The House and Senate will have limited opportunity to change IPAB's recommendations; there are limits on debate of any bill and Congress must agree by joint resolution to discontinue the Board. If Congress fails to act on IPAB's recommendations, CMS will implement them.

The Senate bill also requires IPAB to make an annual public report beginning July 2014 on healthcare costs, access, utilization and quality of care for both Medicare and private payers. In carrying out this requirement IPAB is supposed to make comparisons across regions, services and provider types. The Senate also added a requirement that IPAB, beginning January 2015 and at least every 2 years after that, submit a report to the President and Congress recommending ways to slow growth in national health spending. The Board will use data from public and private payers in developing its recommendations.

### **Prevention and Wellness**

Health promotion and chronic disease prevention are cornerstones of the Senate-passed health reform bill. In particular, the Senate-passed health reform bill takes substantial steps to improve the national health care infrastructure through the establishment of a National Prevention, Health Promotion and Public Health Council, led by the directors of the relevant Executive agencies (HHS, USDA, DOL, etc.), to develop and help execute a national prevention and health promotion strategy. In addition, the Senate-passed health reform bill also calls for the establishment of a dedicated Prevention and Public Health Fund to support prevention, wellness, and public health activities authorized by the Public Health Service Act (PHSA).

Furthermore, the Senate-passed health reform bill authorizes a number of new programs and benefits to, among other things, increase access to clinical preventive services. Several of the new programs are slated to be implemented by the Centers for Disease Control and Prevention (CDC) through new demonstration program authority (e.g., the oral healthcare prevention education campaign) and through grants to states, community-based organizations, and other specified eligible entities (e.g., the Community Transformation Grants), the latter of which are likely to be promulgated in accordance with the formal federal grant-making processes. With respect to the new Medicare and Medicare preventive benefits or cost-sharing requirements, such changes are likely to be effectuated via program transmittals (e.g., Change Requests) used by CMS to communicate new or changes policies and/or procedures that are being incorporated into a specific CMS program manual (mainly the Medicare-related changes) or, through SMD and SHO transmittals (Medicaid policy changes only). Moreover, concurrent with the release of such guidance, CMS is likely to disseminate any new coverage-related changes via informal provider education channels (e.g., listserv® lists, ODFs, etc.).

## **Health Care Workforce**

The Senate-passed health reform bill includes a number of provisions that aim to train, recruit, and retain skilled health care workers. In particular, the Senate-passed health reform bill establishes a 15-member National Healthcare Workforce Commission (with members to be appointed by the Comptroller General not later than September 30, 2010). The Commission will serve as both a resource and a partner to Congress, relevant Executive agencies (including HHS and DOL), and states and localities to develop recommendations as to how to best allocate federal health care workforce resources with current needs.

In addition, the Senate-passed health reform bill includes federal student loan program reforms to increase the supply of the health care workforce – particularly to incentivize students to practice in high-demand fields, such as primary care and nursing – as well as to help recruit and retain health care professionals in high priority areas, such as Health Professional Shortage Areas, Medically Underserved Areas, or serving Medically Underserved Populations. Furthermore, the Senate-passed health reform bill provides for a host of new grants to states, higher educational institutions, not-for-profit organizations, and health care facilities to support such initiatives. In particular, through the establishment of the State Health Care Workforce Development Grant Program, states will be able to compete for federal dollars to support state and local health care workforce planning and implementation activities.

Although not always expressly stated, most of the above-referenced provisions are likely to be effectuated by HRSA via amendments to existing health professional loan and loan repayment program guidelines; or, with respect to many of the new grant programs, likely through the promulgation of federal notices of funding availability (NOFAs) that are likely to be published in the *Federal Register* and/or through centralized federal funding grant portals, such as [grants.gov](http://grants.gov).

## **Fraud and Abuse**

The bill includes a package of reforms designed to minimize waste, fraud and abuse in public programs. It requires that the Integrated Data Repository at CMS include claims and payment data from Medicare, Medicaid, CHIP, Veterans Affairs and Department of Defense health programs, Social Security and Indian Health Services – a challenging administrative goal. Those who engage in fraudulent activity may be excluded from participating in federal health programs, fined up to \$50,000 for each violation and – significantly – may have their payments suspended pending a fraud investigation. The bill also directs the Secretary of HHS to establish a national health care fraud and abuse data collection program to report actions against providers, suppliers and practitioners, and to submit information to the National Practitioner Data Bank. The Secretary will have authority to dis-enroll a Medicare physician or supplier who fails to maintain written orders for durable medical equipment, certification for home health

services or referrals for other items and services. Additionally, states must terminate individuals or entities from their Medicaid programs if they were terminated from Medicare or another state's Medicaid program. Federal interaction with the states will be a key challenge in implementing these new requirements.

Other provisions direct considerable regulatory authority to Executive agencies in implementing new programs intended to curtail fraud and abuse. For example, the bill requires skilled nursing facilities in Medicare and nursing facilities in Medicaid to disclose ownership information and establish compliance programs; requires national and state background checks for individuals providing patient care in long-term care facilities; bans physician-owned hospitals that do not have provider agreements before August 2010 (amended to December 2010 in sidecar bill); requires manufacturers of drugs, devices, biologics and medical supplies to disclose gifts to physicians; requires disclosure of rebates, discounts and related information by pharmacy benefit managers; and requires providers and suppliers enrolling or re-enrolling in Medicare, Medicaid and CHIP to pay a new fee and disclose affiliations with other providers or suppliers who have uncollected debt, or have been subject to certain sanctions from federal healthcare programs.

The reconciliation bill would allow CMS to share data with the Internal Revenue Service (IRS), includes steps to prevent fraud at community health centers, and permits pre-payment review of Medicare claims and allows an enhanced 90-day oversight period for initial claims by Durable Medical Equipment (DME) suppliers when there is a significant risk of fraud.

### **Revenue Provisions**

With passage of the reconciliation sidecar, the package would levy a 40% excise tax on high-value health insurance group coverage costing more than \$10,200 and \$27,500 (with higher amounts for retirees and those in high-risk professions). It excludes certain benefits, including stand-alone dental and vision plans, from the tax, which would not be implemented until 2018 (per the sidecar).

The legislation also raises Medicare payroll taxes on high earners. The Senate-passed health reform bill increases the amount by 0.9% for individuals making \$200,000 and families earning \$250,000. (The sidecar applies the tax to investment income). Further, the Senate bill raises the threshold for qualifying to deduct medical expenses from 7.5% to 10% of adjusted gross income, with a temporary exemption through 2016 for the elderly, increases tax penalties on early distributions from Health Savings Accounts (HSAs) and limits contributions to Flexible Spending Accounts (FSAs).

The Senate bill also includes a number of healthcare industry fees that will be implemented primarily by the IRS:

- \$2.3 billion annual fee on drug-makers, based on market share and excluding small manufacturers. (Total revenue raised was increased by \$4.8 billion in the sidecar and implementation was delayed by a year).
- A fee of \$2 billion a year from 2011 through 2017 and \$3 billion after 2017 on manufacturers of medical devices, with an exemption for small companies and for Class I products and Class II products sold retail and costing less than \$100. (The original sidecar language delayed implementation until 2013, converted the fee into a 2.9% excise tax and exempted Class I retail sales. The manager's amendment reduced the tax to 2.3% but removed the Class I exemption).
- An annual fee on health insurers of \$2 billion in 2011, \$4 billion in 2012, \$7 billion in 2013, \$9 billion from 2014 through 2016 and \$10 billion thereafter. It exempts small insurers and those non-profit plans meeting a certain medical loss ratio. (The sidecar delayed the fee by 3 years and adjusted the annual amount to maintain budget neutrality, and broadens the exemption for non-profits by excluding some premium revenue from the levy, as well as excluding non-profits that derive at least 80% of their revenue from plans that serve Social Security Act programs targeting the poor, elderly or disabled).

## **XI. Conclusion**

Taken together, these policy changes present a daunting challenge to the federal and state administrators tasked with implementing them, as well as the stakeholders such as anesthesiologists who will need to track, understand, influence, and ultimately abide by them in the coming years. It will be necessary to develop a focused, practical approach to analyzing and managing both the risks and opportunities posed by this new environment.

**Prepared for the American Society of Anesthesiologists  
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