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Secretary Sebelius Announces the Establishment of the HHS Office of Health Reform

The national health care reform movement took another step forward on Monday, May 11, when Kathleen Sebelius, Secretary of Health and Human Services (HHS), announced the establishment of the HHS Office of Health Reform. President Obama previously called for the creation of the HHS Office of Health Reform and established the White House Office of Health Reform (collectively, "Offices") in an Executive Order signed on April 8, 2009. According to the Executive Order, the White House Office of Health Reform is tasked with "establishing policies, priorities, and objectives for the Federal Government's comprehensive effort to improve access to health care, the quality of such care, and the sustainability of the health care system," and the Offices will work together to achieve these goals. Through issuance of the Executive Order, President Obama further delivered on a campaign promise to reduce the cost of health care in the United States and to implement a system of universal health care coverage.

In a statement announcing the creation of the HHS Office of Health Reform, Secretary Sebelius explained that the Offices will collaborate to advance health care reform legislation and develop strategies to cut health care costs, and to ensure that Americans have access to quality, affordable health care. Secretary Sebelius also announced the staff members appointed to the HHS Office of Health Reform. Secretary Sebelius's announcement came on the same day that health industry leaders joined President Obama in announcing that the health care industry will proactively join the administration's efforts to reduce the growth of health care spending (see "Developments in the Health Care Reform Debate").

Developments in the Health Care Reform Debate

This week was a significant week in the ongoing debate over health care reform. It began with major industry stakeholders pledging to reduce costs in the nation's health care system by $2 trillion over the next decade. On the same day, Senate Finance Committee leaders released a set of policy options for expanding health care coverage through reform legislation. Additional momentum was added to the health reform charge on May 13 when House leaders pledged to pass comprehensive health care legislation by July 31.

Industry Stakeholders Offer $2 Trillion in Savings

In a May 11 letter to President Obama, health care industry executives from the American Medical Association, the Advanced Medical Technology Association, America's Health Insurance Plans, the American Hospital Association, Pharmaceutical Research and Manufacturers of America, and the Service Employees International Union pledged to help reduce the annual health care spending growth rate by 1.5 percentage points, saving an estimated $2 trillion over the next decade. As stated in the letter, "[t]he times demand and the nation expects that we, as health care leaders, work with you to reform the health care system."

The industry groups propose to reduce costs by:

- focusing on administrative simplification, standardization, and transparency;
- reducing over-use and under-use of health care by aligning quality and efficiency incentives among providers;
- encouraging coordinated care and adherence to evidence-based best practices that reduce hospitalizations and efficiently manage chronic diseases;
- improving health information technology; and
- implementing regulatory reforms.

This proposal is significant because a wide range of industry representatives with often conflicting interests are speaking as a single group. The move shows that the private sector is eager to appear cooperative as Congress tries to pass major health care legislation by summer.

Many of the groups are seeking to prevent creation of a public health insurance program that would compete with private insurers. The public plan option is one of the most contentious elements of the national health reform debate. Industry representatives, such as America's Health Insurance Plans, have voiced opposition to a new public insurance option, saying rigorous regulation alone could improve the health insurance market. Democrats feel that the public plan option is crucial for covering the approximately 46 million uninsured Americans, and argue that the public plan option would pressure private insurers to control costs and improve quality.

Senate Finance Committee Releases Overview of Policy Options

Also on Monday, the Senate Finance Committee released a set of policy options for expanding health care coverage. The overview includes a number of options for public insurance plans that would compete with private plans, as well as an option without any new public plans.

The overview recommends establishment of a national health insurance exchange portal that would allow customers to compare available health plans. Whether to include a publicly run health insurance plan as part of that exchange portal is the subject of vigorous debate.

The Committee offers three options for a public insurance plan:

1. a government-administered plan that resembles the existing Medicare program and includes government-established rates;
2. a public plan administered by regional third-party administrators under contract with the government; and
3. a state-run plan that allows each state to establish and administer their own public health insurance plans.

The Committee also proposes a fourth option that does not include a public plan and instead relies on private options and improved regulation of the insurance market to make coverage more accessible. Finally, the overview also discusses the option of requiring Americans to buy health insurance. Under such a mandate, individuals who do not purchase health insurance, and who do not meet certain exemption criteria, would pay a tax equal to the premium for the lowest cost health insurance option. In the overview, the Committee does not specifically endorse any of the options.

Whichever option is adopted, the Committee recommends that all insurance plans (except those grandfathered into the system) be required to provide a minimum level of coverage, including emergency care services, maternity and newborn care, prescription drugs, and mental health and substance abuse services. The Committee also advises that insurance companies shouldn't be allowed to deny coverage to individuals due to pre-existing conditions.

While health care industry groups have expressed their willingness to cooperate with Congress in formulating health reform legislation, the debate will likely grow more contentious in the coming weeks as legislators begin to focus on the details of how to expand the nation's health insurance coverage and how to pay for this unprecedented reform.

False Claims Act Amendments Gain Traction in Both the House and Senate

Two bills to amend the False Claims Act (FCA) have gained significant momentum in the past weeks in both the House and the Senate. The Obama Administration as well as members of both parties have expressed support for the bills. Senator Patrick Leahy (D-VT), Chairman of the Senate Judiciary Committee, introduced S. 386, the Fraud Enforcement and Recovery Act of 2009 (the "Leahy Bill"), on February 5, 2009. The Leahy Bill sailed through the Senate on April 28 by a 92-4 vote and then through the House on May 6 by a vote of 367-59. Representative Howard Berman (D-CA) introduced the Leahy Bill's House counterpart, H.R. 1788, the False Claims Correction Act of 2009 (the "Berman Bill"). The Berman Bill passed the House Judiciary Committee on April 28 by a 20-6 vote and has been placed on the calendar for a full vote before the House.

Even once the Berman Bill is brought to vote, the two bills must still be reconciled. The Leahy Bill, if enacted, would substantially expand the scope of liability under the FCA and effectively overturn the Supreme Court's decision in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008). The *Allison Engine* decision had focused on section 3729(a)(2) of the FCA, which, as a general matter, imposes liability on anyone who knowingly makes a false statement to get a claim paid or approved by the government. The Supreme Court had interpreted section 3729(a)(2) to limit liability to those who intended that the false statement be material to the government's decision to pay or approve the claim and those who intended for the government itself to pay the claims. The Leahy Bill would eliminate the basis for the intent requirements that the Supreme Court had outlined in *Allison Engine* and would apply prospectively except for the revised section 3729(a)(2), which would apply retroactively to all claims pending as of June 7, 2008 (the date of the Supreme Court's *Alison Engine* decision).

The Berman Bill contains more sweeping changes to the FCA and would expand its liability provisions. It would, among other things, permit government employees to file qui tam suits, lift much of the public disclosure bar, and extend the statute of limitations. Some experts have contended, though, that despite any actions taken to reconcile the two bills, at least some of the amendments to the liability provisions in the Leahy Bill will become law, marking the first significant amendment to the FCA in 25 years.

Senate Finance Committee Proposes Bundling of Post-Acute Payments

On April 28, 2009, Senate Finance Committee Chairman Max Baucus (D-MT) and Committee ranking minority member Chuck Grassley (R-IA) released several draft policy options for reforming the country's health care delivery system, one of which recommends that Medicare should bundle payments for post-acute care services occurring or initiated within 30 days of a hospital discharge. Under this proposal, Medicare would pay hospitals bundled payments to cover the first hospitalization and 30 days of follow-up care from certain post-acute providers (including home health, skilled nursing facility, rehabilitation hospitals and long-term care hospital services), instead of reimbursing post-acute care providers for follow-up care on a fee-for-service basis.

Current Law

Currently, Medicare pays for most acute care hospital stays and post-acute care services under the prospective payment system (PPS) established for each type of provider. For those Medicare beneficiaries who move from a hospital to any number of post-acute care providers due to complex health conditions or multiple co-morbidities, Medicare makes separate payments to each provider for the covered service across the entire continuum of care.

The MedPAC Report

According to a June 2008 Medicare Payment Advisory Commission (MedPAC) report, the current payment system fosters unnecessary and preventable hospital readmissions because it does not give hospital and post-acute care providers the necessary financial incentive to coordinate care with one another, which in turn leads to unnecessary and sometimes preventable hospital readmissions. The report also found that 18% of Medicare hospital admissions result in readmissions within 30 days post-discharge, at a cost of $15 billion, $12 billion of which represent potentially preventable readmissions.

The Proposed Bundling Policy

In light of MedPAC's finding, the Committee proposed that, starting in fiscal year (FY) 2015, acute inpatient PPS hospital services and post-acute care services occurring or initiated within 30 days of discharge from a hospital be paid through a bundled payment. These bundled payments would be implemented in three phases: starting first in FY 2015, then in FY 2017, and finally in 2019, the bundling policy would apply to admissions for conditions that account for the top 20%, 30% and remaining 50% of post-acute spending, respectively.

Under the proposal, the hospital would receive the bundled payment for each patient served, regardless of whether the patient receives post-acute care services, but the Centers for Medicare & Medicaid Services (CMS) could permit post-acute care providers and other entities to receive bundled payments if the hospital is involved. No additional payments would be made to the hospital for readmissions, and Medicare would no longer make separate payments to post-acute providers for care initiated during the 30 day post-discharge period. CMS would be required to conduct on-going monitoring to ensure against unintended consequences, and after three years, evaluate the program and report its findings to Congress.

According to the Committee's budget outline, this proposal would likely lead to fewer readmissions, saving the government approximately $26 billion over 10 years.

Health Information Technology Policy and Standards Committee Members Named

HHS has announced the members of the Health Information Technology ("HIT") Policy Committee and the HIT Standards Committee, both of which were established by the American Recovery and Reinvestment Act of 2009 ("ARRA"). In addition to the 13 members of the HIT Policy Committee previously announced by the U.S. Government Accountability Office Comptroller General, the Senate and House majority and minority leaders each appointed a member, the Secretary of HHS appointed three, and the President may appoint additional members to represent federal agencies before June 2009. The membership of each committee is listed below.

Pursuant to the ARRA, the HIT Policy Committee will make recommendations to David Blumenthal, the National Coordinator of HHS' Office of the National Coordinator for Health Information Technology (ONCHIT), on issues related to the implementation of a national health

information technology infrastructure that permits the electronic exchange and use of health information. The HIT Standards Committee will advise the National Coordinator on the standards, implementation specifications, and certification criteria for such electronic exchange and use of health information. In addition, within 90 days of the signing of the ARRA, the HIT Standards Committee must develop a schedule for the assessment of policy recommendations developed by the HIT Policy Committee.

The HIT Policy Committee held its first meeting on May 11, 2009, and the HIT Standards Committee will hold its first meeting on May 15, 2009. The public is invited to attend and comment after the conclusion of these meetings. More information about the committees and their scheduled meetings is available on the ONCHIT website.

The members of the HIT Policy Committee are as follows:

3 members appointed by HHS Secretary Kathleen Sebelius

Chair
1. David Blumenthal, M.D., HHS/Office of the National Coordinator for Health Information Technology

Members
2. Michael Klag, M.D., Dean of the Johns Hopkins Bloomberg School of Public Health
3. Deven McGraw, Director at the Health Privacy Project at the Center for Democracy and Technology

4 members appointed by the Senate and House majority and minority leaders

House Speaker Nancy Pelosi (D-Calif.)
1. Paul Egerman, Chair and CEO, eScription Inc.

House Minority Leader John Boehner (R-Ohio)
2. Gayle Harrell of Stuart, Florida, a former member of the Florida House of Representatives

Senate Majority Leader Harry Reid (D-Nev.)
3. Frank Nemec, M.D., Gastroenterology Associates

Senate Majority Leader Mitch McConnell (R-Ky.)
4. Richard Chapman, Kindred Healthcare

13 members the GAO Comptroller General appointed across 10 different categories

Advocates for Patients or Consumers
1. Christine Bechtel, Washington, D.C. (3-year term) – Vice President, National Partnership for Women & Families

2. Arthur Davidson, M.D., Denver, Colorado (2-year term) – Denver Public Health Department; Director, Public Health Informatics; Director, Denver Center for Public Health Preparedness; medical epidemiologist; Director, HIV/AIDS Surveillance, City and County of Denver

3. Adam Clark, Ph.D., Austin, Texas (1-year term) – Director of Research and Policy, Lance Armstrong Foundation

Representatives of Health Care Providers, including one physician

4. Marc Probst, Salt Lake City, Utah (3-year term) – Chief Information Officer, Intermountain Healthcare

5. Paul Tang, M.D., Mountain View, California (2-year term) – Vice President and Chief Medical Information Officer, Palo Alto Medical Foundation

Labor Organization Representing Health Care Workers

6. Scott White, New York City, New York (1-year term) – Assistant Director, Technology Project Director, 1199 SEIU Training and Employment Fund

Expert in Health Information Privacy & Security

7. LaTanya Sweeney, Ph.D., Pittsburgh, Pennsylvania (3-year term) – Director, Data Privacy Lab, Associate Professor of Computer Science, Technology and Policy, Carnegie Mellon University

Expert in Improving the Health of Vulnerable Populations

8. Neil Calman, M.D., New York, New York (2-year term) – President and CEO, The Institute for Family Health, Inc.

Research Community

9. Connie Delaney, R.N., Ph.D., Minneapolis, Minnesota (1-year term) – Dean, School of Nursing, University of Minnesota

Representative of Health Plans or Other Third-Party Payers

10. Charles Kennedy, M.D., Camarillo, California (3-year term) – Vice President, Health Information Technology, Wellpoint, Inc.

Representative of Information Technology Vendors

11. Judith Faulkner, Verona, Wisconsin (2-year term) – Founder, CEO, President, and Chairman of the Board, Epic Systems Corporation

Representative of Purchasers or Employers

12. David Lansky, Ph.D., San Francisco, California (1-year term) – President and CEO, Pacific Business Group on Health

Expert in Health Care Quality Measurement and Reporting

13. David Bates, M.D., Boston, Massachusetts (3-year term) – Medical Director for Clinical and

Quality Analysis, Chief of General Internal Medicine, Partners HealthCare/Brigham & Women's Hospital

The members of the HIT Standards Committee are as follows:

Chair

1. Jonathan Perlin, Hospital Corporation of America

Vice Chair

2. John Halamka, Harvard Medical School

Members

3. Dixie Baker, Science Applications International Corporation

4. Anne Castro, BlueCross BlueShield of South Carolina

5. Christopher Chute, Mayo Clinic College of Medicine

6. Janet Corrigan, National Quality Forum

7. John Derr, Golden Living, LLC

8. Linda Dillman, Wal-Mart Stores, Inc.

9. James Ferguson, Kaiser Permanente

10. Steven Findlay, Consumers Union

11. Douglas Fridsma, Arizona State University

12. C. Martin Harris, Cleveland Clinic Foundation

13. Stanley M. Huff, Intermountain Healthcare

14. Kevin Hutchinson, Prematics, Inc.

15. Elizabeth O. Johnson, Tenet Healthcare Corporation

16. John Klimek, National Council for Prescription Drug Programs

17. David McCallie, Jr., Cerner Corporation

18. Judy Murphy, Aurora Health Care

19. J. Marc Overhage, Regenstrief Institute

20. Gina Perez, Delaware Health Information Network

21. Wes Rishel, Gartner, Inc.

22. Sharon Terry, Genetic Alliance

23. James Walker, Geisinger Health System

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