



Report of the Director of Government Relations

Keith Studdard, March 2010

Health Care Reform Overview

Please see attached enclosed side by side outline of the major provisions at stake in the current Congressional debate on health care reform. As you are well aware, the current debate on health care reform has hit a snag since Congress returned to DC in January. While President Obama continues to address health care reform as a “must do” item, both the White House and Congress have also begun talking about other issues such as a jobs bill, immigration, climate legislation, and tax issues that must be addressed in 2010. We should be privy to a more clearer picture of how things will move forward after President Obama’s Health Care Summit with Congressional leaders on February 25th.

Medicare Physician Payment

On December 19, 2009, the United States Senate approved the “2010 Department of Defense Appropriations Act” (H.R. 3326) by a vote of 88-10. The Senate defeated a motion to table H.R. 3326 by a vote of 63-35 and then defeated a budget point of order against the bill 63-35 clearing the way for final passage. The House approved the legislation on December 17. President Obama signed the bill into law later on the 19th. H.R. 3326 includes a 2-month extension of current Medicare physician payment policy, preventing implementation of the 21.2% cut in Medicare physician payments until March 1, 2010. Physician payments under Medicare for the period of January 1, 2010 until February 28, 2010 remain at 2009 levels – except for those payments either increased or decreased as part of the 2010 Medicare Physician Fee Schedule Final Rule, which took effect on January 1, 2010.

President Obama Release FY 2011 Budget Proposal

On Monday February 1, President Barack Obama released the Administration’s proposed 2011 budget, totaling \$3.83 trillion. The President’s spending plan anticipates \$5.08 trillion in deficits over the next five years. Based on projections from the Office of Management and Budget, a sustainable budget could not be achieved before 2014-2015. Even then, tackling long-term spending on entitlement programs such as Social Security and Medicare will be necessary to curtail future deficit increases.

The Budget institutes a three-year non-security discretionary freeze that will save \$250 billion over the next decade. The administration aims to cap spending through cuts to or elimination of programs that are ineffective, duplicative, or wasteful and has identified over 120 government programs that they believe should be terminated or reduced. The freeze is expected to generate \$20 billion in savings.

President Obama’s budget seeks to reduce the deficit primarily through four strategies:

- 1) **Impose Pay-go.** Statutory “pay-go” legislation supported by the President and recently passed in the House and Senate requires all spending increases to be offset by equivalent reductions in other areas.
- 2) **Increase tax revenues and decrease subsidies.**
 - a. Allow for an expiration of the 2001 and 2003 tax cuts enacted under President George W. Bush.
 - b. End subsidies for certain energy-related industries.
 - c. “Responsibility fee” on large banks.
- 3) **Create a bipartisan fiscal commission.** Establish a bipartisan, fiscal commission to examine cost-cutting proposals and put forward a bipartisan recommendation to balance the budget excluding interest payments on the debt by 2015.
- 4) **Enact health care reform.** Enact health care reform legislation that would reduce the federal deficit.

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With respect to health care, the budget assumes passage of health care reform in its calculations despite the current gridlock in Congress, projecting \$150 billion in savings over 10 years. The proposal includes an extra \$25 billion in Medicaid funding for states and a six-month extension of the Medicaid funding increase that was part of last year's stimulus bill. Many states had planned on receiving extra Medicaid funding from the comprehensive health care reform bill. Funding for the Department of Health and Human Services will increase "in the range of inflation or less," but NIH funding would grow by about \$1 billion, or 3%. Community health centers would also see an increase of \$290 billion. The majority of the \$900 billion allocated for health care will be dedicated to the Medicare and Medicaid programs.

Physicians are scheduled to take a 21% reduction in reimbursements for treating Medicare patients starting March 1, unless Congress votes to stall the cuts. The president's budget assumes no payment update over the next decade, which means Congress would either have to continue its annual tradition of voting to push the cuts down the road, or it would have to pass a permanent SGR fix. The budget estimates that it will cost \$371 billion over the next decade to wipe clean the debt that has accumulated from not enacting the physician payment cuts.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Department of Health and Human Services (HHS) is the principal Federal agency charged with protecting the health of all Americans and providing essential human services. This Budget includes \$81.3 billion to support HHS' mission.

FY2011 Request: \$81.3 billion

FY2010 Enacted: \$79.6 billion*

* Excludes the \$2.4 billion transfer of the Bioshield Special Reserve Fund balances from the Department of Homeland Security to HHS.

Support Health Insurance Reform

- \$110 million for continuing efforts to strengthen health IT policy, coordination, and research activities.
- \$286 million for research that compares the effectiveness of different medical options, building on the expansion of this research begun under Recovery Act.
- \$2.5 billion for health centers to provide affordable high quality primary and preventive care to underserved populations, including the uninsured. This will allow health centers to continue to provide care to the 2 million additional patients they served under Recovery Act and support approximately 25 new health center sites. In 2008, health centers provided direct health care services to 17 million people.
- New Medicare demonstration projects that evaluate reforms to provide higher quality care at lower costs, improve beneficiary education and understanding of benefits offered, and better align provider payments with costs and outcomes.

Protect Access to Health Care for Low-Income Americans

- \$25.5 billion for additional Federal Medicaid assistance to help states maintain their Medicaid programs and ensure access to health care for millions of Americans.

Support Biomedical Research at the National Institutes of Health (NIH)

- \$32.1 billion for the National Institutes of Health, including more than \$6 billion for cancer research to:
 - Initiate 30 new drug trials in 2011, and double the number of novel compounds in Phase 1 – 3 clinical trials by 2016; and

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- Support the completion of a comprehensive catalog of cancer mutations for the 20 most common malignancies, setting the stage for complete genomic characterization of every cancer as part of medical care within 10 years.

Increase Number of Primary Health Care Providers

- \$169 million in the National Health Service Corps (NHSC) to place providers in medically underserved areas to improve access to needed health care services. Under the NHSC, primary health professionals such as physicians, nurse practitioners, and dentists serve in a medically underserved community in exchange for having a portion of their student loans paid off.
- Add 400 NHSC clinicians to the more than 8,100 who will provide essential primary and preventative care services in health care facilities across the country.
- The president requests approximately \$509 million for the Title VII and Title VIII health professions programs, an \$11 million (2.2 percent) increase over FY 2010 enacted levels.

Improve the Access to, and Quality of, Health Care in Rural Areas

- \$79 million for an initiative to strengthen regional and local partnerships among rural health care providers, increase the number of health care providers in rural areas, and improve the performance and financial stability of rural hospitals.

Expand and Strengthen Prevention and Wellness Activities

- Bolsters core prevention activities by expanding community health activities, strengthening the public health workforce, and enhancing surveillance and health statistics to improve detection and monitoring of chronic disease and health outcomes.
- \$20 million to fund a new effort in up to 10 of the largest U.S. cities to reduce the rates of morbidity and disability due to chronic disease.
- \$10 million to improve workforce capacity of state and local health departments.
- \$10 million for the federal employee workplace wellness initiative. This initiative will implement prototype wellness programs in select locations that will be rigorously evaluated for their ability to produce a healthier workforce and lower health care costs.

Electronic Health Record Incentive Program

The Centers for Medicare and Medicaid Services released its proposed rule on the Electronic Health Record Incentive Program, which would implement provisions of the American Recovery and Reinvestment Act of 2009. These provisions are known as the HITECH Act. (The Office of the National Coordinator (ONC) released its interim final rule on Standards and Certification Criteria. A separate memo will cover that rule. Both rules will be in the Jan.13 Federal Register. The deadline for comments on both rules is March 15.)

The purpose of the EHR program is to provide incentive payments to eligible professionals (i.e., physicians) and hospitals, participating in Medicare and Medicaid, that adopt and meaningfully use certified electronic health record (EHR) technology. The goals are to: 1) Improve quality, safety, and efficiency; 2) engage patients and their families; 3) improve care coordination; 4) improve population and public health; and 5) ensure privacy and security protections. While the proposed rule covers physicians and hospitals, this memo will focus on the criteria for physicians.

Participation in the incentive program is voluntary. Physicians could qualify for incentive payments through Medicare Fee-For-Service, Medicare Advantage, or Medicaid. Physicians could participate in the incentive program either through Medicare or Medicaid, but not both. In addition, under the proposed rule hospital-based physicians could not participate in the incentive program.

Based on public and stakeholder input, CMS proposes a phased approach with three stages. The initial meaningful use criteria are Stage 1, which is detailed in this proposed rule. Stage 2 criteria will be proposed by the end of 2011 and the Stage 3 proposal will come out by the end of 2013. This proposed rule specifies the eligibility requirements; criteria for Stage One; reporting methodology and timeframes; payment periods; payment calculations/procedures for Medicare

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and Medicaid; Medicare penalties for failing to use meaningful use certified EHRs; and Medicaid agencies' implementation of incentives.

Stage 1 meaningful use criteria focuses on electronically capturing health information in a coded format; using that information to track key clinical conditions and communicating that information for care coordination purposes; implementing clinical decision support tools to facilitate disease and medication management; and reporting clinical quality measures and public health information.

Included in Stage 1 are 25 objectives and measures for eligible physicians. Of the 25 objectives, 17 require attestation and 8 require data submission. Included in the objectives are electronic prescriptions; quality measure reporting; implementation of five clinical decision support rules relevant to specialty or high clinical priority; and providing patients access to electronic health information, as well as electronic copies of health information and summaries for each office visit.

While the incentive program for Medicare FFS, Medicare Advantage, and Medicaid contain many common elements, State Medicaid agencies may propose an alternate definition of meaningful use for Medicaid incentives, provided that: 1) states cannot propose fewer or less rigorous criteria; 2) states cannot propose an alternative that would require additional functionality beyond that of certified EHR technology; and 3) CMS must approve Medicaid agencies' proposed definitions.

The first payment year begins in 2011 (the only exception is in certain cases Medicaid Eligible Professionals (EP) would be able to participate in the Medicaid EHR incentive program with CY 2010 for adopting, implementing, or upgrading certified EHR.) For the first year of participation, physicians would have to demonstrate meaningful use over any continuous 90-day period in the calendar year; for subsequent years, the physician would have to demonstrate meaningful use over the entire year.

While the first payment year begins in 2011, a physician practice does not have to start participating in that year. Physicians could start as late as 2014, however they would receive less of an incentive payment. Under Medicare FFS, physicians who are meaningful EHR users during the relevant EHR reporting period would be entitled to an incentive payment amount, subject to an annual limit, equal to 75 percent of the Secretary's estimate of the Medicare allowed charges for covered professional services furnished by the physician during the relevant payment year. A physician would be entitled to an incentive payment for up to 5 years, but there shall be no incentive payments made with respect to a year after 2016. Physicians who begin participation in 2011 or 2012 could receive as much as \$18,000 in incentive payments for that first year. (For those who practice in a Health Professional Shortage Area (HPSA), the incentive payment for each year would be increased by 10 percent.)

Maximum Payment

Adoption Year	2011	2012	2013	2014	2015	2016	Total	Penalty*
2011	\$18,000	\$12,000	\$8,000	\$4,000	\$2,000	\$0	\$44,000	
2012		\$18,000	\$12,000	\$8,000	\$4,000	\$2,000	\$44,000	
2013			\$15,000	\$12,000	\$8,000	\$4,000	\$39,000	
2014				\$12,000	\$8,000	\$4,000	\$24,000	
2015							\$0	1%
2016							\$0	2%
2017							\$0	3%

*Starting in 2015 and in subsequent years, for physicians who are not meaningful EHR users, fee schedule payments will be reduced by 1 percent in 2015, 2 percent in 2016, and 3 percent in 2017.

Similar incentive payment limitations apply to Medicare Advantage. In addition, the Medicare FFS incentive payment program does not include payment for professional services provided to MA enrollees, but only for services paid under Part B. Similarly CMS proposes to limit payment to an MA organization to only payment for their physicians' services

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to MA enrollees of plans offered by the MA organization. Any services reimbursed under Part B would not be included in the calculation of the incentive payment under Medicare Advantage.

Payment incentives differ under Medicaid. Physicians could receive a total of \$63,750 over the extent of the incentive program with \$21,250 in the first year and \$8,500 for each of the subsequent five years. To be eligible under the Medicaid incentive program, physicians would need a minimum of 30 percent of all patient encounters attributable to Medicaid over any continuous 90-day period within the most recent calendar year prior to reporting. The two exceptions are: 1) a pediatrician may have at least 20 percent Medicaid patient volume; and 2) physicians practicing predominantly in an FQHC or RHC would need a minimum of 30 percent patient volume attributable to “needy individuals.” Medicaid physicians would be required to annually re-attest to patient volume thresholds to continue to qualify for incentive payments. Under Medicaid, physicians could participate in the incentive program for up to six years. Physicians could begin receiving payments as late as 2016, and still receive up to the maximum payments under the program.

In addition, CMS proposes for a Medicaid physician who has already adopted, implemented, or upgraded certified EHR technology and can meaningfully use this technology in the first incentive payment year, that physician would be permitted to receive the same maximum payments, for the same period of time, as the Medicaid physician who “merely adopted, implemented, or upgraded certified EHR technology in the first year.” State Medicaid agencies are responsible for administering and disbursing incentive payments.

Physicians cannot participate in both the Medicare and Medicaid incentive programs, however they would have an opportunity to switch from one program to the other one time prior to 2015.

Based on preliminary analysis of the proposed rule, there are areas of concern. The Medical Group Management Association (MGMA) referred to overly burdensome requirements including the thresholds for some of the meaningful use criteria; potentially difficult meaningful use attestation after the first year; and the requirement that physician offices provide patients and others with electronic copies of medical records.

In addition, given the proposed requirements, solo practitioners and small group practices may find it difficult to participate. The incentive payments may not be enough of an incentive to get physicians to participate. Almost 30 percent of physicians would not be considered eligible for the program. Some measures would require additional paperwork and add to the administrative burden.

CMS solicits comments on the entire proposed rule and requests specific recommendations.

Health Information Technology Certification

The American Recovery and Reinvestment Act (ARRA) which was signed into law on February 17, 2009 creates two key concepts to determine whether eligible professionals qualify for HIT incentive payments - they must make “meaningful use” of HIT and in addition use a qualified or certified electronic health record. The portion of ARRA that addresses HIT, the HITECH Act, requires that HHS specify through an interim final rule an initial set of certification criteria, standards, and implementation specifications.

Two rules on certification criteria and meaningful use have been released by ONC (Office of the National Coordinator for HIT) and CMS (Centers for Medicare and Medicaid Services) respectively and were published in the Federal Register on January 13. The ONC interim final rule on certification criteria becomes effective on February 12. Both rules have a sixty day comment period with comments due March 15. It is important to note that these rules are closely linked and that CMS and ONC collaborated in developing these rules. The CMS rule addresses meaningful use requirements for receiving incentive payments under Medicare and Medicaid, and the ONC rule sets forth the standards for certified EHR technology. ONC seeks comments on the rule and requests specific recommendations. The complete rule can be accessed at: http://www.access.gpo.gov/su_docs/fedreg/a100113c.html

Certification criteria specified in the interim final rule establish capabilities and standards that certified electronic health record (EHR) technology must have to achieve proposed Stage 1 meaningful use requirements which begin January 1, 2011. Proposed stage 1 meaningful use criteria focus on: electronically capturing health information in a coded format, tracking of key clinical conditions, using information for care coordination, implementing clinical decision support tools, and reporting of quality measures and public health information. CMS has outlined proposed goals for Stage 2

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(2013) and Stage 3 (2015) and forthcoming regulations will address in greater detail the requirements to achieve meaningful use for Stages 2 and 3.

Criteria

Adopted certification criteria for certified EHR technology that support achieving Stage 1 meaningful use objectives include:

- **Computerized Provider Order Entry (CPOE)** - Required for medications, laboratory, radiology/ imaging, and provider referrals.
- **Clinical Decision Support** - Implement automated electronic clinical decision support rules according to specialty or clinical priorities that use demographic data, patient diagnoses, conditions, test result and/or medications list. Generate at the point of care real-time alerts, drug-drug, drug-allergy, and drug formulary checks.
- **Patient Information** - Ability to generate and provide reminders, clinical summaries, problem list, and lab results. Ability to store, retrieve, receive, and manage medications and lab results.
- **E-Prescribing** – Ability to generate and transmit prescriptions electronically.
- **Insurance Information** – Ability to check insurance eligibility and submit claims electronically.
- **Quality and Public Health Reporting** – Ability to generate list of patients by specific conditions for quality improvement purposes and also be able to report quality measures as specified by CMS and/or the States. Certified E HR technology must be capable of using the CMS PQRI 2008 Registry XML Specification. Ability to record, retrieve, and transmit information to immunization registries and public health agencies.

Standards

The adopted standards that must be met by certified E HR technology to exchange health care information to meet Stage 1 meaningful use objectives are organized into four categories as recommended by the HIT Standards Committee:

- **Vocabulary Standards** - Standards that describe clinical problems and procedures, medications, and allergies. Vocabulary standards are applicable to: problem list, medication list, procedures, lab orders and results, and electronic prescribing.
- **Content Exchange Standards** – Standards that are used to share clinical information such as clinical summaries and prescriptions. Content exchange standards are applicable to: patient summary record, drug formulary check, electronic prescribing, administrative transactions, and quality and public health reporting.
- **Privacy and Security Standards** - Standards for authentication, transmission, security and encryption of information. Privacy and security standards are applicable to: encryption, decryption, authentication, and disclosure. The rule notes that the HIPAA Security Rule is the starting point for establishing capabilities for certified E HR Technology and does not change existing HIPAA Privacy or Security Rule requirements.
- **Transport Standards** - Standards used to establish secure communication between electronic systems. Transport standards adopted are: Simple Object Access Protocol (SOAP version 1.2) and Representational State Transfer (REST).

Implementation Specifications

With regard to implementation specifications, the rule notes that there are few implementation specifications currently ready to be adopted to support Stage 1 meaningful use objectives. ONC seeks comments on this and plans to seek input from the HIT industry and relevant federal advisory committees to obtain further information regarding implementation specifications for Stage 2 meaningful use Stage 2.

However, one implementation example important to note is in the area of quality reporting. As noted above, certified E HR technology must be capable of using the CMS PQRI 2008 Registry Specification. The adopted implementation specification for quality reporting is the Physician Quality Reporting Initiative Measure Specification Manual for Claims and Registry.

Definitions

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The interim final rule provides key terms definitions:

- **Standard** - A technical, functional, or performance-based rule, condition, or requirement, or specification that stipulates instructions, fields, codes, data, material, characteristics, or actions.
- **Certification Criteria** – Criteria that meet applicable standards and implementation specifications adopted by the Secretary or criteria used to test and certify and HIT includes required capabilities.
- **Implementation Specification** – Specific requirements or instructions for implementing a standard.
- **Disclosure** – The release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding information. **Note:** With regard to disclosures, adopted standards specify that the date, time, patient identification, user identification, and a description of the disclosure must be recorded.
- **Qualified E HR** - A qualified E HR is an electronic record of health related information on an individual which: includes patient demographic and clinical health information (medical history, problem lists, etc.), has the ability to provide clinical decision support, support physician order entry, capture and query information relevant to health care quality, and ability to exchange and integrate electronic health information from other sources.
- **Complete E HR** – A complete E HR is one that has been developed to have all capabilities meeting all applicable certification criteria adopted by the HHS Secretary.
- **E HR Module** – Any service, component, or combination that can meet at least one certification criterion. Example of modules include: Interface or other software program that provides capability to exchange information electronically, clinical decision support rules engine, or a quality measure reporting service or software program. **Note:** If E HR modules are used, it is the responsibility of the clinician to ensure such modules work together to support meaningful use.
- **Certified E HR Technology**– Is a complete E HR or combination of certified E HR modules that meets the requirements of a qualified E HR and is tested and certified in accordance with the certification program established by ONC as having met all applicable certification criteria. Certified HER technology must present information in a human readable format.

Costs

This rule estimates costs vendors, developers, and federal agencies will incur to prepare Complete E HRs and E HR modules to be tested and certified to adopted standards, certification criteria, and implementation specifications. The rule estimates that to prepare a Complete E HR or E HR Module for testing and certification the cost per certification criterion will range between \$10,000 and \$250,000.

This rule does not provide costs that eligible professionals and hospitals will incur to implement certified E HR technology. Those costs are outlined in the CMS proposed rule on meaningful use.

HHS Regulatory Actions

In developing this rule, ONC has noted it has considered other HHS regulatory actions – two areas noted in the rule are HIPAA and electronic prescribing. ONC states that it has worked to ensure that these standards are consistent with previously adopted HIPAA and electronic prescribing standards.

It was noted previously that an additional rule will be issued that outlines the certification process. This rule has not been released yet but it is anticipated that it will be released shortly.