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Life Sciences Health Industry Alert

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# Health Information Privacy and Incentives, Medicaid Funding, and Other Health Care Provisions in the American Recovery and Reinvestment Act

## *I. Introduction*

On Feb. 17, 2009, President Obama signed into law H.R. 1, the American Recovery and Reinvestment Act (the "ARRA").[1] The sweeping $790 billion economic stimulus package includes a number of health care policy provisions, including, among many other things:

- $19 billion in funding to accelerate the adoption of health information technology systems, including through Medicare incentive payments to physicians and hospitals
- Strengthened federal privacy and security provisions to protect personally-identifiable health information, including notification requirements for health data security breaches
- Approximately $87 billion in additional federal matching funds over two years to help states maintain their Medicaid programs in the face of state budget shortfalls
- $1.1 billion to support comparative effectiveness research
- Provisions blocking a number of Bush Administration Medicare and Medicaid regulatory policies
- Provisions to help unemployed workers maintain health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA") law
- Whistleblower protections against reprisals for employees of state and local governments or private contractors who disclose gross mismanagement, waste, or violations of law related to contracts or grants using ARRA funds, which presumably extends to health care funding

The following memorandum summarizes the major health policy provisions of the Act. We would be pleased to provide additional information about any of these policies upon request.

## *II. Health Information Technology—Infrastructure and Incentives*

### A. Health IT Infrastructure

The ARRA puts in place a framework to develop policies and standards to create a national health information technology infrastructure. A primary and overarching goal to achieve this end is enterprise integration, or the electronic linkage of health care providers, health plans, the government, and other interested parties. The framework includes an Office of the National Coordinator for Health Information Technology (the "ONC") and two supporting committees—a HIT Policy Committee and a HIT Standards Committee (collectively, "the Committees"). ARRA further provides for direction with respect to the adoption and use of HIT and funding for studies, reports, grants, loan programs, and a demonstration project.

#### 1. Office of the National Coordinator for Health Information Technology

The ONC is to be appointed by the Secretary of Health & Human Services ("the Secretary" or "HHS"). The National Coordinator will be primarily responsible for developing an HIT strategic plan and coordinating and collaborating with others, including federal agencies and public entities, to implement it. As such, the National Coordinator will review standards and coordinate policies recommended by the HIT Policy and Standards Committees, and will act as a liaison between the two. One of its primary responsibilities is to maintain and update the Health IT Strategic Plan, which was developed by the previous ONC.

Objectives, milestones, and metrics to be included in the Strategic Plan are specific and encompass a broad scope. The objectives include maintaining and updating a website and developing and

publishing a comprehensive estimate of the resources required annually to meet the goal of having an electronic health record for each person in the United States by 2014.

**2. Health Information Technology Policy Committee**

The HIT Policy Committee is at the heart of the administrative framework and is charged with developing policies to achieve the goals of the program. The Committee is directed to consider various issues in developing these recommendations, including the use of technology to protect privacy of health records, ensuring the accuracy of health information exchanged, ensuring the development of a certified health record for each person in the United States by 2014, improving the quality of health care for all, assuring the ability to collect and control demographic information, and protecting vulnerable populations, such as children. This Committee is to serve as "a forum for broad stakeholder input with specific expertise in policies" relating to its duties. Membership in the Committee will be by appointment, and appointment authority is allocated to different executive and legislative bodies. In addition to representatives of federal agencies, the panel will include representatives of consumers, health care providers, labor organizations, health information privacy and security experts, and information technology vendors, among others.

**3. The Health Information Technology Standards Committee**

The HIT Standards Committee is to recommend to the National Coordinator standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. As such, this Committee is to develop and test standards and specifications that can be harmonized to allow for consistent implementation, and may provide for pilot testing of such standards. The Committee must develop a schedule for the assessment of policy recommendations developed by the HIT Policy Committee not later than 90 days after the enactment of ARRA.

With respect to membership on the HIT Standards Committee, ARRA designates that the National Coordinator shall provide leadership in establishing and operating the Committee, and that the members "shall at least reflect providers, ancillary healthcare workers, consumer, purchaser, health plans, technology vendors, researchers, relevant federal agencies, and individuals with technical expertise on health care quality, privacy and security and the electronic exchange and use of health information." The Committee is to conduct open public meetings and develop a process to allow for public comment on its scheduled undertakings.

**4. Adoption and Use of Endorsed HIT Recommendations**

The ARRA establishes an aggressive schedule for the National Coordinator and the corresponding HIT Committees to move from development to implementation of this program. After the National Coordinator has considered and recommended standards, implementation specifications, and certification criteria for adoption, the Secretary must, no later than 90 days after receiving them, consult with representatives of other federal agencies and determine whether or not to propose their adoption. If the Secretary determines that the standards should be proposed, it is to do so by regulation; if deciding not to propose adoption, the National Coordinator and HIT Standards Committee must be notified in writing. All determinations made must be published in the Federal Register. The deadline for adopting the initial set of HIT Policy Committee standards, implementation specifications, or certification criteria is not later than Dec. 31, 2009.

Once the standards are formalized, the National Coordinator is directed to ensure that qualified electronic health records ("EHR") technology is made publicly available to providers, unless the Secretary and the HIT Policy Committee determine that the needs and demands of providers "are substantially and adequately met through the marketplace." If the technology is made publicly available, the National Coordinator must ensure that the technology is properly certified. All determinations made with respect to recommended standards, implementation specifications and certification criteria must be published in the *Federal Register*. The National Coordinator is authorized to charge a nominal fee for the adoption of a health information technology system it has developed or approved.

For federal agencies, the use of standards and implementation specifications and certification criteria adopted through ONC is, if it is available, required when the agency implements, acquires or upgrades health information technology systems. Private entities that contract with federal government agencies will be required, where available, to utilize health information technology systems and products that meet standards and implementation specifications that are adopted. Otherwise, participation of private entities is voluntary.

**5. Studies and Reports on the Application and Use of HIT**

The ARRA provides funding for research and development programs to further develop technology, and requires several follow-up studies and reports on the progress that is being made toward the adoption and maintenance of health information technology. An annual report that describes actions taken and barriers to adopting HIT is to be published annually beginning in February 2011. Another study and report is to focus on methods to create efficient reimbursement incentives for improving health care quality in federally qualified health centers, rural health clinics, and free clinics. A report on this study is to be issued not later than two years after the enactment of the ARRA, or February 2011. A third study is to examine matters relating to the potential use of new aging services technology to assist seniors, individuals with disabilities, and their caregivers throughout the aging process. A report on this study is to be issued not later than 24 months after the enactment of the ARRA.

**6. Grants, Loans and Demonstration Programs**

The Secretary is directed to "invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States with the goals outlined in the strategic plan developed by the National Coordinator." Funds are to be invested through various agencies, based on an agency's area of expertise. Some areas of focus for investment include developing technology to support the secure exchange and use of health information on a national scale, providing training and disseminating information on best practices to integrate HIT into the delivery of medical care, and improving and expanding the use of HIT by public health departments. Funding will be available for awards for Health Information Technology Extension Centers, grants to states to promote the adoption of HIT, and a demonstration program to integrate information technology into the clinical education of health professionals.

**7. Health Information Technology Research Centers**

The Secretary, acting through the Office of the National Coordinator, is directed to establish a Health Information Technology Extension Program to provide health information technology assistance services. To this end, a national Health Information Technology Research Center will be established to provide technical assistance and to develop or recognize best practices to support and accelerate the adoption, implementation and effective utilization of health information technology. Financial assistance also will be available for the creation and support of Health Information Technology Regional Extension Centers. These regional centers will be affiliated with United States-based nonprofit organizations that apply and are awarded financial assistance. Regional centers are to be designed to provide assistance and education to all providers in a region, but are to particularly focus on public or not-for-profit hospitals or critical access hospitals ("CAHs"); federally qualified health centers; entities that are located in rural and other areas that serve uninsured, underinsured and medically underserved individuals; and individual or small group practices that are primarily focused on providing primary health care. A draft description of this program is to be published in the *Federal Register* not later than 90 days after the enactment of ARRA.

**8. State Grants to Promote Health Information Technology**

Planning and/or implementation grants may be available to a state or a qualified state-designated entity to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards. This program involves a required match that begins in fiscal year ("FY") 2011 at $1 for each $10 of federal funds provided, and moves to not less than $1 for each of $3 of federal funds provided in 2013. For years funded prior to FY 2011, the Secretary is authorized determine whether a non-federal matching contribution would be appropriate.

The National Coordinator is further authorized to award competitive grants to eligible states or Indian tribes that want to provide loans to health care providers to (i) facilitate the purchase of EHR technology; (ii) enhance the utilization of certified EHR technology; (iii) train personnel in the use of such technology; or (iv) improve the secure electronic exchange of health information. The program imposes restrictions on loan terms and requires that applicants meet certain conditions. This program involves a match requirement of not less than $1 for each $5 of federal funds provided.

**9. Grants to Integrate HIT into Medical Education**

The ARRA funds a demonstration program for academic medical center projects that "develop academic curricula integrating certified EHR technology in the clinical education of health professionals." These awards are to be made on a competitive basis and pursuant to peer review. To be eligible to receive a demonstration grant, an entity must submit an application as designated by

the Secretary, submit a strategic plan for integrating certified EHR technology in the clinical education of health professionals, provide for collecting data regarding the effectiveness of the demonstration project, and agree to provide 50 percent of the costs (absent a waiver of this requirement because of national economic conditions). The Secretary is required to submit a report to Congress on these projects within one year of the enactment of the ARRA. Awards to institutions of higher education to establish or expand medical health informatics education programs will also be available in the form of a matching program.

### B. Health IT Incentives

The ARRA provides for temporary monetary incentive payments under the Medicare and Medicaid programs for eligible professionals and hospitals that adopt and become "meaningful users" of certified electronic health record technology. It also provides penalties in the form of payment reductions for professionals and hospitals that do not timely become meaningful users. Certified EHR technology refers to a qualified electronic health record that is certified pursuant to the standards set forth in the ARRA HIT provisions, discussed above.

#### 1. Medicare Incentives for Professionals

Under the ARRA, "eligible professionals" who are meaningful users of EHR when providing covered professional services will be entitled to enhanced Medicare payments. The term "eligible professional" includes medical doctors, doctors of osteopathy, dentists, podiatrists, optometrists, and chiropractors.

##### a. Meaningful EHR User

To be considered a "meaningful user" of EHR technology, a professional must meet three requirements:

- The professional must demonstrate that, during the applicable period, he has used certified EHR technology in a meaningful manner.
- The professional must demonstrate that the certified EHR technology he is using is connected in a manner that provides the electronic exchange of health information to improve the quality of health care.
- The professional must submit information on clinical quality and other potential measures in a form and manner that will be determined.

The Secretary is to specify the manner in which the professional may demonstrate use and connectivity, and the Secretary is required to provide notice and opportunity for public comment before selecting the reporting measures.

##### b. Payment Amounts

An eligible professional will be entitled to receive a decreasing annual incentive payment amount over five years, beginning with the first year that the professional is eligible. The payment amounts are as follows:

- $15,000 during the first payment year for the professional, unless the professional becomes eligible in 2011 or 2012, in which case the payment amount will be $18,000
- $12,000 during the second payment year
- $8,000 during the third payment year
- $4,000 during the fourth payment year
- $2,000 during the fifth payment year

Professionals first adopting and using EHR technology after the 2014 payment year will receive no incentive payment. Thus, the greatest total payments will be made to professionals who become early meaningful users of EHR technology.

Professionals who furnish services in an area that is designated as a health professional shortage area will receive an additional 10 percent payment. However, physicians who furnish substantially all of their services in a hospital setting, such as pathologists, anesthesiologists, or emergency physicians, are not eligible to receive any incentive payments.

The ARRA authorizes the Secretary to specify whether the payments will be made as a single consolidated payment or in the form of periodic installments. The ARRA further directs the Secretary to establish rules to coordinate incentive payments for professionals who provide services in more

than one practice, and to avoid duplicative requirements from federal and state governments with respect to demonstrating meaningful use of EHR.

#### c. Payment Disincentives (Penalties)

In addition to providing extra compensation to professionals who adopt and use EHR technology, the ARRA penalizes professionals who fail to do so promptly. Specifically, if the professional is not a meaningful EHR user during 2015, the Medicare fee schedule payment amounts to that professional will be reduced by 1 percent. This payment reduction increases to 2 percent for 2016 and 3 percent for 2017. For 2018 and each subsequent year, if the Secretary finds that the proportion of eligible professionals who are meaningful EHR users is less than 75 percent, the percentage reduction will be increased by 1 additional percentage point per year, up to 5 percent. A "significant hardship exception" is available for professionals practicing in a rural area without sufficient Internet access, and is left to the discretion of the Secretary.

#### d. Professionals in Medicare Advantage Organizations

The ARRA also provides for incentive payments to Medicare Advantage ("MA") organizations in connection with their eligible professionals. If an eligible professional is (i) employed by a qualifying MA organization or is employed by or is a partner of an entity that, through a contract with the organization, furnishes at least 90 percent of the entity's Medicare patient care services to the MA organization enrollees, and (ii) furnishes at least 20 hours per week of patient care services, the MA organization may receive incentive payments if the professional is a meaningful user of certified EHR. The Secretary is given discretion to pay an amount to the MA organization that is similar to the amount that would have been paid had the professional's services been reimbursed under Medicare Part B.

To receive such payments, the MA organization seeking incentive payments must submit an attestation as part of its initial bid and identify whether each eligible professional is a meaningful EHR user, and whether each hospital is a meaningful EHR user for the applicable period. The Secretary is further directed to develop a process to ensure that duplicate payments are not made to providers with respect to this section, and to collect data from MA organizations to ensure against such duplication.

The ARRA further contemplates payment of incentives to professionals in private practice who provide all of their services to MA patients. The statute directs that the Secretary, within 120 days of the enactment of ARRA, conduct a study on the extent to and manner in which payment incentives and adjustments could be made available to professionals who are not eligible for HIT incentive payments, and receive payments for Medicare patient services nearly exclusively through contractual arrangements with one or more MA organizations, or an intermediary organization or organizations with contracts with MA organizations.

#### e. Limitation on Judicial Review

For incentive payments provided to either eligible professionals under Part B or to qualifying MA organizations, the ARRA provides limited avenues for judicial challenge. The statute states that there shall be no administrative or judicial review available of the methodology and standards for determining payment amount and payment adjustments, the methodology and standards for determining a meaningful EHR user, the methodology and standards for determining a hospital-based eligible professional, the specification of reporting periods, or the selection of the method of payment.

### 2. Medicare Incentives for Hospitals

Under the ARRA, hospitals furnishing inpatient services reimbursed under the Medicare inpatient prospective patient system ("IPPS") will be entitled to Medicare incentive payments if they are meaningful EHR users. In addition, CAHs, which are reimbursed by Medicare on a reasonable cost basis, will be entitled to bonus payments if they are meaningful EHR users.

#### a. Meaningful EHR User

To be considered a meaningful EHR user, a hospital must meet the following criteria:

- The hospital must demonstrate that it is using certified EHR technology in a meaningful manner.
- The hospital must demonstrate that the EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.

- The hospital must submit information on clinical quality and other measures in a form and manner specified by the Secretary.

Despite setting forth these criteria, the ARRA gives the Secretary discretion to require increasingly stringent measures of meaningful use in order to improve the use of EHR and health care quality. The Secretary is to specify the manner in which hospitals may demonstrate use and connectivity, and the Secretary is required to provide notice and opportunity for public comment before selecting the reporting measures.

**b. Payment Amounts**

The incentive payment for eligible IPPS hospitals is the product of the following three factors:

- The first factor is the sum of a designated $2 million base payment and an amount corresponding to the number of discharges the hospital has over a 12-month period designated by the Secretary. For the 1,150th through 23,000th discharge, $200 per discharge is added to the base amount. For the first through 1,149th discharge and for discharges over 23,000, no additional funds are made available.
- The second factor, referred to as the Medicare share, is a fraction. The numerator is the sum of the estimated number of inpatient-bed-days attributable to Medicare Part A and MA Part C patients. The denominator is the hospital's total estimated number of inpatient-bed days multiplied by the amount of eligible hospital charges, less charity care, divided by the estimated total amount of the hospital's charges during the period. (If the Secretary determines that data is not available on charity care, the Secretary may use data on uncompensated care as a proxy, including a downward adjustment to eliminate bad debt data.)
- The third factor, known as the transition factor, begins with one for the first payment year and reduces by one-quarter each year until it reaches zero at year five. As is the case for professional providers, early adoption and use of EHR technology is more highly rewarded. For hospitals that would have their first incentive payment year after 2013, the transition factor for that hospital would apply as though its first payment year was 2013 and would decrease accordingly. If a hospital's first payment year is after 2015, then the transition factor for that and any subsequent year will be zero.

These incentive payments to hospitals may be made in the form of a single consolidated payment, or in the form of such periodic installments as the Secretary may specify.

**c. Incentive Market Basket Adjustments (Penalties)**

As with professionals, IPPS hospitals that fail to report quality data or are not meaningful users of EHR technology by FY 2015 will be subject to a reduction in their annual market basket updates. Specifically, hospitals failing to report quality data will be subject to a 25 percent reduction in their market basket update. For hospitals that are not meaningful EHR users, three-quarters of market basket update would be subject to a one third reduction in FY 2015, a two-thirds reduction in FY 2016 and a 100 percent reduction in FY 2017. The Secretary is given discretion to exempt a hospital from this adjustment if the decrease would result in a significant hardship, such as if the hospital was in a rural area without sufficient Internet access. No hospital may be granted such an exemption for more than five years.

**d. Limitations on Review**

As is the case with physician incentive payments, incentive payments to hospitals are provided limited avenues for challenge in the judiciary. The ARRA states that there shall be no administrative or judicial review available of the methodology and standards for determining and making estimates or using proxies of, discharges, inpatient-bed-days, hospital charges, charity charges and the Medicare share, the standards for determining a meaningful EHR user, or the specification of EHR reporting periods.

**e. Critical Access Hospitals**

A CAH also will receive enhanced reimbursement if it is a meaningful EHR user. First, a CAH may receive accelerated Medicare reimbursement by claiming its costs associated with the purchase of certified EHR technology in a single payment year, rather than being required to depreciate those costs over several years. Second, Medicare reimbursement to a CAH is increased by increasing the hospital's Medicare share by 20 percentage points. Payment to CAHs for EHR incentives is to be made through "a prompt interim payment" after submission and review of information necessary to make the payment has been received and evaluated. No incentive payments will be made for cost

reporting years beginning after payment year 2015, and no CAHs may receive incentive payments for more than four consecutive payment years.

CAHs also will see a negative adjustment if they are not meaningful users of EHR technology before FY 2015. For cost reporting periods beginning in 2015, rather than receiving payment of 101 percent of reasonable costs, the applicable percentage would decrease to 100.66 percent. For non-users in FY 2016, the percentage would decline to 100.33 percent, with a further decline to 100 percent for FY 2017.

As is the case with physician and IPPS hospital payments, there is no administrative or judicial review available with respect to the methodology and standards for determining the amount of payment and reasonable cost, for determining and making estimates or using proxies of, inpatient-bed-days, hospital charges, charity charges, Medicare share, the specification of EHR reporting periods, or the identification of costs for CAHs.

**f. Application to Medicare Advantage Hospitals**

A hospital that is under common corporate governance with a qualifying MA organization that serves individuals enrolled under a MA plan offered by the organization also will be eligible for incentive payments, as long as it is deemed to be a meaningful EHR user pursuant to the terms of the statute. Instead of the additional payment described above, these hospitals would receive an amount determined by the Secretary to be similar to the estimated amount in the aggregate, had the services been furnished under Part A instead of Part C.

Likewise, payment adjustments will apply to these hospitals if the qualifying MA organization attests that not all eligible hospitals are meaningful EHR users with respect to an applicable period. In these cases, the Secretary shall specify and apply a payment adjustment based on a methodology taking into account the proportion of eligible hospitals or discharges from these hospitals. As is the case with all other incentive payments, no administrative or judicial review will be available to contest the methodologies applied by the Secretary in determining payments and payment adjustments.

**3. Studies and Reports on Health Information Technology**

The ARRA requires that two studies relating to EHR incentive payments be conducted. The first is a study relating to providers receiving minimal or no payment incentives under ARRA. This study is to be designed to examine the adoption rates of certified EHR by these providers, whether the services the providers supply would benefit from the use of such technology, and the potential costs and benefits of making such payments. The report on this study is due not later than June 30, 2010.

The second study involves the availability of open source health information technology systems, their availability and the cost of ownership compared with the cost of proprietary commercial products that are available, and the capacity of these systems to facilitate interoperability. The report on this study is due not later than Oct. 1, 2010.

**4. Medicaid Provider HIT Adoption and Operation Payments/Implementation Funding**

In addition to providing incentive payments through the Medicare program, ARRA provides funding for states to spend money to encourage the adoption of certified EHR technology. The statute specifically provides for funding 100 percent of amounts attributable to payments to Medicaid providers to encourage the adoption and use of certified EHR technology, and 90 percent of funds paid that are attributable to payments for reasonable administrative expenses related to the administration of these payments.

The funding is limited to no more than 85 percent of the net average allowable costs for a Medicaid provider's certified EHR technology (including fees for maintenance and training that is necessary for the adoption and operation of the technology). Average allowable costs include the first year of payment with respect to such a provider, the average costs for the purchase and initial implementation or upgrade of technology, and a subsequent year of payment with respect to the operation, maintenance and use of the technology. Net average allowable costs may not exceed $25,000 for the first year of payment or $10,000 for the second year. No payments for first year adoption may be made later than 2016, and payments for subsequent costs may not be made after 2021, or over a period of longer than five years. These amounts are subject to change based on studies of the average costs to Medicaid providers for such technology that are to be undertaken by the Secretary. Payments with respect to a Medicaid provider may not exceed: (i) in the aggregate, the product of the overall hospital EHR amount for the provider (established by the Secretary in consultation with the state) and the Medicaid share for such provider (calculated the same way as

the Medicare share for hospitals); (ii) 50 percent of the product described in clause (i) in any one year; and (iii) in any two-year period, 90 percent of the product described in clause (i).

The breadth of individuals eligible for Medicaid funding is a bit larger than those under the Medicare program. Under this program, eligible professionals include physicians, dentists, certified nurse-midwives, nurse practitioners, and physician assistants practicing in a rural health clinic that is led by a physician assistant, or is practicing in a federally qualified health center that is so led. Eligible professionals may not be hospital-based and must have at least 30 percent of their patient volume attributable to individuals receiving medical assistance, or must be a non-hospital based pediatrician with at least 20 percent of patient volume attributable to patients receiving medical assistance. Funding is also available for professionals who practice predominantly in a federally qualified health center or rural health clinic, and have at least 30 percent of their patient volume attributable to needy individuals. A children's hospital or an acute care hospital with at least 10 percent of its patient volume attributable to individuals who are receiving medical assistance also would qualify. Additionally, an eligible provider must have waived any right to payment under the Medicare incentive EHR program.

In order to be provided federal financial participation, a state must demonstrate to the satisfaction of the Secretary that it is (i) using the funds for the purposes of administering payments, including tracking of meaningful use by Medicaid providers; (ii) conducting adequate oversight of the program, including routing tracking of meaningful use attestations and reporting mechanisms; and (iii) pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information.

The Secretary is required to periodically submit reports to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate with respect to the status, progress and oversight of payments under this program.

### *III. Health Information Privacy and Security/HIPAA Provisions*

Subtitle D (which addresses privacy and security issues) of the ARRA includes significant changes and additions to the landscape of federal privacy and security law. In general, the privacy and security portions of the ARRA become effective 12 months after the enactment of the ARRA, which is approximately February 2010. It is also important to note that the ARRA directs the Secretary to amend the Health Insurance Portability and Accountability Act ("HIPAA") Privacy and Security Rules to implement the legislative changes. As such, the effective dates associated with the rulemaking process will vary.

#### A. Applicability of HIPAA Security and Privacy Rules Extended to Business Associates

##### 1. Security Rule

The HIPAA Security Rule's information safeguards are not new considerations for Business Associates. Business Associate Agreements contractually obligate Business Associates to implement administrative, physical, and technical safeguards to reasonably and appropriately protect electronic protected health information that the Business Associate creates or maintains on behalf of a Covered Entity. The ARRA, however, changes the fundamental framework of the Security Rule in this regard. Specifically, Business Associates are now required to directly comply with the Security Rule's provisions on administrative, physical, and technical safeguards, as well as to develop implementing policies and procedures. As a practical matter, however, it is unclear whether these provisions only apply vis-à-vis the protected health information created or received from a Covered Entity, or whether they implicate other information of the Business Associate.

As a means to assist Business Associates (as well as Covered Entities) with effectively addressing the requirements of the Security Rule, HHS is required to publish annual guidance on "the most effective and appropriate technical safeguards for use in carrying out" the requirements of the Security Rule. Additionally, the ARRA requires that Business Associate Agreements reflect the new direct obligations of Business Associates. Finally, adding enforcement teeth, the ARRA provides that Business Associates will be subject to civil and criminal penalties for violating the Security Rule.

##### 2. Privacy Rule

The ARRA requires a Business Associate that "obtains or creates protected health information pursuant to a written contract" to take direct responsibility for its uses and disclosures of protected health information. As a result of the new legislation, and regardless of the contractual obligations of a Business Associate Agreement, the manner in which Business Associates approach Privacy Rule

requirements and obligations has been significantly altered, although the extent of these changes will not be clear until regulations are promulgated.

At a minimum, it is clear that Business Associates that violate the Privacy Rule obligations set forth in their Business Associate Agreements will be subject to HIPAA's civil and criminal enforcement provisions. The statutory language also appears to require a Business Associate to take reasonable steps to cure a Covered Entity's violation of a Business Associate Agreement if the Business Associate knows of a pattern of activity or practice of the Covered Entity that constitutes a material breach or violation of the Covered Entity's obligation under the Business Associate Agreement. If cure is not possible, and termination of the Business Associate is not feasible, then the Business Associate must report the problem to HHS.

It is likely that the requirement that Business Associates' new privacy and security obligations be reflected in Business Associate Agreements will, de facto, require the amendment of current Business Associate Agreements. Although the standard language typically found in Business Associate Agreements may be sufficient to address some of the increased privacy and security requirements, it may behoove Covered Entities and Business Associates to review their current Business Associate Agreements. Amendments to current Business Associate Agreements will enable the parties to ensure that both the Privacy and Security Rules are properly and thoroughly addressed. Furthermore, it seems likely that Covered Entities will want the security breach notification requirements discussed below to be set forth in detail in Business Associate Agreements.

#### 3. Definition of Business Associate Expanded

The ARRA expands the definition of "Business Associate" to any organization that, with respect to a Covered Entity, provides data transmission of protected health information to a Covered Entity (or its Business Associate) if the organization requires routine access to the protected health information. Examples include a Health Information Exchange Organization, a Regional Health Information Organization, an E prescribing Gateway, or a Vendor of Personal Health Records. (ARRA provisions related to Vendors of Personal Health Records are described below.) The new universe of entities will be treated as "Business Associates," and must, among other things, enter into a Business Associate Agreement with Covered Entities.

### B. Notification Standards for Breaches of "Unsecured" Protected Health Information

#### 1. Covered Entities

Much like the security breach notification laws of many states, ARRA imposes significant breach notification obligations on a Covered Entity that "accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured protected health information." Thus, any such Covered Entity that knows or should reasonably have known that protected health information has been acquired, accessed, used, or disclosed without authorization, must provide notice of the breach to individuals and designated entities within a prescribed period of time.

The ARRA includes detailed requirements regarding when, how, and to whom notifications of a breach must be provided, but, generally, the notifications must be provided to the individual about whom the information pertains without unreasonable delay (and, in any event, no later than within 60 days of discovery of the breach). In addition to notifying the individuals, notification must always be provided to HHS (immediately if the breach involves more than 500 individuals, or annually otherwise), and depending on the scope or severity of the breach, to prominent media outlets serving the respective state or jurisdiction. The one exception to a Covered Entity's obligation to provide a security breach notification is if a law enforcement official determines that such a notification would impede a criminal investigation or cause damage to national security. HHS will maintain a website that identifies Covered Entities involved in a breach of unsecured protected health information for more than 500 individuals.

The ARRA defines unsecured protected health information to mean "protected health information that is not secured through the use of a technology or methodology specified by the Secretary [of HHS] in" guidance that will be issued no later than 60 days after the enactment of the ARRA. In case the aforementioned guidance is not issued by HHS on the date promised, the ARRA provides the following default definition of unsecured protected health information, which appears to essentially require encryption – "protected health information that is not secured by a technology standard that renders protected health information unusable, unreadable, or indecipherable to unauthorized individuals and is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute."

No later than 180 days after the enactment of the ARRA (approximately August 2009), HHS shall promulgate interim final regulations. The security breach notification provisions of the ARRA shall be effective 30 days after the publication of these interim final regulations (approximately September 2009). Note that this is sooner than the effective date for the ARRA generally.

**2. Business Associates**

The breach notification requirements extend to Business Associates insofar as Business Associates must report discovered breaches of unsecured protected health information to the Covered Entity following a Business Associate's discovery of a breach. If a Business Associate fails to provide the required notice in a timely fashion, the Business Associate may be subject to direct enforcement and penalties. Notification from a Business Associate must include the identification of each individual about whom the breached information pertains. Covered Entities will likely include specific notification timing requirements in Business Associate Agreements.

**3. Vendors of Personal Health Records**

The ARRA also imposes breach notification requirements on "Vendors of Personal Health Records." Under the ARRA, a Vendor of Personal Health Records is any entity "other than a covered entity [as defined in the HIPAA regulations] that offers or maintains a personal health record." The term "personal health record" is defined to be "an electronic record of [individually identifiable health information (as defined in the Social Security Act)] on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or for the individual."

Vendors of Personal Health Records must notify the individual about whom the information pertains, as well as the Federal Trade Commission ("FTC") (which will in turn notify HHS) upon discovery of a breach of security with respect to the individually identifiable health information that is in a personal health record. The ARRA defines "breach of security" to mean any acquisition of the aforementioned information without the authorization of the individual to whom the information pertains. Third-party service providers engaged by Vendors of Personal Health Records are treated similarly to Business Associates, and must notify the vendor of a breach of security.

For Vendors of Personal Health Records and third-party service providers, the requirements regarding when and how they must provide notifications of a breach of security are the same as for Covered Entities and Business Associates, respectively. A Vendor of Personal Health Records or third-party service provider's violation of the notification requirements shall be considered an unfair and deceptive act or practice in violation of FTC regulations.

These provisions are intended to be temporary and will sunset if Congress enacts new legislation establishing specific security breach notification requirements for entities that are not Covered Entities or Business Associates under HIPAA. The FTC is required to promulgate implementing regulations within 180 days of the enactment of the ARRA (approximately August 2009), which will likely clarify the definitions and requirements set forth in the ARRA.

**C. Enhanced Privacy Guidance and Education Initiative**

Within six months after the enactment of the ARRA (approximately August 2009), HHS is required to designate an individual in each HHS regional office to offer guidance and education to Covered Entities, Business Associates, and individuals on their "rights and responsibilities related to federal privacy and security requirements for protected health information." Additionally, within one year after the enactment of the ARRA, the HHS Office for Civil Rights is required to develop and maintain a multi-faceted national education initiative to enhance public transparency regarding the uses of protected health information.

**D. Obligations Related to Electronic Health Records**

**1. Accounting of Protected Information Stored in Electronic Health Records**

Although under the HIPAA Privacy Rule Covered Entities are not required to account for uses and disclosures of protected health information for the purpose of treatment, payment, and health care operations, the ARRA specifically eliminates this exception for Covered Entities that use or maintain "electronic health records." The ARRA defines an "electronic health record" to mean "an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff."

A Covered Entity must provide the new, broader, accounting upon request. For disclosures made by a Covered Entity's Business Associates, however, the Covered Entity may provide an individual with a list of the Business Associates. If an individual is provided such a list of Business Associates, then the

Business Associates must provide the accounting to the individual upon request from the individual. Accountings made by Covered Entities and Business Associates that use and maintain electronic health records must cover a period of three years (as opposed to the six-year period required under HIPAA).

These accounting provisions are effective as follows:

- For Covered Entities, insofar as they acquired an electronic health record as of Jan. 1, 2009, the accounting requirement applies to disclosures made on or after Jan. 14, 2014.
- For Covered Entities insofar as they acquire an electronic health record after Jan. 1, 2009, the provision will be effective for disclosures on the later of Jan. 1, 2011, or the date upon which the entity acquires the electronic health record.
- HHS can impose a later effective date, but it can be no later than 2016 for the Covered Entities with an electronic health record as of Jan. 1, 2009, and 2013 for all other Covered Entities with an electronic health record.

#### 2. Access to Protected Health Information in Electronic Format

Expanding on the Privacy Rule's access provisions, Covered Entities that use or maintain an electronic health record with respect to the protected health information of an individual must, per ARRA, provide access to such information by producing an electronic copy to the individual (or a recipient designated by the individual). Individuals making such a request may only be charged for a Covered Entity's labor costs associated with providing the requested information.

#### 3. Sale of Electronic Health Records or Protected Health Information

The ARRA provides that a Covered Entity or Business Associate cannot directly or indirectly receive remuneration in exchange for an individual's protected health information (including such information stored in an electronic health record), except pursuant to a valid HIPAA authorization that specifies the extent to which the recipient may engage in further exchanges of the individual's information.

This prohibition does not apply to the exchange of the information if the purpose for the exchange is one of the following:

- Public health activities, as defined by the Privacy Rule (45 C.F.R. § 164.512(b))
- Research purposes (as defined in 45 C.F.R. §§ 164.501, 164.512(i)), subject to limitations on the remuneration
- Treatment, unless HHS determines otherwise
- Transfers in connection with the sale or merger of a Covered Entity
- Remuneration that is paid by the Covered Entity to a Business Associate related to the Business Associate's services as to the exchange of protected health information
- Providing an individual with a copy of the individual's protected health information
- Other situations, as determined by HHS

The Secretary is required to promulgate regulations implementing these provisions no later than 18 months after the enactment of the ARRA (approximately August 2010). Furthermore, this provision of the ARRA applies only to an exchange of protected health information that occurs at least six months after the regulations have been released.

### E. Enhanced Ability of Individuals to Control Protected Health Information

#### 1. Requested Restrictions on or Disclosures of Protected Health Information

Prior to the enactment of the ARRA, a Covered Entity was not required to grant an individual's request to limit the use and disclosure of protected health information to carry out treatment, payment, or health care operations. The ARRA, however, requires Covered Entities to comply with an individual's request for such restrictions on disclosure if:

- The disclosure is made to a health plan for the purposes of carrying out payment or health care operations (unless the use or disclosure is required by law)
- The protected health information at issue pertains only to a health care item or service that the individual pays for (1) out-of-pocket, and (2) in full

### 2. Minimum Necessary Standard Further Explained

Under the Privacy Rule, a Covered Entity's use and disclosure of protected health information for purposes other than treatment, payment, and health care operations must be limited to the "minimum necessary" amount needed to accomplish the underlying purpose of the use or disclosure. To provide assistance to Covered Entities in this regard, the ARRA directs HHS to issue guidance on what constitutes "minimum necessary" no later than 18 months after the enactment of the ARRA. Until the release of this guidance, the ARRA provides that uses and disclosures unrelated to treatment, payment, or health care operations must be in the form of a limited data set (as defined by the Privacy Rule), unless a Covered Entity (or Business Associate) determines that a limited data set is not "practicable" for a particular use or disclosure, in which case the "minimum necessary" standard still applies.

### 3. Marketing and Fund-Raising Communications

The ARRA contains new restrictions on marketing communications. Specifically, marketing communications to an individual from a Covered Entity or Business Associate that were previously considered "health care operations" (and therefore not curtailed by the Privacy Rule) are no longer considered health care operations (and therefore no longer exempt from the Privacy Rule's general prohibition against disclosure) if the Covered Entity or Business Associate receives or has received direct or indirect remuneration (as defined under federal fraud and abuse regulations) for making the communication, except where:

- The communication describes a current drug or biologic that is currently prescribed for the recipient, and the remuneration received by the Covered Entity in exchange for the information is "reasonable" (as will be defined by HHS)
- The communication is made by the Covered Entity based on a valid HIPAA authorization
- The communication is made by a Business Associate of the Covered Entity in accordance with a written Business Associate Agreement

Although fund-raising communications are still considered "health care operations," such communications must clearly and conspicuously provide individuals with an opportunity to opt-out of receiving further fund-raising communications. The decision by an individual to opt-out shall be considered a revocation of authorization under HIPAA.

## F. Continued Focus on Enforcement Activities

Building on recent enforcement actions (settlements and informal compliance agreements) from the Office of Civil Rights and the Centers for Medicare & Medicaid Services ("CMS"), the ARRA amends the relevant enforcement provisions of HIPAA by, among other things, requiring HHS to "formally investigate any complaint of a violation of [the Privacy and Security provisions of the ARRA] if a preliminary investigation of the facts of the complaint indicate [that] such a possible violation [is] due to willful neglect." Notwithstanding this heightened focus on enforcement, the ARRA specifically permits the Office for Civil Rights to utilize corrective action without penalty as a means to address civil infractions of the Privacy Rule.

Except as separately provided in the ARRA, the amendments made to enforcement provisions shall be effective 24 months after the enactment of the ARRA (approximately February 2011).

### 1. State Attorneys General Can Initiate Federal Action for HIPAA Violations on behalf of State Residents

Furthermore, the ARRA authorizes state attorneys general to initiate civil actions in federal court (for injunctive relief or monetary damages) on behalf of a state resident when the attorney general reasonably believes that the resident's interests have been threatened or adversely affected by a person or entity that violates HIPAA. Additionally, the court may award the costs of the action and reasonable attorney fees to the state. Prior to bringing any such claim, a state attorney general must provide HHS with prior written notice of intent to file the action, after which HHS may intervene in the action. If HHS brings a HIPAA action against a person, then state attorneys general may not bring an action against the person relative to the same HIPAA violation.

### 2. Enforcement Clarification Regarding Individuals

The ARRA clarifies a point of confusion regarding the criminal enforcement of individuals for the wrongful access or disclosure of protected health information under HIPAA. The ARRA makes it clear that individuals (who are not Covered Entities, but who may be employees of Covered Entities) fall within HIPAA's enforcement purview.

### 3. Increase to Civil Monetary Penalties

With regard to civil monetary penalties, the ARRA replaces the manner in which such penalties are determined with a new tiered approach:

- Unknown violations (i.e., if a person did not know and by exercising reasonable due diligence would not have known that a violation occurred): The penalty shall be at least $100 for each violation, not to exceed $25,000 for all such identical violations during a calendar year, but may be no more than $50,000 for each violation, not to exceed $1.5 million for all such violations of an identical requirement or prohibition during a calendar year.
- Violations because of reasonable cause and not to willful neglect: The penalty shall be at least $1,000 for each violation, not to exceed $100,000 for all such identical violations during a calendar year, but may be no more than $50,000 for each violation, not to exceed $1.5 million for all such violations of an identical requirement or prohibition during a calendar year.
- Violations because of willful neglect (and the violation has been corrected): The penalty shall be at least $10,000 for each violation, not to exceed $250,000 for all such identical violations during a calendar year, but may be no more than $50,000 for each violation, not to exceed $1.5 million for all such violations of an identical requirement or prohibition during a calendar year.
- Violations because of willful neglect (and has not been corrected): The penalty shall be at least $50,000 for each violation, not to exceed $1.5 million for all such violations of an identical requirement or prohibition during a calendar year.

Also note that, within three years of the enactment of the ARRA, HHS is required to publish regulations that establish a methodology that distributes a portion of collected civil monetary penalties to the individuals harmed by a Covered Entity's act of willful neglect. The application of this new tiered approach to civil monetary penalties applies to violations that occur after the date of enactment of the ARRA.

## *IV. Medicaid Provisions*

### A. Medicaid Funding

The ARRA includes provisions granting states an increase in federal Medicaid funding. The provisions allow for a state to use its highest federal medical assistance percentage ("FMAP") from the years 2008 through 2010 in each of the years 2009, 2010, and the first quarter of 2011, rather than using its actual calculated FMAP for each of these years. More substantially, the bill increases the FMAP by 6.2 percentage points during the recession period, defined as the period between Oct. 1, 2008 and Dec. 31, 2010. Furthermore, a state will qualify for additional percentage points if the state's average unemployment rate increases by a percentage, ranging from 1.5 to 3.5 percent, in a calendar quarter. If a state's unemployment rate increases to certain thresholds, the percentage points added to the state's FMAP will also increase. To maintain the highest FMAP possible for each state, if the additional percent applied to a state for any calendar quarter in the recession adjustment period beginning on or after Jan. 1, 2009, and ending before July 1, 2010, is less than the percent applied for the preceding quarter, the higher percent will continue in effect for each subsequent calendar quarter prior to July 1, 2010.

To be eligible for the higher FMAP rate, states are subject to three limitations and requirements. Specifically, the state must: (1) not use FMAP increases if any amounts attributable (directly or indirectly) to such increase are deposited or credited into any state reserve or rainy day fund; (2) ensure that the state's eligibility standards, methodologies, and procedures are no more restrictive than those that were in effect July 1, 2008 (there is no comparable requirement with respect to maintenance of provider rates); and (3) comply with the prompt payment requirements under section 1902(a)(37)(A) of the Social Security Act. Under this latter provision, states must ensure that 90 percent of claims for payment made for covered services (for which no further written information or substantiation is required in order to make payment) are paid within 30 days of the date of receipt of such claims, and that 99 percent of such claims are paid within 90 days of the date of receipt. This requirement applies to claims submitted by practitioners, hospitals, and nursing facilities. However, states will receive a grace period for claims submitted by hospitals and nursing facilities, and no period of ineligibility will be imposed against a state prior to June 1, 2009 on the basis of the state failing to pay a claim in accordance with the prompt payment mandate. Furthermore, in no case may an increase in FMAP under the provisions of the ARRA result in an FMAP that exceeds 100 percent.

The ARRA also extends the transitional medical assistance ("TMA") program. Under the amended 42 USCS § 1396r-6, states will have the option of granting eligible individuals a 12-month initial

period, rather than a six-month period. The amended provisions remove the requirement that individuals must have been recipients of medical assistance previously to be eligible for the program. Furthermore, the bill amends the Qualifying Individual ("QI") Program, which provides state coverage of Medicare cost-sharing for low-income Medicare beneficiaries, by extending it and by providing additional funding. The ARRA also covers Native Americans in a section entitled "Protections for Indians under Medicaid and CHIP," which contains a number of provisions amending and supplementing current legislation.

For the purpose of oversight and for ensuring the proper expenditure of federal funds under the Medicaid program, the HHS Office of the Inspector General ("OIG") has been appropriated $31.25 million for FY 2009, which will remain available until Sept. 30, 2011, and will be in addition to any other amounts made available to the OIG for such purposes. Moreover, the Secretary is appropriated $5 million for FY 2009, which will remain available for expenditure until Sept. 30, 2011, and will be in addition to any other amounts appropriated to the Secretary for purposes of implementing the increased FMAP.

**B. Disproportionate Share Hospital ("DSH") Payments**

The ARRA provides for a temporary increase in DSH allotments to states during the recession. For FY 2009, the DSH allotment will be 102.5 percent of the DSH allotment that would be determined for the state for FY 2009. In 2010, the DSH allotment will be equal to 102.5 percent of the DSH allotment for the state for FY 2009. For each succeeding fiscal year, the DSH allotment is calculated as it was prior to the ARRA. An increase in the DSH allotment will not apply to a state for a year in the case that the DSH allotment determined without applying the special increase detailed above would be higher than the DSH allotment specified under the temporary increase provisions.

**C. Moratoria on Regulations**

The ARRA extends current moratoria on several CMS final Medicaid rules issued during the Bush administration that were scheduled to expire April 1, 2009. Specifically, the ARRA blocks through July 1, 2009 CMS final rules on: (1) targeted case management services, (2) provider taxes, and (3) school-based administration and school-based transportation services. The ARRA also adds a new moratorium on implementation of a Nov. 7, 2008 final rule that modifies the definition of outpatient hospital facility services under the Medicaid programs. This moratorium is in effect through June 30, 2009.

Moreover, the conference agreement states the sense of the Congress that the Secretary should not promulgate as final, certain CMS proposed Medicaid regulations relating to:

- Graduate medical education (published May 23, 2007)
- Rehabilitative services (published Aug.13, 2007)
- Cost Limit for Public Providers (proposed Jan.18, 2007). The conference report states that while CMS published a "purported" final rule on this subject May 29, 2007, the rule was determined by the United States District Court for the District of Columbia to have been "improperly promulgated."

***V. Comparative Effectiveness***

Comparative effectiveness is the analysis of the impact of different health care treatment options on patients or patient subgroups. The analysis may be limited to a comparison of medical benefits and risks, or it can also weigh the costs of treatment options.

The ARRA includes a major expansion of federal efforts to compare the effectiveness of different medical treatments, including both infrastructure changes and an infusion of funding. First, to spearhead comparative effectiveness research projects, the law establishes a "Federal Coordinating Council for Comparative Effectiveness Research" (the "Council"), which is tasked with reducing duplicative comparative effectiveness efforts being conducted by various federal agencies and encouraging coordinated use of resources. The Council also is charged with advising the President and Congress on (1) strategies regarding the infrastructure needs of comparative effectiveness research within the federal government; and (2) organizational expenditures for comparative effectiveness research by relevant federal agencies. The Council will consist of up to 15 federal officers with responsibility for health-related programs, including representatives of the Agency for Healthcare Research and Quality ("AHRQ"), CMS, the National Institutes of Health ("NIH"), the Office of the National Coordinator for Health Information Technology, the Food and Drug Administration, the Veterans Health Administration, and the Department of Defense Military Health Care System. The

Council must report to the President and Congress by June 30, 2009 on current federal comparative effectiveness research and recommendations research conducted under ARRA funding.

The ARRA includes $1.1 billion in funding for the comparative effectiveness efforts. Of this funding, $300 million is to be administered by the AHRQ, $400 million will be administered by the NIH, and $400 million will be allocated to the HHS Secretary. The HHS Secretary is directed to use the funding to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies. Specifically, these efforts are intended to:

- Conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions
- Encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data

The HHS Secretary is directed to contract with the Institute of Medicine to produce a report for Congress and the Secretary with recommendations on the national priorities for comparative effectiveness research under this new program. The report, which must include stakeholder input, is due by June 30, 2009. The Secretary also is directed to consider the recommendations of the Council in designating activities to receive comparative effectiveness funding.

In making grants under this program, the Secretary may consider federal agencies and private sector entities that have demonstrated experience and capacity to achieve the goals of comparative effectiveness research. The Secretary must publish information on the grants and contracts awarded with the ARRA funds. Moreover, the Secretary must disseminate research findings from its grants and contracts to clinicians, patients, and the general public. The ARRA provides that, to the extent feasible, the Secretary should ensure that funding recipients offer an opportunity for public comment on the research. Moreover, research conducted under this program should comply with HHS policies regarding the inclusion of women and minorities in research.

Note that this has been a controversial provision of the legislation, given health care provider, manufacturer, and patient advocate concerns that such research ultimately could be used to block patient access to the full range of medical technologies. In particular, alarms were raised by language in a House Appropriations Committee summary of an earlier version of the stimulus package that stated that by using comparative effectiveness, technologies "that are found to be less effective and in some cases, more expensive, will no longer be prescribed."[2] In an attempt to address such concerns, the final version of the ARRA specifies that "[n]othing in this section shall be construed to permit the Council to mandate coverage, reimbursement, or other policies for any public or private payer." Moreover, the ARRA provides that none of the Council's reports or recommendations "shall be construed as mandates or clinical guidelines for payment, coverage, or treatment." Likewise, the accompanying conference report specifies that "the conferees do not intend for the comparative effectiveness research funding included in the conference agreement to be used to mandate coverage, reimbursement, or other policies for any public or private payer." Moreover, the report adds that "a 'one-size-fits-all' approach to patient treatment is not the most medically appropriate solution to treating various conditions," and notes the importance of ensuring that subpopulations are considered when research is conducted with ARRA funds. Note, however, that the ARRA uses the term "comparative effectiveness research," rather than the term used in the Senate version—"comparative clinical effectiveness"—which advocates had hoped would serve to prevent ARRA funding from being used to support cost-effectiveness research.

### *VI. Medicare Regulatory Provisions*

In addition to the provisions regarding Medicare payment incentives related to the adoption and use of health information technology discussed above, the ARRA includes three other Medicare policy changes:

- **Hospice Budget Neutrality Adjustment Factor** – In the final rule updating the Medicare hospice wage index for FY 2009, CMS included a 1.1 percent decrease in payments in FY 2009 resulting from a phase-out of the hospice wage index budget neutrality adjustment factor ("BNAF"). Specifically, the rule phases out the BNAF over three years, beginning with a 25 percent reduction in FY 2009 (which began Oct. 1, 2008), a 75 percent reduction in FY 2010, and a complete elimination in FY 2011. CMS estimated that phasing-out this adjustment would reduce Medicare hospice spending by $2.18 billion over five years. The ARRA prevents the Secretary from phasing-out or eliminating the budget neutrality adjustment factor before Oct. 1, 2009. The hospice wage index used for FY 2009 will be recomputed as if there had been no reduction in the budget

neutrality factor. The conference report notes that conferees "do not anticipate extending this provision as they expect the hospice community to seek a permanent fix in the annual rulemaking cycle for Medicare hospice payments."

- **Medicare Payments for Teaching Hospitals** – The ARRA blocks a 50 percent cut in Medicare payments to teaching hospitals related to capital payments for indirect medical education ("IME") under the inpatient prospective payment system ("IPPS") in FY 2009. The law does not affect a scheduled elimination of the capital IME adjustment in FY 2010. Again, conferees state that they do not anticipate further extension of this provision, since they "expect the hospital community to seek a permanent fix in the annual IPPS rulemaking cycle."
- **Long-Term Care Hospitals** – The ARRA makes technical corrections to the Medicare, Medicaid, and SCHIP Extension Act of 2007 related to Medicare payments for long-term care hospitals ("LTCHs") to provide further relief from certain unfavorable LTCH payment policies, and to allow LTCHs that previously obtained an approved bed certificate-of-need to qualify for an exception to the moratorium on new LTCH beds.

The ARRA also delays for one year a provision in the "Tax Increase Prevention and Reconciliation Act of 2005" that requires federal, state, and local government entities to withhold income tax when making payments to persons providing property or services. The withholding requirement, which equals 3 percent of payments made, applies to Medicare payments of $10,000 or more, but Medicaid payments are exempt from the requirement. The provision originally applied to payments made after December 31, 2010; under the ARRA the withholding requirement applies to payments made on or after Dec. 31, 2011.

### *VII. Other Health Policy Provisions*

In addition to the provisions described above, the ARRA includes a number of other health policy provisions, particularly the following:

- **Prevention and Wellness Fund** – The ARRA includes $1 billion to establish a "Prevention and Wellness Fund" to be administered by the HHS Secretary. The fund is to be used to support evidence-based clinical and community-based prevention and wellness strategies that deliver specific, measurable health outcomes that address chronic disease rates. Of this funding, $300 million is set aside for Centers for Disease Control and Prevention ("CDC") immunization efforts, and $50 million is to be provided to states to implement health care-associated infections reduction strategies.
- **Community Health Centers** – The ARRA includes $500 million for services provided at community health centers. Specifically, these funds are to be used to support new sites and service areas, to increase services at existing sites, and to provide supplemental payments for spikes in uninsured populations. On March 2, 2009, the Obama Administration announced the first grants awarded under this provision. [3]
- **Health Professions Training** – The conference agreement provides $500 million for health professions training programs, including $300 million for National Health Service Corps recruitment and field activities, and $200 million for all of the disciplines trained through the primary care medicine and dentistry program, the public health and preventive medicine program, certain health professions, and nurse training scholarship and loan repayment programs authorized under the Public Health Service Act, and grants to training programs for equipment. Funds are also to be used to foster cross-state licensing agreements for health care specialists.
- **NIH Funding** – The ARRA includes $10 billion for the NIH to fund the construction and renovation of extramural research facilities, shared instrumentation and other capital research equipment, research projects, and buildings and facilities.
- **COBRA Insurance Coverage** – The ARRA includes provisions to help unemployed workers maintain health insurance coverage under COBRA, the federal law that provides certain former employees and their families the right to temporary continuation of health coverage at group rates. Specifically, for employees who are involuntarily terminated (as defined in the legislation), the ARRA provides a 65 percent subsidy of the COBRA plan premium. This premium reduction will last for up to nine months. Workers involuntarily terminated during the period of Sept. 1, 2008 through Dec. 31, 2009 and their families are eligible. To qualify for the subsidy, participants must attest that their income for the year will not exceed $125,000 for individuals and $250,000 for families. The ARRA also permits group health plans to allow assistance-eligible individuals to change coverage options under the plan in conjunction with electing COBRA continuation coverage in certain circumstances.

### *VIII. Whistleblower Protections*

The ARRA provides "whistleblower" protections for non-federal government employees or employees of private contractors who disclose fraud and abuse in connection with ARRA funds. Specifically, in response to concerns about alleged fraud and mismanagement in recent federal government expenditures, the legislation provides protections against reprisals for employees of state and local governments or private contractors who disclose to federal officials information reasonably believed to be evidence of gross mismanagement, gross waste, or violations of law related to contracts or grants if at least some of the funds are appropriated or otherwise made available by the ARRA. The provision does not replace or preempt any other remedies available under federal or state law.

While more detailed guidance on this provision will likely be forthcoming, the whistleblower protections would likely extend to health care entities receiving health information technology grants and payments, and state Medicaid agencies receiving ARRA funds, among others. It is unclear at this time whether this provision will extend broadly to Medicaid-participating providers, given that it may not be clear the extent to which particular Medicaid provider payments are linked to increased stimulus funding.

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1 P.L. No. 111-5. The text of the ARRA and the accompanying conference report are available **here**.

2 Available **here**.

3 See **link**.

## About Reed Smith

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