



BALCH & BINGHAM LLP

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## HEALTHCARE BULLETIN

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### **HEALTH CARE REFORM – THE IMPACT ON HEALTH CARE PROVIDERS AND SUPPLIERS PARTICIPATING IN MEDICARE AND MEDICAID PROGRAMS**

Following a year of sustained negotiations, wrangling, and ultimately enactment, President Obama signed the Patient Protection and Affordable Care Act (Pub. L. No. 111-148) on March 24 and modifying legislation, the Health Care and Education Reconciliation Act (Pub. L. No. 111-152) (jointly, the Act), on March 30, setting the stage for dramatic Medicare and Medicaid payment revisions, for the establishment and further development of new health care delivery models, for new disclosure, reporting and repayment requirements, and for significant expansion, auditing and enforcement of fraud and abuse laws during the next decade.

This Bulletin is prepared by the Balch & Bingham Health Law Practice Group addressing selected payment and program integrity provisions affecting a variety of providers and suppliers participating in the Medicare and Medicaid programs. All section references contained in this Bulletin, unless otherwise indicated, are to the Patient Protection and Affordable Care Act (PPACA).

#### **PROVIDERS – MEDICARE PAYMENT REFORMS**

The Act includes a number of provisions increasing, decreasing or changing the structure of payment mechanisms for federal and federal/state health care insurance programs. Below are brief descriptions of selected important payment provisions.

#### ***Market Basket Reductions and Disproportionate Share Reductions***

Sprinkled throughout the Act are an assortment of adjustments, by way of increases and reductions, to various provider Medicare payments, including those to hospitals, hospice, home health, long-term care, and inpatient rehabilitation facilities.



Hospitals, hospice, home health, long-term care, inpatient rehabilitation facilities, and other providers subject to prospective payment systems will all face continued reductions in market basket rates. Periodic market basket reductions of up to 1% per year are slated for all prospective payment systems' participants through fiscal year 2019. (Section 3401)

Medicare disproportionate share hospital (DSH) payments will be reduced as the number of uninsured patients is reduced. Beginning in fiscal year 2014, a subsection (d) hospital will be paid 25% of the DSH payment it would otherwise receive, representing the empirically justified amount for such payment, as determined by the Medicare Payment Advisory Commission in its March 2007 Report to Congress. Additional payments, based on a number of factors, will also be available to subsection (d) hospitals in addition to the empirically justified amounts. (Section 3133 of PPACA and Section 1104 of Reconciliation Bill)

### ***Independent Payment Advisory Board***

A new 15-member Independent Payment Advisory Board (IPAB) is established. The IPAB will be required to develop proposals to reduce per-capita Medicare spending if spending increases exceed inflation-related thresholds. The first determination will be made in April 2013 and the first spending reduction proposals (if required) will be due in January 2014.

IPAB proposals to reduce payments made to Medicare providers and suppliers, including physicians, must be implemented by the Secretary of Health and Human Services (HHS) unless the Congress passes an alternative set of payment reductions that meet the savings targets set forth in the IPAB's proposals. The IPAB proposals may not ration care, raise Part B premiums, or change benefits, eligibility, or cost sharing. Hospitals and hospices will be exempt from IPAB spending reduction through 2019. (Sections 3403 and 10320)

### ***Hospital Readmission Penalties***

In order to reduce avoidable readmissions, beginning in 2013, Medicare payments that would otherwise be made to a hospital will be decreased by the product of the base operating DRG payment amount for the discharge and the hospital's fiscal year adjustment factor for avoidable readmissions. The reduction amount will be computed differently for Medicare-dependent small rural hospitals and sole community hospitals. Readmissions for conditions and procedures that are unrelated to the prior discharge or which fall below a minimum threshold will not be included. (Section 3025)

### ***Productivity Adjustments***

Beginning in 2011, ambulatory surgery centers, durable medical equipment suppliers, ESRD facilities and clinical laboratories will all face full productivity adjustments. Most adjustments will be incorporated into market basket updates that do not already include such adjustments, but those relating to clinical laboratories will be incorporated into annual updates.



Full productivity adjustments will also be incorporated into market basket updates for hospitals in 2012, and into annual updates for skilled nursing facilities and long-term care hospitals during the same year. Similarly, a productivity adjustment will be incorporated into annual updates for hospice in 2013 and for home health agencies in 2015.

The productivity adjustment, with respect to a percentage, factor, or update for a fiscal year, a calendar year, cost reporting period, or other annual period, is an adjustment equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity. (Section 3401)

### ***Post-Acute Care Bundling***

The Secretary of HHS is charged with establishing a National Pilot Program on Payment Bundling for integrated care during an episode of care (three days prior to hospital admission through 30 days following discharge) in order to improve the coordination, quality, and efficiency of health care services. The Secretary of HHS will select up to eight conditions, taking into consideration a mix of chronic and acute conditions, a mix of surgical and medical conditions, whether the condition provides an opportunity to improve quality of care and reduce expenditures, whether the condition has a significant variation in the number of readmissions and expenditures for post-acute care, and whether the condition is high-volume and might result in high post-acute care expenditures. Participation is voluntary, effective 2013, and the program may be expanded after January 1, 2015.

Under the pilot program, participating entities will receive bundled payments that cover the costs of applicable services and other appropriate services furnished to an individual during the episode of care. Payment procedures will be established during the pilot program for treatment provided to an individual who requires continued post-acute care services.

An initial report will be submitted to Congress two years after implementation of the pilot program. (Section 3023)

### ***Payment System Revisions: Medicare Home Health, Skilled Nursing Facilities and Hospice***

In addition to market basket reductions and productivity adjustments, payment adjustments will be made for home health agencies beginning in 2013 with a four-year phase in. HHS is directed to rebase payments, with payment reductions limited to 3.5% annually. Additionally, from April 2010 to January 2016, a 3% add-on payment is available for rural agencies. (Section 3131)

Hospice care payment reforms will go into effect in October 2013. The Secretary of HHS shall, by regulation, implement revisions to the methodology for determining payment rates based on an analysis of data collected beginning in 2011. Effective 2014, a quality reporting program will be established, including a 2% penalty for failure to report. (Section 3132)



The skilled nursing prospective payment system will be altered as well. Under the Act, RUG-IV classification has been temporarily delayed, with system implementation scheduled to occur after October 2011. The lookback period is also changed to ensure that only those services furnished after admission to a skilled nursing facility are used as factors in determining a case mix classification under the skilled nursing facility prospective payment system. (Section 10325)

### ***Value-Based Purchasing***

A value-based purchasing program for hospitals will be implemented in 2013 and will apply to payments for discharges occurring on or after October 1, 2012. For value-based incentive payments made for discharges occurring on or after October 1, 2014, efficiency measures, including Medicare spending per beneficiary, will be included and will be adjusted for factors such as age, sex, race, and severity of illness. (Section 3001)

Additionally, HHS must develop and submit a value-based purchasing implementation program for skilled nursing facilities, home health agencies, and ambulatory surgery centers by October 2011. The program must take into account all dimensions of quality and efficiency; the reporting, collection, and validation of quality data; the structure of value-based adjustments, including determination of thresholds or quality improvements; and methods for public disclosure. (Sections 3006 and 10301)

Physicians will not be exempt from the value-based purchasing program. A value-based payment modifier will also be established that provides for differential payment under the physician fee schedule based upon the quality of care furnished compared to cost during a performance period. The modifier will be separate from the geographic adjustment factors and will be phased in over a two-year period beginning January 1, 2015. (Section 3007)

### ***Graduate Medical Education***

Payments for direct and indirect expenses will be available to qualified teaching health centers that are listed as sponsoring institutions of approved graduate medical education and residency training programs. Payments will be equal to the product of the national per resident amount for direct graduate medical education and the average number of full-time equivalent residents in the teaching health center's training programs.

The sum of \$230 million has been appropriated for the period of fiscal years 2011 through 2015. Participant teaching health centers must submit an annual report, including (i) types of primary care approved training programs; (ii) number of approved training positions for residents; and (iii) number of residents who completed training at end of academic year and care for vulnerable populations living in underserved areas. Failure to report may result in a 25% reduction in payments. (Section 5508)



## **PROVIDERS AND PHYSICIANS – MEDICAID PAYMENT REFORMS**

The Act includes multiple adjustments, by way of increases and reductions, to various provider Medicaid payments, including those for health-care acquired conditions and DSH payments.

### ***Medicaid Adjustments for Health Care-Acquired Conditions and Disproportionate Share Reductions***

Federal payments to states for medical assistance may not be used to pay for health care-acquired conditions (as opposed to hospital-acquired conditions). Health care-acquired conditions are those medical conditions that could be identified by a secondary diagnostic code. HHS must identify current state practices that prohibit payment for health care-acquired conditions and must apply those deemed appropriate to the Medicaid program through regulations that will be come effective July 1, 2011. (Section 2702)

Medicaid DSH payments will be reduced as the number of uninsured patients is reduced. Effective fiscal year 2014, the aggregate reductions in Medicaid DSH payments for all states will be reduced by a total of \$18.1 billion from 2014 through 2020. (Section 2551 of PPACA and Section 1203 of Reconciliation Bill)

### ***Medicaid Payment Increases for Primary Care Services***

The Act also increases Medicaid payment for primary care services furnished in 2013 and 2014 by a physician with a primary specialty designation of family medicine, general internal medicine, or pediatric medicine to 100% of the payment rate that applies to such services and physician under Medicare. (Section 1202 of Reconciliation Bill)

### ***Medicaid Global Payment Demonstration***

The Secretary of HHS is required to establish a Medicaid Global Payment System Demonstration Project under which a participating state shall adjust the payments made to an eligible safety net hospital system or network from a fee-for-service payment structure to a global capitated payment model. The demonstration project will operate during fiscal years 2010-2012 and will involve no more than five states. A report must be submitted to Congress one year after completion of the demonstration project. (Section 2705)

### ***Bundled Payments Demonstration Project***

A demonstration project to evaluate the use of bundled payments for the provision of integrated care for a Medicaid beneficiary will be established, beginning January 1, 2012, and ending December 31, 2016. The demonstration project is to be conducted in eight states, determined by the Secretary of HHS based on consideration of the potential



to lower costs under the Medicaid program while improving care for Medicaid beneficiaries. (Section 2704)

### ***Expansion of Recovery Audit Contractor Program***

The recovery audit contractor (RAC) program will be expanded to Medicaid claims. States must contract with RAC(s) by December 31, 2010, for the purposes of identifying underpayments and overpayments and recouping overpayments made by Medicaid program. HHS and CMS will coordinate the program's expansion. (Section 6411)

### ***Expansion of Medicaid Eligibility***

Perhaps the most significant revision for state Medicaid programs involves the Act's expansion of Medicaid coverage to virtually all working adults whose income is at or below 133% of the Federal Poverty Level. While initially federal payments will supplement state shortfalls, once the federal payments are reduced, states may look for additional funding sources and/or reductions in health care provider payments in order to comply with the Act's provisions.

### **TAX-EXEMPT HOSPITALS**

In addition to other requirements under Section 501 of the Internal Revenue Code, a Section 501(c)(3) charitable hospital must (i) meet community health needs assessment requirements, (ii) have a written financial assistance policy and policy relating to emergency medical care, (iii) limit amounts charged for emergency or other medically necessary care provided to individuals under the financial assistance policy and prohibit the use of gross charges, and (iv) not engage in extraordinary collection actions before making reasonable efforts to determine whether the individual is eligible for financial assistance.

If a hospital fails to meet the requirements for any taxable year, a tax of \$50,000 will be imposed, effective immediately. The Secretary of the Treasury must review at least once every three years the community benefit activities of each 501(c)(3) hospital. (Section 9007)

### **PROVIDERS AND PHYSICIANS – NEW HEALTH CARE DELIVERY MODELS**

The Act establishes and funds multiple new models, pilot programs and demonstration projects that focus on reducing costs and improving the quality of patient care. Below are descriptions of several of these programs.

#### ***Medicare Shared Savings Program and Pediatric Accountable Care Organization Demonstration Project***

The Act requires the HHS Secretary to establish, no later than January 1, 2012, a Medicare Part A and B shared savings program, grouping various providers and suppliers of services to manage and coordinate care for Medicare fee-for-service



beneficiaries through accountable care organizations (ACOs) that meet specific quality performance standards. While multiple provider and supplier groups may be eligible, all must allow for shared governance. Eligible provider and supplier groups include group practice arrangements, networks of individual physician practices, partnerships or joint venture arrangements between hospitals and ACO professionals, hospitals employing ACO professionals and other groups of providers and suppliers that the Secretary may identify as appropriate through rule-making. Only Medicare Subsection Part D hospitals may participate (excluding critical access hospitals, long-term care hospitals, psychiatric hospitals, cancer and children's hospitals).

ACOs must have a separate legal existence and must include sufficient primary care physicians to adequately serve the Medicare fee-for-service beneficiaries assigned to the ACO. Each ACO must service at least 5,000 Medicare beneficiaries, must identify processes to promote evidenced-based medicine, quality and cost measure reporting and coordination of care through telehealth, remote patient monitoring and other technologies.

ACOs' success will be measured through quality and other reporting requirements. Payment received by ACO participants may be based upon multiple methodologies, including payment calculated based on estimated average per capita Medicare expenditures by the ACO for fee-for-service beneficiaries, a partial capitated payment model or payment models that the Secretary may identify and develop. ACOs already participating in similar arrangements with other payors will be given a preference for inclusion in the Medicare Shared Savings Program. The majority of provisions, including the assignment of Medicare fee-for-service beneficiaries, are not subject to administrative or judicial review. (Section 3022)

A demonstration project targeting pediatric patients is required to be developed by the Secretary for operation between January 1, 2012, and December 31, 2016. The program will permit participating states to allow pediatric medical providers meeting certain requirements recognition as ACOs for purposes of receiving incentive payments as described above in the Medicare Shared Savings Program. Pediatric ACOs must meet performance guidelines and establish and achieve annual minimal expenditure savings in order to receive incentive payments that will be some portion of excess savings. (Section 2706)

### ***Patient-Centered Medical Home***

The Act directs the HHS Secretary to establish a program that will put in place community-based interdisciplinary, interprofessional teams to support primary care physicians within a specific hospital service area. The goal is to establish patient-centered medical homes and to provide through grants or by contract capitated payments to primary care providers. Entities eligible to receive a grant may be either a state or a state-designated entity or Indian tribe or tribal organization. Entities must submit a plan that will provide for three-year financial sustainability, that will incorporate prevention initiatives and that will insure that an interdisciplinary, interprofessional team is provided to treat chronically ill individuals. (Section 3502)



### ***Creation of Center for Medicare and Medicaid Innovation***

No later than January 1, 2011, the Centers for Medicare and Medicaid Services must create a new Center for Medicare and Medicaid Innovation (CMI). CMI's purpose is to test new payment and service delivery models with the goal of reducing program expenditures and increasing quality of care received by beneficiaries.

Significant funds are allocated to CMI including \$10 billion for activities during fiscal years 2011 through 2020 and each subsequent ten-year period for activities. At least \$25 million annually must be used for the design, implementation and evaluation of the various models. Congressional reports will describe the models tested and the results of evaluations and will include recommendations by the Secretary. (Section 3021)

### **QUALITY REPORTING REQUIREMENTS**

Within two years, reporting requirements, including quality reporting, are to be developed with respect to plan or coverage benefits and health care provider reimbursement structures. The requirements are designed to improve health outcomes through quality reporting, effective case management, care coordination, chronic disease management, activities to prevent hospital readmission through patient-centered education and discharge planning, activities to improve patient safety and reduce medical errors, and wellness/health promotion activities. (Section 1001)

Additionally, the Act makes changes to the physician quality reporting system. If an eligible professional does not satisfactorily submit data on quality measures for covered professional services furnished during 2015 or any subsequent year, the payment amount will be reduced. HHS is required to develop a plan to integrate quality reporting measures with those requirements relating to meaningful use of electronic health records by January 1, 2012. (Section 3002)

Similarly, any long-term care hospital, hospice, inpatient rehabilitation hospital, or psychiatric hospital that fails to satisfactorily submit quality data, beginning in 2014, will face a 2% penalty. (Sections 3004 and 10322)

Beginning in fiscal year 2014, PPS-exempt cancer hospitals must also begin quality reporting. (Section 3005)

### **STARK LAW**

#### ***Changes to Stark Law In-Office Ancillary Services Exception***

The in-office ancillary services exception under the Stark Law has been changed to require a referring physician to inform patients in writing, at the time of a referral, that the patients may obtain specified imaging services (MRI, CT, and PET), or other designated health services from a person other than the referring physician, a physician who is a member of the same group practice, or an individual directly supervised by the physician or by another physician in the group practice.





The provision requires the referring physician to provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides. This provision is effective immediately.

***Limit on Physician-Owned Hospitals: Revisions to Stark Whole Hospital and Rural Provider Exceptions***

The Stark Law generally prohibits physicians from referring Medicare patients for certain designated health services to facilities in which they (or their immediate family members) have an ownership or investment interest. Currently, the Stark Law prohibition does not apply to physicians with ownership or investment interests in a “whole hospital” as opposed to a specific hospital department or facility or in a rural provider. The new law narrows both exceptions to apply only to physician-owned hospitals that have physician ownership and provider agreements in operation on December 31, 2010, and that meet certain other requirements. Physician-owned hospitals that qualify for the exception would have limited opportunities for further expansion.

The amended exceptions require hospitals to report to HHS annually the identity of each physician owner and investor, to have procedures in place requiring any referring owner or investor physician to disclose such ownership or investment to the patient, and to not condition ownership or investment on referrals from the physician. Beginning in November 2011, HHS will conduct audits to determine if hospitals have violated such requirements. (Section 6001)

**FRAUD, WASTE AND ABUSE – ENFORCEMENT**

***Increased Funding for Fraud and Abuse Enforcement***

Beginning in 2011, the Act appropriates \$250 million for increased government fraud and abuse enforcement efforts over a six year period. The additional funding will be phased in as follows: \$95 million in 2011, \$55 million in 2012, \$30 million in 2013 and 2014, and \$20 million in 2015 and 2016. (Section 6402)

***Compliance Programs for All Providers and Suppliers***

The Act authorizes the Secretary to require as a condition of enrollment in the Medicare, Medicaid, and CHIP programs that providers and suppliers implement compliance programs. The Secretary has discretion to dictate the timelines for implementation of compliance programs, as well as the types of providers and suppliers who will be required to adopt compliance programs. In addition, the Act directs the Secretary to develop core elements of compliance programs for each class of provider or supplier. (Section 6401)



### ***Anti-Kickback Statute Enforcement Provisions***

The intent element of the Anti-Kickback Statute (AKS) has been revised to explicitly reject 9<sup>th</sup> Circuit case law. Under current 9<sup>th</sup> Circuit case law, the government is required to show that a defendant had (i) actual knowledge that the conduct was prohibited, and (ii) a specific intent to violate the AKS. The Act revises the AKS to state that, to meet the “knowing and willing” intent element, “a person need not have actual knowledge” that the AKS prohibits a particular conduct. (Section 6402)

### ***Stark Law Enforcement Provisions***

Within six months, HHS must develop and implement a disclosure protocol for actual and potential Stark violations in collaboration with the OIG. The Secretary is allowed to reduce the amount due and owing by considering certain factors, including the nature/extent of the improper/illegal practice, the timeliness of self-disclosure, and the cooperation in providing additional information related to the disclosure. (Section 6409)

### ***False Claims Act Enforcement Provisions***

Returning Medicare overpayments within 60 days of the overpayment’s identification is now an obligation under the False Claims Act. Providers or suppliers who fail to return an overpayment within 60 days of identification will be guilty of False Claims Act violations. The 60 day period commences when a person “knows” of the overpayment. (Section 6402)

The Act also explicitly clarifies that claims for payment submitted in violation of the AKS can constitute grounds for False Claims Act lawsuits. This clarification codifies the long-standing practice of bootstrapping False Claims Act claims onto AKS violations.

### ***Civil Monetary Penalties Enforcement Provisions***

The Act expands the scope of the existing Civil Monetary Penalties Law to include two new bases for the imposition of civil monetary penalties (CMPs) by the Secretary. First, in addition to False Claims Act implications, knowingly making a false statement that is material to obtaining payment for services or items furnished under a federal health care program now constitutes grounds for CMPs. Second, the Secretary may impose CMPs on providers or suppliers who fail to grant timely access to information requested by the OIG to perform audits, inspections, evaluations, or other statutory functions. (Section 6408)



**Other Enforcement Tools**

The Act also grants the Secretary the following new, powerful enforcement tools.

- The Secretary may exclude individuals who knowingly make a false statement, representation, or omission as part of Medicare enrollment or bidding from participating in the Medicare program.
- The Secretary may suspend Medicare payments to providers or suppliers based on “credible allegations of fraud” against the provider or supplier. The Secretary is required to consult with OIG in determining whether a fraud allegation is credible.

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