A Summary of Health Reform Provisions Affecting Health Care Providers

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (or the "Act") into law. The Act includes many provisions affecting health care providers, such as new disclosure requirements and changes in the fraud and abuse laws. This Alert highlights some of the more notable provisions.

New Transparency And Disclosure Provisions

Payments and Transfers of Value. Effective on March 31, 2013, and annually thereafter, any drug or device "manufacturer" (as defined below) that provides a payment or other transfer of value to a "covered recipient" must disclose the name, address, and NPI number of the recipient, the amount of payment or value, dates such payment or value was provided, and a description of the nature of the payment. If the payment is related to marketing, education or research specific to a product, the name of that product also must be disclosed. Payments made to an entity on behalf of a covered recipient must be disclosed under the name of the covered recipient. Payments or transfers of value include gifts and payments for meals, travel, honoraria, research, and certain consulting and educational payments, as well as current or prospective ownership and investment interests, royalties and licenses, profit distributions, dividends, and option grants.

Physician Ownership Disclosures. Section 6002 of the Act requires the disclosure of any ownership or investment interests (other than ownership or investment interests in a publicly traded security and mutual fund) held by a physician (or immediate family member) in a manufacturer or group purchasing organization (GPO). The Act also requires annual reporting of the amount of the investment, the value and terms of such investment, and all payments and transfers of value to that physician.

Definitions. A "manufacturer" is defined as an entity engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for which payment is made under a federally-funded plan, such as Medicare or Medicaid. Distributors are not specifically covered by this new provision, although entities under common ownership with a manufacturer "which provide assistance or support to such entity" with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply are covered by the Act. It is not clear whether research affiliates are covered by these provisions. A "covered recipient" is defined as physicians and teaching hospitals.

Exclusions. Exclusions exist for certain payments in connection with an activity or service which payments are made indirectly to a covered recipient through a third party and where the manufacturer is unaware of the identity of the covered recipient. This exclusion applies to some market research activities, such as surveys. Other exceptions are: (a) payments or transfers of $10 or less (unless the aggregate annual payments or transfers exceed $100, indexed for inflation beginning in 2012); (b) educational materials that directly benefit patients or are intended for patient use; (c) product samples; (d) a

loan of a covered device for a short-term trial period, not to exceed 90 days; (e) items or services provided under a contract warranty; (f) discounts (including rebates); (g) in-kind items used for the provision of charity care; and (h) dividends and other distributions from publicly traded securities and mutual funds. In addition, as described below, manufacturers may delay reporting payments for services furnished pursuant to a product research or development agreement or in connection with a clinical investigation of a new drug, device, biological, or medical supply, or with a new application of an existing drug, device, biological, or medical supply. Such a delay extends the reported deadline until the earlier of (1) the date of the approval or clearance of the covered drug, device, biological, or medical supply by the FDA, or (2) four calendar years after the date such payment or other transfer of value was made. Information subject to the delayed reporting would be considered confidential and not subject to disclosure under the Freedom of Information Act (FOIA) or any other state or federal law.

Public Disclosure. Beginning in 2013, information submitted to U.S. Department of Health and Human Services (HHS) will be made available on a searchable Internet website. The website will also include enforcement actions and penalties imposed.

Penalties. Penalties for failure to comply with these reporting requirements in a timely manner range from $1,000 to $10,000 for each unreported payment (not to exceed $150,000), and $10,000 to $100,000 for each knowing failure to report a payment (not to exceed $1,000,000). Both federal authorities and state attorney generals have the authority to enforce these reporting provisions.

State Laws. Many states have also adopted various similar reporting and disclosure requirements. The Act does not preempt state laws that require additional reporting obligations, nor does it preempt provisions in state laws that impose restrictions on the types of transfers of value that may be made by manufacturers, such as the "gift" limits and restrictions which are in effect in Minnesota, Vermont and Massachusetts. The Act also does not preempt state law requirements for the adoption of codes of conduct, such as in California, Nevada and Massachusetts.

Prescription Drug Samples. Beginning in 2012, Section 6004 of the Act requires each manufacturer and authorized distributor to submit the identity and quantity of drug samples requested and distributed.

Imaging Services. For services furnished on or after January 1, 2010, physicians referring patients for radiology services under the in-office ancillary services exception to the Stark law must inform patients, in writing at the time of the referral, that the patient may obtain the services from another provider and provide a list of other prospective providers.

Nursing Homes. The Act requires significant disclosures related to nursing home operations. Such disclosure includes ownership, organizational structure, direct care staffing, wages and benefits paid to direct care staff, turnover, summary of complaints, criminal violation by staff and nursing facility closures, and will be made available on a public website. Certain facilities are also required to implement compliance and ethics programs. The Act creates programs to improve the quality and safety of nursing home facilities and includes incentives to self-report and correct deficiencies for which civil monetary penalties were imposed.

Fraud and Abuse Provisions

Restrictions on Physician Owned Hospitals. The Act amends the Stark self-referral law to restrict the formation of "new" physician-owned hospitals under Stark's whole-hospital ownership exception. As amended, the exception allows "grandfathered" physician-owned hospitals only if the hospital's Medicare provider agreement is in place as of December

31, 2010. Additionally, a hospital may not have been converted from an ambulatory surgical center to a hospital after the date of enactment. Existing physician-owned hospitals may continue to qualify for this exception, but the current physician ownership must be fixed as of the date of the Act. The Act also imposes additional restrictions on grandfathered physician-owned hospitals with respect to potential expansion, as well as additional compliance and safety requirements. Each qualifying hospital must disclose all ownership information, including the nature and extent of ownership and investment interests, and implement disclosure procedures requiring both the hospital and referring physician owners to disclose such physician ownership interests to patients, and the general public.

Self-Referral Disclosures. The Act requires HHS, along with the Office of Inspector General (OIG), to establish a Medicare Self-Referral Disclosure Protocol (SRDP), by which health care providers and suppliers must disclose actual and potential violations of the Stark law. The Act gives HHS authority to compromise any amount due and owing for Stark law violations if the provider has self-disclosed the violation. HHS may consider various factors in determining the amount owed in connection with a violation, such as: (i) the nature and extent of the improper of illegal practice; (ii) the timeliness of any self-disclosure; and (iii) the level of the provider's cooperation in providing additional information related to the disclosure.

The Anti-Kickback Statute. The Act adds a provision to the Anti-Kickback Statute that states: "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." This new provision does not eliminate the requirement that the government prove a defendant knew that the conduct was unlawful. Instead, it rejects the interpretation of "knowingly and willfully" adopted by the Ninth Circuit, which required the government to prove a defendant: (1) knew that the Anti-Kickback Statute prohibited the conduct they were alleged to have committed, and (2) engaged in prohibited conduct "with the specific intent to disobey the law."

Overpayment Reporting. The Act requires health care providers and Medicare/Medicaid managed care organizations to report and return any overpayment to HHS, applicable state, intermediary, carrier, or contractor, along with a written notification of the reason for the overpayment. The deadline for reporting and returning such overpayments is the later of (i) 60 days after the date on which the overpayment was identified or (ii) the date that any corresponding cost report is due.

Civil Monetary Penalties. The Act extends the government's ability to impose civil monetary penalties for health care fraud. For example, civil monetary penalties now may be imposed on any person who knows of an overpayment, but does not report such overpayment, for any false statement or omission on a provider enrollment application, knowingly making any false record or statement, or for failure to grant timely access in connection with an audit or investigation.

False Claims Act Provisions. The Act adds provisions to enhance and simplify enforcement of the False Claims Act by the government and by whistleblowers in qui tam actions. Notably, the Act provides that violations of the Anti-Kickback Statute also constitute false or fraudulent acts under the False Claims Act. The government now has the ability to suspend payments to a provider or supplier pending investigation of "credible allegations of fraud."

Increased Funding. The Act provides for increased funding to the Health Care Fraud and Abuse Control Fund.

Focus on Nursing Homes. Within three years, skilled nursing facilities are now required to establish compliance and ethics programs to prevent and detect criminal, civil and administrative violations.

Registration requirements effective on January 1, 2011, agents, clearing-houses and other payees that submit claims on behalf of the health care providers must register with HHS as well as the applicable state.

New Payment Provisions

Medicare Changes. The Act contains a number of Medicare reimbursement changes. The Act provides for a Medicare value-based purchasing incentive payment for hospitals that meet specific performance standards, such as quality measures. Notably, payments made to Medicare Advantage plans will be cut over the next 10 years. Beginning in 2012, bonus payments will be implemented for Medicare Advantage plans that meet certain quality standards, although total payments will be capped at 2009 payment levels. Section 5501 of the Act establishes a 5% Medicare bonus payment for certain primary care evaluation and management codes, to be effective on January 1, 2011. The bonus is increased to 10% for providers in health professional shortage areas. The Act does not address the Sustainable Growth Rate methodology for setting Medicare reimbursement for physicians. Unless Congress addresses this provision, physicians face a 21.2% Medicare fee reduction. The fee cut was scheduled to take place on April 1, 2010, but the Centers for Medicare and Medicaid Services (CMS) are holding payments for services delivered after April 1, 2010 for 10 business days, pending potential action from Congress.

Demonstration Projects. The Act creates a number of demonstration projects with the goal to pay for performance and generate better quality health care results. The demonstration projects include:

a) Up to five states can participate in a demonstration project to adjust their payment structure for "safety net" hospitals to a global capitated payment arrangement.

b) Up to eight states can evaluate the use of bundled payments for the provision of integrated care involving in-patient and related physician services.

c) A national independent monitor program will conduct oversight of interstate and large intrastate skilled nursing facility and nursing facility chains.

d) Two demonstration projects to develop best practices in skilled nursing facilities for using information technology to improve patient care.

e) Up to six demonstration projects to extend the current gainsharing demonstration project, and test and evaluate other methodologies and arrangements between hospitals and physicians to improve the quality and efficiency of care provided and to develop improved operational and financial performance.

f) An "independence at home" demonstration program to test a payment incentive and service delivery model that utilizes physician- and nurse practitioner-directed home-based primary care teams.

Extension of the 340B Discounts. The Act extends the 340B discounts on inpatient drugs and extends participation to certain children's hospitals, cancer hospitals, critical care and sole community hospitals, and rural referral centers.

Independent Payment Advisory Board. Section 3403 of the Act establishes an Independent Payment Advisory Board

(IPAB) to submit proposals to reduce per capita Medicare spending when such spending exceeds the Consumer Price Index growth rate. With respect to payments made under Medicare Advantage plans and Medicare Part D, the IPAB's proposals for spending reductions must be automatically implemented by HHS unless Congress passes an alternative measure that meets the same savings targets. The IPAB is prohibited from submitting any idea that would ration care, raise taxes or change benefits.

Quality Provisions

Physician Quality Provisions. The Act extends the physician quality reporting initiative (PQRI) until 2014 and provides for coordination between the physician quality reporting initiative and electronic health records reporting efforts. Beginning in 2014, physicians who fail to submit quality data pursuant to PQRI will face Medicare payment reductions. The Act also continues and expands the feedback program for physicians, whereby HHS provides reports to physicians measuring resources involved with care. The reports will be expanded to focus on quality of care and comparative patters of resources used. Finally, in 2015, physicians face a value-based payment modifier under the physician fee schedule. This modifier will adjust payment based on quality of care as compared to costs incurred.

Hospital Quality Provisions. The Act provides for a Medicare value-based purchasing incentive payment to any hospital that meets specific performance standards. Under this program, a percentage of the hospital's Medicare payment is tied to quality performance measures related to common and high-cost conditions. Similarly, a hospital may be ineligible for incentive payments if the hospital is found to have quality deficiencies. Value based incentive payments will initially focus on: acute myocardial infarction, heart failure, pneumonia, surgeries, and health care-associated infections. In addition, hospitals face reductions in Medicare inpatient hospital payments due to potentially preventable readmissions measures identified by the National Quality Forum, such as heart attack, heart failure, pneumonia, acute myocardial infarction, and other vascular issues and will also face payment reductions if the hospital experiences a high level of hospital acquired conditions relative to the national average.

Other Providers. The Act provides for the establishment of value-based purchasing for long-term care hospitals, inpatient rehabilitation facilities, and hospice providers beginning in 2014. These providers must submit a report on quality measures, which will be available to the public. Providers who do not submit quality data will be subject to a payment reduction.

Accountable Care Organizations. Section 3022 of the Act creates a shared savings program to promote coordination and accountability for patient care among providers, as well as investment in infrastructure, quality of care and efficient delivery of care. Groups of providers meeting the standards for an Accountable Care Organization may be eligible to receive payments for shared savings.

Other Notable Provisions Affecting Health Care Providers

Healthcare Workforce Changes. The Act requires a background check, including fingerprinting, to be completed for each long-term care facility employee who has direct contact with patients, similar to the requirements already mandated by many states. In addition, the Act provides for the redistribution of residency positions and hospitals will be able to receive indirect funding for medical and direct graduate education for resident time spent in a non-provider setting or at educational seminars.

New Non-Profit Community Benefit Requirements. The Act adds new requirements on non-profit hospitals, including

development of a community needs assessment every three years. In addition, non-profit hospitals must establish financial assistance policies and billing practices to prevent hospitals from engaging in extraordinary collection activities until reasonable efforts have been made to determine whether the patient is eligible for financial assistance under the policy. The United States Treasury will review a hospital's tax exemption every three (3) years.

Tort Reform. The Act provides funding for five-year state demonstration programs to address alternatives to existing medical malpractice litigation.

The Health Care Practice Group at Seyfarth Shaw LLP is holding a webinar on May 4, 2010 at 12:00 pm Central to analyze these provisions further. Please contact any member of the Health Care Practice Group with any questions regarding the Act.

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